DATREND
Systems Inc.

ES601-US

Automated Electrical Safety Analyzer

Operating Manual

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Systems Inc.

Revision	Revision History Description	Date
B	Improve Text	2012-Aug-30
C	Update Address & Logo	2014-Nov-04

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Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the freight carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking Checkitems, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Claims

Our routine method of shipment is via common carrier. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim.
If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact your local sales representative or DSI immediately.

Standard Terms and Conditions

Refunds & Credits

Please note only serialized products (products labelled with a distinct serial number) and accessories are eligible for partial refund and/or credit. Non-serialized parts and accessory items (cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. In order to receive a partial refund/credit, the product must not have been damaged, and must be returned complete (meaning all manuals, cables, accessories, etc.) within 90 days of original purchase and in "as new" and resalable condition. The *Return Procedure* must be followed.

Return Procedure

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from Datrend Customer Service. All items being returned must be sent *prepaid* (freight, duty, brokerage, and taxes) to our factory location.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15%. Products returned in excess of 30 days after purchase, but prior to 90 days, are subject to a minimum restocking fee of 20%. Additional charges for damage and/or missing parts and accessories will be applied to all returns. Products which are not in "as new" and resalable condition, are not eligible for credit return and will be returned to the customer at their expense.

Certification

This instrument was thoroughly tested and inspected and found to meet DSI's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Research Council of Canada (NRC) and/or the National Institute of Standards and Technology (NIST). Devices for which there are no NRC/NIST calibration standards are measured against in-house performance standards using accepted Checklists.

Warranty and Product Support

Warranty and Product Support

Datrend Systems Inc. ("DSI") warrants this instrument to be free from defects in materials and workmanship under normal use and service for one (1) year from the date of original purchase. This warranty will be automatically extended on a yearly basis, to a **maximum of five (5) years** from the date of original purchase, provided that calibration is performed on an **annual** basis by a Datrend Authorized Service Center. During the warranty period DSI will, at our option, either repair or replace defects in materials and workmanship at no charge; provided the product is returned (shipping, duty, brokerage and taxes prepaid) to DSI. Any and all transportation charges incurred are the responsibility of the purchaser and are not included within this warranty. This warranty extends only to the original purchaser and does not cover damage from abuse, neglect, accident or misuse or as the result of service or modification by other than DSI. IN NO EVENT SHALL DATREND SYSTEMS INC. BE LIABLE FOR CONSEQUENTIAL DAMAGES.

This warranty is subject to the following limitations:
● Touch Screen LCD Display: 1 year limited warranty; punctures, dents and scratches are not covered
● Standard Accessories: 90 day limited warranty
● Damage due to activation of devices under test which are connected to the "applied parts" inputs is not covered under the warranty
● Re-calibration of the instrument, which has a recommended annual calibration frequency, is not covered under the warranty.

No warranty shall apply when damage is caused by any of the following:
● Power failure, surges, or spikes,
● Damage in transit or when moving the instrument,
● Improper power supply such as low voltage, incorrect voltage, defective wiring or inadequate fuses,
● Accident, alteration, abuse or misuse of the instrument,
● Fire, water damage, theft, war, riot, hostility, acts of God, such as hurricanes, floods, etc.

Only serialized products (those items bearing a distinct serial number tag) and their accessory items are covered under this warranty. PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and non-serialized modules are not covered under this warranty.

This warranty gives you specific legal rights and you may have other rights, which vary from province to province, state to state, or country to country. This warranty is limited to repairing the instrument to DSI's specifications.

When you return an instrument to DSI for service, repair or calibration, we recommend shipment using the original shipping foam and container. If the original packing materials are not available, we recommend the following guide for repackaging:
● Use a double-walled carton of sufficient strength for the weight being shipped.
● Use heavy paper or cardboard to protect all instrument surfaces. Use non-abrasive material around all projecting parts.
● Use at least four inches of tightly packed, industrial-approved, shock-absorbent material all around the instrument.

DSI will not be responsible for lost shipments or instruments received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a prepaid basis (freight, duty, brokerage, and taxes). No returns will be accepted without a Return Materials Authorization ("RMA") number. Please contact Datrend (refer to Chapter 9 of this manual) to obtain an RMA number and receive help with shipping/customs documentation.

Warranty Disclaimer

Should you elect to have your instrument serviced and/or calibrated by someone other than Datrend Systems, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization. We strongly recommend, therefore, that you send your instrument to Datrend Systems for service and calibration, especially during the original warranty period.
In all cases, breaking the tamper-resistant Quality Seal should be avoided at all cost, as this seal is the key to your original instrument warranty. In the event that the seal must be broken to gain internal access to the instrument (e.g., in the case of a customer-installed firmware upgrade), you must first contact Datrend Systems at 1-800-667-6557. You will be required to provide us with the serial number for your instrument as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your instrument without interruption.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Datrend Systems will not be responsible for any injuries sustained due to unauthorized equipment modifications.

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Table of Contents

Abbreviations and Definitions

The following abbreviations, terms and acronyms are used throughout this manual:

uA	Micro-ampere
A	Ampere
AAMI	American Association of Medical Instrumentation
AutoSequence	A series of measurements or test operations that are run automatically in a predefined order, with or without user involvement.
Cct.	Abbreviation for circuit (ie. electrical circuit in a power distribution system)
Checklist	A type of AutoSequence that can be linked to the control number of a device through an Equipment Record.
DUT	Device Under Test. The electrical equipment or device being tested.
Earth	Same as "GND" or "ground" (see below).
Equipment Record	Contains the control number of a device and a reference to an associated maintenance procedure (Checklist) for that device.
Flash Memory	Non-volatile memory used for storing Test Records and other configuration-related data such as user settings, AutoSequences, Checklists and Equipment Records. The contents of the flash memory are retained when the power to ES601-US is switched off.
GND or Ground	The line (conductor) connected to a place that is maintained at "Ground" or "Earth" potential.
Hz	Hertz
IEC	International Electrotechnical Commission
kHz	kilohertz
L1 or Line 1	The "Hot" or "Live" line (conductor) of the AC supply.
L2 or Line 2	The "Neutral" line (conductor) of the AC supply.
LA	Left arm ECG lead
LL	Left leg ECG lead
MAINS	The voltage provided by the building installation, nominally 120 VAC or 230 VAC depending on the country
M.A.P. / MAP	Mains-on-Applied-Part(s). An isolation test of one or more patient leads.
Measurement Category I Terminal	Intended for measurements on circuits with no direct connection to MAINS (CAT I)
Measurement Category II Terminal	Intended for measurements on circuits which may have a direct connection to MAINS (CAT II)

MHz	Megahertz
PE	Protective Earth. The line (conductor) connected to a place that is maintained at "Ground" or "Earth" voltage.
QWERTY Keypad	The user interface device for entering text or numeric figures. The layout of the keypad is that of a standard North American PC Keyboard.
RA	Right arm ECG lead
RL	Right leg ECG lead
RMS	Root-Mean-Square measurement of amplitude.
Safety Standard	Standards established by various national and international regulatory agencies. The most recognized Standards Organizations include: AAMI - Association for Advancement of Medical Instrumentation IEC - International Electrotechnical Commission VDE - Verband der Elektrotechnik, Elektronik und Informationstechnik
Test Record	Safety, ECG and other test result data which have been saved to the non-volatile flash memory as a record of all tests performed on a particular device, as identified by the equipment control number. A Test Record may be recalled from the flash memory for viewing on the LCD or printing. Test Records can be downloaded in bulk to a PC using ES601pc-US software.
Type B (Body)	Non-patient equipment, or equipment with grounded patient connection.
Type BF (Body Floating)	Equipment with a floating patient connection
Type CF (Cardiac Floating)	Equipment with a floating connection intended for direct cardiac application
V	Volt
V1-V6	Precordial ECG leads
Vrms	Volts rms

Symbol Definitions

The following symbols may be found on ES601-US:

⚠ CONSULT MANUAL FOR PROPER OPERATION

The operating manual provides valuable information on the proper use of ES601-US. It is highly recommended the operator read the Checkitems thoroughly before operating the device. It is possible to damage the Device Under Test (DUT) and/or cause harm to the operator if ES601-US is used incorrectly.

⚠ AUX1: LINE VOLTAGE TO FLOATING I/O ~264V max

During testing of the isolation of (floating) input/output connections on the DUT, an AC voltage of 110% of the line voltage is applied to the AUX1 (CAT I) connector (Yellow 4mm banana jack), which is connected to the (floating) input/output connector(s). This AC voltage may reach a maximum of ~264 VAC and, while current limited, represents a serious shock hazard to the operator. Proper precautions should be taken when performing a test which includes the application of this voltage to the (floating) input/output connector(s). When a hazardous voltage is present at the AUX1 connector, a red LED adjacent to the AUX1 connector will be ON .

⚠ APPLIED PARTS: Hazardous Voltage: 264 VAC or 500 VDC max

This warning appears on the Applied Parts (patient leads) label on the front of ES601-US. During testing of the isolation of the DUT patient leads with respect to either ground, or to the power input leads, a voltage of either 110% of the AC line voltage or 500 VDC may be present on the applied part (CAT I) connectors. This voltage may reach a maximum of ~264 VAC or 500 VDC and, while current limited, represents a serious shock hazard to the operator. Proper precautions should be taken when performing a test which includes the application of this voltage to the applied part connectors. When a hazardous voltage is present at the connectors, a red LED adjacent to the warning on the APPLIED PARTS label will be ON .

⚠ CAUTION: Electrical Shock Hazard, Refer Servicing to Qualified Personnel
CAUTION: Consult Accompanying Documents

These warnings appear on the serial number label of ES601-US. ES601-US contains hazardous electrical voltages internally which WILL BE present when the covers are removed. The operator should read the Operating Manual to determine what actions to take in the event of failure of ES601-US. Refer to the Troubleshooting and Maintenance Section of the Operating Manual.

⚠️ Kelvin Cable

The Kelvin Cable (CAT I) is used to measure the Ground Resistance, using a 1A current. Consult the Operating Manual for the proper operation of the Ground Resistance test.

⚠️ DO NOT EXCEED THE FOLLOWING CURRENT LOAD ON THE D.U.T . RECEPTACLE:

15AMPS @ 100 - 120 VAC, 60 Hz (in 20A circuit)
11AMPS @ 100 - 120 VAC, 60 Hz (in 15A circuit)
12AMPS @ 230 VAC, 50 Hz (in 16A circuit)

The regulatory requirements for loading a circuit (cct.) in a power distribution system sets a current limit on any individual receptacle to 80% of the value of the circuit breaker on that circuit. For instance, in a circuit with a 15A circuit breaker (or fuse), the maximum current allowed to be drawn from any individual receptacle is 12A. Allowing 1A for the circuitry, the load current for the Device Under Test (D.U.T.) should not exceed 11A. These limits are set by the Electrical Code in most jurisdictions in an attempt to avoid unexpected circuit overloads and subsequent circuit failure. If the D.U.T. load is expected to approach the maximum value on a routine basis, it is recommended that a circuit with only a single receptacle be provided for use with ES601-US.

⚠️ WARNING: OPENING THE ES601 MAY COMPROMISE USER SAFETY. REFER SERVICING TO DATREND AUTHORIZED AGENT.

ES601-US is a complex instrument which contains internally distributed line voltages and other high voltages for specific measurement purposes. Failure to observe appropriate measures when the instrument has been opened, or failure to reassemble correctly may compromise the safety of the user.

⚠️ WARNING: GROUNDING CIRCUIT CONTINUITY IS VITAL FOR SAFE OPERATION. NEVER OPERATE THE ES601 WITH GROUNDING CONDUCTOR DISCONNECTED.

Proper grounding is essential to ensure operator safety. Do not bypass the grounding provisions inherent in the design of ES601-US, otherwise, the operator may be subjected to an electrical shock risk.

⚠️ WARNING: HAZARDOUS VOLTAGES OR CONDITIONS MAY EXIST DURING TESTS. CONSULT THE ACCOMPANYING DOCUMENTS FOR APPROPRIATE PRECAUTIONS.

During the execution of an electrical safety test on the D.U.T., ES601-US may apply high voltages (up to 264 VAC or 500 VDC) to the D.U.T. While these voltages are current limited, they do represent a shock hazard to the operator if precautions are not followed. Consult the instructions in this manual regarding patient lead leakage current tests and Insulation Resistance tests for further information.

ES601-US OPERATING MANUAL

Chapter

1

1   Specifications

Equipment Performance Specifications

1.1 Electrical Safety Testing Standards
- ANSI/AAMI-ES1:1996
- IEC60601-1:2005, Third Edition
- IEC60601-2-4:2002, Second Edition
- DIN VDE 0751-1:2001
- IEC62353:2007, FDIS Edition 1
- IEC61010-1:2001, Second Edition
- AAMI-BAT (AAMI-ES1 for battery-powered medical device)
- IEC601-BAT (IEC60601 for battery-powered medical device)
- VDE-BAT (VDE-0751 for battery-powered medical device)
- IEC353-BAT (IEC62353 for battery-powered medical device)

1.2 Automated Testing
- By Control Number Search
- By PM Checklist
- By Safety AutoSequence
- By ECG AutoSequence
- By Physical Inspection
- By Tester AutoSequence

1.3 Manual Mode Safety Tests
- Line Voltage
- Load Current
- Insulation Resistance
- Ground Resistance
- Leakage Current

Voltage Measurement
- Range: 0.0 to 300.0 VAC
- Accuracy: DC to 100Hz, V≥ 90 VAC, ±1% of reading ±1LSD
                    DC to 100Hz, V< 90 VAC, ± 2.5 VAC

Load Current
- Range: 0 - 20.00 A AC
- Accuracy: ±2% of reading ±1LSD

Insulation Resistance
- Range: 0.5 to 999.9 megohms
- Accuracy: R ≤ 100 megohm, ±2% of reading ±1LSD

Ground Resistance
- Range: 0.001 to 3.000 ohms at ±1A DC bipolar
- Accuracy: ±1% of reading ±1LSD

Leakage Current
- Standards: IEC60601-1, AAMI-ES1:1996, VDE-0751,
                    IEC62353, IEC61010
- Range: 0 to 14000 uA RMS
                    0 to 25000 uA DC
- Method: True RMS reading
- Accuracy: DC & 25Hz-200kHz - ±1% of reading ±2LSD
                    200kHz-1MHz - ±4% of reading ±3LSD

Lead isolation test voltage is 110% of AC supply for IEC60601 tests, or 100% of AC supply for other safety standards.

1.4 Electrical Safety Measurement Terminals

Test Receptacle:
- CAT II
- Max Voltage: 132 VAC (North America)/ 264 VAC (Europe)
- Max Current: 15A AC (North America)/ 13A AC (Europe)

Kelvin Cable:
- CAT I
- Max Voltage: 8 VAC out, Black Terminal (Source)
- Max Current: 40A AC out, Black Terminal (Source)
- Max Voltage: 8 VAC in, Red Terminal (Sense)
- Max Current: 1mA AC in, Red Terminal (Sense)

AUX1 Terminal:
- CAT I
- Max Voltage: 264 VAC out
- Max Current: 2mA AC out

AUX2 Terminal:
- CAT I
- Max Voltage: Ground potential
- Max Current: 6.5mA AC, 20mA DC

To DUT Case Terminal:
- CAT I
- Max Voltage: Ground Potential
- Max Current: 40 A AC

Applied Part (patient lead) Terminals:
- CAT I
- Max Voltage: 264 VAC (Isolation Test), 500 VDC (Insulation Test)
- Max Current: 14mA AC @264 VAC, 50mA DC @ 500 VDC

⚠️ Connect measurement terminals **ONLY** as instructed in this manual, see Chapter 4, Connecting to ES601

1.5 ECG Simulator

Performance Waveforms
- DC Pulse: 4 seconds
- Square Wave: 2 Hz
- Triangle Wave: 2 Hz
- Havertriangle Pulse: 10, 25, 40, 100 and 200 msec, @ 60 BPM
- Sine Wave: 0.5, 10, 20, 40, 50, 60, 70 and 100 Hz
- Normal Sinus Rhythm: 30, 60, 90, 120, 150, 180, 240 and 300 BPM

Arrhythmia Waveforms
- Second Degree A-V Block (BLK II)
- Premature Atrial Contraction (PAC)
- Right Bundle Branch Block (RBBB)
- Premature Ventricular Contraction (PVC)
- R-on-T PVC
- Run of 5 PVC
- Multifocal PVC
- Bigeminy

Defibrillator/AED Test Waveforms
- Atrial Fibrillation (AFIB)
- Asystole
- Supraventricular Tachycardia (SVT)
- Polymorphic VTach @ 140 BPM (PVT140)
- Monomorphic VTach @ 160 BPM (PVT160)
- Ventricular Fibrillation (VFIB)
- Missed beat @ 80, 120 BPM

Output Amplitude
- Selectable: 1mV, 2mV, or 0.5 mV on Lead ll

Accuracy
- Rate: $\pm 0.2\%$
- Amplitude: $\pm 2\%$

1.6 User Interface

Display
- Graphic LCD 4.53" x 3.40" (11.5 cm x 86 cm)
- Monochrome backlit
- 320 x 240 pixel graphics
- 53 character x 30 lines text

Keypad
- Touch screen

Audio Indicator
- Single-frequency piezoelectric

1.7 Non-Volatile Memory

Memory Type
1 Megabyte flash memory

Data Capacity
- 170 Test Records (safety and ECG test data)
- 3072 PM Test Data Items (checklist test results)
- 18432 Equipment Records
- 500 PM Checklists
- 24 Safety Test Autosequences
- 6 ECG Test Autosequences
- 18 Physical Inspections
- 12 AutoSequences for Oxitest +7 Pulse Oximeter Tester
- 12 AutoSequences for Infutest 2000 IV Pump Tester
- 24 AutoSequences for Phase 3 Defibrillator/Pacemaker Tester
- 60 AutoSequences for user-defined Testers

AutoSequences, Inspections and PM Checklists are user-programmable via the ES601pc-US software package (included on CDROM).

1.8 Printer Port Data Output

Hardware Interface
DB25F, Centronix standard

1.9 RS-232 Port Data Output

Hardware Interface
DB9F

Serial Protocol
9600 baud, N, 8, 1

1.10 USB Data Transfer/Capture

Hardware Interface
USB Device

Protocol
USB 2.0 compliant

Data Transfer Rate
1 Mbit/sec

1.11 Ethernet Data Transfer/Capture

Hardware Interface
RJ-45

Protocol
TCP/IP

Data Transfer Rate
10baseT - 10 Mbits/sec, maximum

1.12 Keyboard and Barcode Scanner Ports
- RS-232 barcode scanner
- PS/2 keyboard or PS/2 barcode scanner

Equipment Technical Specifications

1.13 Electrical Specifications

120 VAC(+/- 10%), 60 Hz, 16A in 20A circuit
120 VAC(+/- 10%), 60 Hz, 12A in 15A circuit

Notes:

- This instrument has been designed to test equipment that meets local power distribution standards, which limit devices to draw no more than 80% of the specified current capacity of a circuit. For instance, a single device should draw no more than 16A from a single receptacle on a 20A circuit.

- Externally Accessible Fuses: 1A/250V AGC

- Transient overvoltages typically present on the mains supply are expected to be impulse withstand (overvoltage) category II of IEC 60364-4-443.

1.14 Environment for Use

- 15 to 40 °C
- 10% to 90% RH
- Altitude: 2000m max.
- Indoor use only
- Pollution Degree 2

1.15 Dimensions

- 9" (23 cm) W x 9" (23 cm) D x 10" (25 cm) H

1.16 Weight

- 12 lbs (5.4 kg) Standard
- 17 lbs (7.7 kg) with PETM option

1.17 Standard Accessories

- Kelvin Cable (P/N 3140-425)
- USB Cable (P/N 3140-403)
- Power Cord, North America 15A (P/N 3000-009)
- Accessory Bag (P/N 7006-052)
- ES601-US Product CD (P/N 6950-019), including:
    - Quick Start Guide
    - Operating Manual
    - ES601pc-US application software for Microsoft Windows®

1.18 Optional Accessories

For a complete list of available accessories, visit www.datrend.com or contact Datrend Customer Service (see Chapter 9 for contact details)

1.19 Installed Software Modules

- Safety AutoSequences
- User-Defined Safety Limits
- ECG AutoSequences
- Oxitest +7 AutoSequences
- Infutest 2000 AutoSequences
- Phase 3 AutoSequences

- Physical Inspections
- User-Defined Testers
- Checklists
- Equipment Records
- CMMS Interface
- Test Report Generator

1.20 Compliance With Standards

ES601-US has been certified to meet the following safety standards:

CAN/CSA-C22.2 No. 61010-1-(2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements

UL Std. No. 61010-1 (2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements

IEC/EN 61010-1 (Ed.2.0) - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirement

Following manufacture, all units are subjected to, and have passed the requirements of the 'Routine Tests' defined in Annex F of the above Standard(s).

Chapter

2
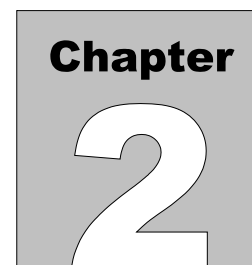
2   Overview

ES601-US is designed to be the hub of a total Equipment Management System. The large, graphical touch screen display provides excellent visibility along with a full QWERTY keyboard and numeric keypad for data and text input.

ES601-US provides an interface to PC based equipment management systems and can maintain up to 18,432 Equipment Records in memory for fast access to test protocols. Each Equipment Record contains a reference to a PM Checklist, for quick and easy test selection. 24 editable safety test sequences, 6 editable ECG test sequences and 11 other autosequence modules are available for interfacing ES601-US to other test devices such as defibrillator testers, infusion pump analyzers and pulse oximeter testers. These automated test sequences can be combined, following specific guidelines, into a PM Checklist. There are up to 500 editable PM Checklists that can be linked to a control number or run independently.

In addition to the industry standard input/output connections, RS-232 and Centronix, ES601-US has added both USB and Ethernet connectivity for ease of control and rapid data transfer to both stand alone and networked PC systems. ES601-US also provides connections for RS-232 barcode scanners and PS/2 keyboards or PS/2 barcode scanners.

ES601-US is a fully AUTOMATED Electrical Safety Analyzer designed to verify the electrical safety of medical devices, and provides the most complete implementation of international electrical safety standards testing available, with implementation of signal I/O isolation tests and specific tests for battery-powered devices.

Automated Safety Tests (Safety Autosequences) are configured to test only those parameters applicable to the safety standard in use.

ES601-US can operate in MANUAL mode, allowing individual measurements of a safety test to be manually selected; or in AUTO mode, running Safety Autosequences.

ES601-US also provides ECG waveform simulations that, like safety tests, can run manually or by using ECG autosequences.

In addition to Safety and ECG tests, ES601-US provides Tester Autosequences that allow the user to remotely operate and/or acquire test data from an external testing device (e.g. a multimeter, a defibrillator analyzer, etc.) via any of six RS232 Tester Ports. Checklists can integrate an optional safety test with inspection steps and tester remote control steps, which can then be linked to specific equipment control

numbers. These parameters can be programmed by the user by using the *ES601pc-US* software package for Microsoft Windows® 7 or XP.

2.1 Testing Electrical Safety

ES601-US performs a number of measurements related to testing the electrical safety of medical devices. Electrical safety measurements performed by ES601-US include:

2.1.1 Insulation Resistance

This is a test of the breakdown strength of electrical insulating materials that provide electrical isolation between certain electrical conductors and the ground connection at the AC receptacle. At the AC line cord of the DUT, ES601-US applies a high voltage (500 VDC) between hot and neutral shorted together, and the ground. ES601-US measures the resulting current and reports the test result as resistance in megohms. In a variation of this test, ES601-US applies the high voltage between the patient leads and the line cord ground pin, and measures the resistance.

2.1.2 Ground Resistance

In this test, ES601-US will source one amp of DC current through the dead short circuit that should exist from the ground pin on the line cord of the DUT to any exposed metal part on the DUT's enclosure. In practice, the connection from the ground pin to the enclosure of the DUT has a non-zero resistance in the range of 0.02 to 0.2 ohms, and this is what ES601-US measures and reports as the test result.

By providing multiple measurement and point-to-point test modes, ES601-US accommodates special test requirements of permanently-installed equipment, and manufacturer-recommended protocols where continuity of ground must be verified at several locations on the equipment. Multiple resistance measurements and point-to-point testing can be enabled for manual tests or automated test sequences.

2.1.3 Line Voltage

In this test, ES601-US connects an internal voltmeter to the AC supply input and reports the AC RMS voltages measured between hot and neutral, hot and ground, and neutral and ground.

2.1.4 Load Current

To perform this measurement, ES601-US connects an internal ammeter to the DUT and measures the current it draws from the AC line when the DUT is powered up and running.

2.1.5 Leakage Current

Different safety standards require different types of leakage measurements to be performed. ES601-US focuses on medical device testing and implements the four general types of leakage measurement specified in the AAMI-ES1 and IEC60601 standards. The alternative leakage measurements and the direct leakage measurements of the VDE0751 and IEC62353 safety standards are also provided. ES601-US can also perform a leakage test according to the IEC61010 standard for laboratory instruments.

In all, ES601-US incorporates measurements encompassing the requirements of nine different electrical safety standards used worldwide.

In accordance with the AAMI-ES1 and IEC60601 safety standards, the types of leakage measurement performed by ES601-US are:

2.1.6 External Case Leakage Current

Depending on the safety standard, "external case leakage" may alternatively be referred to as "touch current", "enclosure risk current" or "enclosure leakage".

In this test, ES601-US measures the current that flows from a metal part on the DUT enclosure that should be grounded, to the actual ground from the AC electrical supply. The current is obtained by measuring the voltage developed across a resistor/capacitor network simulating the AC impedance of the human body, as defined by the safety standard. ES601-US measures the current in microamps, while simulating a variety of test conditions at the equipment line cord and isolated data interfaces (for example, a transformer-isolated ethernet port on the device under test or "DUT").

For each test condition, the current flowing out of the enclosure of the DUT to ground is measured and compared to a maximum limit specified in the safety standard. When measuring the external case leakage, ES601-US can be configured to record AC and DC values for these test conditions:

Normal Polarity	Normal Condition	(NP:NORM.)
	Single-Fault Condition, Neutral Open	(NP:OPEN N.)
	Single-Fault Condition, Ground Open	(NP:OPEN G.)
Reverse Polarity	Normal Condition	(RP:NORM.)
	Single-Fault Condition, Neutral Open	(RP:OPEN N.)
	Single-Fault Condition, Ground Open	(RP:OPEN G.)

2.1.7 Internal Case Leakage Current

Depending on the safety standard, "internal case leakage" may alternatively be referred to as "earth leakage current" or "ground leakage".

In this test, ES601-US measures the current that flows in the ground wire of the DUT when the connection to ground is broken and the human body load is placed across the open circuit. Similar to external case leakage, internal case leakage current is measured in microamps, while simulating a variety of test conditions at the DUT line cord. When testing internal case leakage, ES601-US can be configured to record AC and DC values for these test conditions:

Normal Polarity	Normal Condition	(NP:NORM. COND.)
	Single-Fault Condition, Neutral Open	(NP:OPEN NEUT.)
Reverse Polarity	Normal Condition	(RP:NORM. COND.)
	Single-Fault Condition, Neutral Open	(RP:OPEN NEUT.)

2.1.8 Lead Leakage Current

In this test, ES601-US measures the current that flows out of the patient leads of the DUT though the human body load when the leads are either connected to ground (normal condition), or to an isolated AC voltage via a current-limiting resistor (lead isolation test). For most safety standards such as AAMI-ES1, the isolated voltage is equal to the AC line voltage. For the IEC60601 standard, the isolated voltage equals 110% of the AC line voltage supplying the DUT. As with all leakage tests, lead leakage current is measured in microamps, while simulating various conditions at the DUT.

In addition to specifying the individual test cases, the lead leakage measurement for some safety standards requires the patient leads to be tested in related "functional groups". Such groups are classified as "body" (Type B), "body-floating" (Type BF) or "cardiac-floating" (Type CF). "Type B" parts are not isolated and have the least stringent safety requirements; "Type CF" parts are isolated and have the most stringent safety requirements since they are intended for cardiac application; "Type BF" parts are also isolated but associated safety requirements are less stringent than for cardiac "Type CF" parts.

ES601-US allows up to five groups of patient leads to be defined, where each group can be a different "Type" and can include from one to ten leads. Groups can be assigned names, as can the individual leads within a group. A group of leads may also be "disabled", and therefore excluded from the test. For the AAMI-ES1 standard, leads are preassigned into two functional groups with predefined "Type": Group 1 is allocated to testing isolated leads (Type BF/CF), and Group 2 is allocated to testing non-isolated leads (Type B).

The way in which lead leakage must be measured is highly dependent on the standard and on the specified group "Type". For AAMI-ES1 standard, collective leakage is measured for patient source current, but then is measured individually from each lead for patient sink current (isolation test of Group 1, Type BF/CF). If the safety standard is IEC60601, and a patient lead group is designated "Type CF", then the leakage current produced by each patient connection within that group is measured individually. For a patient lead group which is "Type B" or "Type BF", then the collective leakage of the group is measured. In accordance with the Third Edition of IEC60601, if testing Mains on Applied Parts (MAP) of a specific group of patient connections, then any other patient lead groups provided by the DUT that are not being MAP-tested must be connected to ground. If testing "Type CF" defibrillator paddles in accordance with the IEC60601-2-4 standard, then collective leakage of the paddles is measured, but only when performing the MAP test. For this special case, a higher leakage is permitted than is otherwise allowed under the general standard. For VDE-0751 and IEC62353 standards, patient connections are also tested in functional groups, however, collective leakage of each group is always measured regardless of the group "Type".

The complicated details of testing patient lead leakage are managed automatically by ES601-US, simply by making a choice of safety standard and selecting an appropriate "Type" for each different group of patient connections provided by the DUT (ECG; invasive blood pressure; temperature; SpO2; and so on). Setting up ES601-US to perform patient leakage measurements is relatively simple and is further explained in section 5.10.

When testing patient leakage, ES601-US can be configured to record the following AC and DC values for each group of parts defined in the test setup:

Normal Polarity	Normal Condition	(NP:NORM.)
	Single-Fault Condition, Neutral Open	(NP:OPEN N.)
	Single-Fault Condition, Ground Open	(NP:OPEN G.)
	Single-Fault Condition, Isolation Test[1]	(NP:ISO. TST.)
Reverse Polarity	Normal Condition	(RP:NORM.)
	Single-Fault Condition, Neutral Open	(RP:OPEN N.)
	Single-Fault Condition, Ground Open	(RP:OPEN G.)
	Single-Fault Condition, Isolation Test[1]	(RP:ISO. TST.)

(1) Type BF or CF patient leads only; not tested for Type B

Under the IEC60601 standard, patient connections within "Type CF" groups are tested individually in turn. In this case, for each normal (NC) and single-fault (SF) condition ES601-US will record the number of the patient connection that produces the highest leakage.

In addition to NC and SF conditions listed above, IEC60601 and AAMI-ES1 standards require supplementary test conditions (STC). ES601-US allows the user to optionally enable or disable the STC in the leakage setup, according to the characteristics of the DUT. Optional STC include:

- performing tests with the DUT power switch in the "ON" position and also in the "OFF" position (ON/OFF test conditions);

- applying mains supply voltage to isolated signal inputs/outputs[1] on the DUT, or connecting such isolated signals to ground (IOS/IOG test conditions), and;

- connecting floating (ungrounded) metal parts on the DUT to ground (ME test condition).

During the test, ES601-US measures the lead leakage for each NC or single-fault SF condition in combination with all STC enabled by the user. For each NC or SF condition, ES601-US records the maximum leakage observed and the STC that produced the maximum leakage.

Patient leakage tests can be performed manually, but may be complex and time consuming to set up, particularly if there are a large number of patient leads or supplementary test conditions to specify. To save you time, ES601-US allows you to program and save such setups as automated test sequences, which are further described in Section 2.1.12.

2.1.9 Lead-to-Lead Leakage Current

In this test, sometimes called an "auxiliary leakage" test, ES601-US measures the current that flows out of one patient lead, through the human body load, and into all the other patient leads shorted together. As with all leakage tests, lead-to-lead leakage is measured in microamps, while simulating a variety of test conditions at the DUT.

In addition to specifying the individual test cases, the lead-to-lead leakage measurement requires the kind of patient leads tested to be classified as "B" - body, "BF" - body-floating or "CF" - cardiac-floating. This is done through the Group setup as described in the preceding section. Up to ten patient leads can be arbitrarily partitioned into the five Groups provided by the test setup.

When testing lead-to-lead leakage, ES601-US can be configured to record the following AC and DC values for each patient lead defined in the test setup:

Normal Polarity	Normal Condition	(NP:NORM. COND.)
	Single-Fault Condition, Neutral Open	(NP:OPEN NEUT.)
	Single-Fault Condition, Ground Open	(NP:OPEN GND.)
Reverse Polarity	Normal Condition	(RP:NORM. COND.)
	Single-Fault Condition, Neutral Open	(RP:OPEN NEUT.)
	Single-Fault Condition, Ground Open	(RP:OPEN GND.)

---

[1] An example of an isolated signal input/output would be a transformer-coupled data connection, for example, an Ethernet communications port on the DUT.

In addition to these six test conditions, IEC60601 and AAMI-ES1 standards require a supplementary test condition (STC) where the power switch on the DUT can be set to either "ON" or "OFF". If this STC is enabled, ES601-US measures lead-to-lead leakage for each normal (NC) or single-fault (SF) condition in combination with the DUT power switch in "ON" or "OFF" position. For each NC or SF test condition, ES601-US records the maximum leakage observed and the STC ("ON" or "OFF") that produced the maximum leakage.

2.1.10 Alternative and Direct Methods of Leakage Current Measurement

These methods for measurement of Device Leakage and Patient Leakage are set out in VDE-0751, which is the electrical safety standard for medical devices developed by Verband der Elektrotechnik, Elektronik und Informationstechnik (VDE), the organization that sets standards for all electrical equipment marketed in Germany. VDE-0751 procedures are simplified forms of IEC60601 test methods, and are specifically intended for post-repair testing of serviced electromedical equipment. Acceptance limits are comparable to IEC60601 but are tailored to suit the simplified nature of the test protocols.

The advantage of the "Alternative Method" or "Direct Method" of leakage testing under VDE-0751 is either method requires far fewer leakage measurements than either the IEC60601 standard or AAMI-ES1 standard. VDE-0751 allows safety tests to be completed much more rapidly, particularly when executed by ES601-US.

Another electrical safety standard provided by ES601-US, designated IEC62353, is a standard developed by IEC for medical device safety tests following repair service of equipment. The IEC62353 standard is similar to VDE-0751, particularly with respect to leakage testing. A significant difference, however, is that VDE-0751 specifies acceptance limits for the insulation resistance test, whereas IEC62353 requires the test to be performed but does not specify a limit. Additionally, VDE-0751 specifies DC limits for certain leakage measurements, whereas IEC62353 does not.

For VDE-0751 and IEC62353 standards, ES601-US records all results from all leakage measurements enabled by the user in the test setup. For the "direct method" of measurement, ES601-US will record AC and DC values for these test conditions:

Device Leakage:

Normal Polarity Single-Fault Condition, Ground Open (NP:OPEN GND.)

Reverse Polarity Single-Fault Condition, Ground Open (RP:OPEN GND.)

Patient Leakage (record for each Group defined by the user):

Normal Polarity	Normal Condition[2]	(NP:NORM.)
	Single-Fault Condition, Isolation Test	(NP:ISO. TEST)
Reverse Polarity	Normal Condition[2]	(RP:NORM.)
	Single-Fault Condition, Isolation Test(s)	(RP:ISO. TEST)

(2) VDE-0751 only: normal condition (patient lead(s) to ground) is measured if user enables "per IEC60601" method in the test setup.

2.1.11 Battery-Power Protocols

If the DUT is an internally-powered device, and cannot be operated from or connected to the AC line, then a subset of the above tests is applicable. If the DUT is defined as battery-powered by the user, ES601-US will test only patient lead leakage and lead-to-lead leakage of the DUT, and measure insulation resistance of the patient leads to ground.

To accommodate the unique needs of battery-powered devices, ES601-US incorporates special protocols designated "AAMI-BAT" (AAMI-ES1 standard for self-powered device), "IEC601-BAT" (IEC60601 standard for self-powered device), "VDE-BAT" (VDE-0751 standard for self-powered device) and "IEC353-BAT" (IEC62353 standard for self-powered device).

2.1.12 Safety AutoSequences

ES601-US can be programmed to automatically conduct the safety measurements described above. Automated safety measurements are always performed by ES601-US in a predefined order. The settings of an ES601-US Safety AutoSequence determine which measurements within the sequence are enabled, but do not affect the order in which the measurements are conducted.

ES601-US provides memory for storage of 24 user-programmable Safety AutoSequences. These sequences can be programmed and saved using the operator interface of ES601-US. Alternatively, the sequences can be programmed and loaded into ES601-US memory by means of the Safety AutoSequence module of the ES601pc-US software package (see Chapter 8). ES601pc-US software is included on CD ROM with ES601-US or may be downloaded or upgraded from Datrend's website - www.datrend.com.

A Safety AutoSequence can include measurements of line voltage, load current, ground resistance, insulation resistance, and leakages (external case, internal case, patient leads, lead-to-lead, etc.). For equipment having patient leads, each Safety Autosequence can be set up to organize the parts into *Functional Groups* of defined *Protection Class*, with names assignable to each Group as well as to each lead within each Group. Up to ten

patient leads can be arbitrarily assigned to the five Groups provided by ES601-US. *Sequence Control* settings, programmable as part of each AutoSequence setup, provide means for introducing variable time delays in the sequence, and for breaking the sequence at specific steps to allow the user to operate the "ON/OFF" power switch of the DUT. Other Sequence Control settings enable specific features within the ground resistance test, such as multiple resistance measurements or point-to-point testing.

ES601-US is shipped from the Datrend factory with 24 default Safety AutoSequences programmed into its memory. These default sequences are useful for testing many typical devices such as patient monitors, defibrillators, electrosurgical units, infusion pumps and other electromedical equipment. However, the defaults can easily be modified to suit the particular needs of the user's equipment inventory using the editor menus provided by ES601-US, or by means of ES601pc-US software.

2.2 Characteristics of ES601-US

2.2.1 Test Receptacle Configuration

The test receptacle of ES601-US is configured for North America.

North America /
120 VAC / 20A

2.2.2 Standard Accessories
Power Cord, N. America 15A (P/N 3000-009)
Kelvin Cable (P/N 3140-425)
USB Cable (P/N 3140-403)
ES601-US Product CD (P/N 6950-019)
Operator's Manual (included on P/N 6950-019)
ES601pc-US Application Software
                    (included on P/N 6950-019)

Installed Software Modules:
- Safety AutoSequences
- User-Defined Safety Limits
- ECG AutoSequences
- Oxitest +7 AutoSequences
- Infutest 2000 AutoSequences
- Phase 3 AutoSequences
- Physical Inspections
- User-Defined Testers
- PM Checklists
- Equipment Records
- CMMS Interface Module
- Test Report Generator

2.2.3 Optional Accessories
Barcode Scanner (P/N 7600-051 or 7600-052)
Dymo LabelWriter Printer Cable (P/N 7200-099)
PC Interface Cable DB9F-DB9M (P/N 3140-010)
AMPS1-to-ES601 Adaptor Cable (P/N 3140-429)
Phase3/Solo-to-ES601 Adapter Cable (P/N 7500-435)
Oxitest-to-ES601Adapter Cable (P/N 3140-060)
Infutest 2000-to-ES601Adapter Cable (P/N 7500-437)
Impulse-to-ES601 Adapter Cable (P/N 7500-438)
ECG/Banana Adapter (set of 10) (P/N 7500-425)
Power Cord, North America 20A (P/N 3000-010)
Crocodile Clip Test Lead, Black (P/N 7500-427)
Crocodile Clip Test Lead, Blue (P/N 7500-428)
Crocodile Clip Test Lead, Yellow (P/N 7500-429)
Crocodile Clip Test Lead, Green (P/N 7500-430)
Accessory Bag, Small 8.5" x 3" (P/N 7006-051)
Accessory Bag, Medium 7" x 5" (P/N 7006-052)
Accessory Bag, Large 8.5" x 6" (P/N 7006-050)
Soft Carry Case, ES601 size (P/N 7006-055)

2.3 Interface Layout

REAR PANEL:
1.   POWER SWITCH: Two-position (toggle) rocker switch
2.   AC POWER INPUT (MAINS SUPPLY)
20.   FUSES (2): AGC 1A / 250V

SIDE PANEL:
3.   RS-232 TESTER INTERFACES (6) for connection to external test instruments
4.   PRINTER INTERFACE PORT for connection of standard Centronics Printer
5.   RS-232 INTERFACE PORT provides RS-232 serial connection to serial printer or to COM Port of PC
6.   ETHERNET INTERFACE PORT provides communication with PC via *ES601pc-US* software
7.   USB INTERFACE PORT provides communication with PC via *ES601pc-US* software
8.   PS/2 INTERFACE for connection of PS/2 Keyboard or PS/2 Barcode Scanner
9.   CONTRAST ADJUSTMENT POTENTIOMETER (embedded)
10.   RS-232 BARCODE INTERFACE for connection of RS-232 Barcode Scanner
11.   FIRMWARE UPLOAD SWITCH (embedded) toggles between normal and firmware update mode

FRONT PANEL:
12.   ECG/PATIENT LEADS - ten safety-style banana jacks for connecting ECG
            and other patient leads
13.   Graphic LCD, 53 character x 30 lines, backlit, touch-screen

TOP PANEL:
14.   Three safety-style banana jacks, which provide signal connections:
            RED – Kelvin Cable input for Ground Resistance Test
            BLACK – Kelvin Cable input for Ground Resistance Test
            GREEN – direct connection to ground pin of TEST RECEPTACLE
15.   AUX1 and AUX2 provide connection for special leakage tests
16.   TEST RECEPTACLE for Device Under Test (DUT)

ES601-US OPERATING MANUAL

Chapter

3
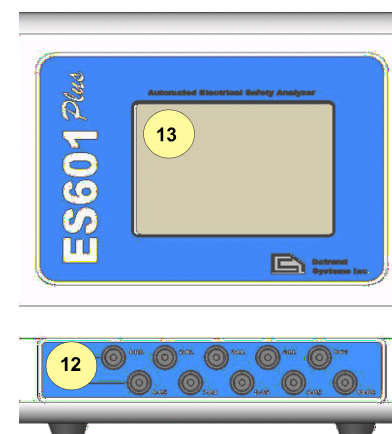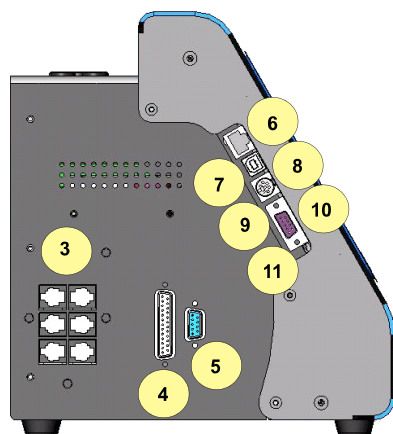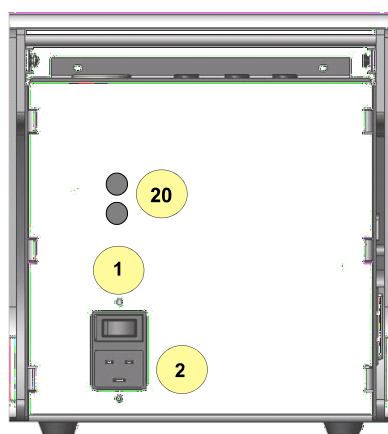
3   Setup

3.1 Powering Up

When the power to ES601-US is switched on, the Start-Up menu is displayed while internal self-tests are conducted. The Start-Up menu displays the firmware version and the current time and date. After a few seconds, the Startup Menu is replaced by the MAIN MENU of ES601-US.

Figure 3 - *Startup Menu*
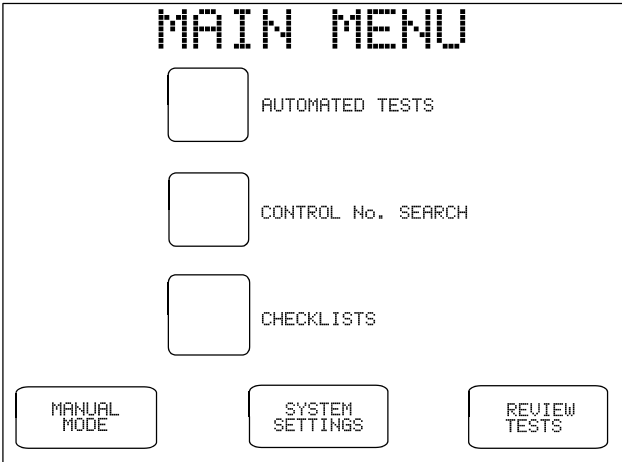
Figure 4 - *Main Menu*

Optionally, the "STARTUP MODE" of ES601-US can be set to enable a test of the AC supply voltage at power-on. If the AC supply test at startup has been enabled, ES601-US will produce an alarm if a reversed-supply condition is detected. Note that a reversed AC supply may affect test results, particularly the leakage measurements. In the event of a reversed-supply alarm, connect to a different wall outlet or investigate the wiring of the wall outlet in use before proceeding.

3.2 System Settings Menu #1

Press the **SYSTEM SETTINGS** button on the MAIN MENU to view or modify the configuration of ES601-US. System settings are distributed across three menus (#1, #2 and #3), with the third menu allowing for password protection.
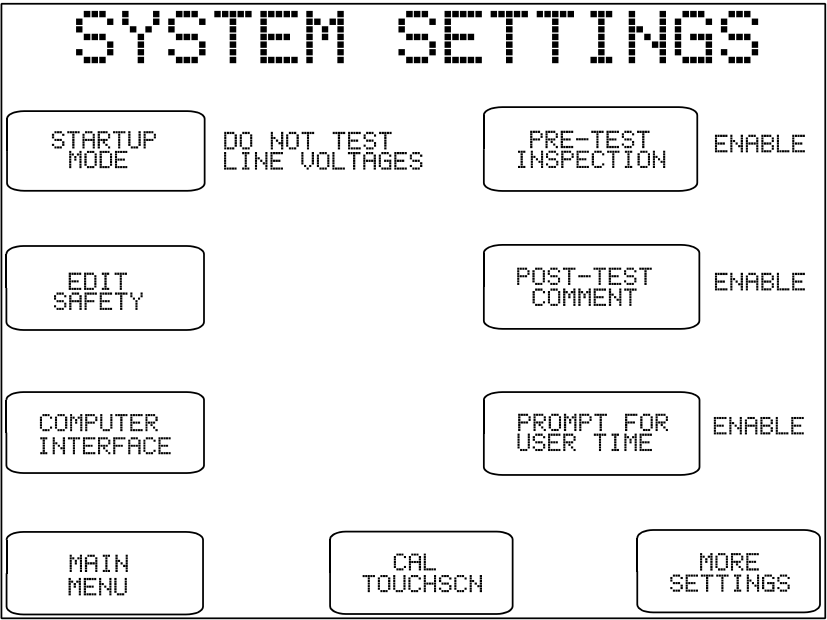
Figure 5: *System Settings Menu #1*

The buttons provided on Systems Settings Menu #1 are:

STARTUP MODE:	Determines whether or not ES601-US performs a test of the AC supply voltage at power-on. The default is "do not test".
EDIT SAFETY:	Enters a menu for editing the settings of Safety AutoSequences. Refer to Section 3.6, following.
COMPUTER INTERFACE:	Enters a menu for uploading instrument configuration data (AutoSequences; Checklists; equipment control number lists) into ES601-US, as transmitted by a personal computer (PC) running the ES601pc-US software program. This menu is also used for downloading test data from ES601-US, into the ES601pc-US program. Buttons provided on the COMPUTER INTERFACE menu are used to select the physical connection to the PC, as follows:

RS-232 PORT:	Opens the connection via the RS-232 Port and awaits communication from the PC running ES601pc-US.
USB PORT:	Opens the connection via the USB Port and awaits communication from the PC running ES601pc-US.
ETHERNET PORT:	Opens the connection via the ETHERNET Port and awaits communication from the PC running ES601pc-US.
BACK:	Exit Computer Interface mode to the System Settings menu.

CAL TOUCHSCN: Enters a utility for calibrating the touch screen of ES601-US. Note: If the user chooses to perform the calibration procedure, the calibration must be completed as directed by the instructions presented on the LCD, otherwise, an unuseable touch screen may result (see Chapter 9).

PRE-TEST INSPECTION: Determines whether or not a physical inspection of the equipment is requested at the start of an automated test (autosequence or checklist). If enabled, the user will be asked to enter up to two lines of comments to describe the inspection that was performed and the results.

POST-TEST COMMENT: Determines whether or not the user will be prompted to enter comments at the end of an automated test (autosequence or checklist).

PROMPT FOR USER TIME: Determines whether or not the user will be prompted to enter a "user time" at the end of an automated test (autosequence or checklist). The user time is the time taken to complete an assigned work task, and is a data entry required by some computerized maintenance management systems (CMMS).

MAIN MENU: Return to the MAIN MENU. On exit, changes made to settings are saved in the non-volatile memory of ES601-US.

MORE SETTINGS: Displays System Settings Menu #2. Refer to the following section.

3.3 System Settings Menu #2
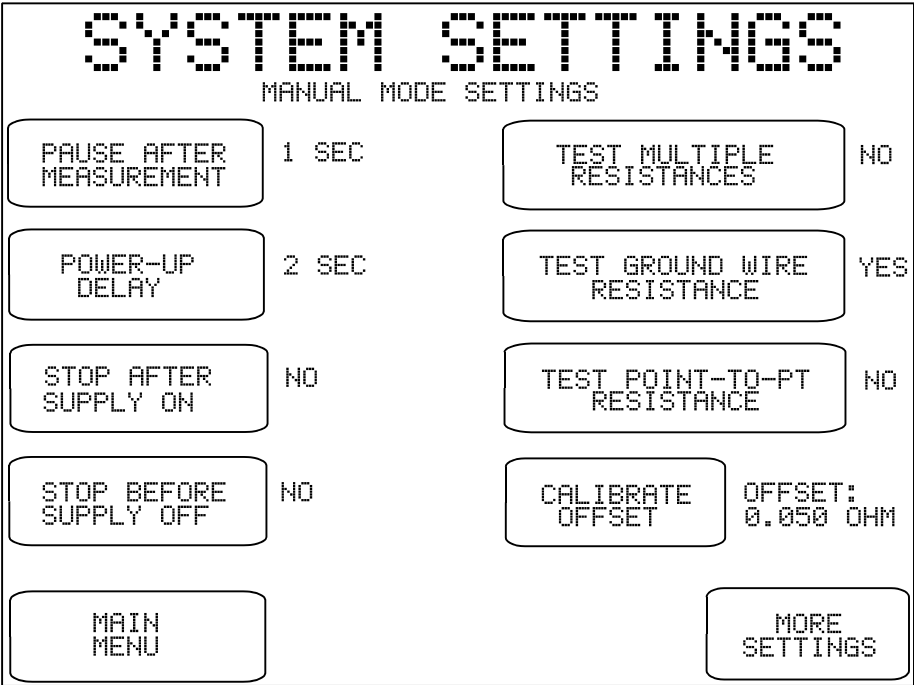
Figure 6: *System Setting Menu #2*

System Settings Menu #2 shows default *Sequence Controls* for MANUAL MODE tests. Buttons on the left of this menu pertain to manual leakage and load current tests, and buttons on the right pertain to manual ground resistance tests.

When a leakage or ground resistance test is selected from the MANUAL MODE menu, the applicable Sequence Controls from System Settings Menu #2 are recalled and are shown on the display. Before proceeding with the test, the user may modify the default Sequence Controls to suit the specific needs of the equipment being tested. After the manual test is completed, the Sequence Controls revert to the default settings shown on System Settings Menu #2. System Settings Menu #2 should therefore be configured to suit the user's preference for manual tests, based on the requirements of equipment most often tested in manual mode.

The buttons provided on Systems Settings Menu #2 are:

PAUSE AFTER MEASUREMENT: After each measurement of a manual leakage test, ES601-US will pause for the indicated time before proceeding with the next measurement of the sequence. The available settings are "NO" (no pause); 1 second (factory default); 2, 3, 4 and 5 seconds. The delay provided by this control allows the user to more easily interrupt a leakage sequence in progress, so a particular measurement of interest can be repeated as desired.

POWER UP DELAY: During a manual leakage test, ES601-US will wait for the indicated time when the AC supply is applied to the DUT, before proceeding with the test sequence. This delay allows the DUT to start up and stabilize before subsequent leakage measurements are taken. The available options are 2 seconds (factory default), or 3 to 9 seconds in one second steps. Equipment requiring more than 9 seconds to start up are better accommodated through the "STOP AFTER..." control, described below.

STOP AFTER SUPPLY ON: If set to "YES", this control will override the power-up delay setting described above and will cause a manual leakage test to *fully stop* immediately after the AC supply is connected to the DUT by ES601-US. ES601-US will then prompt the user to activate the DUT and will not proceed until the user acknowledges by pressing the **CONTINUE** button. This feature accommodates equipment with a momentary ON/OFF power switch, which cannot be switched ON until a full AC supply is provided to the equipment. The factory default setting for this control is "NO", which then enables the power-up delay described above.

STOP BEFORE SUPPLY OFF: If set to "YES", this control will cause a manual leakage test to *fully stop* immediately before a test step which disconnects the AC supply from the DUT. ES601-US will then prompt the user to shut down the DUT and will not proceed until the user acknowledges by pressing the **CONTINUE** button. After **CONTINUE** is pressed, ES601-US will then disconnect the AC supply from the DUT. This feature accommodates equipment having special shutdown requirements, such as diagnostic imaging equipment or equipment incorporating a personal computer. The factory default setting for this control is "NO".

TEST MULTIPLE RESISTANCES: If set to "YES", this control will enable multiple ground and/or point-to-point resistance measurements within the scope of a manual ground resistance test. Up to ten resistance measurements may be recorded by ES601-US in multiple resistance mode. If set to "NO" (factory default), a manual ground resistance test is completed by performing a single measurement of the resistance.

TEST GROUND WIRE RESISTANCE: If set to "YES" (factory default), this control will enable measurement of the ground wire or power cord resistance in a manual test. For this type of test, resistance is measured between the ground terminal on the line cord plug and the Kelvin Cable of ES601-US, which would typically be connected to a grounding stud (ground terminal) or the metal enclosure of the DUT. If set to "NO", point-to-point resistance measurements will then be enabled by means of the control below.

TEST POINT-TO-PT RESISTANCE: If set to "YES", this control will enable measurement of resistance between two points, one being the point of attachment of the Kelvin Cable of ES601-US, and the other being the point of attachment of a test lead which connects to the "TO DUT CASE" jack of ES601-US. If set to "NO" (factory default), point-to-point resistance testing is disabled in manual mode. This control works with the "TEST MULTIPLE RESISTANCES" control and the "TEST GROUND WIRE" control above, thereby providing a variety of protocols for testing the ground resistance as described in Section 5.9.

CALIBRATE OFFSET: The "OFFSET:" displayed to the right of this control is the resistance of the test lead used in measuring point-to-point resistance. In a point-to-point test, the OFFSET calibration shown on Systems Settings Menu #2 is subtracted from the measured resistance to obtain the result which is displayed by ES601-US. The factory default value is 0.050 ohms, which is representative of a typical test lead of 2-metre length. However, prior to performing point-to-point tests, the OFFSET of the actual test lead connected to ES601-US should be determined. Section 5.9 provides instructions for calibration of the test lead OFFSET.

The OFFSET calibration differs from other Sequence Controls on Systems Settings Menu #2 in that it pertains to manual safety tests *as well as* automated safety tests.

CALIBRATE OFFSET (continued): However, OFFSET is similar to other Sequence Controls in that the OFFSET will be displayed by ES601-US at the start of every ground test, manual or automated. This permits temporary modification of the OFFSET value to suit a particular test lead that may be in use at the time. After the test is completed, the OFFSET will revert to the default setting as shown on System Settings Menu #2.

Refer to Section 5.9 for more details on operation of the ground resistance test, and for point-to-point test instructions in particular.

MAIN MENU: Returns the display to the MAIN MENU. On exit, changes made to the Sequence Controls are saved in the non-volatile memory of ES601-US.

MORE SETTINGS: Displays System Settings Menu #3.

If a password has been enabled via SYSTEM SETTINGS Menu #3, the user will be prompted to enter the password when MORE SETTINGS on Menu #2 is pressed. The password is entered via the QWERTY touch keypad. Operations and features of the QWERTY touch keypad are discussed at the end of this chapter.

If a password is enabled but forgotten, an override password may be obtained from Datrend Customer Service. After the override password is entered, the user's password can be disabled or changed.

3.4 System Settings Menu #3
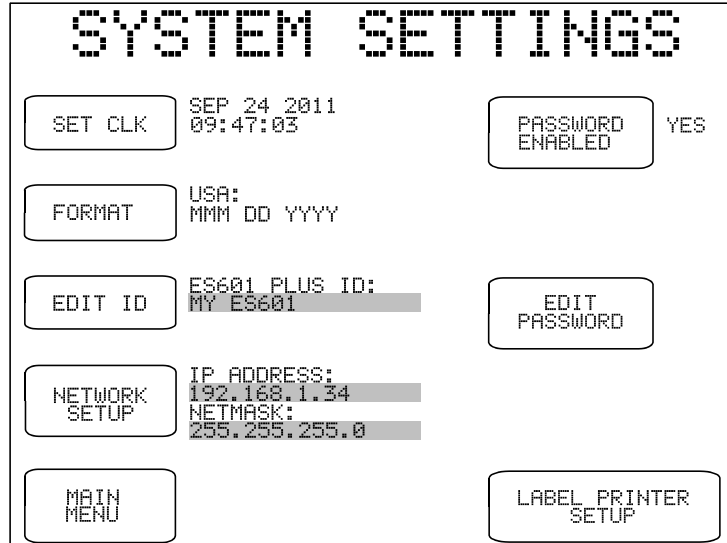
Figure 7 - *System Settings Menu #3*

The buttons provided on System Settings Menu #3 are:

SET CLK: Allows setting the internal real time clock.

FORMAT: Select date format for the internal real-time clock, as follows:
- USA (MMM DD YYYY)
- Europe (DD MMM YYYY)
- ISO (YYYY MMM DD)

EDIT ID: ES601-US I.D. is set at time of manufacture to "MY ES601", and can be edited using this utility which allows the user to input a unique I.D. to identify ES601-US within the user's equipment management system. This I.D. is meant to be a control number or similar reference, and should not be confused with the unit serial number.

          Pressing this button will activate the QWERTY touch keypad of ES601-US, allowing the user to type in an I.D. Refer to Section 3.5 for more information on operation and features of the QWERTY keypad.

PASSWORD ENABLED: Referring to System Setup Menu #2, this global enable/disable switch for the password may be toggled between "YES" and "NO". Default is "NO".

EDIT PASSWORD: When pressed, this button displays the QWERTY keypad for entering a password. The maximum length of the password is 17 characters. By default, the password is set to all-whitespace. The password is shown as it is typed for verification. Refer to Section 3.5 for more information on operation and features of the QWERTY keypad.

NETWORK SETUP: Allows the user to input Ethernet settings (IP address, netmask, and gateway) for ES601-US (see *Figure 6*). Addresses are entered with decimal delimiters. A touch keypad that provides for numerical input only is displayed in response to pressing any of the **CHANGE** keys. Pressing **BACK** saves changes made and restores the Systems Settings Menu #3.

```
         NETWORK  SETUP
     ┌──────────────────────────────────┐
     │             WARNING              │
     │  INVALID SETTINGS MAY CAUSE UNPREDICTABLE │
     │  BEHAVIOUR OR DISRUPTION. CONSULT NETWORK │
     │     ADMINISTRATOR WHERE APPROPRIATE.      │
     └──────────────────────────────────┘

   Enter all settings using decimal address delimiters.
        MAC ADDRESS: 00:90:C2:C1:10:45

         IP ADDRESS: 192.168.1.2      ┌────────┐
                                      │ CHANGE │
                                      └────────┘

            NETMASK: 255.255.255.0    ┌────────┐
                                      │ CHANGE │
                                      └────────┘

  DEFAULT GATEWAY: 192.168.1.1        ┌────────┐
                                      │ CHANGE │
                                      └────────┘

                                      ┌────────┐
                                      │  BACK  │
                                      └────────┘
```
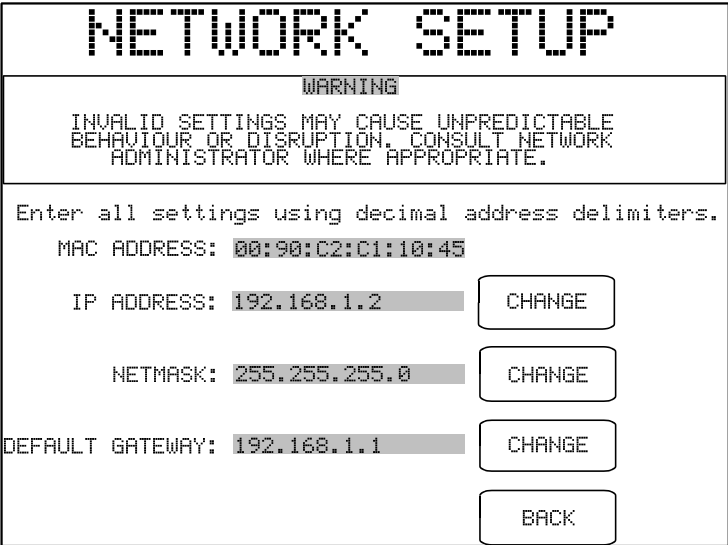
Figure 8 - *Network Setup*

MAIN MENU: Returns the display to the MAIN MENU. On exit, changes made to the Sequence Controls are saved in the non-volatile memory of ES601-US.

LABEL PRINTER SETUP:

A Dymo SE300 LabelWriter printer may be connected to the RS-232 Port of ES601-US, which will allow printing of adhesive labels which are sometimes referred to as "PM Tags". The PM Tag is applied to the tested equipment, identifying the equipment as fit for use and a date when the next PM inspection is due. The LABEL PRINTER SETUP button enters a menu for configuring the PM Tag printer. Options on this menu are:

PRINT LABEL: Enables printing of a PM Tag upon completion of an autosequence or checklist, after the Test Record has been saved to the memory of ES601-US.

EDIT TITLE: Displays the QWERTY keypad, allowing the user to enter the title which appears at the top of the printed label. Typically, this would be the name of the institution which owns the equipment.

NEXT TEST IN: These increment/decrement buttons allow adjustment of the "PM interval" for the equipment tested. The "PM DUE" date which is printed on the PM Tag is obtained by adding this value to the current date from the ES601-US clock.

TEST PRINT: Outputs a sample PM Tag to a Dymo model SE300 printer connected to the RS-232 Port of ES601-US.

BACK: Save changes and return to the System Settings menu.

The above settings are defaults, which may be modified by the user at the time the PM Tag is actually printed.
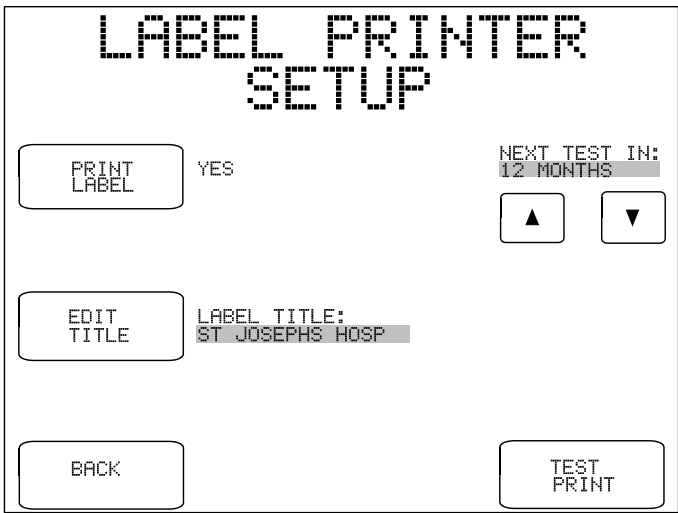
Figure 9 - *Label Printer Setup*

3.5 About the QWERTY Keypad

The QWERTY touch keypad of ES601-US is used for entering system settings, equipment information, control numbers, comments and test data. An example of the QWERTY keypad is shown in *Figure 8*, for entering the ES601 I.D. of System Settings Menu #3.

When the QWERTY keypad is activated on the display, ES601-US will also optionally accept character data from ES601-US Barcode Reader Port or from the PS/2 Keyboard / Barcode Port. When activity is sensed from any one of these input devices, the other two are disabled until the next time the QWERTY keypad is displayed.
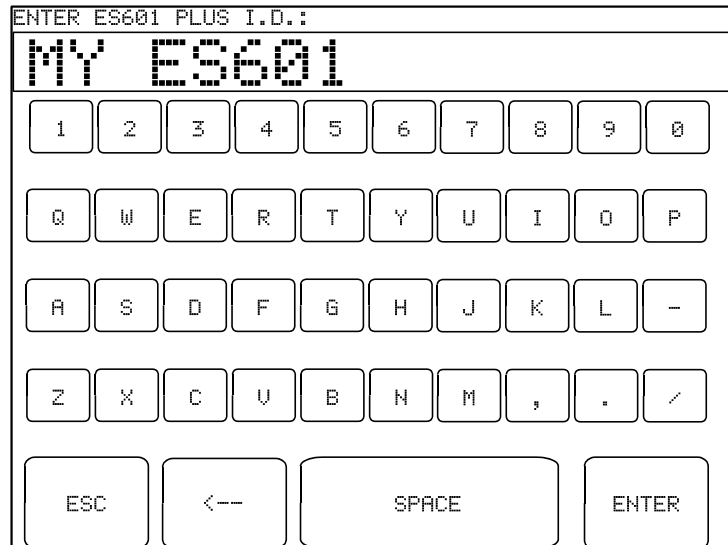
Figure 10 - *QWERTY Keypad*

ES601-US reacts differently to data arriving via the Barcode Reader Port, compared to data from a PS/2 keyboard. For data received via the Barcode Port, ES601-US will wait until a complete string of characters, terminated by carriage return, is received. After sensing a carriage return, ES601-US removes the QWERTY keypad from the LCD display, and shows the Barcode data on the LCD along with **ENTER** and **CANCEL** buttons, allowing the user to accept or reject the received data.

For the case of data received via the PS/2 Keyboard Port, ES601-US displays each character as it is received from the external keyboard. In this case, characters typed on the external keyboard simply appear at the top of the QWERTY display until a carriage return is sensed.

3.6 Safety AutoSequence Editor

ES601-US can be programmed to automatically perform the measurements which comprise a complete test of electrical safety. In an automated test or "*AutoSequence*", the measurements are performed in a continuous sequence, one after the other. According to the user's programming, the sequence can be optionally broken at specific steps to allow operation of the DUT or changes in electrical connections. AutoSequences can save a significant amount of time when testing complicated equipment with multiple patient leads, such as patient monitors.

ES601-US provides memory for storage of 24 user-programmable Safety AutoSequences. These sequences can be programmed by means of the Safety AutoSequence module of the ES601pc-US software package included with ES601-US (see Chapter 8). Alternatively, the sequences can be programmed using the operator interface of ES601-US as described in this section. Note that figures appearing in this section illustrate example settings only; the specific appearance of menus on your ES601-US will depend on how your instrument may have been programmed previously.

The AutoSequence programmer is entered from System Settings Menu #1, via the **EDIT SAFETY** button (see Section 3.2). A menu will then be displayed allowing the user to select an AutoSequence for editing:

```
          SAFETY AUTOSEQ

  ┌──┐  #01                ┌──┐  #02
  │  │  A1,A6: 10LD X,I    │  │  A2,A7: 3LD X,I
  └──┘  10-LEAD ECG TEST   └──┘  3-LEAD ECG TEST


  ┌──┐  #03                ┌──┐  #04
  │  │  A3,A8: 4LD X,I     │  │  A4,A9: CASE X,I
  └──┘  4-LEAD ECG TEST    └──┘  CASE LKG (CRITICAL)


  ┌──┐  #05                ┌──┐  #06
  │  │  A5,A10: GEN X,I    │  │  A11: BLANK
  └──┘  CASE LKG (GENERAL)

              PAGE: 1 OF 4
  ┌──────────┐  ┌───────────┐  ┌───────────┐
  │   BACK   │  │ PREV PAGE │  │ NEXT PAGE │
  └──────────┘  └───────────┘  └───────────┘
```
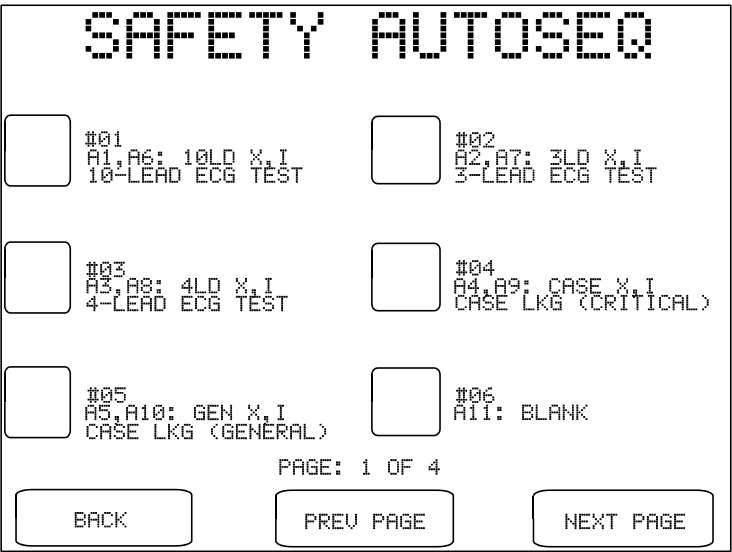
Figure 11 *- AutoSequence selector menu.*

On the selector menu, use **PREV PAGE** and **NEXT PAGE** buttons to view the four menu screens provided. When the desired AutoSequence appears on the screen, press the button to the left of the title to view the editor main menu:
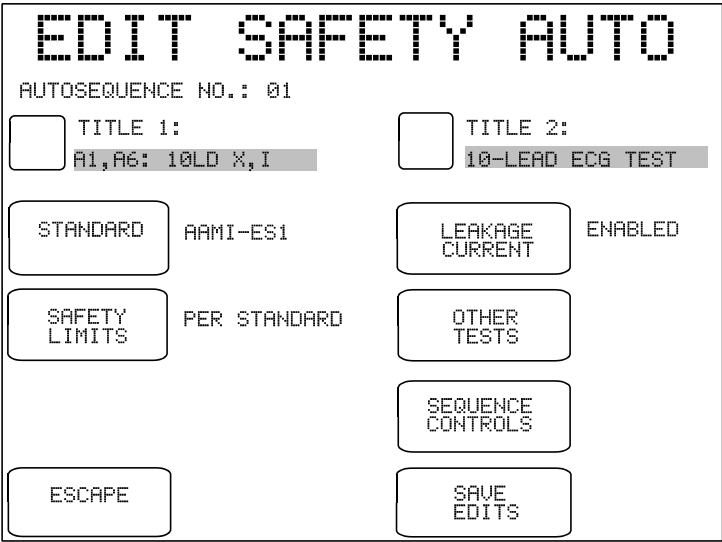
Figure 12 *- AutoSequence editor, Main Menu.*

The buttons provided on the main menu of the AutoSequence editor are:

TITLE 1 / TITLE 2:   Press to modify line #1 or line #2 of the AutoSequence title. The QWERTY keypad will be displayed. Refer to Section 3.5 for details on QWERTY keypad operation.

STANDARD: Press to change the safety standard. The available standards include AAMI-ES1, IEC60601, IEC62353, IEC61010, VDE-0751, and their variants for battery-powered devices. This setting will affect which tests are provided by the other buttons on the editor.

SAFETY LIMITS: Press to choose between "PER STANDARD" and "USER-DEFINED". User-defined safety limits allow you to set alternative ground and leakage current limits to suit older equipment, manufacturer specifications, or other special test requirements. One user-defined table of limits is provided for each of the safety standards, and these special tables are programmed and loaded into ES601-US memory by means of a corresponding module of the ES601pc-US software package (see Chapter 8).

LEAKAGE CURRENT: Press to enter a menu for configuring the leakage current measurements of the AutoSequence. The appearance of this menu and the range of settings provided by it will depend on the safety standard chosen. The example menu below is for the AAMI-ES1 standard.

Settings of the leakage current menu determine which single-fault conditions will be enabled in the AutoSequence. Additional buttons enable or disable testing of patient leads, and enable or disable supplementary test conditions such as mains on isolated data I/O and testing of ungrounded metal parts. Refer to Section 5.10 for further details on the leakage test conditions configured by the buttons on this menu.
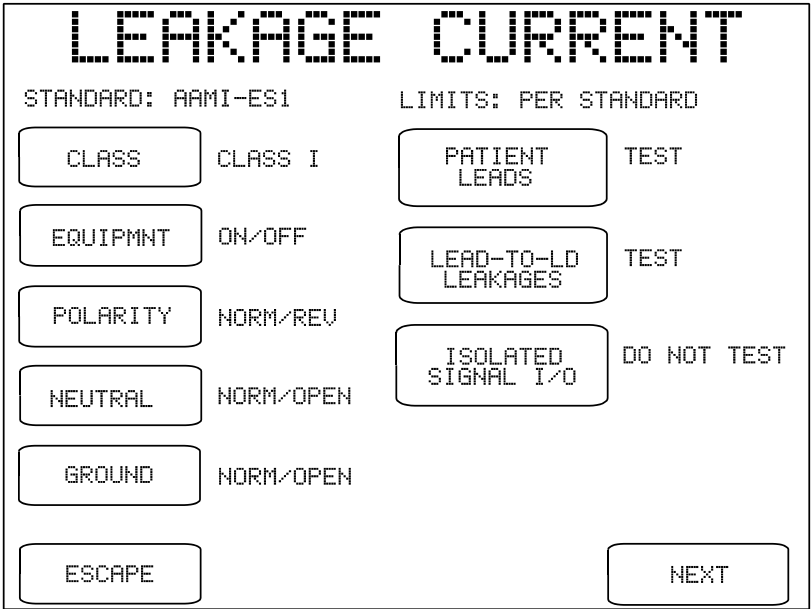
Figure 13 - Leakage current menu for AAMI-ES1 standard.

Specific buttons provided by the leakage current menu have a common function regardless of the safety standard. These buttons are:

ESCAPE: Press this button to disable all leakage measurements in the AutoSequence and return to the main menu of the AutoSequence editor. On the main menu of the editor, "DISABLED" will then appear to the right of the **LEAKAGE CURRENT** button.

NEXT: Press this button to enable leakage measurement in the AutoSequence and proceed to the next menu. If **PATIENT LEADS** of the leakage current menu is set to "TEST", the next menu will be the patient leads editor (see Section 5.10). If **PATIENT LEADS** is set to "DO NOT TEST", the **NEXT** button restores the main menu of the AutoSequence editor.

OTHER TESTS: Referring back to the main menu of the AutoSequence editor (**Figure 10**), this button enters a submenu for enabling or disabling tests of line voltage; load current; insulation resistance of line input to ground (LINE-GND); insulation resistance of patient leads to ground (AP-GND); and ground resistance.

Tests provided by this submenu will depend on the safety standard. For example, if the safety standard pertains to battery-powered equipment, then the only test provided on this menu will be insulation resistance of patient leads to ground.

The **BACK** button of this menu restores the main menu of the AutoSequence editor.
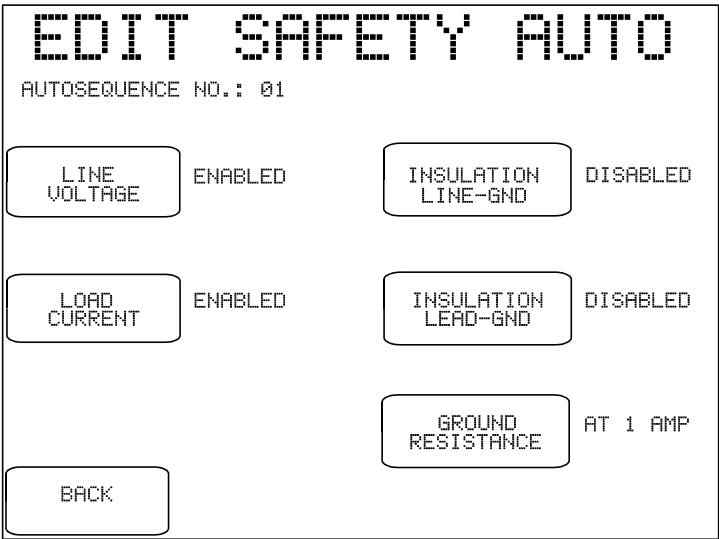
Figure 14 - Enable/disable "other tests" of the safety standard.

SEQUENCE CONTROLS:

Referring back to the editor main menu (**Figure 10**), pressing this button activates a submenu for setting the Sequence Controls of the AutoSequence. Each Safety AutoSequence has its own dedicated set of Sequence Controls.

Buttons on the left of the Sequence Controls menu pertain to leakage current measurement as described in Section 3.3. These controls affect time delays or optional breaks which may occur at specific steps in the test sequence. Buttons on the right of the Sequence Control menu affect operation of the ground resistance test as described in Sections 3.3 and 5.9.

Note that Safety AutoSequences do not include an offset calibration for point-to-point resistance measurement; there is only one OFFSET calibration for ES601-US and this is input by means of System Settings Menu #2, according to Section 3.3. When a Safety AutoSequence is executed, the OFFSET calibration is recalled from the System Settings and is displayed; if necessary, the user may then temporarily modify the OFFSET to suit the test lead being used for point-to-point measurement. If modified, the OFFSET will revert to the System Setting upon completion of the AutoSequence.

Figure 15 - *Editor for Sequence Controls.*

SAVE EDITS: Referring back to the main menu of the AutoSequence editor (***Figure 10***), pressing this button causes ES601-US to prompt you to store the AutoSequence in non-volatile memory. Responding "YES" to the displayed prompt will store the AutoSequence settings to the memory location indicated, and will return ES601-US to System Settings Menu #1. Pressing "NO" will return ES601-US to Systems Settings Menu #1 without storing the AutoSequence.

```
┌──────────────────────────────────────────┐
│                                          │
│     EDIT SAFETY AUTO                     │
│                                          │
│                                          │
│                                          │
│     SAVE EDITS AS SAFETY AUTOSEQUENCE #01?│
│   ┌──────────────┐      ┌──────────────┐ │
│   │      NO      │      │     YES      │ │
│   └──────────────┘      └──────────────┘ │
│                                          │
│                                          │
│                                          │
│                                          │
└──────────────────────────────────────────┘
```

Figure 16 *- Prompt to save AutoSequence edits.*

ESCAPE: Referring back to the main menu of the editor, pressing this button causes ES601-US to return to System Settings Menu #1. Any changes which may have been input are discarded.

Chapter

4

4   Connecting to ES601-US

When using ES601-US, the operator is expected to be familiar with the particular Electrical Safety Standard to which the DUT is being tested. It is recommended the operator have access to the Standard and refer to the Standard, as needed, during the test.

4.1 Connecting an AC-Powered DUT to ES601-US

Connection instructions for AC-powered DUT:

- Whenever connecting or disconnecting a DUT or peripheral devices to ES601-US, the power switches of all equipment should be OFF.

- Connect the DUT power cable to the ES601-US Test Receptacle. Note that the Test Receptacle power is controlled by the particular sequence or test you are running. This control is inherent to the Electrical Safety s, ECG Simulator and Test Device Autosequences; but, if you wish to have power applied during other types of Autosequences or Checklists, power must be applied or removed through the use of the TRPN or GTOL commands (see 6.1.5.7 The M Checkitem).

- Connect the Kelvin Cable to a grounded terminal on the enclosure of the DUT.

- AUX1 connects to electrically isolated input/output signals. Typically this connection would be for testing a transformer-isolated data communications interface on the DUT, such as an Ethernet Port. Review DUT documentation or check with the DUT manufacturer before making this connection, or performing tests of isolated input/output signals.

- AUX2 connects to any exposed ungrounded metal on the DUT.

- Note AUX1 and AUX2 connections are optional depending on the characteristics of the DUT and the requirements of the testing standard.

- DUT patient leads (or "applied parts"), if any, are connected to ES601-US jacks AP1 through AP10 as required.
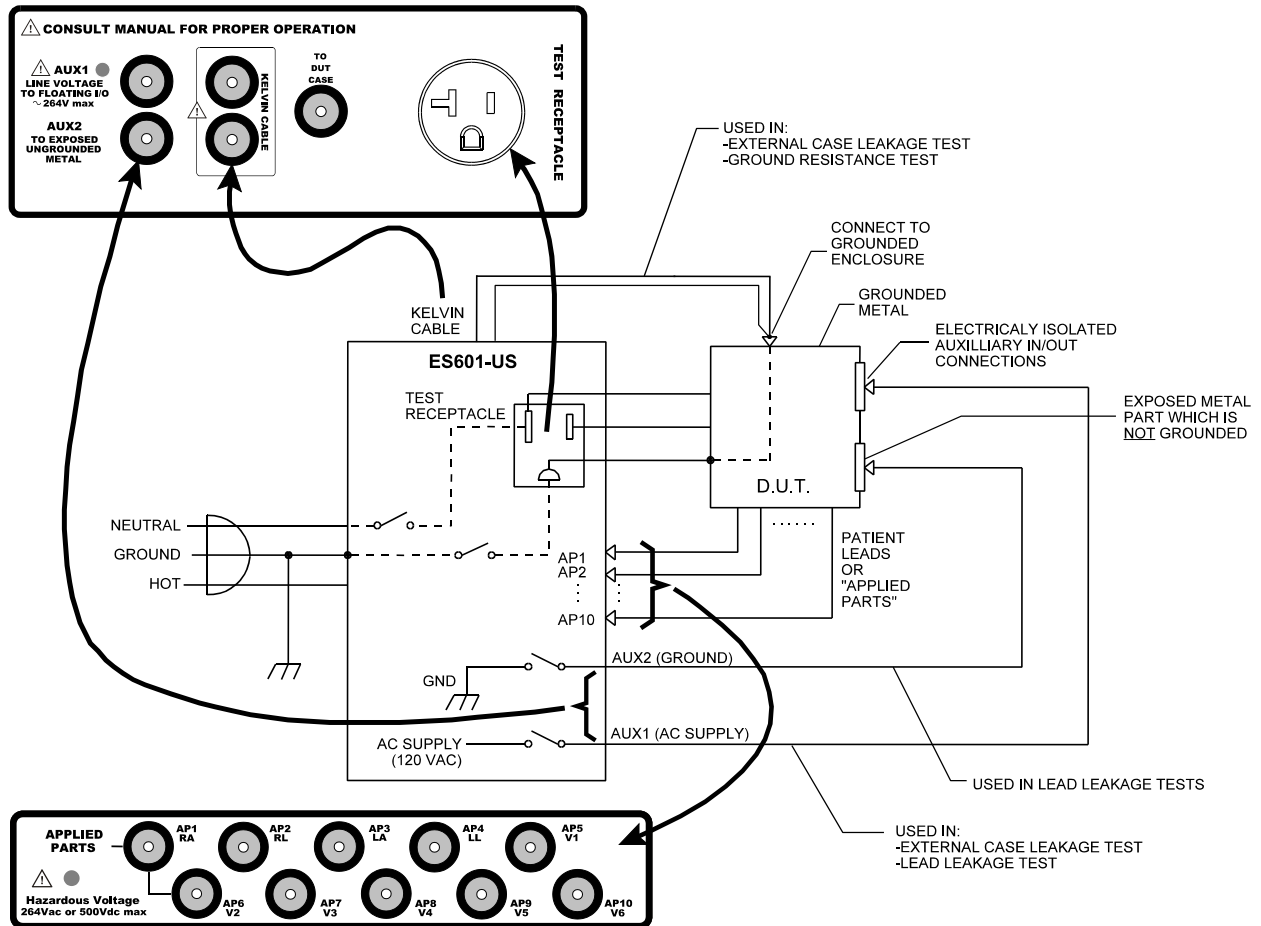
Figure 17 - *Connecting to a line-powered DUT*

4.2 Connecting a Battery-Powered DUT to ES601-US
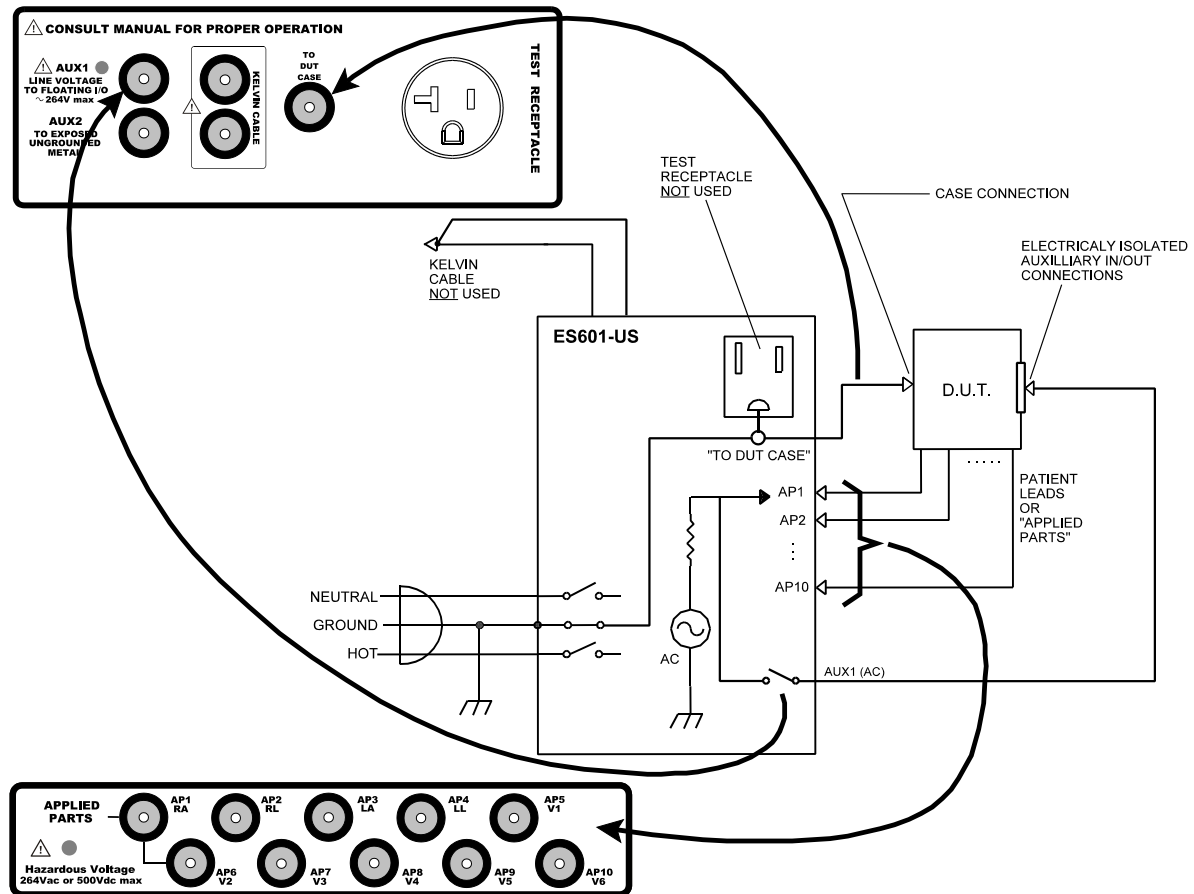
Figure 18 - *Connecting to a battery-powered DUT*

Connection instructions for battery-powered DUT:

• Whenever connecting or disconnecting a DUT or peripheral devices to ES601-US, the power switches of all equipment should be OFF.

• The "TO DUT CASE" jack of ES601-US connects to the enclosure of the DUT, or alternatively, to aluminum foil which is wrapped over the DUT if the enclosure is made of plastic.

• As required, AUX1 may connect to electrically isolated input/output signals. Most typically, this connection would be for testing a transformer-isolated data communications interface on the DUT, such as an Ethernet Port.

• Note the Test Receptacle and the Kelvin Cable are not used for testing internally-powered devices.

4.3 Connecting Peripheral Devices

Input connections for data entry during tests are optional. Data can always be entered via the on-screen QWERTY keyboard.

Connect a PS/2 keyboard or barcode scanner to the PS/2 input of the ES601- US.

OR...

Connect an RS-232 barcode scanner (DB9F) to the BARCODE input of the ES601-US.

Peripheral testing devices, if used, should be connected to RS232 TESTER PORTS before powering the ES601-US on. RJ-12 serial cables are required.

Connect Centronix printer cable (DB25M) as necessary for direct output printing.

Connect RS-232 cable (DB9M) to serial printer or to PC for outputting test record data via a terminal program (i.e., Windows 98/2000/XP HyperTerminal or equivalent) as discussed in Chapter 5 of this manual.
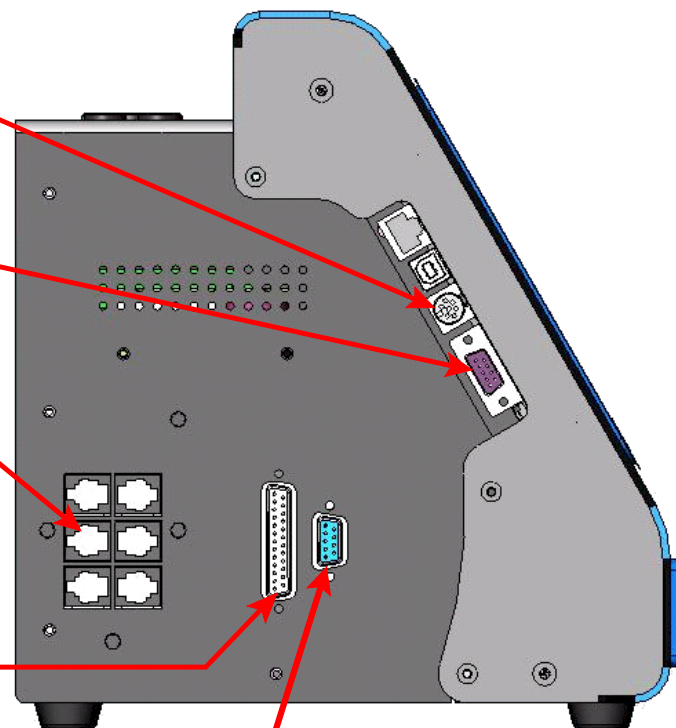
Figure 19 - *Connecting Peripheral Devices*

Chapter

5

5   Manual Testing

5.1 Manual Mode Display

The **MANUAL MODE** button on the MAIN MENU of ES601-US enters a menu which permits the electrical safety analyzer to be operated manually. The MANUAL MODE menu also provides access to a submenu for manually operating the ECG simulator, via the **ECG MENU** button
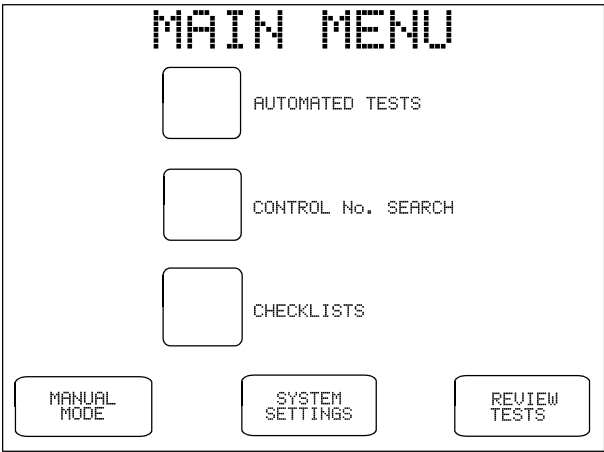
Figure 20 - *Main Menu of ES601-US.*
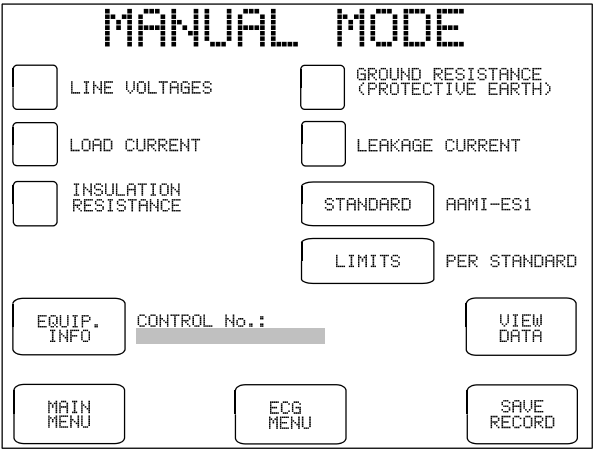
Figure 21 - *Manual safety tests.*

5.2 Data Buffer

As safety measurements are performed in MANUAL MODE, each measurement result may be copied to a temporary data buffer. Current contents of the buffer may be viewed from the MANUAL MODE menu via the **VIEW DATA** button. When manual testing is complete, a non-volatile Record of the results stored in the data buffer may then be created, by pressing the **SAVE RECORD** button.

Returning to the MAIN MENU will cause the temporary data buffer to be ***erased***. If you wish to save results obtained during manual testing, do so via the **SAVE RECORD** button before returning to the MAIN MENU.

5.3 Safety Standards

NOTE:

The safety standard should not be changed ***during*** a manual test. Pressing this button during a manual test will cause the temporary data buffer to be ***erased***. Select the standard ***first***, then proceed with manual safety tests.

The **STANDARD** button on the MANUAL MODE menu allows you to select the electrical safety standard to be applied. Available options are:

- AAMI-ES1
- IEC60601
- VDE0751
- IEC62353
- IEC601-BAT (IEC60601 standard for battery-powered equipment)
- AAMI-BAT (AAMI standard for battery-powered equipment)
- VDE-BAT (VDE0751 standard for battery-powered equipment)
- IEC353-BAT (IEC62353 standard for battery-powered equipment)
- IEC61010

When one of the "-BAT" safety standards is selected on the MANUAL MODE menu, buttons for LINE VOLTAGE; LOAD CURRENT; and GROUND RESISTANCE are removed from the menu, leaving just the LEAKAGE CURRENT and INSULATION RESISTANCE buttons, and other buttons related to saving or viewing test data.

To save the safety standard in the non-volatile flash memory of ES601-US, select the desired standard via the **STANDARD** button, then exit to the MAIN MENU. On return to the MANUAL MODE menu, the safety standard will be restored from the flash memory.

5.4 Safety Limits

ES601-US provides for "user-defined" safety limits. This feature allows the user to select the pass/fail limits to be applied to electrical safety measurements performed under a given standard. This setting may be toggled between:

  • Per Standard (default)
  • User-Defined

Each of the primary electrical standards (IEC60601; AAMI-ES1; VDE0751; IEC62353; and IEC61010) is allocated one user-programmable table of limit values. The five user tables are maintained in the non-volatile flash memory of ES601-US. Leakage and other limit values in these tables may be edited using the Electrical Safety Limits module of the ES601pc-US software package, provided with the analyzer.

5.5 Equipment Information Menu

Press the **EQUIP. INFO** button to enter information about the equipment being tested. The EQUIPMENT INFO menu allows entry of information such as the equipment control number, type (description), manufacturer, model, serial number, facility, location and "TECH CODE" (technician identification).

Figure 22 - *Equipment information menu.*

Equipment information is held in the temporary data buffer and can be updated at any time during a manual test, until the data buffer is saved via the **SAVE RECORD** button. When a Test Record is saved, the Control Number and Serial Number fields of the equipment information are automatically cleared. The remaining equipment information will remain unchanged, so multiple devices of the same make, model, location and facility can be tested without having to re-enter the information.

The equipment information fields are printed in the heading of the Test Report generated by ES601-US. This information helps identify the equipment beyond the Control Number. This is helpful for those facilities that do not use a Computerized Maintenance Management System, and rely more on hardcopy records.

On the EQUIPMENT INFO menu, pressing the button located to the left of each data field activates the QWERTY touch keypad with an appropriate prompt displayed on the top line of the display. Using an external PS/2 keyboard to enter device information is also possible, and may prove to be more efficient. Refer to Chapter 3 for further details on operation and features of the QWERTY touch keypad.

Device information fields accept up to 17 characters, except for the technician code ("TECH CODE"), which can be up to 5 characters. The equipment information fields are retained in the temporary data buffer, along with manually acquired safety test measurements.

Note the EQUIPMENT INFO menu will be automatically displayed by ES601-US if the Control Number field is blank and the **SAVE RECORD** button is pressed. A Test Record *must* have a Control Number to be saved.

In addition to the field-edit buttons, other buttons on the menu provide these functions:

BACK: Returns the display to the MANUAL MODE menu

CLEAR ALL: Clears all information fields shown on menu

CLEAR CONTRL NO.:   Clears control number field only

5.6 Line Voltage Test

Pressing the **LINE VOLTAGES** button on the MANUAL MODE menu allows you to measure the AC supply voltages HOT-NEUTRAL; HOT-GROUND; and NUETRAL-GROUND.

During the measurement, the **ESCAPE** button may be pressed at any time to abort the measurement and return to the MANUAL MODE menu. No results are obtained.

Each supply voltage requires approximately 1 second to measure, and is sequentially displayed on the LCD as acquired. If a reversed-supply condition is detected ($V_{NEUT-GND} > V_{HOT-GND}$), ES601-US will produce an alarm. Safety tests should not be performed if the AC supply is reversed, as this may affect leakage results. In the event of a reversed-supply alarm, connect to a different wall outlet or investigate the wiring of the wall outlet in use before proceeding with further tests.

```
            LINE VOLTAGES
     HOT-NEUT: 117.8V
      HOT-GND: 120.4V
     NEUT-GND:    2.6V
     CONTINUE: SAVE MEASUREMENT TO DATA BUFFER
     REPEAT:   REPEAT THIS MEASUREMENT
     ESCAPE:   ABORT MEASUREMENT; DO NOT SAVE

    [ ESCAPE ]   [ REPEAT ]   [ CONTINUE ]
```
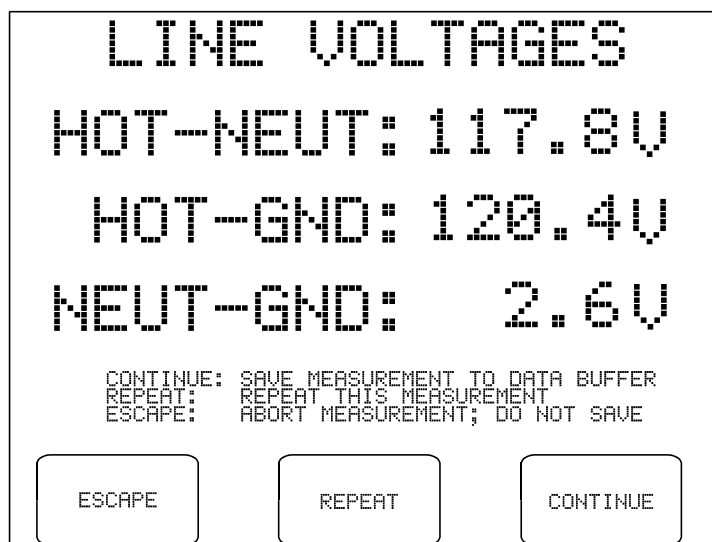
Figure 23 - *Line voltage measurement results.*

After all three voltages have been displayed, the following options become available:

CONTINUE: Copies the displayed values to the temporary data buffer. Previous line voltage data in the buffer, if any, are overwritten. Returns to the MANUAL MODE menu.

REPEAT: Repeats the Line Voltage measurements.

ESCAPE: Returns to the MANUAL MODE menu. Results are discarded and are not copied to the data buffer.

5.7 Load Current Test

Pressing the **LOAD CURRENT** button on the MANUAL MODE menu allows you to measure the AC current drawn from the supply by the DUT. The power switch of the DUT should be set to "ON" before selecting this test.

If "STOP AFTER..." of the System Settings is "NO" (see Section 3.3), ES601-US will activate the test socket and then pause for the power-up delay specified in the System Settings, after which ES601-US will measure the current. If "STOP AFTER..." of the System Settings is set to "YES", ES601-US will activate the test socket and then wait until you press the **CONTINUE** button:

```
                        BREAK


     1. AC SUPPLY IS NOW APPLIED TO THE TEST SOCKET.


     2. ACTIVATE THE EQUIPMENT UNDER TEST.


     3. PRESS "CONTINUE" WHEN EQUIPMENT IS READY.




        ESCAPE                        CONTINUE
```
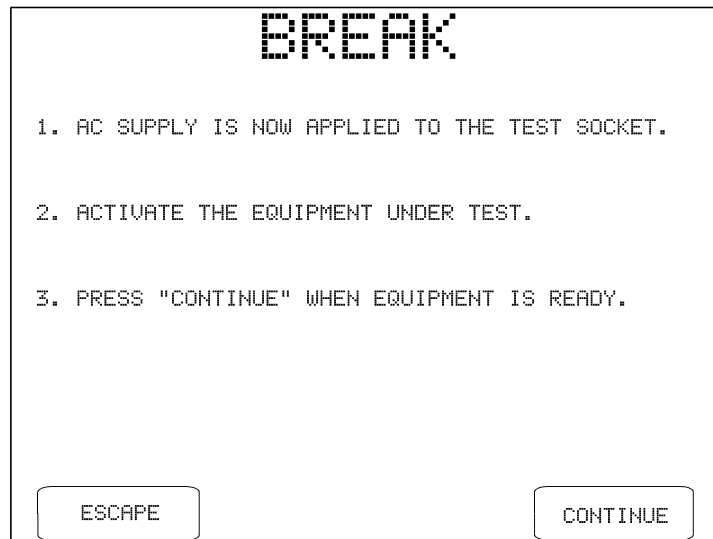
Figure 24 *- Break if "STOP AFTER..." system setting is "YES".*

The measurement is performed after you press **CONTINUE**. Alternatively, you may press **ESCAPE** to abort the measurement and return to the MANUAL MODE menu. Note the purpose of the "STOP AFTER..." break is to allow you activate a DUT which cannot be switched ON until a full AC supply is provided to the DUT.

The load current measurement will require approximately 1 second to complete, after which ES601-US will stop and display the value:

```
 LOAD CURRENT


 12.34 AMPS rms



 CONTINUE: SAVE MEASUREMENT TO DATA BUFFER
 REPEAT:   REPEAT THIS MEASUREMENT
 ESCAPE:   ABORT MEASUREMENT; DO NOT SAVE

   ┌──────────┐   ┌──────────┐   ┌──────────┐
   │  ESCAPE  │   │  REPEAT  │   │ CONTINUE │
   └──────────┘   └──────────┘   └──────────┘
```
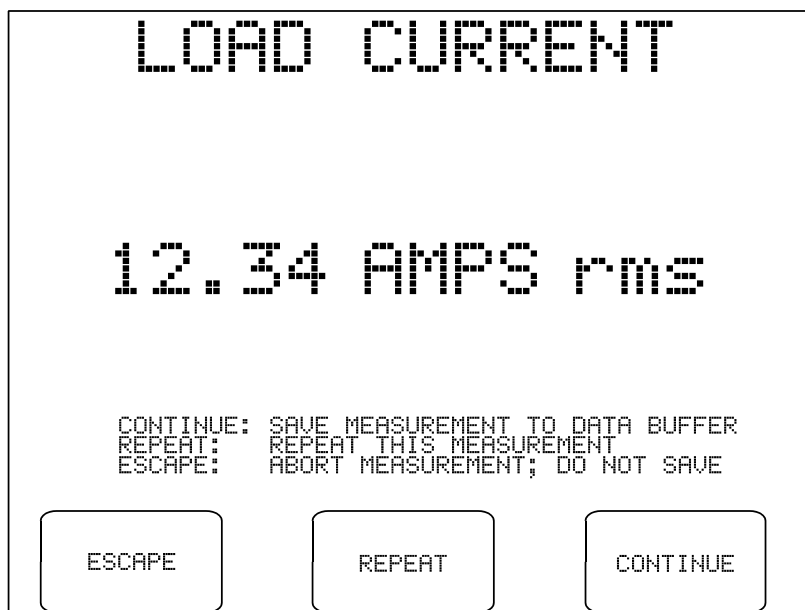
Figure 25 *- Load current result.*

After the load current is displayed, the following options become available:

CONTINUE: Copies the displayed value to the temporary data buffer. Previous load current data in the buffer, if any, are overwritten. Returns to the MANUAL MODE menu.

REPEAT: Repeats the Load Current measurement.

ESCAPE: Returns to the MANUAL MODE menu. The result is discarded and is not copied to the data buffer.

After pressing either **REPEAT** or **CONTINUE**, and if "STOP BEFORE..." of the System Settings is "NO" (see Section 3.3), ES601-US will switch OFF the test socket and return to the MANUAL MODE menu. If "STOP BEFORE..." is "YES", ES601-US will prompt you to shut down the equipment before the test socket is switched OFF:

```
            BREAK

1. AC SUPPLY WILL BE REMOVED FROM THE EQUIPMENT
   UNDER TEST WHEN YOU PRESS "CONTINUE".


2. PERFORM EQUIPMENT SHUTDOWN PROCEDURE.


3. PRESS "CONTINUE" AFTER EQUIPMENT IS SHUT DOWN.




                                    ┌──────────┐
                                    │ CONTINUE │
                                    └──────────┘
```
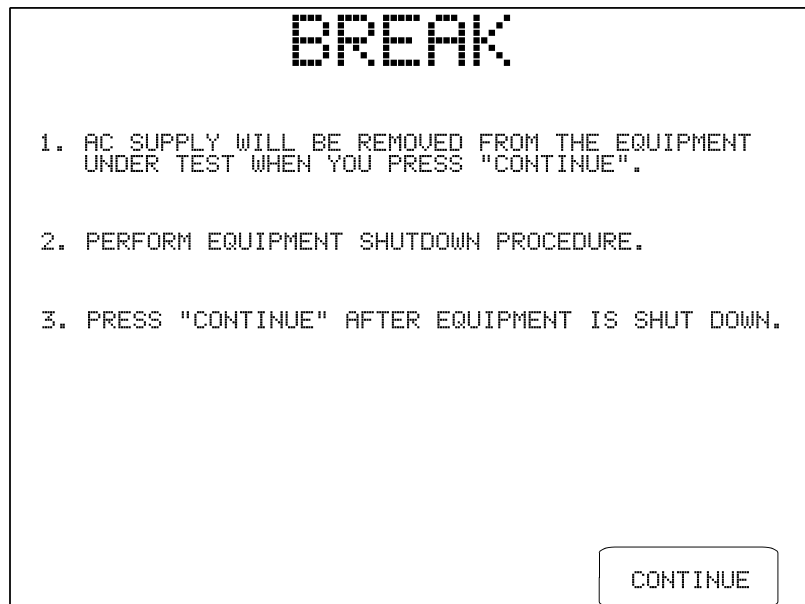
Figure 26 - Break if "STOP BEFORE..." system setting is "YES".

Note the purpose of the "STOP BEFORE..." break is to allow you to accommodate power-sensitive equipment, such as a personal computer or equivalent DUT, which cannot be arbitrarily disconnected from the AC supply without potentially damaging the DUT.

5.8 Insulation Resistance Test

Pressing the INSULATION RESISTANCE button on the MANUAL MODE menu allows you to measure the resistance of the DUT's insulation from hot and neutral supply inputs to the ground connection; or alternatively from all patient leads shorted together to ground. Note the power switch of the DUT should be set to "ON" before selecting this test from the menu. AC Power is removed from the test receptacle for the duration of this test.

```
            INSULATION
            RESISTANCE


     SELECT RESISTANCE TEST AND PRESS 'RUN TEST'.


        ┌──────────┐   BETWEEN GROUND AND
        │          │   HOT+NEUTRAL SHORTED
        │   TEST   │
        └──────────┘


   ┌──────────┐              ┌──────────┐
   │  ESCAPE  │              │ RUN TEST │
   └──────────┘              └──────────┘
```
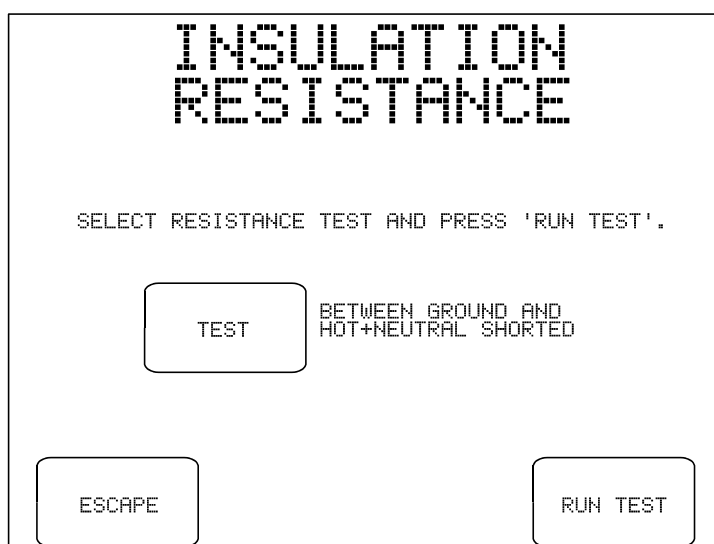
Figure 27 *- Insulation test selection menu.*

Options available on the insulation test selection menu are:

TEST: Toggles the test between measuring insulation resistance "BETWEEN GROUND AND HOT+NEUTRAL SHORTED" and "BETWEEN GROUND AND ALL PATIENT LEADS".

ESCAPE: Returns the display to the MANUAL MODE menu. No insulation test result is copied to the data buffer.

RUN TEST: Starts the selected insulation resistance test. If possible, set the power switch of the DUT to the "ON" position before starting the test.

<div style="border:2px solid black; padding:10px;">

⚠️   <u>**WARNING:**</u>

If testing insulation resistance of patient leads, HIGH VOLTAGE (500 VDC) will be output from the AP jacks for a few seconds during the test.

The high voltage is internally current-limited to 2 milliamperes maximum. Unterminated leads attached to the AP jacks therefore present a minor, non-lethal shock hazard to the careless user.

Always take care to make proper electrical connections to the DUT before starting an insulation resistance test. Disconnect all unused leads or cables from the AP jacks on ES601-US.

</div>

After approximately two seconds, the measurement result in megohms is displayed:

```
       INSULATION
       RESISTANCE
          STANDARD: AAMI-ES1

            LIMIT: --.- MEGOHMS

  RESISTANCE, HOT+NEUT TO GND:

     999.9 Megohms

      CONTINUE: SAVE MEASUREMENT TO DATA BUFFER
      REPEAT:   REPEAT THIS MEASUREMENT
      ESCAPE:   ABORT MEASUREMENT; DO NOT SAVE

   ┌──────────┐  ┌──────────┐  ┌──────────┐
   │  ESCAPE  │  │  REPEAT  │  │ CONTINUE │
   └──────────┘  └──────────┘  └──────────┘
```

Figure 28 - *Insulation test result.*

On the insulation test result screen, select one of these three options:

CONTINUE: Copies the displayed value and Pass/Fail limit (if shown) to the temporary data buffer. If there is a previous result from this test in the Clip Record, it is overwritten. The user interface returns to the MANUAL MODE menu.

REPEAT: Repeats the insulation resistance measurement.

ESCAPE: Returns to the MANUAL MODE menu. The result is discarded and is not copied to the data buffer.

5.9 Ground Resistance Test

Pressing the **GROUND RESISTANCE** button on the MANUAL MODE menu allows you to measure the resistance of the DUT's ground circuit, using a test current of 1 AMP.

Upon selecting this test from the menu, ES601-US will recall the Systems Settings for the manual ground resistance test and will then display these on the LCD:
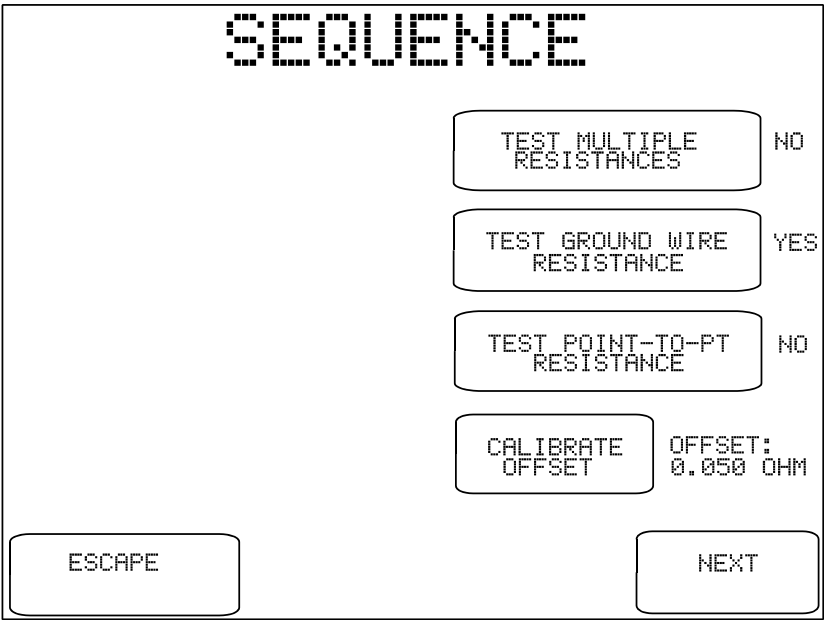
Figure 29 - *Sequence Controls for manual PE test.*

You may change these settings to suit the upcoming test. After the test is completed, the Sequence Controls will revert to their System Setting defaults.

The buttons provided on the Sequence Control menu are:

TEST MULTIPLE RESISTANCES: If set to "YES", this control will enable multiple ground and/or point-to-point resistance measurements within the scope of the test. Up to ten resistance measurements may be recorded by ES601-US in multiple resistance mode. If set to "NO", the test will be completed after performing a single measurement of resistance.

TEST GROUND WIRE RESISTANCE:

If set to "YES", this control will enable measurement of the ground wire (power cord) resistance. For this type of test, resistance is measured between the ground terminal on the power cord connected to the test receptacle of ES601-US, and the Kelvin Cable which will be connected to a grounding stud or the metal enclosure of the DUT.

TEST POINT-TO-PT RESISTANCE:

If set to "YES", this control will enable measurement of resistance between two points, one being the point of attachment of the Kelvin Cable, and the other being the point of attachment of a test lead which connects to the "TO DUT CASE" jack of ES601-US. If set to "NO", point-to-point resistance testing is disabled. This control works with the other two controls to provide various protocols for ground resistance testing as shown in the table below.

MULTI	GND WIRE	POINT-TO-PT	Test Protocol	Test Application
NO	**YES**	**NO**	Measure resistance once, between Kelvin Cable and test receptacle of ES601-US.	Conventional ground resistance test of equipment which connects to the AC supply by means of a power cord.
NO	**NO**	**YES**	Measure resistance once, between Kelvin Cable and "DUT CASE" lead. The OFFSET calibration is subtracted from the measurement to obtain the final result. The Kelvin Cable is connected to an equipotential (grounding) stud located near the DUT, and the "DUT CASE" lead connects to the DUT itself.	Single ground resistance test of permanently-installed equipment which is directly wired to the AC supply. Example: test of X-RAY equipment.
YES	**YES**	**NO**	Measure resistance up to 10 times, between Kelvin Cable and test receptical of ES601-US. For the first measurement, the Kelvin Cable is connected to a designated ground test stud on the equipment chassis, per the standard test for power cord-connected equipment. For subsequent tests, the Kelvin Cable may be re-attached at arbitrary locations on the equipment enclosure to confirm continuity of the ground to those points.	Multiple ground resistance test of cord-connected equipment. Example: test of patient monitor system.

MULTI	GND WIRE	POINT-TO-PT	Test Protocol	Test Application
YES	**NO**	**YES**	Measure resistance up to 10 times, between Kelvin Cable and "DUT CASE" lead. The `OFFSET` calibration is subtracted from all measurements. For the first measurement, the Kelvin Cable should be connected to an equipotential (grounding) stud located near the DUT, and the "DUT CASE" lead connects to the DUT itself. For subsequent measurements, the Kelvin Cable may be re-attached at arbitrary locations on the DUT to confirm continuity of the ground between the Kelvin Cable and "DUT CASE" lead.	Ground resistance test of permanently-installed equipment, followed by continuity test of grounded metal parts on the equipment. Example: test of X-RAY equipment.
YES	**YES**	**YES**	Measure resistance between Kelvin Cable and the test receptacle of ES601-US, one time. After this measurement, the user disconnects the DUT line cord from ES601-US and connects the "DUT CASE" lead to the DUT. For measurement #2, 3, 4... , the resistance between the Kelvin Cable and "DUT CASE" lead is then measured, with the `OFFSET` calibration being subtracted to obtain the results. The Kelvin Cable and test lead may be moved to arbitrary points of attachment and up to 9 additional resistance measurements are acquired. These additional measurements confirm continuity of the ground between the Kelvin Cable and "DUT CASE" lead.	Ground resistance test of cord-connected equipment, followed by continuity test of grounded metal parts on the equipment. Example: test of a hospital bed.

Only those combinations shown in the above table are permitted by ES601-US; other combinations of settings are inhibited.

Referring back to the Sequence Control menu, other buttons provided on the menu are:

CALIBRATE OFFSET:

The "`OFFSET:`" displayed to the right of this control is the resistance of the test lead used in measuring point-to-point resistance. In a point-to-point test, the `OFFSET` calibration is subtracted from the measured resistance to obtain the result which is displayed by ES601-US.

Calibrate the `OFFSET` when required, particularly if the test lead used for point-to-point measurement is changed. Performing the calibration from System Settings Menu #2 (see Section 3.3) records the `OFFSET` in non-volatile memory. Performing the calibration from the Sequence Controls menu updates the `OFFSET` for the manual test, but does not store the calibration in the non-volatile memory.

Calibrate the `OFFSET` according to this procedure:

1.   Connect the Kelvin Cable to the corresponding jacks of ES601-US.

2.   Connect the test lead which will be used for point-to-point measurement to the "TO DUT CASE" jack of ES601-US.

3.   Connect the free ends of the Kelvin Cable and the test lead together. Verify a solid mechanical contact exists between the two cables at the far end.

4.   Press the **CALIBRATE OFFSET** button. The resistance will be measured and displayed within one second.

5.   The result should be 0.05 ohms or lower for a typical test lead of 2-meter length. For best results, avoid use of a poor-quality or excessively long cable having a resistance exceeding 0.1 ohm. ES601-US will produce an alarm and reject the calibration if the resistance exceeds 3 ohms.

6.   If the resistance seems unreasonably high, verify the connection between the test lead and the Kelvin Cable. Also confirm the test lead makes a solid contact when inserted into the "TO DUT CASE" jack. Repeat the calibration as required until an acceptable result is obtained.

ESCAPE:

This button on the Sequence Controls menu aborts the test in progress and returns the display to the MANUAL MODE menu.

NEXT:

Advances the test to the next step, which starts the resistance measurement.

For AAMI-ES1 and IEC60601 standards, ground resistance is measured continuously and is updated on the LCD display two times per second. If an open-circuit or high resistance condition is detected, the display will show "**X.XXX**" instead of a resistance value.

Figure 30 - Ground resistance test in progress.

As resistance is continuously measured during the test, while viewing the display above you may move the connection of the Kelvin Cable to various points on the equipment enclosure to locate a point which produces the worst case (highest) resistance. When ready, press the **ACCEPT** button to capture the resistance value and compare the value to the maximum limit which is shown at upper left on the LCD display.
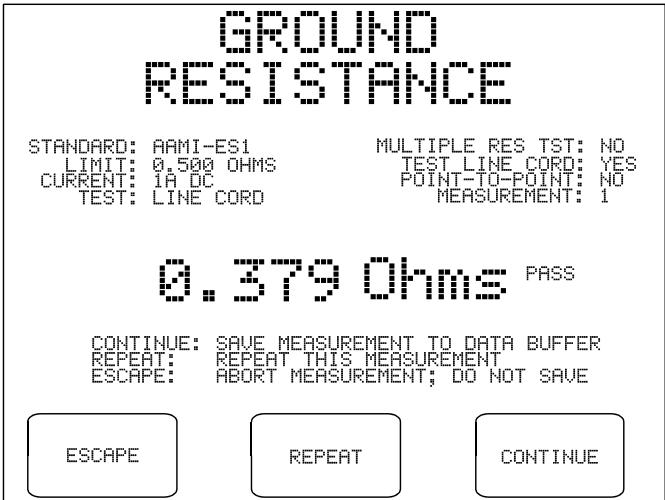
Figure 31 - Ground resistance test result.

The limit for the ground test depends on the safety standard and type of limits (default, or user-defined) as selected on the MANUAL MODE menu. A value higher than the displayed limit produces a "FAIL" indication and an alarm tone from ES601-US.

If "TEST MULTIPLE RESISTANCES" is set to "NO", three buttons will be displayed upon completion of one measurement according to the figure above. The three buttons will provide these functions:

CONTINUE: Moves the resistance measurement and Pass/Fail limit to the temporary data buffer. If there is a previous result from this test in the buffer, it is overwritten. The user interface returns to the MANUAL MODE menu.

REPEAT: Causes the measurement to be repeated.

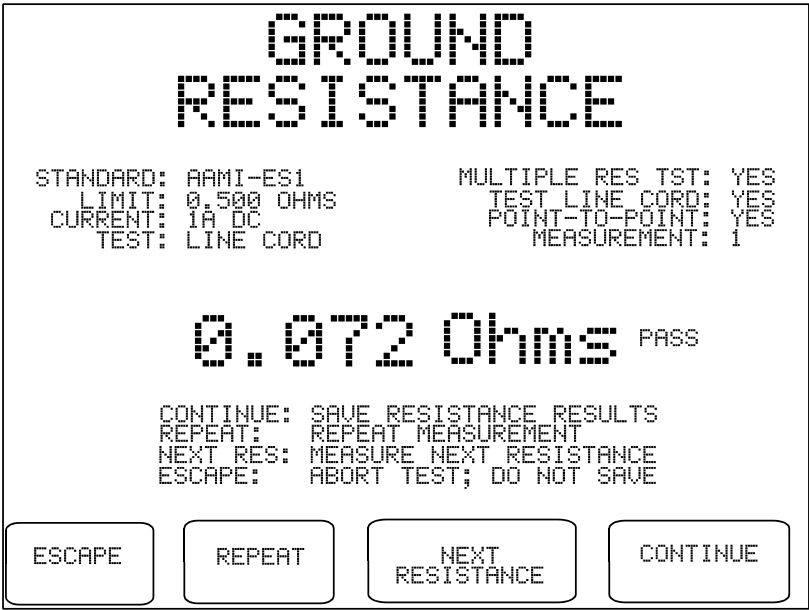**ESCAPE:** Returns the display to the MANUAL MODE menu. The result is discarded and not saved to the data buffer.

If "TEST MULTIPLE RESISTANCES" is set to "YES", four buttons will be displayed upon completion of each resistance measurement according to *Figure 30*.

Figure 32 - *Ground resistance result (multiple resistance mode).*

The buttons provided on this result display are:

ESCAPE: Returns the display to the MANUAL MODE menu. Acquired measurements are discarded and not saved to the data buffer.

REPEAT: Causes the displayed measurement to be repeated. The "MEASUREMENT:" counter on the display is not incremented.

NEXT RESISTANCE: Causes the displayed measurement to be retained and the test to advance to the next measurement of resistance. The "MEASUREMENT:" counter is incremented by one. Up to ten resistance values can be recorded by means of this button. If the button is pressed more than ten times, the additional measurements overwrite the tenth resistance recorded.

Normally, the user will change the connection of the Kelvin Cable and/or "DUT CASE" lead immediately before pressing this button. This will depend on test requirements and the selected protocol.

CONTINUE: Moves the acquired resistance values and the Pass/Fail limit to the data buffer. If there are previous results from this test in the data buffer, they are overwritten. The user interface returns to the MANUAL MODE menu.

Continuous measurement and display of resistance is performed for AAMI-ES1 and IEC60601 safety standards, as described above. For other safety standards, such as VDE0751 and IEC62353, a different method of measurement is used according to the requirements of those standards. For these standards, the resistance is measured for one second with the test current flowing from the Kelvin Cable to the DUT ground. The test current is then reversed so that it flows from DUT ground to the Kelvin Cable, and a second resistance is measured over an interval of one second. The resistance shown on the LCD display is the larger of the two values obtained, which is then compared to the pass/fail limit according to the standard.

5.10 Leakage Current Test

Pressing the **LEAKAGE CURRENT** button on the MANUAL MODE menu allows you to set up the parameters for a leakage current test. Once the parameters have been set, the test itself will run as an automated sequence of measurements. During the test, buttons are provided on the LCD to allow the sequence to be paused at any given step. With the test sequence paused, the selected leakage measurement can then be repeated, if desired.

```
          LEAKAGE CURRENT
STANDARD: AAMI-ES1        LIMITS: PER STANDARD

   ┌─────────┐              ┌─────────┐
   │  CLASS  │  CLASS I     │ PATIENT │   TEST
   └─────────┘              │  LEADS  │
                            └─────────┘
   ┌─────────┐
   │ EQUIPMNT│  ON/OFF      ┌─────────┐
   └─────────┘              │LEAD-TO-LD│  TEST
                            │ LEAKAGES │
   ┌─────────┐              └─────────┘
   │ POLARITY│  NORM/REV
   └─────────┘              ┌─────────┐
                            │ ISOLATED │ DO NOT TEST
   ┌─────────┐              │SIGNAL I/O│
   │ NEUTRAL │  NORM/OPEN   └─────────┘
   └─────────┘

   ┌─────────┐
   │  GROUND │  NORM/OPEN
   └─────────┘

   ┌─────────┐                          ┌─────────┐
   │ ESCAPE  │                          │  NEXT   │
   └─────────┘                          └─────────┘
```
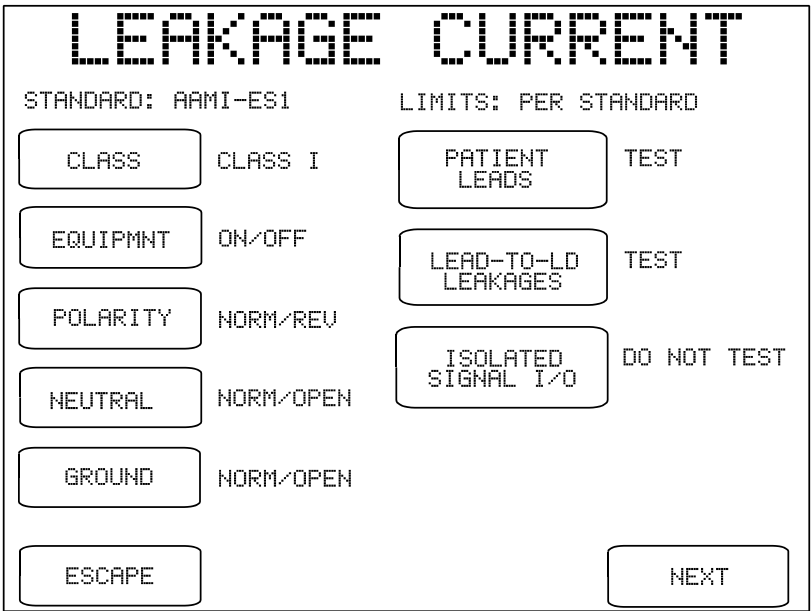
Figure 33 - Leakage test conditions for AAMI-ES1 standard.

Test conditions provided by the leakage setup menu will depend on the safety standard which has been selected on the MANUAL MODE menu. For the AAMI-ES1 menu shown above, the test conditions are:

CLASS: Selects Class I (default) or Class II. "Class I" equipment has a 3-wire AC supply connection, incorporating ground; "Class II" is two-wire, with no ground. Depending on the safety standard, this control may affect leakage pass/fail limits.

EQUIPMNT: If set to "ON", leakage tests are performed with the power switch of the DUT in the "ON" position only. If set to "ON/OFF", leakage tests are performed with the DUT power switch "ON", and then the entire leakage test sequence is repeated after the DUT power switch is set to "OFF".

"DUT OFF" leakage tests are a mandatory requirement of AAMI-ES1 and IEC60601 standards. These standards recognize some types of equipment do not disconnect from the AC supply when switched "OFF", but simply enter a standby state in which, for example, an internal battery is charged. When operating in this state, DUT leakage may potentially be greater than leakage observed with DUT switched "ON".

According to AAMI-ES1 and IEC60601, "DUT OFF" is a supplementary test condition which is required for equipment that does not fully disconnect from the AC supply when the power switch is set to "OFF".

POLARITY: If set to "NORMAL", tests are performed with the AC supply at normal polarity only. If set to "NORM/REV", tests are performed with the AC supply in normal and reversed polarities. "NORM/REV" is the typical setting and is the test requirement specified by all safety standards.

NEUTRAL: If set to "NORMAL", tests are performed with Neutral of the AC supply in normal condition only. If set to "NORM/OPEN", tests are performed with Neutral in normal and single-fault conditions ("open"). "NORM/OPEN" is the typical setting and is the test requirement specified by most safety standards.

GROUND: If set to "NORMAL", tests are performed with Ground of the AC supply in normal condition only. If set to "NORM/OPEN", tests are performed with Ground in normal and single-fault conditions ("open"). "NORM/OPEN" is the typical setting and is the test requirement specified by most safety standards.

PATIENT LEADS: If set to "TEST", measurement of patient lead leakage is enabled. If set to "DO NOT TEST", patient lead leakage is disabled. All safety standards require patient leads to be tested if the DUT provides patient leads (e.g.: ECG leads; blood pressure transducer; temperature probe; SpO2 probe; etc).

LEAD-TO-LD LEAKAGE:

If set to "TEST", measurement of lead-to-lead (IEC auxiliary) leakage is enabled. If set to "DO NOT TEST", lead-to-lead leakage is disabled.
To enable lead-to-lead measurements, patient leads must be set to "TEST".

For full compliance with requirements of AAMI-ES1 and IEC60601 standards, this control should be set to "TEST". However, this setting will cause each patient connection to be individually tested. This will increase the length of time required to complete the leakage test, and will substantially increase the amount of information which will be included in the reported test results. The extent of such increases in test time and reported data will depend on the number of leads that must be tested.

ISOLATED SIGNAL I/O:

Options are "DO NOT TEST" (default) or "TEST!" This parameter determines whether an isolated voltage equal to the AC supply will be output from the AUX1 jack of ES601-US (for IEC60601 standard, the isolated voltage will equal 110% of the AC supply). The AUX1 output is current-limited to a few milliamperes.

AUX1 is intended to connect to isolated input or output signals provided by the DUT. An example of an isolated signal input/output would be a Ethernet data connection which achieves isolation by means of a signal transformer internal to the DUT.

This test is mandatory under AAMI-ES1 and IEC60601 standards when the DUT has an _**isolated**_ data connection such as an Ethernet port. If enabled, the test does **<u>NOT</u>** measure the leakage current of the data connection. In this test, the mains voltage is applied to the data connection and leakage current is then measured from the DUT enclosure to ground, from DUT patient leads to ground, and (for AAMI standard) between interconnected patient leads. When measuring the mains-on-applied-part leakage, ES601-US will connect AUX1 to ground, rather than isolated mains.

Therefore, the "ISOLATED SIGNAL I/O" button enables a supplementary test condition for case leakage, patient and lead-to-lead leakage measurements under AAMI and IEC60601 safety standards. The expected result is these leakages should not be affected by applying mains voltage to the data connection, or by earthing the data connection, since the input/output signals are supposedly isolated from the DUT enclosure and patient leads.

<div style="border:2px solid black; padding:1em;">

⚠️   <u>**WARNING:**</u>

If ISOLATED SIGNAL I/O is set to "TEST!", a warning message is displayed: <u>(!) CHECK D.U.T. SPECS.</u>

When enabling this test, users must be sure the data interfaces being tested are ***fully isolated***. Otherwise, ***severe damage to the DUT*** could result when AUX1 is activated during the test. If in doubt, contact the DUT manufacturer or supplier for guidance.

Datrend Systems Inc. will not be responsible for damage resulting from incorrect application of this test.

</div>

UNGROUNDED METAL:

This parameter is not shown on the menu for AAMI-ES1 as there is no requirement in that standard to test lead leakage while connecting floating metal parts on the DUT to the ground. However, this test condition is a requirement for testing per IEC60601.

Options are "DO NOT TEST" (default) or "TEST". This parameter determines whether the AUX2 output of ES601-US will be connected to ground of the AC supply.

AUX2 is intended to connect to ***floating exposed*** metal on the DUT. Therefore, this button enables a supplementary test condition for patient leakage tests per IEC60601. The expected result is the patient leakage is unaffected by connecting such metal parts to ground, since the metal is supposed to be electrically isolated.

ESCAPE:

Aborts leakage measurement and returns to MANUAL MODE menu. No leakage test data will be copied to the Clip Record.

NEXT:

Advances ES601-US to the next step of the leakage test.

If **PATIENT LEADS** is set to "DO NOT TEST", Sequence Controls for manual leakage testing will be displayed when the **NEXT** button is pressed. If **PATIENT LEADS** is set to "TEST", a setup menu for the patient leads is displayed when **NEXT** is pressed:

Figure 34 - *Example setup for ECG monitor with 4 patient connections.*

Buttons provided by the PATIENT LEADS menu are:

AP1:   Pressing this button causes the QWERTY touch keypad to be displayed. The user may enter up to seven letters and/or digits as a name for the ECG lead or other patient connection that will be connected to jack "AP1" of ES601-US.

Only the name can be entered via this menu, and only if the corresponding GROUP is "ENABLED". If the part is "DISABLED", a name entered by the QWERTY keypad will be rejected.

AP2-10:   As above for button AP1.

EDIT: Enter the GROUPS editor menu, described following.

BACK: Returns to the menu for leakage test conditions.

NEXT: Advances ES601-US to the next step of the leakage test.

AAMI, IEC and VDE safety standards require patient leads or "applied parts" to be tested in related **Groups**.

For the AAMI-ES1 standard, there are only two Groups defined, organized by **electrical characteristics**: Group 1 is pre-assigned to patient leads which are *electrically isolated* from AC supply ground (Type "BF"); Group 2 is pre-assigned to patient leads which are **not** isolated from ground (Type "B").

For IEC and VDE safety standards, Groups are organized by **medical function**: ECG, defib paddles, blood pressure transducer, etc. ES601-US provides connections for up to ten patient leads via the AP jacks located on the front panel, where the AP jacks can be organized in up to **five** functional Groups.

The assignment of patient leads to Groups is indicated on the PATIENT LEADS menu. Lead assignments can be changed by pressing the **EDIT** button on the menu, which then displays the GROUPS editor:

Figure 35 - Example setup for ECG monitor with 4 patient connections.

The buttons appearing on the GROUPS editor are:

LEAD GROUP: Selects the group of leads to be edited (1 or 2 for AAMI; 1, 2 3, 4 or 5 for IEC and VDE).

GROUP STATUS:	Selects "ENABLED" or "DISABLED". Patient leads of disabled groups are excluded from patient leakage and lead-to-lead leakage measurements. Group 1 cannot be disabled.
GROUP TYPE:	Selects the type of group: "B NON-ISOLATED", "BF ISOLATED" (default), or "CF ISOLATED". Refer to Chapter 2 to review the meaning of "Type B", "Type BF", and "Type CF" protection classes of the safety standard. The setting of GROUP TYPE affects the limits applied in patient leakage tests.
NAME OF GROUP:	Pressing this button causes the QWERTY touch keypad to be displayed. The user may enter up to seven letters and/or digits as a description of the lead group.
NUMBER OF LEADS:	Determines the number of leads in the group being displayed. Leads are incorporated into the group consecutively, starting at jack AP1 on the front panel. The simplest permitted setup is one patient lead (AP1) in one enabled group (Group 1).
BACK:	Returns to the PATIENT LEADS menu.
RESET ALL:	Resets all settings, leaving Group 1 enabled as Type BF with one patient lead (AP1).

If the DUT is a defibrillator and has been specified by the manufacturer as meeting the requirements of the IEC60601-2-4 standard ("*Particular requirements for the safety of cardiac defibrillators*"), group settings can be programmed via the GROUPS editor menu to enable special leakage tests which are required by that standard. For testing a defibrillator per IEC60601-2-4:

- Assign ECG leads to one group, and set the GROUP TYPE to "CF ISOLATED"

- Assign the defibrillator paddles to a second group, and set NUMBER OF LEADS equal to two. Set the GROUP TYPE to "BF ISOLATED" or "CF ISOLATED" according to manufacturer specifications. Finally, enter "PADDLES", "PIASTRE" or "PALETTE" for the NAME of the group.

The above special settings will enable ES601-US to perform leakage testing of the paddles per IEC60601-2-4, with modified acceptance limits according to that standard.

After configuring the leakage test conditions and, if necessary, specifying the DUT patient leads, the next step displays the Sequence Controls for manual leakage tests, as recalled from System Settings Menu #2 (see Section 3.3). You may change the displayed settings to suit the upcoming test. After the test is completed, the Sequence Controls will revert to their System Setting defaults.
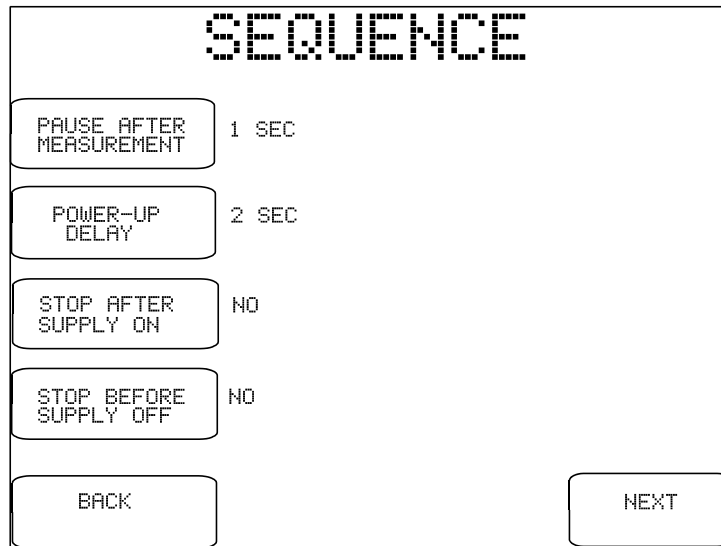
Figure 36 *- Sequence Controls for manual leakage test.*

The buttons provided on the Sequence Control menu are:

PAUSE AFTER MEASUREMENT:
After each measurement of the test, ES601-US will pause for the indicated time before proceeding with the next leakage measurement. The delay provided by this control allows the user to more easily interrupt a sequence in progress, so a particular leakage measurement of interest can be repeated as desired. This control can be set to "NO" to disable the pause.

POWER UP DELAY:
During the test, ES601-US will wait for the indicated time when the AC supply is applied to the DUT, before proceeding with the sequence. This delay allows the DUT to start up and stabilize before subsequent leakage measurements are taken. The available options are 2 to 9 seconds in one second steps. Equipment requiring more than 9 seconds to start up are better accommodated through the "STOP AFTER..." control, described following.

STOP AFTER SUPPLY ON:
If set to "YES", this control will override the power-up delay setting described prior and will cause the test to ***fully stop*** immediately after the AC supply is connected to the DUT by ES601-US. ES601-US will prompt the user to activate the DUT and will not proceed until the user acknowledges by pressing the **CONTINUE** button. This feature accommodates equipment with a momentary ON/OFF power switch, which cannot be switched ON until a full AC supply is provided to the equipment.
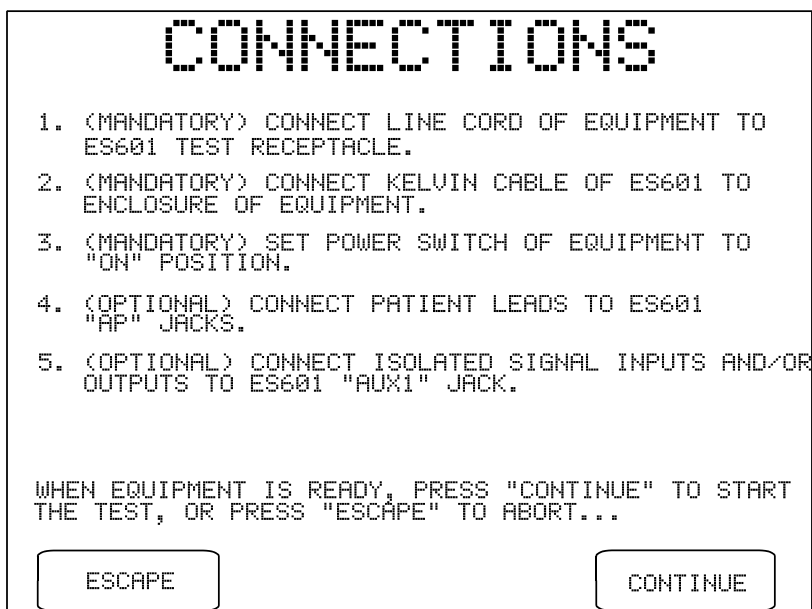
STOP BEFORE SUPPLY OFF: If set to "YES", this control will cause the test to *fully stop* immediately before a step which disconnects the AC supply from the DUT. ES601-US will prompt the user to shut down the DUT and will not proceed until the user acknowledges by pressing the **CONTINUE** button. After **CONTINUE** is pressed, ES601-US will then disconnect the AC supply from the DUT. This feature accommodates equipment having special shutdown requirements, such as diagnostic imaging equipment or equipment incorporating a PC.

BACK: Returns to the previous menu (leakage test conditions or patient lead setup, as appropriate).

NEXT: Displays instructions for connecting the DUT to ES601-US. The instructions displayed will depend on the safety standard. The example menu shown following is for the AAMI-ES1 standard.

```
            CONNECTIONS

1. (MANDATORY) CONNECT LINE CORD OF EQUIPMENT TO
   ES601 TEST RECEPTACLE.
2. (MANDATORY) CONNECT KELVIN CABLE OF ES601 TO
   ENCLOSURE OF EQUIPMENT.
3. (MANDATORY) SET POWER SWITCH OF EQUIPMENT TO
   "ON" POSITION.
4. (OPTIONAL) CONNECT PATIENT LEADS TO ES601
   "AP" JACKS.
5. (OPTIONAL) CONNECT ISOLATED SIGNAL INPUTS AND/OR
   OUTPUTS TO ES601 "AUX1" JACK.


WHEN EQUIPMENT IS READY, PRESS "CONTINUE" TO START
THE TEST, OR PRESS "ESCAPE" TO ABORT...

   [ESCAPE]                      [CONTINUE]
```

Figure 37 - *DUT connection instructions for AAMI safety test.*

According to the CONNECTIONS menu, at minimum a AAMI safety test will require the user to connect the DUT to the test receptacle and the Kelvin Cable of ES601-US to the enclosure of the DUT. The power switch of the DUT must also be set to "ON" before the test is started. Depending on how the user has chosen to set up the test via preceding menus, additional connections may be required between AP jacks on ES601-US and DUT patient leads; between AUX1 of ES601-US and DUT signal I/O; and between AUX2 and exposed ungrounded metal on the DUT.
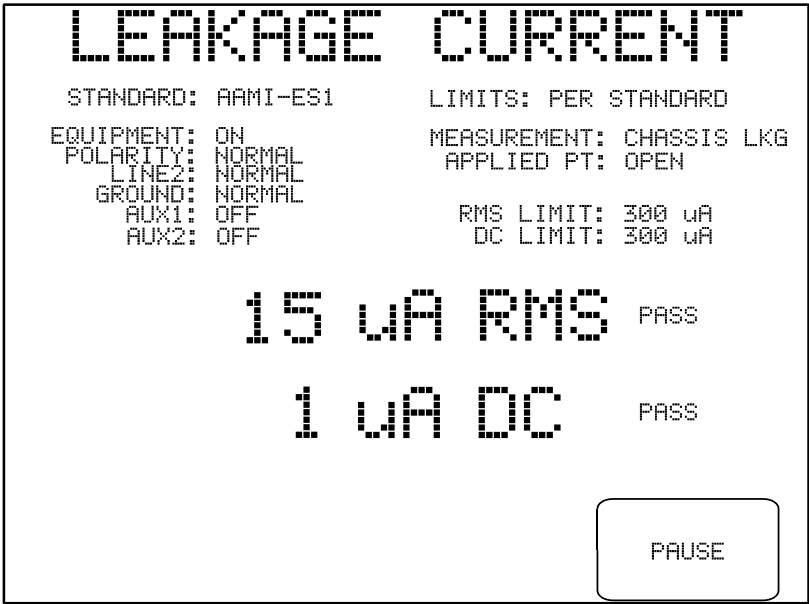

⚠️ **WARNING:**

If testing of **Type BF** or **Type CF** patient leads has been enabled, HIGH VOLTAGE (isolation test voltage) will be periodically output from the AP jacks during the test.

The isolation test voltage is isolated from the AC mains and is internally current-limited to 8 milliamperes maximum at 264 VAC output. Unterminated leads attached to the AP jacks therefore present a minor, non-lethal shock hazard to the careless user.

Always take care to make proper electrical connections to the DUT before starting a leakage test. Disconnect all unused leads or cables from the AP jacks on ES601-US.

Once the leakage test has been set up and the connections are made, the test is started by pressing the **CONTINUE** button on the CONNECTIONS menu. The required measurements are performed automatically in a sequence. AC RMS and DC currents are measured simultaneously, and the display is updated with new data approximately two times every second. If the "PAUSE AFTER..." Sequence Control is <u>not</u> set to "NO", ES601-US will delay an additional 1 to 5 seconds between consecutive leakage measurements.


```
LEAKAGE CURRENT
     STANDARD: AAMI-ES1      LIMITS: PER STANDARD

   EQUIPMENT: ON           MEASUREMENT: CHASSIS LKG
    POLARITY: NORMAL         APPLIED PT: OPEN
       LINE2: NORMAL
      GROUND: NORMAL
        AUX1: OFF            RMS LIMIT: 300 uA
        AUX2: OFF             DC LIMIT: 300 uA


          15 uA RMS   PASS

           1 uA DC    PASS


                              ┌─────────┐
                              │  PAUSE  │
                              └─────────┘
```

Figure 38 - *Leakage current test in progress.*

The type of measurement being performed and the AC supply conditions are shown on the display, above the leakage readings. RMS and DC limits corresponding to the test conditions are also shown on the right, above the readings. Each RMS and DC value is respectively compared to its limit and is either "PASSED" or "FAILED" automatically by ES601-US. The **PAUSE** button may be pressed at any time to pause the sequence and freeze the most recent measurement on the display (see **Figure 37**).
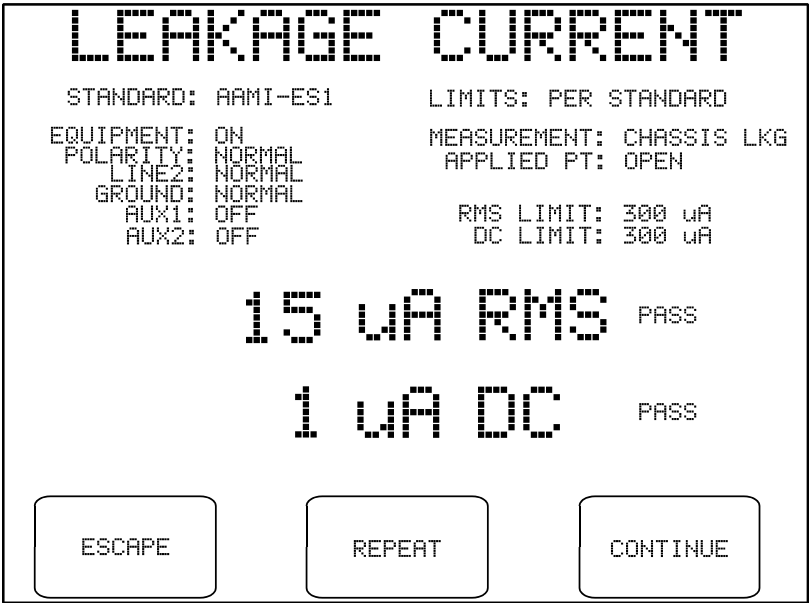
Figure 39 - *Leakage test paused during sequence.*

Individual leakage readings are rapidly made by ES601-US, each reading usually requiring less than one second. If it is expected you may want to pause individual values during a test in order review them, you should set the "PAUSE AFTER..." setting on the Sequence Control menu (**Figure 34**) to at least 2 seconds, so the time between readings is increased to allow for user reaction time. "PAUSE AFTER..." can be set from 1 to 5 seconds in steps of one second, or the pause can be completely disabled, allowing you to trade off operation of the **PAUSE** button against total execution time of the leakage test.

If the leakage test is paused, the keypad buttons will be changed to:

ESCAPE: Aborts the sequence in progress and return to the MANUAL MODE menu. No leakage results are copied to the temporary data buffer.

REPEAT: Repeats the measurement for the test conditions listed at the top of the display.

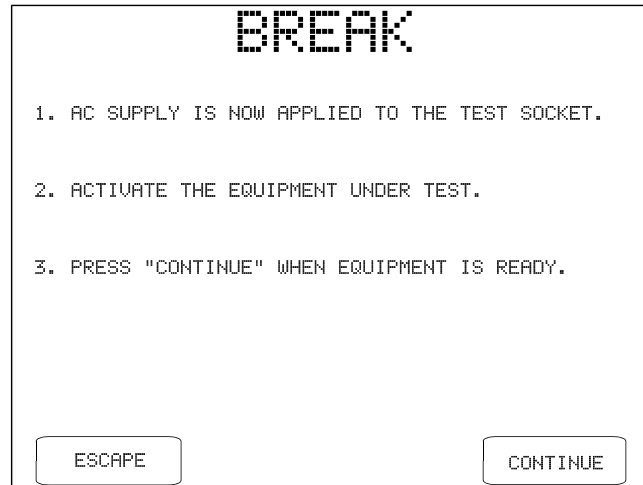**CONTINUE:**   Allows the sequence to proceed to the next measurement.

If a value exceeding either of the posted limits is obtained, the sequence is automatically stopped at that measurement and an audible alarm is produced by ES601-US. In this case, the display will offer the same functions described above.

For IEC60601 and AAMI-ES1 standards, AC supply conditions will be tested in the following order, according to test conditions initially specified by the user on the leakage setup menu:

1   Reverse polarity; Neutral in single-fault condition (**RP:OPEN N.**)

2   Reverse polarity; supply in normal condition (**RP:NORM.**) or with Ground in single-fault condition (**RP:OPEN G.**)

3   Normal polarity; Neutral in single-fault condition (**NP:OPEN N.**)

4   Normal polarity; supply in normal condition (**NP:NORM.**) or with Ground in single-fault condition (**NP:OPEN G.**)

At each configuration (1.)-(4.) of the AC supply, measurements of external and internal case leakage are performed. Following these measurements, patient and lead-to-lead leakage will be measured if those tests were enabled by the user on the setup menu.

When ES601-US changes the AC supply from neutral-open to normal condition, and if "STOP AFTER..." of the Sequence Controls is "NO" (***Figure 34***), ES601-US will pause according to the "POWER-UP DELAY" setting before proceeding to measure the leakage. This delay of 2 to 9 seconds allows the DUT to startup up and stabilize before leakage readings are taken. Alternatively, if "STOP AFTER..." of the Sequence Controls is "YES", ES601-US will change the AC supply from neutral-open to normal condition and wait until you press the **CONTINUE** button:

```
            BREAK

1. AC SUPPLY IS NOW APPLIED TO THE TEST SOCKET.


2. ACTIVATE THE EQUIPMENT UNDER TEST.


3. PRESS "CONTINUE" WHEN EQUIPMENT IS READY.




    ESCAPE                      CONTINUE
```

Figure 40 - *Break if "STOP AFTER..." is set to "YES".*

The leakage sequence proceeds with normal AC supply after you press **CONTINUE**. Alternatively, you may press **ESCAPE** to abort the leakage test and return to the MANUAL MODE menu. Note the purpose of the "STOP AFTER..." break is to allow you activate a DUT which cannot be switched ON until a full AC supply is provided to the DUT.

When ES601-US changes the AC supply from normal condition to neutral-open, ES601-US will not stop if "STOP BEFORE..." of the Sequence Controls is "NO" (*Figure 34*). If "STOP BEFORE..." is "YES", ES601-US will stop and prompt you to shut down the equipment before the Neutral is opened, interrupting the AC supply to the DUT:

```
            BREAK

1. AC SUPPLY WILL BE REMOVED FROM THE EQUIPMENT
   UNDER TEST WHEN YOU PRESS "CONTINUE".

2. PERFORM EQUIPMENT SHUTDOWN PROCEDURE.

3. PRESS "CONTINUE" AFTER EQUIPMENT IS SHUT DOWN.




    ESCAPE                      CONTINUE
```
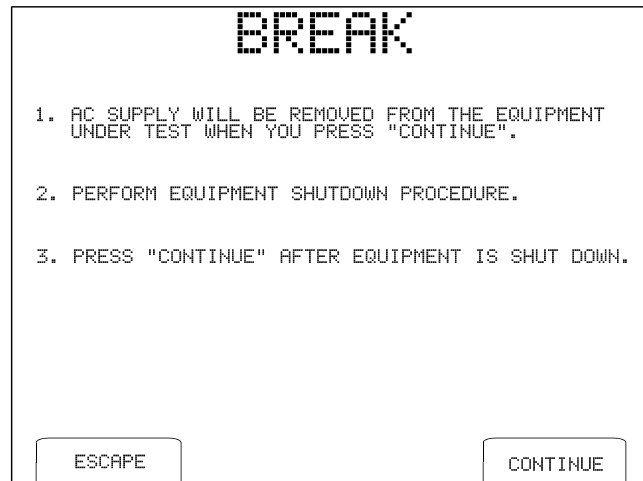
Figure 41 - *Break if "STOP BEFORE..." is set to "YES".*

After **CONTINUE** is pressed, ES601-US will open the Neutral and will then prompt you to reset the DUT power switch to "ON". This is necessary to satisfy the requirements of the leakage test, but the instruction can be ignored if the DUT is of the type that cannot be set to "ON" unless a full AC supply is provided.

```
                   BREAK

    1. AC SUPPLY WILL BE REMOVED FROM THE EQUIPMENT
       UNDER TEST WHEN YOU PRESS "CONTINUE".

    2. PERFORM EQUIPMENT SHUTDOWN PROCEDURE.

    3. PRESS "CONTINUE" AFTER EQUIPMENT IS SHUT DOWN.

    4. SET EQUIPMENT POWER SWITCH TO "ON" AND PRESS
       "CONTINUE" WHEN READY.



     ┌───────────┐              ┌───────────┐
     │  ESCAPE   │              │ CONTINUE  │
     └───────────┘              └───────────┘
```
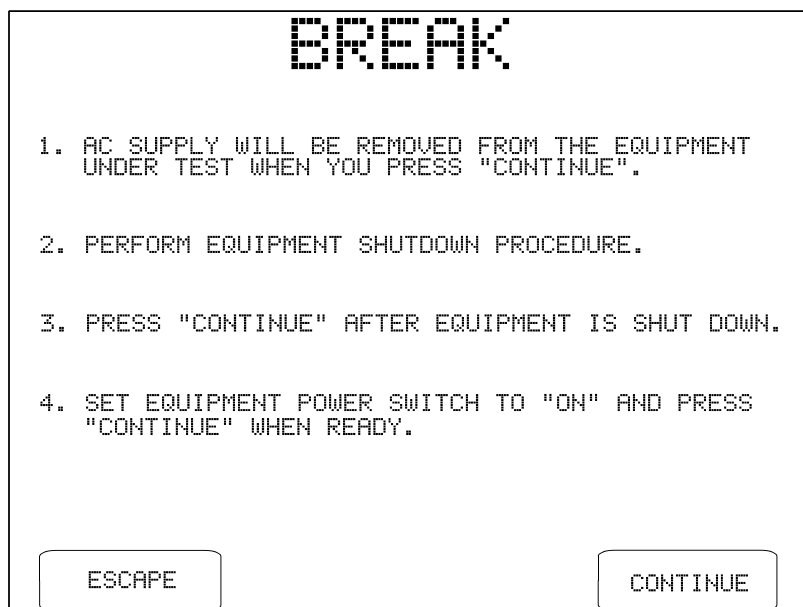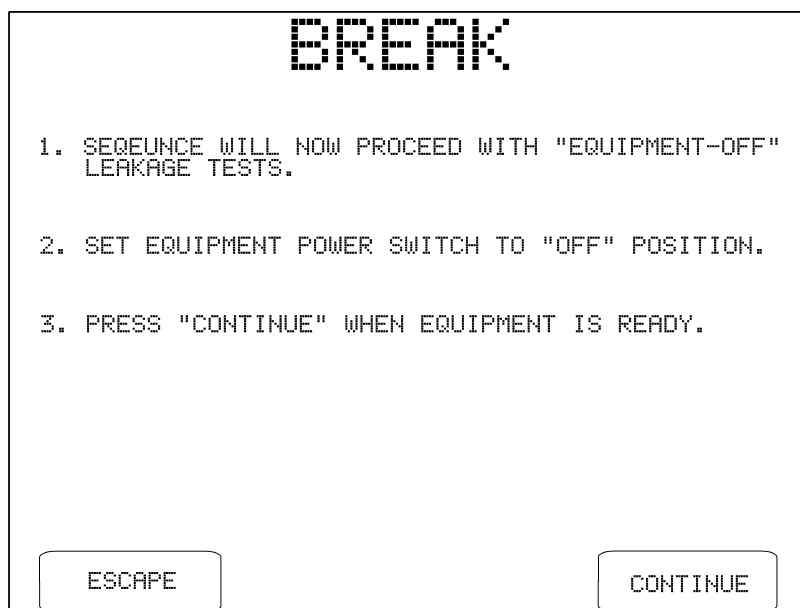
Figure 42 - Switch DUT to "ON" for upcoming "neutral open" tests.

Note the purpose of the "STOP BEFORE..." break is to allow you to accommodate power-sensitive equipment, such as a personal computer or equivalent DUT, which cannot be arbitrarily disconnected from the AC supply without potentially damaging the DUT. This type of equipment is much less common than equipment that can be switched "OFF" at any time. The more typical setting of "STOP BEFORE..." is therefore "NO", in which case the BREAK menus of *Figure 39* and *Figure 40* will not be displayed.

Many types of medical equipment do not fully disconnect from the AC supply when the power switch is set to "OFF". Even when "OFF", this type of equipment remains effectively connected to the AC supply and continues to operate in a standby state, for example, by charging an internal battery. For this type of equipment, "DUT OFF" leakage tests are required under AAMI-ES1 and IEC60601 standards.

"DUT OFF" leakage measurements are optionally enabled by the user before the test is performed, by means of the leakage setup menu. If "DUT OFF" tests are enabled, ES601-US will stop after all leakage measurements have been completed with DUT power switch in "ON" position. ES601-US will then display instructions as shown in the following figure.

```
          BREAK

1. SEQEUNCE WILL NOW PROCEED WITH "EQUIPMENT-OFF"
   LEAKAGE TESTS.


2. SET EQUIPMENT POWER SWITCH TO "OFF" POSITION.


3. PRESS "CONTINUE" WHEN EQUIPMENT IS READY.




   ESCAPE                          CONTINUE
```

***Figure 43** - Switch DUT to "OFF" for "DUT OFF" tests.*

Upon pressing **CONTINUE** on the above menu, ES601-US repeats all leakage tests that were enabled by the user. Since the DUT power switch remains "OFF" for all measurements, ES601-US does not stop when the AC supply is changed and no further breaks in the sequence occur until the end of the test.

Once the leakage measurement sequence has stepped through all specified test conditions, ES601-US will stop and display the last measurement taken during the leakage test. Pressing the **CONTINUE** button on the display copies the leakage measurement results to the temporary data buffer, along with the limits corresponding to each measurement. Refer to Chapter 2 for a discussion of the leakage current protocols of ES601-US, and the data which is saved by each protocol.

5.11 Viewing the Data Buffer

At any time during manual testing, equipment information and measurement results accumulated in the data buffer may be examined by pressing the **VIEW DATA** button on the MANUAL MODE menu.

The data buffer contents will be shown on the LCD as a multi-page "report". This is the same display as would result from recalling a Test Record from flash memory for viewing or printing. Refer to the *Reviewing Tests* section later in this chapter for more details on Record viewing and printing features.

5.12 Saving a Test

Press the **SAVE RECORD** button on the MANUAL MODE menu to save safety test data and equipment information in the data buffer to a Test Record. Usually, this is the final step of a manual safety test.
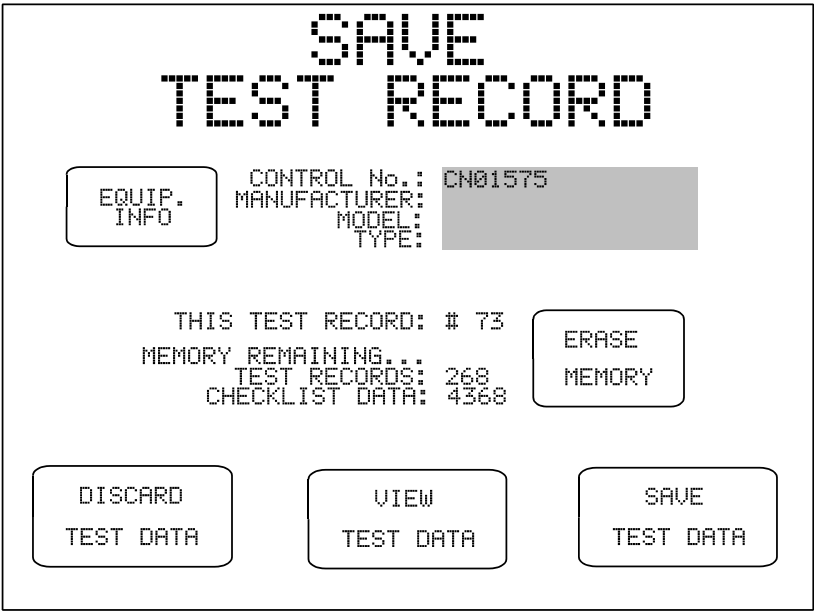

Figure 44 - *Menu for saving a Test Record.*

The SAVE TEST RECORD menu shows selected fields of the equipment information, the test record number, and the current memory status.

The options available on the SAVE TEST RECORD menu are:

EQUIP. INFO: This selection opens the EQUIPMENT INFO menu as described earlier in this chapter.

ERASE MEMORY: Opens the Erase Memory menu. The user is provided with options for erasing the last (i.e. most recent) Test Record stored in flash memory, or all Records in flash memory.

DISCARD TEST DATA: Discards all equipment information and measurement data for the test in progress and returns to the MANUAL MODE menu. The data buffer is erased by pressing this button.

VIEW TEST DATA: View measurement data currently stored in the data buffer.

SAVE TEST DATA: Saves the equipment information and measurement results to a Test Record in flash memory, and returns the display to the MANUAL MODE menu. Manufacturer, model, location, facility and Tech Code fields of the equipment information are retained, preparing ES601-US to test another similar device. All other equipment information and measurements in the data buffer are erased.

5.13 Reviewing Tests

Test Records which have been saved to the flash memory of ES601-US may be recalled by pressing the **REVIEW TESTS** button on the MAIN MENU. A particular Test Record can be located by scrolling up or down using the scroll buttons, until the desired Record is highlighted. Display the Record by pressing the **SELECT RECORD** button. The selected Record will appear on the LCD as a multi-page "report", which is explained in the following section of this chapter.
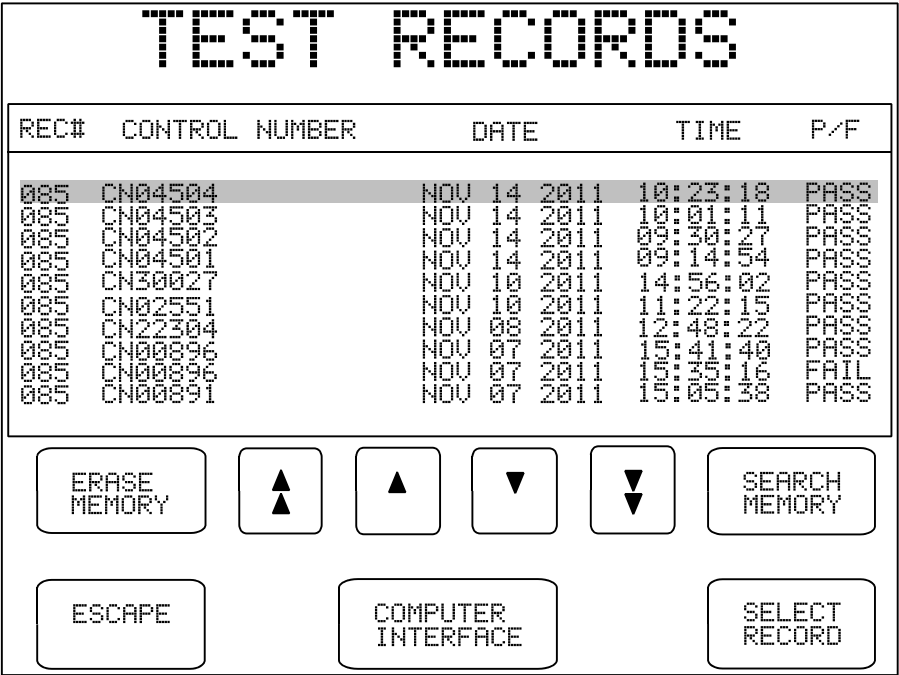

Figure 45 - *Select a Test Record*

If a previously stored Test Record is recalled from the flash memory in this manner, any safety test data or equipment information that may exist in the data buffer will be overwritten with the data of the recalled Record. Any manual test data that may have been collected in the buffer will therefore be **lost**, unless it is first saved via the **SAVE RECORD** button on the MANUAL MODE menu.

The TEST RECORDS menu lists all Test Records stored in the flash memory by Record number. Additional information displayed includes the Control Number, the Date and Time of the test, and the overall result of the test (PASS or FAIL).

Buttons provided on the TEST RECORDS menu are:

ERASE MEMORY: This button accesses a menu for erasing the record which is currently selected on the TEST RECORDS menu, or all of the records stored in memory. The **ERASE MODE** button on this menu allows the user to toggle between the currently-selected record or "ERASE ALL RECORDS". An **ESCAPE** button allows you to return to the TEST RECORDS menu.

Erasing the last record stored in memory, or all records in memory, is completed instantly and places no stress on the internal flash memory of ES601-US . But, if there are a large number of records stored in the memory, selecting and erasing a record stored near the beginning of the memory requires a few seconds to complete as the deleted record is removed, and the remaining records are then reorganized to create free memory space. Such erasing should be done sparingly as reorganizing a large number of stored records places some stress on the internal flash device.

ES601-US monitors flash memory erase stress, and to prevent loss of retained data, will prevent you from erasing individual records one at a time once a maximum stress level has been reached. Once maximum erase stress is reached, you will then only be able to erase all records currently stored in the memory. When all records are erased, the flash memory will then be reset, refreshed, and ready to begin storing new data.

Note the flash memory is stressed only by erasing single records on an individual basis, not by saving records during testing or by erasing all records in memory.

SEARCH MEMORY: Activates the QWERTY touch keypad to allow entry of a Control Number.

If the flash memory contains a record for the control number entered, the Test Record will be displayed. If more than one record exists for a recognized control number, only the earliest Test Record will be displayed. If the control number is not found, "TEST RECORD NOT FOUND IN MEMORY" is displayed momentarily, and the display returns to the TEST RECORDS menu. The search will only locate exact matches to what is entered via the QWERTY keypad.

SCROLL BUTTONS: Allows scrolling through the Records, either by single record (up ▲ or down ▼) or by page (10 records up ⬆ or down ⬇)

ESCAPE: Returns to the MAIN MENU of ES601-US.

COMPUTER INTERFACE: Opens the COMPUTER INTERFACE menu to allow for communication with the ES601pc-US software. (See Chapter 8).

SELECT RECORD: Displays the contents of the highlighted Test Record. Within the Record viewing menu, the various pages comprising a multi-page test result report can be seen on the LCD. The report can be printed via the PRINTER PORT or the RS-232 PORT.

5.14 Viewing Test Data and Report Output

5.14.1 Viewing a Record

Previously-saved Test Records may be recalled from the flash memory as described in the immediately preceding section. Over the course of a manual test, the current contents of the data buffer may also be checked periodically, via the **VIEW DATA** button on the MANUAL MODE menu. In either case, test data is shown on the LCD as a multi-page report which is comprised of a number of "pages". The term "page" in this case refers not to a printed page, but to the amount of data that can be shown on the display of ES601-US at one time; this is typically 20 lines or less.

If no data has been obtained when **VIEW DATA** is pressed, or if the buffer has been erased by changing the safety standard or saving a Test Record, ES601-US will display "THERE IS NO MEASUREMENT DATA TO VIEW", and will automatically return to the MANUAL MODE menu.

If a safety test has been performed, page 1 of the Test Record will include results for line voltage, load current and insulation resistance. Page 2 of the Record, an example of which appears below, will list results of the ground resistance test if this test was performed. For multiple resistance tests, this page may list up to ten resistance measurements according to the test protocol conveyed by the information appearing near the top right of the page. For tests where only a single resistance was recorded, only one resistance will appear in the "VALUE" column. If no point-to-point measurements were performed, then the "OFFSET:" will be represented as "-.---".

Figure 46 - *Example test result, multiple resistance test.*

Buttons provided by the TEST RECORD display are:

ESCAPE: Returns to TEST RECORDS menu.

OUTPUT REPORT: Enters the REPORT OUTPUT menu, which allows a formatted report of the test results to be printed via the PRINTER PORT or RS-232 PORT of ES601-US.

PREV PAGE: If more than one screen of data exists, the **PREV PAGE** button appears and allows backward scrolling through the Record.

NEXT PAGE: Scrolls to the next available page of data in the Record.

Pressing **NEXT PAGE** will advance through each page of data stored in the Record. Depending on the safety standard used in testing, and the testing conditions chosen, the first several pages of the Record will consist of safety test results. If the DUT provided a full complement of ten patient-patient leads organized as five functional groups of leads, there may be up to 18 pages of safety test results in the Record, where the latter 15 pages will list values recorded for patient and lead-to-lead leakage tests. This represents are large volume of data, however, such recording and reporting of results is a mandatory requirement of the AAMI and IEC60601 standards. Other standards, such as IEC62353, do not require as many safety measurements and therefore produce far shorter reports than tests performed according to AAMI or IEC60601.

Leakage results follow the page of ground resistance results. For AAMI-ES1 standard, the first page of leakage results will list the internal and external case leakage results (see example following). For AAMI-ES1 standard, the first page of leakage results will list the internal and external case leakage results (see example following). For IEC60601 standard, this page will show earth leakage and touch current results. For IEC62353 and VDE0751 standards, this page will show device leakage results. For all types of leakage measurement under any safety standard, the Test Record reports the testing conditions in mnemonic form, as follows:

NP   Normal AC supply polarity

RP   Reversed AC supply polarity

NORM.   AC supply in normal condition (neutral and ground closed)

OPEN N.   Single-fault condition, AC supply neutral (line 2) open

OPEN G.   Single-fault condition, ground (earth) connection open

ISO. TST.   Isolation test of patient lead(s) (mains on applied part test)

Figure 47 - *Example of internal and external case leakage results.*

For IEC62353 and VDE0751 safety standards, the test condition for the leakage results may be shown as "ALTERNATIVE METHOD", if the Alternative Method of device leakage or patient leakage testing was selected by the user for the test. Consult these standards for further information on the Alternative Method of measurement and its applicability.

In the Test Record, supplementary or optional test conditions for leakage measurement are reported in parentheses "(   )". Depending on the safety standard, the type of leakage measurement, and the supplementary conditions enabled by the user for the test, mnemonics appearing in brackets may be as follows:

---	No supplementary condition (condition not applicable to test, or condition not enabled by user)
ON	DUT power switch in "ON" position
OFF	DUT power switch in "OFF" position
LDO	All patient leads disconnected from ground
LDG	All patient leads connected to ground
IOS	Isolated signal inputs/outputs connected to AC supply
IOG	Isolated signal inputs/outputs connected to ground

ME   Exposed floating metal parts connected to ground

For each supplementary test condition enabled by the user in the test setup, ES601-US measures all combinations of the supplementary condition with the AC supply conditions specified in the safety standard. ES601-US then records the AC and DC leakage results for the supplementary condition that produced the highest leakage. The supplementary condition producing the worst case is also recorded and appears in parentheses in the Test Record report.

If the user chose to set up the test so certain conditions were disabled, then AC and DC measurement results for the disabled tests appear in the Record as "-----". For conditions pertaining to the AC supply (OPEN N., OPEN G.), "-----" results indicate the user may have inadvertently forgotten to enable the test. This may prompt the user to repeat the test with the correct conditions.

For all safety standards except IEC61010, patient leakage results will follow enclosure leakage results if the user has enabled testing of patient leads. One page is provided for each functional group of patient leads, as configured by the user in the test setup (see example below).
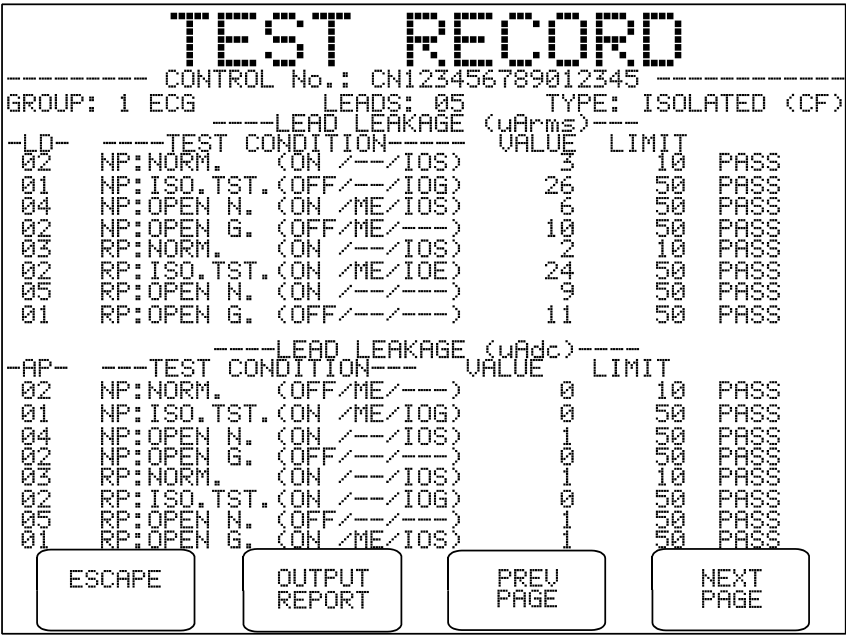

Figure 48: Example of patient leakage results (1 page per Group).

For the IEC60601 safety standard, the patient leads of a "Type CF" group are tested individually in turn. On the patient leakage page, in the "AP" column ES601-US shows the patient connection that produced the highest leakage for the given test condition. For "Type B" and "Type BF" groups, or for testing of any

"Type" done under the IEC62353 safety standard, the leads are tested collectively and so "**ALL**" will appear in the "AP" column of the patient leakage results.

In addition to patient leakage, AAMI-ES1 and IEC60601 standards also specify lead-to-lead (auxiliary) leakage tests. If this test was enabled by the user, patient leakage results will be followed by the lead-to-lead leakage results, with one page being provided for each individual patient lead.
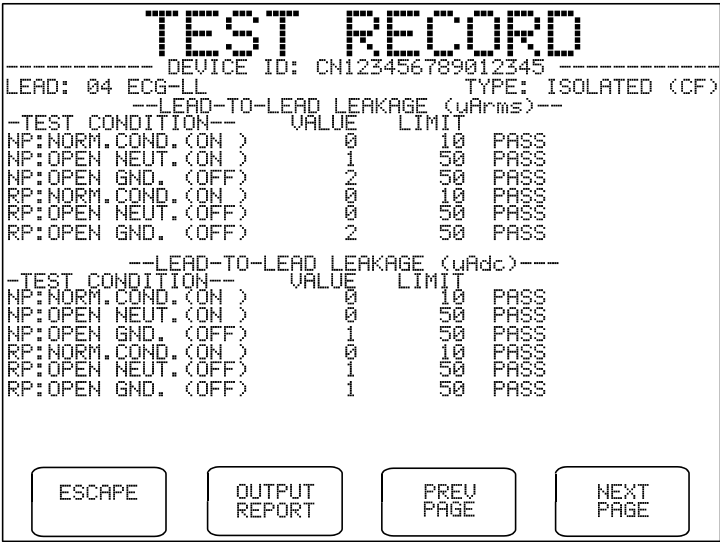

Figure 49: *Example of lead-to-lead leakage results (1 page per lead).*

Additional pages may follow the safety test data if results were obtained from automated tests, for example an ECG AutoSequence or a Checklist. Examples of such data are provided in the two figures which follow. Automated testing is discussed in Chapter 6 of this manual.
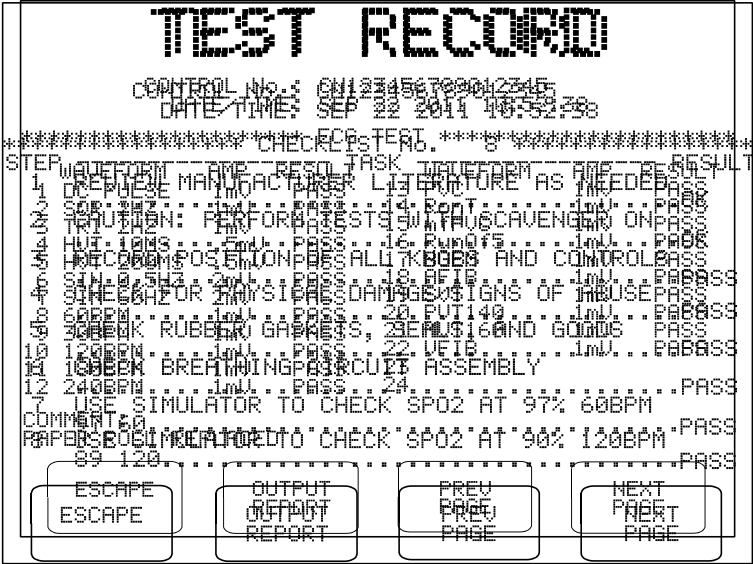
Figure 50: *Example of ECG AutoSequence results.*
Figure 51: *Example of results from a Checklist.*

5.14.2 Report Output

A hardcopy of the results shown on the LCD may be output to either the Printer Port or the RS-232 Port of ES601-US by pressing the **OUTPUT REPORT** button on the Test Record screen.
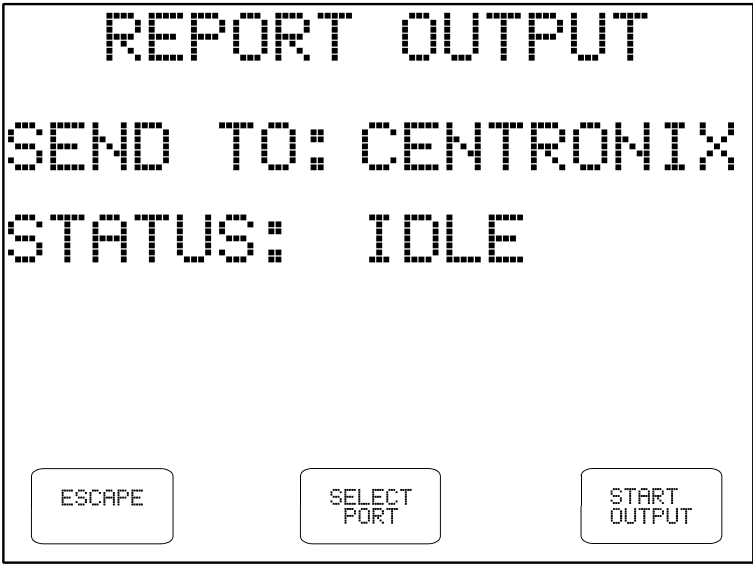

***Figure 52*** - *Select Printer Port*

> *NOTE*:
>
> If outputting the report to a serial printer, the printer's serial protocol must be configured for:
> **9600 baud, No Parity, 8 data bits, and 1 stop bit, or:**
>
> **9600,N,8,1**

The buttons provided on the REPORT OUTPUT menu are:

ESCAPE: Return to Test Record view screen

SELECT PORT: Select the "Send To:" destination for the generated Test Report as either Centronix Printer Port or RS-232 Port.

OUTPUT REPORT: Send the report to the selected Port

Once a print job has been started by pressing OUTPUT REPORT, the status of the print job is shown on the LCD. If ES601-US determines the receiving device is off-line, an alarm message is displayed. The ABORT button can be pressed to abort the print job and return to the Test Record viewer.
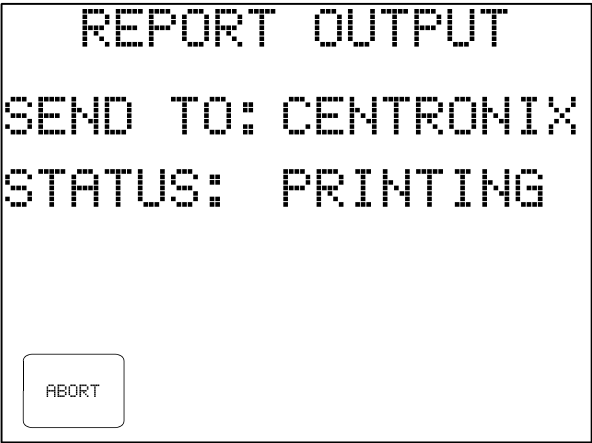
Figure 53 - *Print job in progress.*
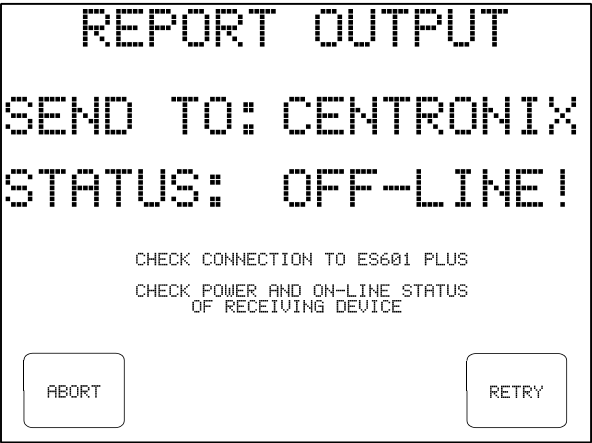
Figure 54 - *Printer Off-line Error*

If the print job is completed successfully, the screen will automatically return to the Test Record viewer.

### 5.14.3 Using HyperTerminal to Capture Test Results

In some situations, the user may not have access to a personal computer which has the ES601pc software package installed on it. As an alternative to utilizing the ES601pc software to download Test Record data from ES601-US, a terminal emulation program such as Windows 98/2000/XP *HyperTerminal* may be used to receive Test Records transmitted over RS-232 by the REPORT OUTPUT menu, and then save the data to a text file. Follow the Checkitems below to set up *HyperTerminal* for use with ES601-US.

From the Windows desktop, click Start, point to All Programs, point to Accessories, point to Communications and click on *HyperTerminal*. You will be prompted to enter a name for the *HyperTerminal* connection and select an icon associated with this new connection. Enter a suitable name, select the desired icon, and click on OK. Subsequently, click on this icon from Explorer or the Start menu to avoid having to set up a new connection every time you wish to use *HyperTerminal*.

A dialogue box will appear asking which port to connect to. Select the appropriate COM port and click on OK.

Another dialogue box will appear to configure the port settings. Configure the port settings as shown in **Figure 53**, then click on OK. As shown below, the COM port configuration settings are:

9600 Baud, 8 Data bits, Parity: None, 1 Stop bit, No Flow Control
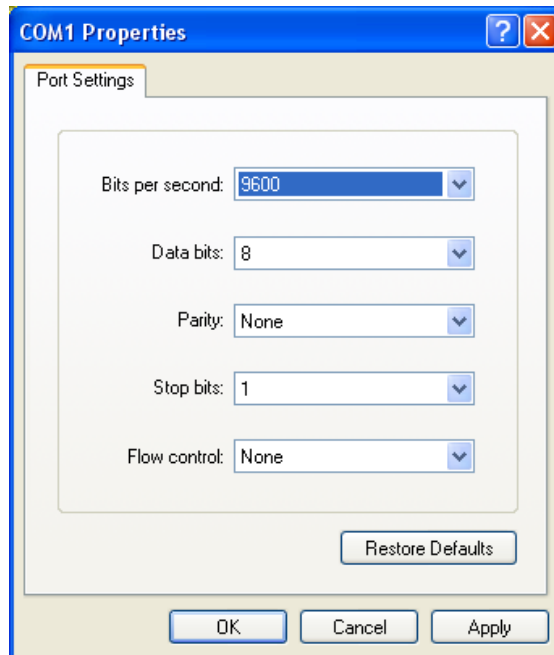
Figure 55 - *Setting up a HyperTerminal connection.*

In the *HyperTerminal* program window, click on Transfer in the menu bar and click on Capture Text to save all Test Records to a file. In the File box, type a descriptive name for the file, and click Start.

HyperTerminal is now ready to receive data sent from ES601-US to the PC. Connect the RS-232 Port of ES601-US to the PC COM Port selected in *HyperTerminal*, and use the REPORT OUTPUT menu to send the test results via the RS-232 Port.

Once all Test Records have been transferred, stop capturing text. In the Transfer menu of *HyperTerminal*, point to Capture Text and click on Stop.

5.15 ECG Simulator

Output signals from the ECG simulator of ES601-US are available at the AP jacks located on the front panel of the unit. Before using the simulator, connect the patient monitoring device under test to the corresponding ECG signals at the AP jacks ("RA" for right arm etc.). The AP connections are safety-style female banana jacks; an adapter plug is available to convert the AP jacks to ECG snap connections, if required (P/N 7500-425).

The ECG MENU button on the MANUAL MODE menu accesses the submenu for manual operation of the ECG simulator.
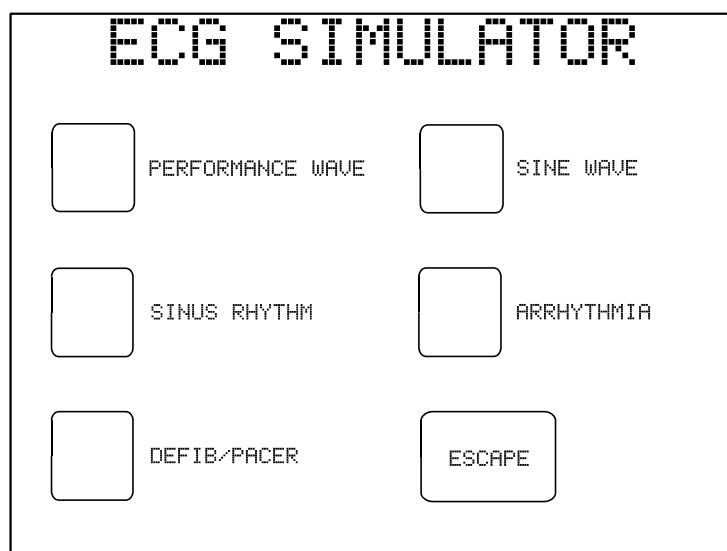
Figure 56 - *ECG simulator main menu, manual mode.*

There are five main ECG simulator category selections in the manual operating mode. The five submenus below the main menu provide eight waveforms within each category, as listed below.

PERFORMANCE WAVE
        DC Pulse, 4 seconds (a)
        Square Wave, 2 Hz (b)
        Triangle Wave, 2 Hz (c)
        Havertriangle Pulse, 10 msec, 60BPM (d)
        Havertriangle Pulse, 25 msec, 60BPM (d)
        Havertriangle Pulse, 40 msec, 60BPM (d)
        Havertriangle Pulse, 100 msec, 60BPM (d)
        Havertriangle Pulse, 200 msec, 60BPM (d)

SINE WAVE
> Sine Wave, 0.5 Hz (e)
> Sine Wave, 10 Hz (e)
> Sine Wave, 20 Hz (e)
> Sine Wave, 40 Hz (e)
> Sine Wave, 50 Hz (e)
> Sine Wave, 60 Hz (e)
> Sine Wave, 70 Hz (e)
> Sine Wave, 100 Hz (e)

SINUS RHYTHM
> ECG, 30 BPM (f)
> ECG, 60 BPM (f)
> ECG, 90 BPM (f)
> ECG, 120 BPM (f)
> ECG, 150 BPM (f)
> ECG, 180 BPM (f)
> ECG, 240 BPM (f)
> ECG, 300 BPM (f)

ARRHYTHMIA
> Second Degree A-V Block (blk II) (g)
> Premature Atrial Contraction (PAC) (g)
> Right Bundle Branch Block (RBBB) (g)
> Premature Ventricular Contraction (PVC) (g)
> R-on-T PVC (RonT) (g)
> Multifocal PVC (mfPVC) (g)
> Run of 5 PVC (Run5) (g)
> Bigeminy (BGEM) (g)

DEFIB/PACER
> Atrial Fibrillation (AFIB) (h, I)
> Asystole (ASYS) (h, j)
> Supraventricular Tachycardia (SVT) (h)
> Polymorphic VTach @ 140BPM (PVT140) (h)
> Monomorphic VTach @ 160BPM (MVT160) (h)
> Ventricular Fibrillation (VFIB) (h, I)
> Missed Beat at 80 BPM (MB80) (k)
> Missed Beat at 120 BPM (MB120) (k)

The following table describes specific instances where the waveforms listed prior are especially useful. The letter, below, corresponds to the letter at the end of each waveform description prior.

(a)   Tests monitor/chart recorder low-frequency performance
(b)   Tests monitor/chart recorder gain and damping performance
(c)   Tests monitor/chart recorder linearity performance
(d)   Tests monitor R-wave detection performance
(e)   Tests monitor/chart recorder frequency response
(f)   Tests monitor BPM accuracy and R-wave recognition
(g)   Tests arrhythmia detection algorithms
(h)   Tests AED shock/no shock, or defibrillator shock advisory report
(i)   "Coarse" waveform
(j)   Random, low-frequency baseline fluctuation
(k)   Tests pacemaker in demand mode

When a waveform is selected, its title is highlighted on the LCD and the simulator begins to output the corresponding signal immediately.

The RELATIVE SCALE button on the menu allows the amplitude of the output signal to be set to: x1 (default, 1 mV QRS on Lead II), x2, x0.5, or OFF (ECG output set to zero).
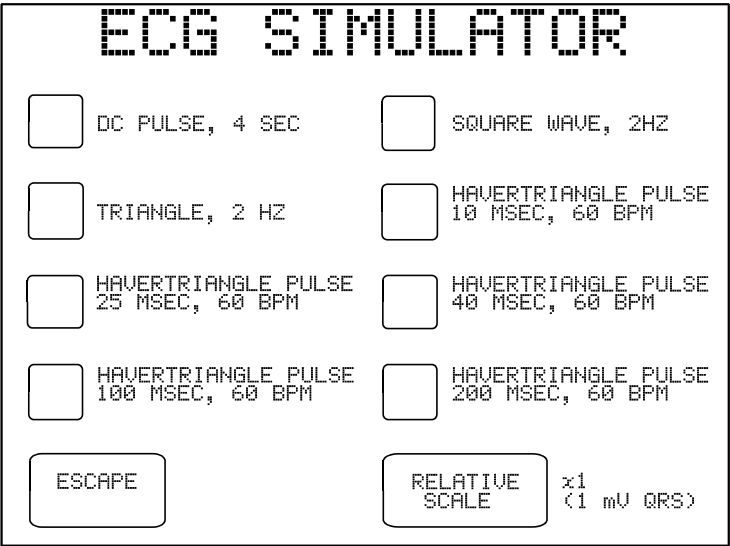
Figure 57 - *Performance wave submenu.*

The RELATIVE SCALE will retain its setting as different waveforms are selected, but will return to the default – X1 (1 mV) – after escaping from the ECG simulator menu.

The ESCAPE key may be pressed on any submenu to return to the main ECG menu. On the main ECG menu, pressing ESCAPE returns the display to the MANUAL MODE menu.

When manually operating the ECG Simulator via the prior menu system, it is not possible to save "ECG test results" in the Clip Record. ECG test results can be obtained and saved to the Clip Record by running an ECG AutoSequence as described in the ECG AutoSequence section of Chapter 6.

5.16 Capturing Test Time

Some institutions require monitoring and recording of the time spent performing certain types of work. This requirement is satisfied in part by a timer internal to ES601-US, which is started and stopped in response to activity of the analyzer.

When ES601-US is powered up, the "Test Time" counter is initially reset to zero and is inhibited from counting.

When any measurement is selected from the menu, the timer is started if it is not currently running. The timer counts upward in elapsed seconds and has sufficient range to clock up to 18 hours. The timer continues to run until a Test Record is saved. The "Test Time" is then saved in the Test Record along with the measurement data.

The actual time spent performing an assigned work task may be significantly greater than the time taken by ES601-US to complete a series of measurements. To allow for this difference and to accurately capture labor expenditure, automated tests such as *Checklists* and *AutoSequences* can be configured to prompt the user to enter the overall time spent performing a task. This "User Time" is input via the on-screen QWERTY keypad, and is saved in the record in addition to the safety analyzer's "Test Time" and the measurement data. Automated testing is covered in Chapter 6, and enabling of the prompt for "User Time" is described in Section 3.2.

ES601-US OPERATING MANUAL

Chapter

6

6   Automated Testing

6.1 AutoSequence Overview

An automated test sequence or "*AutoSequence*" is a series of measurements or test operations that are run automatically by ES601-US in a predefined order, with or without involvement of the user. The **AUTOMATED TESTS** button on the MAIN MENU accesses the AUTOMATED TESTS menu, the entry point for selection of an automated test of electrical safety or performance. In addition to automated safety tests, ES601-US provides automated performance tests for specific equipment types such as patient monitors, pulse oximeters, infusion pumps, defibrillators, pacemakers, electrosurgical units, NIBP monitors and other medical devices.
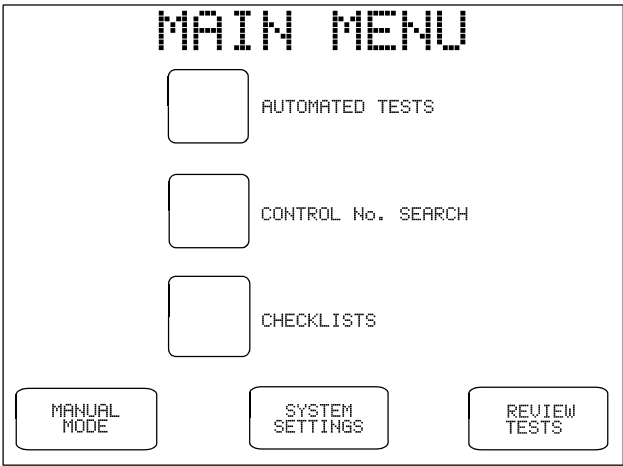
```
 MAIN MENU

  [ ]  AUTOMATED TESTS

  [ ]  CONTROL No. SEARCH

  [ ]  CHECKLISTS

 (MANUAL    (SYSTEM     (REVIEW
  MODE)     SETTINGS)    TESTS)
```

```
 AUTOMATED TESTS

 [ ] ELECTRICAL SAFETY    [ ] OXITEST PLUS 7
     AUTOSEQUENCES            AUTOSEQUENCES

 [ ] ECG SIMULATOR        [ ] INFUTEST 2000
     AUTOSEQUENCES            AUTOSEQUENCES

                          [ ] PHASE 3 DEFIB+PACER
                              AUTOSEQUENCES

                          [ ] USER-DEFINED TESTER
                              AUTOSEQUENCES

 (MAIN                    [ ] PHYSICAL
  MENU)                       INSPECTIONS
```

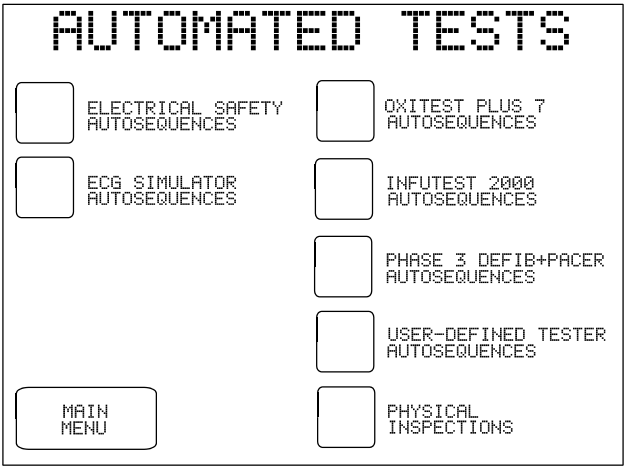*Figure 58* - *Main Menu of ES601-US.*   *Figure 59* - *Automated tests menu.*

All automated tests provided by ES601-US follow the same general pattern at test startup and conclusion, according to configuration settings which can be made via the System Settings menu. Refer to Section 3.2 for more information on configuring those settings which affect automated test execution, as described below.

To begin, the desired test is selected by navigating from the AUTOMATED TESTS menu, shown above. Once a test has been selected, the user will then be requested by ES601-US to enter information about the equipment being tested, for example, the Control Number of the equipment. This data entry is optional and

---

the user can proceed immediately to the test by simply pressing a **RUN TEST** button on the screen. Refer to Section 5.5 for instructions on use of the Equipment Information menu, shown below.

Figure 60 - *Prompt for equipment information at test startup.*

According to System Settings, as the next step the user may be prompted to perform a physical inspection of the equipment and enter details of the inspection. Up to two lines of 40 characters each may be entered to describe the inspection. Inspection prompts can be skipped if desired, by pressing a **SKIP** button which is at lower left on the screen. As with all QWERTY touchscreen displays, the user may alternatively input the requested information by means of an external keyboard or barcode scanner connected to ES601-US.

Figure 61 - *Prompt for equipment physical inspection.*

After equipment inspection, the actual test begins in which various measurements of electrical safety or device performance will be executed automatically by ES601-US, in accordance with the test chosen. Note that if you wish to have power applied during Autosequences or Checklists (other than Electrical Safety, ECG or Test Device Autosequences) power must be applied or removed through the use of the TRPN or GTOL commands (see 6.1.5.7 The M Checkitem). After all test measurements have been completed, according to System Settings the user may be optionally prompted to input concluding comments about the test performed. As with the prompt for physical inspection, this data entry can be skipped by pressing the **SKIP** button.

```
TEST COMPLETE - ENTER ADDITIONAL COMMENTS:
_                                              ***********

    1    2    3    4    5    6    7    8    9    0

      Q    W    E    R    T    Y    U    I    O    P

      A    S    D    F    G    H    J    K    L    -

      Z    X    C    V    B    N    M    .    /    #

    SKIP      <--        SPACE            ENTER
```

Figure 62 - *Prompt for test comments.*

Entry of test comments may be optionally followed by a prompt to input "user time", that is, the labor time (in hours) spent by the user in performing the assigned work task. As with other requests for data input from the user, entry of a user time may be skipped via a **SKIP** button on the screen.

Figure 63 *- Prompt for input of labor time.*

Upon completing these steps, the user will then be shown a menu for saving a permanent Record of the test performed. If an equipment Control Number has not been entered by this stage in the test sequence, the user will be requested to enter it in order to create a Test Record.

Figure 64 *- Prompt to save a Test Record.*

Upon saving the Test Record to the flash memory, according to System Settings the user may be prompted to print a PM tag or label. Such printing is accomplished with an accessory adhesive label printer (Dymo SE300), which can be optionally connected to ES601-US.

Figure 65 - Prompt to print a PM tag or label.

The printed PM tag, which per the menu above specifies equipment control number, pass/fail status, date of test, and next test due date, is then applied to the equipment. This concludes the automated test process, and returns the display of ES601-US to the MAIN MENU.

6.1.1 Safety AutoSequences

Safety AutoSequences of ES601-US correspond to lists of sequential voltage, current and resistance measurements made on the DUT. Twenty-four default Safety AutoSequences allow ES601-US to be immediately usable upon delivery. Descriptions of the default Safety AutoSequences are provided in Appendix A.

Safety AutoSequences can be programmed as desired by means of the System Settings Menu (see Section 3.6). Alternatively, Safety AutoSequences can be edited and uploaded to ES601-US by means of the Safety Autosequence module of the ES601pc-US software package. ES601pc-US is described fully in Chapter 8.

Selecting **ELECTRICAL SAFETY AUTOSEQUENCES** from the AUTOMATED TESTS menu opens the Safety AutoSequence menu.
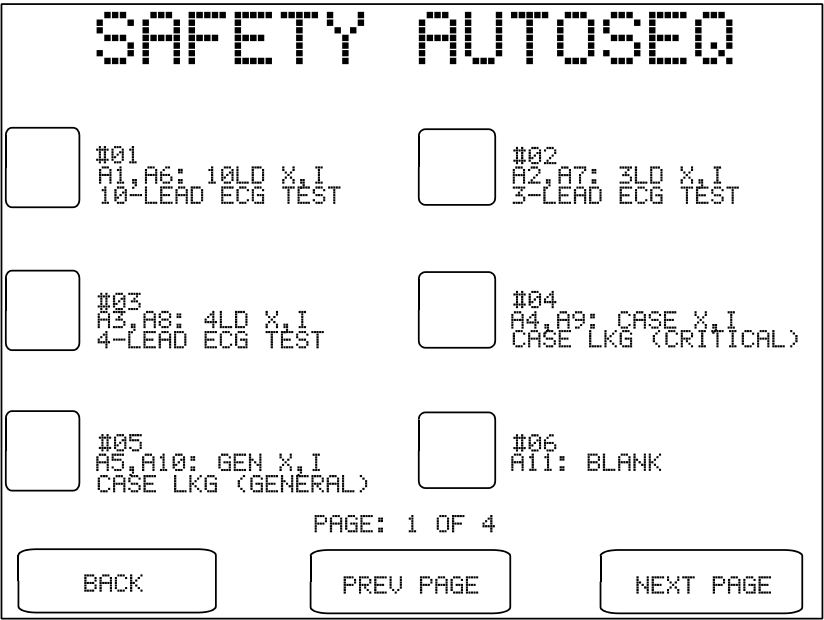
Figure 66 - *Safety AutoSequence menu*

Twenty-four Safety AutoSequences are listed across four menu screens or "pages". Default AutoSequences delivered with the analyzer provide a number of examples for several safety standards (IEC; AAMI; VDE). Scroll through these screens using the **PREV PAGE** or **NEXT PAGE** buttons to locate the desired Safety AutoSequence. Select the Safety AutoSequence by pressing the button to the left of the sequence's title. **BACK** returns to the AUTOMATED TESTS menu.

As described in Section 6.1 *AutoSequence Overview*, after selecting a safety test you will be prompted to input information about the equipment under test. At this stage, it is not mandatory to enter any equipment information and the safety test can be launched immediately, simply by pressing the **RUN TEST** button. However, to save a Record of the test it will be necessary to enter at least a Control Number, which can be done after the safety test is complete.

Per Section 6.1, if pre-test inspection has been enabled in the System Settings, you will be prompted to inspect the equipment and enter comments. Following the inspection prompts, you are presented with various menus that will allow you to modify the settings of the Safety AutoSequence before the test is started. These displays will be similar to menus described in detail in Sections 3.3 and 5.10 of this manual. Any changes made to AutoSequence settings will remain in effect for the duration of the test, then will revert to the AutoSequence setup stored in memory when the test is completed. If modifications are necessary for more than one test, you should consider programming and saving such changes by means of the Edit Safety menu, described in Section 3.6.

For a safety test, the first menu presented will be instructions for connecting the DUT to ES601-US. On

this and any setup menu which follows, the **ESCAPE** key may be pressed to abort the test and return to the MAIN MENU. Alternatively, **CONTINUE** may be pressed to advance the sequence to the next setup menu.

```
         CONNECTIONS

1. (MANDATORY) CONNECT LINE CORD OF EQUIPMENT TO
   ES601 TEST RECEPTACLE.
2. (MANDATORY) CONNECT KELVIN CABLE OF ES601 TO
   ENCLOSURE OF EQUIPMENT.
3. (MANDATORY) SET POWER SWITCH OF EQUIPMENT TO
   "ON" POSITION.
4. (OPTIONAL) CONNECT PATIENT LEADS TO ES601
   "AP" JACKS.
5. (OPTIONAL) CONNECT ISOLATED SIGNAL INPUTS AND/OR
   OUTPUTS TO ES601 "AUX1" JACK.



WHEN EQUIPMENT IS READY, PRESS "CONTINUE" TO START
THE TEST, OR PRESS "ESCAPE" TO ABORT...

  [ ESCAPE ]                        [ CONTINUE ]
```

Figure 67 *- Connections for AAMI safety test.*

If patient leads have been specified in the AutoSequence setup, the next menu displayed will show the patient lead configuration. Names of the patient leads may be modified by means of the menu. Assignment of patient leads to functional groups and protection class (B; BF; CF) can be modified after pressing the **EDIT** button. If the AutoSequence setup does not specify patient leads, this menu is bypassed.

Figure 68 - *Patient lead setup.*

The final setup menu displayed before the test actually starts shows the Sequence Controls of the AutoSequence. These settings are described in more detail in Sections 3.3, 5.9 and 5.10 of this manual. Any changes made to these settings are retained for the duration of the test, and revert to the values stored in memory upon test completion. This includes the OFFSET calibration shown on this display, which pertains to point-to-point measurement in the ground resistance test. Note also for an AutoSequence the "PAUSE AFTER..." control will introduce a delay following every measurement of the sequence, not only the leakage measurements.

Figure 69 - *Sequence Controls setup.*

The **NEXT** button of the Sequence Controls menu launches the safety test. As the test sequence progresses, the display of ES601-US provides user prompts and instructions as necessary, and reflects real-time information about the tests performed. This includes the type of test currently being executed within the sequence (line voltage, ground, leakage current, etc.), the safety standard used, AC supply status, the measured value(s), the pass/fail limits, and the pass/fail assessment of the measurement result. Throughout the test sequence, **PAUSE**, **ESCAPE**, **REPEAT** and **CONTINUE** buttons are available as applicable to the test being performed. The functions of these keys are described in Chapter 5.
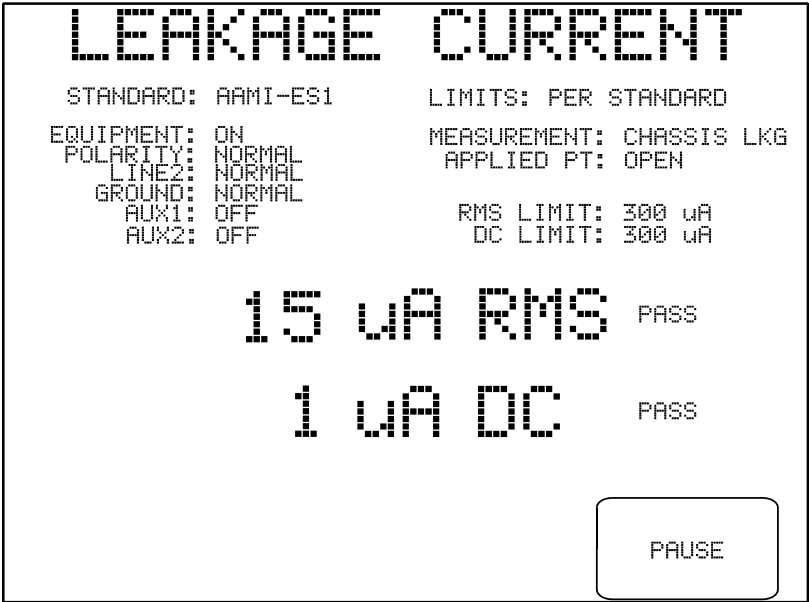
Figure 70 - *Safety AutoSequence in progress.*

Depending on "STOP AFTER..." and "STOP BEFORE..." settings of the Sequence Control setup, ES601-US may stop at selected steps in the test sequence and prompt you to operate the power switch of the DUT. These "BREAK" prompts are described in Section 5.10.

The order of measurements in the sequence is set by ES601-US, but the enabling of the measurements is defined by the user through the AutoSequence programming. The table below lists the order of the measurements and the corresponding status of the AC supply to the DUT.

Step	Safety Measurement	AC supply to DUT
1	Ground resistance	OFF
2	Insulation resistance	OFF
3	Line voltage	OFF
4	Leakage: reverse polarity, open neutral	OFF
5	Leakage: reverse polarity, closed neutral	***ON***
6	Leakage: normal polarity, open neutral	OFF
7	Leakage: normal polarity, closed neutral	***ON***
8	Load current	***ON***
9	Test completion	OFF

Upon completion of the safety test sequence, operation of ES601-US will depending on settings configured via the SYSTEM SETTINGS menu. After a test sequence has ended the user may be optionally prompted to input concluding comments about the safety test as well as a labor time ("user time"). After saving the Test Record, the user may be prompted to print a PM tag or label, which can then be applied to the equipment tested. Refer to Section 6.1 *AutoSequence Overview* for further details.

6.1.2 ECG AutoSequences

ES601-US provides six programmable ECG AutoSequences, each with up to 24 waveform/amplitude steps. As the ECG AutoSequence is executed, simulator waveform, amplitude scale, and pass/fail result for each sequence step are stored. When the sequence is completed, a Record of the ECG test may then be saved to the flash memory.

ES601-US is supplied with one of its ECG AutoSequences configured, the other five AutoSequences being blank and available to the user for programming as required. ECG AutoSequences can be edited and uploaded to ES601-US by means of the ECG AutoSequence module of the ES601pc-US software package. Editing of ECG AutoSequences is described in Chapter 8.

Selecting **ECG SIMULATOR AUTOSEQUENCE** from the AUTOMATED TESTS menu opens the ECG AutoSequence menu. Press the appropriate button to invoke the desired ECG AutoSequence, or press **BACK** to return to the AUTOMATED TESTS menu.
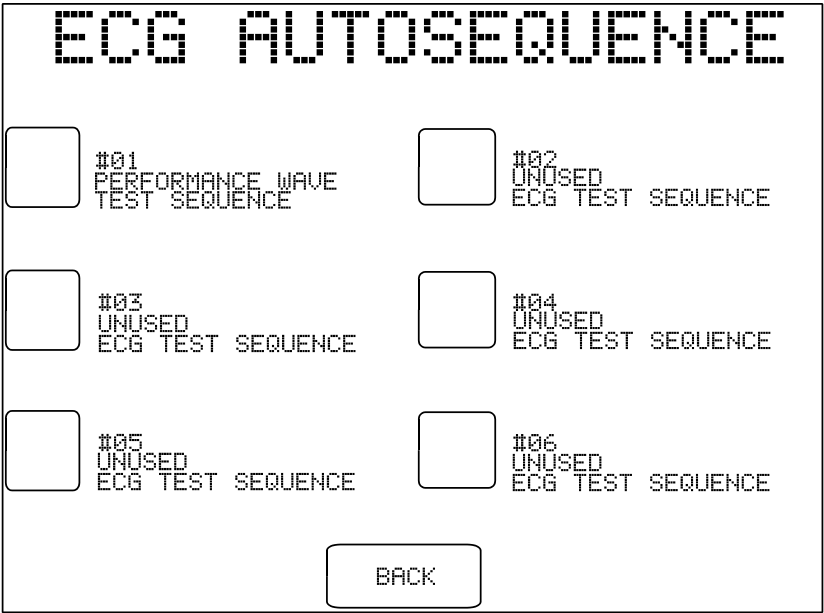
Figure 71 - *ECG AutoSequence menu.*

As with all automated tests performed by ES601-US, selecting an ECG AutoSequence from the menu will cause the EQUIPMENT INFO menu to be displayed. A control number and other equipment information may be optionally entered at this point. Press the **RUN TEST** button to start the ECG test. Prompts for equipment physical inspection may be displayed, according to System Settings. Refer to Section 6.1 *AutoSequence Overview* for further details.

Following the optional physical inspection, the ECG test sequence begins. At each step of the test sequence, the display of ES601-US will indicate the waveform and output amplitude or "scale" of the ECG simulator. The displayed amplitude corresponds to peak QRS on Lead II of the ECG.
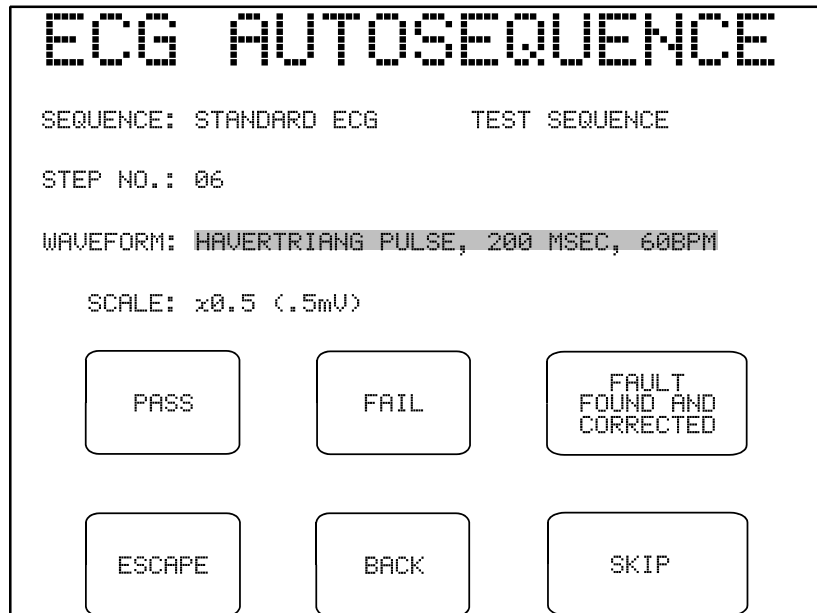
Figure 72 - ECG AutoSequence in progress.

Throughout the ECG AutoSequence, **PASS**, **FAIL** and **FAULT FOUND AND CORRECTED** buttons are available. Pressing the **PASS** button indicates the DUT responds correctly to the waveform output by the ECG simulator. **FAIL** indicates the waveform is not correctly displayed on the DUT. Pressing the **FAULT FOUND AND CORRECTED** button means that a problem seen with the DUT was resolved by the user (for example, a bad lead may have been replaced).

Upon completion of the ECG AutoSequence, operation of ES601-US will depending on settings configured via the SYSTEM SETTINGS menu. After a test sequence has ended the user may be optionally prompted to input concluding comments about the ECG test as well as a labor time ("user time"). After saving the Test Record, the user may be prompted to print a PM tag or label, which can then be applied to the equipment tested. Refer to Section 6.1 *AutoSequence Overview* for further details.

6.1.3 Tester (Test Device) AutoSequences

In addition to Safety and ECG AutoSequences, ES601-US provides for other types of automated tests. On its left side panel, ES601-US provides six RS232 serial interfaces or "TESTER PORTS", which can be connected to external measuring instruments or "**Testers**" by means of accessory adapter cables. Tester AutoSequences of ES601-US remotely control these external Testers via the TESTER PORTS, allowing ES601-US to automatically execute tests of medical device performance and acquire and store the results.

ES601-US provides Tester AutoSequences for Datrend products such as the **Oxitest Plus 7** pulse oximeter tester, **Infutest 2000** infusion pump tester, and **Phase 3** defibrillator/pacemaker tester. AutoSequences for Oxitest, Infutest and Phase 3 can be user-programmed and uploaded to the ES601-US analyzer by means of corresponding modules of the ES601pc-US software package, which is described in Chapter 8.

Optionally, ES601-US can be interfaced to test instruments from manufacturers other than Datrend. The Inspections and User-Tester Editor module of ES601pc-US software allows the user to program and upload AutoSequences for up to five **User-Defined Testers** or analyzers. Compared to setting up Oxitest, Infutest and Phase 3 AutoSequences with ES601pc-US software, AutoSequence programming for a User-Defined Tester requires greater knowledge on the part of the user, for example, knowledge of the remote command language of the Tester and an understanding of ES601-US *Checkitems* and *Checklists*, which are explained later in this chapter. As illustrative examples, ES601-US is provided with default example AutoSequences installed for Fluke Biomedical **Impulse 4000** defibrillator/pacemaker tester, as well as for Pronk **SimCube**®NIBP monitor tester.

Accessory cables are available for connecting ES601-US to test equipment from various manufacturers. The table below lists adaptor cables for specific instruments, as well as the default TESTER PORT which can be used for the RS232 serial connection. Note the TESTER PORT specified in the table is simply a factory default setting, and this setting can be modified as desired by the user when a test is started; any of the six TESTER PORTS of ES601-US can be used to connect to the specified instrument, via the specified accessory cable.

Tester	Application	Default Port	Interface Cable
Datrend Oxitest +7	Pulse oximeter performance testing	P-1	P/N 7500-436
Datrend Infutest 2000	Infusion pump performance testing	P-2	P/N 7500-437
Datrend Infutest Solo	Infusion pump performance testing	P-4	P/N 7500-435
Datrend Phase 3	Defib/pacemaker performance testing	P-3	P/N 7500-435
Datrend Accusim-BP-DT	NIBP monitor performance testing	P-4	P/N 7500-436
Datrend AMPS-1	Patient monitor performance testing	P-4	P/N 3140-429 [1]
Fluke Biomedical Impulse 4000	Defib/pacemaker performance testing	P-3	P/N 7500-438
Pronk Technologies SimCube®	NIBP monitor performance testing	P-4	P/N 7500-436
Clinical Dynamics AccuPulse	NIBP monitor performance testing	P-4	P/N 7500-436

Note (1): Cable 3140-429 is provided with AMPS-1 as a standard accessory

To select a medical device performance test, start at the MAIN MENU and press **AUTOMATED TESTS**. Menus for the various Tester AutoSequences are listed on the right-hand side of the screen.
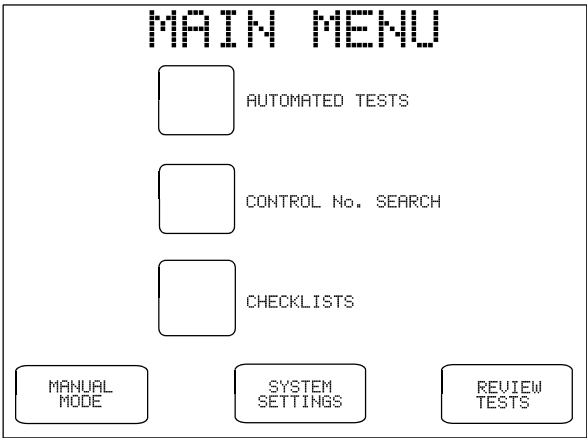
Figure 73 - *Main Menu of ES601-US.*
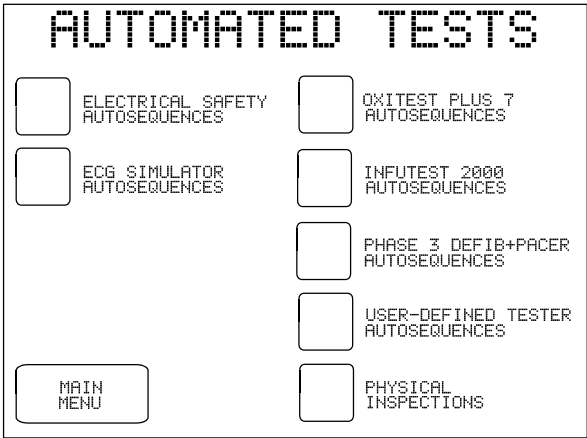
Figure 74 - *Automated tests menu.*

Performance tests for pulse oximeter, infusion pump and defibrillator/pacemaker are accomplished with Datrend Oxitest, Infutest, and Phase 3 instruments respectively, with submenus of corresponding AutoSequences being provided on the right of the AUTOMATED TESTS menu.

Performance tests for ESU, NIBP and others are accessed from the USER-DEFINED TESTER menu, shown below. This menu also provides access to alternative AutoSequence tests for defibrillator and pacemaker, which may be executed with the Impulse 4000 analyzer from Fluke Biomedical. NIBP monitor tests are performed with the Datrend Accusim-BP-DT simulator, as indicated on the menu. MISCELLANEOUS AUTOSEQUENCES are provided which function with other test instruments, for example, Pronk Technologies SimCube®.
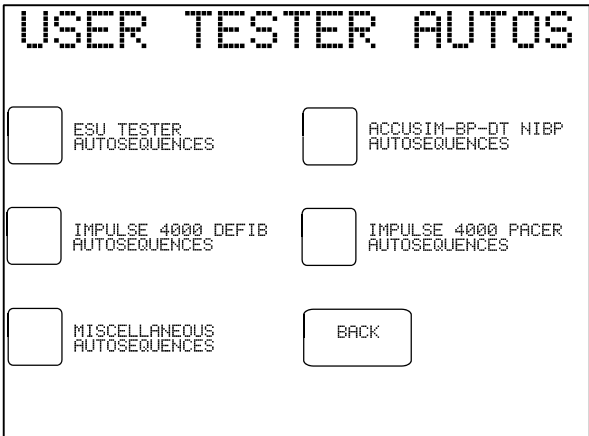
Figure 75 -*"User-Defined" Tester menu.*

Figure 73 shows factory default AutoSequences which will be seen on delivery of ES601-US. Default AutoSequences may be modified or new AutoSequences created for other test instruments using the Inspections and User Tester module of ES601pc-US software, included with the safety analyzer. See Chapter 8 for instructions on use of ES601pc-US software.

Individual menus for Tester AutoSequences operate similarly to menus described earlier in this chapter for Safety and ECG AutoSequences. For example, *Figure 74* shows example AutoSequences which work with the Datrend Infutest 2000 infusion pump tester.

Figure 76: Test selection for IV pump tester Infutest 2000.

As with all automated tests performed by ES601-US, selecting an AutoSequence from a menu such as *Figure 74* will cause the EQUIPMENT INFO menu to be displayed. A Control Number and other equipment information may be optionally entered at this point. Press the **RUN TEST** button to start the test. Power will be applied to the Test Receptacle at this point. Prompts for equipment physical inspection may be displayed, according to System Settings. Refer to Section 6.1 *AutoSequence Overview* for further details.

Tester AutoSequences differ from other automated tests of ES601-US in that a specific test instrument is interfaced to ES601-US via an accessory cable connected to a TESTER PORT, thereby allowing ES601-US to remotely control the external instrument and acquire the test results. Following optional prompts for physical inspection, ES601-US will display a menu which allows the user to check the cable which connects to the external instrument, via the **CHECK CONNECTION** button (see *Figure 75*). Pressing this button will transmit a "*IDENT*" command from ES601-US to the test instrument, with the corresponding response from the instrument being displayed immediately below the button. If necessary, settings for RS232 serial data communications may be modified by other buttons on this menu, before initiating the test with the **RUN TEST** button.

```
INFUTEST AUTOSEQ

    TITLE: A50: PUMP 1        RATE TEST, 60-240

REMOTE CONTROL SETTINGS
      ┌─────────┐  ··      ┌──────────────┐
      │ TESTER  │  ··      │    CHECK     │
      │  PORT   │  2       │  CONNECTION  │
      └─────────┘  ··      └──────────────┘
                           STATUS:
      ┌─────────┐            INFUTEST DETECTED
      │  BAUD   │  9600
      │  RATE   │
      └─────────┘


      ┌─────────┐          ┌──────────────┐
      │ ESCAPE  │          │     RUN      │
      │         │          │    TEST      │
      └─────────┘          └──────────────┘
```
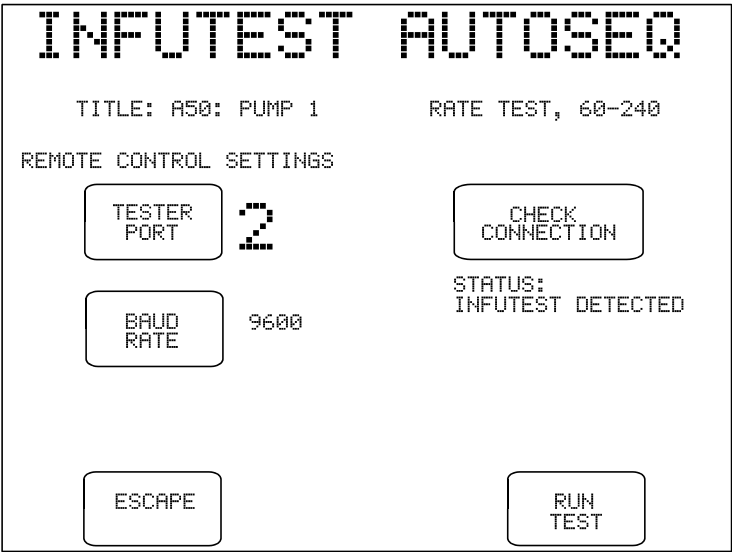
Figure 77*: Serial communication settings for Tester AutoSequence.*

Following display of the serial communication settings as above, subsequent displays will depend on the test instrument being controlled and the test parameters which have been programmed by the user as part of the AutoSequence setup. ***Figures 76 - 80*** show how the test process works for the case of Datrend Infutest 2000 analyzing the flow rate performance of a 2-channel infusion device (4-channel pumps can also be tested this way using Infutest 2000 with RSM). Although specific details will differ, display screens are similar in principle for the case of Datrend Oxitest+7 testing a pulse oximeter, or Datrend Phase 3 testing a defibrillator or pacemaker.

```
INFUTEST AUTOSEQ

    TITLE: ALARIS SIGNATURE    DUAL-CHANNEL

STEP NO.: 03



    TASK: INITIALIZING INFUTEST. PLEASE WAIT...
```
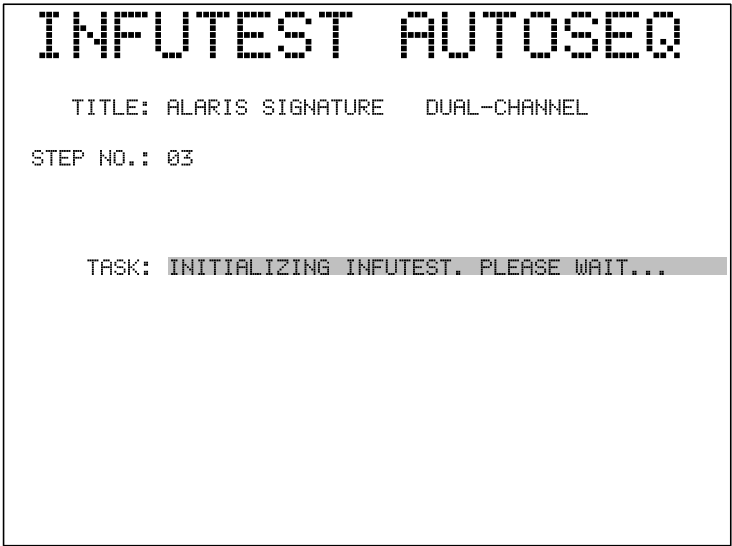
Figure 78*: ES601 configures Infutest to run a 2-channel test.*

INFUTEST AUTOSEQ

```
TITLE: ALARIS SIGNATURE    DUAL-CHANNEL

STEP NO.: 03                         ┌──────────┐
                                     │  ESCAPE  │
                                     └──────────┘



  TASK: START INFUSION DEVICE (2 CHANNELS)

        PLEASE WAIT FOR INFUTEST TO SYNCRO-START.

        ELAPSED TIME: XXXX SECONDS



                     ┌──────────┐
                     │   SKIP   │
                     └──────────┘
```

Figure 79: ES601 prompts user to start the IV pump.

INFUTEST AUTOSEQ

```
TITLE: ALARIS SIGNATURE    DUAL-CHANNEL

STEP NO.: 03                         ┌──────────┐
                                     │  ESCAPE  │
                                     └──────────┘



  TASK: RUNNING TEST.........  DURATION:  360 SEC




                     ┌──────────┐
                     │   SKIP   │
                     └──────────┘
```

Figure 80: ES601 monitors Infutest status while Infutest tests the IV pump.

```
INFUTEST AUTOSEQ

     TITLE: ALARIS SIGNATURE    DUAL-CHANNEL

 STEP NO.: 03



     TASK: RUNNING TEST...       DURATION: 360 SEC

CHANNEL A: 00:06:04 38.97 ml 389.9 ml/h
CHANNEL B: 00:06:02 39.04 ml 391.0 ml/h
```
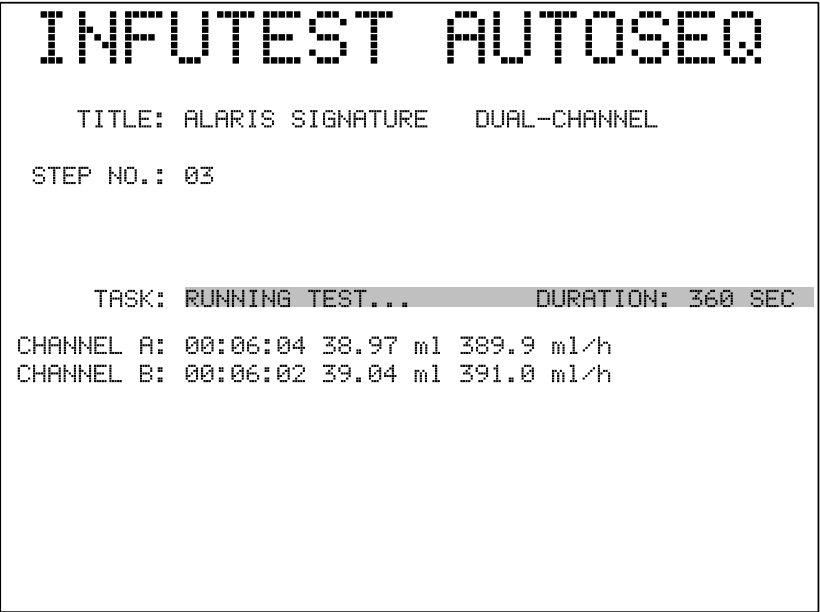
Figure 81: After Infutest is finished, ES601 downloads measurement data.

```
INFUTEST AUTOSEQ

     TITLE: ALARIS SIGNATURE    DUAL-CHANNEL

 STEP NO.: 03                        ESCAPE

TEST DATA: VOL A=39.86,B=38.99/RATE A=398.2,B=390.1

     TASK: PUMP TEST COMPLETE

   RESULT: PASS




                       OK
```

Figure 82: ES601 automatically passes or fails the final test results.

6.1.4 Checklists

A "***Checklist***" is an automated sequence of work tasks, combining inspection, electrical safety testing, and performance testing activities into one comprehensive maintenance procedure targeted at a specific kind of medical device, for example, a patient monitor, defibrillator, anaesthesia gas machine, etc. The flash memory of ES601-US provides storage for up to 500 Checklists.

Checklists are written on a personal computer, and are then uploaded to the ES601-US analyzer. Checklists can be created using the Checklist module of the ES601pc-US software package, provided with the analyzer. Alternatively, checklists for Fluke Biomedical **medTester 5000C** can be transferred from a Computerized Maintenance Management System (CMMS) to the ES601pc-US software, where they can be converted by the CMMS Interface module and then uploaded to the ES601-US. The Checklist and CMMS Interface modules of ES601pc-US are described in Chapter 8.

Checklists are accessed by pressing the **CHECKLISTS** button on the MAIN MENU of ES601-US. Increment/decrement buttons on the CHECKLISTS menu allow a Checklist title to be highlighted in the list. The Checklist is then initiated by pressing the **SELECT** button.
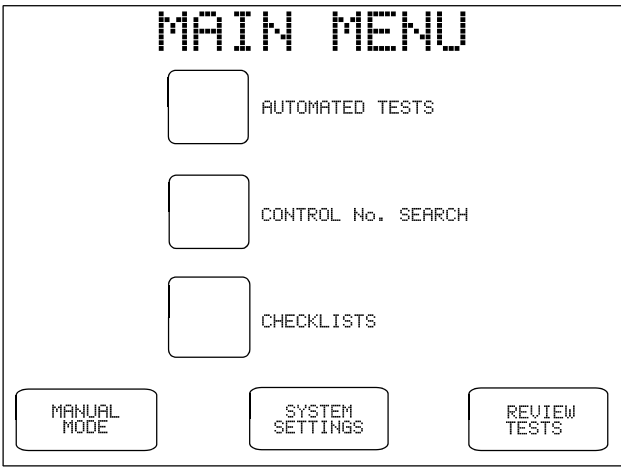

Figure 83 - *Main Menu of ES601-US.*   *Figure 84* - *Checklist menu.*

ES601-US is supplied with three factory default Checklists installed in memory. The DEMO CHECKLIST is an example which illustrates the use of various types of "***Checkitem***", the user and machine instructions which implement the individual steps of a Checklist. QUICK PM and STANDARD PM Checklists are two examples which implement the typical steps of a preventative maintenance inspection (a "PM"), integrated with a basic electrical safety test which measures power cord resistance and chassis leakages. These examples illustrate the basics of Checklist automation and provide a starting point for the development of additional Checklists to suit the specific equipment to be maintained.

As with all automated tests performed by ES601-US, selecting a Checklist from the menu will cause the EQUIPMENT INFO menu to be displayed. A Control Number and other equipment information may be

optionally entered at this point. Press the **RUN TEST** button to start the test. Prompts for equipment physical inspection may be displayed, according to System Settings. Refer to Section 6.1 *AutoSequence Overview* for further details.

If the Checklist includes Checkitems which transmit remote control commands via a TESTER PORT, after physical inspection prompts the user will be presented with a menu for setting RS232 serial communication options, similar to the menu of *Figure 75*. Although remote control operation of an external test instrument is possible with a Checklist, such interface is more typically accomplished with a Tester AutoSequence as described in Section 6.1.3. As it is possible to simply call a Tester AutoSequence from within a Checklist, it is normally unnecessary to place tester control commands in a Checklist, except in special circumstances. Note that the power is not automatically applied to the Test Receptacle when a Checklist is 'run'. This is to allow for tasks to be performed which should not be done with the power applied. Iif you wish to have power applied during Checklists, power must be applied or removed through the use of the TRPN or GTOL commands (see 6.1.5.7 The M Checkitem). Some entries in a Checklist, such as Electrical Safety or ECG Simulator, or a Tester Autosequence, will automatically apply power to perform the test.

Following optional prompts, execution of a Checklist begins with display of the first Checkitem of the list. A highlighted TASK provides a work instruction to the user. Depending on the type of Checkitem, various buttons may appear on the touchscreen. Most Checkitems provide list navigation buttons: **BACK** (go back one step in the Checklist); **SKIP** (skip this step and display the next step of the Checklist); and **ESCAPE** (abort work in progress and return to the MAIN MENU). The "*P*" (pass/fail) Checkitem is used frequently in Checklists and a typical example shown below. The various types of Checkitems and their associated functions are explained in the following section.
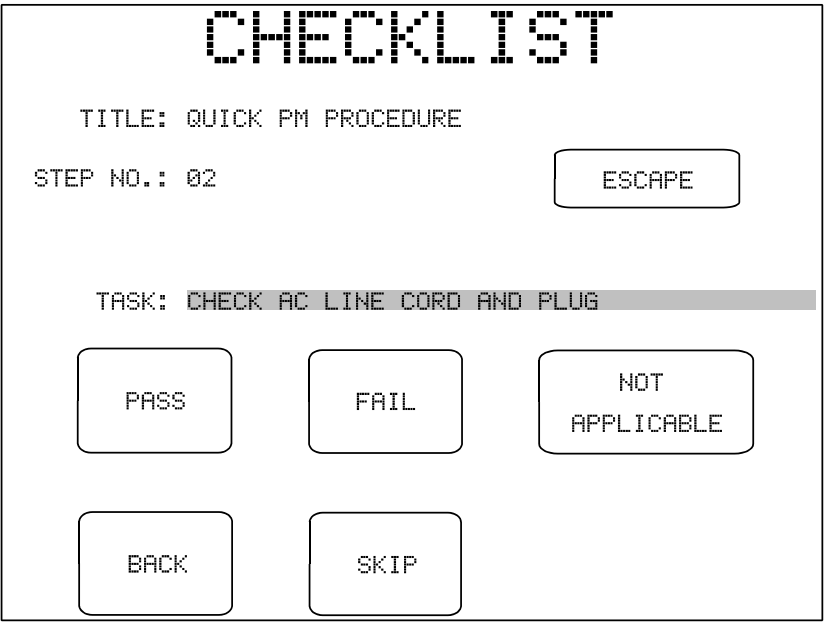
Figure 85: Example of a "P" (pass/fail) Checkitem.

6.1.5 Checkitems

As explained more fully in the preceding section, a Checklist is an automated sequence of work tasks, combining inspection, electrical safety testing, and performance testing activities into one comprehensive maintenance procedure. The steps of a Checklist are called Checkitems, and a Checklist may have from 1 to 96 such Checkitems[1].

In ES601-US, Checkitems are used for more than Checklists. Specific Checkitems which are capable of transmitting remote control commands via a TESTER PORT are also used for implementing User-Defined Tester AutoSequences, which were explained in Section 6.1.3. With ES601pc-US software, the user can create Checkitems to control an external test instrument, and then use these Checkitems to create a Tester AutoSequence that implements a device performance test. ES601pc-US software can also be used to create Checkitems for visual inspection, and then use these Checkitems to create a detailed Physical Inspection procedure that suits a particular device. With ES601pc-US software, the user can compose Checklists which consist of Checkitems alone, AutoSequences alone, Physical Inspections alone, or any combination of AutoSequences, Physical Inspections, and individual Checkitems together. ES601pc-US software provides a flexible system for efficient composition of automated maintenance procedures of varying complexity, but the underlying basis of all such automation is the Checkitem.

ES601-US Checkitems comprise a ***command*** and an ***op code.*** The op code defines what the Checkitem does and what buttons are shown on the touchscreen of ES601-US when the Checkitem is executed. Depending on the op code, the user may be required to enter a measurement value or a comment via the QWERTY touch keypad when that Checkitem is encountered in the sequence. Some Checkitem op codes cause the command to be transmitted to an external device via a TESTER PORT, as described in Section 6.1.3. Some Checkitems cause ES601-US to jump to execution of another automated procedure, for example an electrical safety test, an ECG test, an automated Physical Inspection, or a medical device performance test such as an Oxitest, Infutest or Phase 3 AutoSequence, or a User-Defined Tester AutoSequence.

The following sections explain the Checkitem capabilities of ES601-US, according to op code.

---

[1] If prompts for physical inspection are enabled under Systems Settings, then the maximum number of Checkitems in a Checklist is reduced by two Checkitems. Enabling the prompt for post-test comment reduces the maximum number of Checkitems by one, as does enabling the prompt for input of user time. If all of these prompts are enabled under Systems Settings, maximum Checklist length will then be reduced from 96 to 92 Checkitems. Refer to Section 3.2.

6.1.5.1 The P Checkitem

The operator interface for the **P** Checkitem is shown in **Figure 84**. The **command** of the P Checkitem is
displayed on the LCD as the "TASK", and may be up to 41 characters in length. Buttons provided on the
LCD allow the user to save a test result for the displayed TASK as "pass"; "fail"; "not applicable"; or "skip"
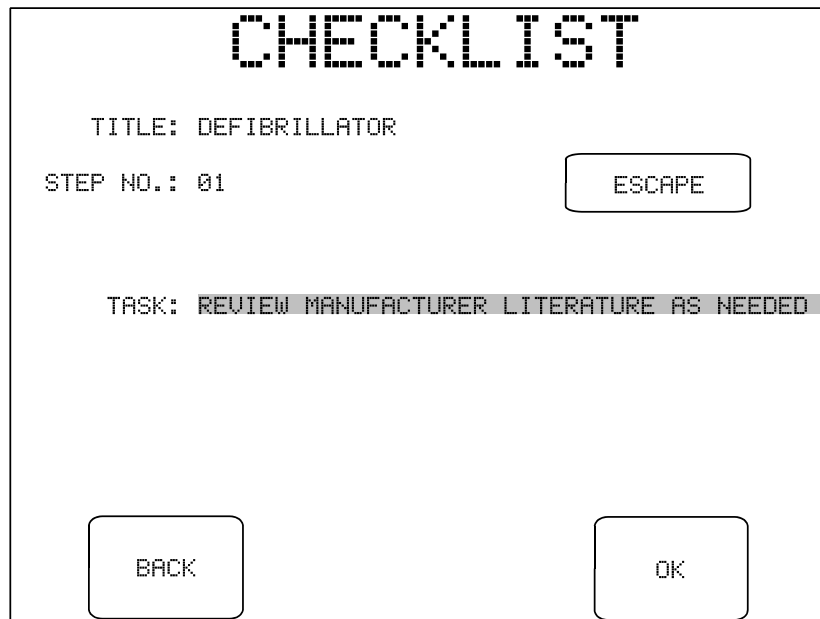(i.e. item was not inspected or tested).

Figure 86 - *Checklist in progress, P Checkitem.*

When any of the test result buttons (**PASS**, **FAIL**, **NOT APPLICABLE**) is pressed, ES601-US records
the button pressed as the inspection result, and automatically advances to the next step of the Checklist. A
BACK button on the LCD allows the user to move back to the previous step in the Checklist, and an
ESCAPE button allows the Checklist in progress to be aborted at the current step.

6.1.5.2 The K Checkitem

The user interface for the **K** Checkitem, which is intended for displaying comments, prompts or setup instructions, is shown in **Figure 85**.
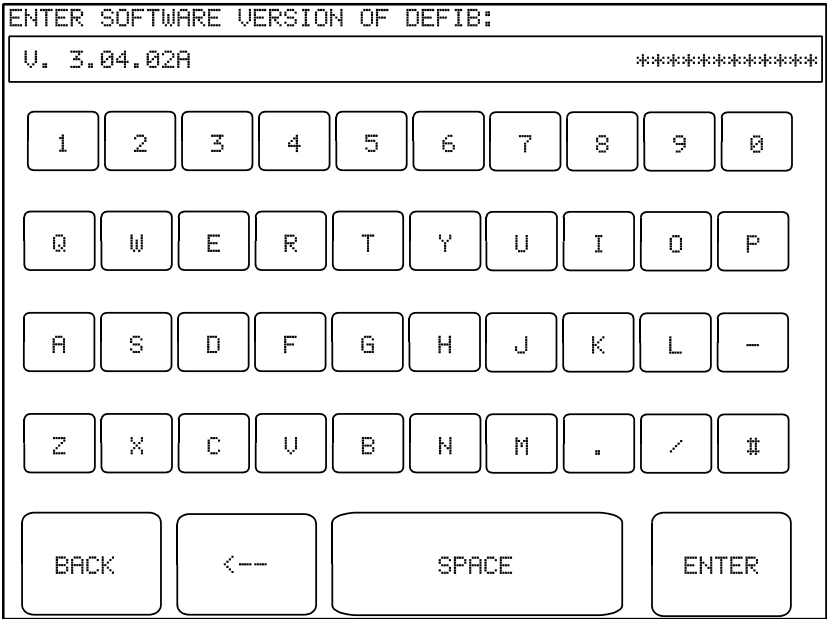

Figure 87 - *Checklist in progress, K Checkitem.*

The buttons provided for the K Checkitem are **ESCAPE** and **BACK**, plus an **OK** button. Pressing **OK** causes an "OK" to be saved as the test result for that step, recording the fact the user took the indicated action. The Checklist is then incremented to the next Checkitem.

6.1.5.3 The I Checkitem

The **I** Checkitem prompts the user to enter information or comments (**Figure 86**). The requested information can be entered by means of the QWERTY touch keypad displayed on the LCD, or by means of an external PS/2 keyboard connected to ES601-US. Up to 41 characters can be entered, which are saved as the test data for that step. The command of the I Checkitem is displayed on the top line of the LCD, providing a prompt to the user.

```
ENTER SOFTWARE VERSION OF DEFIB:
 V. 3.04.02A                         ************

    1    2    3    4    5    6    7    8    9    0

    Q    W    E    R    T    Y    U    I    O    P

    A    S    D    F    G    H    J    K    L    -

    Z    X    C    V    B    N    M    .    /    #

    BACK    <--          SPACE          ENTER
```

Figure 88 - Checklist in progress, I Checkitem.

6.1.5.4 The E Checkitem

The buttons on the operator interface of the **E** Checkitem (**Figure 87, Figure 89**) allow a user to optionally "**PASS**" or "**FAIL**" the displayed TASK, or alternatively enter more explicit data rather than simple a "pass" or "fail" result. If entering data via QWERTY touchscreen or external keyboard/barcode scanner, ES601-US will interpret a "**#**" in the data entry as a "FAIL" mark.

Figure 89 - *Checklist in progress, E Checkitem.*

SKIP, **BACK** and **ESCAPE** buttons provide the functions described for the P Checkitem. Note that the E Checkitem does not force the user to enter any test data; if no data is entered, the test data field will appear blank when results of the Checklist are reviewed.
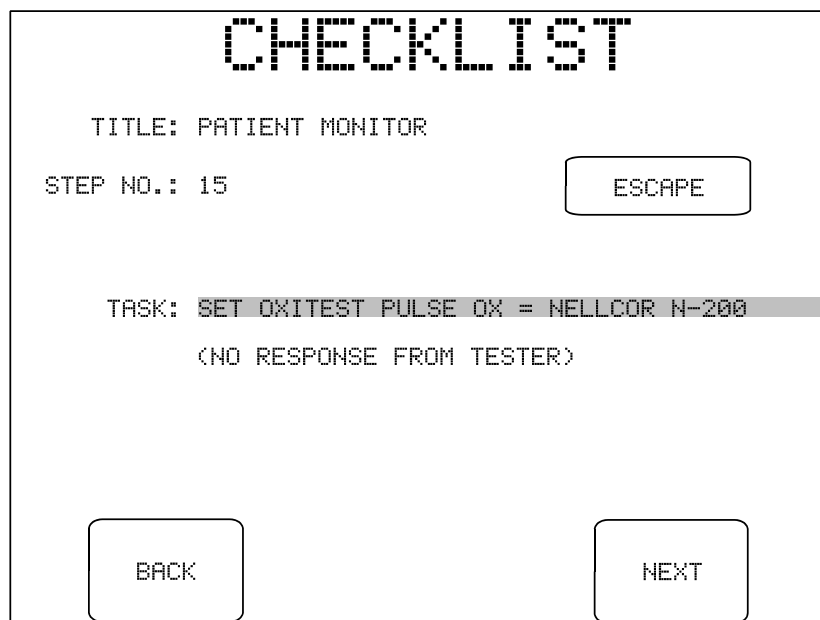
6.1.5.5 The C Checkitem

The *C* Checkitem will cause ES601-US to transmit a remote control command to an external device, such as a medical device analyzer or "tester", which ES601-US expects to be connected to the RS232 Tester Port (#1 through #6) specified in the AutoSequence or Checklist setup.

The C Checkitem combines a command (data which will be transmitted to the external Tester), together with a user prompt. The prompt is optional information which may be entered via the Checkitem Editor of the AutoSequence or Checklist plug-in, to help you remember what the command does when you are creating Tester AutoSequences and Checklists.

When ES601-US executes a C Checkitem, it will transmit the command via the Tester Port specified in the AutoSequence or Checklist, and will wait for a response from the Tester. If a response is received, ES601-US will record "OK" as the test result for that step and will automatically continue with the next step with no intervention from the user. If a response is not received from the Tester after a 0.25 second timeout, ES601-US will display the Checkitem's prompt on the LCD and will wait for the user to press one of the touch screen keys provided, as shown in *Figure 88*.

Figure 90 - *Checklist in progress, C Checkitem.*

6.1.5.6 The R Checkitem

The *R* Checkitem combines features of the C Checkitem (remote control) and the E Checkitem (data entry). The user interface for the R Checkitem is the same as that for the E Checkitem. The R Checkitem can be useful with patient simulators (e.g. ECG, SpO2, or NIBP) which do not, by themselves, generate measurement data.

When ES601-US executes the R Checkitem, it will transmit the command portion of the Checkitem via the Tester Port specified in the AutoSequence. The prompt portion of the Checkitem will be displayed on the LCD as the "TASK". The ENTER TEST DATA button on the LCD allows the user to record measurement data or observations via the QWERTY touch keypad, or by means of a PS/2 keyboard connected to ES601-US.

6.1.5.7 The M Checkitem

The Multi-Function or *M* Checkitem can:

- switch the test receptacle of ES601-US on or off;

- cause the ES601-US ECG simulator to output a selected waveform; or

- send a command to an external medical device analyzer or "tester", causing the tester to return a measurement value or a test result, which will then be displayed on the LCD of ES601-US.

Test receptacle and ECG simulator control are achieved through use of the following predefined commands with the M op code:

Command	Description
TRPN	Switch the test receptacle ON with normal polarity
GTOL	Reset command: switch the test receptacle OFF; if the ECG simulator is outputting a waveform, shut down the ECG simulator
W001	Enable output of ECG performance wave: 2 HZ SQR
W002	Enable output of ECG performance wave: 4 SEC PUL
W003	Enable output of ECG performance wave: 10 HZ SINE
W004	Enable output of ECG performance wave: 40 HZ SINE
W005	Enable output of ECG performance wave: 60 HZ SINE
W006	Enable output of ECG performance wave: 100 HZ SINE
W007	Enable output of ECG arrhythmia: ASYS
W008	Enable output of ECG performance wave: 2 HZ TRI
W009	Enable output of ECG performance wave: 60 HZ CMMR
W010	Enable output of ECG sinus rhythm: 30 BPM
W011	Enable output of ECG sinus rhythm: 60 BPM
W012	Enable output of ECG sinus rhythm: 120 BPM
W013	Enable output of ECG sinus rhythm: 240 BPM
W014	Enable output of ECG performance wave: 0.5 HZ
W015	Enable output of ECG arrhythmia: AFIB
W016	Enable output of ECG arrhythmia: 2nd degree A-V block
W017	Enable output of ECG arrhythmia: PAC

Command	Description
W018	Enable output of ECG arrhythmia: missed beat @ 80 BPM
W019	Enable output of ECG arrhythmia: missed beat @ 120 BPM
W020	Enable output of ECG arrhythmia: PVC
W021	Enable output of ECG arrhythmia: SVTACH
W022	Enable output of ECG arrhythmia: multi-focal PVC
W023	Enable output of ECG arrhythmia: R-on-T PVC
W024	Enable output of ECG arrhythmia: Bigeminy
W025	Enable output of ECG arrhythmia: Run-5 PVC
W026	Enable output of ECG arrhythmia: polymorphic VTACH @140BPM
W027	Enable output of ECG arrhythmia: RBBB
W028	Enable output of ECG arrhythmia: monomorph. VTACH @160BPM
W029	Enable output of ECG arrhythmia: VFIB
W030	Enable output of ECG arrhythmia: Asystole

Optionally, a predefined "M-command" may be followed by a whitespace character and a comment. The M-command with optional comment are displayed on the LCD for two seconds when the Checkitem is executed, as shown in the example below for the TRPN command.
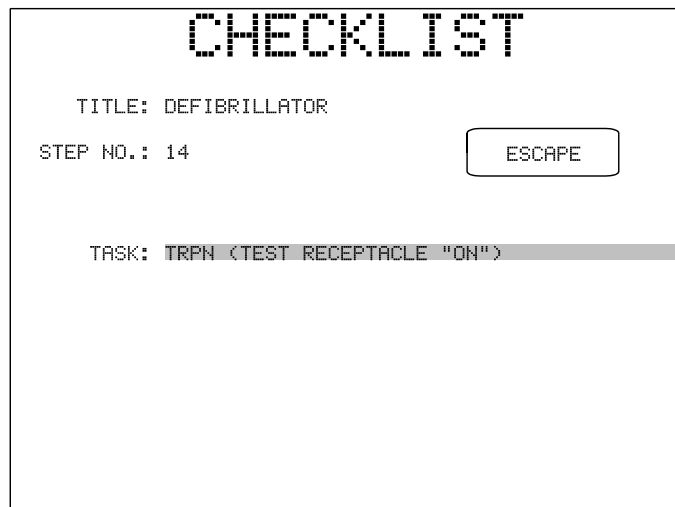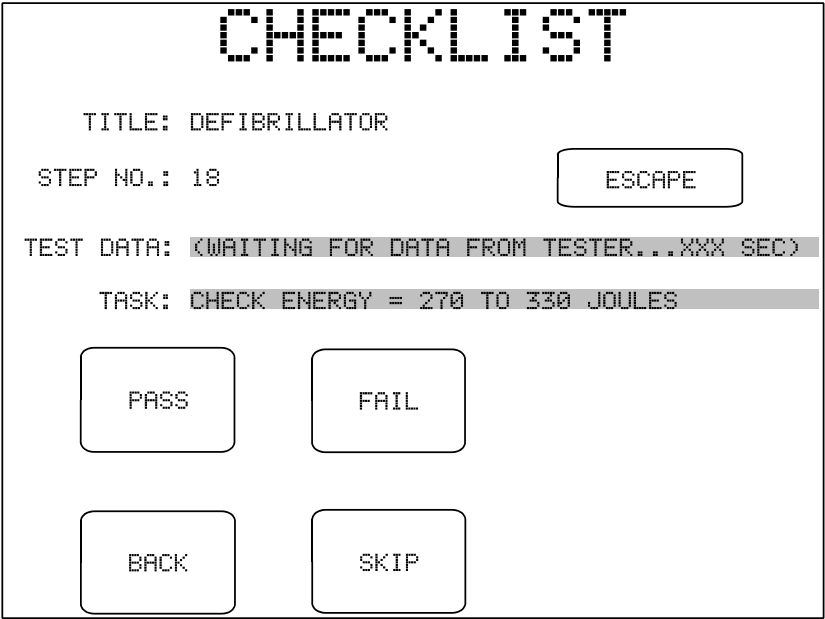

Figure 91 - *Checklist in progress, M (TRPN) Checkitem.*

If the command of the M Checkitem is not one of the predefined commands in the table above, ES601-US will then transmit the command via the RS232 Tester Port specified in the AutoSequence setup. The prompt portion of the Checkitem will then be displayed on the LCD as the "TASK". However, if the first character of the Checkitem command is a whitespace or a <TAB> character, ES601-US does not transmit anything and will immediately display the user interface of **Figure 90**.

```
              CHECKLIST

       TITLE: DEFIBRILLATOR

     STEP NO.: 18                  ┌──────────┐
                                   │  ESCAPE  │
                                   └──────────┘
  TEST DATA: (WAITING FOR DATA FROM TESTER...XXX SEC)

       TASK: CHECK ENERGY = 270 TO 330 JOULES

     ┌──────────┐        ┌──────────┐
     │          │        │          │
     │   PASS   │        │   FAIL   │
     │          │        │          │
     └──────────┘        └──────────┘

     ┌──────────┐        ┌──────────┐
     │          │        │          │
     │   BACK   │        │   SKIP   │
     │          │        │          │
     └──────────┘        └──────────┘
```

Figure 92 - *Checklist in progress, M (Tester) Checkitem.*

In the event that data is not immediately received from the tester in response to the command, a count-up timer is displayed on the "TEST DATA" line, as shown above. Once test data is received, the timer is removed from the LCD, replaced by the received data. While waiting for data, or after data is received, **PASS**, **FAIL**, **BACK** and **SKIP** buttons are active and take their usual functions (see P Checkitem).

6.1.5.8 The D Checkitem

The D Checkitem can be used to provide timed delays in Tester AutoSequences and Checklists (**Figure 91**). The delay of the Checkitem may range from 1 to 32000 seconds. The Checkitem also provides a prompt which is displayed on the LCD as the "TASK" while the timer counts down.
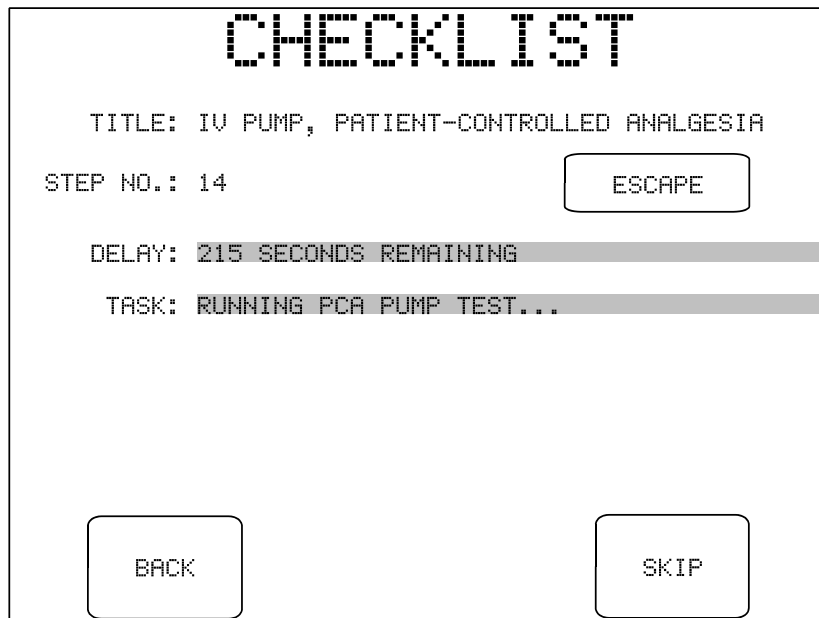
Figure 93 - *Checklist in progress, D Checkitem.*

ES601-US will automatically advance to the next step of the Checklist when the timer reaches zero count. In this case, an "OK" is saved as the test result for the delay Checkitem. Alternatively, the user may press **SKIP** to bypass any remaining delay. The **BACK** button also cancels the delay and causes ES601-US to go back to the previous Checkitem.

6.1.5.9 The A Checkitem

The **A** Checkitem is utilized **only in _Checklists_** and allows ES601-US to invoke a Safety AutoSequence, a ECG AutoSequence, Tester AutoSequences, or Physical Inspections from within the Checklist. Tester AutoSequences and Physical Inspections **_cannot_** include an A Checkitem.

In a Checklist, any one of the Checkitems can optionally be a Safety AutoSequence, and any one of the Checkitems can optionally be a ECG AutoSequence. A Checklist cannot have more than one A Checkitem that invokes a Safety AutoSequence, or more than one A Checkitem that invokes a ECG AutoSequence.

A Checklist can optionally have **one or more** A Checkitems that invoke Tester AutoSequences and/or Physical Inspections. The total number of Checkitems resulting from the inclusion of such Physical Inspections and/or Tester AutoSequences in a Checklist, via corresponding A Checkitems, cannot exceed a maximum of **96 steps**.

Practically speaking, since Physical Inspections and other Tester AutoSequences may have up to 24 Checkitems each, a Checklist will be able to optionally incorporate, at most, 3 to 4 Physical Inspections and/or Tester AutoSequences within it.

The **command** portion of the A Checkitem encodes the AutoSequence that will be run from within the Checklist. The **prefix** of the command comprises three alphabetic characters that define the type of AutoSequence, followed by two numeric digits "**NN**" that specify the number of the AutoSequence, according to **Figure 92**, **Figure 122**.

Command prefix	Type of AutoSequence	"NN"
SAF	Safety AutoSequence	01 to 24
ECG	ECG AutoSequence	01 to 12
POX	Oxitest +7 AutoSeqeunce	01 to 12
IVP	Infutest Autosequence	01 to 12
DFB	Phase 3 AutoSequence	01 to 24
UT1	User-Defined Tester #1	01 to 12
UT2	User-Defined Tester #2	01 to 12
UT3	User-Defined Tester #3	01 to 12
UT4	User-Defined Tester #4	01 to 12
UT5	User-Defined Tester #5	01 to 12
GEN	Physical Inspection	01 to 18

Figure 94

For example, and according to **Figure 92**, **Figure 122**, if a Checklist includes an A Checkitem having the command "SAF01", this will cause ES601-US to execute Safety AutoSequence #01 from the SAFETY AUTOSEQUENCE menu, which was described earlier in this chapter. If a Checklist includes an A Checkitem having the command "ECG03", this will cause ES601-US to execute ECG AutoSequence #03 from the ECG AUTOSEQUENCE menu. If a Checklist includes an A Checkitem having the command "UT408", this will cause ES601-US to execute AutoSequence #08 for User-Defined Tester #4, from the USER TESTER AUTOS menu.

When an A Checkitem is executed, the type of AutoSequence is displayed on the LCD as the "TASK", the title and number of the AutoSeqeuence are also shown. A **SKIP** button allows the AutoSequence to be bypassed. Pressing the **CONTINUE** button runs the displayed AutoSequence. **BACK** and **ESCAPE** keys provide the same functions described previously for other Checkitems.

CHECKLIST

```
    TITLE: DEFIBRILLATOR

STEP NO.: 38                    ┌──────────────┐
                                │    ESCAPE    │
                                └──────────────┘


     TASK: EXECUTE SAFETY AUTOSEQUENCE

      NO.: 04

    TITLE: A4,A9: CASE X,I
           CASE LKG (CRITICAL)


  ┌──────────┐   ┌──────────┐   ┌──────────┐
  │   BACK   │   │   SKIP   │   │ CONTINUE │
  └──────────┘   └──────────┘   └──────────┘
```

Figure 95 - *Checklist in progress, A Checkitem.*

6.1.5.10 Checkitem Summary

| Op Code	Checkitem Type	Buttons shown on LCD
A	Run AutoSequence	ESCAPE; BACK; SKIP; CONTINUE
C	Tester Remote Control	If no tester response: ESCAPE; BACK; NEXT
D	Timed Delay, in seconds	ESCAPE; BACK; SKIP
E	Data Entry with Pass/Fail	ESCAPE; PASS; FAIL; NOT APPLICABLE; BACK; SKIP; ENTER TEST DATA
I	Input Requested	QWERTY touch keypad
K	OK Prompt	ESCAPE; BACK; OK
M	Multi-function	If tester control command: ESCAPE; PASS; FAIL; BACK; SKIP
P	Pass/Fail	ESCAPE; PASS; FAIL; BACK; SKIP; FAULT CORRECTED
R	Tester Remote Control with User Data Entry	ESCAPE; PASS; FAIL; NOT APPLICABLE; BACK; SKIP; ENTER TEST DATA

6.1.6 Physical Inspections

A Physical Inspection is a type of Checklist which is intended for the specific purpose of performing a visual inspection procedure. ES601-US provides 18 Physical Inspections, each Inspection being targeted at a general class of equipment, for example, equipment which can be powered from the AC supply, and which is thus expected to have a power cord and internal fuses, each of which will require checking as part of a PM.

Physical Inspections can be user-programmed and uploaded to the ES601-US, using the Inspections and User Tester module of ES601pc-US software. Due to user-programmability, Physical Inspections can be made as specific and detailed as required to suit the equipment being inspected, thus improving on the two generic prompts for physical inspection which may appear at the start of any automated test, and which can be globally enabled or disabled under the System Settings as explained in Section 3.2.

Like Checklists, Physical Inspections are comprised of Checkitems. Physical Inspections differ from Checklists in that Inspections are shorter, providing a maximum of 24 Checkitems per Inspection. Unlike a Checklist, a Physical Inspection cannot invoke another automated test such as a Safety AutoSequence. However, Checklists can invoke one or more Physical Inspections along with other Checkitems and automated tests.

An advantage of Physical Inspections is the simplified menu display used for accessing them. Physical Inspections are easily browsed and selected since a specific button is provided for each Inspection, similar to a Tester AutoSequence. This makes selecting a Physical Inspection somewhat easier and faster than browsing the list of 500 Checklists to find the desired test. To select a Physical Inspection, enter the AUTOMATED TESTS menu from the MAIN MENU, and press **PHYSICAL INSPECTIONS**. The factory default menu is shown below.
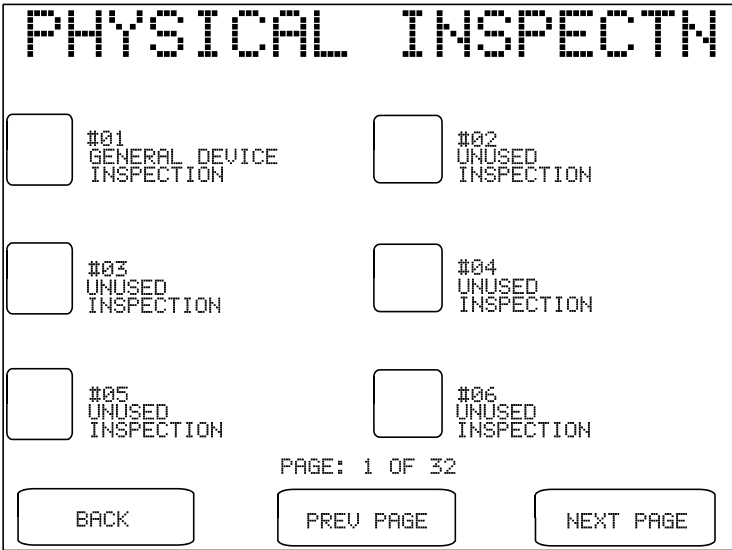
Figure 96 - *Physical Inspections menu.*

Per the above, ES601-US is provided with one Physical Inspection installed in memory, which is intended to provide an example for users to develop their own Inspection procedures. For reference, the Checkitems which comprise this default Inspection are tabulated below.

| Step	Category	Op Code	Command
1.	General	P - Pass/Fail	CHECK FOR SIGNS OF PHYSICAL DAMAGE/ABUSE
2.	General	P - Pass/Fail	CHECK FOR SECURE MOUNTING
3.	General	P - Pass/Fail	CHECK AC LINE CORD AND PLUG
4.	General	P - Pass/Fail	CHECK FUSES MATCH LABELLING
5.	General	P - Pass/Fail	CHECK CABLES AND STRAIN RELIEFS
6.	Receptacle	M - Multi-Func	TRPN (TEST RECEPTACLE "ON")
7.	General	P - Pass/Fail	POWER UP AND CHECK POWER-ON SEQUENCE
8.	General	P - Pass/Fail	RUN SELF-TEST, IF EQUIPPED
9.	General	P - Pass/Fail	CHECK CONTROLS AND SWITCHES
10.	General	P - Pass/Fail	CHECK INDICATORS AND DISPLAYS
11.	General	P - Pass/Fail	CHECK AUDIO ALARMS AND SIGNALS
12.	General	P - Pass/Fail	CHECK BATTERY CHARGER, IF EQUIPPED
13.	General	P - Pass/Fail	CHECK BATTERY AND REPLACE IF NECESSARY
14.	General	P - Pass/Fail	PERFORM MANUFACTURER'S PM CHECKLIST
15.	General	M - Multi-Func	GTOL (TEST RECEPTACLE "OFF")
16.	General	P - Pass/Fail	CLEAN INTERIOR/EXTERIOR AS REQUIRED
17.	General	K - OK Prompt	RETURN CONTROLS TO ORIGINAL SETTINGS
18.	General	K - OK Prompt	END OF TEST SEQUENCE

6.2 Equipment Records

ES601-US can store up to 18,432 Equipment Records, these Records containing the Control Number of a medical device and a reference to an ES601-US Checklist (ranging from 1 to 500).

Equipment Records are created, edited and managed through the Equipment Record module of the ES601pc-US software package. The Equipment Record module can optionally import control numbers and other equipment data from an existing CMMS application, to facilitate the user's assignment of ES601-US Checklists to equipment control numbers from the equipment management system.

6.2.1 Control Number Search

The Equipment Record capability of ES601-US provides for easy test initiation by entering the equipment control number using the **CONTROL No. SEARCH** button on the MAIN MENU.
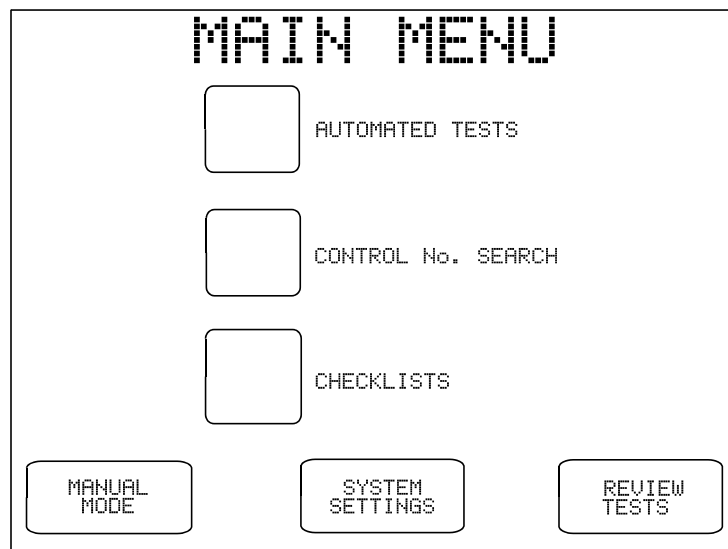
Figure 97 - *Main Menu of ES601-US.*

Pressing the **CONTROL No. SEARCH** button displays the QWERTY keypad, through which a control number belonging to an Equipment Record can then be entered. When displaying the prompt for a control number, ES601-US will also accept data via RS-232 Barcode Reader, PS/2 keyboard or PS/2 Barcode Reader.

Control number data will also be immediately accepted from a Barcode Reader or PS/2 keyboard while ES601-US is at the MAIN MENU. Simply scan an equipment barcode to immediately launch an associated Checklist procedure stored in the ES601-US.

6.2.2 Test Startup

If an entered control number is recognized by ES601-US, the EQUIPMENT INFO menu will be displayed. The EQUIPMENT INFO menu allows input of additional equipment information as previously described in Chapter 5. The EQUIPMENT INFO menu will also display the title of the associated Checklist.


Figure 98 - *Device Info menu, following entry of valid Device ID.*

Pressing the **RUN TEST** button on the menu will initiate the associated Checklist. Prompts for equipment physical inspection may be displayed, according to System Settings. Refer to Section 6.1 *AutoSequence Overview* for further details. When the test is completed, the SAVE TEST RECORD menu will be displayed.

6.2.3 Equipment Records by Checklist

Device information on the EQUIPMENT INFO menu can be modified at Checklist startup, or immediately before a Record of a test is saved. This capability suggests an alternative or additional application of the Equipment Record feature: the "control number" field of the Equipment Record can alternatively be set to the *title* of a Checklist, using the Equipment Record module of ES601pc-US software. After uploading such Equipment Records to ES601-US, on scanning a barcode of a Checklist title, or entering a title via QWERTY touchscreen or PS/2 keyboard, the Checklist can be immediately recalled at the MAIN MENU, without having to browse through the Checklist directory. At Checklist startup or once the test is complete and prior to saving, the user may modify the control number field on the EQUIPMENT INFO menu, replacing the Checklist name with the actual control number of the equipment tested.

Chapter

7
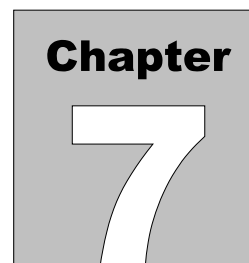
7   Computer Control

7.1 Overview of Computer Control

ES601-US provides a communications interface that allows personal computer (PC) software to control the safety analyzer and acquire measurement data in realtime as safety tests are being performed. Although a terminal emulation program such as Windows *HyperTerminal* may be used to operate ES601-US in this manner, computer control is more suited to users who intend to develop their own PC software to satisfy particular testing or documentation requirements. Alternatively, users may prefer existing third-party software that provides means for instrument control and data acquisition through simple user-written scripts (e.g. MEBEDO *fundamed*).

When testing leakage, ES601-US saves results in the Test Record for all normal and single fault conditions enabled by the user in the test setup. However, if the user has enabled supplementary test conditions ("DUT-OFF" tests; isolated data I/O tests; ungrounded metal part tests), then ES601-US records only the maximum leakage result observed under the supplementary conditions. ES601-US computer control allows user-supplied software to acquire leakage data from every measurement performed, whether the test condition is normal, single-fault, or supplementary.

For computer control, ES601-US is connected to a serial COM Port on the PC. For PC's without a COM Port, any third-party USB-to-RS232 converter cable can be used, which will allow the user's software to communicate with ES601-US via a *Virtual COM Port* (a Virtual COM Port or "VCP" is driver software which is supplied with the USB converter cable, or which may exist as part of the PC operating system).

In general principle, the user's PC software begins by opening a COM Port (physical, or VCP for USB connections). The software transmits a command via the COM Port to ES601-US which selects and starts a Safety AutoSequence. As each step of the sequence is completed, ES601-US transmits measurement results to the PC as a string of formatted ASCII text containing data fields delimited by the comma character (CSV data format). Upon conclusion of the sequence, ES601-US sends an "END" message to the PC. Optionally, the user's software may then issue another command to cause ES601-US to return a formatted Test Report document containing the measurements recorded by ES601-US during the test. The format of this document is the same as that obtained when printing a previously-saved Test Record to either the

Centronics or RS232 port of ES601-US (see Section 4).

7.2 Connections

For computer control, connect the PC to the RS232 serial port of ES601-US. The RS232 connector of ES601-US is DB9 female, which is compatible with USB-to-Serial converter cables. For connection to a physical COM Port at the PC, use a standard DB9F-DB9M serial cable. Do not use a NULL-modem cable for this connection. A suitable serial cable is available from Datrend Systems as Part Number 3140-010.

7.3 Communication Settings

To prepare ES601-US for computer control, from MANUAL or AUTO MODE menu select SYSTEM SETTINGS ➤ COMPUTER INTERFACE ➤ RS232 MODE.

At the PC, the required COM Port or VCP settings are:

19200 baud, No parity, 8 data bits, 1 stop bit (19200,N,8,1)

Note that for computer control, the baud rate (19200) is <u>not</u> the same as that used for printing Test Record reports via the ES601-US serial port.

No handshaking is required and should be disabled in the PC COM setup.

7.4 Protocol

7.4.1 General Format of Data

Commands and data are conveyed as strings of ASCII text. The carriage return character (**\r**, or 0x0D in hexadecimal) terminates PC commands and measurement data returned by ES601-US. Upon conclusion of the safety test sequence, the last character sent by ES601-US is form feed (**\f**, or 0x0C), which terminates the "END" message. ES601-US also sends a form feed **\f** as the last character of a Test Report download. Optionally, user software may detect form feed **\f** as an event marker in the ES601-US data stream.

7.4.2 Safety Test Execution

Under computer control, a Safety AutoSequence is initiated by means of this exchange:

a. PC software transmits

RSAF\r

to ES601-US via the serial connection.

b. ES601-US responds by returning

*\r

(0x2A 0x0D) to the PC. If the **RSAF\r** command is received by ES601-US without errors, the ***\r** response should be returned to the PC within 0.2 seconds.

c. PC software sends one ASCII character to ES601-US to specify the AutoSequence. Send:

a (0x61) to select AutoSequence #1; or
b (0x62) to select AutoSequence #2; or
c (0x63) to select AutoSequence #3;
...

and so on up to **x** (0x78) to select AutoSequence #24. PC software must send this character within two seconds of the ***\r** response from ES601-US, otherwise ES601-US will time out and abort the protocol. If ES601-US receives a character other than **a** to **x**, ES601-US returns **?\r** to the PC and aborts the protocol.

As an alternative to sending a lower-case letter, PC software can alternatively send an upper case letter: **A** (0x41) specifies AutoSequence #1, **B** (0x42) specifies AutoSequence #2, and so on up to **X** (0x58) which specifies AutoSequence #24. The difference is that sending lower-case causes ES601-US to execute a complete AutoSequence as if the test had been selected from the SAFETY AUTOSEQUENCE menu, beginning with CONNECTION Checkitems, patient leadS setup, and SEQUENCE control menus. Alternatively, for upper-case letters, these initial information and setup menus are bypassed and execution of the test begins immediately with the first measurement.

d. In response to the sequence character from the PC, ES601-US initiates the test and within one second or less returns a message specifying the safety standard of the selected sequence, for example:

> **STD, IEC60601\r**

    e.   After this step, the user may operate ES601-US via the touch screen in the conventional manner, responding to prompts displayed by ES601-US as described in Chapter 5. As each measurement of the sequence is completed, ES601-US transmits the measurement data to the PC as either one or two lines of CSV text, each line being terminated by carriage return **\r**. Refer to Section 7.4.4 following for description of the measurement data format.

    f.   Upon conclusion of the sequence, ES601-US sends:

> **END\r\f**

    to the PC. PC software may detect this message, or simply the form feed **\f**, to identify end-of-protocol.

    g.   Optionally, the user may choose to abort the sequence in progress by pressing the **ESCAPE** key which appears on the ES601-US touch screen. In this event, the protocol is terminated and ES601-US sends:

> **ESC\r\f**

    to the PC.

7.4.3 Test Report Download

Upon conclusion of the test protocol described in the preceding section, user software may optionally send a "report download" command:

> **SREP\r**

In response to this command, ES601-US will internally generate and then transmit a complete Test Report document as ASCII text to the PC. The format of this report is highly dependent on the safety standard, but will be the same as the document that could otherwise be obtained by printing a Test Record saved earlier for a similar type of safety test.

The last character sent in the report download is form feed **\f** (0x0C). Optionally, user software may detect this form feed as an end-of-transmission marker. Alternatively, user software can employ a timeout mechanism to determine the point at which ES601-US stops sending characters.

7.4.4 Format of Measurement Data

Once initiated by computer control as previously described, ES601-US will transmit one or two lines of ASCII text for each measurement completed during the test sequence. Two lines of data are sent for leakage measurements (AC result, followed by DC result); for all other measurements ES601-US sends one line of data. Each line of data is terminated with a carriage return **\r** (0x0D). Measurement data is separated into fields by the comma character **,** (0x2C). This type of format is referred to as "comma-separated variables" (CSV) and files containing such data are directly compatible with Microsoft® Excel.

The first field of the CSV data is a 3-character mnemonic which specifies the type of measurement performed. Depending on the type of measurement, the acceptance limit specified in the standard may be included in the data, and if so, the last field before the terminating carriage return **\r** will be either a **P** (pass) or **F** (fail) character as appropriate.

For each measurement performed by ES601-US, the format of the return data is listed in the following table.

Safety standard	`STD,[standard]\r`
Line voltages	`ACV,<V`$_{L1-L2}$`>,<V`$_{L1-GND}$`>,<V`$_{L2-GND}$`>,Vrms\r`
Equipment load current	`CUR,<current>,Arms\r`
Insulation, L1+L2 to ground	`ILG,<value>,<limit>,Megohm,[-|P|F]\r`
Insulation, AP to ground	`IAP,<value>,<limit>,Megohm,[-|P|F]\r`
Ground	`PRE,[ 1A|25A],[LC|PP],<value>,<limit>,ohm,[P|F]\r`
Leakage, Encl., IEC60601/AAMI	`LEN,O??/?P/L2?/E?/AP?/X1?/X2?,<value>,<limit>,[uArms|uAdc],[P/F]\r`
Leakage, Earth, IEC60601/AAMI	`LEA,O??/?P/L2?/E?/AP?/X1?/X2?,<value>,<limit>,[uArms|uAdc],[P/F]\r`
Leakage, Patient, IEC60601/AAMI	`LPA,O??/?P/L2?/E?/AP?/X1?/X2?,GPx,APyy,<value>,<limit>,[uArms|uAdc],[P|F]\r`
Leakage, Auxiliary, IEC60601	`LAX,O??/?P/L2?/E?,APyy,<value>,<limit>,[uArms|uAdc],[P|F]\r`
Leakage, Interlead, AAMI	`LLD,O??/?P/L2?/E?,APyy,<value>,<limit>,[uArms|uAdc],[P|F]\r`

Leakage, Device VDE/IEC62353 (direct method)	`LDV,ON/?P/L2N/EO,<value>,<limit>,[uArms	uAdc],[P	F]\r`
Leakage, Device VDE/IEC62353 (alternate method)	`LDV,ALTERNATE METHOD,<value>,<limit>,[uArms	uAdc],[P	F]\r`
Leakage, Patient VDE/IEC62353 (direct method)	`LPA,ON/?P/L2N/EN/AP?,GPx,APyy,<value>,<limit>,[uArms	uAdc],[P	F]\r`
Leakage, Patient VDE/IEC62353 (alternate method)	`LPA,ALTERNATE METHOD,GPx,APyy,<value>,<limit>,[uArms	uAdc],[P	F]\r`
Leakage, Encl., IEC61010	`LEN,ON/?P/L2?/E?,<value>,<limit>,[uArms	uAdc],[P	F]\r`
Leakage, pt-to-pt, IEC61010	`LPP,ON/?P/L2?/E?,<value>,<limit>,[uArms	uAdc],[P	F]\r`
Test completed	`END\r\f`
Test aborted	`ESC\r\f`

In the table above, numeric data fields are identified by angled brackets: **<   >**. Text fields are indicated by square braces: **[   ]**. For predefined text fields having two possible options for the character string, both options are shown and are separated by pipe: **|** .

For leakage measurements, a special data field specifying the leakage test conditions immediately follows the 3-character prefix; the individual conditions are separated by the slash character **/**, and the variable characters for a given condition are represented by: **?**. The mnemonics of this field are interpreted as follows:

Mnemonic	Pertinent Test Condition	Possible options
O??	DUT power switch	"ON " or "OFF"
?P	Supply polarity	"NP" (normal) or "RP" (reversed)
L2?	Supply line 2	"L2N" (normal) or "L2O" (single-fault condition)
E?	Ground	"EN" (normal) or "EO" (single-fault condition)
AP?	patient lead(s)	"AP-" (disconnected); "APE" (to earth, normal condition); or "APM" (to mains, single-fault condition)
X1?	Mains on isolated data I/O	"---" (mains not connected to isolated I/O) or "X1M" (mains on I/O, single-fault condition)
X2?	Floating metal to earth	"---" (floating metal not earthed) or "X2E" (floating metal earthed)
GPx	patient lead Group 'x'	'x' = 1, 2, 3, 4 or 5
APyy	patient lead 'yy'	'yy' = 01, 02, 03... 10

Chapter

8

8   ES601pc-US Software

Datrend Systems ES601pc-US software provides a communication utility for ES601-US and allows the user to configure Safety AutoSequences, electrocardiogram (ECG) AutoSequences, Tester AutoSequences, Physical Inspections, and Checklists of ES601-US Safety Analyzer.
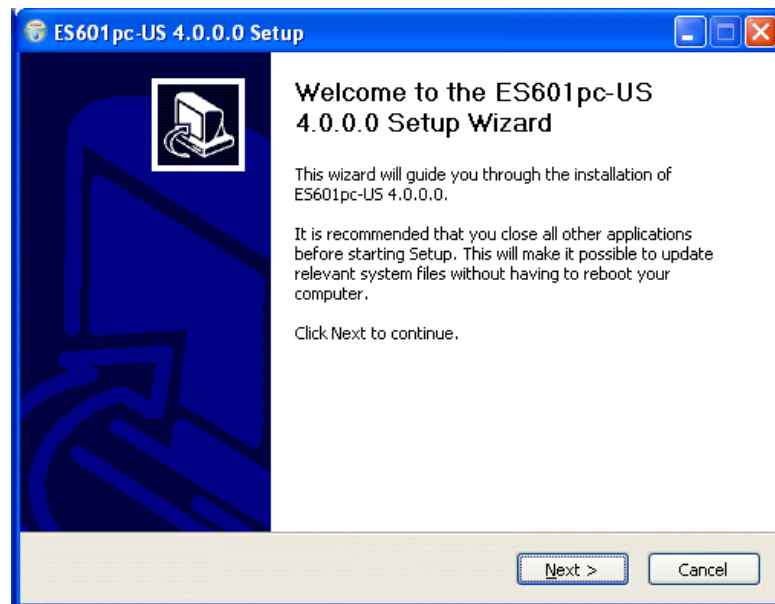
8.1 Installation

To install ES601pc-US to your computer, place the ES601-US Product CD into your computer's CDROM drive and close the drive. The CD menu application will begin automatically unless your computer is set to ignore autorun applications.

In the event the CD menu does not start automatically, use the file explorer utility on your computer to locate the CDROM drive. Browse this drive to locate the file called **autorun.exe**. Double-click or otherwise execute this file to open the CD menu.

Figure 100 - *CD menu for ES601-US.*

Click the "Install Software" button on the menu to install ES601pc-US software. The installer application will then guide you through the installation process. We recommend all default installation locations be left intact so future upgrades and enhancements will run smoothly.

Figure 101 *- ES601pc-US installer.*

8.2 Installing USB Drivers

When installation is complete, connect ES601-US to your PC using the USB cable provided. When ES601-US is connected to the PC for the first time, Windows® should detect the connection and automatically launch the New Hardware Wizard which will prompt you for the USB driver.

Figure 102 - *New Hardware*

The USB drivers for ES601-US are provided on the ES601-US Product CD. When the Hardware Wizard asks for the files, direct the Hardware Wizard to your CD drive. There are two folders on the CD. One folder contains USB drivers for Windows® 7 x64 systems. The other folder contains drivers for all other systems. Direct the Wizard to the appropriate folder for your Windows system, and the driver files should then be installed.

During installation the dialog box shown in **Figure 101** may appear. If it does, select "Continue Anyway" and the USB driver will be installed (**Figure 102**).

Figure 103 - *Driver*

Figure 104 - *Driver Installation*

NOTE:

During installation of the USB drivers, Windows XP users may receive a warning message that the driver has not been "Logo Tested". Please ignore this warning and clear the message by clicking the "Continue Anyway" button.

8.3 Running ES601pc-US

Find the "ES601pc-US" icon on your Windows desktop and double-click it to launch the program. When ES601pc-US is executed, you will be presented with the main window from which the various software modules may be selected.

Figure 105 *- Main program window of ES601pc-US.*

From the Menu Bar in the ES601pc-US application the following options are available:

Tools   From this drop-down you can select the following utilities:

       Set the Background Image – this opens a dialogue box that allows you to select the image (.bmp format) you wish to use as the background image for ES601pc-US.
       Clear the Background Image – this will clear the background image completely, leaving a blue screen as the background.

Help   From this drop-down you can select **the** following utilities:

       Help – a comprehensive help utility for ES601pc-US

       About ES601pc – displays current software version and contact information for Datrend Systems.

8.4 Backup and Restore

In addition to the **Exit Program** and the **Help** buttons on the application window, a **Backup And Restore** button is provided. When changes are made with the various Editors, the changes are saved immediately, as the changes are made. There are limited cancel or undo features available within the Editor utilities.

In order to allow the user to save current configurations of the numerous AutoSequences, the **Backup And Restore** function allows the user to save the configuration as it exists on entry to the ES601pc-US program. Each **Backup** created through the Backup and Restore feature is identified by date and time in a listing, making it easy to select a particular configuration for restoration. After a **Restore** operation, AutoSequences and other configuration data can be uploaded into the memory of ES601-US.

Making changes to any AutoSequence before a Backup is created will make the original AutoSequence unavailable, requiring the user to manually re-input the original settings for the AutoSequence if the original settings are later desired.

8.5 Test Report Generator

This utility is used to download test report data from ES601-US and view, print and save these reports.

8.5.1 Downloading Test Reports

To download test reports generated by ES601-US, press the "Download Test Reports" button. Choose to download via USB, Ethernet, or Serial Port, and then press "Connect". If the connection is via ethernet, enter the IP address assigned to ES601-US (note this IP address is displayed on the LCD of ES601-US when the Safety Analyzer is operating in "Ethernet Mode"). If the connection is via serial port, choose the COM port to which the Safety Analyzer is connected (see **Figure 108**, under Safety AutoSequences).

After pressing "Connect", a message box with a transfer progress bar will appear (see **Figure 109**, under Safety AutoSequences). After the transfer is complete, each test report will appear as a row denoted by the test number, equipment control number, date, equipment type, make, and model.

Figure 106 *- Test Report listing.*

8.5.2 "Pass" Indication

On the right side of the list of test reports that have been downloaded is a column labelled 'Pass'. If this column contains a green check mark, then all components of the test have been given a pass indication during the test on ES601-US. If a red X is in this column, one or more components in this test report have a fail indication. This provides an indication to the user the test report should probably be reviewed more closely to determine the causes of the failure(s).

8.5.3 "New" Indication

Next to the 'Pass' column is a 'New' column. If this column contains a 'dot' for any given record, this is an indication the equipment information included in this test record has been either input or modified by the test technician. This can be an indication the equipment tested is new (the control number was not in the Equipment Record system of ES601-US), or it may mean additional data was entered on the EQUIPMENT INFO screen during a test (Tech Code, Facility, Location, etc.). This provides an indication to the user the equipment information in the test record should be reviewed. Some equipment information will appear on the screen directly if data is available (Description, Make or Model).

8.5.4 Searching For Test Reports

In the main window, there is a search text box in the upper right hand corner. Use this to filter the Test Record results by control number, type, make, and model. The search is real-time, so results will display as the characters are typed into the search box. To cancel a search, press the gray "Cancel Search" button to the right of the search box.

The filter looks at ALL the fields listed prior and performs a non-case sensitive, sub-string search for the search text string. As the search string is input, the filtered result appears on the screen (the speed of the search will depend on the number of records, and the filtered result may be slightly delayed).

An alternate to the search filter is ordering the fields alphanumerically. Pressing on a field name (eg. Model) will sort the field appropriately.

8.5.5 Opening Existing Test Reports

To open a previously saved test report for viewing, press "Open Existing" and a standard Windows Openfile dialogue box will be presented. Browse for the test report file to open for viewing in the Test Report Viewer (see next section).

Test Reports opened in this way are 'temporary', in they are not added to the list of reports shown on the screen.

> ⚠ Attempting to open a file that is **not** TEXT-only may cause the ES601pc-US program to lock up. Ensure only ES601-US test report text files are selected for viewing.

8.5.6 Viewing Test Reports

To view one or more test reports, simply click the checkbox of the desired test report and press "View Checked". The checked test reports will appear in the Test Report Viewer. Double-clicking anywhere along the row will also select a test report. To select all the test reports for viewing, click the Check All checkbox. Unchecking the Check All checkbox will deselect all test reports. To select a range of test reports, simply highlight a number of test reports and click the Check Range checkbox. Uncheck the Check Range checkbox to deselect the selected test reports.
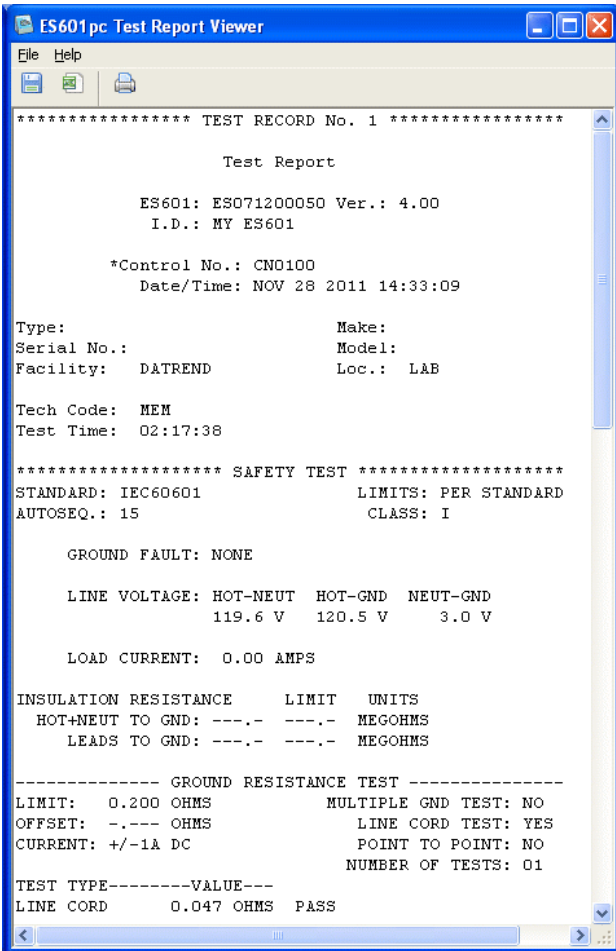
Figure 107 - *Report Viewer.*

8.5.7 Printing Test Reports

In the Test Report Viewer, press the "Print" button to show the print dialogue. Select the printer and press OK to print all the test reports currently in the viewer. Pressing Cancel will close the print dialogue without printing.

8.5.8 Saving Test Reports

Test Reports that are displayed on the Test Report Generator screen must be saved before exiting the ES601pc-US program, or they must be downloaded again the next time the program is run. The Test Reports shown on the screen after downloading will remain active in the program until ES601pc is exited. The reports will still be available if the Report Generator is exited and re-entered, but the main program is not shut down. Be sure to save any records you wish to keep **before** deleting them from ES601-US.

8.5.8.1 Saving as TXT

In the Test Report Viewer, test reports can be saved in both TXT (Text) and CSV (Comma Separated Values) formats. To save test reports in text format, press Save To Text in the Test Report Viewer. A directory browser will appear. Select the directory where the test reports should be saved. A report for each individual test will now be saved in its own file with the following filename format:

> `DeviceID.yyyy_mm_dd.hh_mm_ss.txt`

Where DeviceID is the equipment control number or other ID, yyyy is the year, mm is the month, dd is the day, hh is the hour, mm is the minute, and ss is the second in which the Test Report was created.

8.5.8.2 Saving as CSV

Saving test reports in CSV is exactly like saving to text format, except a CSV file is also created listing each device and a path to the test report file for that device. Each line of the CSV file consists of:

> *Device ID, Test Date, Test Time, Overall Pass, Tech, Description, Make, Model, Serial Number, Facility, Location, Info Edited, Parent ID, Tech Time, Filename and Path.*

Before creating the CSV file, a save file dialog will appear. Select the desired directory and specify a name for the CSV file. The CSV file and all corresponding test reports will be saved in the chosen directory.

8.6 Safety AutoSequence Editor

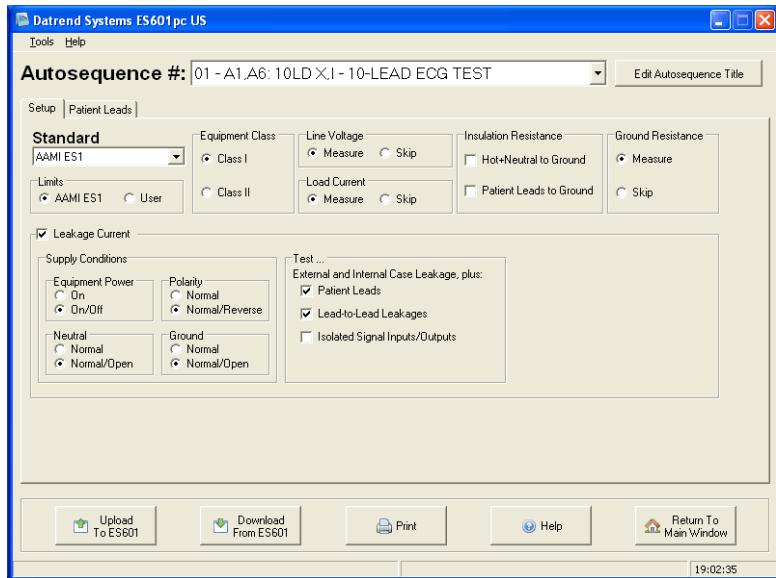Press the **Safety AutoSequence** button on the main window of ES601pc-US to view the Safety AutoSequence Editor.

Figure 108 *-Safety AutoSequence Editor.*

Safety AutoSequences loaded into the Editor are those last edited with this utility, or those which have been **Restored** from a **Backup** before entering the Editor.

8.6.1 Editing the AutoSequence Title

The sequence title can be modified by first selecting the sequence in the Safety Autosequence dropdown menu. Press the "Edit Autosequence Title" button and a window will appear, prompting you to enter a new autosequence title. The two lines can hold up to 20 characters each.
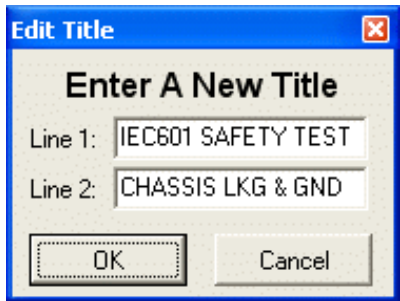
Figure 109

8.6.2 Choosing the Standard

To choose a standard, use the Standard dropdown menu. The configuration of the display will change depending on the options available in the safety standard. The standards that may be selected are:

> AAMI ES1 Standard
> IEC60601 Standard*
> VDE0751 Standard
> IEC62353 Standard
> AAMI-Battery Standard
> IEC601-Battery Standard
> VDE-Battery Standard
> IEC353-Battery Standard
> IEC61010 Standard

*Note: Limits used are those specified in IEC60601 3rd Edition. For equipment that must be tested according to IEC60601 2nd Edition, limits may be adjusted with the Safety Limits Editor of ES601pc-US (see Section 8.7).

8.6.3 Limits (All Standards)

The limits of each test can be set to the values specified by the Standard, or user-defined limits may be selected using the Safety Limits Editor (see Section 8.7).

8.6.4 Equipment Class (AAMI-ES1, IEC60601, VDE0751 and IEC62353)

A Class I device has a ground conductor (AC supply has 3 wires). A Class II device does not have a ground conductor (AC supply has 2 wires). The equipment class may be selected by radio buttons.

8.6.5 Line Voltage (AAMI-ES1, IEC60601, VDE0751, IEC62353 and IEC61010)

Line Voltage is a test where ES601-US connects an internal voltmeter to the AC line input and reports the AC RMS voltages seen from Hot to Neutral, from Hot to Ground, and from Neutral to Ground. This test can be enabled under the Line Voltage radio group by selecting Measure, or disabled by selecting Skip.

8.6.6 Insulation Resistance (AAMI-ES1, IEC60601, VDE0751, IEC62353 and IEC61010)

Insulation Resistance is a test of the breakdown strength of insulating materials between electrical conductors that should be electrically isolated from the ground connection at the AC receptacle. Two tests

can be enabled: Hot+Neutral to Ground and patient leads to Ground. ES601-US can perform one of the tests, both tests, or neither.

If Hot+Neutral to Ground is checked, ES601-US will apply a high voltage between the hot and neutral shorted together and the ground pin at the AC line cord of the DUT that would normally be connected to ground. ES601-US will measure the resulting current and report the test result as resistance in megohms.

If patient leads to Ground is checked, ES601-US will apply a high voltage across the patient leads and the line cord ground pin of the DUT. ES601-US will measure the resulting current and report the test result as resistance in megohms. The patient leads to Ground test is not provided under the IEC61010 standard.

8.6.7 Load Current (AAMI-ES1, IEC60601, VDE0751, IEC62353 and IEC61010)

Load Current is a test where ES601-US connects an internal ammeter to the DUT and measures the current drawn from the AC line when the DUT is powered and running. This test can be enabled under the Load Current radio group by selecting Measure, or disabled by selecting Skip.

8.6.8 Ground Resistance (AAMI-ES1, IEC60601, VDE0751, IEC62353 and IEC61010)

Ground resistance is a test where ES601-US tries to source current into the dead short circuit that should exist from the ground pin on the line cord of the DUT to any exposed metal part on the DUT's enclosure. ES601-US measures the resulting resistance in ohms.

8.6.9 Leakage Current (AAMI-ES1 and IEC60601)

If the Leakage Current checkbox is checked, ES601-US will perform external case leakage (AAMI) or touch current (IEC60601) tests, and internal case leakage (AAMI) or earth leakage (IEC60601) tests. Patient leads and lead-to-lead tests may be optionally enabled. Conditions of the AC power supply for these leakage tests can be set under the Supply Conditions panel.

8.6.10 Leakage Current (VDE0751 and IEC62353)

If the Leakage Current checkbox is checked, ES601-US will perform a Device Leakage Current test. A Patient Leakage Current test may be optionally enabled. Note: The AC supply conditions for each test are: Equipment Power is On, Neutral is Normal (connected), and Ground is Normal, according to the requirements of VDE0751.

8.6.11 Leakage Current (Battery-powered devices)

Under AAMI-BAT, IEC601-BAT, VDE-BAT and IEC353-BAT, which are intended for self-powered devices, the leakage current test cannot be disabled. The type of test performed is Patient Leakage Current.

8.6.12 Leakage Current (IEC61010)

If the Leakage Current checkbox is checked, ES601-US will perform only an Enclosure Leakage Current test. A point-to-point Enclosure Leakage test may be optionally enabled. Conditions of the AC power supply for these leakage tests can be set under the Supply Conditions panel. Note the Device Power condition is ON, according to the requirements of IEC61010.

Supply Conditions

8.6.13 Equipment Power (AAMI-ES1, IEC60601, AAMI-Battery and IEC60601-Battery)

Test with equipment power ON only, or test with the equipment power ON, then repeat with equipment power OFF.

8.6.14 Polarity (AAMI-ES1, IEC60601, VDE0751 and IEC62353)

Perform the leakage current test with AC Line polarity Normal; or, test with polarity Normal, then repeat with Line polarity Reversed.

8.6.15 Neutral (AAMI-ES1, IEC60601 and IEC61010)

Perform the leakage current test with AC neutral Normal (connected); or, test with neutral Normal, then repeat with neutral Open (disconnected).

8.6.16 Ground (AAMI-ES1, IEC60601 and IEC61010)

Perform the leakage current test with ground Normal (connected); or, test with ground Normal, then repeat with ground Open (disconnected).

Note: The ground option is disabled if the device is a Class II device.

8.6.17 Patient leads (all standards except IEC61010)

This test is enabled by checking the "Patient Leads" box, unless the safety standard is one of the "-BAT" standards, in which case this test is always enabled. In this test, ES601-US measures the current that flows out of the patient leads of the DUT through the human body load, when the parts are either connected to ground, or they are connected to an isolated AC supply. This latter test is referred to as a lead isolation test or "mains-on-applied-part" (MAP) test. Under the IEC60601 standard, the MAP voltage equals 110% of the AC supply voltage to the DUT; for all other standards the MAP voltage is equal to the AC supply voltage. For the "-BAT" standards, patient-patient leads must be isolated from ground (Type BF or Type CF under AAMI-BAT and IEC601-BAT; or Type F under VDE-BAT or IEC353-BAT).

8.6.18 Patient Lead Groups (all standards except IEC61010)

A Group of patient leads consists of one to ten **contiguous** ECG or other patient leads. Also, Groups encompass the patient leads in order, starting from patient lead 1 (AP1). For example, Group 1 may consist of patient leads #1 to #3, Group 2 may consist of patient leads #4 to #5, and Group 3 may consist of patient lead #6. In all but the AAMI Standard, Group 1 is always enabled and has at least 1 patient lead.

The patient lead editor is accessed by clicking on the patient leads tab. The patient leads tab will be accessible only if Leakage Current is enabled and one of "Patient Leads" or "Lead-to-Lead Leakages" is selected. After clicking the Patient Leads tab, a Group of leads can be enabled by either checking the Group checkbox, or by entering a non-zero number of patient leads for that Group. The patient lead Names and Status panel will display the patient leads that have been enabled. A name can be given to the patient lead Group by editing the Name textbox.

A Patient Lead Group may be disabled after entering a non-zero number of patient leads for that Group. The disabled Group will then separate the enabled Groups on the front panel connections to the analyzer.

The type of protection class can be changed by selecting either the B, BF or CF radio button. In the AAMI-ES1 and AAMI-Battery Standards, Group 1 always has a protection class of "Isolated", which corresponds to "Body-Floating"; and Group 2 always has a protection class of "Non-Isolated", which corresponds to "Body".

Type B refers to "Body" or "Non-Isolated" protection class. That is, the patient leads are not electrically isolated from ground. Type B parts have the least stringent safety requirements. ES601-US will measure patient leakage current while all the Type B patient leads in the patient lead Group are shorted to ground.

Type BF refers to "Body-Floating" or "Isolated" protection class. That is, the patient leads are electrically isolated from ground but are not intended for direct contact with cardiac tissue. ES601-US will measure patient leakage current while all the patient leads in the Type BF patient lead Group are shorted to ground, or alternatively to the isolated mains (AC supply).

Type CF refers to "Cardiac-Floating" protection class. The patient leads are electrically isolated from ground and have been designed for direct contact with cardiac tissue. Type C parts have the most stringent safety requirements. ES601-US measures patient leakage current while each patient lead in the Type CF patient lead Group is shorted to ground, or alternatively to the isolated mains (AC supply).

Each patient lead can be assigned a name. Patient lead names can be input via the textboxes provided in the patient lead Name and Status panel.

8.6.19 Lead-to-Lead Leakages
(AAMI-ES1, IEC60601, AAMI-Battery and IEC60601-Battery)

In this test, ES601-US measures the current that flows out of one patient lead, through the human body load, and into all the other patient leads shorted together. The test will be repeated for each patient lead. This test is pertinent to AAMI and IEC60601 standards only.

8.6.20 Isolated Signals Inputs/Outputs
(AAMI-ES1, IEC60601, AAMI-Battery and IEC60601-Battery)

If Isolated Signals Inputs/Outputs is enabled, the effect on patient lead leakage by connecting isolated input/output signals of the DUT to ground or to mains will be observed. An example of an isolated input/output would be an ethernet connection or similar transformer-isolated data interface on a medical device, for example, a multi-parameter patient monitor. This test is pertinent to AAMI and IEC60601 standards only.

When enabling tests of Isolated Signal Inputs/Outputs, the signals must be isolated from ground, otherwise damage to equipment under test may result. Check equipment manufacturer's specifications.

8.6.21 Exposed Ungrounded Metal Parts (IEC60601)

If Exposed Ungrounded Metal Parts is enabled, the effect on patient lead leakage by connecting exposed ungrounded metal parts of the DUT to ground will be observed. An example of such a part may be an electrically floating conductive faceplate, a fastener in a plastic enclosure, bracket, or similar feature on the enclosure of the DUT. This test is pertinent to the IEC60601 standard only.

8.6.22 Protocol (VDE0751 and IEC62353)

The Protocol defines the device and patient leakage measurement protocols under VDE0751 and IEC62353 safety standards. In the VDE Alternate Method, the DUT is connected to an isolated mains source rather

than the AC supply. In the Direct Method, the DUT is powered by the AC supply, and patient leakage is determined by connecting isolated patient leads to AC supply only (Type B non-isolated leads are not tested). For VDE0751 and IEC62353 standards, the "IEC60601 method" means the DUT is powered by the AC supply and patient leakage is determined by connecting patient leads either to mains or to ground (Type B parts will be tested).

> ⚠️ The Alternate method of leakage measurement can only be used with Type F Isolated Leads.

8.6.23 Test Point-to-Point (IEC61010)

Clicking this check box enables measurement of Enclosure Leakage Current from one arbitrary point on the DUT enclosure to a second arbitrary point. The point-to-point enclosure connections are made via jacks AP1 and AP2 on ES601-US. This test is pertinent to the IEC61010 standard only.

8.6.24 Uploading AutoSequences

To upload Safety AutoSequences to ES601-US, press the "Upload To ES601" button. Choose either uploading via USB, Ethernet, or Serial Port, and then press "Connect". If the connection is via ethernet, enter the IP address assigned to ES601-US (the IP address of ES601-US is displayed on the LCD when the analyzer is operating in Ethernet Mode). If the connection is via serial port, choose the COM port to which the ES601-US is connected (**Figure 108**).
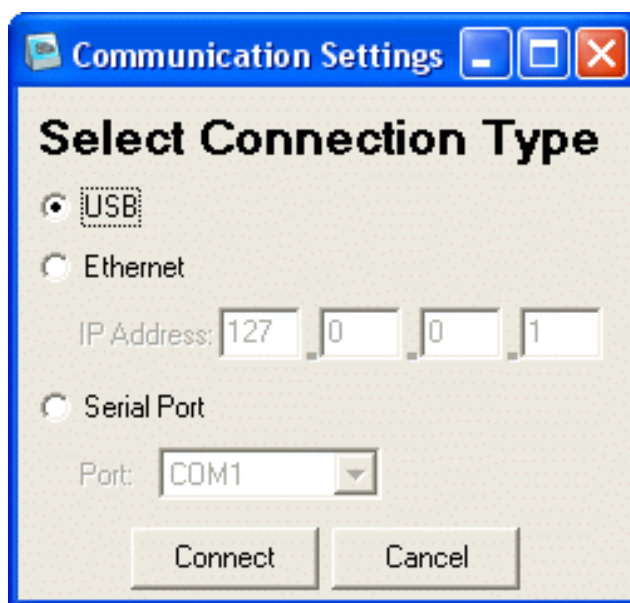
Figure 110 - *Communications dialog.*

After pressing "Connect", a message box with a transfer progress bar will appear (**Figure 109**). After the transfer is completed, a Transfer Complete message will appear and the message box will disappear .
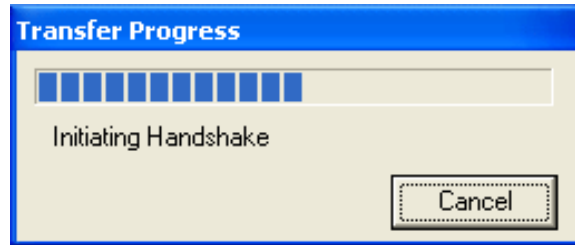
Figure 111

8.6.25 Downloading AutoSequences

Sometimes it is desirable to bring data stored in the ES601-US back into your PC. This way, you can transfer AutoSequence setups from one ES601-US analyzer to another.

You can retrieve AutoSequence setups from a ES601-US by pressing the "Download From ES601" button. Choose to download via USB, Ethernet, or Serial Port. Doing so will overwrite the configuration of all 24 Safety AutoSequences in ES601pc-US with the sequences from the ES601-US.

These sequences can then be uploaded to a different ES601-US, or they can be optionally modified and uploaded to the same ES601-US unit, or additional ES601-US units.

8.6.26 Printing AutoSequences

Press the Print button to show the print dialogue. Select the current sequence radio button and press OK to print out the current AutoSequence. Select the All Sequences radio button and press OK to print out all 24 AutoSequences. Pressing Cancel will close the print dialogue without printing.

8.6.27 Return to Main Menu

When edits have been completed, the user may return to the main menu of ES601pc-US by pressing this button. When this button is pressed, all changes which have been made will be saved on your computer.

If the configuration that existed when entering the Editor may be required at a later time, be sure to **Backup** the configuration *before* making any edits.

8.7 Safety Limits Editor

The Safety Limits Editor of ES601pc-US allows you to program ES601-US with one set of alternate limits, which can be edited or revised at any time, for each of the electrical safety standards supported by the analyzer.

Electrical safety standards specify a limit for each measurement performed on a device under test. During a safety test, a measured value which exceeds its corresponding limit is assigned a "fail" mark by ES601-US.

Reference tables of safety limits are incorporated into the firmware of ES601-US. There is one reference table assigned to each regulatory standard supported by the safety analyzer. These reference or standard tables conform to the latest revisions of the regulatory standards. For example, the standard table for AAMI-ES1 dates from 1996.

If the equipment being tested was manufactured prior to release of the safety standard being used, limits applied during safety tests may be inappropriate and could produce invalid failing results. To allow testing of equipment that predates a given regulatory standard, ES601-US provides one alternate or user-defined limit table for each of the standards. With the Safety Limits Editor, you can tailor the pass/fail limits of a user-defined table to suit the device being tested.

Prior to starting a safety test, you can choose to apply limits according to the regulatory standard (the "standard limits"), or you can optionally choose to apply user-defined limits to suit the equipment under test. User-defined limits can be selected via the MANUAL MODE screen for manual measurements. Safety AutoSequences can also be programmed to apply user-defined limits during a test sequence, via the Safety AutoSequence Editor of ES601pc-US. When a safety test is performed, as part of the test result ES601-US automatically saves either the standard limit or the user-defined limit for each measurement taken.

8.7.1 Editing Safety Limits

Each safety standard provided by ES601-US has its own tab in the Safety Limits Editor. To view the default and user-defined limits for a particular standard, click on the corresponding tab at the top of the editor window (*Figure 110*).

Figure 112 - *Safety Limits Editor.*

The first time the Safety Limits Editor is run, the values shown in the textboxes will be the limits defined in the safety standard. These are the default values for the standard. To change a safety limit, click on the desired textbox and type in a value. Any value that differs from the default limit will appear in green text, otherwise, the value will appear in black. Hovering the mouse pointer over a textbox will show the default value of the safety limit.

All safety limit values on all tabs provided by the editor are automatically saved by ES601pc-US after uploading the data to ES601-US. The safety limit data are also saved after downloading limits from ES601-US into the editor, or exiting the editor to the main menu of ES601pc-US. An individual limit can be reverted to its most recently-saved value by right-clicking on its textbox and choosing "Revert" in the popup menu which will appear (**Figure 111**). Clicking the "Revert All" button at the bottom of the editor window will revert all safety limits displayed on the current tab to the most recently-saved values.

An individual limit can be returned to its default value by right clicking on its textbox and choosing "Set Default Limit" in the popup menu that will appear (**Figure 111**). Clicking the "Set All to Default" button at the bottom of the editor window will return all the safety limit values on the current tab to their default values.

Figure 113 *- Right-click to see parameter menu.*

8.7.2 Uploading Safety Limits

To upload safety limits to ES601-US, press the "Upload To ES601" button. Choose either uploading via USB, Ethernet, or Serial Port, and then press "Connect". If the connection is via ethernet, enter the IP address assigned to ES601-US (the IP address of ES601-US is displayed on the LCD when the analyzer is operating in Ethernet Mode). If the connection is via serial port, choose the COM port to which the ES601-US is connected (see ***Figure 108***, under Safety AutoSequence).

After pressing "Connect", a message box with a transfer progress bar will appear (***Figure 109***, under Safety AutoSequences). After the transfer is completed, a Transfer Complete message will appear and the message box will disappear .

8.7.3 Downloading Safety Limits

Sometimes it is desirable to bring data stored in the ES601-US back into your PC. This way, you can transfer setups from one ES601-US analyzer to another.

You can retrieve safety limits stored in a ES601-US by pressing the "Download From ES601" button. Choose to download via USB, Ethernet, or Serial Port. Doing so will overwrite the safety limits which are maintained by ES601pc-US.

These safety limits can then be uploaded to a different ES601-US, or they can be optionally modified and uploaded to the same ES601-US unit, or additional ES601-US units.
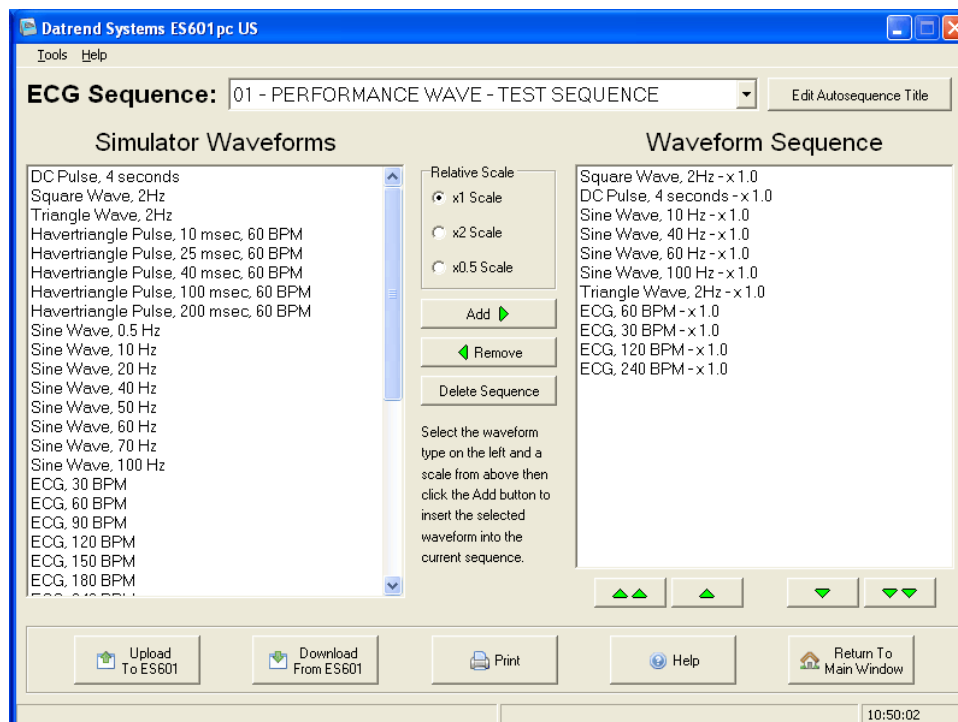
8.8 ECG AutoSequence Editor

In addition to an electrical safety analyzer, ES601-US incorporates an electrocardiogram (ECG) simulator. The ECG Simulator of ES601-US generates 40 different test signals the user can activate manually using a menu system. In addition to the waveform, the amplitude of the output signal can be set to one of three values: 1 mV (standard), 2 mV, or 0.5 mV (in Lead II).

As an alternative to manually operating the simulator, the user can run an ECG AutoSequence in which ES601-US can be stepped through a predetermined list of up to 24 selected waveforms of given amplitudes. At each step of the ECG AutoSequence, the user can enter either a "PASS" or "FAIL". At the end of the ECG AutoSequence, the user can optionally enter a comment of up to 40 characters (e.g. "LEAD III NOT WORKING").

ES601-US provides 6 programmable ECG AutoSequences, each having from one to 24 steps. ES601pc-US is used to select the waveforms and amplitudes for each step of each ECG AutoSequence and program this setup into ES601-US.

Upon selecting **ECG AutoSequences** on the main window of ES601pc-US, you are taken to the editor screen (*Figure 112*).
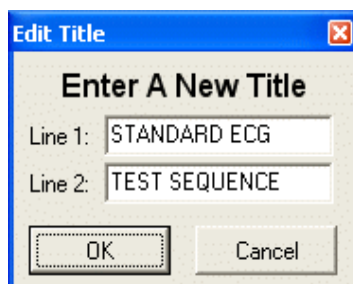
Figure 114 - *ECG AutoSequence Editor.*

8.8.1 Editing the AutoSequence Title

The AutoSequence title can be modified by first selecting the sequence in the ECG Sequence dropdown menu. Press the "Edit Autosequence Title" button and a window will appear prompting you to enter a new autosequence title (*Figure 113*). The two lines can hold up to 18 characters each.

Figure 115

8.8.2 Adding a Waveform

To add a step to a sequence, select a waveform from the Simulator Waveforms pane (on left side of the screen). Select the desired relative scale by clicking on the "Relative Scale" radio buttons. The options are x1, x2, or x0.5 scale, corresponding to 1 mV, 2 mV or 0.5 mV QRS amplitude on ECG Lead II. Press the "Add" button. The waveform will appear in the Waveform Sequence pane on the right side of the screen.

Optionally, you can select a waveform from the Simulator Waveforms pane, and drag and drop the waveform to the Waveform Sequence pane. The waveform will appear in the Waveform Sequence window at the end of the sequence.

8.8.3 Removing a Waveform

Select a waveform in the Waveform Sequence pane (on the right side of the screen) and press the "Remove" button. The waveform will be removed from the sequence.

8.8.4 Modifying the Order of Waveforms in a Sequence

Select a waveform in the Waveform Sequence pane (on the right) and press one of the green arrow buttons under the window. The double arrow up will move the waveform to the first step of the sequence. The single arrow up will move the waveform one step up in the sequence. The single arrow down will move the waveform one step down in the sequence. The double arrow down will move the waveform to the last step of the sequence.

8.8.5 Deleting a Sequence

An entire sequence can be deleted by pressing the "Delete Sequence" button. A message box will appear prompting you to be sure you want to delete the sequence. Press "Yes" if you are sure, and all the waveforms in the sequence will be removed as well as the sequence title.

8.8.6 Uploading AutoSequences

To upload ECG AutoSequences to ES601-US, press the "Upload To ES601" button. Choose either uploading via USB, Ethernet, or Serial Port, and then press "Connect". If the connection is via ethernet, enter the IP address assigned to ES601-US (the IP address of ES601-US is displayed on the LCD when the analyzer is operating in Ethernet Mode). If the connection is via serial port, choose the COM port to which the ES601-US is connected (see *Figure 108*, under Safety AutoSequences).

After pressing "Connect", a message box with a transfer progress bar will appear (see *Figure 109*, under Safety AutoSequences). After the transfer is completed, a Transfer Complete message will appear and the message box will disappear.

8.8.7 Downloading AutoSequences

Sometimes it is desirable to bring data stored in the ES601-US back into your PC. This way, you can transfer AutoSequence setups from one ES601-US analyzer to another.

You can retrieve AutoSequence setups from a ES601-US by pressing the "Download From ES601" button. Choose to download via USB, Ethernet, or Serial Port. Doing so will overwrite the configuration of all 24 Safety AutoSequences in ES601pc-US with the sequences from the ES601-US.

These sequences can then be uploaded to a different ES601-US, or they can be optionally modified and uploaded to the same ES601-US unit, or additional ES601-US units.

8.8.8 Printing AutoSequences

Press the Print button to show the print dialogue. Select the current sequence radio button and press OK to print out the current sequence. Select the All Sequences radio button and press "OK" to print out all the sequences. Pressing "Cancel" will close the print dialogue without printing.

8.8.9 Return to Main Window

When edits have been completed, the user may return to the main menu of ES601pc-US by pressing this button. When this button is pressed, all changes which have been made will be saved on your computer.

⚠️ If the configuration that existed when entering the Editor may be required at a later time, be sure to **Backup** the configuration *before* making any edits.

8.9 Checklist Module

"*Checklists*" are automated maintenance procedures which are described in Chapter 6 of this manual. The Checklist module of ES601pc-US allows the user to create up to 500 Checklists which can be uploaded and then run on the ES601-US analyzer.

Pressing **Checklists** on the main window of ES601pc-US will display the Checklist Library window, which lists all available Checklists. Three example or "starter" Checklists are included with ES601pc-US, and following installation of the software these examples will be evident as the first three Checklists in the Library as shown below, with the remaining 497 Checklists being blank or "unused".
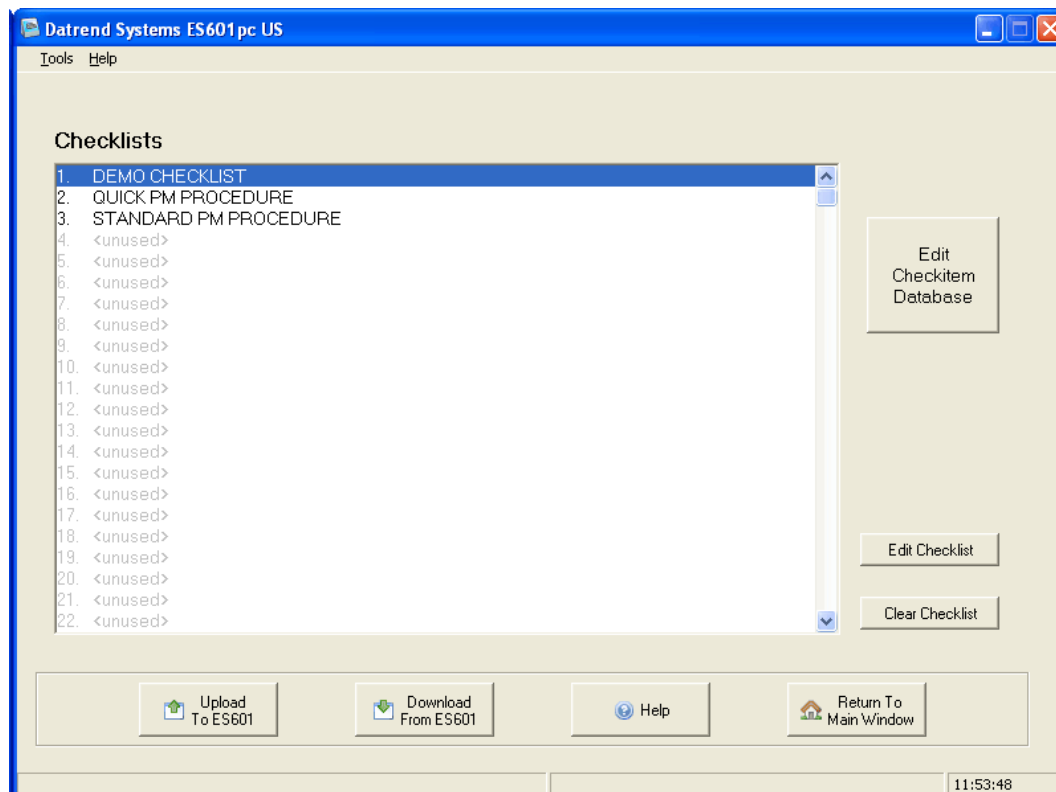

Figure 116 - *Checklist Library window.*

8.9.1 Uploading Checklists

To upload Checklists to ES601-US, press the "Upload To ES601" button. Choose uploading via USB, Ethernet, or Serial Port, and then press "Connect". If the connection is via ethernet, enter in the IP address assigned to ES601-US (the IP address of ES601-US is displayed on the LCD when ES601-US is operating in Ethernet Mode). If the connection is via serial port, choose the COM port to which ES601-US is connected.
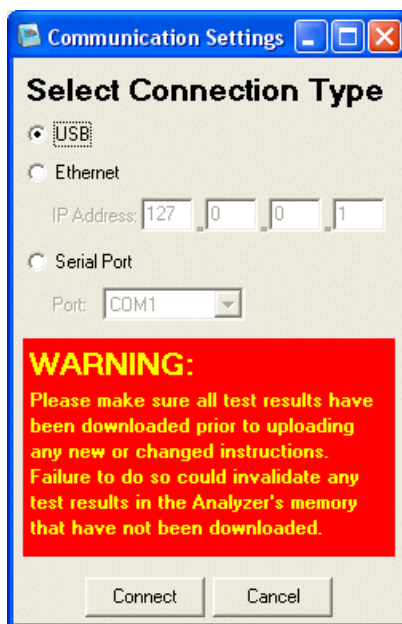
Figure 117

After pressing "Connect", a message box with a transfer progress bar will appear. After the transfer is completed, a Transfer Complete message will appear and the message box will disappear.

8.9.2 Downloading Checklists

Sometimes it is desirable to bring data stored in the ES601-US back into your PC. This way, you can transfer Checklists from one ES601-US analyzer to another.

You can retrieve Checklists from a ES601-US by pressing the "Download From ES601" button. Choose to download via USB, Ethernet, or Serial Port. Doing so will overwrite the configuration of all 500 Checklists in ES601pc-US with Checklists downloaded from the analyzer.

These Checklists can then be uploaded to a different ES601-US, or they can be optionally modified and uploaded to the same ES601-US unit, or additional ES601-US units.

8.9.3 Editing a Checklist

Begin editing by double-clicking on a Checklist in the Library, or highlight a Checklist and press the "Edit Checklist" button. If desired, a blank Checklist can be created by selecting an item and pressing the "Clear Checklist" button, followed by "Edit Checklist" to open the Checklist Editor window.

On the Checklist Editor screen (***Figure 116***), controls are provided for modifying the Title, Tester Port Number (1 to 6) and Tester Port Baud Rate (2400 to 19200 baud). If the Checklist does not issue remote control commands to externally connected test instruments, then the Tester Port can be set to "unused" and the Baud Rate left blank. Items from the Checkitem Database, listed in the table on the left, can be added to and removed from the Checklist on the right by using the appropriate buttons in the center margin of the screen.
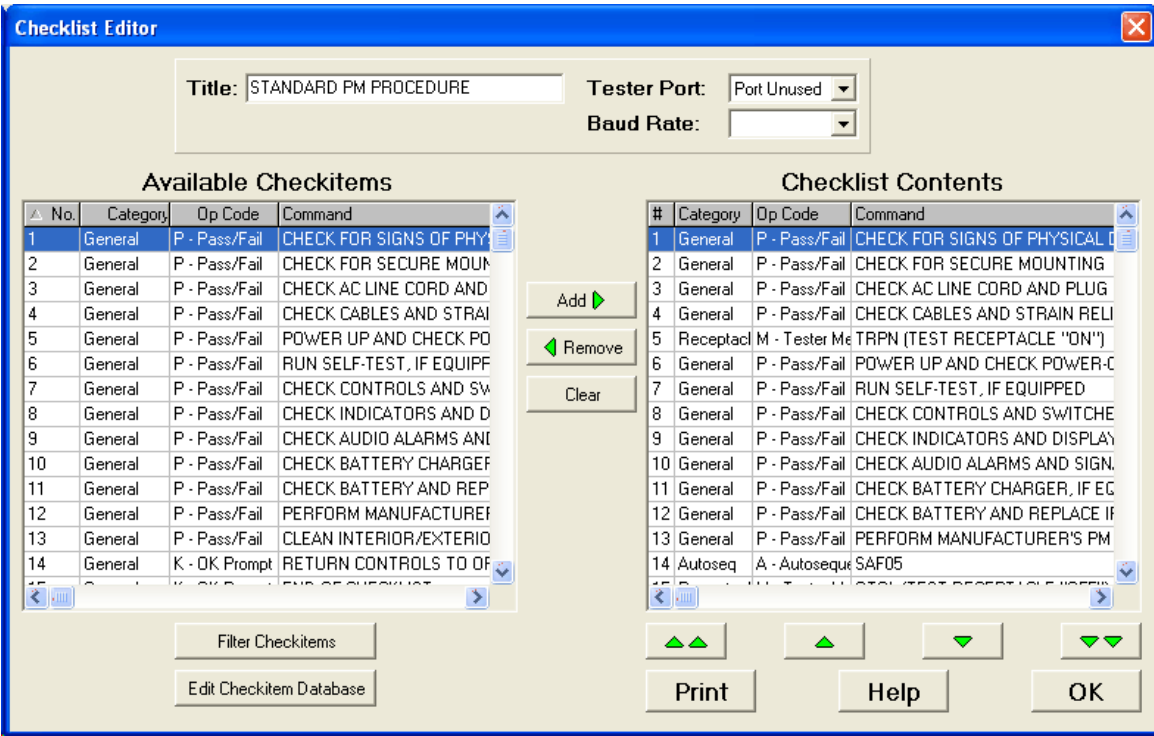

Figure 118 - *Checklist Editor window.*

All Checkitems can be removed from the Checklist by pressing the "Clear" button in the center margin. Checklist contents can be re-ordered by selecting the desired Checkitem in the Checklist and using the "Up" or "Down" arrows below the column to move the selected item up or down. The selected item can be moved to the top or bottom of the Checklist by using the Double Up or Down arrows. The "Print" button opens a standard Windows Print dialog, allowing the Checklist on the right to be sent to a printer.

8.9.4 Checkitem Database Editor

Individual Checkitems can be created or modified by clicking the "Edit Checkitem Database" button. This button appears on the Checklist Library window and on the Checklist Editor window.

In the Checkitem Database, double-click on a Checkitem in the list or highlight a Checkitem and then click "Edit Checkitem". This will enable editing of the Checkitem via the properties panel at the bottom of the window.
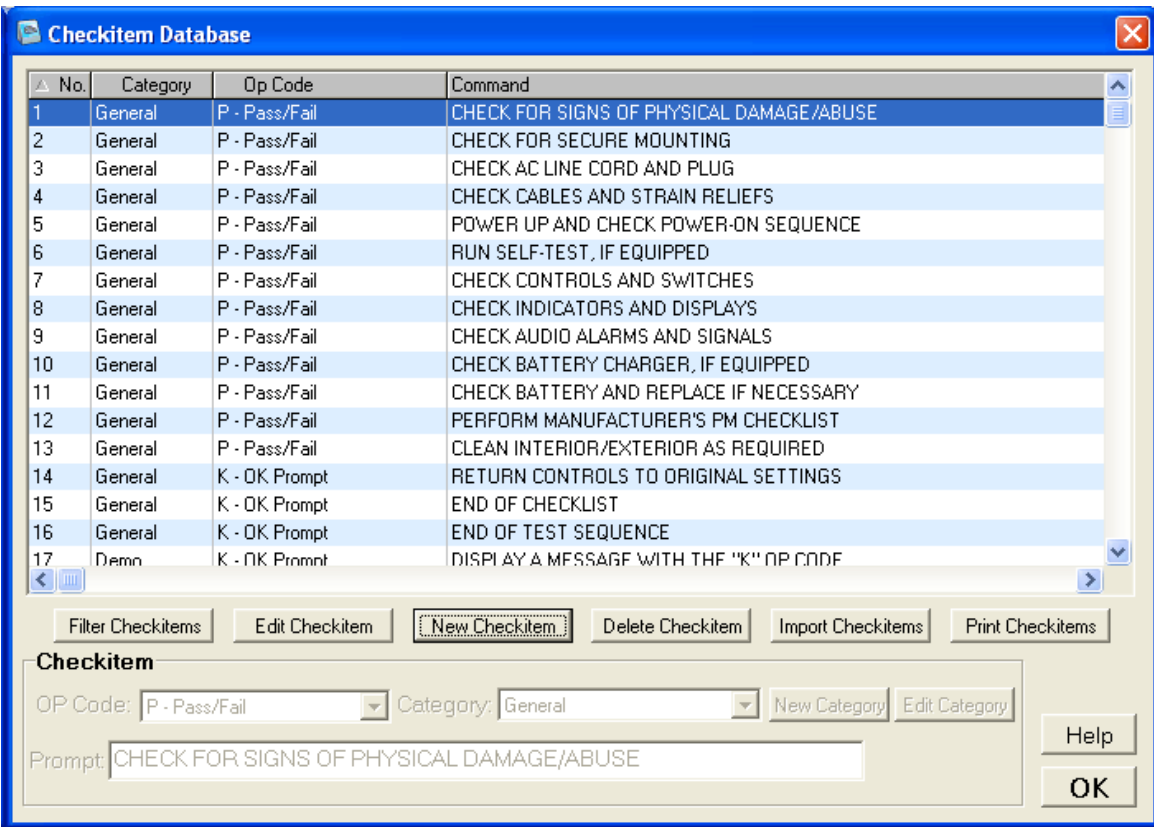
Figure 119 - *Checkitem Database window.*

The Checkitem properties panel includes an op code dropdown, category dropdown and a number of command textboxes, according to the Checkitem's op code.

8.9.4.1 Selecting the Op Code

The Op Code defines what the Checkitem does and which buttons are presented to the user on ES601-US display. Depending on the op code, the user may be required to enter a measurement value or a comment when that Checkitem is reached during execution of the Checklist.

Op Codes provided are:

- Pass/Fail (op code = 'P')
- OK prompt (op code = 'K')
- Input requested from user (op code = 'I')
- User data input with Pass/Fail (op code = 'E')
- Time delay (op code = 'D')
- Tester remote control (op code = 'C')
- Tester remote control with user data entry (op code = 'R')
- Multi-Function - test receptacle, ECG simulator, or external tester control (op code = 'M')
- AutoSequence procedure call (op code = 'A')

See **Automated Testing Principles** in Chapter 6 for a more complete discussion of the Op Codes and their functionality.

Under the Op Code dropdown menu, select the desired op code. Depending on the op code, the command will show a different number of text boxes which accept different kinds of data.

8.9.4.2 Selecting the Category

Category is used by ES601pc-US to select and sort Checkitems based on description or intended application. Categories are user-defined and associate the category name with an upper-case ASCII letter. For example, the user can create a "Defib" Category and assign to this the letter 'D'. In the Checkitem Database, Checkitems can thereby be created or modified under the "Defib" category.

In the Checkitem Editor, select a Category of a Checkitem via the Category drop-down menu. Create a new category in the Checkitem Editor by pressing "New Category". The Category Editor will appear.
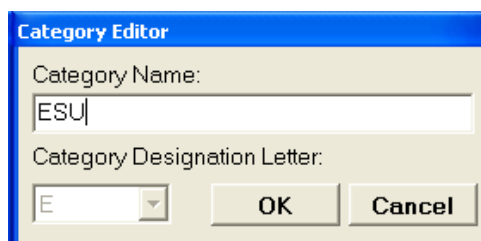
Figure 120

Type in a new category name in the Category Name textbox, and select the associated category letter in the Category Designation Letter dropdown. Press "OK" and the new category will appear in the category dropdown menu.

Edit a category by selecting a category and pressing Edit Category. The Category Editor will appear. Type in the desired name in the Category Name textbox and press "OK".

8.9.4.3 Entering the Command/Prompt

Op Codes P, E, K and I will allow editing or entering a **_Prompt_**. The Prompt is the text which ES601-US will display when this step of the Autosequence is encountered (see **_Automated Testing Principles_** in Chapter 6). In principle, the Prompt is intended to ask the technician to enter "OK", "PASS", "FAIL" comments or results such as "RF LEAKAGE IS 248 UA" and so on, which will then be saved in the Test Record.
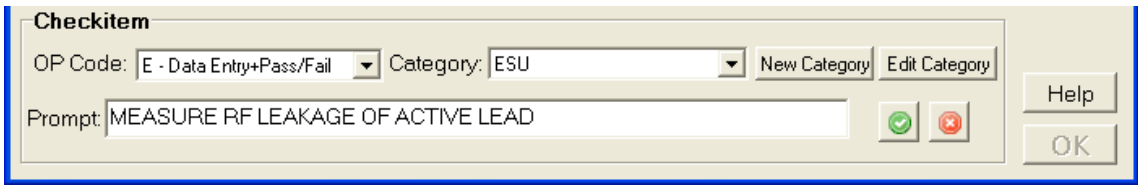
Figure 121 - _Editing a data entry ("E") Checkitem._

Op Codes C, M, D and R will, in addition to the Prompt, allow editing or entering a **_Command_**. The Command is used to transmit a message via a TESTER PORT to an external testing device, for example a patient simulator such as Datrend AMPS-1, to start or stop a function, send measurement data, etc. For more information, refer to the Checkitem descriptions given in **_Automated Testing Principles_** of Chapter 6.

Figure 122 - _Editing a remote control ("R") Checkitem._

8.9.4.4 <u>Configuring "A" Checkitems</u>

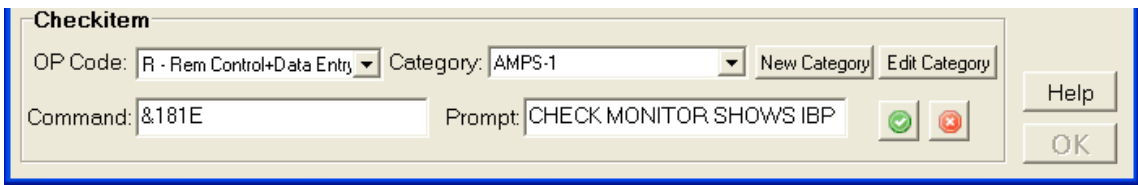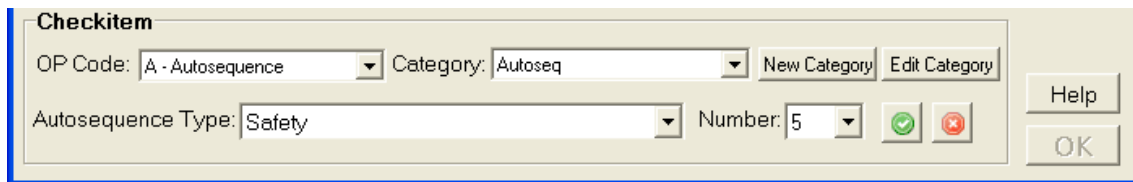To include a complete AutoSequence or Inspection as part of a Checklist, an **A** Checkitem which invokes that AutoSequence as a "procedure call" must first be created in the Checkitem Database.

Press "Edit Checkitem Database" on either the Checklist Library or Checklist Editor window and select Type 'A' for the op code. Choose an "AutoSequence Type" (Safety, ECG, Physical Inspection, User Tester, etc.) and a sequence "Number". The command string of the resulting Checkitem will encode the AutoSequence required. For example, selecting Safety AutoSequence #05 will create the Checkitem command "SAF05" in the database, or selecting User Tester #1, sequence #5, will create the Checkitem command "UT105".

Figure 123 - *Editing an AutoSequence ("A") Checkitem.*

To help in creating AutoSequence Checkitems for use in Checklists, it is assumed the user of the ES601pc-US program will have a list of Safety, ECG or User-Tester AutoSequence titles printed out and available for reference. Such printouts can be made from the Editors used to make those types of sequences. Alternatively, the user can run a second instance of ES601pc-US and use the Safety Autosequence Editor, ECG AutoSequence Editor, or any other Editor of ES601pc-US to view the titles and other details of the AutoSequences, and choose the desired AutoSequence number for the AutoSequence Checkitem being created in the Checkitem Editor.

Do not try to make modifications in the second instance of ES601pc-US, as it may be possible to corrupt the data files if both instances of the program are trying to write to the same file(s). **Use the second instance of ES601pc-US for <u>viewing only</u>**.

The type of AutoSequence and the related commands that are generated by the Checkitem Editor are as follows:

Command prefix	Type of AutoSequence	"NN"
SAF	Safety AutoSequence	01 to 24
ECG	ECG AutoSequence	01 to 12
POX	Oxitest +7 AutoSeqeunce	01 to 12
IVP	Infutest Autosequence	01 to 12
DFB	Phase 3 AutoSequence	01 to 24
UT1	User-Defined Tester #1	01 to 12
UT2	User-Defined Tester #2	01 to 12
UT3	User-Defined Tester #3	01 to 12
UT4	User-Defined Tester #4	01 to 12
UT5	User-Defined Tester #5	01 to 12
INS	Physical Inspection	01 to 18

Figure 124

A Checklist may have one Safety Autosequence, one ECG Autosequence, both, or neither. A Checklist may invoke any number of Inspections or Tester Autosequences via "A" Checkitems, provided the total number of procedural steps created by including these Autosequences does not exceed **96**.

More information on the "A" Checkitem can be found in **Automated Testing Principles** of Chapter 6.

8.9.5 Creating a New Checkitem

Press "New Checkitem" on the Checkitem Editor window. A new, empty Checkitem will appear at the end of the Checkitem Table. The Checkitem Properties panel will also be enabled. To edit the new Checkitem, follow the same procedure as in Editing an Checkitem.

The Checkitem may be saved, after all information is added or edited, by pressing the OK button 🟢 or quit without saving by pressing the QUIT button 🔴 .

8.9.6 Filtering Checkitems

Press "Filter Checkitems". The Checkitem Filter window will appear. Under the Basic Filter tab, select a Category and/or an Op Code and then press "OK". Only the Checkitems with the selected category or op code will appear in the Available Checkitems window. To see all available Checkitems again, press "Filter Checkitem List" and then "OK" in the Checkitem Filter window.
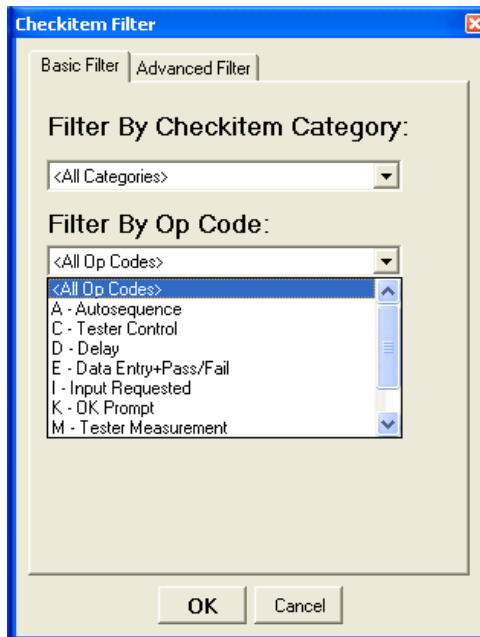
Figure 125
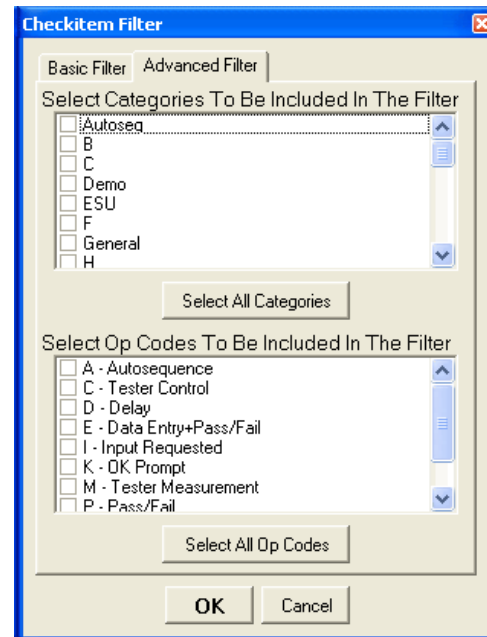
Figure 126

In order to select multiple categories or multiple op codes, select the Advanced Filter tab in the Checkitem Filter window. Check the categories or op codes of the Checkitems that should appear. Press "Select All Categories" or "Select All Op Codes" to select all the checkboxes. Press "OK" to filter the Checkitem Table.

8.9.7 Deleting a Checkitem

While viewing the Checkitem Editor, select a Checkitem from the Checkitem Table. Press "Delete Checkitem". A warning message will appear which will list the sequences which currently use the Checkitem. If there are no sequences listed and it is desired to delete the Checkitem, press "Yes".

Removing or changing an Checkitem may have significant effects on previously defined Physical Inspections and/or Tester AutoSequences. Take care when making this type of change to avoid unexpected results with historical Inspections and AutoSequences.

8.9.8 Importing Checkitems

Checkitems can be imported into the database from a CSV (Comma Separated Values) file. Press "Import Checkitems" on the Checkitem Editor window and browse for the CSV file. For the import to be successful, the CSV file must list Checkitems in the following format:

        [Category],[Op Code],[Command]

where [Category] is a single capital letter denoting the category designation.

If the category does not exist, a new one will be created. [Op Code] is a single capital letter denoting the op code. If the op code is not recognized, the new Checkitem will default to the C op code. [Command] is a string of up to 40 characters. If the op code calls for more than one value, separate the values with a tab character. After selecting the desired CSV file and pressing "Open", the Checkitems in the file will be added at the end of the database.

8.9.9 Printing Checkitems

The Checkitem Database can be printed by clicking "Print Checkitems" on the Checkitem Editor window. Clicking this button displays a standad Windows Print dialog, allowing the printer to be selected and the print job initiated. The Checkitem Database is printed as it is shown in the table; if filtering has been applied to the database, then the filtered result will appear in the printout.

8.10 Inspections and User Testers

Physical Inspections and User Tester AutoSequences are Checklists which are intended for use in specific applications. A "***Physical Inspection***" is a list of inspection checkpoints, typically visual inspection checks, targeted at a general class of equipment, for example, patient monitor, defibrillator, infusion pump and so on. A "***Tester AutoSequence***" is a program which is intended to control and acquire measurement data from a specific test instrument which connects to the ES601-US analyzer via a TESTER PORT. Inspections and Tester AutoSequences are limited in length to 24 steps, and either or both can be "called" from a Checklist by means of the **A** Checkitem. More information can be found in the ***Automated Testing Principles*** section of Chapter 6.

Pressing **Inspections and User Tester** on the main window of ES601pc-US will display the Inspections and User Testers window. By default, the Physical Inspections tab is selected. One example or "starter" Inspection is included with ES601pc-US, and following installation of the software this example will be evident as the first Inspection as shown below, leaving 17 blank or "unused" Inspections for programming as desired by the user.
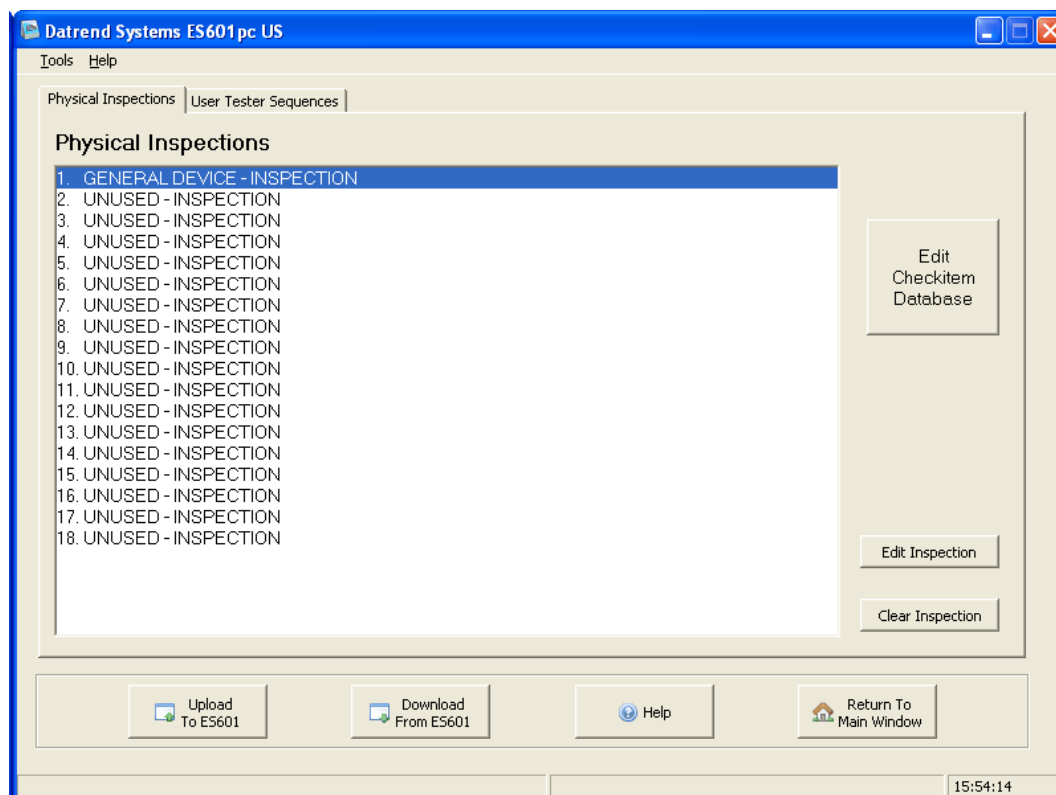
Figure 127 *- Physical Inspections selector menu.*

Selecting the User Tester Sequence tab will open that window. To select a User Tester Sequence, first expand one of the five User Tester Sequences by clicking on the "plus symbol" next to the User Tester name. Example Tester AutoSequences for a number of popular test instruments and patient simulators are included with ES601pc-US, and following installation of the software these examples will be evident on the User Testers tab as shown below.
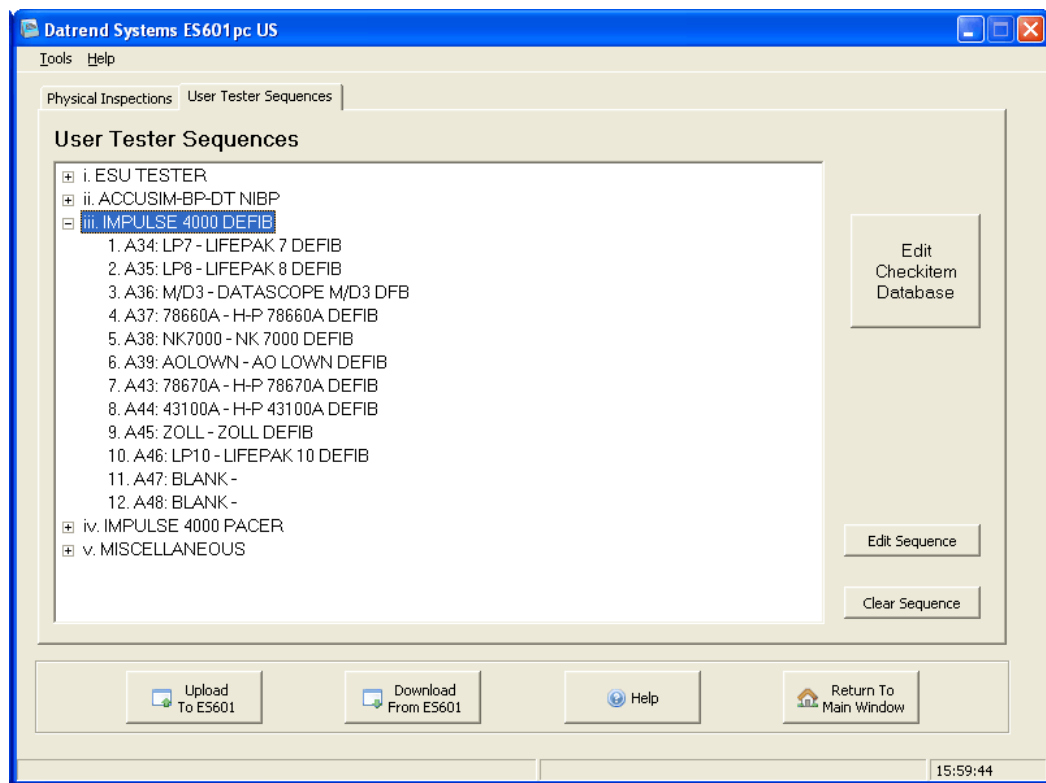
Figure 128 - *User Tester selector menu.*

The name assigned to a User Tester can be modified. Double-click on a User Tester in the list above, and a dialog will appear, allowing you the enter the name of the test instrument that the associated AutoSequences are intended to work with.
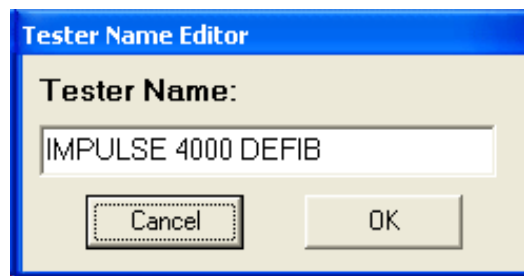
Figure 129

8.10.1 Uploading AutoSequences

To upload to ES601-US, press the "Upload To ES601" button. Choose uploading via USB, Ethernet, or Serial Port, and then press "Connect". If the connection is via ethernet, enter in the IP address assigned to ES601-US (the IP address of ES601-US is displayed on the LCD when ES601-US is operating in Ethernet Mode). If the connection is via serial port, choose the COM port to which ES601-US is connected.

Figure 130

After pressing "Connect", a message box with a transfer progress bar will appear. After the transfer is completed, a Transfer Complete message will appear and the message box will disappear.

8.10.2 Downloading AutoSequences

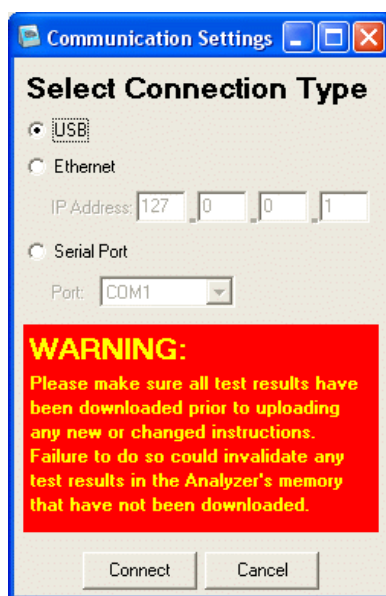Sometimes it is desirable to bring data stored in the ES601-US back into your PC. This way, you can transfer Inspections and AutoSequences from one ES601-US analyzer to another.

You can retrieve data from a ES601-US by pressing the "Download From ES601" button. Choose to download via USB, Ethernet, or Serial Port. Doing so will overwrite the configuration of all Inspections and User Tester AutoSequences in ES601pc-US with the data downloaded from the analyzer.

These Inspections and AutoSequences can then be uploaded to a different ES601-US, or they can be optionally modified and uploaded to the same ES601-US unit, or additional ES601-US units.

8.10.3 Editing an Inspection or User Tester Sequence

Begin editing by double-clicking on a Physical Inspection on the Inspections tab, or highlight the Inspection and press the "Edit Inspection" button. If desired, a blank Inspection can be created by selecting an item and pressing the "Clear Inspection" button, followed by "Edit Inspection" to open the Inspection+User Tester Editor window. Similar buttons are provided on the User Testers tab, for selecting and editing a User Tester AutoSequence.

On the Inspection+User Tester Editor screen (**Figure 129**), controls are provided for modifying Title 1, Title 2, Tester Port Number (1 to 6) and Tester Port Baud Rate (2400 to 19200 baud). If the Inspection/AutoSequence does not issue remote control commands to externally connected test instruments, then the Tester Port can be set to "unused" and the Baud Rate left blank. Normally, this is the case for Physical Inspections. Items from the Checkitem Database, listed in the table on the left, can be added to and removed from the Inspection/Autosequence ("test sequence") on the right by using the appropriate buttons in the center margin of the screen.
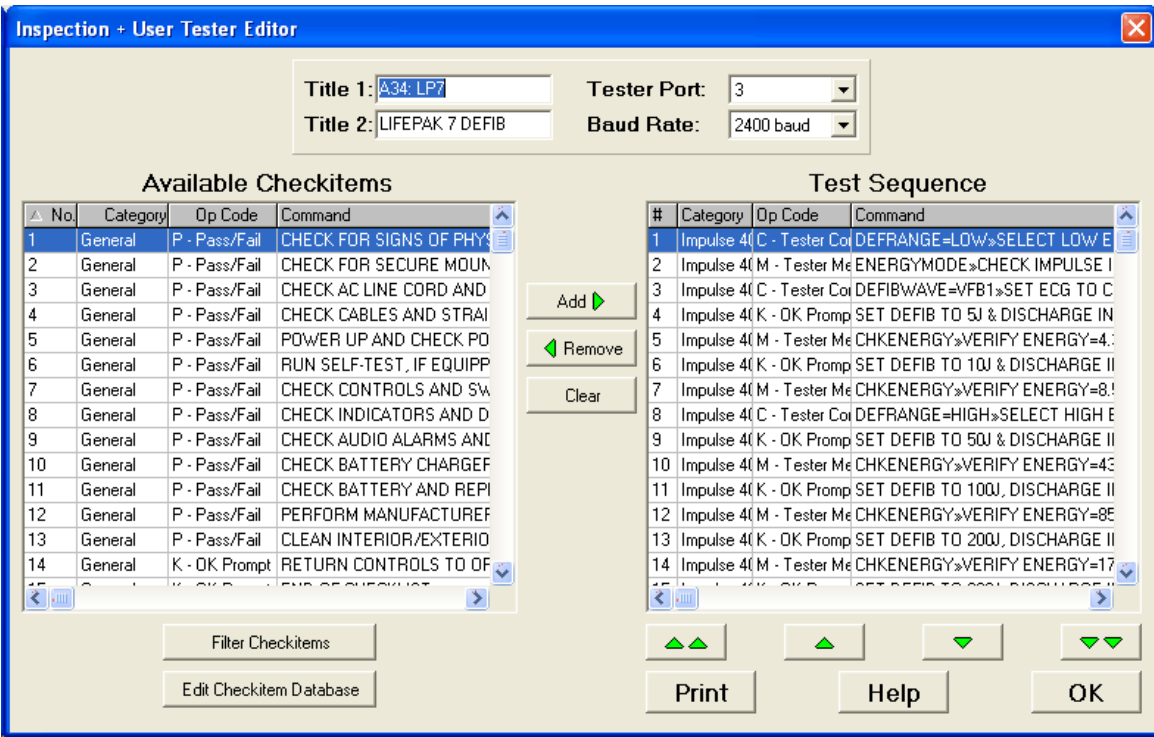
Figure 131 - *Inspection or User Tester Editor window.*

All Checkitems can be removed from the test sequence by pressing the "Clear" button in the center margin. Sequence contents can be re-ordered by selecting the desired Checkitem in the sequence and using the "Up" or "Down" arrows below the column to move the selected item up or down. The selected item can be

moved to the top or bottom of the sequence by using the Double Up or Down arrows. The "Print" button opens a standard Windows Print dialog, allowing the test sequence on the right to be sent to a printer.

Available Checkitems listed on the left of the window can be created or modified by clicking the "Edit Checkitem Database" button. This button appears on the main Inspections/Autosequences window and on the Inspection+User Tester Editor screen (*Figure 129*). Refer to Section 8.9.4 for more information on the Checkitem Database Editor.

8.11 Equipment Record Module

ES601-US "***Equipment Records***" relate an equipment control number of a medical device to a Checklist, allowing you to initiate comprehensive inspection and performance testing activities for a specific piece of equipment simply by entering the control number of the equipment into the ES601-US. Such control numbers can be entered using the QWERTY touch keypad of the analyzer, or by an external PS/2 keyboard, or by an external barcode scanner.

Equipment Records are created with the Equipment Record Editor for the ES601pc-US software package. The Editor allows you to create and/or modify up to 18432 Equipment Records which can then be loaded into the non-volatile memory of the ES601-US.

Additionally, the Editor allows you to input and save additional information about each device, such as description, make, model, and several other equipment details. Although this extra information is not communicated to the ES601-US and saved in its memory, any additional information you may input is retained in the file system of the Equipment Record Editor. In conjunction with the Checklist Editor and Test Report Generator of ES601pc-US, the Equipment Record Editor provides you with a simple computer-based system for equipment tracking and maintenance, including means for:

- creating and monitoring an equipment inventory;

- retaining and reviewing the service history of equipment in your inventory; and

- creating PM inspection procedures for specific types of equipment.

If you already have a PC-based equipment management system (CMMS), the Equipment Record Editor provides data importing features that allow ES601-US Equipment Records to be easily and rapidly generated from pre-existing equipment information exported from your CMMS database.

To run the Equipment Record Editor, click on the "Equipment Record Editor" button on the ES601pc-US main menu. The Equipment Record Table will then appear (***Figure 130***).

To provide an example how to develop an equipment database in ES601pc-US, one-thousand default Equipment Records with control numbers ranging from "CN0001" to "CN1000" are initially installed along with the software. As shown in ***Figure 130***, all control numbers are set up to link to Checklist #2, a short preventative maintenance inspection procedure which is named "QUICK PM PROCEDURE". The details of this procedure can be seen using the Checklist Editor, described in Section 8.9.
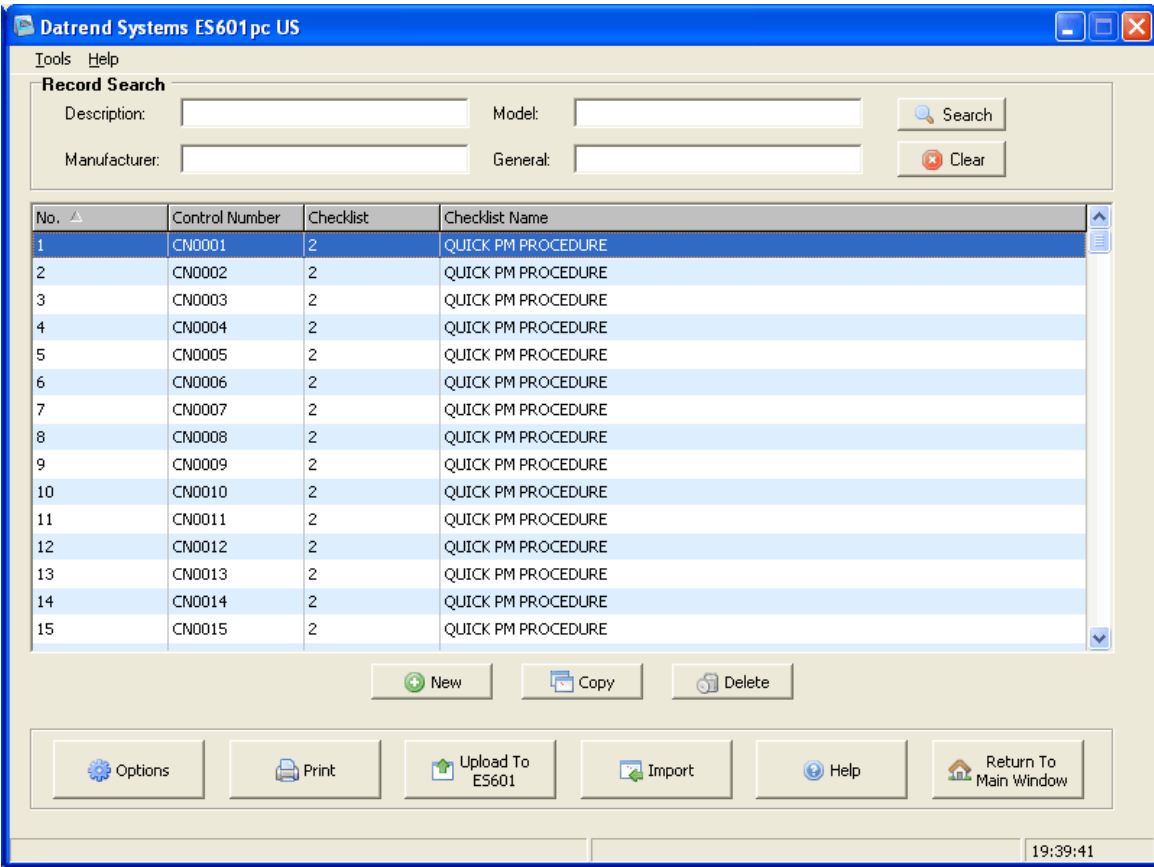
Figure 132 *- Equipment Record main menu.*

8.11.1 Creating A New Equipment Record

To create a new Equipment Record, click the "New" button below the Equipment Record Table. This will cause a new entry to be added at the end of the Table. The Equipment Record Editor will then appear, allowing you to enter specific information about the device such as its control number, make, model and so on.

8.11.2 Copying Equipment Records

To copy one or more pre-existing Equipment Records, click on a specific Record in the Table or click and drag the mouse over a group of consecutive Records, and then click "Copy". At the end of the Table, new Records will be created having the same attributes as the selected Records, except the control number field of each new Record will be left blank for later editing.

8.11.3 Deleting Equipment Records

To delete one or more Equipment Records, click on a specific Record in the Table or click and drag the mouse over a group of consecutive Records, and then click "Delete". You will be asked to confirm the deletion. Click "Yes", and the selected Records will be removed from the Table.

8.11.4 Editing Equipment Records

To edit the contents of an Equipment Record, double-click the Record in the Equipment Record Table, or select a Record and hit the <Enter> key on the keyboard. The Equipment Record Editor will appear.
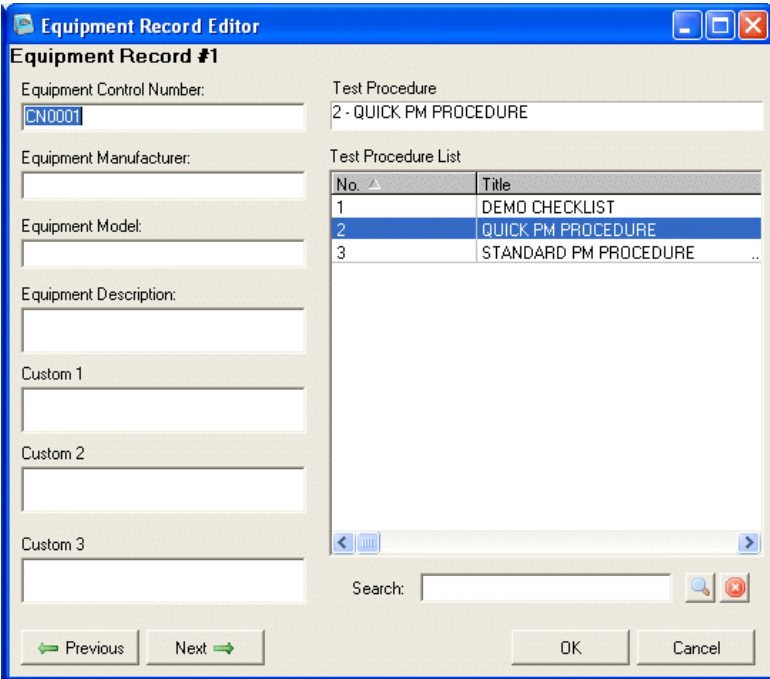
Figure 133 - *Record Editor menu.*

Text boxes are provided allowing you to input an Equipment Control Number, Manufacturer, Model, and Description. The Editor also provides three user-defined Custom Fields into which you can enter any desired information.

The Checklist to be associated with the Control Number is selected by clicking on a Checklist in the list at the right of the dialog. If there are a large number of Checklists, enter part or all of the Checklist's name in the Search box, and then click the "Search" button or hit the <Enter> key on the keyboard. The list will then be filtered according to what you entered in the Search box. To restore the full listing, click the "Search Clear" button to the right of the "Search" button.

To view the previous or next Equipment Record in the system without returning to the Equipment Record Table, click the "Previous" or "Next" buttons of the Equipment Record Editor.

Click "OK" to save the changes entered via the Editor, or click "Cancel" to return to the Equipment Record Table without saving.

Of the information you may potentially input via the Editor dialog, only the Control Number and the Checklist number will be transmitted to the ES601-US for storage in the non-volatile memory of the safety analyzer. Any additional equipment information you may input, such as Model or Description, is saved to disk by the Editor but it is not transmitted to the ES601-US since the information is not needed by the safety analyzer in order to run the Checklist. However, the additional equipment information you may choose to enter into a Record may prove helpful later on, when reviewing Equipment Records to determine how Checklists were assigned to Control Numbers in your system, or when creating new Equipment Records for devices added to your system in the future.

8.11.5 Searching Equipment Records

To search Equipment Records, enter search terms in one or more of the Search boxes located above the Equipment Record Table (see **_Figure 130_**). After entering one or more Search terms, you may then click the "Search" button or hit the <Enter> key on the keyboard. To search based on an equipment description, enter part or all of the description into the "Description" Search textbox. To search manufacturers, use the "Manufacturer" Search textbox. To search by equipment model name or number, use the "Model" Search textbox. To search all text fields provided by the Equipment Records, use the "General" Search textbox.

When the "Search" button is clicked, the Equipment Record Table is filtered by the search terms entered. Entering search terms into more than one search box will display all Equipment Records that include any of the terms specified.

To restore the full listing of Equipment Records after a search, click the "Search Clear" button below the "Search" button.

8.11.6 Importing Equipment Records

To import Equipment Records from a Comma Separated Values (CSV) file, click the "Import" button below the Equipment Record Table (see ***Figure 130***). The Import Equipment Records dialog will then appear, as shown below. Click "Browse" to select the CSV file containing the equipment data.
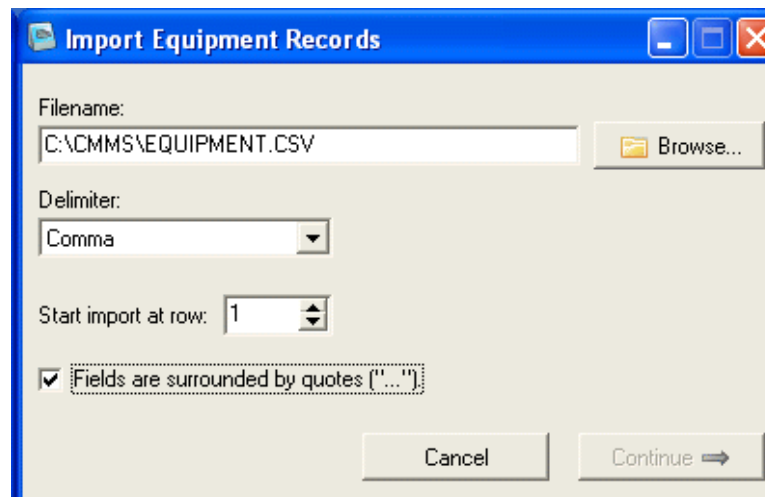
Figure 134 *- Import dialog.*

Each line of the CSV file must correspond to one piece of equipment, which typically will be identified by a unique control number in an equipment management system. The information fields appearing in each line of the equipment data are referred to as "columns" by the Equipment Record importer. In each line of equipment data, the columns must be delimited by a specific character, and the same character must be used consistently throughout the CSV file to delimit the columns. The delimiter character can be specified through the Delimiter dropdown list of the Import Records dialog. To specify a delimiter other than those appearing in the list, select "Other" and then enter a single character into the Delimiter textbox which appears.

If one or more lines at the beginning of the CSV file do not contain equipment information, use the spinner buttons to specify the number of lines to be skipped at the start of the file. The value shown corresponds to the line number of the CSV file at which equipment data importing will begin.

If the equipment information fields or columns are, in addition to being separated by a delimiter, also surrounded by quotation characters ("), then check the "Fields are Surrounded by Quotes" box on the Import Records dialog.

Once the import settings have been selected, click the "Continue" button. If the "Continue" button is not enabled, either the filename or the delimiter has not been entered correctly. Make sure the CSV file exists and review your delimiter settings in this case.

After "Continue" is clicked, the Import Records dialog will change appearance and will show how the first line of equipment-related information in the CSV file will be imported (**Figure 133**). Via this dialog, you can choose which CSV data fields or columns are mapped to the fields of the Equipment Record. The fields of the Equipment Record are listed on the left-hand side of the dialog and include "Device ID" (control number); "Device Description"; "Manufacturer"; and so on. Three "Custom" fields which can contain arbitrary data are also provided.
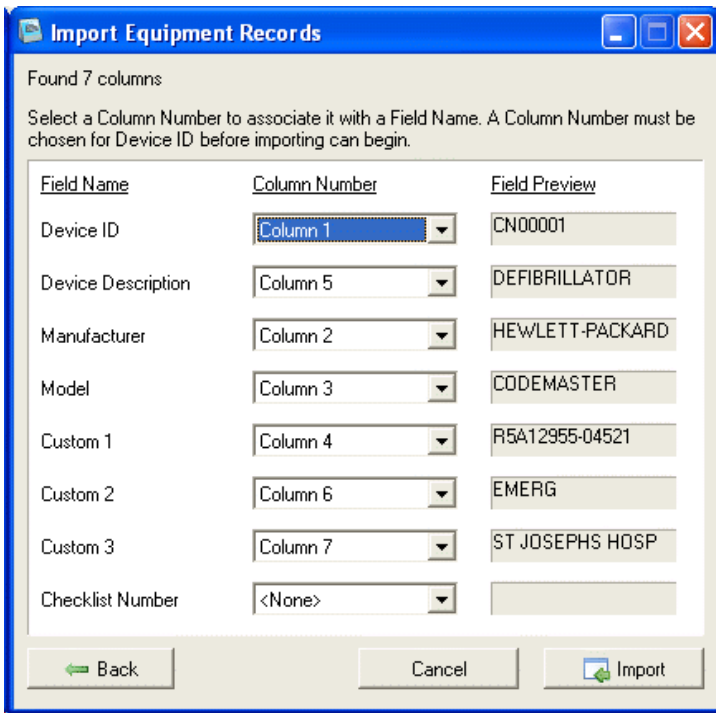
Figure 135 - *Data import options.*

Refer to Appendix D for an illustrative example of importing Equipment Records into ES601pc-US, from a CSV export file produced by a CMMS.

8.11.7 Uploading Equipment Records

To upload to ES601-US, press the "Upload To ES601" button. Choose uploading via USB, Ethernet, or Serial Port, and then press "Connect". If the connection is via ethernet, enter in the IP address assigned to ES601-US (the IP address of ES601-US is displayed on the LCD when ES601-US is operating in Ethernet Mode). If the connection is via serial port, choose the COM port to which ES601-US is connected.

After pressing "Connect", a message box with a transfer progress bar will appear. After the transfer is completed, a Transfer Complete message will appear and the message box will disappear.

8.11.8 Printing Equipment Records

To print Equipment Records, click the "Print" button below the Equipment Record Table (see *Figure 130*). You may optionally choose to print all Records, selected Records, or filtered results as they are currently being shown in the Table (*Figure 134*). As well, certain Equipment Record fields can be excluded from the printout, by unchecking the box corresponding to the undesired information. By default, all fields of the Equipment Record are included in the printout.
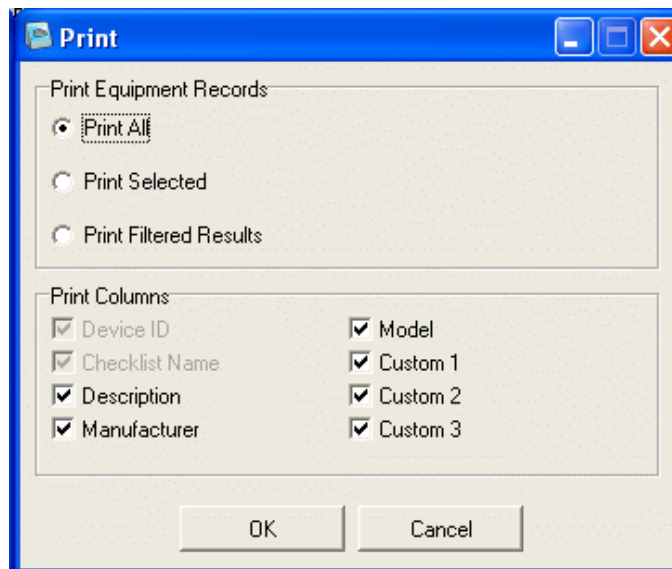
Figure 136 - *Record printing options.*

8.11.9 Record Viewing Options

To modify the viewing options of the Equipment Record Table, click the "Options" button below the Table (see *Figure 130*). The Options dialog will then appear (*Figure 135*). Columns can be unchecked and excluded from view in the Table. The names assigned to the three Custom fields of the Equipment Record can also be edited via the textboxes provided. Click "OK" to accept and save the changes, or click "Cancel" to return to the Equipment Record Table without saving.

Figure 137 - *Record viewing options.*

8.12 CMMS Interface Module

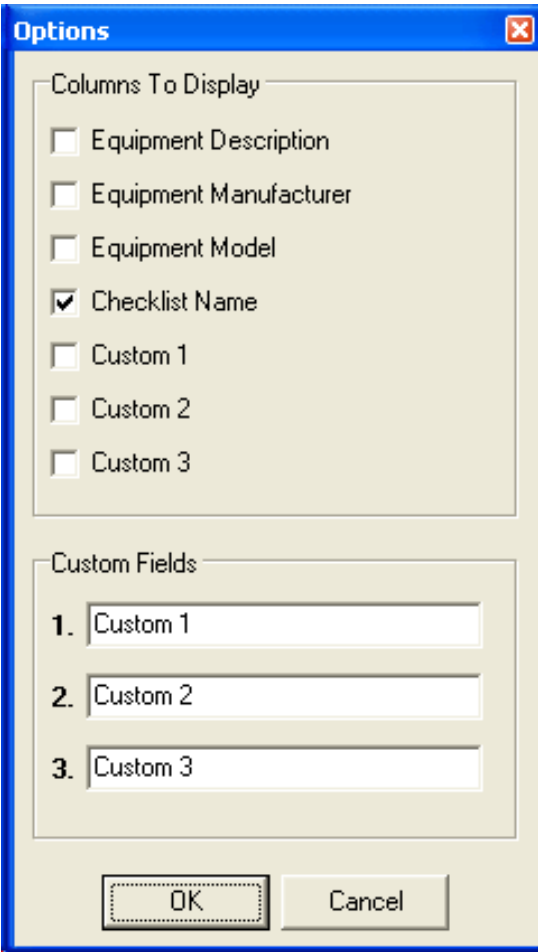*__HEMS Enterprise__* from EQ2 Inc. provides comprehensive support of ES601-US with a direct data interface. Users can create ES601-US Checklists and Equipment Records within *__HEMS__* and export them directly from the CMMS to ES601-US via a USB connection. *__HEMS__* can also download ES601-US Test Records directly from the analyzer into the maintenance record system. Refer to *__HEMS__* user guides for more information.

The CMMS Interface Module described in this section provides a "data communication bridge" to computerized maintenance systems which do not currently provide a direct interface to ES601-US, as described below.

The CMMS Interface Module of ES601pc-US imports checkitems, checklists, and equipment control numbers from a Computerized Maintenance Management System (CMMS), and transmits this data to the ES601-US analyzer. The CMMS Interface Module also reads test results stored in the ES601-US analyzer and prepares a test result data file in a specific format, which can then be imported by the CMMS.

The CMMS Interface Module is intended to work in conjunction with CMMS applications that currently provide an interface to Fluke Biomedical medTester by means of "*__MTEXPORT__*" and "*__MUP__*" data files. CMMS packages which use the "MTEXPORT" and "MUP" file interface include *__Sentinel32__* and *__TMA.__*

8.12.1 Exporting CMMS Data to ES601-US

To load CMMS data into the ES601-US analyzer, you must first create export files for a medTester from within the CMMS. The export files required are designated MTEXPORT.ITM, MTEXPORT.LST, and MTEXPORT.IDN by the CMMS.

If the CMMS is Sentinel32, generate these files by selecting "medTester Serial Interface" from the main menu of the Sentinel32 program. Click the "Medtester Data Selection" button and verify that the radio buttons for Equipment Selection and Checklist Selection are set as you require. Click the "Send Data" tab, then click the button marked "Prepare medTester 5000C Export Files Only". This will cause Sentinel32 to generate medTester data files containing checkitems, checklists, and equipment control numbers. You now have the data you need to port over to the ES601Plus.

If you are running TMA, and you have previously transferred PM checklists to a medTester 5000C, then the required MTEXPORT data files exist and there is no need for you to regenerate them. If MTEXPORT files have never been created on your system, in TMA navigate to "Transactions > Generate PMs". Check the box for "medTester PM's". From the "Other Functions" drop-down, select either "Send all checklists..." or "Send filtered checklists..." according to your requirements. TMA will create the MTEXPORT files, after which the files will then be transmitted to a medTester safety analyzer. If no medTester is connected to your computer, the data transfer will time out, however, the MTEXPORT files will now exist and will provide the data needed for porting to the ES601-US.

After having used your CMMS to produce the MTEXPORT files, minimize or exit the CMMS, run ES601pc-US, and then click the "**CMMS Interface**" button. When the plugin runs, the CMMS Interface will look for the three MTEXPORT files (MTEXPORT.ITM, MTEXPORT.LST and MTEXPORT.IDN) in the folder specified in the "CMMS File Folder..." textbox. If the three files are found, the "Export..." button of the CMMS Interface will be enabled, as shown below.
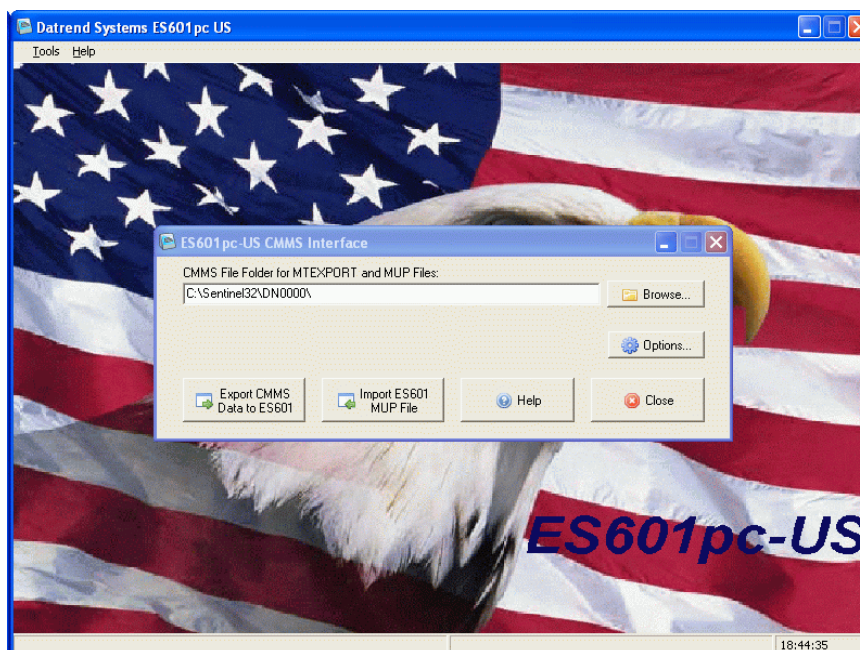
Figure 138

If the MTEXPORT files are not found, an error mesage will be displayed to you. In this case, use the Browse button on the dialog to select the path to the location of the MTEXPORT files. If you are running Sentinel32, browse to the folder where Sentinel32 is installed, and then select the "DN0000" folder. If you are running TMA, browse to the "MT" folder. If you are unable to locate the files by browsing your local drives, try using Windows Search to find them.

When you click "Export CMMS Data...", the plugin will warn you that ES601pc-US Checklists, Equipment Records, and all Checkitems of category type 'Z' will be overwritten with data from the CMMS. Checkitems from the CMMS will be assigned to the 'Z' Instruction category, which will be given the category name "CMMS". Before starting the import, ES601pc-US will automatically make a backup of its current data, including all Checklist, AutoSequences, Checkitems and other configuration-related data. If desired, this data can be restored later using the "Backup And Restore" feature provided by the ES601pc-US main menu.

Before the export starts, a communications selector will appear. Choose to communicate via USB, Ethernet, or Serial Port, and then press "Connect". If the connection is via ethernet, enter the IP address assigned to the ES601-US (note this IP address is displayed on the LCD when the analyzer is operating in "Ethernet Mode"). If the connection is via serial port, choose the COM port to which the ES601-US is connected.
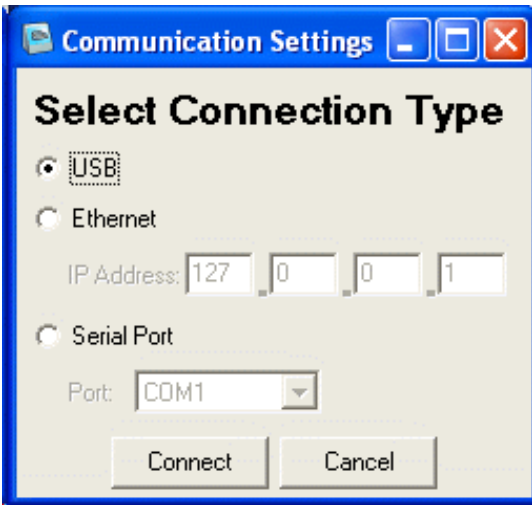
Figure 139

Once the communication options have been set, the CMMS Interface will then start the conversion and transmission of CMMS data to the ES601-US analyzer. The process involves converting the imported data into ES601-compatible format, backing up the existing data of ES601pc-US, saving the newly-converted CMMS data to disk, and then uploading the information into the non-volatile memory of the safety analyzer.
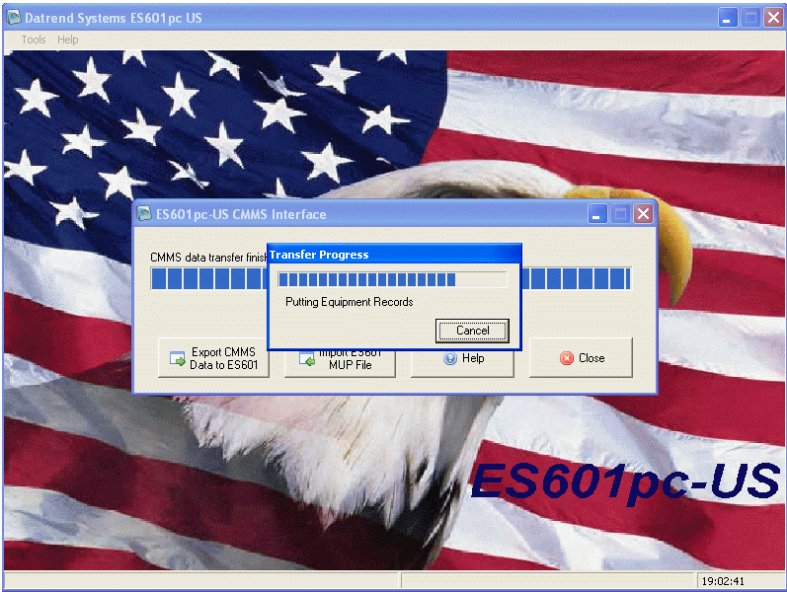
Figure 140

8.12.2 Importing a MUP File from ES601-US

The CMMS Interface allows test results from the ES601-US analyzer to be brought into the CMMS program, by converting the results into a medTester-style "MUP" file. The CMMS can then read this "MUP" file into its Work Order system.

To begin the import process, click the "Import ES601 MUP File" button of the CMMS Interface. The communications selector will appear. After choosing a communications method, a "Save File" dialog will appear. Select the directory and filename for the "MUP" file produced by the CMMS Interface. The default directory is the directory specified in the textbox on the dialog, and the default filename will follow the medTester's naming convention of month, day, hour, and minutes (each specified as 2-digit numbers), followed by a ".MUP" file extension (e.g.: 02171432.MUP, corresponding to Feb. 17, 14:32).
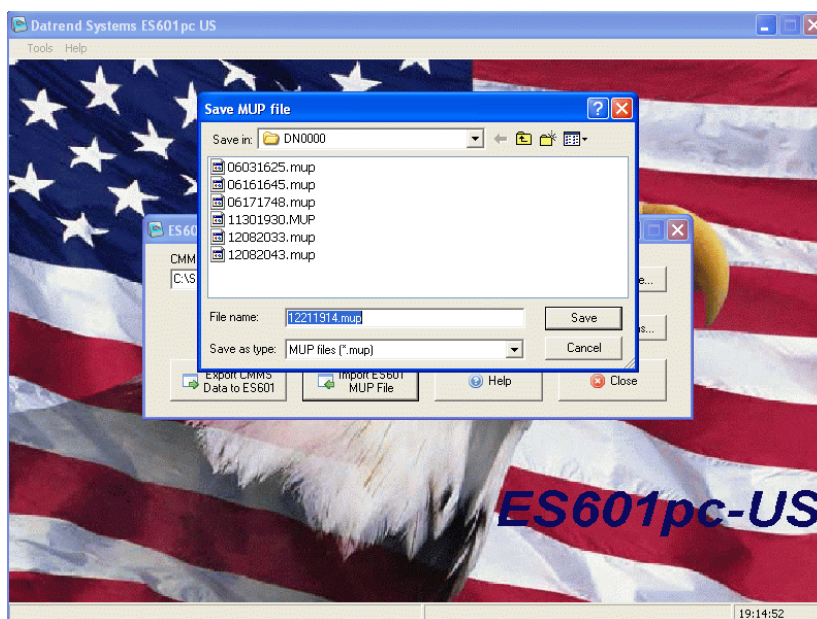
Figure 141

After selecting the default or entering an alternative name for the exported file, the plugin will then begin to download Test Report data from the ES601-US. The test results will then be converted into medTester "MUP" format, and will be saved to the folder specified on the dialog.

Once the "MUP" file has been generated by the CMMS Interface, you may then read this file into the CMMS in exactly the same way as if the file had been produced by a medTester. For example, to import a "MUP" file in Sentinel32, select "medTester Serial Interface" from the main menu of the program. Click the "Receive Data" tab, then click the button marked "Update Sentinel From Existing medTester File". Sentinel32 will display an "Open File" dialog from which you can select the "MUP" file created by the CMMS Interface plugin.

8.12.3 Modifying Options

The CMMS Interface provides user-selectable options that determine how medTester checkitems created within the CMMS are converted into checkitems for the ES601-US analyzer. To open the Options window of the CMMS Interface, click the "Options" button.
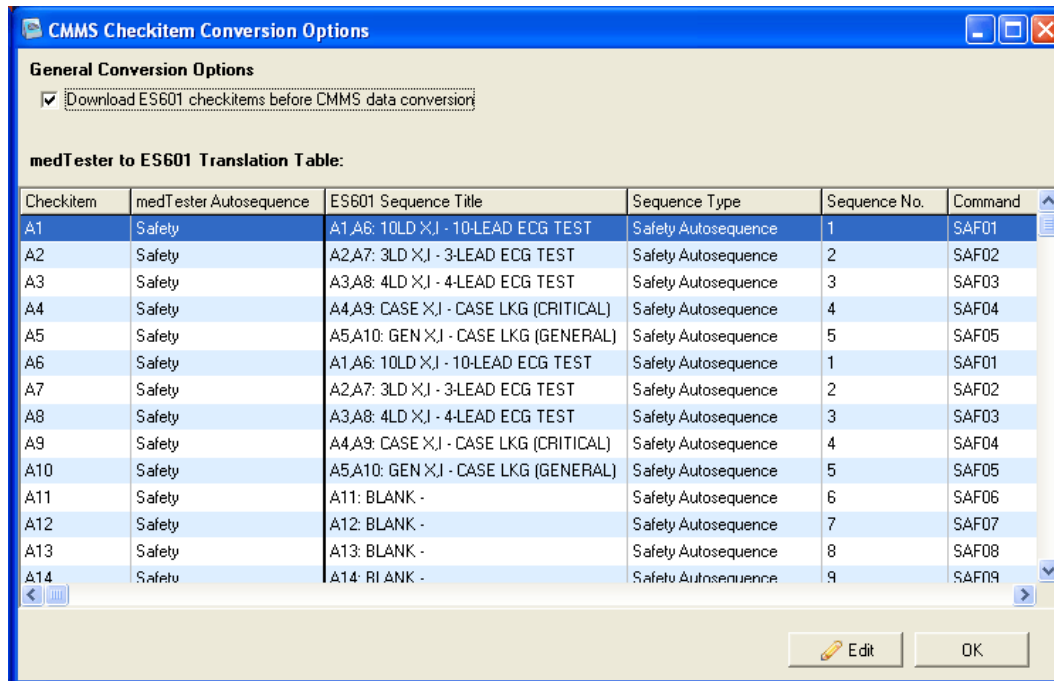
Figure 142 - Checkitem Conversion Options menu.

8.12.3.1 Download Checkitems Option

The Options dialog (*Figure 140*)provides a checkbox designated as: "Download ES601 checkitems before exporting CMMS checkitems". If this box is checked, the plugin will download the Checkitem Database currently stored in the memory of the ES601-US, immediately before it opens the MTEXPORT data from the CMMS. The purpose of this option is to make sure that certain AutoSequence data stored in the safety analyzer is correctly preserved before the export process modifies the Checkitem Database in the analyzer. As such data preservation is essential to successful conversion, the safest option is to always leave this box checked. The consequence is that the conversion process will require a few seconds longer to complete due to the download time. If you are already certain that AutoSequence-related Checkitems in the ES601-US are synchronized with ES601pc-US, then the preliminary download operation is unnecessary and this box can then be unchecked.

8.12.3.2 medTester-to-ES601 Translation Table

The Translation Table of the Options dialog (**Figure 140**) shows how medTester Autosequence checkitems (designated in the CMMS by "A" checkitems) will be converted by ES601pc-US into corresponding AutoSequences for the ES601-US analyzer (designated by commands listed at extreme right in the table, such as "SAF..." or "UT..."). On installation of ES601pc-US, default AutoSequence files for the ES601-US analyzer are installed and the Translation Table of the CMMS Interface is initialized to suit these default AutoSequences, as shown in **Figure 140**. If you modify a ES601-US AutoSequence in ES601pc-US, it may then be necessary to choose a different AutoSequence in the CMMS Translation Table, so that the ES601-US analyzer operates as expected when running a medTester checklist produced by the CMMS.

Chapter

9

9   Calibration and Maintenance

Calibration of ES601-US by a Datrend Authorized Service facility is recommended on an ***annual*** basis, and is ***required*** to extend the product warranty. The basic one (1) year warranty can be extended to a maximum of five (5) years provided that annual calibration is performed by a Datrend Authorized Service Center on an ***annual*** basis. Refer to the Calibration Decal applied to the rear panel of the unit to determine calibration status of your ES601-US.

ES601-US contains no user serviceable parts, other than two 1 Amp/250V AGC fuses located on the back panel. Certain functions of ES601-US are internally fused (isolated AC supply on patient leads, internal voltmeter). Failure of these functions will require return of ES601-US to an authorized service facility for repair. ***Opening the case of ES601-US for any reason will void the warranty and may compromise user safety.***

For calibration or service assistance, contact Datrend for a Return Materials Authorization (RMA) number and the location of the nearest Service Facility.

Datrend Systems Inc.
Unit 130 - 4020 Viking Way
Richmond, BC • CANADA • V6V 2L4
Tel 604.291.7747 or 800.667.6557 • Fax 604.294.2355
e-mail **customerservice@datrend.com**
www.datrend.com

ES601-US should be cleaned with a soft, lint free, damp cloth using a mild detergent. Use of other cleaning agents on the touch screen may result in scratching, discolouration, streaking or even failure.

⚠️ Electrical safety protection of the operator may be compromised if the instructions in this manual are not followed, or if ES601-US is used for a purpose not specified in this manual.

ES601-US OPERATING MANUAL
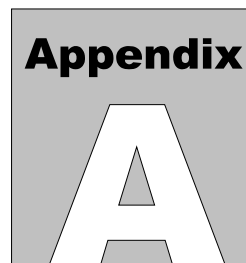
APPENDIX A. Safety AutoSequences

The following are the default Safety AutoSequences of ES601-US. ES601-US is supplied with these AutoSequences pre-loaded in the flash memory. The default AutoSequences may be modified using the ES601pc-US software, supplied on CDROM with ES601-US.

AutoSequences in the following list are identified as "*SAFETY AUTOSEQUENCE #NN (SAFNN).*" (SAFNN) refers to the command assigned by Datrend to the AutoSequence, to allow the AutoSequence to be invoked from a Checklist (see **Automated Testing Principles**, Chapter 6; and **Checklist Editor**, Chapter 8).

SAFETY AUTOSEQUENCE 1   (SAF01)
A1,A6: 10LD X,I
10-LEAD ECG TEST

```
Standard: AAMI-ES1
Limits Used: AAMI-ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
   Equipment Power: On/Off
   Polarity: Normal/Reverse
   Neutral: Normal/Open
   Ground: Normal/Open
   Test External and Internal Case Leakages, plus:
      Patient Leads
      Lead to Lead Leakages
Patient Lead Groups
   Group 1:
      Name: ECG
      Type: Isolated
      Leads: 10
      LD 1 - RA
      LD 2 - RL
      LD 3 - LA
```

```
            LD 4 - LL
            LD 5 - V1
            LD 6 - V2
            LD 7 - V3
            LD 8 - V4
            LD 9 - V5
            LD 10 - V6
```

SAFETY AUTOSEQUENCE 2 (SAF02)
A2,A7: 3LD X,I
3-LEAD ECG TEST

```
Standard: AAMI-ES1
Limits Used: AAMI-ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
   Equipment Power: On/Off
   Polarity: Normal/Reverse
   Neutral: Normal/Open
   Ground: Normal/Open
   Test External and Internal Case Leakages, plus:
      Patient Leads
      Lead to Lead Leakages
Patient Lead Groups
   Group 1:
      Name: ECG
      Type: Isolated
      Leads: 3
      LD 1 - RA
      LD 2 - RL
      LD 3 - LA
```

SAFETY AUTOSEQUENCE 3 (SAF03)
A3,A8: 4LD X,I
4-LEAD ECG TEST

```
Standard: AAMI-ES1
Limits Used: AAMI-ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Skip
```

```
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
    Equipment Power: On/Off
    Polarity: Normal/Reverse
    Neutral: Normal/Open
    Ground: Normal/Open
    Test External and Internal Case Leakages, plus:
        Patient Leads
        Lead to Lead Leakages
Patient Lead Groups
    Group 1:
        Name: ECG
        Type: Isolated
        Leads: 4
        LD 1 - RA
        LD 2 - RL
        LD 3 - LA
        LD 4 - LL
```

SAFETY AUTOSEQUENCE 4   (SAF04)
A4,A9: CASE X,I
CASE LKG (CRITICAL)

```
Standard: AAMI-ES1
Limits Used: AAMI-ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
    Equipment Power: On/Off
    Polarity: Normal/Reverse
    Neutral: Normal/Open
    Ground: Normal/Open
    Test External and Internal Case Leakages
Patient Lead Groups
        None
```

SAFETY AUTOSEQUENCE 5 (SAF05)
A5,A10: GEN X,I
CASE LKG (GENERAL)

```
Standard: AAMI-ES1
Limits Used: User-Defined Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
    Equipment Power: On/Off
    Polarity: Normal/Reverse
    Neutral: Normal/Open
    Ground: Normal/Open
    Test External and Internal Case Leakages
Patient Lead Groups
       None
```

SAFETY AUTOSEQUENCE 6 (SAF06)
A11: BLANK

```
Standard: AAMI-ES1
Limits Used: AAMI-ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Skip
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Skip
Leakage Current: Skip
Patient Lead Groups
       None
```

SAFETY AUTOSEQUENCE 7 (SAF07)
A12: BLANK

```
See  SAFETY  AUTOSEQUENCE  6
```

SAFETY AUTOSEQUENCE 8 (SAF08)
A13: BLANK

See SAFETY AUTOSEQUENCE 6

SAFETY AUTOSEQUENCE 9 (SAF09)
A14: BLANK

See SAFETY AUTOSEQUENCE 6

SAFETY AUTOSEQUENCE 10 (SAF10)
A15: BLANK

See SAFETY AUTOSEQUENCE 6

SAFETY AUTOSEQUENCE 11 (SAF11)
A16: LINEMON
AC LINE TEST

```
Standard: AAMI-ES1
Limits Used: AAMI-ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Skip
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Skip
Leakage Current: Skip
Patient Lead Groups
       None
```


SAFETY AUTOSEQUENCE 12 (SAF12)
A17: ENVMON
GROUNDING TEST

```
Standard: AAMI-ES1
Limits Used: AAMI-ES1 Limits
Equipment Class: Class I
Line Voltage: Skip
Load Current: Skip
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured at 1 Amp
Leakage Current: Skip
```

```
Patient Lead Groups
      None
```

SAFETY AUTOSEQUENCE 13 (SAF13)
IEC60601 TEST
GENERAL DEVICE

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
    Equipment Power: On
    Polarity: Normal/Reverse
    Neutral: Normal/Open
    Ground: Normal/Open
    Test External and Internal Case Leakages
Patient Lead Groups
      None
```

SAFETY AUTOSEQUENCE 14 (SAF14)
IEC60601 TEST
DEFIBRILLATOR

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
    Equipment Power: On
    Polarity: Normal/Reverse
    Neutral: Normal/Open
    Ground: Normal/Open
    Test Touch Current and Earth Leakage, plus:
        Patient Leads
        Lead-to-Lead Leakages
Patient Lead Groups
    Group 1:
        Name:  ECG
```

```
        Type: CF
        Leads: 4
              LD 1 -  RA
              LD 2 -  RL
              LD 3 -  LA
              LD 4 -  LL
     Group 2:
        Name:  PADDLES
        Type: CF
        Leads: 2
              LD 5 -  APEX
              LD 6 -  STERNUM
```

SAFETY AUTOSEQUENCE 15 (SAF15)
IEC60601 TEST
DIAGNOSTIC ECG

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
     Equipment Power: On
     Polarity: Normal/Reverse
     Neutral: Normal/Open
     Ground: Normal/Open
     Test Touch Current and Earth Leakage, plus:
          Patient Leads
           Lead to Lead Leakages
Patient Lead Groups
     Group 1:
        Name:  ECG
        Type: CF
        Leads: 10
              LD 1 -  RA
              LD 2 -  RL
              LD 3 -  LA
              LD 4 -  LL
              LD 5 -  V1
              LD 6 -  V2
              LD 7 -  V3
              LD 8 -  V4
              LD 9 -  V5
              LD 10 -  V6
```

SAFETY AUTOSEQUENCE 16   (SAF16)
IEC60601 TEST
MULTI-PARAM MONITOR

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
     Equipment Power: On
     Polarity: Normal/Reverse
     Neutral: Normal/Open
     Ground: Normal/Open
     Test Touch Current and Earth Leakage, plus:
         Patient Leads
         Lead-to-Lead Leakages
Patient Lead Groups
     Group 1:
         Name:   ECG
         Type: CF
         Leads: 5
             LD 1 -  RA
             LD 2 -  RL
             LD 3 -  LA
             LD 4 -  LL
             LD 5 -  V
     Group 2:
         Name:   IBP
         Type: CF
         Leads: 2
             LD 6 -  BP1
             LD 7 -  BP2
     Group 3:
         Name:   TEMP
         Type: BF
         Leads: 1
             LD 8 -  PROBE
```

SAFETY AUTOSEQUENCE 17   (SAF17)
IEC60601 TEST
BLANK

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Skip
Insulation Resistance - Hot+Neutral to Ground: Skip
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Skip
Leakage Current: Skip
Patient Lead Groups
     None
```

SAFETY AUTOSEQUENCE 18   (SAF18)
IEC60601 TEST
BLANK

```
See SAFETY AUTOSEQUENCE 17
```

SAFETY AUTOSEQUENCE 19 (SAF19)
IEC62353 TEST
GENERAL DEVICE

```
Standard: IEC62353
Limits Used: IEC62353 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Measure
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measure
Leakage Current: Measure
     Protocol: Direct Method
     Polarity: Normal/Reverse
Patient Lead Groups
     None
```

SAFETY AUTOSEQUENCE 20   (SAF20)
IEC62353 TEST
DEFIBRILLATOR

```
Standard: IEC62353
Limits Used: IEC62353 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Measure
Insulation Resistance - Patient Leads to Ground: Measure
Ground Resistance: Measure
Leakage Current: Measure
     Protocol: Direct Method
     Polarity: Normal/Reverse
     Test Patient Leads
Patient Lead Groups
     Group 1:
         Name:   ECG
         Type: CF
         Leads: 4
             LD 1 -  RA
             LD 2 -  RL
             LD 3 -  LA
             LD 4 -  LL
     Group 2:
         Name:   PADDLES
         Type: CF
         Leads: 2
             LD 5 -  APEX
             LD 6 -  STERNUM
```

SAFETY AUTOSEQUENCE 21   (SAF21)
IEC62353 TEST
DIAGNOSTIC ECG

```
Standard: IEC62353
Limits Used: IEC62353 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Measure
Insulation Resistance - Patient Leads to Ground: Measure
Ground Resistance: Measure
Leakage Current: Measure
     Protocol: Direct Method
     Polarity: Normal/Reverse
     Test Patient Leads
```

```
Patient Lead Groups
    Group 1:
        Name:  ECG
        Type: CF
        Leads: 10
            LD 1 -  RA
            LD 2 -  RL
            LD 3 -  LA
            LD 4 -  LL
            LD 5 -  V1
            LD 6 -  V2
            LD 7 -  V3
            LD 8 -  V4
            LD 9 -  V5
            LD 10 -  V6
```

SAFETY AUTOSEQUENCE 22 (SAF22)
IEC62353 TEST
MULTI-PARAM MONITOR

```
Standard: IEC62353
Limits Used: IEC62353 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Measure
Insulation Resistance - Patient Leads to Ground: Measure
Ground Resistance: Measure
Leakage Current: Measure
    Protocol: Direct Method
    Polarity: Normal/Reverse
    Test Patient Leads
Patient Lead Groups
    Group 1:
        Name:  ECG
        Type: CF
        Leads: 5
            LD 1 -  RA
            LD 2 -  RL
            LD 3 -  LA
            LD 4 -  LL
            LD 5 -  V
    Group 2:
        Name:  IBP
        Type: CF
        Leads: 2
            LD 6 -  BP1
            LD 7 -  BP2
    Group 3:
```

```
        Name:   TEMP
        Type: BF
        Leads: 1
            LD 8 -  PROBE
```

SAFETY AUTOSEQUENCE 23 (SAF23)
VDE0751 TEST
GENERAL DEVICE

```
Standard: VDE 0751
Limits Used: VDE 0751 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Hot+Neutral to Ground: Measure
Insulation Resistance - Patient Leads to Ground: Skip
Ground Resistance: Measure
Leakage Current: Measure
    Protocol: Direct Method
    Polarity: Normal
Patient Lead Groups
    None
```

SAFETY AUTOSEQUENCE 24 (SAF24)
IEC61010
LABORATORY DEVICE

```
Standard: IEC61010
Limits Used: IEC61010 Limits
Line Voltage: Measure
Load Current: Measure
Insulation Resistance: Skip
Ground Resistance: Measured At 1 Amp
Leakage Current: Measure
    Polarity: Normal/Reverse
    Neutral: Normal/Open
    Ground: Normal/Open
```

Appendix

B

APPENDIX B. Sample Test Record

Below is an example of a report created by the Test Report Generator of ES601pc-US. The ES601-US analyzer also has the capability of generating a report document similar to the one shown here, which can be output via the Printer Port or RS-232 Port as described in Chapter 5.

```
***************** TEST RECORD No. 22 *****************

                  Test Report

         ES601: ES071200050 Ver.: 4.00
          I.D.: MY ES601

        Control No.: CN0472
          Date/Time: 18 DEC 2011 12:14:02

Type::      DEFIB W. PCR+SPO2  Make:  HEWLETT-PACKARD
Serial No.: A14-567100E        Model: CODEMASTER XL+
Facility:   ST. JOSEPH'S HOSP  Loc.:  EMERG

Tech Code:  MEM
Test Time:  00:14:40

******************* SAFETY TEST *******************
STANDARD: IEC60601              LIMITS: PER STANDARD
AUTOSEQ.: 15                     CLASS: I

    GROUND FAULT: NONE

    LINE VOLTAGE: HOT-NEUT   HOT-GND   NEUT-GND
                  120.0 V    120.0 V    2.3 V

    LOAD CURRENT:  0.43 AMPS

INSULATION RESISTANCE     LIMIT    UNITS
  HOT+NEUT TO GND: 999.9   ---.-   MEGOHMS
     LEADS TO GND: 999.9   ---.-   MEGOHMS

-------------- GROUND RESISTANCE TEST ---------------
LIMIT:   0.200 OHMS          MULTIPLE GND TEST: NO
OFFSET:  -.--- OHMS            LINE CORD TEST: YES
CURRENT: +/-1A DC             POINT TO POINT: NO
                             NUMBER OF TESTS: 01
TEST TYPE--------VALUE---
LINE CORD        0.065 OHMS  PASS
```

```
------------------ EARTH LEAKAGE ------------------
----TEST CONDITION----- (uArms) (uAdc) LIMIT
NP:NORM.COND. (ON /LDO)     23     0   5000 PASS
NP:OPEN NEUT. (ON /LDO)    146     0  10000 PASS
RP:NORM.COND. (ON /LDO)     23     1   5000 PASS
RP:OPEN NEUT. (ON /LDO)    148     0  10000 PASS


------------------ TOUCH CURRENT ------------------
----TEST CONDITION----- (uArms) (uAdc) LIMIT
NP:NORM.   (ON /LDG/---)     2     1    100 PASS
NP:OPEN N. (ON /LDO/---)     6     0    500 PASS
NP:OPEN G. (ON /LDO/---)    21     0    500 PASS
RP:NORM.   (ON /LDG/---)     1     1    100 PASS
RP:OPEN N. (ON /LDO/---)     4     0    500 PASS
RP:OPEN G. (ON /LDO/---)    19     0    500 PASS

--------- CONTROL No.: CN0432          -----------
GROUP: 1 ECG       LEADS: 4    TYPE: ISOLATED (CF)
            ----LEAD LEAKAGE (uArms)---
-LD- ----TEST CONDITION-----  VALUE  LIMIT
 01   NP:NORM.    (ON /--/---)     0    10  PASS
 02   NP:ISO.TST.(ON /--/---)     1    50  PASS
 01   NP:OPEN N. (ON /--/---)     0    50  PASS
 03   NP:OPEN G. (ON /--/---)     1    50  PASS
 01   RP:NORM.    (ON /--/---)     0    10  PASS
 01   RP:ISO.TST.(ON /--/---)     0    50  PASS
 02   RP:OPEN N. (ON /--/---)     1    50  PASS
 01   RP:OPEN G. (ON /--/---)     0    50  PASS


            -----LEAD LEAKAGE (uAdc)----
-LD- ----TEST CONDITION-----  VALUE  LIMIT
 02   NP:NORM.    (ON /--/---)     1    10  PASS
 01   NP:ISO.TST.(ON /--/---)     1    50  PASS
 03   NP:OPEN N. (ON /--/---)     1    50  PASS
 01   NP:OPEN G. (ON /--/---)     0    50  PASS
 03   RP:NORM.    (ON /--/---)     1    10  PASS
 02   RP:ISO TST  (ON /--/---)     1    50  PASS
 02   RP:OPEN N. (ON /--/---)     1    50  PASS
 01   RP:OPEN G. (ON /--/---)     1    50  PASS

--------- CONTROL No.: CN0432          -----------
GROUP: 2 PADDLES   LEADS: 2    TYPE: ISOLATED (CF)
            ----LEAD LEAKAGE (uArms)---
-LD- ----TEST CONDITION-----  VALUE  LIMIT
 05   NP:NORM.    (ON /--/---)     0    10  PASS
ALL   NP:ISO.TST.(ON /--/---)    24   100  PASS
 05   NP:OPEN N. (ON /--/---)     0    50  PASS
 05   NP:OPEN G. (ON /--/---)     1    50  PASS
 05   RP:NORM.    (ON /--/---)     0    10  PASS
ALL   RP:ISO.TST.(ON /--/---)    31   100  PASS
 06   RP:OPEN N. (ON /--/---)     1    50  PASS
 06   RP:OPEN G. (ON /--/---)     0    50  PASS


            -----LEAD LEAKAGE (uAdc)----
-LD- ----TEST CONDITION-----  VALUE  LIMIT
 02   NP:NORM.    (ON /--/---)     1    10  PASS
ALL   NP:ISO.TST.(ON /--/---)     1   100  PASS
 03   NP:OPEN N. (ON /--/---)     1    50  PASS
 01   NP:OPEN G. (ON /--/---)     0    50  PASS
 03   RP:NORM.    (ON /--/---)     1    10  PASS
```

```
ALL   RP:ISO TST (ON /--/---)      1    100   PASS
 02   RP:OPEN N. (ON /--/---)      1     50   PASS
 01   RP:OPEN G. (ON /--/---)      1     50   PASS


******************** ECG TEST ********************
              ECG AUTOSEQ: 5

STEP ---------- WAVEFORM -----------   SCALE   RESULT
   1  Square Wave, 2 Hz               1mV     PASS
   2  DC Pulse, 4 seconds             1mV     PASS
   3  Triangle Wave, 2 Hz             1mV     PASS
   4  Sine Wave, 10 Hz                1mV     PASS
   5  Sine Wave, 40 Hz                1mV     PASS
   6  Sine Wave, 60 Hz                1mV     PASS
   7  Sine Wave, 100 Hz               1mV     PASS
   8  ECG, 60 BPM                     1mV     PASS
   9  ECG, 30 BPM                     1mV     PASS
  10  ECG, 120 BPM                    1mV     PASS
  11  ECG, 180 BPM                    1mV     PASS
  12  ECG, 240 BPM                    1mV     PASS


COMMENT:
INTERMITTENT LL LEAD - REPLACED

******************** PROCEDURE ********************

TEST TYPE: Checklist
TEST No.:   089

STEP --------------- TASK ----------------   RESULT
   1  PHYSICAL INSPECTION 1:
         CASE/PADDLES IN GOOD CONDITION.............OK
   2  PHYSICAL INSPECTION 2:
         ......................................SKIP
   3  CAUTION: HIGH VOLTAGE
         ......................................OK
   4  REVIEW MANUFACTURER LITERATURE AS NEEDED
         ......................................OK
   5  TEST EQUIPMENT: DEFIBRILLATOR TESTER
         ......................................OK
   6  TEST EQUIPMENT: PACEMAKER ANALYSER
         ......................................OK
   7  TEST EQUIPMENT: PULSE OXIMETRY TESTER
         ......................................OK
   8  TEST EQUIPMENT: STOP WATCH
         ......................................OK
   9  CHECK FOR SIGNS OF PHYSICAL DAMAGE/ABUSE
         ......................................PASS
  10  CHECK FOR EVIDENCE OF FLUID SPILLS
         ......................................PASS
  11  CHECK AC LINE CORD, AND PLUG/RECEPTACLE
         ......................................PASS
  12  CHECK STRAIN RELIEF AT BOTH ENDS OF CORD
         ......................................PASS
  13  CHECK PATIENT CABLE & LEADS FOR DAMAGE
         ......................................PASS
  14  CHECK CONTROLS AND SWITCHES
         ......................................PASS
  15  CHECK CAUTION/OPERATION LABELLING
```

```
                                          ....................................PASS
16   CHECK PADDLES FOR SIGNS OF DAMAGE/PITTING
                                          ....................................PASS
17   CHECK BATTERY AND REPLACE IF NECESSARY
                                          ................................SERVICED
18   CHECK POWER-ON SEQUENCE
                                          ....................................PASS
19   CHECK FOR UNUSUAL NOISE OR VIBRATION
                                          ....................................PASS
20   CHECK DISPLAY FOCUS, INTENSITY, ALIGNMENT
                                          ....................................PASS
21   CHECK RECORDER OPERATION
                                          ....................................PASS
22   CLEAN INTERIOR/EXTERIOR AS REQUIRED
                                          ....................................PASS
23   ENTER SOFTWARE REVISION LEVEL:
        VERSION 5.10.2...................................OK
24   RUN SELF-TEST, IF EQUIPPED
                                          ....................................PASS
25   TEST ALL AUDIBLE+VISUAL ALARMS/INDICATORS
                                          ....................................PASS
26   ECG01
        EXECUTE ECG AUTOSEQUENCE....................OK
27   UT101
        OXITEST+7 DEMO        AUTOSEQUENCE..........OK
28   SELECT PULSE OXIMETER ON OXITEST+7
                                          ......................................OK
29   SET HEART RATE=60BPM
                                          ......................................OK
30   SET PULSE AMPL=100%
                                          ......................................OK
31   SET ARTIFACT=OFF
                                          ......................................OK
32   CHECK SPO2=96-98%; RATE=59-61BPM
        SPO2=96% RATE=60BPM - OK...................PASS
33   CHECK SPO2=88-92%; RATE=59-61BPM
        SPO2=89% RATE=60BPM - OK...................PASS
34   CHECK SPO2=78-82%; RATE=59-61BPM
        SPO2=79% RATE=60BPM - OK...................PASS
35   CHECK SPO2=68-72%; RATE=59-61BPM
        SPO2=68% RATE=60BPM - OK...................PASS
36   SET SPO2=93%
                                          ......................................OK
37   CHECK SPO2=92-94%; RATE=119-121BPM
        SPO2=92% RATE=119BPM - OK.................PASS
38   CHECK SPO2=92-94%; RATE=178-182BPM
        SPO2=93% RATE=179BPM - OK.................PASS
39   SET HEART RATE=60BPM
                                          ......................................OK
40   CHECK SPO2=92-94% (LOW PERFUSION)
        SPO2=92%, WEAK PLETH SIGNAL...............PASS
41   CHECK LOW SIGNAL ALARM
                                          ....................................PASS
42   SET PULSE AMPL=100%
                                          ......................................OK
43   END OF SEQUENCE
                                          ......................................OK
44   MEASURE & RECORD DEFIB OUTPUT AT 50 J
        49.8 JOULES...............................PASS
45   MEASURE & RECORD DEFIB OUTPUT AT 100 J
```

```
         98.4 JOULES................................PASS
 46  MEASURE & RECORD DEFIB OUTPUT AT 200 J
         198.1 JOULES...............................PASS
 47  MEASURE & RECORD DEFIB OUTPUT AT 300 J
         297.3 JOULES...............................PASS
 48  MEASURE & RECORD DEFIB OUTPUT AT 360 J
         352.8 JOULES...............................PASS
 49  TEST MAX ENERGY WITH DEFIB ON BAT. POWER
         350.2 JOULES - OK..........................PASS
 50  TEST CHARGE TIME WITH DEFIB ON BAT. POWER
         12 SEC - OK................................PASS
 51  TEST DEFIB "SYNC MODE" OPERATION
         .........................................PASS
 52  CHECK PACER, DEMAND MODE OPERATION
         .........................................PASS
 53  MEASURE & RECORD PULSE AMPL & FREQUENCY
         AMP=100MA PRR=80PPM - OK...................PASS
 54  MEASURE & RECORD PULSE WIDTH
         20.2 MSEC..................................PASS
 55  SAF15
         EXECUTE SAFETY AUTOSEQUENCE................OK
 56  AFFIX "BATTERY REPLACED" LABEL IF NEEDED
         .........................................OK
 57  AFFIX "SERVICED"  LABEL
         .........................................OK
 58  NOTE ANY INVENTORY OR PM CHANGES IN CEMS
         .........................................OK
 59  END OF CHECKLIST
         .........................................OK
 60  FINAL COMMENTS:
         .........................................OK
 61  USER TIME (hours):
         1.2.......................................OK

CONTROL No.: CN0472
THIS EQUIPMENT HAS PASSED

Technician:_____ Date:_____
```

The Test Report prior reflects a full PM inspection of a defibrillator, and provides a good example of the potential capabilities of ES601-US. The prior results were obtained by executing Checklist #89, which was created and loaded into ES601-US memory by means of the Checklist Editor of the ES601pc-US software package.

According to the above report, Checklist #89 includes: measurement of earth leakage current; touch current; patient leakage current (ECG leads and paddles); testing of ground resistance; visual inspection of the defibrillator chassis, paddles, ECG leads, battery, and chart recorder; performance tests of the ECG monitor; tests of the defibrillator output energy; tests of the transcutaneous pacemaker output; and tests of the Defibrillator's built-in pulse oximeter by means of an AutoSequence designed to automatically operate the Datrend Systems Oxitest Plus 7 pulse oximeter tester.
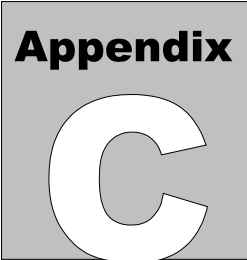
APPENDIX C. Automated Test Examples

Below are examples of a Physical Inspection and a User-Defined Tester AutoSequence, which were created using the Inspections and User Testers module of the ES601pc-US software package. This Appendix also includes an example of a Checklist, created with the Checklist Editor of ES601pc-US. For further details on these types of automated tests provided by ES601-US, refer to the **Automated Testing Principles**, Chapter 6; and the **AutoSequence Editor** and Checklist Editor, Chapter 8.

PHYSICAL INSPECTION #1 (INS01)
GENERIC DEVICE INSPECTION

```
Tester Port:     None
Baud Rate:       N / A
```

Step	Category	Op Code	Command
1.	General	P - Pass/Fail	CHECK FOR SIGNS OF PHYSICAL DAMAGE/ABUSE
2.	General	P - Pass/Fail	CHECK FOR SECURE MOUNTING
3.	General	P - Pass/Fail	CHECK AC LINE CORD AND PLUG
4.	General	P - Pass/Fail	CHECK FUSES MATCH LABELLING
5.	General	P - Pass/Fail	CHECK CABLES AND STRAIN RELIEFS
6.	Receptacle	M - Multi-Func	TRPN (TEST RECEPTACLE "ON")
7.	General	P - Pass/Fail	POWER UP AND CHECK POWER-ON SEQUENCE
8.	General	P - Pass/Fail	RUN SELF-TEST, IF EQUIPPED
9.	General	P - Pass/Fail	CHECK CONTROLS AND SWITCHES
10.	General	P - Pass/Fail	CHECK INDICATORS AND DISPLAYS
11.	General	P - Pass/Fail	CHECK AUDIO ALARMS AND SIGNALS
12.	General	P - Pass/Fail	CHECK BATTERY CHARGER, IF EQUIPPED
13.	General	P - Pass/Fail	CHECK BATTERY AND REPLACE IF NECESSARY
14.	General	P - Pass/Fail	PERFORM MANUFACTURER'S PM CHECKLIST
15.	General	M - Multi-Func	GTOL (TEST RECEPTACLE "OFF")
16.	General	P - Pass/Fail	CLEAN INTERIOR/EXTERIOR AS REQUIRED
17.	General	K - OK Prompt	RETURN CONTROLS TO ORIGINAL SETTINGS
18.	General	K - OK Prompt	END OF TEST SEQUENCE

USER-DEFINED TESTER 3, SEQUENCE #10 (UT310)
A46: LP10
LIFEPAK 10 DEFIB

```
Tester Name:    IMPULSE 4000 DEFIB
Tester Port:    3
Baud Rate:      2400 Baud

1.   Impulse   C - Tester Control   DEFRANGE=LOW• SELECT LOW ENERGY RANGE
2.   Impulse   M - Multi-Func       ENERGYMODE• CHECK IMPULSE IS IN ENERGYMODE
3.   Impulse   C - Tester Control   DEFIBWAVE=VFB1• SET ECG TO COARSE VFIB
4.   Impulse   K - OK Prompt        SET DEFIB TO 5J & DISCHARGE INTO IMPULSE
5.   Impulse   M - Multi-Func       CHKENERGY• VERIFY ENERGY=4.3 TO 5.7 JOULES
6.   Impulse   K - OK Prompt        SET DEFIB TO 10J & DISCHARGE INTO IMPULSE
7.   Impulse   M - Multi-Func       CHKENERGY• VERIFY ENERGY=8.5 TO 11.5 J
8.   Impulse   C - Tester Control   DEFRANGE=HIGH• SELECT HIGH ENERGY RANGE
9.   Impulse   K - OK Prompt        SET DEFIB TO 50J & DISCHARGE INTO IMPULSE
10.  Impulse   M - Multi-Func       CHKENERGY• VERIFY ENERGY=43 TO 58 JOULES
11.  Impulse   K - OK Prompt        SET DEFIB TO 100J, DISCHARGE INTO IMPULSE
12.  Impulse   M - Multi-Func       CHKENERGY• VERIFY ENERGY=85 TO 115 JOULES
13.  Impulse   K - OK Prompt        SET DEFIB TO 200J, DISCHARGE INTO IMPULSE
14.  Impulse   M - Multi-Func       CHKENERGY• VERIFY ENERGY=170 TO 230 JOULES
15.  Impulse   K - OK Prompt        SET DEFIB TO 300J, DISCHARGE INTO IMPULSE
16.  Impulse   M - Multi-Func       CHKENERGY• VERIFY ENERGY=255 TO 345 JOULES
17.  Impulse   K - OK Prompt        SET MAX ENERGY, CHARGE UP, THEN DISCHARGE
18.  Impulse   M - Multi-Func       CHKENERGY• MAX ENERGY AND CHARGE TIME OK?
19.  Impulse   M - Multi-Func       LOC• CHECK IMPULSE IS DISPLAYING MAIN MENU
20.  Impulse   M - Multi-Func       CARDIOMODE• CHECK IMPULSE IS IN CARDIOMODE
21.  Impulse   C - Tester Control   CARDIOWAVE=AF1• SET ECG TO COARSE AFIB
22.  Impulse   K - OK Prompt        SET ENERGY=100J, ENABLE SYNC, & DISCHARGE
23.  Impulse   M - Multi-Func       CHKCARDIO• VERIFY SYNC TIME=20 TO 65 MSEC
24.  Impulse   M - Multi-Func       LOC• CHECK IMPULSE IS DISPLAYING MAIN MENU
```

CHECKLIST 86
DEFIBRILLATOR/MONITOR

```
Tester Port:          None
Baud Rate:            N / A


Step   Category          Op Code          Command

1.                    K - OK Prompt       CAUTION: HIGH VOLTAGE
2.                    K - OK Prompt       REVIEW MANUFACTURER LITERATURE
3.   Defib            K - OK Prompt       TEST EQUIPMENT: DEFIBRILLATOR TESTER
4.   Defib            K - OK Prompt       TEST EQUIPMENT: STOP WATCH
5.                    P - Pass/Fail       CHECK FOR SIGNS OF PHYSICAL DAMAGE/ABUSE
6.                    P - Pass/Fail       CHECK FOR EVIDENCE OF FLUID SPILLS
7.                    P - Pass/Fail       CHECK AC LINE CORD, AND PLUG/RECEPTACLE
8.                    P - Pass/Fail       CHECK STRAIN RELIEF, BOTH ENDS OF CORD
9.   Defib            P - Pass/Fail       CHECK PATIENT CABLE & LEADS FOR DAMAGE
10.                   P - Pass/Fail       CHECK CONTROLS AND SWITCHES
11.                   P - Pass/Fail       CHECK CAUTION/OPERATION LABELLING
12.  Defib            P - Pass/Fail       CHECK PADDLES FOR SIGNS OF DAMAGE/PITTING
13.  Battery          P - Pass/Fail       CHECK BATTERY AND REPLACE IF NECESSARY
14.  Receptacle  M - Multi-Func           TRPN (TEST RECEPTACLE "ON")
15.                   P - Pass/Fail       CHECK POWER-ON SEQUENCE
16.                   P - Pass/Fail       CHECK FOR UNUSUAL NOISE OR VIBRATION
17.                   P - Pass/Fail       CHECK DISPLAY FOCUS, INTENSITY, ALIGNMENT
18.  Defib            P - Pass/Fail       CHECK RECORDER OPERATION
19.                   P - Pass/Fail       CLEAN INTERIOR/EXTERIOR AS REQUIRED
20.                   I - Input Requested ENTER SOFTWARE REVISION LEVEL:
21.                   P - Pass/Fail       RUN SELF-TEST, IF EQUIPPED
22.                   P - Pass/Fail       TEST ALL AUDIBLE+VISUAL ALARMS/INDICATORS
23.                   A - Autosequence    ECG01
24.  Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 50 J
25.  Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 100 J
26.  Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 200 J
27.  Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 300 J
28.  Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 360 J
29.  Defib            E - Data Entry+P/F  TEST MAX ENERGY WITH DEFIB ON BAT. POWER
30.  Defib            E - Data Entry+P/F  TEST CHARGE TIME WITH DEFIB ON BAT. POWER
31.  Defib            P - Pass/Fail       TEST DEFIB "SYNC MODE" OPERATION
32.                   A - Autosequence    SAF01
33.  Battery          K - OK Prompt       AFFIX "BATTERY REPLACED" LABEL IF NEEDED
34.                   K - OK Prompt       AFFIX "SERVICED"  LABEL
35.                   K - OK Prompt       NOTE ANY INVENTORY OR PM CHANGES IN CEMS
36.  End              K - OK Prompt       END OF CHECKLIST
```

APPENDIX D. Importing Equipment Records

Begin by selecting
Equipment Record Editor.

This screen will appear with all the
"default" equipment data. This will be
overwritten when you import other
equipment records.

Press the Options button to
customize some of the fields.

Enter any Field Names you wish. These can include Location, Facility, anything at all.

Press OK when you have finished.

Press the Import button

The Import option screen will open to choose the file to import. Generally, a CSV (comma separated values) file is easiest to work with.
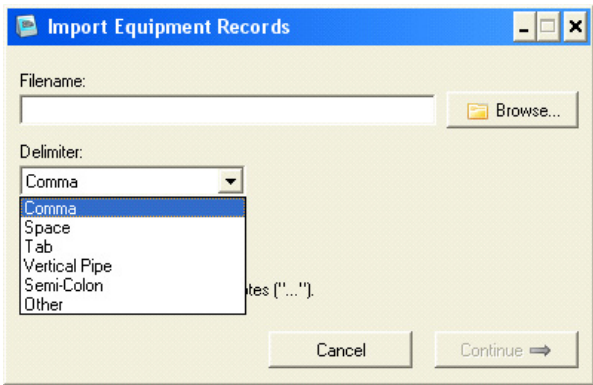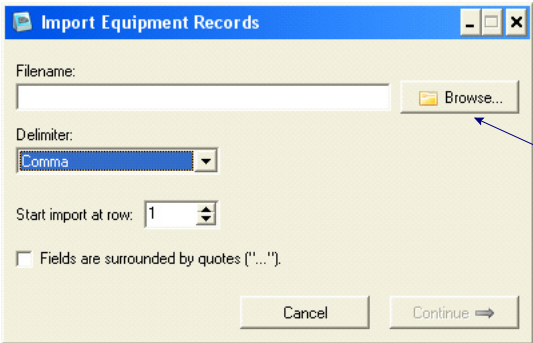
Although columns may be matched later in the process, the equipment records to be imported should be in the following format:
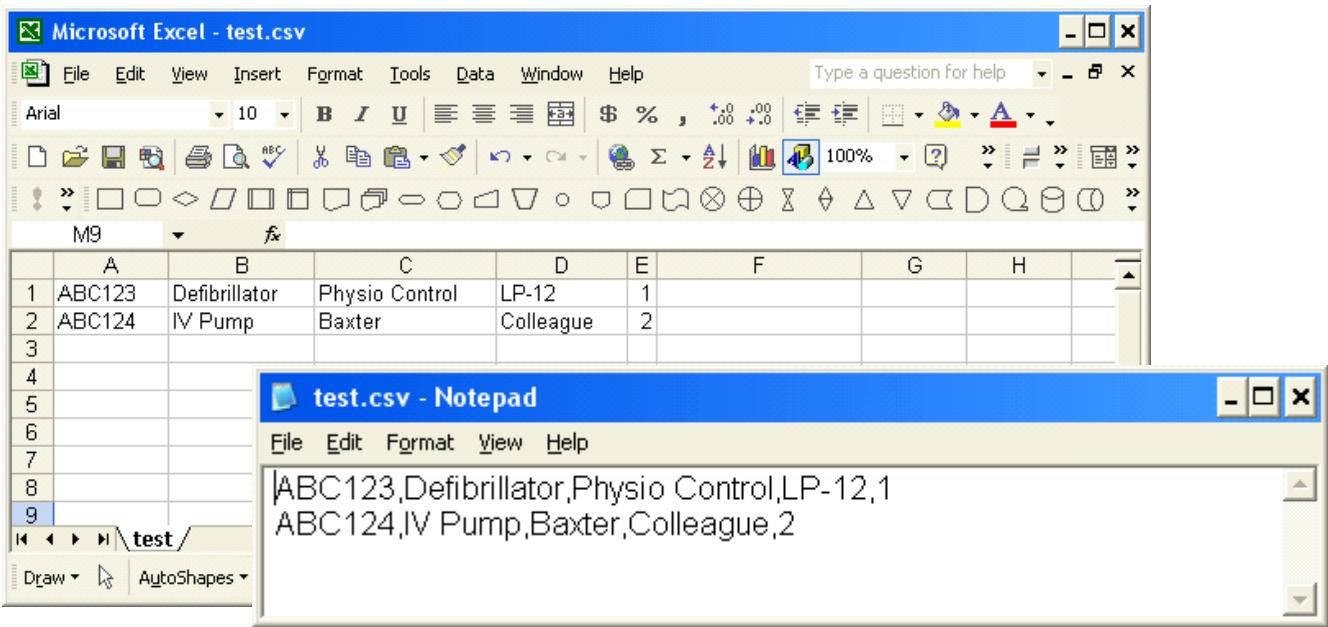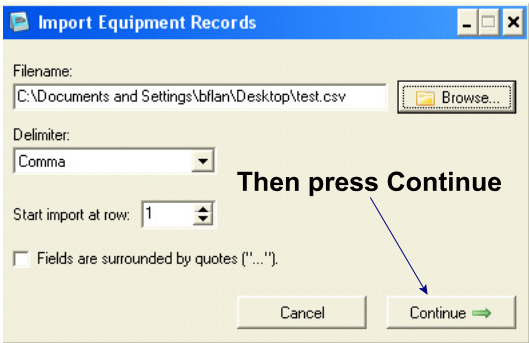
The preceding is an example of a short equipment list. There can be more fields, but this will demonstrate the function. In this case, Column E is the Checklist number - This can be added or changed later.   Be sure to save the file as ".CSV".
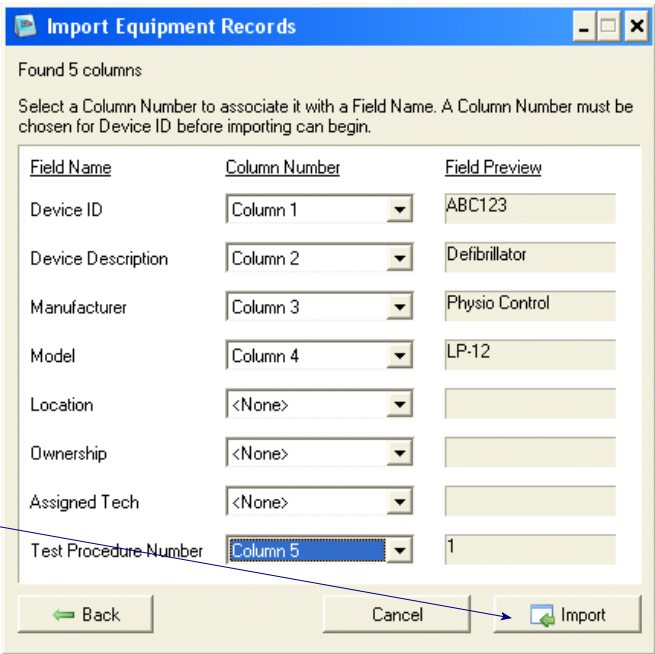
Press Browse to locate the file you wish to import.

Then press Continue

This screen may be used to to match fields with columns. A preview of the field will appear when the column is selected. Match as few (at least the Device ID), or as many, of the fields as you wish.

When finished, press Import.

For this simple example, the import process will run very quickly. The amount of time required to import will depend of the number of records in the input CSV file. Press OK when the import completes.
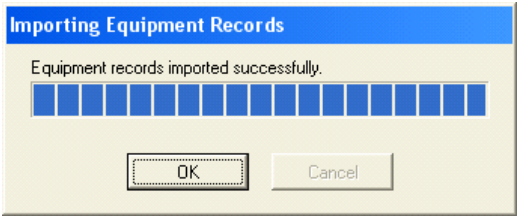
You will notice that the default equipment records have been replaced by the new data.

Double-click a record to view/edit.
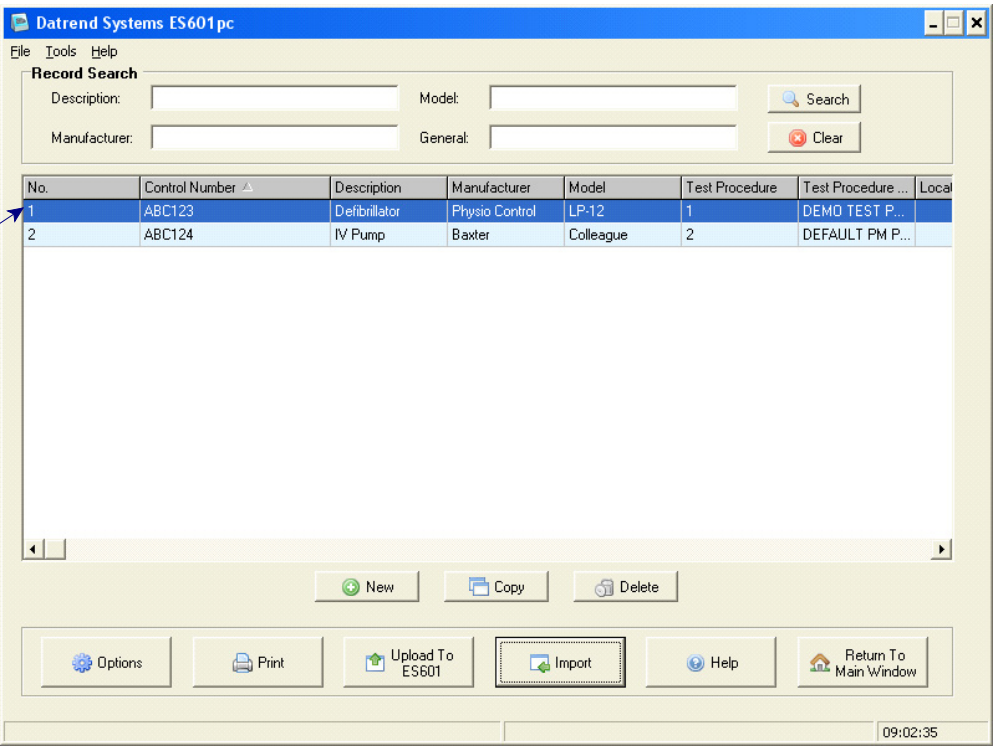
If not already assigned, Checklists can be assigned now, and custom fields can be added or edited.

Ensure that the USB Driver for ES601-US is installed and the unit connected to the PC as per section 8.2; then upload the data to the ES601-US, and the equipment records and associated Checklists will be ready.