DATREND
Systems Inc.

ES601*Plus*

International Automated Electrical Safety Analyzer

Operating Manual

ES601Plus
International Automated Electrical Safety Analyzer
Operating Manual

DATREND Systems Inc.

Revision	Revision History Description	Date
K	Changes per 3.50 Firmware	2015-Oct-14
L	Update Address	2018-May-03
M	Added 100V mains	2020-Feb-13

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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 instructions, 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 test procedures.

Warranty

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
● 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.

DSI DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

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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
AP	Applied Parts
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)
Clip Record	Temporary (volatile) memory where device information and test data is accumulated, until the data is saved as a Test Record.
DUT	Device Under Test. The electrical device being tested.
Earth	See GND
Equipment Record	Contains the control number of a device and a reference to an associated PM procedure (Test Procedure) for that device.
Flash Memory	Non-volatile memory used for storing Test Records and other configuration-related data such as user settings, AutoSequences, Test Procedures and Equipment Records. The contents of the flash memory are retained when the power to ES601*Plus* is switched off.
GND or Ground	The line (conductor) connected to a place that is maintained at "Ground" or "Earth" voltage. Same as Protective Earth.
Hz	Hertz
IEC	International Electrotechnical Commission
kHz	kilohertz
L1 or Line 1	Line 1 of the AC supply voltage, or "mains". In North America, the "Hot" or "Live" line (conductor) of the AC supply.
L2 or Line 2	Line 2 of the AC supply voltage, or "mains". In North America, 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)

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 Procedure	A type of AutoSequence that can be linked to the control number of a device through an Equipment Record.
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 I.D. or 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 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:

⚠ CONSULT MANUAL FOR PROPER OPERATION

The operating manual provides valuable information on the proper use of ES601*Plus*. It is highly recommended the operator read the instructions thoroughly before operating the device. It is possible to damage the Device Under Test (DUT) and/or cause harm to the operator if ES601*Plus* 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 label on the front of ES601*Plus*. During testing of the isolation of the DUT Applied Parts 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 Parts (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 Parts connectors. When a hazardous voltage is present at the Applied Parts 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*Plus*. ES601*Plus* 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*Plus*. Refer to the Troubleshooting and Maintenance Section of the Operating Manual.

⚠️   Kelvin Cable

The Kelvin Cable (CAT I) is used to measure the Protective Earth Resistance, using either a 1A DC current or a 25A AC current (optional). The voltage present at these terminals is low, but the 25A AC current can present a potential hazard if used incorrectly. Consult the Operating Manual for the proper operation of the Protective Earth Resistance test.

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

     15AMPS @ 100 - 120 VAC, 50-60 Hz (in 20A circuit)
     11AMPS @ 100 - 120 VAC, 50-60 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 ES601*Plus* 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*Plus*.

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

ES601*Plus* 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*Plus* WITH GROUNDING CONDUCTOR DISCONNECTED.

Proper grounding is essential to ensure operator safety. Do not bypass the grounding provisions inherent in the design of ES601*Plus*, 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*Plus* 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 Mains on Applied Part leakage current tests and Insulation Resistance tests for further information.

Chapter

1

1   Specifications

Equipment Performance Specifications

1.1 Electrical Safety Testing Standards
- IEC60601-1:2005, Third Edition
- IEC60601-2-4:2002, Second Edition
- ANSI/AAMI-ES1:1996
- DIN VDE 0751-1:2001
- IEC62353:2007, FDIS Edition 1
- IEC61010-1:2001, Second Edition
- IEC601-BAT (IEC60601 for battery-powered medical device)
- AAMI-BAT (AAMI-ES1 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 Safety AutoSequence
- By ECG AutoSequence
- By General Inspection
- By Tester AutoSequence
- By Test Procedure
- By Device ID (Control Number) Search

1.3 Manual Mode Safety Tests
- Line Voltage
- Load Current
- Insulation Resistance
- Protective Earth
- 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

Protective Earth Resistance
- Range: 0.001 to 0.200 ohms at 25A AC
               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

Mains on Applied Parts 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 (MAP):
- CAT I
- Max Voltage: 264 VAC out
- Max Current: 2mA AC out

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

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

Applied Parts Terminals:
- CAT I
- Max Voltage: 264 VAC (MAP 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: ±0.2%
- Amplitude: ±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 (test data)
- 3072 PM Test Data Items
- 18432 Equipment Records
- 500 PM Test Procedures
- 24 Safety Test Autosequences
- 6 ECG Test Autosequences
- 18 General Inspections
- 12 Pulse Oximeter Tester AutoSequences
- 12 IV Pump Tester AutoSequences
- 24 Defibrillator Tester AutoSequences
- 60 AutoSequences for user-defined Testers

AutoSequences, Inspections and PM test procedures are user-programmable via the ES601pc 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

- Country Specific: 100 VAC(+/- 10%), 50-60 Hz, 16A in 20A circuit
100 VAC(+/- 10%), 50-60 Hz, 12A in 15A circuit
120 VAC(+/- 10%), 60 Hz, 16A in 20A circuit
120 VAC(+/- 10%), 60 Hz, 12A in 15A circuit
230 VAC(+/- 10%), 50 Hz, 13A

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)
- ES601pc Software on CDROM (P/N 6950-003)
- Operating Manual on CDROM
- Power Cord (country specific)
    - North America 15A (P/N 3000-009)
    - Continental Europe (P/N 3000-011)
    - United Kingdom (P/N 3000-012)
    - Australia (P/N 3000-018)
- Accessory Bag (P/N 7006-052)

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 Limits Editor	- ECG AutoSequence Editor
- Safety AutoSequence Editor	- Test Report Generator
- Autosequence Editor	- Equipment Record Plug-in
- Test Procedure Editor	- CMMS Data Converters

1.20 Optional Software Modules

Languages: English, French, German, Italian

Note: Language Options can only be installed at the Factory or by an Authorized Service Center only. Contact Datrend Customer Service for complete details. Refer to Chapter 9 for contact information.

1.21 Compliance With Standards

ES601*Plus* 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
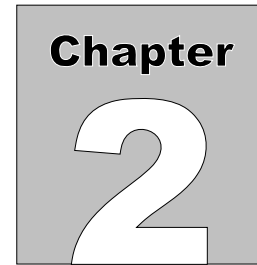
2   Overview

ES601*Plus* 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*Plus* 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 Test Procedure, 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*Plus* 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 Test Procedure. There are up to 500 editable PM Test Procedures 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*Plus* has added both USB and Ethernet connectivity for ease of control and rapid data transfer to both stand alone and networked PC systems. ES601*Plus* also provides connections for RS-232 barcode scanners and PS/2 keyboards or PS/2 barcode scanners.

ES601*Plus* is a truly INTERNATIONAL, truly 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*Plus* can operate in MANUAL mode, allowing individual measurements of a safety test to be manually selected; or in AUTO mode, running Safety Autosequences.

ES601*Plus* 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*Plus* 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 analyser, etc.) via any of six RS232 Tester Ports. Test Procedures 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* software package for Microsoft Windows® 2000/XP.

2.1 Testing Electrical Safety

ES601*Plus* performs a number of measurements related to testing the electrical safety of medical devices. Electrical safety measurements performed by ES601*Plus* 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*Plus* applies a high voltage (500 VDC) between L1 and L2 shorted together, and the ground. ES601*Plus* measures the resulting current and reports the test result as resistance in megohms. In a variation of this test, ES601*Plus* applies the high voltage between the applied parts and the line cord ground pin, and measures the resistance.

2.1.2 Protective Earth

In this test, ES601*Plus* 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*Plus* measures and reports as the test result.

To comply with requirements of various safety standards, ES601*Plus* performs this measurement twice: the first resistance is measured with the DC test current sourced into the DUT enclosure and back through line cord; a second resistance is then measured with the DC test current flowing through the DUT in the opposite direction. The test result reported by ES601*Plus* is the larger of the two measurements.

When an ES601*Plus* with the factory installed Protective Earth Module (or "PETM") is used, an optional variation of this measurement can be performed where the test current is 25 amps AC RMS, rather than 1 amp bipolar DC. The optional PETM allows protective earth tests to be performed in full accordance with the requirements of the IEC60601 and IEC61010 safety standards. When an ES601*Plus* with PETM conducts a 25A test, ten measurements are taken over a ten-second period. The highest result is reported and saved in the Test Record.

By providing multiple measurement and point-to-point test modes, ES601*Plus* accommodates special test requirements of permanently-installed equipment, and manufacturer-recommended protocols where continuity of protective earth 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, and with 1A or 25A test current for units equipped with PETM option.

Note: **The Protective Earth Test Module ("PETM") is a FACTORY installed option and should be specified when the unit is ordered.**

2.1.3 Line Voltage

In this test, ES601*Plus* connects an internal voltmeter to the AC supply input and reports the AC RMS voltages measured between L1 and L2, L1 and PE, and L2 and PE.

2.1.4 Load Current

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

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

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

2.1.6 Touch Current

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

In this test, ES601*Plus* measures the current that flows from a metal part on the DUT enclosure that should be grounded, to the actual protective earth 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*Plus* 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 protective earth is measured and compared to a maximum limit specified in the safety standard. When measuring the touch current, ES601*Plus* can be configured to record AC and DC values for these test conditions:

Normal Polarity	Normal Condition	(NP:NC)
	Single-Fault Condition, Line 2 Open	(NP:SF L2O)
	Single-Fault Condition, Earth Open	(NP:SF EO)
Reverse Polarity	Normal Condition	(RP:NC)
	Single-Fault Condition, Line 2 Open	(RP:SF L2O)
	Single-Fault Condition, Earth Open	(RP:SF EO)

2.1.7 Earth Leakage Current

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

Normal Polarity	Normal Condition	(NP:NC)
	Single-Fault Condition, Line 2 Open	(NP:SF L2O)
Reverse Polarity	Normal Condition	(RP:NC)
	Single-Fault Condition, Line 2 Open	(RP:SF L2O)

2.1.8 Patient Leakage Current

In this test, ES601*Plus* measures the current that flows out of the patient applied parts of the DUT though the human body load when the parts are either connected to protective earth (normal condition), or to an isolated AC voltage via a current-limiting resistor (MAP - Mains on Applied Part test). For the IEC60601 standard, the isolated voltage connected to the applied parts is equal to 110% of the AC line voltage supplying the DUT; for other safety standards the isolated voltage is equal to the AC line voltage. As with all leakage tests, patient leakage current is measured in microamps, while simulating various conditions at the DUT.

In addition to specifying the individual test cases, the patient leakage measurement requires the applied parts 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*Plus* allows up to five groups of applied parts to be defined, where each group can be a different "Type" and can include from one to ten parts. Groups can be assigned names, as can the individual parts within a group. A group of parts may also be "disabled", and therefore excluded from the test.

The way in which patient leakage must be measured is highly dependent on the specified group "Type". If the safety standard is IEC60601, and an applied part group is designated "Type CF", then the leakage current produced by each patient connection within that group is measured individually in turn. For an applied part group which is "Type B" or "Type BF", all patient leads of the group are connected together and then the collective leakage of the group of leads is measured. In accordance with the Third Edition of the standard, if testing Mains on Applied Part (MAP) of a specific group of patient connections, then any other applied part groups provided by the DUT that are not being MAP-tested must be connected to protective earth. 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". For AAMI standard, collective leakage is measured for patient source current, but then is measured individually from each lead for patient sink current.

The complicated details of testing patient leakage are managed automatically by ES601*Plus*, 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*Plus* to perform patient leakage measurements is relatively simple and is further explained in section 5.10.

When testing patient leakage, ES601*Plus* 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:NC)
	Single-Fault Condition, Line 2 Open	(NP:SF L2O)
	Single-Fault Condition, Earth Open	(NP:SF EO)
	SFC, Mains on Applied Part(s)[1]	(NP:SF MAP)
Reverse Polarity	Normal Condition	(RP:NC)
	Single-Fault Condition, Line 2 Open	(RP:SF L2O)
	Single-Fault Condition, Earth Open	(RP:SF EO)
	SFC, Mains on Applied Part(s)[1]	(RP:SF MAP)

(1) Type BF or CF applied parts 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*Plus* 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*Plus* 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 protective earth (MIO/IOE test conditions), and;

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

During the test, ES601*Plus* measures patient 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*Plus* 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 applied parts or supplementary test conditions to specify. To save you time, ES601*Plus* allows you to program and save such setups as automated test sequences, which are further described in Section 2.1.12.

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[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.

2.1.9 Patient Auxiliary Leakage Current

In this test, sometimes called an interlead leakage test, ES601*Plus* measures the current that flows out of one applied part, through the human body load, and into all the other applied parts shorted together. As with all leakage tests, auxiliary leakage current is measured in microamps, while simulating a variety of test conditions at the DUT.

In addition to specifying the individual test cases, the auxiliary leakage measurement requires the kind of applied parts 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 applied parts can be arbitrarily partitioned into the five Groups provided by the test setup.

When testing auxiliary leakage, ES601*Plus* can be configured to record the following AC and DC values for each applied part defined in the test setup:

Normal Polarity	Normal Condition	(NP:NC)
	Single-Fault Condition, Line 2 Open	(NP:SF L2O)
	Single-Fault Condition, Earth Open	(NP:SF EO)
Reverse Polarity	Normal Condition	(RP:NC)
	Single-Fault Condition, Line 2 Open	(RP:SF L2O)
	Single-Fault Condition, Earth Open	(RP:SF EO)

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*Plus* measures auxiliary 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*Plus* 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 test 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 ES601𝒫𝓁𝓊𝓈.

Another electrical safety standard provided by ES601𝒫𝓁𝓊𝓈, 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, ES601𝒫𝓁𝓊𝓈 records all results from all leakage measurements enabled by the user in the test setup. For the "direct method" of measurement, ES601𝒫𝓁𝓊𝓈 will record AC and DC values for these test conditions:

<u>Device Leakage:</u>

Normal Polarity	Single-Fault Condition, Earth Open	(NP:SF EO)
Reverse Polarity	Single-Fault Condition, Earth Open	(RP:SF EO)

<u>Patient Leakage (record for each Group defined by the user):</u>

Normal Polarity	Normal Condition[2]	(NP:NC)
	SFC, Mains on Applied Part(s)	(NP:SF MAP)
Reverse Polarity	Normal Condition[2]	(RP:NC)
	SFC, Mains on Applied Part(s)	(RP:SF MAP)

(2)   VDE-0751 only: normal condition (applied part(s) to protective earth) 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, ES601𝒫𝓁𝓊𝓈 will test only patient leakage and auxiliary leakage of the DUT, and measure insulation resistance of the applied parts to protective earth.

To accommodate the unique needs of battery-powered devices, ES601*Plus* incorporates special protocols designated "IEC601-BAT" (IEC60601 standard for self-powered device), "AAMI-BAT" (AAMI-ES1 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*Plus* can be programmed to automatically conduct the safety measurements described above. Automated safety measurements are always performed by ES601*Plus* in a predefined order. The settings of an ES601*Plus* Safety AutoSequence determine which measurements within the sequence are enabled, but do not affect the order in which the measurements are conducted.

ES601*Plus* provides memory for storage of 24 user-programmable Safety AutoSequences. These sequences can be programmed and saved using the operator interface of ES601*Plus*. Alternatively, the sequences can be programmed and loaded into ES601*Plus* memory by means of the Safety AutoSequence module of the ES601pc software package (see Chapter 8). ES601pc software is included on CD ROM with ES601*Plus* or may be downloaded or upgraded from Datrend's website - www.datrend.com.
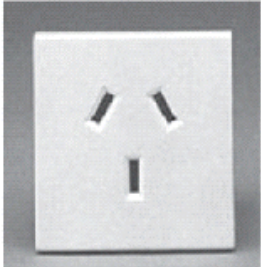
A Safety AutoSequence can include measurements of line voltage, load current, leakage (enclosure or device, earth, patient, auxiliary), protective earth, and insulation resistance. For devices having patient-applied parts, each Safety Autosequence can be set up to organize the parts into *Functional Groups* of defined *Protection Class*, with names assignable to each Group as well as to each Part within each Group. Up to ten applied parts can be arbitrarily assigned to the five Groups provided by ES601*Plus*. *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 protective earth test, such as multiple resistance measurements or point-to-point testing.

ES601*Plus* 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*Plus*, or by means of ES601pc software.

2.2 Characteristics of ES601Plus

2.2.1 Test Receptacle Configuration

The test receptacle is generally configured to meet these broad configurations, but alternate test receptacles may be substituted based upon the destination. For other configurations, please contact Datrend Customer Service.

North America / 120 VAC / 20A	Western Europe 220 VAC / 16A	United Kingdom 250 VAC / 13A	Australia 250 VAC / 10A
(8001-120/121)	(8001-220/221)	(8001-240/241)	(8001-222/223)

2.2.2 Standard Accessories

Power cord (one of):
 - North America 15A (P/N 3000-009)
 - Europe (P/N 3000-011)
 - Australia/China (P/N 3000-018)
 - UK (P/N 3000-012)

Kelvin Cable (P/N 3140-425)
USB Cable (P/N 3140-403)
ES601pc Software
Operator's Manual

Installed Software Modules:
- Safety Limits Editor
- Safety AutoSequence Editor
- ECG AutoSequence Editor
- Test Report Generator
- Autosequence/Test Procedure Editor
- Equipment Record Plug-in
- CMMS Data Converters
- Oxitest Autosequences
- Infutest Autosequences
- Phase 3 Autosequences

2.2.3 Optional Accessories

Barcode Scanner (P/N 7600-051 or 7600-052)
PC Interface Cable: DB9F-DB9M (P/N 3140-010)
RJ-12F to DB9F Adapter (P/N 3140-426)
RJ-12F to DB9M Adapter (P/N 3140-427)
RJ-12M to RJ-12M Cable (P/N 3140-429)
RJ-12F to DB25F Adapter (P/N 3140-430)
Oxitest RS-232 - DB9 Cable (P/N 7100-248)
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)

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 Remote Tester Interface (6) for connection to external testing devices
4.   Centronics Printer Port for connecting standard Centronics Printer
5.   RS-232 PORT serial interface for connecting to serial printer or COM Port of PC
6.   ETHERNET INTERFACE PORT provides communication with PC using ES601pc
7.   USB INTERFACE PORT provides communication with PC using ES601pc
8.   PS/2 INTERFACE for PS/2 Keyboard or PS/2 Barcode Scanner
9.   CONTRAST ADJUSTMENT POTENTIOMETER (embedded)
10.   RS-232 BARCODE SCANNER INTERFACE
11.   FIRMWARE UPLOAD SWITCH toggles between normal and update mode (embedded)

FRONT PANEL:
12.   ECG/APPLIED PARTS Universal ECG jacks for connecting applied parts
          and ECG 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 Protective Earth Resistance
            BLACK – Kelvin Cable input for Protective Earth Resistance
            GREEN – direct connection to Equipment Outlet Earth
15.   AUX1 and AUX2 provide connection for special leakage tests
16.   DUT Test Receptacle (See Test Receptacle Configuration)

Chapter

3
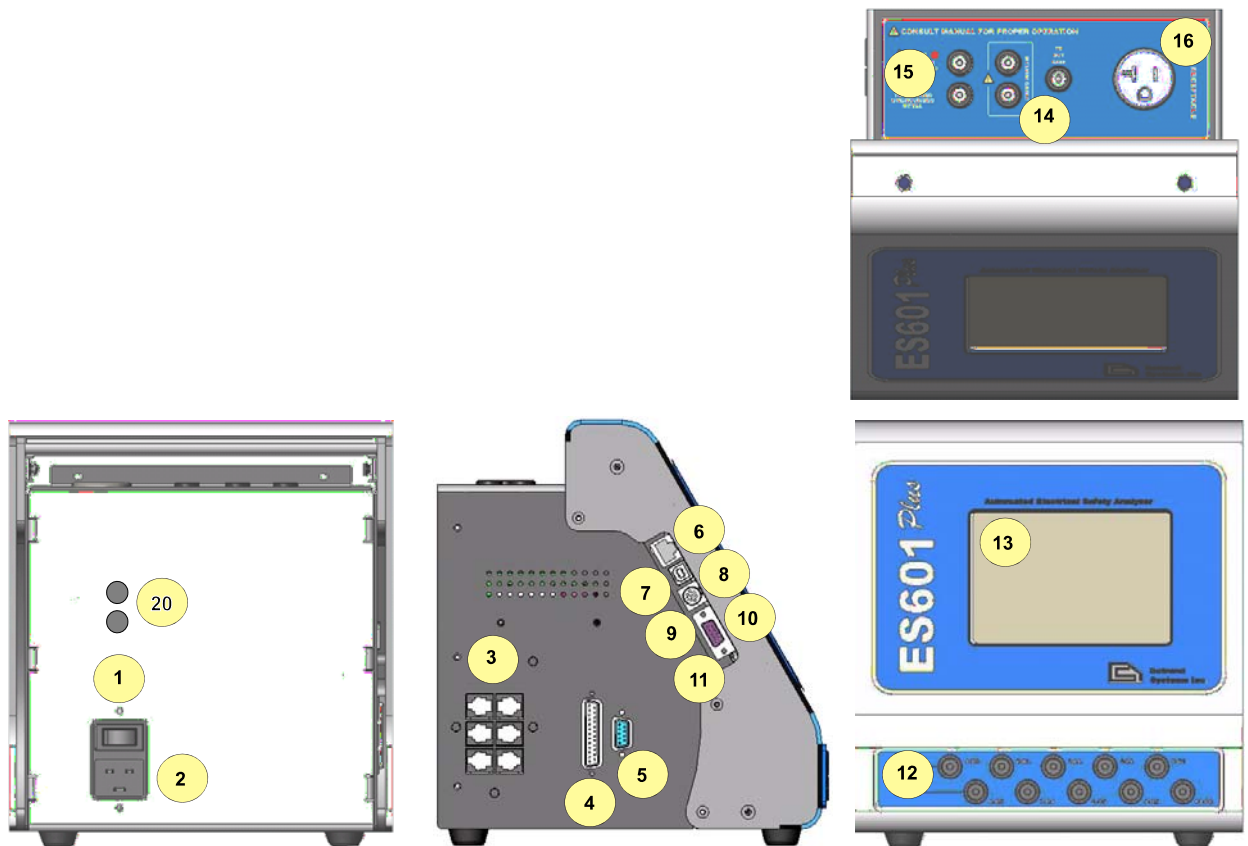
3   Setup

3.1 Powering Up/Start-up Menu

When the power to ES601*Plus* 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.

Depending on how the "STARTUP MODE" has been configured under System Settings, the above menu may remain on the LCD indefinitely, or may be automatically replaced by either the MANUAL MODE menu or the AUTO MODE menu after a few seconds.

Optionally, the "STARTUP MODE" can be set to enable a test of the AC supply voltage at five seconds after power-on. If the AC supply test at startup has been enabled, ES601*Plus* 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.

Figure 1 *- Startup Menu*

The touch screen buttons ("buttons") provided on the Startup menu are:

MANUAL MODE: Enters a menu for performing manual safety tests. Refer to chapter 5.

AUTO MODE: Enters a menu for performing automated safety tests and other types of automated tests. Refer to chapter 6.

SYSTEM SETTINGS: Enters a menu for programming system settings such as time and date, user preferences, and automated safety test setups. Refer to the following Section, 3.2.

REVIEW TESTS: Selects a Test Record previously stored in memory for viewing as a Report on the LCD, printing to an attached printer, or downloading via RS232 to a PC. Refer to Section 5.14.

3.2 System Settings Menu #1

The "System Settings" menus are available from the Start-up Screen, Manual Mode menu and Auto Mode menu, by pressing the **SYSTEM SETTINGS** button. System settings are distributed across three menus (#1, #2 and #3), with the third menu allowing for password protection.
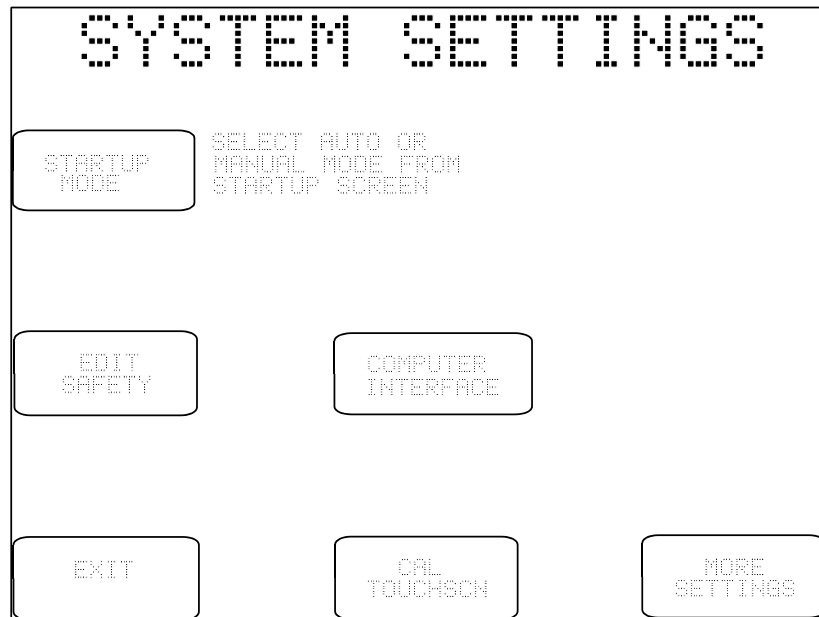
Figure 2: *System Settings Menu #1*

The buttons provided on Systems Settings Menu #1 are:

STARTUP MODE: Determines how ES601*Plus* performs after power is switched on. The options available are:
- Select Auto or Manual Mode from Start-up screen (default)
- Wait 5 seconds, then display Auto Mode Menu
- Wait 5 seconds, then display Manual Mode Menu
- Wait 5 seconds, Test Line Volts, then display Auto Mode Menu
- Wait 5 seconds, Test Line Volts, then display Manual Mode Menu

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; test procedures; equipment control number lists) into ES601*Plus*, as transmitted by a personal computer (PC) running the ES601pc software program. This menu is also used for downloading test data from ES601*Plus*, into the ES601pc 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.

USB PORT: Opens the connection via the USB Port and awaits communication from the PC running ES601pc.

ETHERNET PORT: Opens the connection via the ETHERNET Port and awaits communication from the PC running ES601pc.

ESCAPE: Exit Computer Interface mode to the System Settings menu.

CAL TOUCHSCN: Enters a utility for calibrating the ES601*Plus* analog touch screen. 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).

EXIT: Exits to the previous menu (AUTO or MANUAL), or to AUTO MODE if the Systems Settings menu was entered from the startup screen. On exit, changes made to settings are saved in the non-volatile memory of ES601*Plus*.

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

3.3 System Settings Menu #2
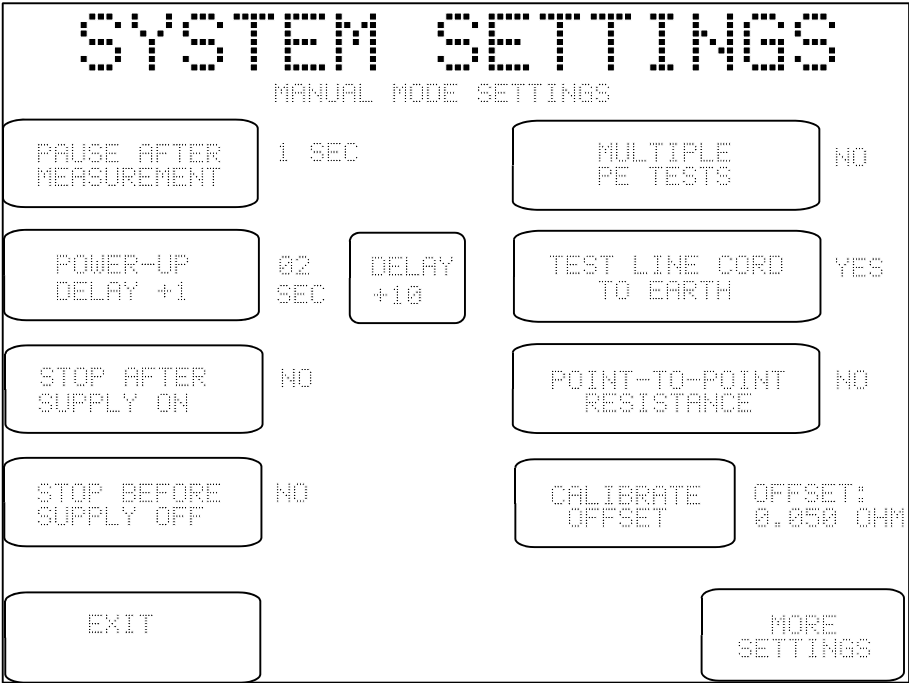
Figure 3: *System Setting Menu #2*

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 protective earth tests.

When a leakage or protective earth 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*Plus* 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*Plus* 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 99 seconds in one second steps.

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*Plus*. ES601*Plus* 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*Plus* 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*Plus* 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".

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

**TEST
LINE CORD
TO EARTH:**
If set to "YES" (factory default), this control will enable measurement of line cord resistance in a manual protective earth test. For this type of test, resistance is measured between the protective earth terminal on the line cord plug and the Kelvin Cable of ES601*Plus*, which would typically be connected to a grounding stud (protective earth 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.

**POINT-TO-POINT
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*Plus*, and the other being the point of attachment of a test lead which connects to the "TO DUT CASE" jack of ES601*Plus*. If set to "NO" (factory default), point-to-point resistance testing is disabled in manual mode. This control works with the "MULTIPLE PE TEST" control and "TEST LINE CORD" control above to provide various protocols for protective earth testing 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*Plus*. 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*Plus* 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*Plus* at the start of every protective earth 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 protective earth test, and for point-to-point test instructions in particular.

EXIT:

Exits to the previous menu (AUTO or MANUAL), or to AUTO MODE if the Systems Settings menu was entered from the startup screen. On exit, changes made to the Sequence Controls are saved in the non-volatile memory of ES601*Plus*.

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
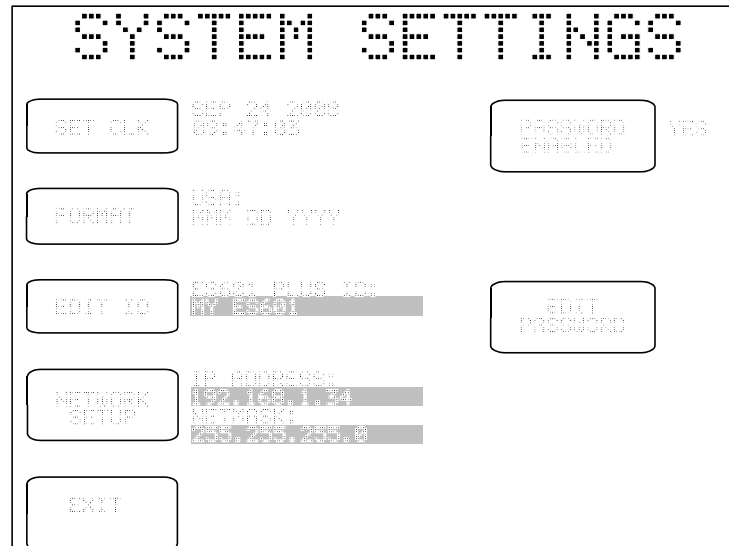
Figure 4 *- System Settings Menu #3*

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*Plus* 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*Plus* 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*Plus*, 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*Plus* (see **Figure 5**). 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 **EXIT** saves changes made and restores the Systems Settings Menu #3.
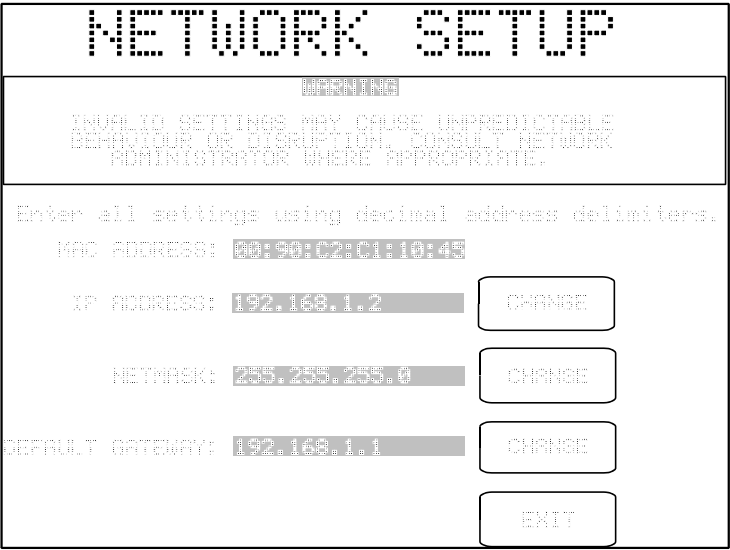
Figure 5 - *Network Setup*

EXIT: Exits to the previous menu (AUTO or MANUAL), or to AUTO MODE if the Systems Settings menu was entered from the startup screen. On exit, changes made to settings are saved in the non-volatile memory of ES601*Plus*.

3.5 About the QWERTY Keypad

The QWERTY touch keypad of ES601*Plus* is used for entering system settings, equipment information, control numbers, comments and test data. An example of the QWERTY keypad is shown in **Figure 6**, for entering the ES601 I.D. of System Settings Menu #3.

When the QWERTY keypad is activated on the display, ES601*Plus* will also optionally accept character data from ES601*Plus* 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.
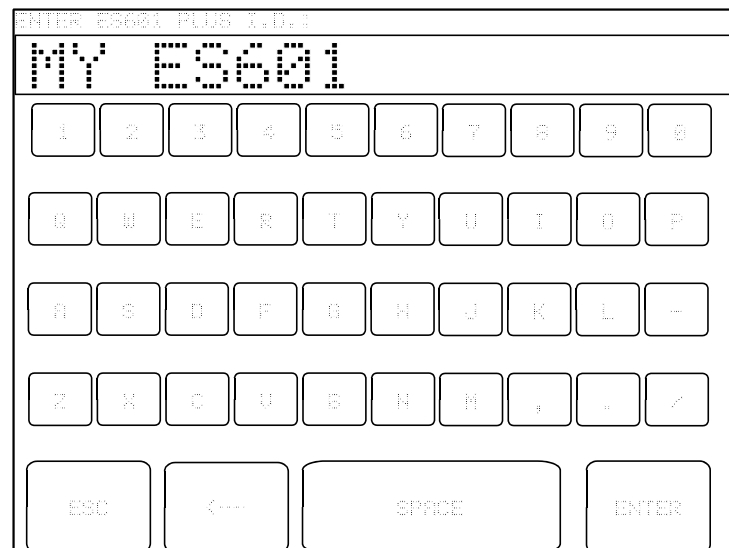
Figure 6 - *QWERTY Keypad*

ES601*Plus* 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*Plus* will wait until a complete string of characters, terminated by carriage return, is received. After sensing a carriage return, ES601*Plus* 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*Plus* 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*Plus* 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 applied parts, such as patient monitors.

ES601*Plus* 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 software package included with ES601*Plus* (see Chapter 8). Alternatively, the sequences can be programmed using the operator interface of ES601*Plus* as described in this section. Note that figures appearing in this section illustrate example settings only; the specific appearance of menus on your ES601*Plus* 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:
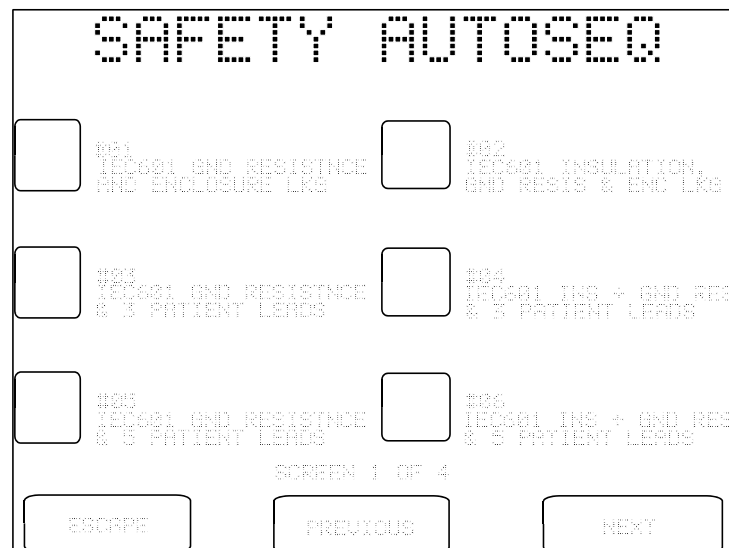
Figure 7 *- AutoSequence selector menu.*

On the selector menu, use **PREVIOUS** and **NEXT** 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:
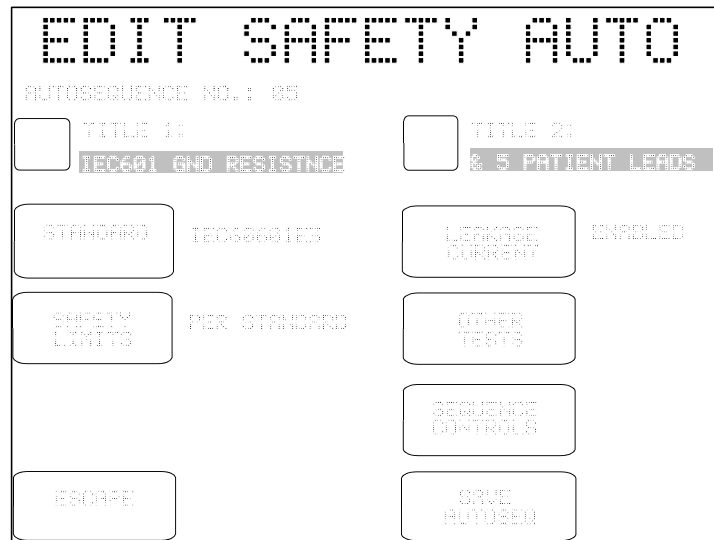
Figure 8 - AutoSequence editor, Main Menu.

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 IEC60601, AAMI-ES1, 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 protective earth 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*Plus* memory by means of a corresponding module of the ES601pc software package (see Chapter 8).

User-defined safety limits are an accessory option of ES601*Plus*. The **SAFETY LIMITS** setting will remain fixed at "PER STANDARD" if this accessory option has not been installed in your ES601*Plus*.

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 IEC60601 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 applied parts, 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.
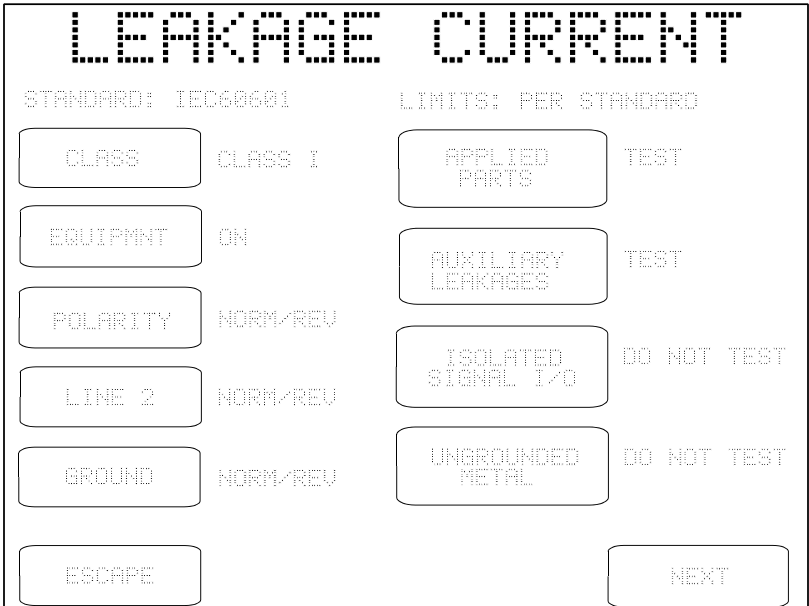
Figure 9 - Leakage current menu for IEC60601 standard.

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 **APPLIED PARTS** of the leakage current menu is set to "TEST", the next menu will be the applied parts editor (see Section 5.10). If **APPLIED PARTS** 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 8**), 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 applied parts to ground (AP-GND); and protective earth 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 applied parts to ground.

The **BACK** button of this menu restores the main menu of the AutoSequence editor.
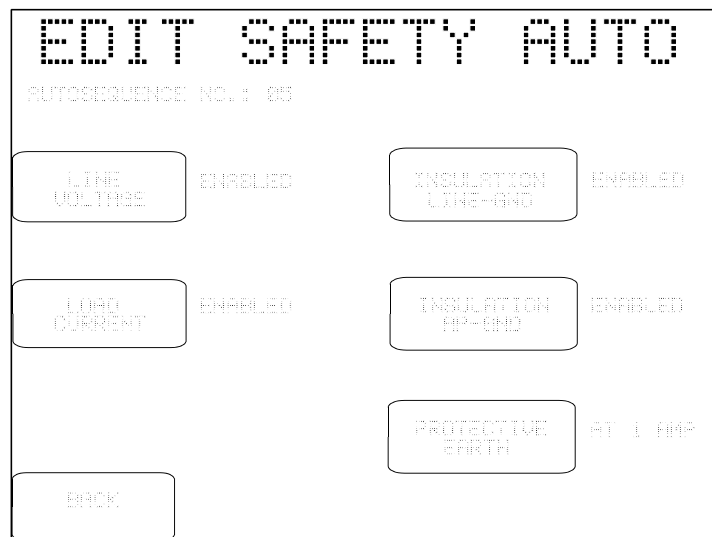
Figure 10 - *Enable/disable "other tests" of the safety standard.*

SEQUENCE CONTROLS:

Referring back to the editor main menu (***Figure 8***), 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 protective earth 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*Plus* 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.
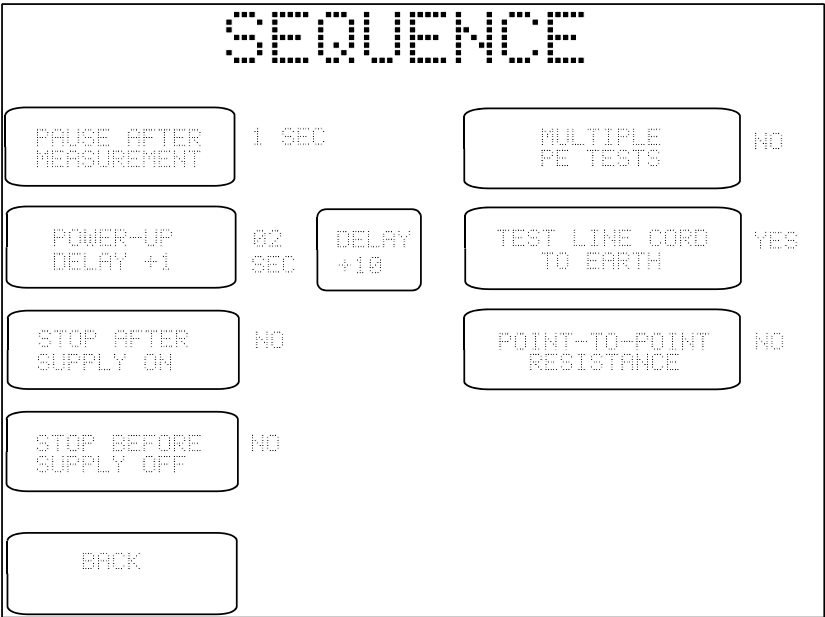
Figure 11 *- Editor for Sequence Controls.*

SAVE AUTOSEQ: Referring back to the main menu of the AutoSequence editor (**Figure 8**), pressing this button causes ES601*Plus* 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*Plus* to System Settings Menu #1. Pressing "NO" will return ES601*Plus* to Systems Settings Menu #1 without storing the AutoSequence.

```
EDIT SAFETY AUTO




       SAVE EDITS AS SAFETY AUTOSEQUENCE #05?

        ┌─────────────┐              ┌─────────────┐
        │     NO      │              │     YES     │
        └─────────────┘              └─────────────┘
```

Figure 12 - *Prompt to save AutoSequence edits.*

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

Chapter

4

4 Connecting to ES601*Plus*

When using ES601*Plus*, 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*Plus*

Connection instructions for AC-powered DUT:

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

- Connect the DUT power cable to the ES601*Plus* Test Socket.

- 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*Plus* jacks AP1 through AP10 as required.
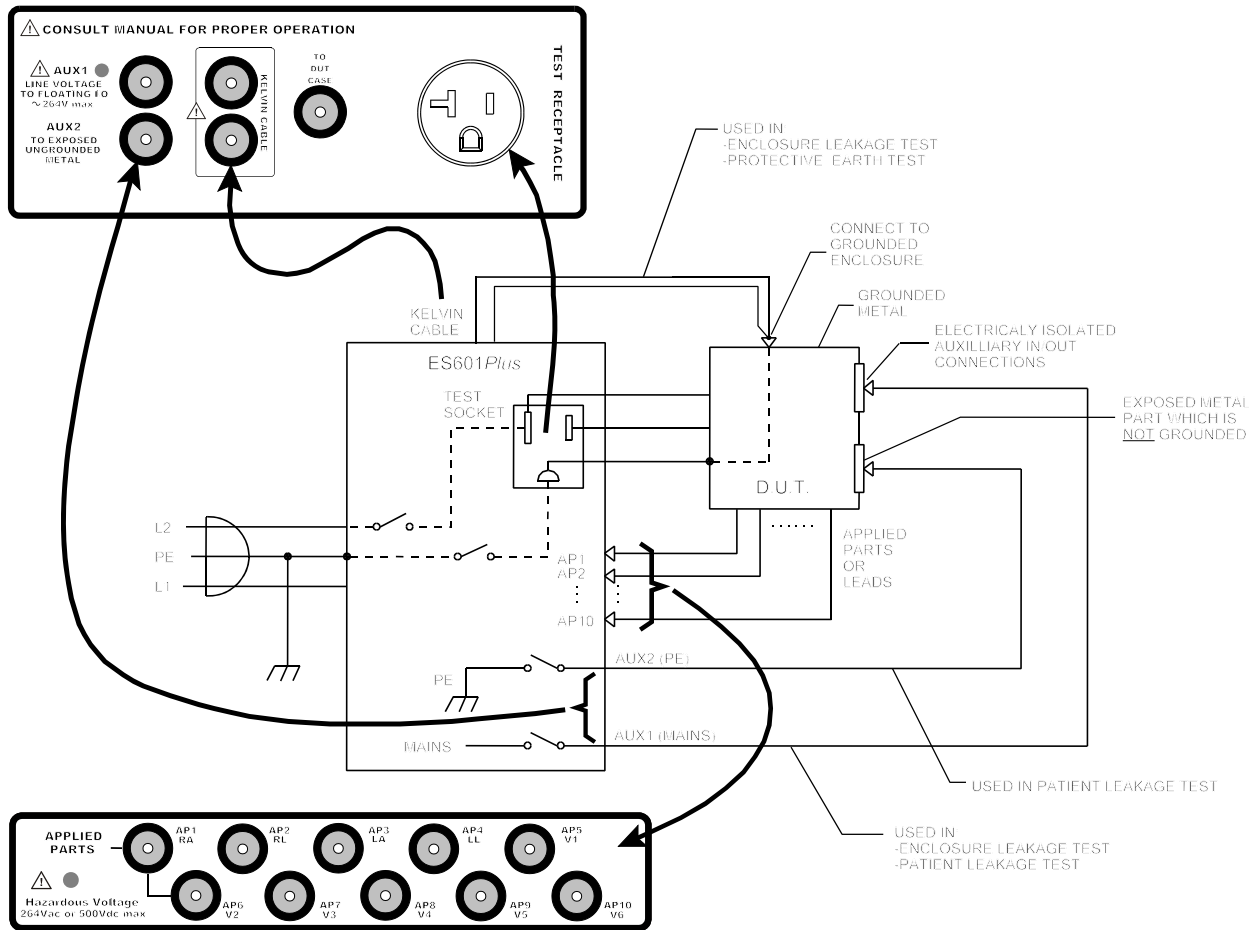
Figure 13 - *Connecting to a line-powered DUT*

4.2 Connecting a Battery-Powered DUT to ES601*Plus*
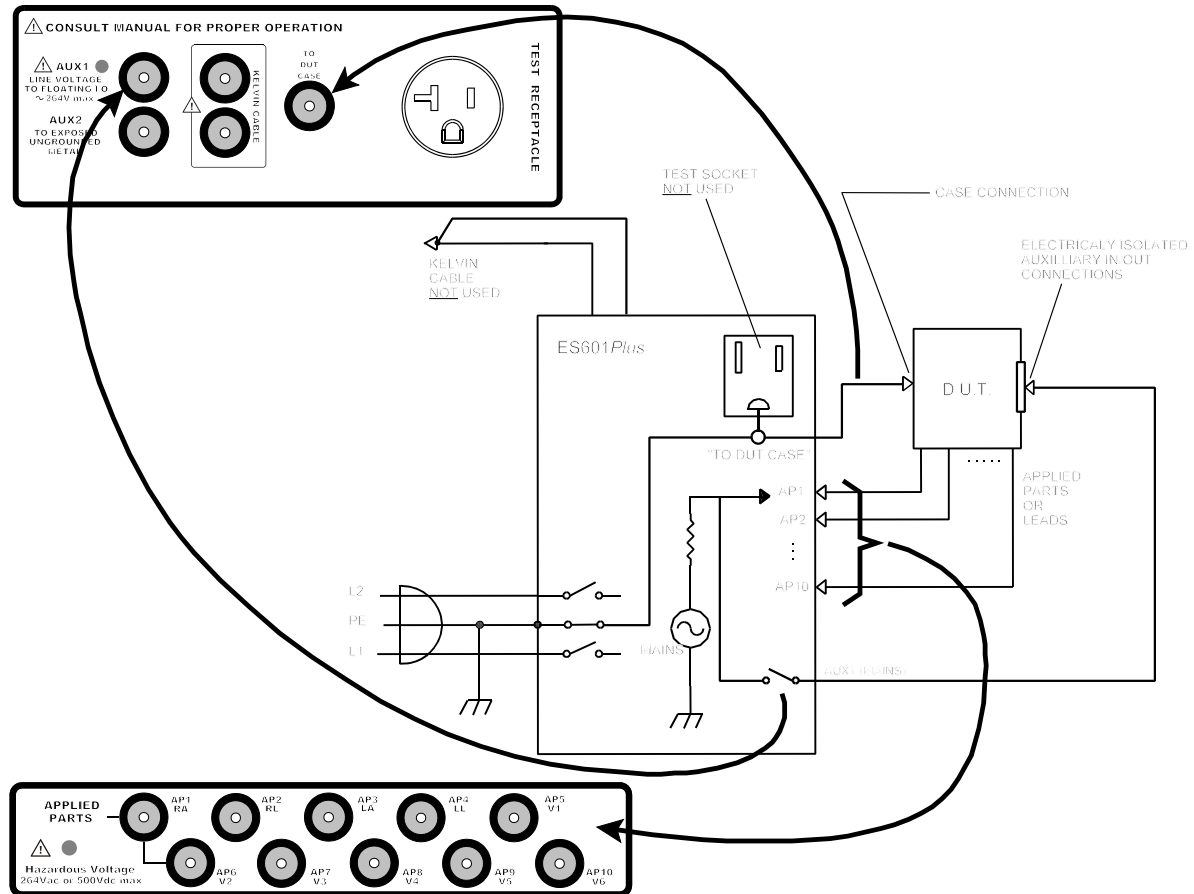
Figure 14 - *Connecting to a battery-powered DUT*

Connection instructions for battery-powered DUT:

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

- The "TO DUT CASE" jack of ES601*Plus* 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 Socket 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 ES601Plus.

OR...

Connect an RS-232 barcode scanner (DB9F) to the BARCODE input of the ES601Plus.

Peripheral testing devices, if used, should be connected to RS232 TESTER PORTS before powering the ES601Plus 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 4 of this manual.
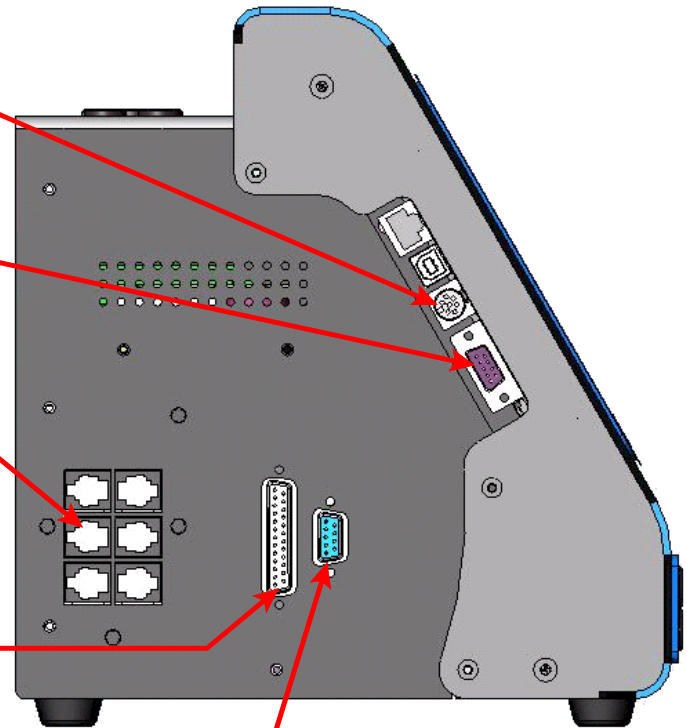
Figure 15 - *Connecting Peripheral Devices*

Chapter

5

5   Manual Testing

5.1 Manual Mode Display

MANUAL MODE is entered from either the STARTUP menu or the AUTO MODE menu of ES601*Plus*. This menu allows the user to select various types of individual electrical safety measurements such as protective earth (ground resistance) or leakage current. The menu also provides access to a submenu for manually operating the ECG simulator.
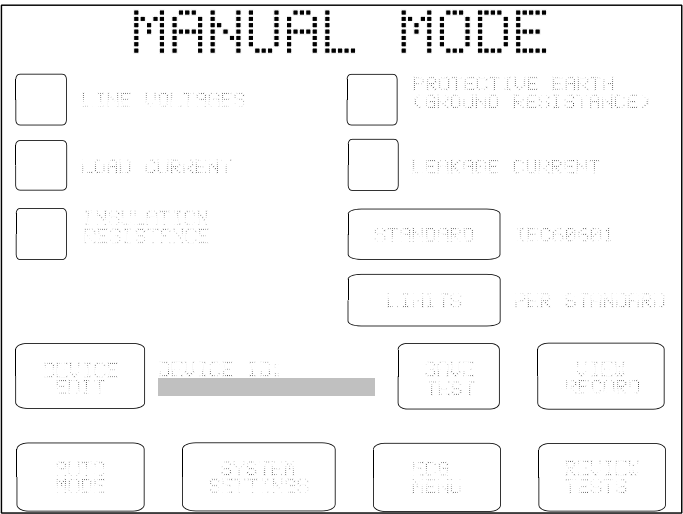
Figure 16 - *Manual mode main menu.*

5.2 Clip Record

As safety measurements and other tests are performed with ES601*Plus*, the individual test results are collected in a temporary area of memory which is designated the "*Clip Record*". When testing is complete and results are saved, the contents of the Clip Record are copied to a "*Test Record*", which resides in non-volatile or "flash" memory. When a Test Record is recalled from flash memory, the Record data is placed in the Clip Record. The Clip Record is in volatile memory and any data stored in it will be lost if the power to ES601*Plus* is interrupted before the Clip Record data is saved as a Test Record. Test Records saved in flash memory are retained when power to ES601*Plus* is switched off.

As ES601*Plus* is used to perform safety and other tests, the Clip Record will accumulate the following data:

- • Device Information (control number, description , make, model, etc)
- • Safety Test Measurements (voltage, current, and resistance values)
- • ECG AutoSequence test data (waveform and test result) – AUTO MODE only.
- • Data from other types of automated testing, such as Test Procedures - AUTO MODE only.

Data accumulated in the Clip Record may be reviewed at any point during the manual testing process by selecting the **VIEW RECORD** button.

If a test is repeated, the results from the repeated test will overwrite the Clip Records contents for that test.

Pressing the **STANDARD** button or **AUTO MODE** button on the MANUAL MODE menu will *clear the Clip Record*. Clip Record data which has not been saved as a Test Record will be *erased*.

5.3 Safety Standards

⚠️   **NOTE:**

The safety standard should not be changed *during* a manual test. Pressing this button during a manual test will erase all measurement data in the Clip Record. Select the standard *first*, then proceed with manual safety tests.

This button on the MANUAL MODE menu allows you to select the safety standard to be applied. Available options are:

- • IEC60601
- • AAMI-ES1
- • 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 PROTECTIVE EARTH are removed from the menu, leaving just the LEAKAGE CURRENT and INSULATION RESISTANCE buttons, and other buttons related to saving or reviewing test data.

Any of the above safety standards may be programmed as the MANUAL MODE default. The MANUAL MODE default is selected by ES601*Plus* at power-up, or if MANUAL MODE is entered from the AUTOSEQUENCE MODE menu. If the safety standard is temporarily changed from the default, it remains as set by the user for as long as ES601*Plus* remains operating in MANUAL MODE.

To program the MANUAL MODE default:

a.) select the desired default safety standard for the MANUAL MODE menu by pressing the **STANDARD** button;

b.) press the **SYSTEM SETTINGS** button immediately after setting the standard; and

c.) return to the MANUAL MODE menu by pressing the **EXIT** button on the SYSTEM SETTINGS menu.

The above procedure will program the default setting of the safety standard for the MANUAL MODE into the non-volatile flash memory of ES601*Plus*. This default may be changed at any time by repeating the above procedure.

5.4 Safety Limits

User-defined Safety Limits are an accessory option for ES601*Plus*. This accessory feature allows the user to select the pass/fail limits to be applied for the given standard. This setting may be toggled between:

> • Per Standard (default)
> • User-Defined

Each of the primary safety 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 or "flash" memory of ES601*Plus*. Leakage and other limit values in these tables may be edited using the optional Safety Limits Editor plug-in of the ES601pc software package.

Note: If the Safety Limits accessory option has not been installed in ES601*Plus*, pressing the LIMITS button of *Figure 16* will cause "*(DISABLED)*" to be displayed beside the button.

5.5 Device Information Editor

Press the **DEVICE EDIT** button on the MANUAL MODE menu to enter information about the DUT in the Clip Record of ES601*Plus*. The DEVICE INFO menu allows entry of equipment information such as I.D. [control] number, make, model, serial number, facility, location and Tech Code.

Device information can be updated at any time during a manual test, until the test data is saved as a Test Record. When a Test Record is saved, the I.D. Number and Serial Number fields of the device information are automatically cleared. The remaining device information will remain intact, so multiple devices of the same make, model, location and facility can be tested without having to re-enter any additional information.

The device information fields are printed in the heading of the Test Report generated by ES601*Plus*. This information helps identify the equipment beyond the I.D. or control number. This is helpful for those facilities that do not use a Computerized Maintenance Management System, and rely more on hardcopy records.

Figure 17 *- Device information data entry menu.*

On the DEVICE 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 device information fields are retained in the Clip Record, along with manually acquired safety test measurements.

Note the DEVICE INFO menu will be automatically displayed by ES601𝓟𝓵𝓾𝓼 if the ID Number field is blank and SAVE TEST on the MANUAL MODE menu is pressed. A Test Record ***must*** have an ID Number to be SAVED.

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

ESCAPE: Returns the display to the MANUAL MODE menu

CLEAR ALL: Clears all information fields shown on menu

CLEAR I.D.:   Clears I.D. and Serial Number fields only

5.6 Line Voltage Test

Pressing the **LINE VOLTAGES** button on the MANUAL MODE menu allows you to measure the AC supply voltages L1-L2; L1-GND; and L2-GND.

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 ($V_{L2-GND} > V_{L1-GND}$), ES601*Plus* 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.
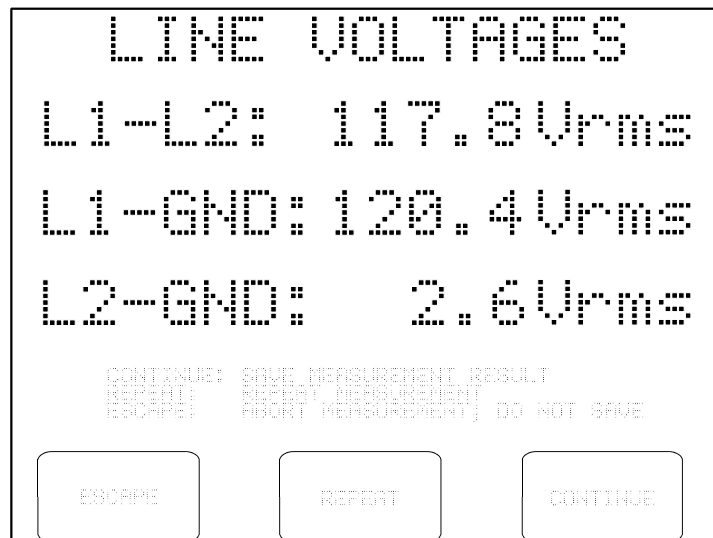
Figure 18 - *Line voltage measurement results.*

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

ESCAPE:	Returns to the MANUAL MODE menu. Results are discarded and are not copied to the Clip Record.
REPEAT:	Repeats the Line Voltage measurements.
CONTINUE:	Saves the results to the Clip Record. Previous line voltage data in the Clip Record, if any, are overwritten. Returns to the MANUAL MODE menu.

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), ES601Plus will activate the test socket and then pause for the power-up delay specified in the System Settings, after which ES601Plus will measure the current. If "STOP AFTER..." of the System Settings is set to "YES", ES601Plus will activate the test socket and then wait until you press the **CONTINUE** button:

Figure 19 - *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 ES601Plus will stop and display the value:
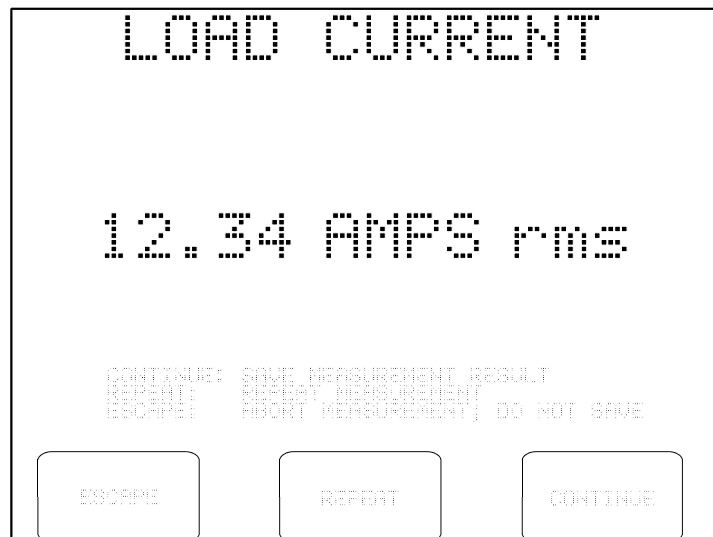
Figure 20 - *Load current result.*

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

ESCAPE: Returns the display to the MANUAL MODE menu. The result is discarded and not copied to the Clip Record.

REPEAT: Causes the measurement to be repeated.

CONTINUE: Causes the load current result to be moved to the Clip Record where other safety test measurements are collected. If there is a previous load current measurement in the Clip Record, it is overwritten.

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

Figure 21 - 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 L1 and L2 supply inputs to the ground connection; or alternatively from all applied parts 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.
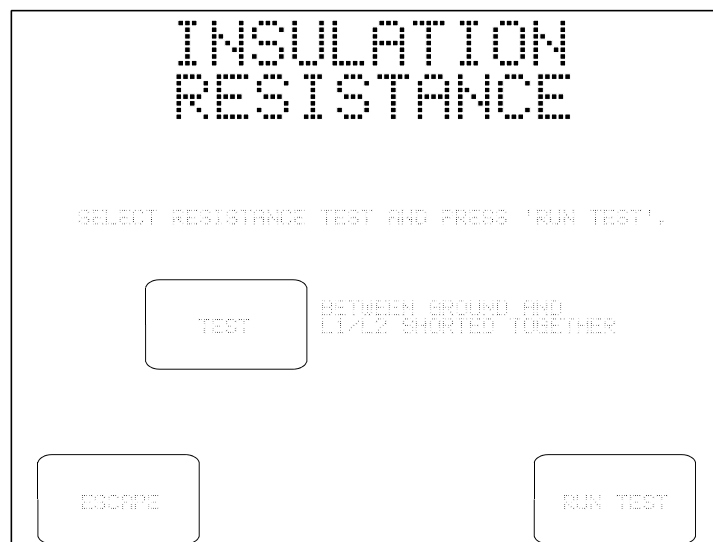
Figure 22 - *Insulation test selection menu.*

Options available on the insulation test selection menu are:

TEST: Toggles the test between measuring insulation resistance "BETWEEN GROUND AND L1/L2 SHORTED TOGETHER" and "BETWEEN GROUND AND ALL APPLIED PARTS".

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

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.

┌───┐
│   ⚠️   │
│   __WARNING:__   │
│   │
│ If testing insulation resistance of applied parts, 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*Plus*.   │
└───┘

After approximately two seconds, the measurement result in megohms is displayed.
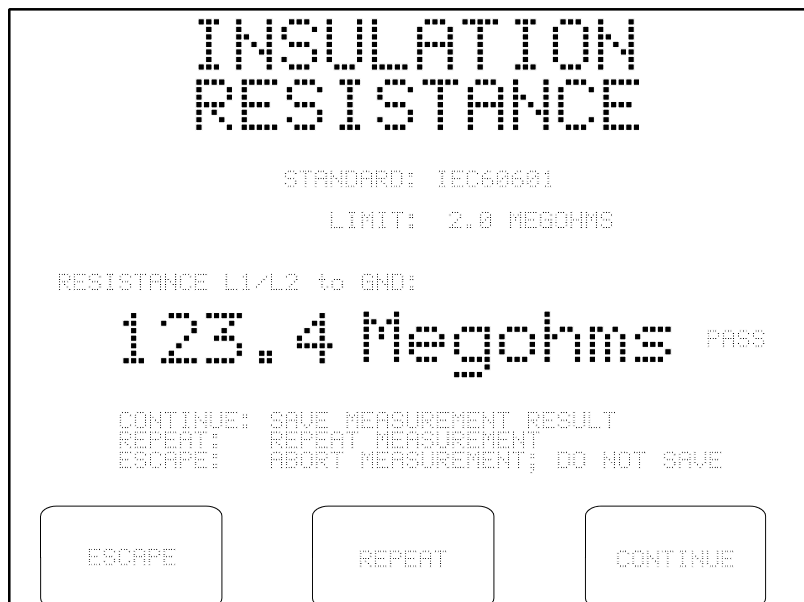
Figure 23 *- Insulation test result.*

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

ESCAPE: Returns the display to the MANUAL MODE menu. The result is discarded and not saved to the Clip Record.

REPEAT: Causes the measurement to be repeated.

CONTINUE: Moves the measurement data and Pass/Fail limit (if shown) to the Clip Record. 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.

5.9 Protective Earth Test

Pressing the **PROTECTIVE EARTH** 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 DC bipolar or, if using ES601*Plus* with accessory PETM, 25 amps AC RMS.

Upon selecting this test from the menu, ES601*Plus* will recall the Systems Settings for the manual protective earth (PE) test and will then display these on the LCD:
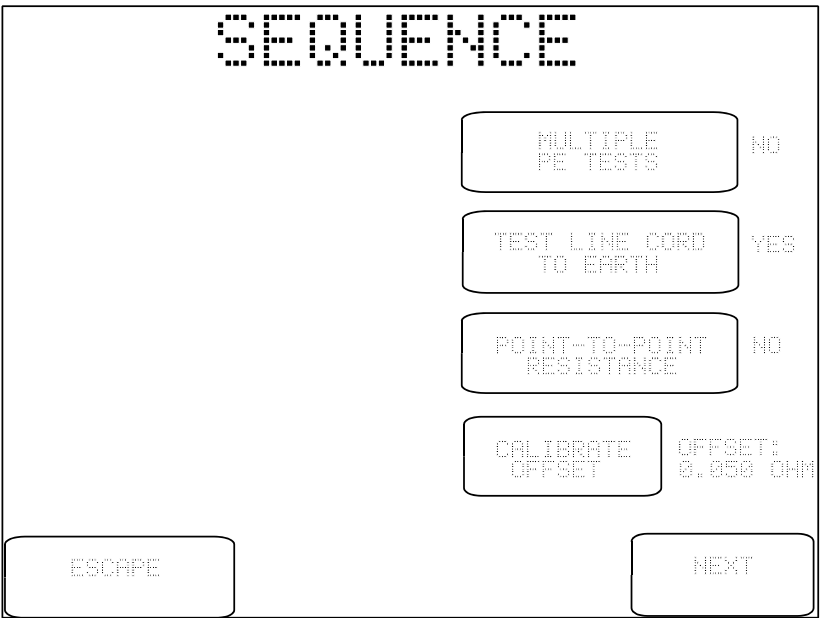
Figure 24 - Sequence Controls for manual PE test.

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:

MULTIPLE PE TEST: If set to "YES", this control will enable multiple protective earth and/or general resistance measurements within the scope of the test. Up to ten resistance measurements may be recorded by ES601*Plus* in multiple PE mode. If set to "NO", the test will be completed after performing a single measurement of resistance.

TEST LINE CORD TO EARTH: If set to "YES", this control will enable measurement of the line cord resistance. For this type of test, resistance is measured between the protective earth terminal on the line cord connected to the test socket of ES601*Plus*, and the Kelvin Cable which will be connected to a grounding stud or the metal enclosure of the DUT.

POINT-TO-POINT 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*Plus*. If set to "NO", point-to-point resistance testing is disabled. This control works with the other two controls to provide various protocols for protective earth testing as shown in the table below.

MULTI	LINE CORD	POINT-TO-PT	Test Protocol	Test Application
NO	**YES**	**NO**	Measure resistance once, between Kelvin Cable and test socket of ES601*Plus*.	Conventional PE test of equipment which connects to the AC supply by means of a line 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 a PE equipotential stud located near the DUT, and the "DUT CASE" lead connects to the DUT itself.	Single PE 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 socket of ES601*Plus*. For the first measurement, the Kelvin Cable is connected to a designated PE test stud on the equipment chassis, per the standard PE test for cord-connected equipment. For subsequent tests, the Kelvin Cable may be re-attached at arbitrary locations on the equipment enclosure to confirm continuity of PE to those points.	Multiple PE test of cord-connected equipment. Example: test of patient monitor system.

MULTI	LINE CORD	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 a PE equipotential 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 PE between the Kelvin Cable and "DUT CASE" lead.	PE test of permanently-installed equipment, followed by continuity test of earthed metal parts on the equipment. Example: test of X-RAY equipment.
YES	**YES**	**YES**	Measure resistance between Kelvin Cable and the test socket of ES601*Plus*, one time. After this measurement, the user disconnects the DUT line cord from ES601*Plus* 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 PE between the Kelvin Cable and "DUT CASE" lead.	PE test of cord-connected equipment, followed by continuity test of earthed metal parts on the equipment. Example: test of a hospital bed.

Only those combinations shown in the above table are permitted by ES601*Plus*; 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*Plus*.

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*Plus*.

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

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*Plus* 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: This button on the Sequence Controls menu advances the test to the next step. If the PETM accessory option is installed, you will first be prompted to select the test current if the safety standard is either IEC60601 or IEC61010. The 25 amp test cannot be selected if the PETM hardware is not present in ES601*Plus*, or if the safety standard is not set to IEC60601 or IEC61010. In these cases, the 1 amp test is performed by default.

Figure 25 - *Selection of test current (PETM option only).*

Buttons provided on the test current menu are:

CURRENT: Selects either 1 amp DC bipolar, or 25 amp AC RMS test current.

ESCAPE: Aborts the test and returns to MANUAL MODE menu. No results are saved to the Clip Record.

RUN TEST: Initiates the test protocol represented by the Sequence Control settings displayed on the test current menu.

If the 1 Amp test is selected, the resistance measurement will be performed using a regulated, calibrated test current of 1.0 Amp DC. The initial measurement requires one second, after which the first result is shown on the display. The polarity of the test current is then automatically reversed and the measurement is repeated. The higher of the two resistance readings is then shown on the display, along with a pass/fail indication.

Figure 26 - *Protective earth test result (multiple PE = "NO").*

The limit for the protective earth 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*Plus*.

If "MULTIPLE PE TEST" 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:

ESCAPE: Returns the display to the MANUAL MODE menu. The result is discarded and not saved to the Clip Record.

REPEAT: Causes the measurement to be repeated.

CONTINUE: Moves the resistance measurement and Pass/Fail limit to the Clip Record. 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.

If "MULTIPLE PE TEST" is set to "YES", four buttons will be displayed upon completion of each resistance measurement according to ***Figure 27***.

Figure 27 - *Protective earth test result (multiple PE = "YES").*

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 Clip Record.

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 Clip Record. If there are previous results from this test in the Clip Record, they are overwritten. The user interface returns to the MANUAL MODE menu.

For a protective earth test performed at 25 amps, ES601*Plus* measures the actual current flowing through the DUT ground circuit and the potential developed across the circuit, and then calculates and displays the resistance once per second. The total duration of the measurement is 10 seconds as required by the IEC60601 and IEC61010 standards. To determine whether the DUT passes the test, ES601*Plus* compares the highest resistance value observed during the procedure to the specified limit.

When testing at 25 amps in multiple PE mode, and after the first resistance value of the test is recorded, the measurement duration is then shortened from 10 to 3 seconds for the remainder of the protocol. The reduced measurement interval minimizes the risk of overheating the connections and changing the resistance of the test cables, which could potentially invalidate the measurement results.

⚠️ **WARNING:**

You must be careful to ensure you are using a Protective Earth (PE) connection during the 25 amp test.

A true PE connection is designed to conduct in excess of 25 amps. However, exposed metal parts or terminals on the DUT may be Functional Earth (FE) connections, which are designed to function as a circuit ground return path at relatively low currents.

If the 25 amp test current from ES601*Plus* is allowed to pass through a FE connection, there may be damage to the DUT such as burning of internal components or other failures. 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.

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, and individual measurements in the sequence to be repeated, if desired.
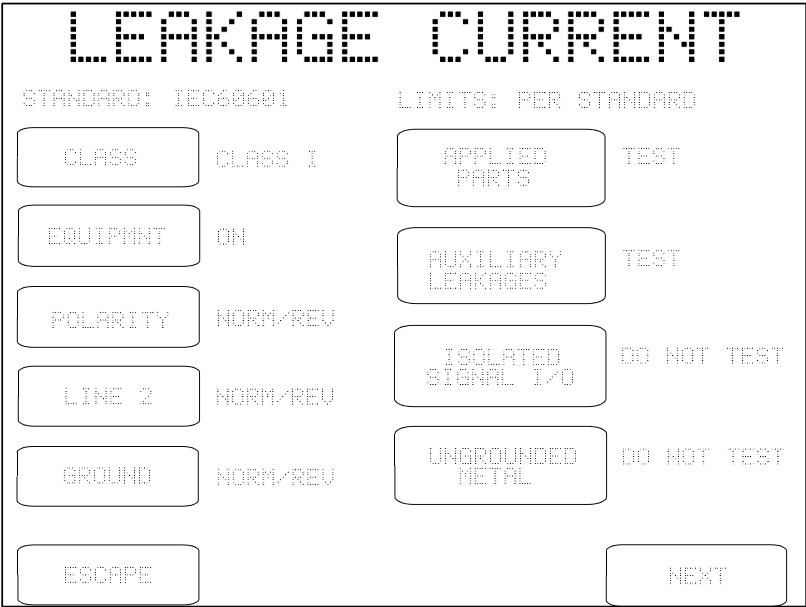
Figure 28 - Leakage test conditions for IEC60601 standard.

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 IEC60601 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 protective earth; "Class II" is two-wire, with no protective earth. 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 IEC60601 and AAMI-ES1 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 IEC60601 and AAMI-ES1, "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.

LINE 2:   If set to "NORMAL", tests are performed with Line 2 (neutral) of the AC supply in normal condition only. If set to "NORM/OPEN", tests are performed with Line 2 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 (protective earth) 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.

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

AUXILIARY LEAKAGE: If set to "TEST", measurement of auxiliary (lead-to-lead) leakage is enabled. If set to "DO NOT TEST", auxiliary leakage is disabled. To enable auxiliary leakage measurements, APPLIED PARTS must be set to "TEST".

For full compliance with requirements of IEC60601 and AAMI-ES1 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 110% of the AC supply will be output from the AUX1 jack of ES601*Plus*. 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 IEC60601 and AAMI-ES1 standards when the DUT has an ***isolated*** data connection such as an Ethernet port. If enabled, the test does **NOT** 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 protective earth, from DUT applied parts to protective earth, and (for AAMI standard) between interconnected patient leads. When measuring the mains-on-applied-part leakage, ES601*Plus* will connect AUX1 to protective earth, rather than isolated mains.

ISOLATED SIGNAL I/O, cont'd:

Therefore, the "ISOLATED SIGNAL I/O" button enables a supplementary test condition for touch current, patient and auxiliary leakage measurements under IEC60601 and AAMI 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.

⚠️ **WARNING:**

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

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.

UNGROUNDED METAL:

Options are "DO NOT TEST" (default) or "TEST". This parameter determines whether the AUX2 output of ES601*Plus* will be connected to protective earth of the AC supply.

AUX2 is intended to connect to **floating exposed** metal on the DUT.

This test is required under the IEC60601 standard if the DUT has metal parts that are electrically isolated or "floating", but are exposed so a user or patient can touch them. If enabled, the test does **NOT** measure the leakage current from the floating metal parts. In this test, the metal is connected to protective earth and then the leakage current of the *patient-applied parts* is measured.

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 earth, 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*Plus* to the next step of the leakage test.

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

Figure 29 - *Applied part setup.*

Buttons provided by the APPLIED PARTS editor 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 patient-applied part (e.g. ECG lead; sensor; etc.) that you will connect to jack AP1 of ES601*Plus*.

                        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*Plus* to the next step of the leakage test.

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

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

For the AAMI 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 (protective earth); Group 2 is pre-assigned to patient leads which are **not** isolated from ground.

The assignment of applied parts to Groups is indicated on the APPLIED PARTS editor menu. Part assignments can be changed by pressing the **EDIT** button on the menu, which then displays the GROUPS editor:

Figure 30 *- Groups editor for applied parts.*

The buttons appearing on the GROUPS editor are:

APPLIED PT GROUP: Selects the applied part group to be edited: 1, 2 3, 4 or 5.

GROUP STATUS: Selects "ENABLED" or "DISABLED". Applied parts of disabled groups are excluded from patient leakage and auxiliary 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 applied part (AP1) in one enabled group (Group 1).

BACK: Returns to the APPLIED PARTS menu.

RESET ALL: Resets all Group settings, leaving Group 1 enabled as Type BF with one applied part (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*Plus* 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 applied parts, 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.
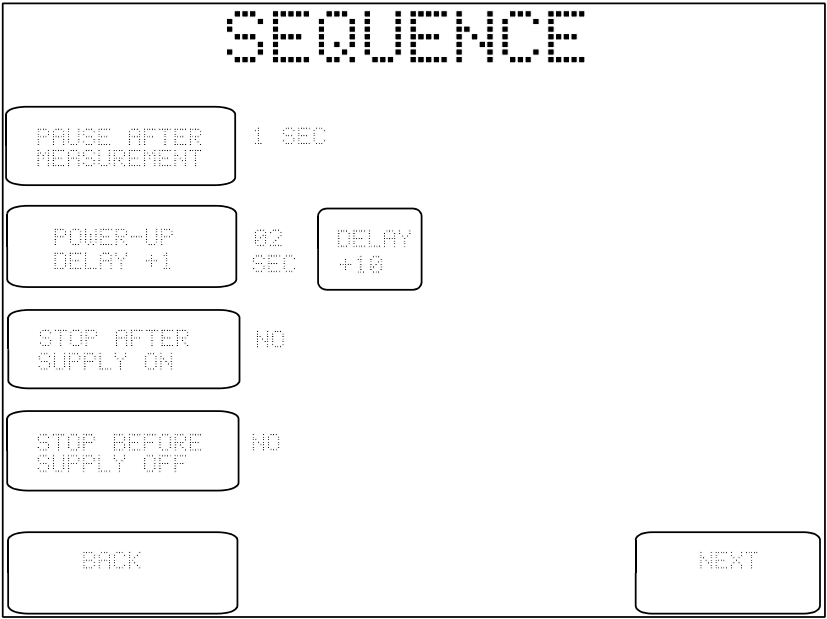
Figure 31 - *Sequence Controls for manual leakage test.*

The buttons provided on the Sequence Control menu are:

PAUSE AFTER MEASUREMENT: After each measurement of the test, ES601*Plus* 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*Plus* 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 99 seconds in one second steps.

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*Plus*. ES601*Plus* 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*Plus* 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*Plus* 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.

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

NEXT: Displays instructions for connecting the DUT to ES601*Plus*. The instructions displayed will depend on the safety standard. The example menu shown following is for the IEC60601 standard.

Figure 32 - *DUT connection instructions for IEC60601 test.*

According to the CONNECTIONS menu, at minimum an IEC60601 test will require the user to connect the DUT to the test socket and the Kelvin Cable of ES601*Plus* 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*Plus* and DUT applied parts; between AUX1 of ES601*Plus* and DUT signal I/O; and between AUX2 and exposed ungrounded metal on the DUT.

⚠️ **WARNING:**

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

The MAP 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*Plus*.

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", ES601Plus will delay an additional 1 to 5 seconds between consecutive leakage measurements.

Figure 33 - 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 ES601Plus. The **PAUSE** button may be pressed at any time to pause the sequence and freeze the most recent measurement on the display (see *Figure 34*).

Figure 34 *- Leakage test paused during sequence.*

Individual leakage readings are rapidly made by ES601*Plus*, 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 31***) 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 new leakage test data is saved to the Clip Record.

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*Plus*. 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; Line 2 (neutral) in single-fault condition (**RP:SF L2O**)

2   Reverse polarity; supply in normal condition (**RP:NC**) or with earth (ground) in single-fault condition (**RP:SF EO**)

3   Normal polarity; Line 2 in single-fault condition (**NP:SF L2O**)

4   Normal polarity; supply in normal condition (**NP:NC**) or with earth in single-fault condition (**NP:SF EO**)

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

When ES601Plus changes the AC supply from SF:L2O to NC, and if "STOP AFTER..." of the Sequence Controls is "NO" (**Figure 31**), ES601Plus 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", ES601Plus will change the AC supply from SF:L2O to NC and wait until you press the **CONTINUE** button:
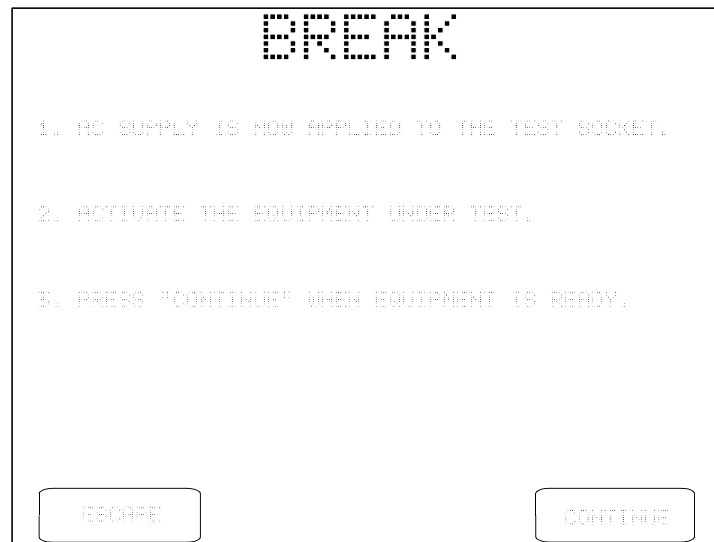
Figure 35 - *Break if "STOP AFTER..." is "set to YES".*

The leakage sequence proceeds with NC tests 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 ES601Plus changes the AC supply from NC to SF:L2O, ES601Plus will not stop if "STOP BEFORE..." of the Sequence Controls is "NO" (**Figure 31**). If "STOP BEFORE..." is "YES", ES601Plus will stop and prompt you to shut down the equipment before supply Line 2 is disconnected:

Figure 36 - *Break if "STOP BEFORE..." is set to "YES".*

After **CONTINUE** is pressed, ES601*Plus* will disconnect Line 2 from the DUT 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.

Figure 37 - *Switch DUT to "ON" for upcoming SF:L2O 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 36*** and ***Figure 37*** 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 IEC60601 and AAMI-ES1 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*Plus* will stop after all leakage measurements have been completed with DUT power switch in "ON" position. ES601*Plus* will then display instructions as shown in the following figure.

BREAK

1. SEQUENCE 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
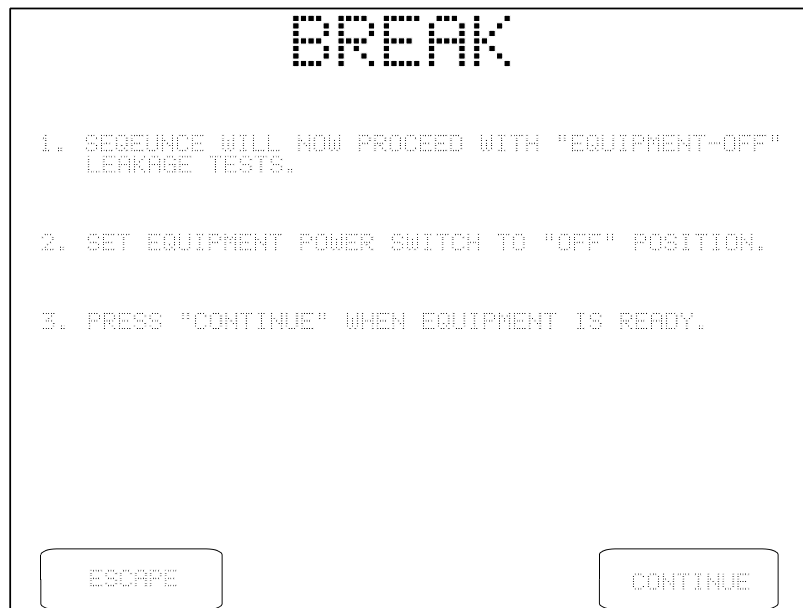
Figure 38 *- Switch DUT to "OFF" for "DUT OFF" tests.*

Upon pressing **CONTINUE** on the above menu, ES601*Plus* repeats all leakage tests that were enabled by the user. Since the DUT power switch remains "OFF" for all measurements, ES601*Plus* 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*Plus* will stop and display the last measurement taken during the leakage test. Pressing the **CONTINUE** button on the display saves the leakage measurement data in the Clip Record, along with the limits corresponding to each measurement. Refer to Chapter 2 for a discussion of the leakage current protocols of ES601*Plus*, and the data which is saved by each protocol.

5.11 Viewing the Clip Record

At any time during manual testing, device information and safety test data accumulated in the Clip Record may be examined by pressing the **VIEW RECORD** button on the MANUAL MODE menu.

The Clip Record data will be shown on the LCD as a multi-page Test Record 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 features.

5.12 Saving a Test

Press the **SAVE TEST** button on the MANUAL MODE menu to save safety test data and device information in the Clip Record to a Test Record. Usually, this is the final step of a manually-conducted safety test.

Figure 39 *- Menu for saving a Test Record.*

The SAVE TEST RECORD menu shows selected fields of the device information, the parent device I.D., the test record number, and the current memory status. The parent device I.D. shown on this menu relates to the creation of linked Test Records for modular multi-parameter patient monitors; refer to SAVE TEST AND ADD MODULE below.

The options available on the SAVE TEST RECORD menu are:

DEVICE EDIT: This selection opens the DEVICE 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 device information and measurement data for the test in progress and returns to the MANUAL MODE menu. The Clip Record is erased by pressing this button.

KEEP TEST DATA: Returns the display to the MANUAL MODE menu, and keeps the measurement data and device information in the Clip Record.

SAVE TEST RECORD: Saves the test data to a Test Record in flash memory, and returns the display to the MANUAL MODE menu. Make, model, location, facility and Tech Code fields of the device information are retained, preparing ES601*Plus* to test another similar device. All other device information and data in the Clip Record are erased.

SAVE TEST AND ADD MODULE: Saves the test data according to the description above for **SAVE TEST RECORD**, and creates a link to the next record to be saved through the Parent ID field of the Test Record.

A practical application of this feature is to link results for a modular patient monitor under the control number of the monitor's mainframe, but where each plug-in module of the monitor could be independently identified by its own control number or other ID in an equipment management system.

The Parent ID is utilized by the Test Report Generator of the ES601pc software package, which can use the Parent ID field within each Test Record to generate a single integrated report for the mainframe and all modules comprising a modular multi-parameter patient monitor. The **SAVE TEST AND ADD MODULE** button will continue to link Test Records for the modules via the Parent ID, until the Test Record for the final module of the patient monitor is stored by pressing the **SAVE TEST RECORD** button. This will break the chain of linked Records by clearing the Parent ID field.

5.13 Reviewing Tests

Test Records which have been saved to the flash memory of ES601*Plus* may be recalled by pressing the REVIEW TESTS button on the MANUAL MODE menu. A particular Test Record can be located by scrolling up or down using the scroll buttons, until the desired Test Report is highlighted. Display the Test Report by pressing the SELECT RECORD button. The selected Record will appear on the LCD as described in the following section of this chapter.

Figure 40 *- Select a Test Record*

If a previously stored Test Record is recalled from the flash memory in this manner, any safety test data or device information that may exist in the Clip Record will be overwritten with the data of the recalled Record. Any manual test data that may have been collected in the Clip Record will therefore be **lost**, unless it is first saved via the SAVE TEST 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 Device ID, and the Date and Time of the test.

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 Data Flash of ES601*Plus* . 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 Data Flash memory.

ES601*Plus* 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 Data 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 the DEVICE ID number.

If the Data Flash contains a record for the Device ID entered, the Test Record will be displayed. If more than one record exists for a recognized Device ID, only the earliest Test record will be displayed. If the Device ID 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 MANUAL MODE menu.

COMPUTER INTERFACE: Opens the COMPUTER INTERFACE menu to allow for communication with the ES601pc 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 ES601 Printer Port or 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. The current contents of the Clip Record may also be viewed while testing is in progress, via the **VIEW RECORD** button on the MANUAL MODE menu. In either case, test data is shown on the LCD as a multi-page report which is referred to as a "Test Record". 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*Plus* at one time; this is typically 20 lines or less.

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

If a safety test was 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 protective earth (PE) test if this test was performed. For multiple PE 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 a single PE test, 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 41 - *Example of multiple PE test result.*

Buttons provided by the TEST RECORD display are:

ESCAPE:	Returns to the MANUAL MODE 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*Plus*.
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-applied parts 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 auxiliary leakage tests. This represents are large volume of data, however, such recording and reporting of results is a mandatory requirement of the IEC60601 standard. Other standards, such as IEC62353, do not require as many safety measurements and therefore produce far shorter reports than tests performed according to IEC60601.

Leakage results follow the page of PE test results. For IEC60601 and AAMI-ES1 standards, the first page of leakage results will list the earth leakage and touch current or enclosure measurements (see example following). 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 supply polarity
RP	Reversed supply polarity
NC	Normal condition
SF	Single-fault condition
L2O	Supply line 2 (neutral) open
EO	Protective earth (ground) open
MAP	Mains on applied part(s)

Figure 42 *- Example of earth leakage and touch current 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
APO	All applied parts disconnected from protective earth
APE	All applied parts connected to protective earth
MIO	Mains voltage connected to isolated signal inputs/outputs
IOE	Isolated signal inputs/outputs connected to protective earth
ME	Exposed floating metal parts connected to protective earth

For each supplementary test condition enabled by the user in the test setup, ES601*Plus* measures all combinations of the supplementary condition with the AC supply conditions specified in the safety standard. ES601*Plus* 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 (SF:L2O, SF:EO), "-----" 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 applied parts. One page is provided for each functional group of applied parts, as configured by the user in the test setup (see example below).

Figure 43: 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*Plus* shows the patient connection that produced the highest leakage for the given NC or SF 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 "--" will appear in the "AP" column of the patient leakage results.

In addition to patient leakage, IEC60601 and AAMI-ES1 standards also specify auxiliary (lead-to-

lead) leakage tests. If this test was enabled by the user, patient leakage results will be followed by the auxiliary leakage results, with one page being provided for each individual patient lead or applied part.

Figure 44: Example of auxiliary leakage results (1 page per Part).

Additional pages may follow the safety test data if results were obtained from automated ECG and/or procedural tests. Examples of such data are provided in the two figures which follow. Automated testing is discussed in Chapter 6 of this manual.

Figure 45: Example of ECG AutoSequence results.
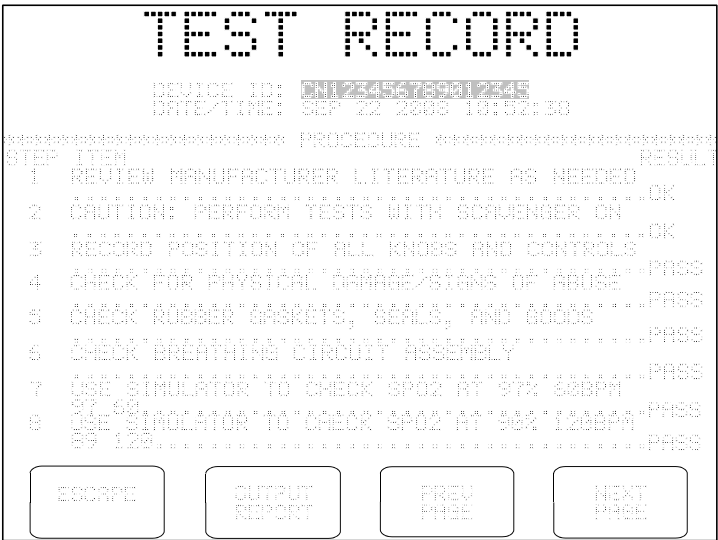
Figure 46: *Example of automated procedure results.*

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*Plus* by pressing the **OUTPUT REPORT** button on the Test Record screen.
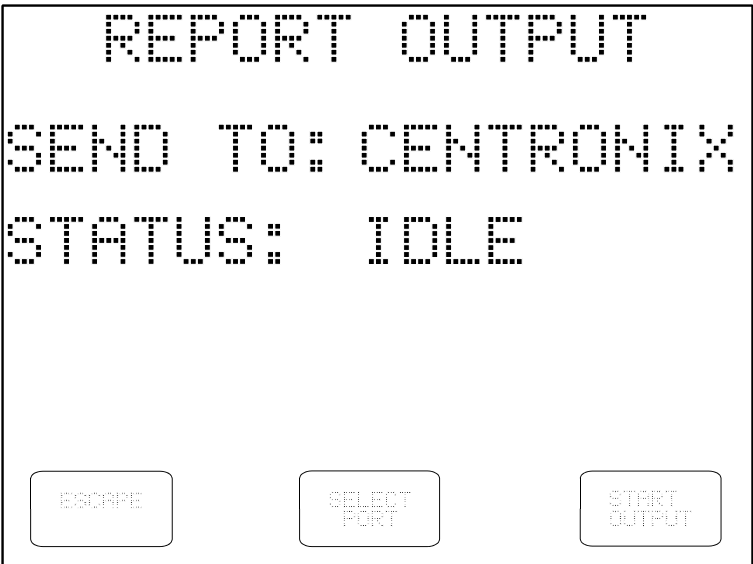
Figure 47 - *Select Printer Port*

> *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*Plus* 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.

```
  REPORT OUTPUT           REPORT OUTPUT

SEND TO: CENTRONIX     SEND TO: CENTRONIX

STATUS:  PRINTING     STATUS:  OFF-LINE!
```
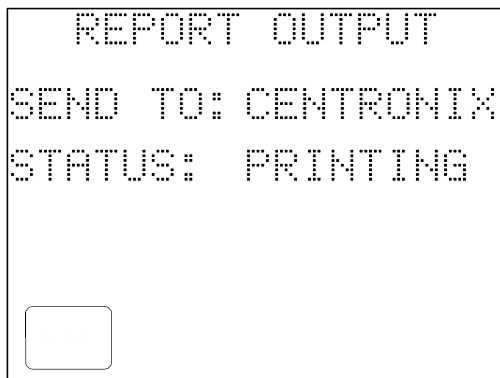
Figure 48 - *Print job in progress.*   **Figure 49** - *Printer Off-line Error*
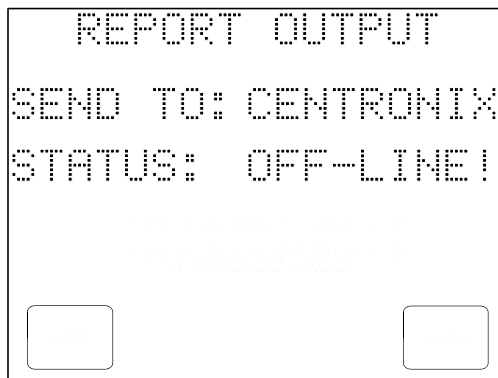
If the print job is completed successfully, the screen will automatically return to the Test Record viewer.

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*Plus*, 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 instructions below to set up *HyperTerminal* for use with ES601*Plus*.

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 50**, 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
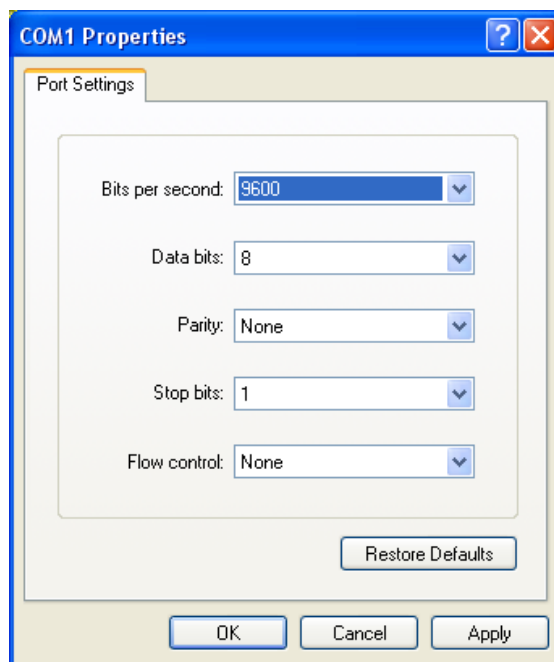
Figure 50 - *Setting up a HyperTerminal connection.*

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*Plus* to the PC. Connect the RS-232 Port of ES601*Plus* 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*Plus* 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.
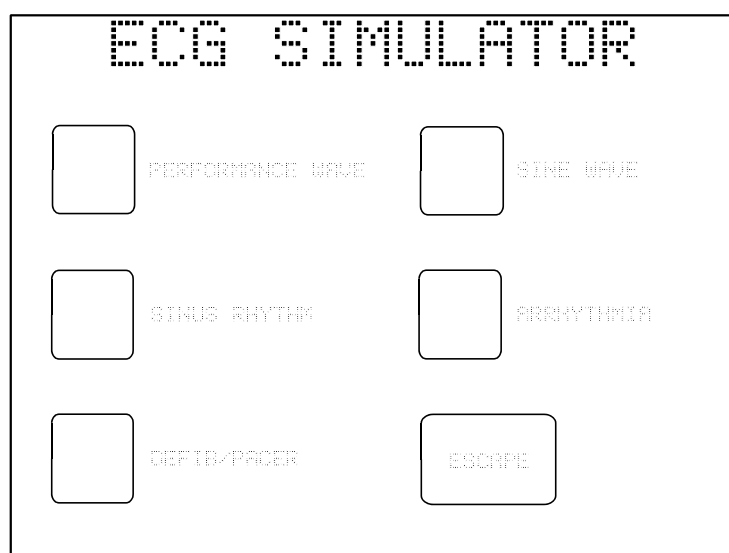
Figure 51 - *ECG simulator main menu, manual mode.*

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).
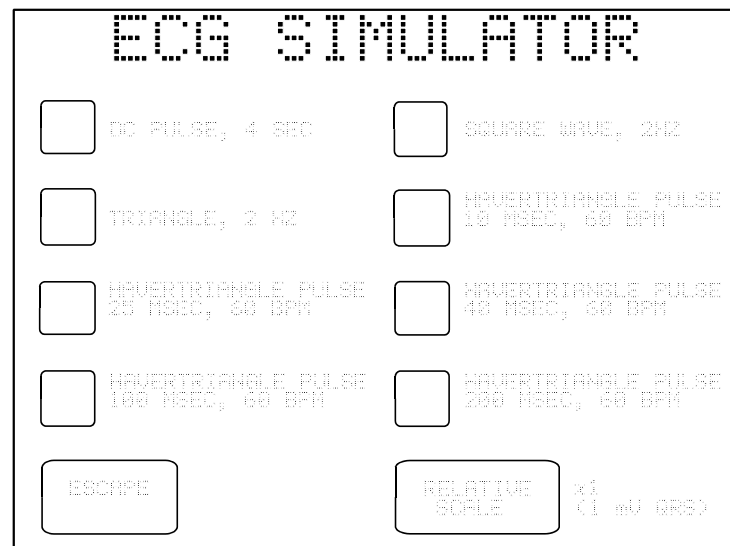
Figure 52 - *Performance wave submenu.*

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 Technician Timer

Some institutions require monitoring and recording of the time spent performing certain types of work. This requirement is satisfied in ES601*Plus* by an elapsed time counter, which is started and stopped in response to activity of the analyzer.

When ES601*Plus* is powered up, the "tech time" counter is initially reset and then stopped.

When any measurement task is selected, 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 continuous hours of work. The timer continues to run until a Test Record is saved by pressing SAVE TEST. The timer value is then saved in the record along with the measurement data.

Operation of the Tech Time counter is similar for all tests performed by ES601*Plus*, including those tests selected from the AUTOSEQUENCE MODE menu.

Chapter

6

6   Automated Testing

6.1 Automated Testing with ES601Plus

AUTOSEQUENCE MODE can be entered from either the power-on STARTUP menu, or by pressing the AUTO MODE button on the MANUAL MODE menu of ES601*Plus*. This menu allows the user to select various automated tests as well as administrative functions (System Settings, Review Tests, etc.) as previously described in Chapter 5.

AUTOSEQUENCE MODE

SELECT TEST BY...

☐ SAFETY AUTOSEQUENCE   ☐ DEVICE ID SEARCH

☐ ECG AUTOSEQUENCE   ☐ TEST PROCEDURE

☐ OTHER AUTOSEQUENCES   SAVE TEST   VIEW RECORD

MANUAL MODE   SYSTEM SETTINGS   DEVICE EDIT   REVIEW TESTS

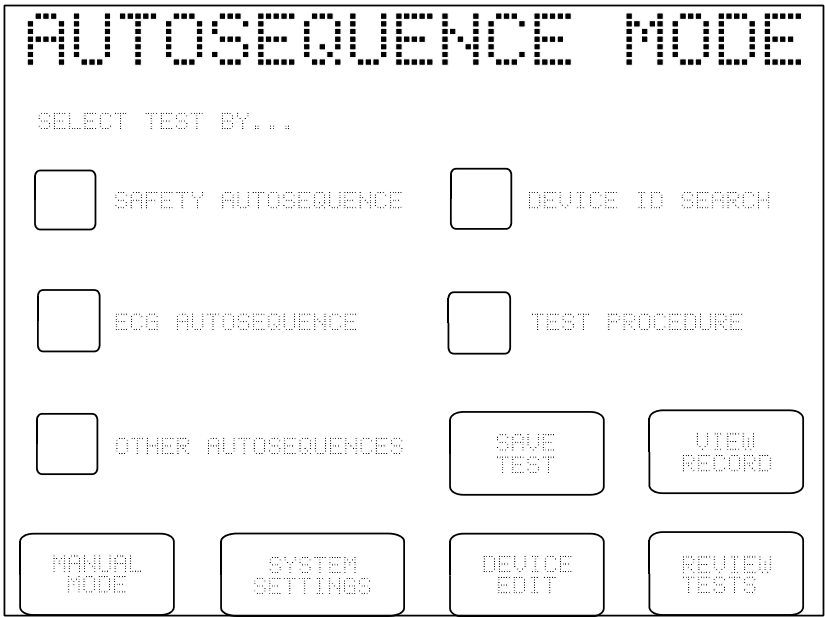***Figure 53*** - *AutoSequence Main Menu*

6.1.1 Safety AutoSequences

Safety AutoSequences of ES601*Plus* correspond to lists of sequential voltage, current and resistance measurements made on the DUT. Twenty-four default Safety AutoSequences allow ES601*Plus* 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 System Settings Menu #2 (see Section 3.6). Alternatively, Safety AutoSequences can be edited and uploaded to ES601*Plus* by means of the Safety Autosequence plug-in of the ES601pc software package. ES601pc is described fully in Chapter 8.

Selecting SAFETY AUTOSEQUENCE from the AUTOSEQUENCE MODE menu of ES601*Plus* opens the Safety AutoSequence menu.
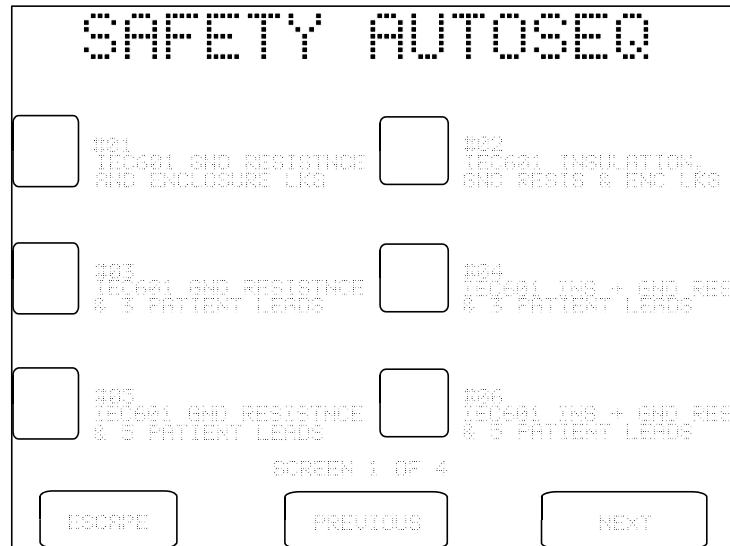
Figure 54 *- Safety AutoSequence menu*

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

Upon selecting the desired test, you will be presented with various menus that will allow you to modify the settings of the 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 setting changes are necessary for more than one test, you should consider programming and saving such changes by means of the AutoSequence editor described in Section 3.6.

The first menu presented after selecting the AutoSequence will be instructions for connecting the DUT to ES601*Plus*. On this and any setup menu which follows, the **ESCAPE** key may be pressed to abort the test and return to the AUTO MODE menu. Alternatively, **CONTINUE** may be pressed to advance the sequence to the next setup menu.

Figure 55 - Connections for IEC60601 test.

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

Figure 56 - Applied part 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 resistance measurement in the protective earth 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.
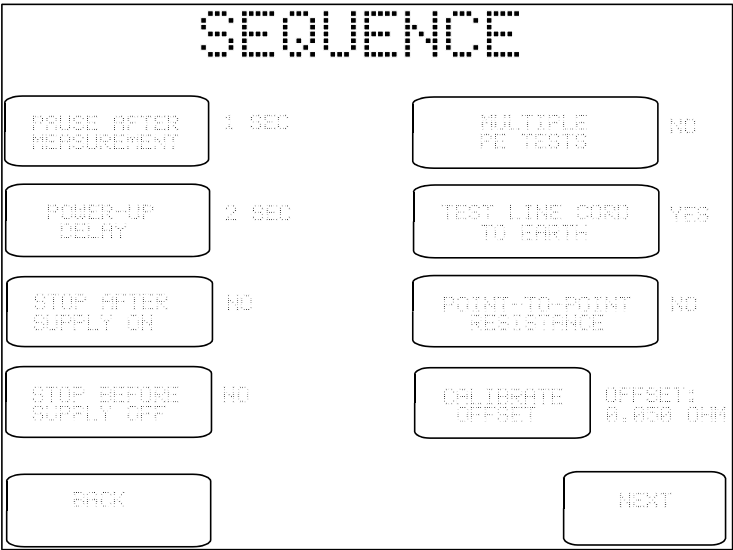
Figure 57 - *Sequence Controls setup.*

The **NEXT** button of the Sequence Controls menu launches the safety test. As the test sequence progresses, the display of ES601*Plus* 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, protective earth, 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. Depending on "STOP AFTER..." and "STOP BEFORE..." settings of the Sequence Control setup, ES601*Plus* may stop at selected steps in the 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*Plus*, but the enabling of the measurements is defined by the user through the AutoSequence programming. The table following 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	Protective earth	OFF
2	Insulation resistance	OFF
3	Line voltage	OFF
4	Leakage (RP:SF L2O)	OFF
5	Leakage (RP:NC)	ON
6	Leakage (NP:SF L2O)	OFF
7	Leakage (NP:NC)	ON
8	Load current	ON
9	Test completion	OFF

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 58 *- Safety AutoSequence in progress.*

6.1.2 ECG AutoSequences

ES601*Plus* provides six programmable ECG AutoSequences, each with up to 24 waveform/amplitude steps. When an ECG AutoSequence is run, the waveform, amplitude scale, and pass/fail result for each sequence step will be stored in the Clip Record, along with measurement data that may have been previously acquired from a Safety AutoSequence or other automated tests. (Refer to Chapter 5 for a discussion of the Clip Record.)

ECG AutoSequences can be edited and uploaded to ES601*Plus* by means of the ECG AutoSequence plug-in of the ES601pc software package. Editing the default ECG AutoSequences is described in Chapter 8. Descriptions of the default ECG AutoSequences are provided in Appendix A.

Selecting ECG AUTOSEQUENCE from the AUTOSEQUENCE MODE menu opens the ECG AutoSequence menu.
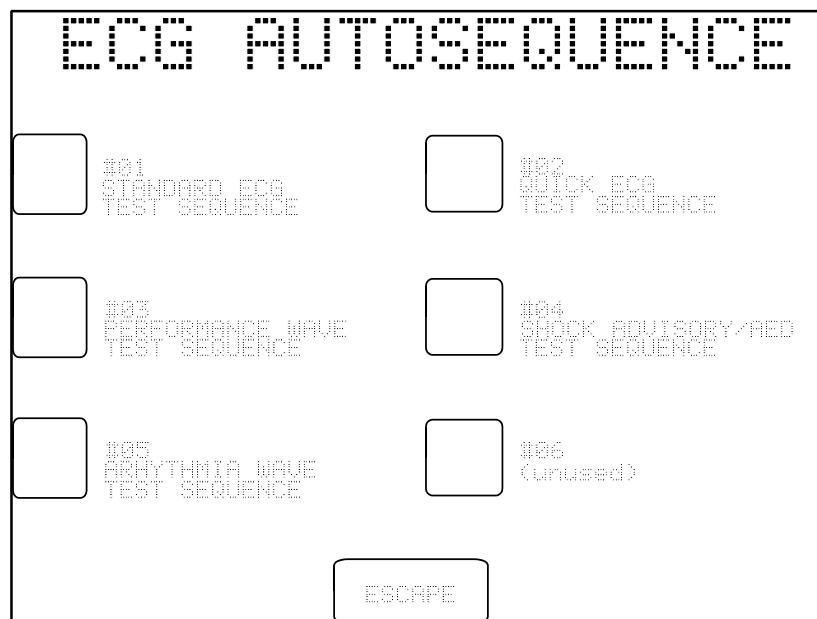
Figure 59 *- ECG AutoSequence menu.*

This menu lists six ECG AutoSequences. Press the appropriate button to invoke the desired ECG AutoSequence. ESCAPE returns to the AUTOSEQUENCE MODE menu.

When the ECG AutoSequence is run, the display of ES601*Plus* reflects real-time information about the tests performed. This includes the sequence name, step number and type of waveform currently being produced within the ECG AutoSequence and its amplitude.

ECG AUTOSEQUENCE

SEQUENCE: STANDARD ECG   TEST SEQUENCE

STEP NO.: 06

WAVEFORM: [UNCERTAING PULSE, 200 PREC, 60BPM]

    SCALE: x0.5 (.5mV)

    PASS   FAIL   FAULT
                                FOUND AND
                                CORRECTED

    ESCAPE   BACK   SKIP
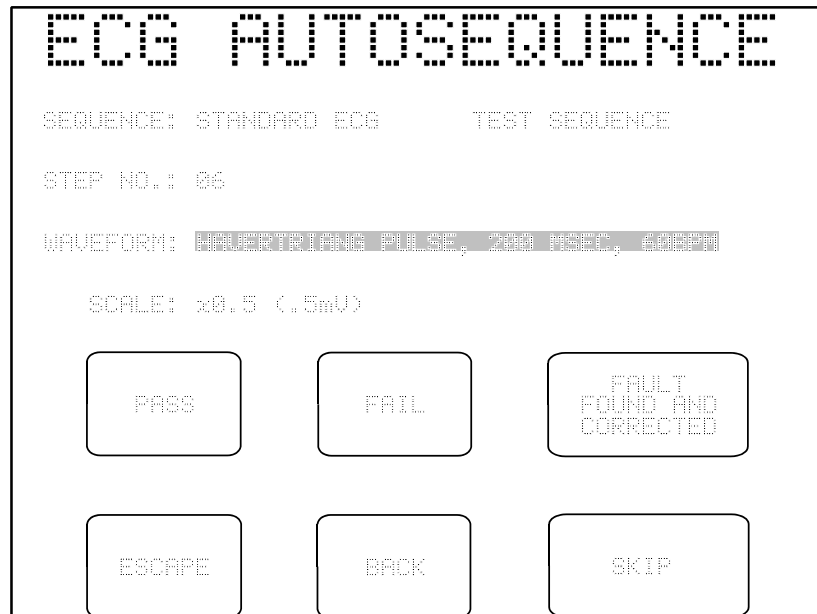
Figure 60 - *ECG AutoSequence in progress.*

Throughout the ECG AutoSequence, **PASS**, **FAIL** and **FAULT FOUND AND CORRECTED** buttons are available. "Pass" indicates the DUT reflects the waveform as produced by ES601*Plus*. "Fail" indicates the waveform is not correctly displayed on the DUT. "Fault Found and Corrected" indicates the problem causing what would normally be a failure was resolved (such as a bad lead that was replaced) during the test.

After stepping through the waveform sequence, the QWERTY keypad is displayed to allow comments to be added to the test, such as "Lead 2 / RL bad – Replaced". The comments field allows for 40 ASCII characters. Entry of the comment is optional. When the **ENTER** key on the QWERTY keypad is pressed, the SAVE TEST RECORD menu is displayed.

6.1.3 Other AutoSequences

In addition to Safety Autosequences and ECG Autosequences, ES601*Plus* optionally provides for other types of automated tests. On its left side panel, ES601*Plus* provides six RS232 Tester Ports which can be connected to external measuring instruments (Analyzers, or "Testers") by means of accessory adapter cables. Tester AutoSequences of ES601*Plus* allow external Testers to be controlled via these RS232 Tester Ports.

The AutoSequence Editor is supplied as part of the ES601pc software package. Provided ES601*Plus* has the required accessory options installed in it, the AutoSequence Editor of ES601pc will allow the user to program AutoSequences for the five User-Defined Testers of ES601*Plus*, as well as the General Inspections. In addition, Datrend product specific AutoSequence selections are available for devices such as pulse oximeter testers (Oxitest Plus7), infusion pump testers (Infutest 2000) and defibrillator testers (Phase3). The AutoSequence Editor of ES601pc is described in Chapter 8. ES601*Plus* menus associated with selecting and running such sequences created by the Editor are discussed below.

Selecting **OTHER SEQUENCES** from the AUTOSEQUENCE MODE menu of ES601*Plus* opens the Other Sequences menu.
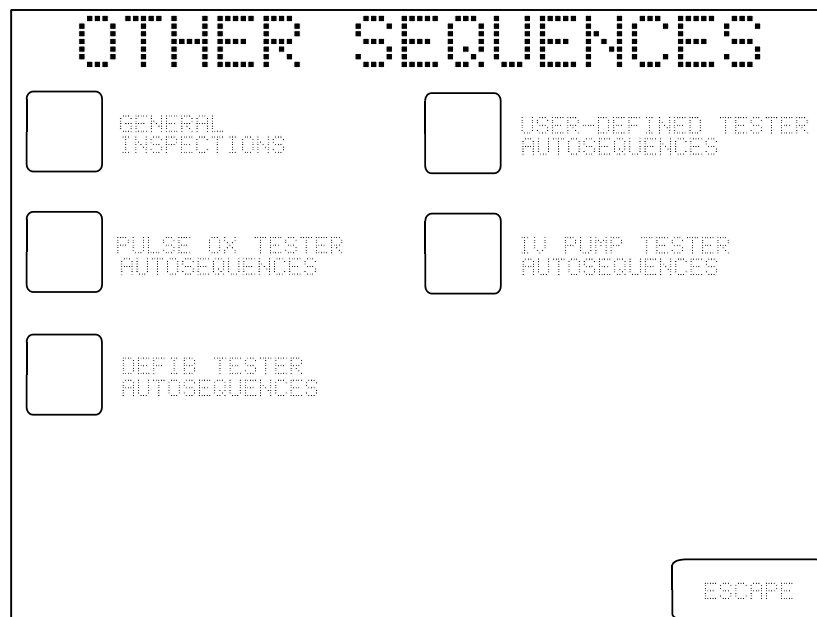
Figure 61*: Other Sequences Menu*

Select the desired submenu of sequences by pressing the button to the left of the submenu title. If the optional accessory feature associated with the AutoSequence menu has not been installed in ES601*Plus*, this will be indicated on the LCD as "(NOT INSTALLED)". In this case, the AutoSequence submenu will not be selectable. **ESCAPE** returns the display to the AUTOSEQUENCE MODE menu.

If the accessory option for General Inspections has been installed in ES601*Plus*, the General Inspection menu will be displayed when the **GENERAL INSPECTION** button is pressed.
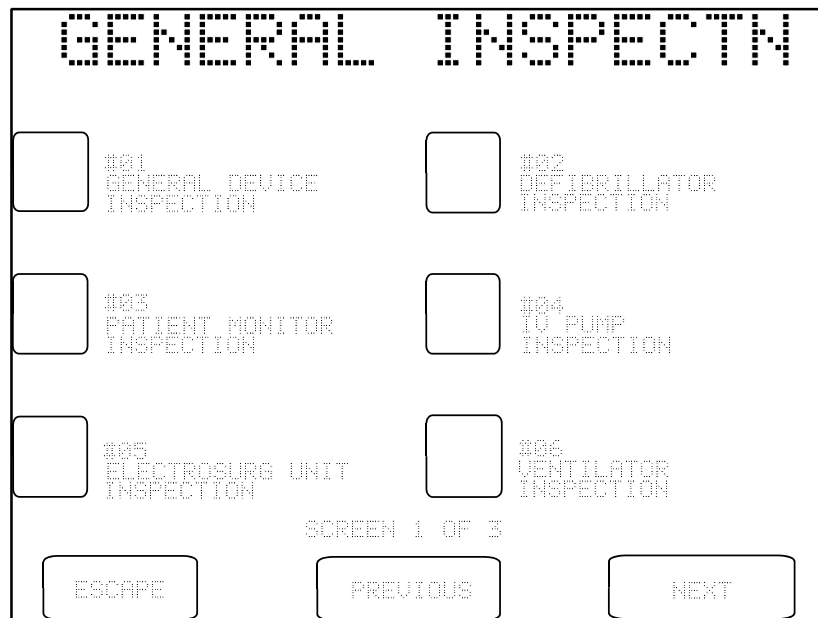
Figure 62 - *General Inspection menu.*

This menu provides access to eighteen General Inspections, listed across three menu screens. Scroll through these screens using the **PREVIOUS** or **NEXT** buttons to locate the desired Inspection. Select the Inspection by pressing the button to the left of the Inspection's title. **ESCAPE** returns to the AUTO MODE main menu.

When a General Inspection is run, the user may be presented with **OK**, **PASS**, **FAIL** and other buttons on the LCD as each step of the Inspection is executed. The appearance of ES601*Plus* LCD at each step of the Inspection will depend on the **Instruction** programmed for that step, using the AutoSequence Editor of the ES601pc software package. ES601*Plus* Instructions are discussed in the **Automated Testing Principles** section, later in this chapter.
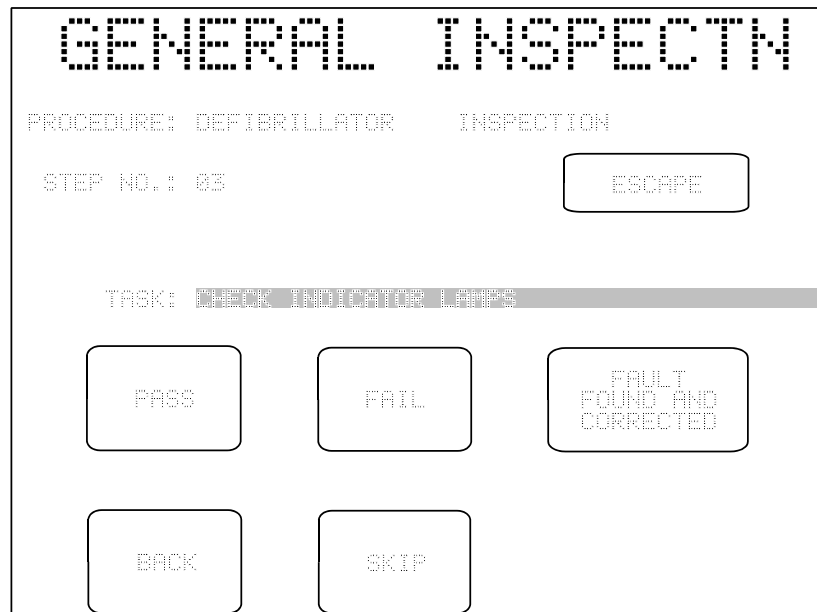
Figure 63 *- Inspection in progress, "Pass/Fail" instruction.*

The buttons that may potentially appear on the LCD, depending on the Instruction being executed at each step, are as follows:

OK: Records an "OK" in the Clip Record for the current step, and advances the test to the next step.

PASS: Records a "PASS" in the Clip Record for the current step, and advances the test to the next step.

FAIL: Records a "FAIL" in the Clip Record for the current step, and advances the test to the next step.

FAULT FOUND AND CORRECTED:

Records "SERVICED" in the Clip Record for the current step, and advances the test to the next step. This button records repairs in-process, where a minor failing item can be corrected without interrupting the procedure.

ENTER TEST DATA:

Displays the QWERTY touch keypad, allowing the user to type in measurement data or a comment, which is recorded in the Clip Record as part of the data for that step. This button does not advance the test to the next step.

BACK: Goes back to the immediately previous step of the test.

SKIP: Records "SKIPPED" in the Clip Record for the current step, and advances the test to the next step. This button could be pressed if the instruction displayed cannot be performed, or is not applicable to the DUT.

ESCAPE: Aborts the test in progress. Procedural data recorded to the Clip Record during the inspection or procedure will be erased.

If the optional accessory feature for General Inspections has been installed in ES601*Plus*, then User-Defined Tester AutoSequences will also be provided via the OTHER SEQUENCES menu discussed earlier. AutoSequences for User-Defined Testers are accessed by pressing the **USER-DEFINED TESTER** button on the OTHER SEQUENCES menu.
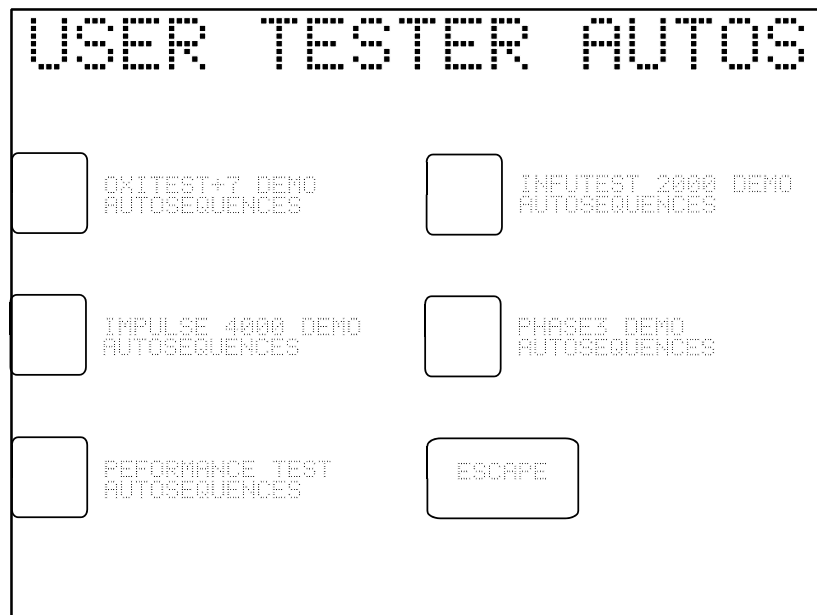
Figure 64 - *User Tester AutoSequence submenu.*

From the five banks of User Tester AutoSequences provided on the menu in **Figure 64**, select the desired bank by pressing the button to the left of the tester or analyzer title. Each bank provides 12 AutoSequences. The menu for selecting a Tester AutoSequence operates similarly to the menu for selecting a General Inspection.

Similar to a General Inspection, when a Tester AutoSequence is run, the user may be presented with **OK**, **PASS**, **FAIL** and other buttons on the LCD as each step of the AutoSequence is executed. **ESCAPE**, **BACK** and **SKIP** buttons are also available and will function as described previously. At particular steps in the sequence, remote control commands may be transmitted from ES601*Plus* to the attached Tester, via one of the RS232 Tester Ports on ES601*Plus* (see Chapter 4). The behaviour of ES601*Plus* at each step in the AutoSequence will depend on the **Instruction** programmed for that step, using the AutoSequence Editor of the ES601pc software package. ES601*Plus* Instructions are discussed in the **Automated Testing Principles** section, later in this chapter.

The OTHER SEQUENCES menu of **Figure 61** optionally provides menus specifically designed for Datrend test products such as Oxitest+7, Infutest 2000, and Phase3. Oxitest AutoSequences allow ES601 to configure the simulator via RS232 remote control, then permit the user to pass or fail the oximeter response, and optionally enter test data by means of the QWERTY keypad or PS/2 keyboard. Automated oximeter alarm tests are also provided by Oxitest AutoSequences. With Infutest 2000 and Phase3 AutoSequences, ES601 automatically configures the tester by RS232 remote control, then monitors and displays tester status while the tester executes the desired test. After the tester has completed its measurements, ES601 downloads the test results and passes or fails the results automatically, according to pass/fail criteria that can be specified by the user via the corresponding Infutest or Phase3 plug-in of the ES601pc software package.

Selector menus for Datrend testers such as Oxitest, Infutest and Phase3 operate the same way as for other types of automated test sequence. **Figure 65** shows the selector menu for Infutest 2000.
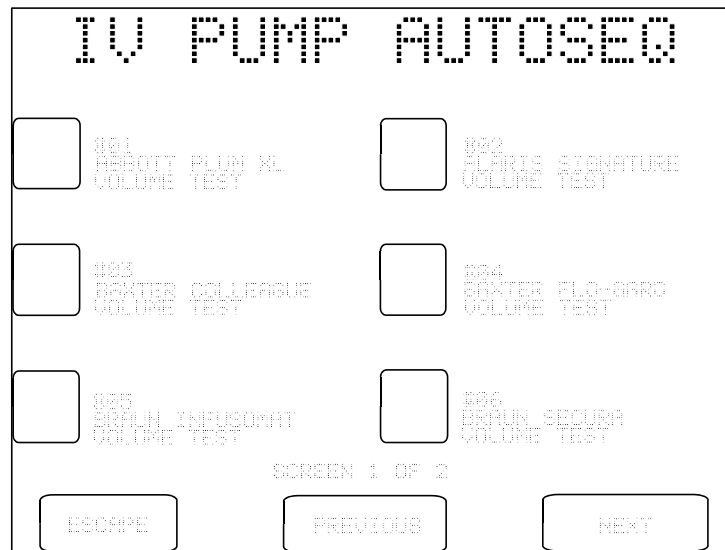
Figure 65: *Test selection for IV pump tester Infutest 2000.*

During the AutoSequence, menus displayed will depend on the tester being controlled and the test parameters which have been programmed by the user as part of the AutoSequence setup. ***Figures 66 - 70*** show how the test process works for the case of 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). Display screens are similar in principle for the case of Phase3 testing a defibrillator or pacer.
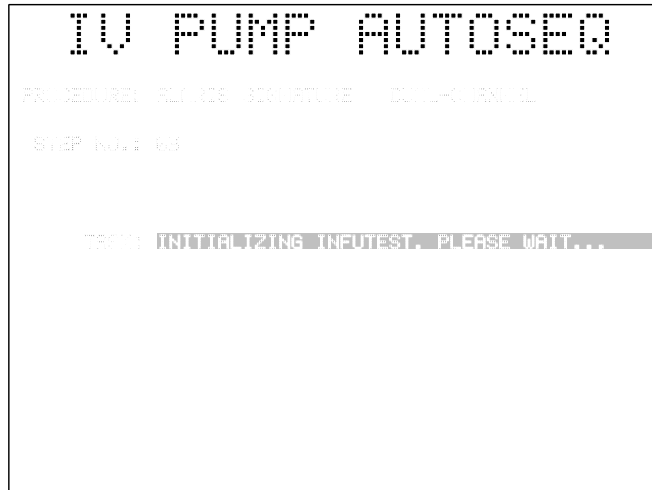
Figure 66*: ES601 configures Infutest to run a 2-channel test.*
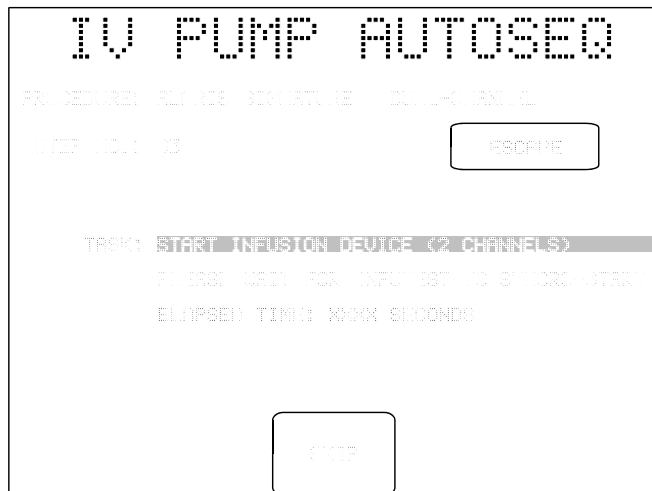
Figure 67*: ES601 prompts user to start the IV pump.*

Figure 68*: ES601 monitors Infutest status while Infutest tests the IV pump.*
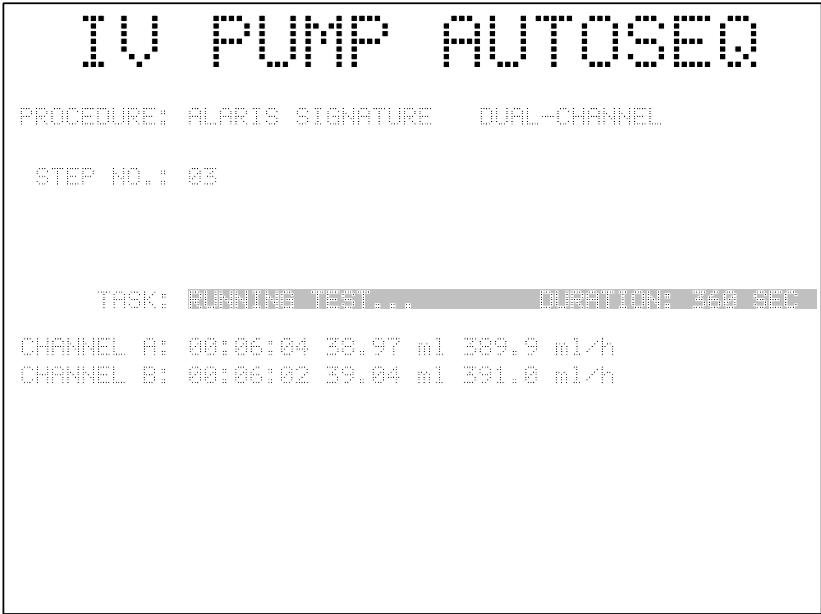
Figure 69*: After Infutest is finished, ES601 downloads measurement data.*
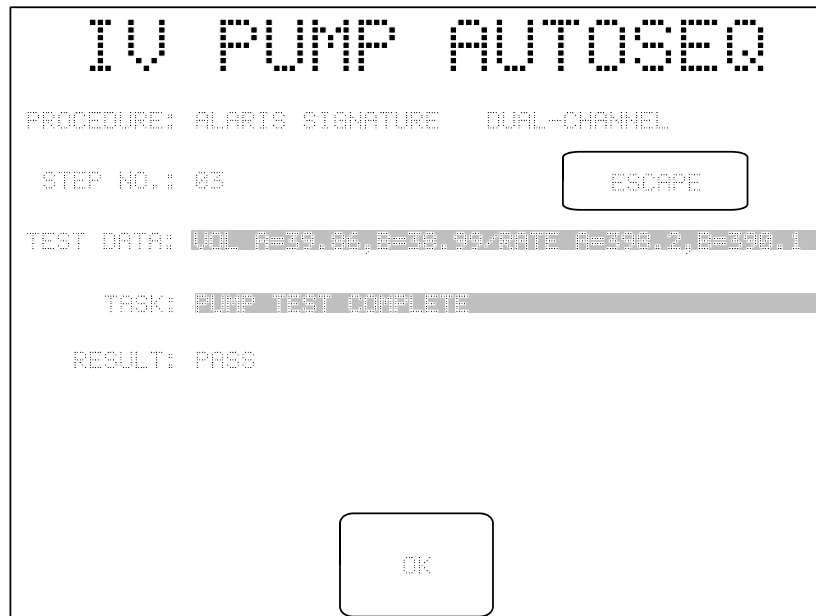
Figure 70: *ES601 automatically passes or fails the final test results.*

If one or more of these Datrend-specific tester options are installed, the ES601pc software package will provide an easy-to-use interface for creating test sequences to meet virtually any need. For instructions on programming Oxitest, Infutest or Phase3 AutoSequences, refer to the Help menus included with the corresponding 'plug-in' module of ES601pc.

6.1.4 Test Procedures

A Test Procedure can integrate visual inspection, safety testing, ECG testing, and performance testing activities into one comprehensive procedure targeted at a specific kind of medical device, for example, a patient monitor, defibrillator, anaesthesia gas machine, infusion pump, etc. The flash memory of ES601*Plus* provides storage of up to 500 Test Procedures.

The Test Procedure Editor is supplied as an optional part of the ES601pc software package. Provided ES601*Plus* has the Test Procedure accessory option installed, the Test Procedure Editor of ES601pc will allow the user to program ES601*Plus* with Test Procedures. The Test Procedure Editor of ES601pc is described in Chapter 8. ES601*Plus* menus associated with selecting and running Test Procedures created by the Test Procedure Editor are discussed below.

If the optional accessory feature associated with Test Procedures has not been installed in ES601*Plus*, this will be indicated on the main menu for AUTOSEQUENCE MODE as "(NOT INSTALLED)". In this case, the Test Procedure menu will not be selectable. Otherwise, selecting **TEST PROCEDURES** from the AUTOSEQUENCE MODE menu opens the Test Procedures menu.

Figure 71 *- Test Procedure selection menu.*

Increment/decrement buttons on the Test Procedure menu allow a Test Procedure title to be highlighted in the list. The Test Procedure is then initiated by pressing the **SELECT** button. **ESCAPE** returns the display to the AUTOSEQUENCE MODE menu.

Similar to a General Inspection, when a Test Procedure is run, the user may be presented with **OK**, **PASS**, **FAIL** and other buttons on the LCD as each step of the Test Procedure is executed. **ESCAPE**, **BACK** and **SKIP** buttons are also available and will function as described earlier in this chapter. At particular steps in the Test Procedure, remote control commands may be transmitted from ES601*Plus* to an attached Analyzer or Tester, via one of the RS232 Tester Ports on ES601*Plus*. The behaviour of ES601*Plus* at each step in the Test Procedure will depend on the *Instruction* programmed for that step, using the Test Procedure Editor of the ES601pc software package. ES601*Plus* Instructions are discussed in the ***Automated Testing Principles*** section which follows.

6.2 Automated Testing Principles

ES601*Plus* provides automated testing through General Inspections, Tester AutoSequences, and Test Procedures. Each type of automated test is based on a sequential list of **Instructions** that an operator can step through using ES601*Plus* touch screen interface.

6.2.1 ES601*Plus* Instructions

ES601*Plus* Instructions comprise a **command** and an **op code.** The op code defines what the Instruction does and what buttons are shown on the touch screen of ES601*Plus* when the Instruction 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 Instruction is encountered in the sequence. Some Instruction op codes cause the command to be transmitted to an external device via a selected **Tester Port**, these RS232 serial ports being located on the left side panel of ES601*Plus*.

6.2.2 General Inspections

ES601*Plus* provides 18 General Inspections, which are user-programmable by means of the AutoSequence Editor of the ES601pc software. A General Inspection can comprise from 1 to 24 steps, where each step corresponds to an ES601*Plus* Instruction. In principle, General Inspections are intended for work tasks in which the user will be visually inspecting the equipment under test, and will be recording simple "pass" or "fail" results for each item inspected. General Inspections are intended to be fairly generic and are targeted at an overall class of medical equipment, such as "IV Pumps" or "Defibrillators". Such Inspections might include steps such as "CHECK PUMP ROLLERS FOR WEAR", or "CHECK DEFIB PADDLES FOR PITTING/SCRATCHES".

General Inspections need not be limited to simple "pass/fail" visual tests, however. Through the AutoSequence Editor of ES601pc, you can create any kind of General Inspection you wish, and which may include pass/fail tests as well as entry of measurement data or remote control operation of an external test instrument or analyzer. However, a General Inspection cannot include an ES601*Plus* Safety AutoSequence or an ECG AutoSequence; to include safety and/or ECG tests within the scope of another automated test requires you to set up a full Test Procedure.

6.2.3 Tester AutoSequences

ES601*Plus* provides automated test sequences for medical device analyzers and testers such as IV Pump Testers, Pulse Oximeter Testers, Defibrillator Testers, ESU Testers, NIBP Testers, plus many others. To accommodate any make or model of test equipment you may own, ES601*Plus* provides five sets of User-Defined Tester AutoSequences, which you can arbitrarily program as desired using the AutoSequence Editor of ES601pc. For each of the User-Defined Testers, ES601*Plus* provides you with 12 programmable AutoSequences.

A Tester AutoSequence can comprise from 1 to 24 steps, where each step corresponds to an ES601*Plus* Instruction. Typically, Tester AutoSequences will be composed of ES601*Plus* **remote control** Instructions. In setting up a Tester AutoSequence, you will also select which ES601*Plus* **Tester Port** will interface with your external analyzer, and the **baud rate** to be used for RS232 serial communications with your analyzer. These selections are made with the AutoSequence Editor of ES601pc.

A Tester AutoSequence cannot include an ES601*Plus* Safety AutoSequence or ECG AutoSequence; to include a safety and/or ECG test within the scope of another automated test requires you to set up a full Test Procedure.

6.2.4 Test Procedures

Test Procedures are created using the Test Procedure Editor of the ES601pc software package. A Test Procedure can comprise from 1 to 96 steps, where each step corresponds to an ES601*Plus* Instruction.

In addition to individual Instructions, Test Procedures can also incorporate General Inspections and Tester AutoSequences, provided the total number of steps created by including such automated tests in a Procedure does not exceed 96. Additionally, any **one** of the Test Procedure steps can optionally be a Safety AutoSequence, and any **one** of the steps can optionally be a ECG AutoSequence. A Test Procedure cannot have more than one Safety AutoSequence, or more than one ECG AutoSequence.

6.2.5 Instruction Specifications

In this section, the capabilities and features of ES601*Plus* Instruction set are explained. Examples of LCD displays are given for the case of a Test Procedure. Instructions will operate the same way for General Inspections and Tester AutoSequences, the only difference being the title shown at the top of the LCD display.

6.2.5.1 The P Instruction

The operator interface for the **P** Instruction is shown in **Figure 72**. The **command** of the P Instruction 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"; "corrected"; or "skip" (i.e. not tested, or not applicable).
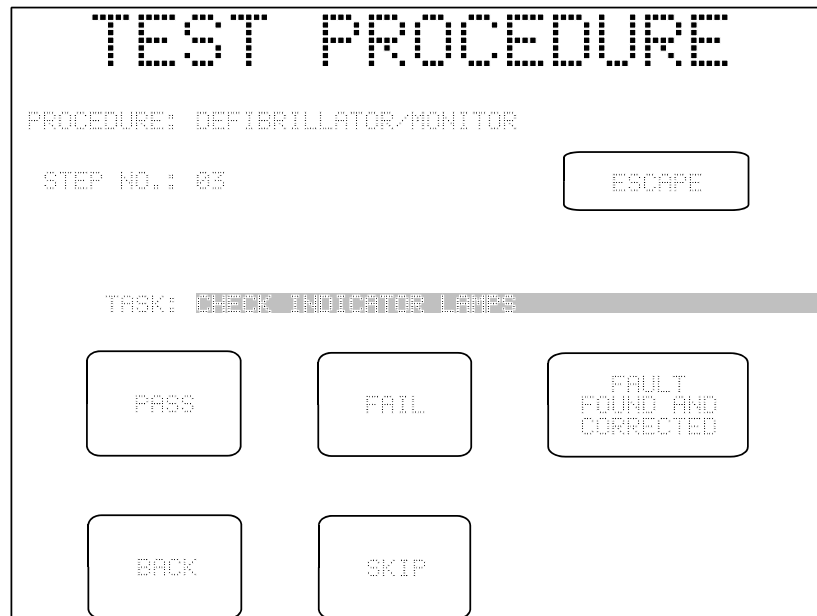
Figure 72 - Test Procedure in progress, P instruction.

When any of the test result buttons (**PASS**, **FAIL**, **CORRECTED** etc) is pressed, ES601*Plus* sequencer automatically advances to the next step of the Test Procedure. A **BACK** button on the LCD allows the user to move back to the previous step in the Procedure, and an **ESCAPE** button allows the Test Procedure in progress to be aborted at the current step.

6.2.5.2 The K Instruction

The user interface for the **K** Instruction, which is intended for displaying comments, prompts or setup instructions, is shown in **Figure 73**.

Figure 73 - *Test Procedure in progress, K instruction.*

The buttons provided for the K Instruction 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 Procedure is then incremented to the next step.

6.2.5.3 <u>The I Instruction</u>

The ***I*** Instruction prompts the user to enter information or comments (***Figure 74***). 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***Plus***. Up to 41 characters can be entered, which are saved as the test data for that step. The command of the I Instruction is displayed on the top line of the LCD, providing a prompt to the user.
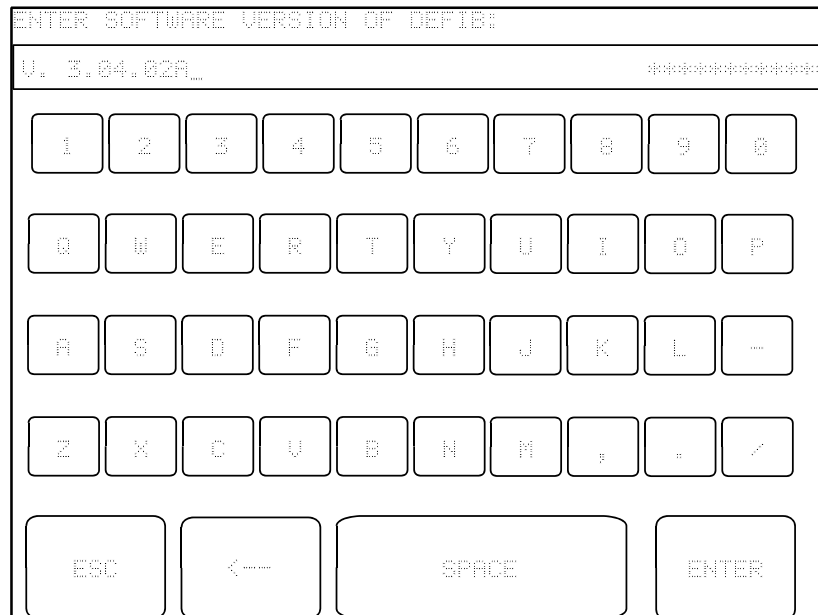
Figure 74 *- Test Procedure in progress, I instruction.*

6.2.5.4 The E Instruction

The operator interface of the **E** Instruction (***Figure 75***) allows the user to optionally enter measurement results or other data into ES601*Plus*, and then "pass" or "fail" the entered data. Data entered by the user and the pass/fail assessment are then saved as the test result for that step.

Figure 75 *- Test Procedure in progress, E instruction.*

For the E Instruction, up to 41 characters can be entered via the QWERTY touch keypad or PS/2 keyboard after the **ENTER TEST DATA** button is pressed. **PASS**, **FAIL**, and **CORRECTED** buttons save the user's assessment with test data that may have been entered, and advances ES601*Plus* sequencer forward one step. **SKIP**, **BACK** and **ESCAPE** buttons provide the functions described for the P Instruction. Note that the E Instruction 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 Procedure are reviewed.

6.2.5.5 The C Instruction

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

The C Instruction incorporates a command (data which will be transmitted to the external Tester), and a prompt. The prompt is optional information which may be entered via the Instruction Editor of the AutoSequence or Test Procedure plug-in, to help you remember what the command does when you are creating Tester AutoSequences and Procedures.

When ES601*Plus* executes a C Instruction, it will transmit the command via the Tester Port specified in the AutoSequence, and will wait for a response from the Tester. If a response is received, ES601*Plus* 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*Plus* will display the Instruction's prompt on the LCD and will wait for the user to press one of the touch screen keys provided, as shown in **Figure 76**.

Figure 76 - *Test Procedure in progress, C instruction.*

6.2.5.6 The R Instruction

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

When ES601*Plus* executes the R Instruction, it will transmit the command portion of the Instruction via the Tester Port specified in the AutoSequence. The prompt portion of the Instruction 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*Plus*.

6.2.5.7 The M Instruction

The M Instruction can retrieve test result data from an external medical device analyzer or "tester", after the tester has been set up and used to perform a test. Typically, an M Instruction might follow one or more C Instructions in an AutoSequence or Test Procedure.

In executing a M Instruction, ES601*Plus* will transmit the command of the Instruction via the RS232 Tester Port specified in the AutoSequence. The prompt portion of the Instruction will then be displayed on the LCD as the "TASK". However, if the first character of the Instruction command is a whitespace or a <TAB> character, ES601*Plus* does not transmit anything and will immediately display the user interface of ***Figure 77***.
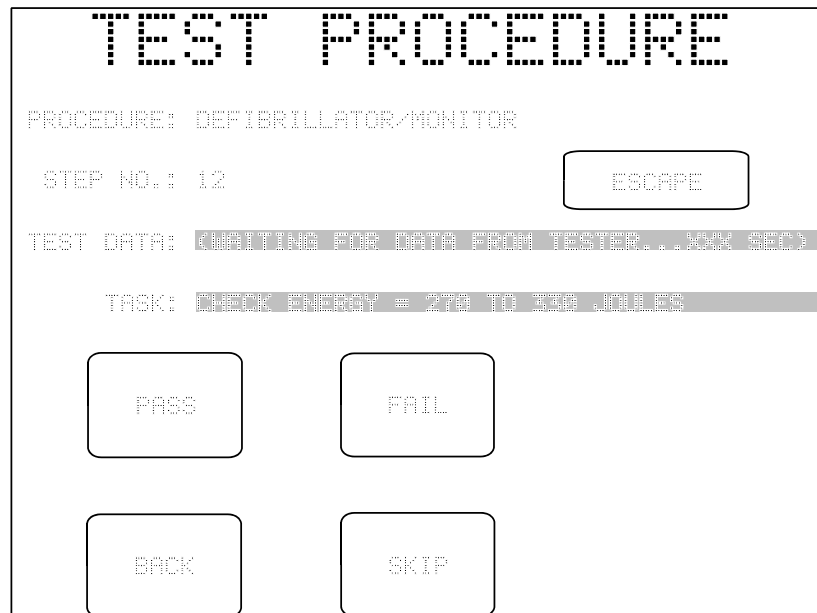
Figure 77 *- Test Procedure in progress, M instruction.*

In the event that data is not immediately received from the tester, 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 Instruction).

6.2.5.8 The D Instruction

The D Instruction can be used to provide timed delays in Tester AutoSequences and Test Procedures (**Figure 78**). The delay of the Instruction may range from 1 to 32000 seconds. The instruction also provides a prompt which is displayed on the LCD as the "TASK" while the timer counts down.

Figure 78 - *Test Procedure in progress, D instruction.*

ES601*Plus* will automatically advance to the next step of the sequence when the timer reaches zero count. In this case, an "OK" is saved as the test result for the delay step. Alternatively, the user may press **SKIP** to bypass any remaining delay. The **BACK** button decrements ES601*Plus* sequencer to the previous step.

6.2.5.9 The A Instruction

The **A** Instruction is utilized **only in Test Procedures** and allows ES601*Plus* to invoke a Safety AutoSequence, a ECG AutoSequence, or Tester AutoSequences from within the procedure. General Inspections and User-Defined Tester AutoSequences **cannot** include an A Instruction.

Any one of the Test Procedure steps can optionally be a Safety AutoSequence, and any one of the steps can optionally be a ECG AutoSequence. A Test Procedure cannot have more than one A Instruction that invokes a Safety AutoSequence, or more than one A Instruction that invokes a ECG AutoSequence.

A Test Procedure can optionally have **one or more** A Instructions that invoke General Inspections and/or Tester AutoSequences. The total number of procedural steps generated by including such General Inspections and/or Tester AutoSequences in a Test Procedure, via corresponding A Instructions, cannot exceed a maximum of **96 steps**.

Practically speaking, since General Inspections and other types of automated tests may have up to 24 steps each, a Test Procedure will be able to optionally incorporate, at most, 3 to 4 General Inspections and/or Tester AutoSequences within it.

The **command** portion of the A Instruction encodes the AutoSequence that will be run from within the Test Procedure. 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 79**:

Command prefix	Type of AutoSequence	"NN"
SAF	Safety	01 to 24
ECG	ECG	01 to 12
INS	General Inspection	01 to 18
POX	Pulse Oximeter Tester	01 to 12
IVP	IV Pump Tester	01 to 12
DFB	Defibrillator Tester	01 to 24
NBP	NIBP Monitor Tester	01 to 12
ESU	ESU Tester	01 to 12
PAC	Pacemaker Tester	01 to 12
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

Figure 79

For example, and according to **Figure 79**, if a Test Procedure includes an A Instruction having the command "SAF01", this will cause ES601*Plus* to execute Safety AutoSequence #01 from the SAFETY AUTOSEQUENCE menu, which was described earlier in this chapter. If a Test Procedure includes an A Instruction having the command "ECG03", this will cause ES601*Plus* to execute ECG AutoSequence #03 from the ECG AUTOSEQUENCE menu. If a Test Procedure includes an A Instruction having the command "UT408", this will cause ES601*Plus* to execute AutoSequence #08 for User-Defined Tester #4, from the USER TESTER AUTOS menu.

Figure 79 is a list of all possible A Instructions; however, some of these will require an optional accessory feature to be installed in ES601*Plus* to operate correctly. If, when running a Test Procedure, ES601*Plus* encounters an A Instruction for which the respective accessory option has not been installed (for example, the option for "ESU Analyzer AutoSequences"), ES601*Plus* will skip over that A Instruction to the next step of the Test Procedure.

When an A Instruction 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 assume the same functions described previously for other Instructions.

Figure 80 *- Test Procedure in progress, A instruction.*

6.2.5.10 Instruction Summary

Op Code	Instruction 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; FAULT CORRECTED; BACK; SKIP; ENTER TEST DATA
I	Input Requested	QWERTY touch keypad
K	OK Prompt	ESCAPE; BACK; OK
M	Tester Measurement	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; FAULT CORRECTED; BACK; SKIP; ENTER TEST DATA

6.3 Equipment Records

Equipment Records are an <u>optional accessory feature</u> that can be installed in ES601*Plus*. With this accessory installed, ES601*Plus* can store up to 18,432 Equipment Records, these Records containing the control number of a medical device and a reference to an ES601*Plus* Test Procedure (ranging from 1 to 500).

Equipment Records are created, edited and managed through the Equipment Record plug-in of the ES601pc software package. This optional plug-in can import device control numbers and other equipment data from an existing CMMS application, to facilitate the user's assignment of ES601*Plus* Test Procedures to device control numbers from the equipment management system.

Optional accessories for ES601*Plus* and the ES601pc software package are also available to automate the process of importing equipment and associated PM procedure data from specific CMMS applications. These "data converter" accessories require the Equipment Record and Test Procedure options to be installed in ES601*Plus*.

6.3.1 Device ID Search

The optional Equipment Record accessory for ES601*Plus* provides for easy test initiation by entering the equipment control number using the **DEVICE ID SEARCH** button on the AUTOSEQUENCE MODE menu.

If Equipment Records have been installed in ES601*Plus*, pressing the **DEVICE ID 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 above the QWERTY keypad, ES601*Plus* 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*Plus* is displaying the AUTOSEQUENCE MODE main menu.

If the control number entered is recognized by ES601*Plus*, the DEVICE INFO menu will be displayed. The DEVICE INFO menu allows input of additional equipment information as previously described in Chapter 5. The DEVICE INFO menu will also display the associated Test Procedure.

Figure 81 - *Device Info menu, following entry of valid Device ID.*

Pressing the **RUN TEST** button on the menu will initiate the associated Test Procedure and, when the test is completed, the SAVE TEST RECORD menu will be displayed.

If, after opening the DEVICE INFO menu, the Device ID (Control) Number is changed, the indicated Test Procedure will still run and, when saved, will display the edited Device ID (Control) Number. This will not, however, update the corresponding Equipment Record in the memory of ES601*Plus*.

Chapter

7
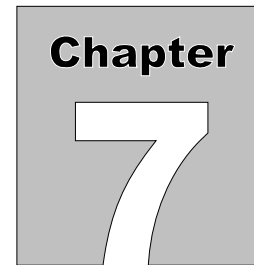
7   Computer Control

7.1 Overview of Computer Control

ES601*Plus* 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*Plus* 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*Plus* 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*Plus* records only the maximum leakage result observed under the supplementary conditions. ES601*Plus* 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*Plus* 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*Plus* 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*Plus* which selects and starts a Safety AutoSequence. As each step of the sequence is completed, ES601*Plus* 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*Plus* sends an "END" message to the PC. Optionally, the user's software may then issue another command to cause ES601*Plus* to return a formatted Test Report document containing the measurements recorded by ES601*Plus* 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*Plus* (see Section 4).

7.2 Connections

For computer control, connect the PC to the RS232 serial port of ES601*Plus*. The RS232 connector of ES601*Plus* 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*Plus* 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*Plus* 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*Plus*. Upon conclusion of the safety test sequence, the last character sent by ES601*Plus* is form feed (**\f**, or 0x0C), which terminates the "END" message. ES601*Plus* 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*Plus* 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*Plus* via the serial connection.

    b.   ES601Plus responds by returning

        *\r

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

    c.   PC software sends one ASCII character to ES601*Plus* 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*Plus*, otherwise ES601*Plus* will time out and abort the protocol. If ES601*Plus* receives a character other than **a** to **x**, ES601*Plus* 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*Plus* to execute a complete AutoSequence as if the test had been selected from the SAFETY AUTOSEQUENCE menu, beginning with CONNECTION instructions, APPLIED PARTS 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*Plus* 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*Plus* via the touch screen in the conventional manner, responding to prompts displayed by ES601*Plus* as described in Chapter 5. As each measurement of the sequence is completed, ES601*Plus* 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*Plus* 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*Plus* touch screen. In this event, the protocol is terminated and ES601*Plus* 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*Plus* 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*Plus* stops sending characters.

7.4.4 Format of Measurement Data

Once initiated by computer control as previously described, ES601*Plus* 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*Plus* 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*Plus*, 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`
Protective earth	`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?/Xl?/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?	Protective earth	"EN" (normal) or "EO" (single-fault condition)
AP?	Applied part(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	Applied part Group 'x'	'x' = 1, 2, 3, 4 or 5
APyy	Applied part 'yy'	'yy' = 01, 02, 03... 10

Chapter

8
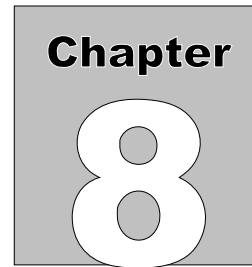
8   ES601pc Software

Datrend Systems ES601pc software provides a communication utility for ES601*Plus* and allows the user to configure Safety AutoSequences, electrocardiogram (ECG) AutoSequences, Test Reports, General Inspections, Tester AutoSequences and Test Procedures of ES601*Plus* Safety Analyzer. The first three of these utilities are standard features of the ES601pc software and will be available for use immediately upon installation. The remaining utilities are optional and may be installed at any time after installation of the main ES601pc software application. These optional utilities are referred to as modules or plug-ins within this manual.

8.1 Installation

To install ES601pc to your computer, place the ES601pc USB thumbdrive into your computer's USB port. Select the ES601 product and install the ES601pc software.

In the event the installation program does not start automatically, use the file explorer utility on your computer to locate the USB drive. Browse this drive to locate the file called **ES601pc**<*version_no*>**_Setup.exe**, where <*version_no*> is the 4-digit version number of the software. Double-click or otherwise execute this file and the installer will guide you through the installation process. We recommend all default installation locations be left intact so future upgrades and enhancements will run smoothly.

At the end of the short installation process, you will be presented with a notification the software has been installed, at which time you may either select or deselect the checkbox which asks if you would like to run ES601pc upon closing the dialogue box. The computer does not have to be restarted before running ES601pc.
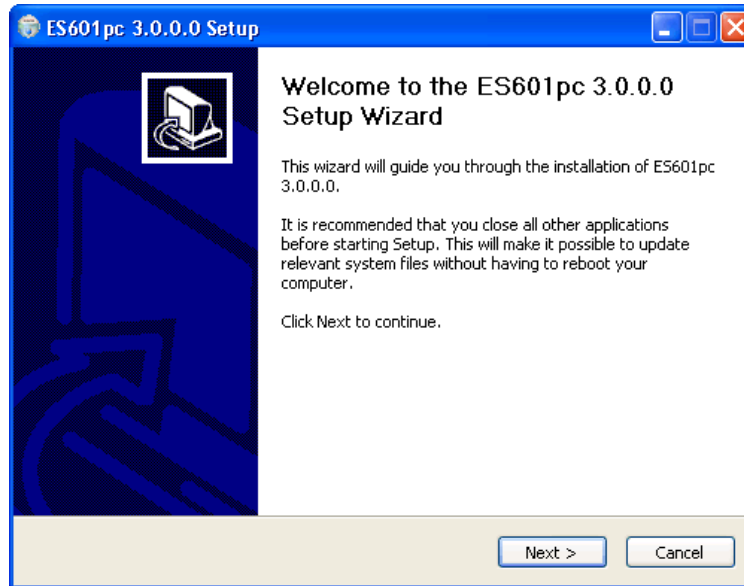
Figure 82

8.2 Installing USB Drivers

When installation is complete, connect ES601*Plus* to your PC using the USB cable provided. When ES601*Plus* 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 83 - *New Hardware*

The USB drivers for ES601*Plus* are provided on the USB with the ES601pc software. When the Hardware Wizard asks for the files, direct the Hardware Wizard to your USB drive, or to the location where the files were downloaded. The Wizard should find and install the required driver files. The files are in a folder "ES601 CDM v2.08.28 Certified USB Driver WinXP-7-8". From within the folder, select the 32 bit (i386) or 64 bit (amd64) folder as the location for the dri

During installation the dialog box shown in ***Figure 84*** may appear. If it does, select "Continue Anyway" and the USB driver will be installed (***Figure 85***).

Figure 84 *- Driver*
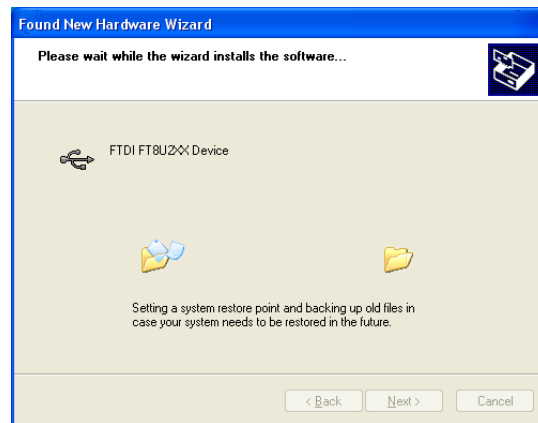
Figure 85 *- Driver Installation*

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

When ES601pc is executed, you will be presented with the ES601pc startup screen. The screen shown following has the three standard utilities (Safety AutoSequence Editor, ECG AutoSequence Editor and Test Report Generator) along with two of the optional plug-in modules (Autosequence Editor and Test Procedure Editor). Additional plug-ins may be added later.
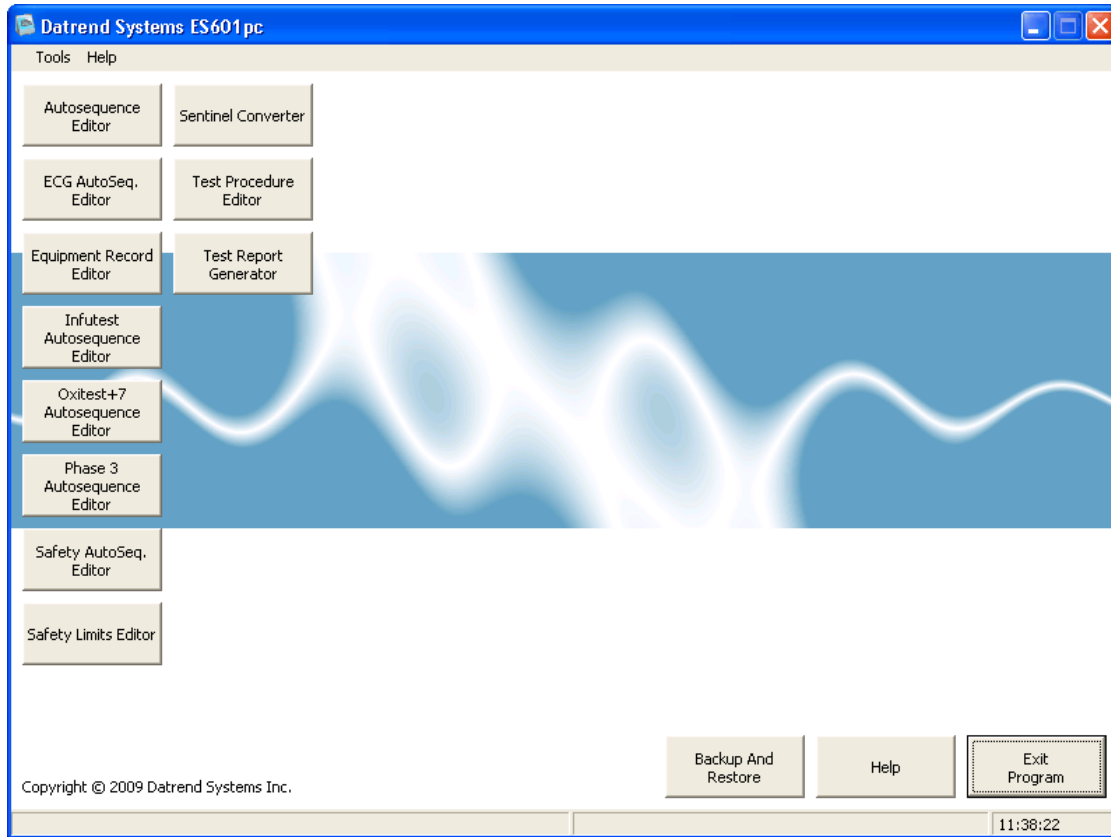
Figure 86 *ES601pc Main Screen*

* Note that the Sentinel Converter button is now titles CMMS Interface.

From the Menu Bar in the ES601pc 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.
> 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

> 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 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 ES601Plus.

> ⚠ 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 Safety AutoSequence Editor (standard accessory)

Upon selecting SAFETY AUTOSEQUENCE EDITOR, you are taken to the editor screen.
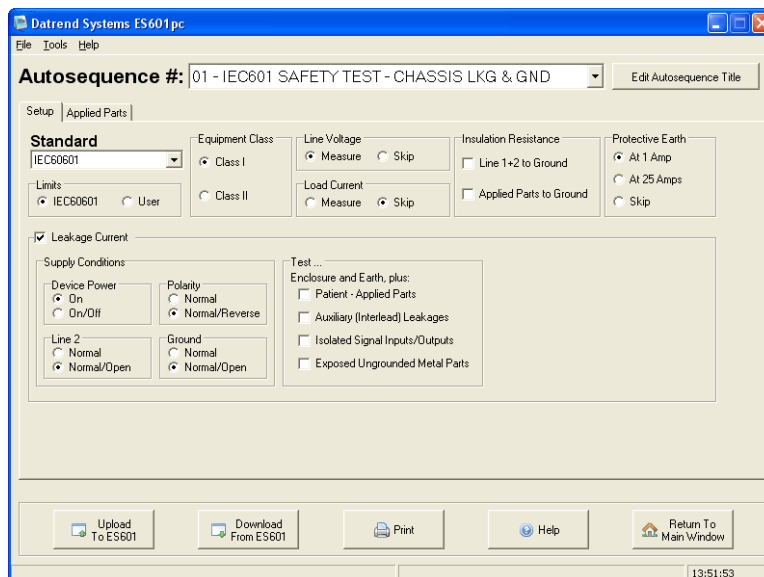
Figure 87 - *Safety Autosequence Editor*

The Safety AutoSequences that are loaded into the Editor are those last edited with this utility or those **Restored** from a **Backup** before entering the Editor.

8.5.1 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.
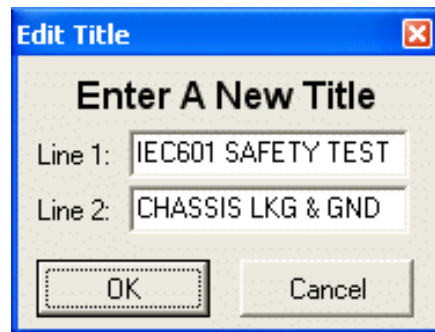
Figure 88

8.5.2 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:

> IEC60601 Standard*
> AAMI ES1 Standard
> VDE0751 Standard
> IEC62353 Standard
> IEC601-Battery Standard
> AAMI-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. Refer to the Safety Limits Editor Operators Manual (MN-051, Datrend Part Number 6100-429) for detailed information on use of the Safety Limits Editor.

8.5.3 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.

8.5.4 Equipment Class (IEC60601, AAMI-ES-1, VDE0751 and IEC62353)

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

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

Line Voltage is a test where ES601*Plus* connects an internal voltmeter to the AC line input and reports the AC RMS voltages seen from Line 1 to Line 2 ("hot" to "neutral" in North America), from Line 1 to protective earth ("hot" to "ground"), and from Line 2 to protective earth ("neutral" to "ground"). This test can be enabled under the Line Voltage radio group by selecting Measure, or disabled by selecting Skip.

8.5.6 Insulation Resistance (IEC60601, AAMI-ES1, 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: Line 1+2 to Ground and Applied Parts to Ground. ES601*Plus* can perform one of the tests, both tests, or neither.

If Line 1+2 to Ground is checked, ES601*Plus* will apply a high voltage between the L1 & L2 shorted together and the ground pin at the AC line cord of the DUT that would normally be connected to protective earth. ES601*Plus* will measure the resulting current and report the test result as resistance in megohms.

If Applied Parts to Ground is checked, ES601*Plus* will apply a high voltage across the applied parts and the line cord ground pin of the DUT. ES601*Plus* will measure the resulting current and report the test result as resistance in megohms. The Applied Parts to Ground test is not provided under the IEC61010 standard.

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

Load Current is a test where ES601*Plus* 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.

8.5.8 Protective Earth (IEC60601, AAMI-ES1, VDE0751, IEC62353 and IEC61010)

Protective Earth is a test where ES601*Plus* 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*Plus* measures the resulting resistance in ohms. The test can be performed with a 25 amp AC test current (per IEC60601 and IEC61010 Standards), but only if ES601*Plus* contains the optional Protective Earth Test Module (PETM) accessory. Otherwise, the test will default to a 1 amp test current, or the 1 amp test current can be selected via the radio button. The Skip option will skip the protective earth test entirely.

8.5.9 Leakage Current (IEC60601 and AAMI-ES1)

If the Leakage Current checkbox is checked, ES601*Plus* will perform Enclosure and Earth Leakage Current tests. Patient and Auxiliary Leakage Current tests may be optionally enabled. Conditions of the AC power supply for these leakage tests can be set under the Supply Conditions panel.

8.5.10 Leakage Current (VDE0751 and IEC62353)

If the Leakage Current checkbox is checked, ES601*Plus* 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: Device Power is On, Line 2 is Normal (connected), and Ground is Normal, according to the requirements of VDE0751.

8.5.11 Leakage Current (Battery-powered devices)

Under IEC601-BAT, AAMI-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.

8.5.12 Leakage Current (IEC61010)

If the Leakage Current checkbox is checked, ES601*Plus* 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

8.5.13 Device Power (IEC60601, AAMI-ES1, IEC60601-Battery and AAMI-Battery)

Test with either device power ON, or test with the device power ON, then repeat with device power OFF.

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

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

8.5.15 Line 2 (IEC60601, AAMI-ES1 and IEC61010)

Perform the leakage current test with AC Line 2 Normal (connected); or, test with Line 2 Normal, then repeat with Line 2 Open (disconnected).

8.5.16 Ground (IEC60601, AAMI-ES1 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.

8.5.17 Patient-Applied Parts (all standards except IEC61010)

This test is enabled by checking the Patient-Applied Parts box, unless the safety standard is one of the "-BAT" standards, in which case this test is always enabled. In this test, ES601*Plus* measures the current that flows out of the applied parts of the DUT through the human body load, when the parts are either connected to protective earth, or they are connected to an isolated mains supply (isolated AC line). This latter test is referred to as a "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-applied parts must be isolated from protective earth (Type BF or Type CF under IEC601-BAT and AAMI-BAT; or Type F under VDE-BAT or IEC353-BAT).

8.5.18 Applied Part Groups (all standards except IEC61010)

An Applied Part Group consists of one to ten **contiguous** applied parts. Also, Groups encompass the applied parts in order, starting from applied part 1 (AP1). For example, Group 1 may consist of applied parts #1 to #3, Group 2 may consist of applied parts #4 to #5, and Group 3 may consist of applied part #6. In all but the AAMI Standard, Group 1 is always enabled and has at least 1 applied part.

The Applied Part editor is accessed by clicking on the Applied Parts tab. The Applied Parts tab will be accessible only if Leakage Current is enabled and one of "Patient - Applied Parts" or "Auxilliary (Interlead) Leakages" is selected. After clicking the Applied Parts tab, an Applied Part Group can be enabled by either checking the Group checkbox, or by entering a non-zero number of applied parts for that Group. The Applied Part Names and Status panel will display the applied parts that have been enabled. A name can be given to the Applied Part Group by editing the Name textbox.

An applied part Group may be disabled after entering a non-zero number of applied parts 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 applied parts are not electrically isolated from protective earth. Type B parts have the least stringent safety requirements. ES601*Plus* will measure patient leakage current while all the Type B applied parts in the applied part Group are shorted to ground.

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

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

Each applied part can be assigned a name. Applied part names can be input via the textboxes provided in the Applied Part Name and Status panel.

8.5.19 Auxiliary (Interlead) Leakages
(IEC60601, AAMI-ES1, IEC60601-Battery and AAMI-Battery)

In this test, ES601*Plus* measures the current that flows out of one applied part, through the human body load, and into all the other applied parts shorted together. The test will be repeated for each applied part. This test is pertinent to IEC60601 and AAMI standards only.

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

If Isolated Signals Inputs/Outputs is enabled, the effect on patient 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. This test is pertinent to IEC60601 and AAMI standards only.

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

8.5.21 Exposed Ungrounded Metal Parts (IEC60601)

If Exposed Ungrounded Metal Parts is enabled, the effect on patient leakage by connecting exposed ungrounded metal parts of the DUT to protective earth 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.

8.5.22 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 applied parts to mains only (Type B parts 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 applied parts 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.

8.5.23 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*Plus*. This test is pertinent to the IEC61010 standard only.

8.5.24 Uploading AutoSequences

To upload Safety AutoSequences to ES601*Plus*, 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*Plus* (the IP address of ES601*Plus* 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*Plus* 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.

8.5.25 Downloading AutoSequences

Sometimes it is desirable to download sequences stored in ES601*Plus*. You can do this 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 with the sequences stored in ES601*Plus*.

These sequences can the be changed and uploaded back to ES601*Plus*.

8.5.26 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.

Return to Main Menu
When edits have been completed, the user may return to the main menu of the ES601pc application by pressing this button. Remember, at this point, all changes that have been made have already been saved.

> ⚠️ 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.

8.6 ECG AutoSequence Editor (standard accessory)

In addition to an electrical safety analyzer, ES601*Plus* incorporates an electrocardiogram (ECG) simulator. The ECG Simulator of ES601*Plus* 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*Plus* 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*Plus* provides 6 programmable ECG AutoSequences, each having from one to 24 waveform/amplitude steps. ES601pc is used to select the waveforms and amplitudes for each step of each ECG AutoSequence and program this setup into ES601*Plus*.

Upon selecting ECG AUTOSEQUENCE EDITOR, you are taken to the editor screen (shown in **Figure 89**).
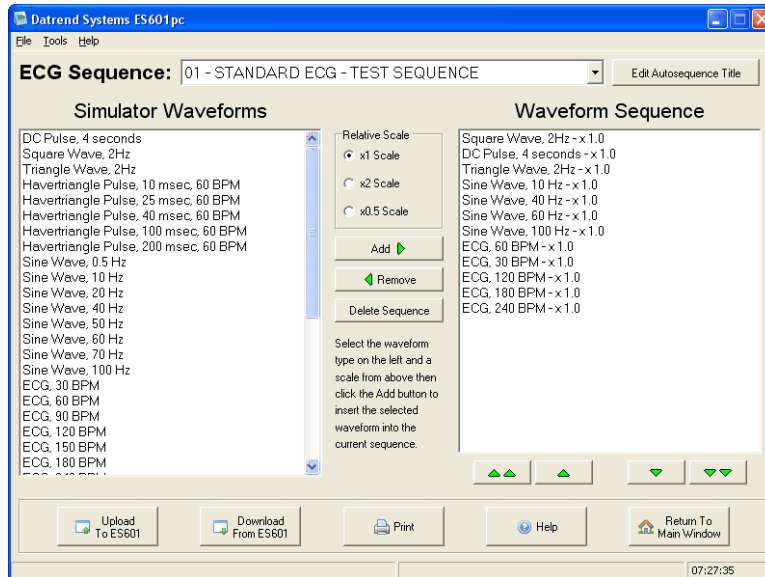
Figure 89

8.6.1 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 (see ***Figure 90***). The two lines can hold up to 18 characters each.
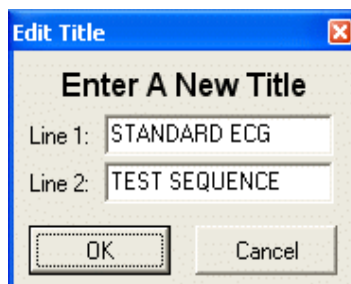
Figure 90

8.6.2 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.

8.6.3 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.

8.6.4 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.

8.6.5 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.

8.6.6 Uploading AutoSequences

To upload ECG AutoSequences to ES601*Plus*, 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*Plus* (the IP address of ES601*Plus* 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*Plus* is connected (see **Figure 91**).

After pressing "Connect", a message box with a transfer progress bar will appear (see **Figure 92**). After the transfer is completed, a Transfer Complete message will appear and the message box will disappear.

8.6.7 Downloading AutoSequences

Sometimes it is desirable to download sequences stored in ES601*Plus*. You can do this by pressing the "Download From ES601" button. Choose to download via USB, Ethernet, or Serial Port. Doing so will overwrite the configuration of all 6 ECG AutoSequences in ES601pc with the sequences stored in ES601*Plus*.

8.6.8 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.

Return to Main Menu

When edits have been completed, the user may return to the main menu of the ES601pc application by pressing this button. Remember, at this point, all changes that have been made have already been saved.

> ⚠ 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 Test Report Generator (standard accessory)

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

8.7.1 Downloading Test Reports

To download test reports generated by ES601*Plus*, 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*Plus* (note this IP address is displayed on the LCD of ES601*Plus* 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 91*).
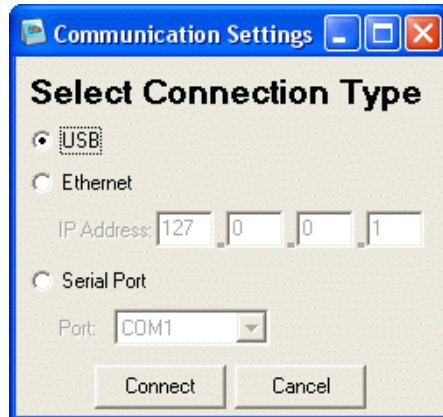
Figure 91
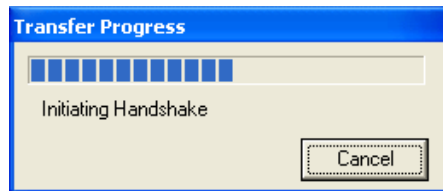
Figure 92

After pressing "Connect", a message box with a transfer progress bar will appear (see *Figure 92*). After the transfer is complete, each test report will appear as a row denoted by the test number, parent I.D., device I.D., date, device description, make, and model (see *Figure 93*).

'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*Plus*. 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).

'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 Device Info for this test record has been modified by the test technician. This can be an indication the device tested is new (the control number was not in the Equipment Record system of ES601*Plus*), or it may mean additional data was entered on the Device Info screen during a test (Tech Code, Facility, Location, etc.). This provides an indication to the user the Device Information should be reviewed. Some Device Info will appear on the screen directly if data is available (Description, Make or Model).

8.7.2 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 Parent ID, Device ID, Description, 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
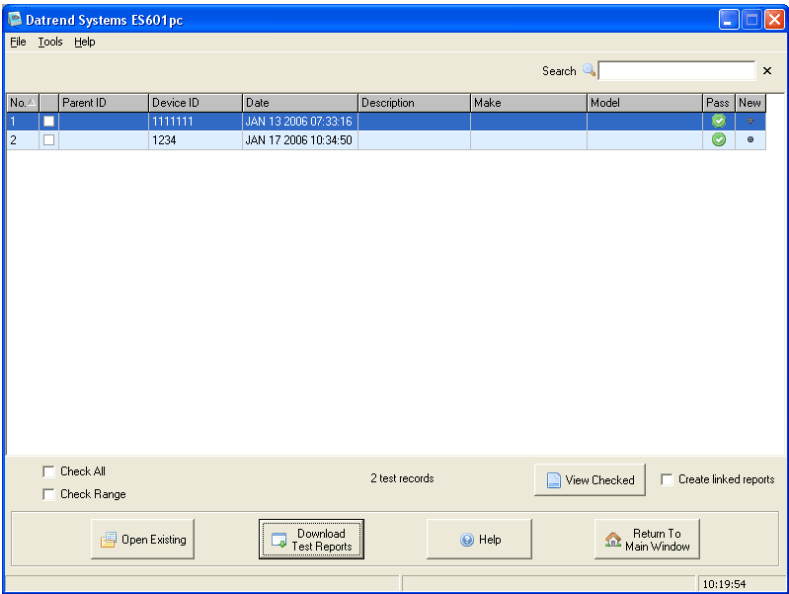
Figure 93

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.

8.7.3 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 program to crash. Ensure only ES601*Plus* test report text files are selected for viewing.

8.7.4 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.


```
📄 Test Report Viewer                                              _ □ ✕
*********************** TEST RECORD No. 2 ********************

                        Test Report

                 ES601: ES050100101 Ver.: 1.00
                  I.D.: DATREND ES601PLUS

                 Device ID: 1234
                 Parent ID:
                 Date/Time: JAN 17 2006 10:34:50

Description:
Make:                           Model:
Facility:                       Location:

Tech Code:
Tech Time:   01:30:58


*********************** SAFETY TEST ************************

STANDARD: AAMI-ES1                         AUTOSEQ: --
LIMITS: PER STANDARD                       CLASS:   I

GROUND FAULT: NONE

LINE VOLTAGE: L1-L2  L1-GND  L2-GND
              117.1   116.8    1.7 VOLTS RMS

----------------- LEAKAGE TEST CONDITIONS -----------------
NP:  Normal Polarity   L2N: Line2 Normal  GNDN: Ground Normal

   💾 Save To Text    📊 Save To CSV    🖨 Print    ❌ Close
```
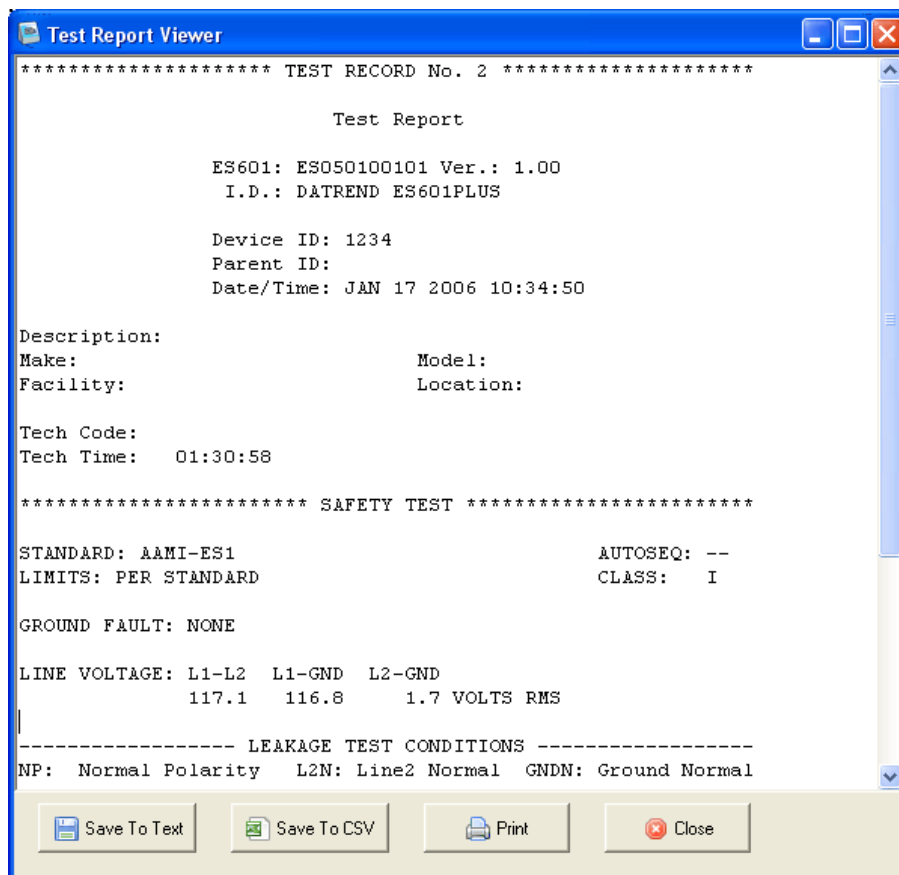
Figure 94

8.7.5 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.

8.7.6 Saving Test Reports

Test Reports that are displayed on the Test Report Generator screen must be saved before exiting the ES601pc 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*Plus*.

Saving to text

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 device ID (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.

Linked test reports can also be created. Test reports are linked by means of a common Parent ID, such as might be the case when modules of a multi-parameter patient monitor (the "devices") all have been tested using the same mainframe video monitor (the "parent"). In a linked report, the test reports of the individual devices are combined into one report and saved as a text file. To create a linked report, check the Create Linked Reports checkbox before viewing selected test reports. Now any test reports having common Parent ID's will be linked and saved as files having filenames in the following format:

`ParentID.yyyy_mm_dd.hh_mm_ss.txt`

where ParentID is the Parent 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.

Saving to 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.

8.8 AutoSequence Editor

Upon selecting AUTOSEQUENCE EDITOR, you are taken to the Inspection Procedures screen (see *Figure 95*).

8.8.1 Editing an Inspection or User Tester Sequence

From the Inspection Procedures tab, edit an Inspection Procedure by selecting the desired procedure and pressing Edit Procedure. The Autosequence Editor window will appear. Alternatively, double-clicking on a procedure will also bring up the Autosequence Editor.
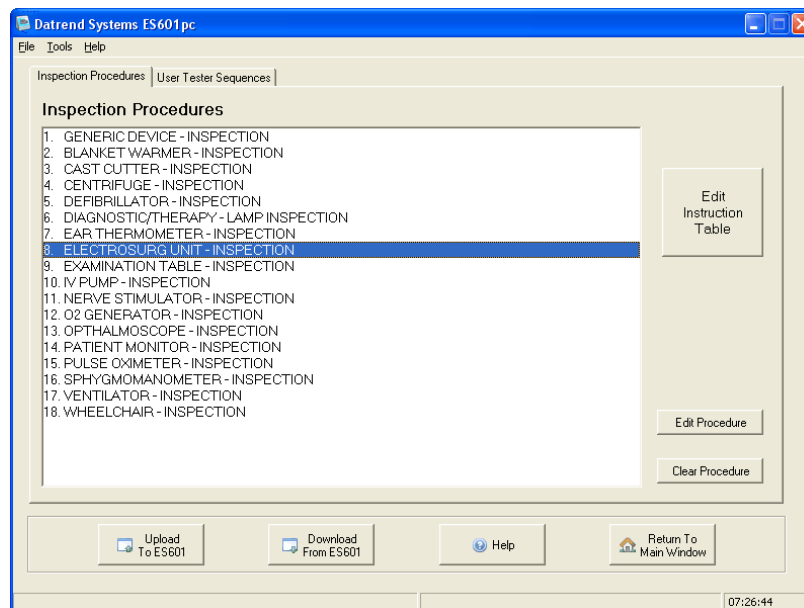
Figure 95

Selecting the User Tester Sequence tab will open that window. To edit 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. Now select the User Tester Sequence and press Edit Sequence, or double-click on the sequence. The AutoSequence Editor will appear (see *Figure 96* and *Figure 97*).

Figure 96

8.8.2 Editing an AutoSequence

From the Autosequence Editor screen, the name (Title1 and Title2), the Tester Port and Baud Rate can be edited. Available Instructions can be added to and removed from the Autosequence by using the appropriate buttons in the center margin of the screen.
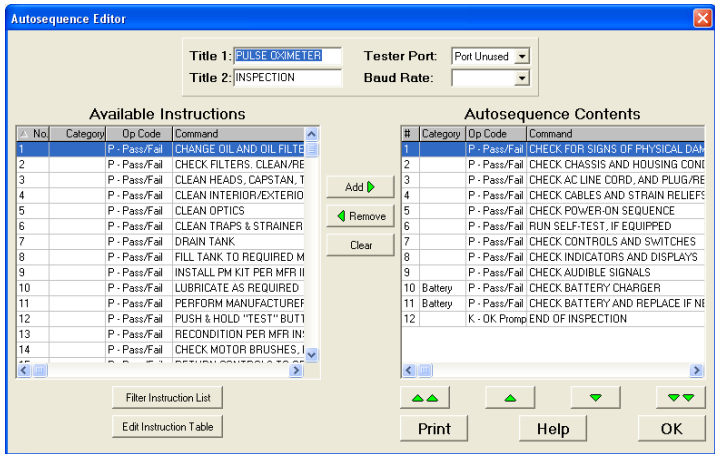
Figure 97

All instructions can be removed from the AutoSequence by pressing the Clear button in the center

margin. AutoSequence contents can be re-ordered by selecting the desired Instruction in the AutoSequence 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.
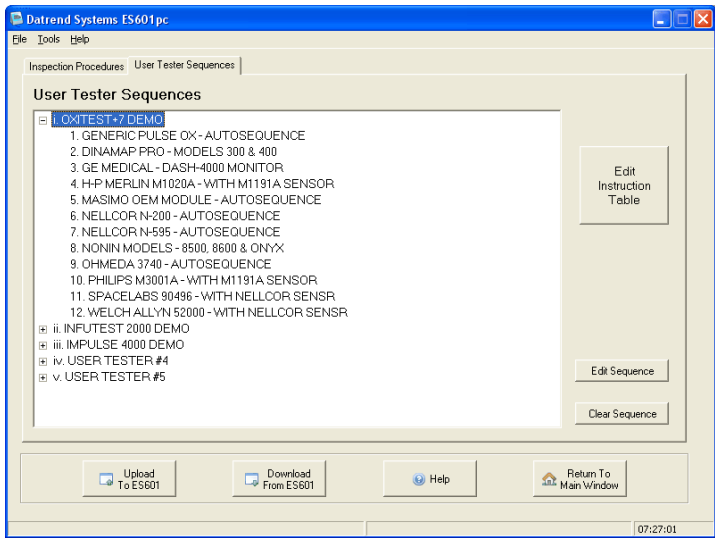
8.8.3 Editing an Instruction

Individual Instructions can be edited by selecting Edit Instruction Table (large button on the right margin of the Inspection Procedure or User Tester Sequence screens, or below the Available Instruction list on the AutoSequence Editor screen).
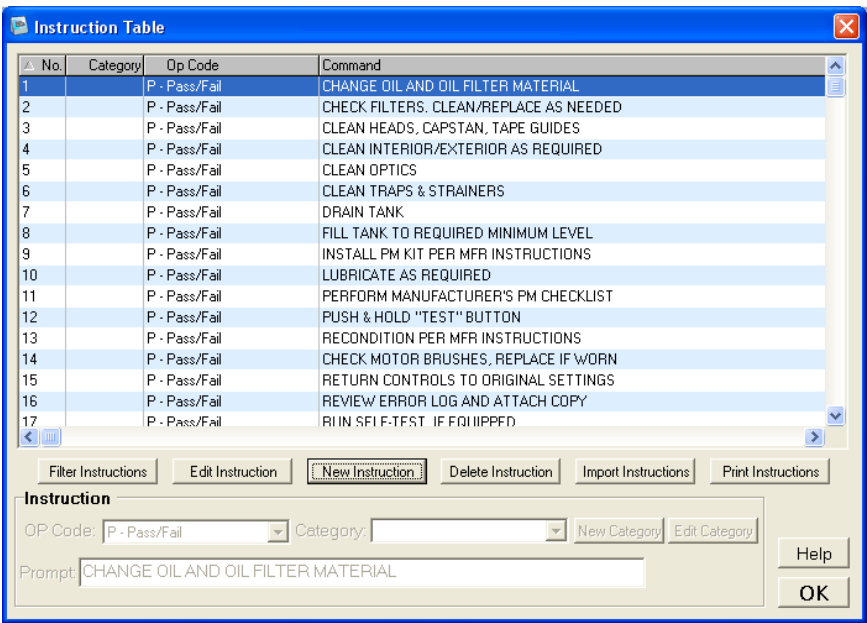
Figure 98

In the Instruction Table, select an instruction, then press "Edit Instruction". The instruction properties in the lower panel must be enabled for editing. Double-clicking on an instruction will also enable the Instruction panel.

The Instruction panel includes an op code dropdown, category dropdown and a number of command textboxes, depending on the instruction's op code (see *Figure 98* and *Figure 99*).
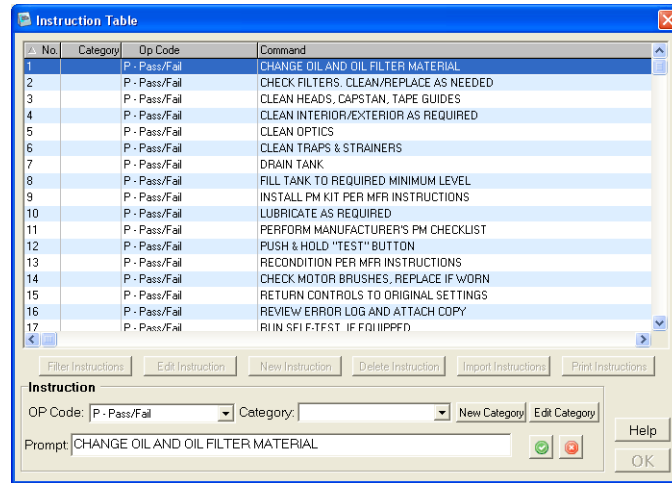
Figure 99

8.8.3.1 Selecting the Op Code

The Op Code defines what the Instruction does and which buttons are presented to the user on ES601*Plus* display. Depending on the op code, the user may be required to enter a measurement value or comment when that Instruction is encountered during the Test Procedure.

Options include:
- Pass/Fail (op code = 'P')
- OK Prompt (op code = 'K')
- Input Requested (op code = 'I')
- Data Entry With Pass/Fail (op code = 'E')
- Delay (op code = 'D')
- Tester Control (op code = 'C')
- Remote Control with User Data Entry (op code = 'R')
- Tester Measurement (op code = 'M')

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.

8.8.3.2 Selecting the Category

Category is used by ES601pc to select and sort Instructions 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'. Using the Autosequence Editor, Instructions can thereby be created or modified under the "Defib" category.
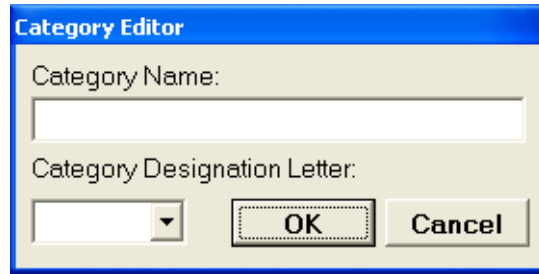
Figure 100

In the Instruction Editor, select a Category of an Instruction via the Category drop-down menu. Create a new category in the Instruction Editor by pressing "New Category". The Category Editor will appear. 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 (see *Figure 100*).

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.

8.8.3.3 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*Plus* will display when this step of the Autosequence is encountered (see *Automated Testing Principles* in Chapter 6). Generally, the Prompt will require the user to enter "OK", "PASS", comments such as "PADDLES CHECKED AND OK" or any other information to be saved as a comment in the Test Record. The Prompt can be up to 40 characters and must be in capital letters. Capital letters are the default when using ES601pc's Instruction Table editor.

Op Codes C, M, D and R will, in addition to the Prompt, allow editing or entering a Command. The Command is used to send an instruction to an external testing device, such as an Infutest 2000, to start or stop a function, execute a pre-programmed autosequence, send data, etc. For more information, refer to the Instruction descriptions given in *Automated Testing Principles* of Chapter 6.

8.8.4 Creating a New Instruction

Press "New Instruction". A new, empty instruction will appear at the end of the Instruction Table. The Instruction Properties panel will also be enabled. To edit the new instruction, follow the same procedure as in Editing an Instruction.

The instructions may be saved, after all information is added or edited, by pressing the OK button [image] or quit without saving by pressing the QUIT button [image] .

8.8.5 Filtering the Instructions

Press "Filter Instructions". The Instruction Filter window will appear (see ***Figure 101***). Under the Basic Filter tab, select a Category and/or an Op Code and then press "OK". Only the instructions with the selected category or op code will appear in the Available Instructions window. To see all available instructions again, press "Filter Instruction List" and then "OK" in the Instruction Filter window.
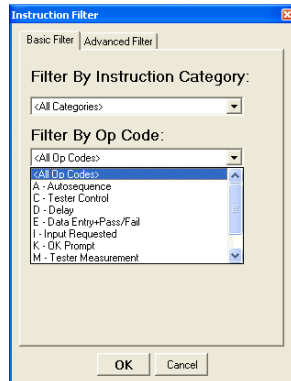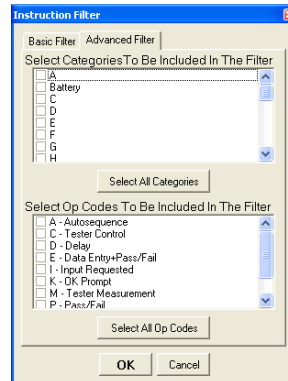
Figure 101   *Figure 102*

In order to select multiple categories or multiple op codes, select the Advanced Filter tab in the Instruction Filter window. Check the categories or op codes of the instructions that should appear (see ***Figure 102***). Press "Select All Categories" or "Select All Op Codes" to select all the checkboxes. Press "OK" to filter the Instruction Table.

8.8.6 Deleting an Instruction

Select an instruction from the Instruction Table. Press Delete Instruction. A warning message will appear which will list the sequences which currently use the instruction. If there are no sequences listed and it is desired to delete the instruction, press "Yes".

Removing or changing an instruction may have significant effects on previously defined General Inspections and/or Tester AutoSequences. Take care when making this type of change to avoid unexpected results with historical Inspections and AutoSequences.

8.8.7 Importing Instructions

Instructions can be imported from a CSV (Comma Separated Values) file and added to the instruction table. Press "Import Instructions" and browse for the CSV file. For the import to be successful, the CSV file must list instructions 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 does not exist, the new instruction 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 instruction will be added to the bottom of the master instruction list.
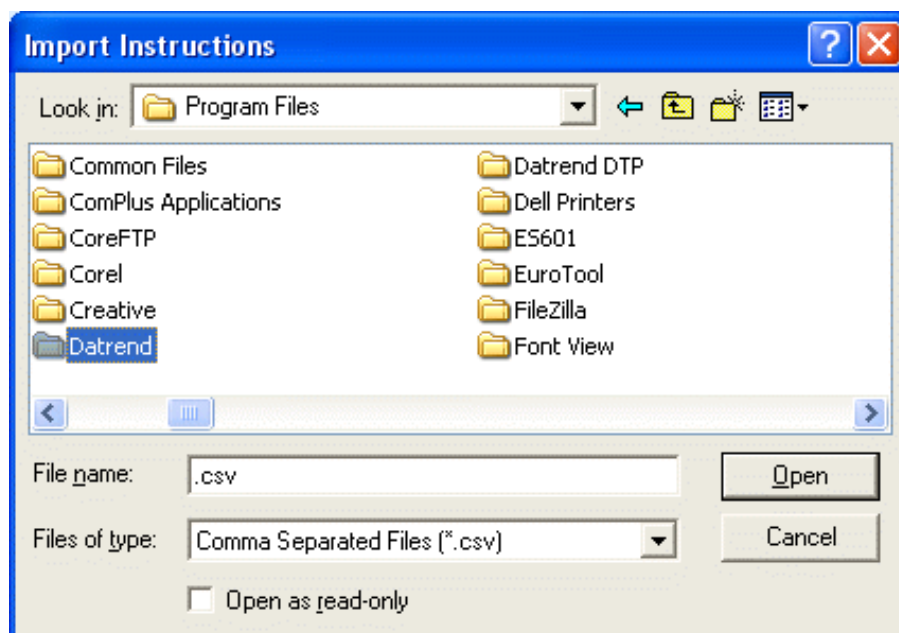
Figure 103

8.8.8 Clearing an Inspection Procedure or User Tester Sequence

To clear an Inspection procedure, select the Inspection procedure and press "Clear Procedure". To clear a User Tester sequence, select the sequence and press "Clear Sequence".

8.8.9 Uploading AutoSequences

To upload the sequences to ES601*Plus*, 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*Plus* (the IP address of ES601*Plus* is displayed on the LCD when ES601*Plus* is operating in Ethernet Mode). If the connection is via serial port, choose the COM port to which ES601*Plus* is connected.
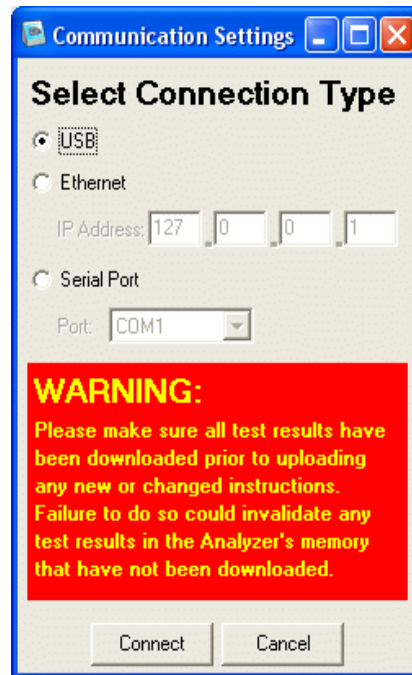
Figure 104

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.

8.8.10 Downloading AutoSequences

Sometimes it is desirable to download sequences stored in ES601*Plus*. You can do this by pressing the "Download From ES601" button. Choose to download via USB, Ethernet, or Serial Port and press "Connect". The connection sequence will proceed as described in Uploading Sequences, above.
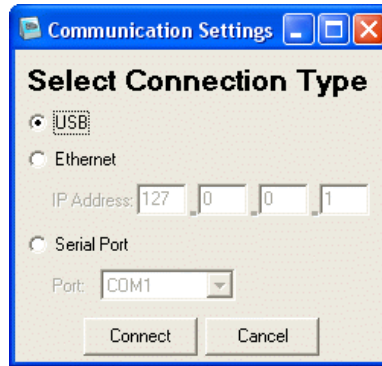
Figure 105

8.9 Test Procedure Editor

The optional Test Procedure Editor allows the user to create and edit up to 500 Test Procedures for ES601*Plus* as described in Chapter 6 of this manual. Pressing TEST PROCEDURE EDITOR from the main menu of ES601pc will display the Test Procedures screen which lists all available Test Procedures.
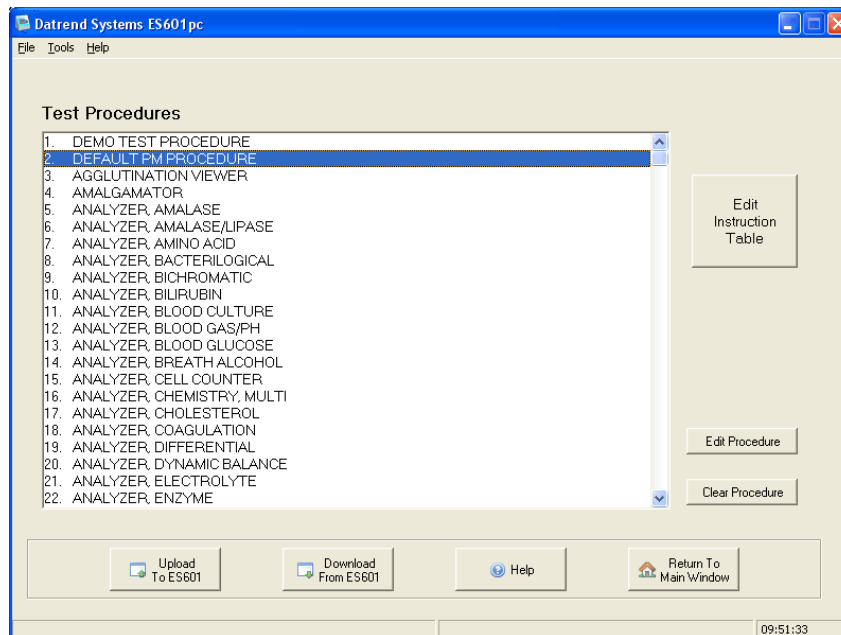
Figure 106

To edit an existing Test Procedure, highlight it and press the "Edit Procedure" button. Similar to editing General Inspections and Tester Autosequences, as described in the immediately preceding section of this chapter, Instructions can be added to and removed from the Test Procedure by using the appropriate buttons in the center margin of the screen.
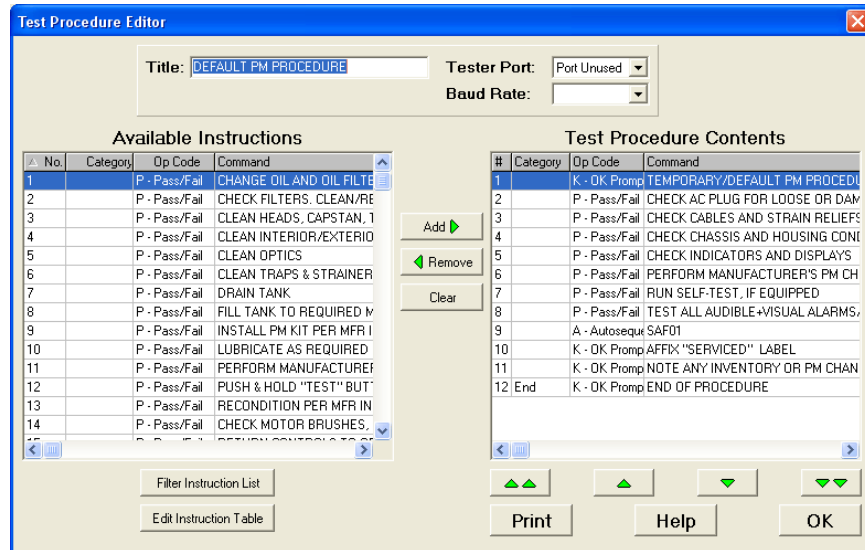
Figure 107

Note: In *Figure 107* the example procedure shown contains an AutoSequence with a "SAF01" Command. This is an Instruction to perform Safety AutoSequence #01 from the available list of 24 Safety Autosequences.

To run an AutoSequence from within a Test Procedure, an Instruction to invoke that AutoSequence must first be created in the Instruction List. Press Edit Instruction Table and select Type 'A' for the op code. Choose the type of AutoSequence (Safety, ECG, General Inspection, User Tester, etc.) and a sequence #. The Instruction created will reflect the type and number of the Instruction required. For example, selecting ECG Autosequence #03 will create the Instruction command "ECG03", or selecting User Tester #1, sequence #5, will create the Instruction command "UT105".

To help in creating AutoSequence Instructions for use in Test Procedures, it is assumed the user of the ES601pc 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 and use the Safety Autosequence Editor, ECG AutoSequence Editor, or any other Editor of ES601pc to view the titles and other details of the AutoSequences, and choose the desired AutoSequence number for the AutoSequence Instruction being created in the Instruction Editor.

⚠️ Do not try to make modifications in the second instance of ES601pc, 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 for viewing only***.

The type of AutoSequence and the related commands that are generated by the Instruction Editor are as follows:

Type	Autosequence	"nn"
SAF	Safety	01 to 24
ECG	ECG	01 to 12
INS	General Inspection	01 to 18
POX	Pulse Oximeter Tester	01 to 12
IVP	IV Pump Tester	01 to 12
DFB	Defibrillator Tester	01 to 24
NBP	NIBP Monitor Tester	01 to 12
ESU	ESU Tester	01 to 12
PAC	Pacemaker Tester	01 to 12
UT1	User Tester #1	01 to 12
UT2	User Tester #2	01 to 12
UT3	User Tester #3	01 to 12
UT4	User Tester #4	01 to 12
UT5	User Tester #5	01 to 12

This list includes all the potentially available selections, however, some of these will require an optional accessory feature to be installed in ES601*Plus* to operate correctly. If, when running a Test Procedure, ES601*Plus* encounters an A Instruction for which the accessory option has not been installed, ES601*Plus* will skip over the Instruction to the next step of the Test Procedure.

> A Test Procedure may have one Safety Autosequence, one ECG Autosequence, both, or neither. A Test Procedure may invoke any number of Inspections or Tester Autosequences via "A" Instructions, provided the total number of procedural steps created by including these Autosequences does not exceed **96**.

More information on the A Instruction can be found in **Automated Testing Principles** of Chapter 6.

Selecting an "(unused)" Test Procedure from the list will open the editor window with no Instructions in the Test Procedure Contents (see ***Figure 108***). The Title, Tester Port and Baud Rate can be changed in this screen, and Instructions can be added to the list on the right to create a custom Test Procedure. Pressing "OK" saves the new Test Procedure, and it will be included in the next upload to ES601*Plus*.

Figure 108

Chapter

9
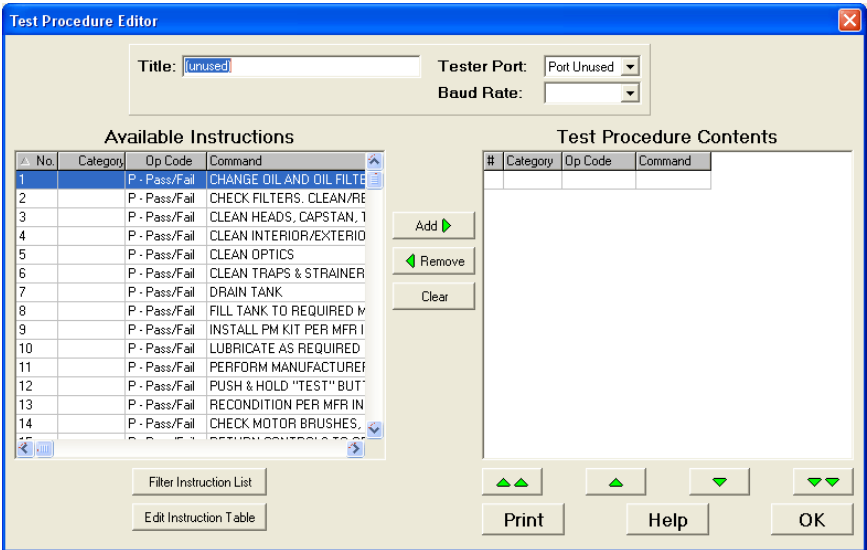
9   Calibration and Maintenance

Calibration of ES601*Plus* 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*Plus*.

ES601*Plus* contains no user serviceable parts, other than two 1Amp/250V AGC fuses located on the back panel. Certain functions of ES601*Plus* are internally fused (Mains on Applied Parts, 25A PE current, internal voltmeter). Failure of these functions will require return of ES601*Plus* to an authorized service facility for repair. **Opening the case of ES601Plus 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.

<div align="center">

Datrend Systems Inc.
Unit 130 - 4020 Viking Way
Richmond, BC • CANADA • V6V 2L4
Tel: 800-667-6557 (North America Only) or
604-291-7747 • Fax 604-294-2355
e-mail: **customerservice@datrend.com**
www.datrend.com

</div>

ES601*Plus* 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*Plus* is used for a purpose not specified in this manual.
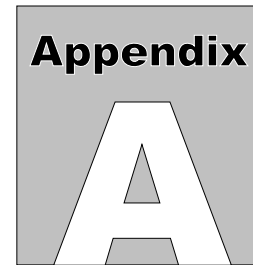
APPENDIX A. Safety & ECG AutoSequences

The following are the default Safety AutoSequences of ES601*Plus*. ES601*Plus* is supplied with these AutoSequences pre-loaded in the flash memory. The default AutoSequences may be modified using the ES601pc software, supplied on CDROM with ES601*Plus*.

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 Test Procedure (see **Automated Testing Principles**, Chapter 6; and **Test Procedure Editor**, Chapter 8).

SAFETY AUTOSEQUENCE 1   (SAF01)
IEC601 SAFETY TEST
CHASSIS LKG & GND

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Skip
Insulation Resistance - Line 1 and 2 to Ground: Skip
Insulation Resistance - Applied Parts to Ground: Skip
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Applied Part Groups
None
```

SAFETY AUTOSEQUENCE 2   (SAF02)
IEC601 CHASSIS LKG,
INSULATION, & GND

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Skip
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Applied Part Groups
None
```

SAFETY AUTOSEQUENCE 3   (SAF03)
IEC601 SAFETY TEST
3 LEADS (ECG)

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 3
AP 1 - RA
AP 2 - RL/LL
AP 3 - LA
```

SAFETY AUTOSEQUENCE 4   (SAF04)
IEC601 SAFETY TEST
5 LEADS (ECG)

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 5
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
```

SAFETY AUTOSEQUENCE 5   (SAF05)
IEC601 SAFETY TEST
10 LEADS (ECG)

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 10
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V1
AP 6 - V2
AP 7 - V3
AP 8 - V4
AP 9 - V5
AP 10 - V6
```

SAFETY AUTOSEQUENCE 6   (SAF06)
IEC601 DEFIB SAFETY
5 LD ECG & PADDLES

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 5
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
Group 2:
Name: PADDLES
Type: CF
Parts: 2
AP 6 - APEX
AP 7 - STERNUM
```

SAFETY AUTOSEQUENCE 7 (SAF07)
IEC601 DEFIB SAFETY
5 LD ECG,PADS,SPO2

Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 5
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
Group 2:
Name: PADDLES
Type: CF
Parts: 2
AP 6 - APEX
AP 7 - STERNUM
Group 3:
Name: SPO2
Type: BF
Parts: 1
AP 8 - PROBE

SAFETY AUTOSEQUENCE 8 (SAF08)
IEC601 NIBP MONITOR
WITH TEMP & SPO2

Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Applied Part Groups
Group 1:
Name: TEMP
Type: BF
Parts: 1
AP 1 - TEMP
Group 2:
Name: SPO2
Type: BF
Parts: 1
AP 2 - SPO2

SAFETY AUTOSEQUENCE 9   (SAF09)
IEC601 MULTIPARAM MONITOR: ECG,BP,TEMP

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 5
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
Group 2:
Name: IBP
Type: CF
Parts: 1
AP 6 - BP XDCR
Group 3:
Name: TEMP
Type: BF
Parts: 1
AP 7 - TEMP
Group 4:
Name: SPO2
Type: BF
Parts: 1
AP 8 - SPO2
```

SAFETY AUTOSEQUENCE 10   (SAF10)
IEC601 MULTIPARAM MONITOR W. ETHERNET

```
Standard: IEC60601
Limits Used: IEC60601 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Isolated Signal Inputs/Outputs
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 5
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
Group 2:
Name: IBP
Type: CF
Parts: 1
AP 6 - BP XDCR
Group 3:
Name: TEMP
Type: BF
Parts: 1
AP 7 - TEMP
Group 4:
Name: SPO2
Type: BF
Parts: 1
AP 8 - SPO2
```

SAFETY AUTOSEQUENCE 11 (SAF11)
IEC601 BAT-POWERED
ECG TELEMETRY, 3 LD

```
Standard: IEC601-Battery
Limits Used: IEC 60601 Limits
Device Power: On
Auxiliary (Interlead) Leakages: Measured
Isolated Signal Inputs/Outputs: Skipped
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 3
AP 1 - RA
AP 2 - RL/LL
AP 3 - LA
```

SAFETY AUTOSEQUENCE 12 (SAF12)
IEC601 BAT-POWERED
ECG TELEMETRY, 5 LD

```
Standard: IEC601-Battery
Limits Used: IEC 60601 Limits
Device Power: On
Auxiliary (Interlead) Leakages: Measured
Isolated Signal Inputs/Outputs: Skipped
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 5
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
```

SAFETY AUTOSEQUENCE 13   (SAF13)
AAMI SAFETY TEST
CHASSIS LKG & GND

```
Standard: AAMI ES1
Limits Used: AAMI ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Skip
Insulation Resistance - Applied Parts to Ground: Skip
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Applied Part Groups
None
```

SAFETY AUTOSEQUENCE 14   (SAF14)
AAMI CHASSIS LKG,
INSULATION, & GND

```
Standard: AAMI ES1
Limits Used: AAMI ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Skip
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Applied Part Groups
None
```

SAFETY AUTOSEQUENCE 15   (SAF15)
AAMI SAFETY TEST
3 LEADS (ECG)

```
Standard: AAMI ES1
Limits Used: AAMI ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG
Type: Isolated
Parts: 3
AP 1 - RA
AP 2 - RL/LL
AP 3 - LA
```

SAFETY AUTOSEQUENCE 16   (SAF16)
AAMI SAFETY TEST
5 LEADS (ECG)

```
Standard: AAMI ES1
Limits Used: AAMI ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG
Type: Isolated
Parts: 5
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
```

SAFETY AUTOSEQUENCE 17   (SAF17)
AAMI SAFETY TEST
10 LEADS (ECG)

```
Standard: AAMI ES1
Limits Used: AAMI ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG
Type: Isolated
Parts: 10
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V1
AP 6 - V2
AP 7 - V3
AP 8 - V4
AP 9 - V5
AP 10 - V6
```

SAFETY AUTOSEQUENCE 18   (SAF18)
AAMI DEFIB SAFETY
5 LD ECG & PADDLES

```
Standard: AAMI ES1
Limits Used: AAMI ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: ECG+PAD
Type: Isolated
Parts: 7
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
AP 6 - APEX
AP 7 - STERNUM
```

SAFETY AUTOSEQUENCE 19   (SAF19)
AAMI NIBP MONITOR
WITH TEMP & SPO2

```
Standard: AAMI ES1
Limits Used: AAMI ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: LEADS
Type: Isolated
Parts: 2
AP 1 - TEMP
AP 2 - SPO2
```

SAFETY AUTOSEQUENCE 20   (SAF20)
AAMI MULTIPARAM
MONITOR: ECG,BP,TEMP

```
Standard: AAMI ES1
Limits Used: AAMI ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Applied Part Groups
Group 1:
Name: LEADS
Type: Isolated
Parts: 8
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
AP 6 - IBP
AP 7 - TEMP
AP 8 - SPO2
```

SAFETY AUTOSEQUENCE 21 (SAF21)
AAMI MULTIPARAM
MONITOR W. ETHERNET

```
Standard: AAMI ES1
Limits Used: AAMI ES1 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Device Power: On
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
Test Enclosure and Earth Plus:
Patient - Applied Parts
Auxiliary (Interlead) Leakages
Isolated Signal Inputs/Outputs
Applied Part Groups
Group 1:
Name: LEADS
Type: Isolated
Parts: 8
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
AP 6 - IBP
AP 7 - TEMP
AP 8 - SPO2
```

SAFETY AUTOSEQUENCE 22   (SAF22)
AAMI BAT-POWERED
ECG TELEMETRY, 5 LD

```
Standard: AAMI-Battery
Limits Used: AAMI ES1
Device Power: On
Auxiliary (Interlead) Leakages: Measured
Isolated Signal Inputs/Outputs: Skipped
Applied Part Groups
Group 1:
Name: ECG
Type: Isolated
Parts: 5
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
```

SAFETY AUTOSEQUENCE 23   (SAF23)
IEC62353 SAFETY TEST
5 LEADS (ECG)
```
Standard: IEC62353
Limits Used: IEC62353 Limits
Equipment Class: Class I
Line Voltage: Measure
Load Current: Measure
Insulation Resistance - Line 1 and 2 to Ground: Measure
Insulation Resistance - Applied Parts to Ground: Measure
Protective Earth: Measure
Leakage Current: Measure
Protocol: Alternate Method
Polarity: Normal
Test Applied Parts
Applied Part Groups
Group 1:
Name: ECG
Type: BF
Parts: 5
AP 1 - RA
AP 2 - RL
AP 3 - LA
AP 4 - LL
AP 5 - V
```

SAFETY AUTOSEQUENCE 24   (SAF24)
IEC61010 SAFETY TEST
LABORATORY EQUIPMENT

```
Standard: IEC61010
Limits Used: IEC61010 Limits
Line Voltage: Measure
Load Current: Measure
Insulation Resistance: Measure
Insulation Resistance - Applied Parts to Ground: Skip
Protective Earth: Measured At 1 Amp
Leakage Current: Measure
Polarity: Normal/Reverse
Line 2: Normal/Open
Ground: Normal/Open
```

The following are the default ECG AutoSequences of ES601*Plus*. ES601*Plus* is supplied with these AutoSequences pre-loaded in the flash memory. The default AutoSequences may be modified using the ES601pc software, supplied on CDROM with ES601*Plus*.

AutoSequences in the following list are identified as "*ECG AUTOSEQUENCE #NN (ECGNN).*" (ECGNN) refers to the command assigned by Datrend to the AutoSequence, to allow the AutoSequence to be invoked from a Test Procedure (see **Automated Testing Principles**, Chapter 6; and **Test Procedure Editor**, Chapter 8).

ECG AUTOSEQUENCE 1   (ECG01)
STANDARD ECG TEST SEQUENCE

```
01 - Square Wave, 2Hz - x 1.0
02 - DC Pulse, 4 seconds - x 1.0
03 - Triangle Wave, 2Hz - x 1.0
04 - Sine Wave, 10 Hz - x 1.0
05 - Sine Wave, 40 Hz - x 1.0
06 - Sine Wave, 60 Hz - x 1.0
07 - Sine Wave, 100 Hz - x 1.0
08 - ECG, 60 BPM - x 1.0
09 - ECG, 30 BPM - x 1.0
10 - ECG, 120 BPM - x 1.0
11 - ECG, 180 BPM - x 1.0
12 - ECG, 240 BPM - x 1.0
```

ECG AUTOSEQUENCE 2 (ECG02)
QUICK ECG TEST SEQUENCE

```
01 - Square Wave, 2Hz - x 1.0
02 - Triangle Wave, 2Hz - x 1.0
03 - Sine Wave, 10 Hz - x 1.0
04 - Sine Wave, 60 Hz - x 1.0
05 - ECG, 60 BPM - x 1.0
06 - ECG, 30 BPM - x 1.0
07 - ECG, 180 BPM - x 1.0
```


ECG AUTOSEQUENCE 3 (ECG03)
FULL PERFORMANCE TEST SEQUENCE

```
01 - Square Wave, 2Hz - x 1.0
02 - Square Wave, 2Hz - x 2.0
03 - Square Wave, 2Hz - x 0.5
04 - DC Pulse, 4 seconds - x 1.0
05 - DC Pulse, 4 seconds - x 2.0
06 - DC Pulse, 4 seconds - x 0.5
07 - Triangle Wave, 2Hz - x 1.0
08 - Triangle Wave, 2Hz - x 2.0
09 - Triangle Wave, 2Hz - x 0.5
10 - Sine Wave, 10 Hz - x 1.0
11 - Sine Wave, 40 Hz - x 1.0
12 - Sine Wave, 60 Hz - x 1.0
13 - Sine Wave, 70 Hz - x 1.0
14 - Sine Wave, 100 Hz - x 1.0
15 - ECG, 60 BPM - x 1.0
16 - ECG, 30 BPM - x 1.0
17 - ECG, 120 BPM - x 1.0
18 - ECG, 180 BPM - x 1.0
19 - ECG, 240 BPM - x 1.0
20 - Havertriangle Pulse, 10 msec, 60BPM - x 1.0
21 - Havertriangle Pulse, 25 msec, 60BPM - x 1.0
22 - Havertriangle Pulse, 40 msec, 60BPM - x 1.0
23 - Havertriangle Pulse, 100 msec, 60BPM - x 1.0
24 - Havertriangle Pulse, 200 msec, 60BPM - x 1.0
```

ECG AUTOSEQUENCE 4 (ECG04)
SHOCK ADVISORY/AED TEST SEQUENCE

01 - Square Wave, 2Hz - x 1.0
02 - DC Pulse, 4 seconds - x 1.0
03 - Triangle Wave, 2Hz - x 1.0
04 - ECG, 60 BPM - x 1.0
05 - ECG, 30 BPM - x 1.0
06 - ECG, 120 BPM - x 1.0
07 - ECG, 240 BPM - x 1.0
08 - Ventricular Fibrillation (VFIB) - x 1.0
09 - Asystole (ASYS) - x 1.0
10 - Atrial Fibrillation (AFIB) - x 1.0
11 - Supraventricular Tachycardia (SVT) - x 1.0
12 - Polymorphic VTach @ 140BPM (PVT140) - x 1.0
13 - Monomorphic VTach @ 160BPM (MVT160) - x 1.0
14 - Second Degree A-V Block (blk II) - x 1.0
15 - Premature Ventricular Contraction (PVC) - x 1.0
16 - Multifocal PVC (mfPVC) - x 1.0

ECG AUTOSEQUENCE 5 (ECG05)
ARRHYTHMIA WAVE TEST SEQUENCE

01 - Square Wave, 2Hz - x 1.0
02 - DC Pulse, 4 seconds - x 1.0
03 - Triangle Wave, 2Hz - x 1.0
04 - ECG, 60 BPM - x 1.0
05 - ECG, 30 BPM - x 1.0
06 - ECG, 120 BPM - x 1.0
07 - ECG, 240 BPM - x 1.0
08 - Second Degree A-V Block (blk II) - x 1.0
09 - Premature Atrial Contraction (PAC) - x 1.0
10 - Right Bundle Branch Block (RBBB) - x 1.0
11 - Premature Ventricular Contraction (PVC) - x 1.0
12 - R-on-T PVC (RonT) - x 1.0
13 - Multifocal PVC (mfPVC) - x 1.0
14 - Run of 5 PVC (Run5) - x 1.0
15 - Bigeminy (BGEM) - x 1.0
16 - Ventricular Fibrillation (VFIB) - x 1.0
17 - Atrial Fibrillation (AFIB) - x 1.0
18 - Missed Beat at 80BPM (MB80) - x 1.0
19 - Missed Beat at 120BPM (MB120) - x 1.0

ECG AUTOSEQUENCE 6 (ECG06)
(unused)
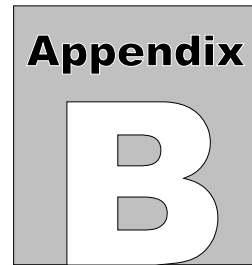
APPENDIX B. Sample Test Record

Below is an example of a report created by the Test Report Generator of ES601pc. ES601*Plus* 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.

To perform the tests listed in the report, the ES601*Plus* analyzer was equipped with the following accessory options:

- General Inspections and User Tester AutoSequences
- Test Procedures

```
***************** TEST RECORD No. 22 *****************

                 Test Report

         ES601: ES071200050 Ver.: 3.00
          I.D.: MY ES601

         Device ID: CN0472
         Parent ID:
         Date/Time: 18 FEB 2009 12:14:02

Descrip.:   DEFIB W. PCR+SPO2  Make:   HEWLETT-PACKARD
Serial No.: A14-567100E        Model: CODEMASTER XL+
Facility:   ST. JOSEPH'S HOSP  Loc.:   EMERG

Tech Code:  MEM
Tech Time:  00:14:40

****************** SAFETY TEST ******************
STANDARD: IEC60601E3              LIMITS: PER STANDARD
AUTOSEQ.: 01                     CLASS: I

    GROUND FAULT: NONE

    LINE VOLTAGE: L1-L2  L1-GND  L2-GND
                  120.0   120.0    2.3 VOLTS RMS

    LOAD CURRENT:  0.43 AMPS RMS
```

```
INSULATION RESISTANCE    LIMIT   UNITS
     L1/L2 TO GND: 999.9  ---.-  MEGOHMS
        AP TO GND: 999.9  ---.-  MEGOHMS


-------------- PROTECTIVE EARTH TEST --------------
LIMIT:   0.200 OHMS         MULTIPLE PE TEST: NO
OFFSET:  -.--- OHMS         LINE CORD TEST: YES
CURRENT: 25A AC             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:NC         (ON /---)     23      0   5000 PASS
NP:SF L2O     (ON /---)    146      1  10000 PASS
RP:NC         (ON /---)     23      0   5000 PASS
RP:SF L2O     (ON /---)    148      0  10000 PASS

------------------ TOUCH CURRENT ------------------
----TEST CONDITION----- (uArms) (uAdc) LIMIT
NP:NC     (ON /---/---)      2      0    100 PASS
NP:SF L2O (ON /---/---)      6      1    500 PASS
NP:SF EO  (ON /---/---)     21      1    500 PASS
RP:NC     (ON /---/---)      1      0    100 PASS
RP:SF L2O (ON /---/---)      4      0    500 PASS
RP:SF EO  (ON /---/---)     19      1    500 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 **********************

PROCEDURE TYPE: Test Procedure
PROCEDURE No.:  089

STEP ---------------- TASK ------------------    RESULT
  1 CAUTION: HIGH VOLTAGE
       .........................................OK
  2 REVIEW MANUFACTURER LITERATURE AS NEEDED
       .........................................OK
  3 TEST EQUIPMENT: DEFIBRILLATOR TESTER
       .........................................OK
  4 TEST EQUIPMENT: PACEMAKER ANALYSER
       .........................................OK
  5 TEST EQUIPMENT: PULSE OXIMETRY TESTER
       .........................................OK
  6 TEST EQUIPMENT: STOP WATCH
       .........................................OK
  7 CHECK FOR SIGNS OF PHYSICAL DAMAGE/ABUSE
       .......................................PASS
  8 CHECK FOR EVIDENCE OF FLUID SPILLS
       .......................................PASS
  9 CHECK AC LINE CORD, AND PLUG/RECEPTACLE
       .......................................PASS
 10 CHECK STRAIN RELIEF AT BOTH ENDS OF CORD
       .......................................PASS
 11 CHECK PATIENT CABLE & LEADS FOR DAMAGE
       .......................................PASS
 12 CHECK CONTROLS AND SWITCHES
       .......................................PASS
 13 CHECK CAUTION/OPERATION LABELLING
       .......................................PASS
 14 CHECK PADDLES FOR SIGNS OF DAMAGE/PITTING
       .......................................PASS
 15 CHECK BATTERY AND REPLACE IF NECESSARY
       ...................................SERVICED
 16 CHECK POWER-ON SEQUENCE
       .......................................PASS
 17 CHECK FOR UNUSUAL NOISE OR VIBRATION
       .......................................PASS
 18 CHECK DISPLAY FOCUS, INTENSITY, ALIGNMENT
       .......................................PASS
 19 CHECK RECORDER OPERATION
       .......................................PASS
 20 CLEAN INTERIOR/EXTERIOR AS REQUIRED
       .......................................PASS
 21 ENTER SOFTWARE REVISION LEVEL:
       VERSION 5.10.2............................OK
 22 RUN SELF-TEST, IF EQUIPPED
       .......................................PASS
 23 TEST ALL AUDIBLE+VISUAL ALARMS/INDICATORS
       .......................................PASS
 24 ECG01
       EXECUTE ECG AUTOSEQUENCE..................OK
 25 UT101
       OXITEST+7 DEMO       AUTOSEQUENCE.........OK

 26 SELECT PULSE OXIMETER ON OXITEST+7
       .........................................OK
 27 SET HEART RATE=60BPM
```

```
                  ..............................................OK
     28  SET PULSE AMPL=100%
                  ..............................................OK
     29  SET ARTIFACT=OFF
                  ..............................................OK
     30  CHECK SPO2=96-98%; RATE=59-61BPM
             SPO2=96% RATE=60BPM - OK...................PASS
     31  CHECK SPO2=88-92%; RATE=59-61BPM
             SPO2=89% RATE=60BPM - OK...................PASS
     32  CHECK SPO2=78-82%; RATE=59-61BPM
             SPO2=79% RATE=60BPM - OK...................PASS
     33  CHECK SPO2=68-72%; RATE=59-61BPM
             SPO2=68% RATE=60BPM - OK...................PASS
     34  SET SPO2=93%
                  ..............................................OK
     35  CHECK SPO2=92-94%; RATE=119-121BPM
             SPO2=92% RATE=119BPM - OK..................PASS
     36  CHECK SPO2=92-94%; RATE=178-182BPM
             SPO2=93% RATE=179BPM - OK..................PASS
     37  SET HEART RATE=60BPM
                  ..............................................OK
     38  CHECK SPO2=92-94% (LOW PERFUSION)
             SPO2=92%, WEAK PLETH SIGNAL................PASS
     39  CHECK LOW SIGNAL ALARM
                  ............................................PASS
     40  SET PULSE AMPL=100%
                  ..............................................OK
     41  END OF SEQUENCE
                  ..............................................OK
     42  MEASURE & RECORD DEFIB OUTPUT AT 50 J
             49.8 JOULES................................PASS
     43  MEASURE & RECORD DEFIB OUTPUT AT 100 J
             98.4 JOULES................................PASS
     44  MEASURE & RECORD DEFIB OUTPUT AT 200 J
             198.1 JOULES...............................PASS
     45  MEASURE & RECORD DEFIB OUTPUT AT 300 J
             297.3 JOULES...............................PASS
     46  MEASURE & RECORD DEFIB OUTPUT AT 360 J
             352.8 JOULES...............................PASS
     47  TEST MAX ENERGY WITH DEFIB ON BAT. POWER
             350.2 JOULES - OK..........................PASS
     48  TEST CHARGE TIME WITH DEFIB ON BAT. POWER
             12 SEC - OK................................PASS
     49  TEST DEFIB "SYNC MODE" OPERATION
                  ............................................PASS
     50  CHECK PACER, DEMAND MODE OPERATION
                  ............................................PASS
     51  MEASURE & RECORD PULSE AMPL & FREQUENCY
             AMP=100MA PRR=80PPM - OK...................PASS
     52  MEASURE & RECORD PULSE WIDTH
             20.2 MSEC..................................PASS
     53  SAF01
             EXECUTE SAFETY AUTOSEQUENCE................OK

     54  AFFIX "BATTERY REPLACED" LABEL IF NEEDED
                  ..............................................OK
     55  AFFIX "SERVICED"  LABEL
                  ..............................................OK
     56  NOTE ANY INVENTORY OR PM CHANGES IN CEMS
                  ..............................................OK
```

```
  57   END OF PROCEDURE
        ..........................................OK
```

```
DEVICE ID: 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*Plus*. The prior results were obtained by executing Test Procedure #89, which was created and loaded into ES601*Plus*' memory by means of the Test Procedure Editor of the ES601pc software package.

According to the above report, Procedure #89 includes: measurement of enclosure and earth leakage current; testing of protective earth 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

APPENDIX C. Automated Test Examples

Below are examples of a General Inspection and a User-Defined Tester AutoSequence, which were created using the optional AutoSequence Editor of the ES601pc software package. This Appendix also includes an example of a Test Procedure, created with the optional Test Procedure Editor of ES601pc. For further details on these types of automated tests provided by ES601*Plus*, refer to the **Automated Testing Principles**, Chapter 6; and the **AutoSequence Editor** and Test Procedure Editor, Chapter 8.

GENERAL INSPECTION 1 (INS01)
GENERIC DEVICE INSPECTION

```
Tester Port:    None
Baud Rate:      N / A


Step  Category      Op Code     Command

1.               P - Pass/Fail   CHECK FOR SIGNS OF PHYSICAL DAMAGE/ABUSE
2.               P - Pass/Fail   CHECK FOR SECURE MOUNTING
3.               P - Pass/Fail   CHECK AC LINE CORD, AND PLUG/RECEPTACLE
4.               P - Pass/Fail   CHECK CABLES AND STRAIN RELIEFS
5.               P - Pass/Fail   CHECK POWER-ON SEQUENCE
6.               P - Pass/Fail   RUN SELF-TEST, IF EQUIPPED
7.               P - Pass/Fail   CHECK CONTROLS AND SWITCHES
8.               P - Pass/Fail   CHECK INDICATORS AND DISPLAYS
9.               P - Pass/Fail   CHECK AUDIBLE SIGNALS
10.  Battery     P - Pass/Fail   CHECK BATTERY CHARGER
11.  Battery     P - Pass/Fail   CHECK BATTERY AND REPLACE IF NECESSARY
12.              P - Pass/Fail   CLEAN INTERIOR/EXTERIOR AS REQUIRED
13.              P - Pass/Fail   PERFORM MANUFACTURER'S PM CHECKLIST
14.              P - Pass/Fail   RETURN CONTROLS TO ORIGINAL SETTINGS
15.  End         K - OK Prompt   END OF INSPECTION
```

USER-DEFINED TESTER 1 (UT101)
OXITEST DEMO AUTOSEQUENCES
GENERIC PULSE OX AUTOSEQUENCE

```
Tester Port:    1
Baud Rate:      9600 Baud


  Step  Category          Op Code           Command

  1.    Oxitest+7  K - OK Prompt      SELECT PULSE OXIMETER ON OXITEST+
  2.    Oxitest+7  C - Tester Ctrl    HR60• SET HEART RATE=60BPM
  3.    Oxitest+7  C - Tester Ctrl    PA100• SET PULSE AMPL=100%
  4.    Oxitest+7  C - Tester Ctrl    AF0SET ARTIFACT=OFF
  5.    Oxitest+7  R - Rem Ctrl+Entry SO1• CHECK SPO2=96-98%; RATE=59-61
  6.    Oxitest+7  R - Rem Ctrl+Entry SO3• CHECK SPO2=88-92%; RATE=59-61
  7.    Oxitest+7  R - Rem Ctrl+Entry SO4• CHECK SPO2=78-82%; RATE=59-61
  8.    Oxitest+7  R - Rem Ctrl+Entry SO5• CHECK SPO2=68-72%; RATE=59-61
  9.    Oxitest+7  C - Tester Ctrl    SO2• SET SPO2=93%
  10.   Oxitest+7  R - Rem Ctrl+Entry HR120• CHECK SPO2=92-94%; RATE=119
  11.   Oxitest+7  R - Rem Ctrl+Entry HR180• CHECK SPO2=92-94%; RATE=178
  12.   Oxitest+7  C - Tester Ctrl    HR60• SET HEART RATE=60BPM
  13.   Oxitest+7  R - Rem Ctrl+Entry PA4• CHECK SPO2=92-94% (LOW PERFUSION)
  14.   Oxitest+7  R - Rem Ctrl+Entry PA0• CHECK LOW SIGNAL ALARM
  15.   Oxitest+7  C - Tester Ctrl    PA100• SET PULSE AMPL=100%
  16.   END        K - OK Prompt      END OF SEQUENCE
```

TEST PROCEDURE 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.                    P - Pass/Fail       CHECK POWER-ON SEQUENCE
15.                    P - Pass/Fail       CHECK FOR UNUSUAL NOISE OR VIBRATION
16.                    P - Pass/Fail       CHECK DISPLAY FOCUS, INTENSITY, ALIGNMENT
17.   Defib            P - Pass/Fail       CHECK RECORDER OPERATION
18.                    P - Pass/Fail       CLEAN INTERIOR/EXTERIOR AS REQUIRED
19.                    I - Input Requested  ENTER SOFTWARE REVISION LEVEL:
20.                    P - Pass/Fail       RUN SELF-TEST, IF EQUIPPED
21.                    P - Pass/Fail       TEST ALL AUDIBLE+VISUAL ALARMS/INDICATORS
22.                    A - Autosequence    ECG01
23.   Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 50 J
24.   Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 100 J
25.   Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 200 J
26.   Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 300 J
27.   Defib            E - Data Entry+P/F  MEASURE & RECORD DEFIB OUTPUT AT 360 J
28.   Defib            E - Data Entry+P/F  TEST MAX ENERGY WITH DEFIB ON BAT. POWER
29.   Defib            E - Data Entry+P/F  TEST CHARGE TIME WITH DEFIB ON BAT. POWER
30.   Defib            P - Pass/Fail       TEST DEFIB "SYNC MODE" OPERATION
31.                    A - Autosequence    SAF01
32.   Battery          K - OK Prompt       AFFIX "BATTERY REPLACED" LABEL IF NEEDED
33.                    K - OK Prompt       AFFIX "SERVICED"  LABEL
34.                    K - OK Prompt       NOTE ANY INVENTORY OR PM CHANGES IN CEMS
35.   End              K - OK Prompt       END OF PROCEDURE
```

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:

ES601Plus OPERATING MANUAL
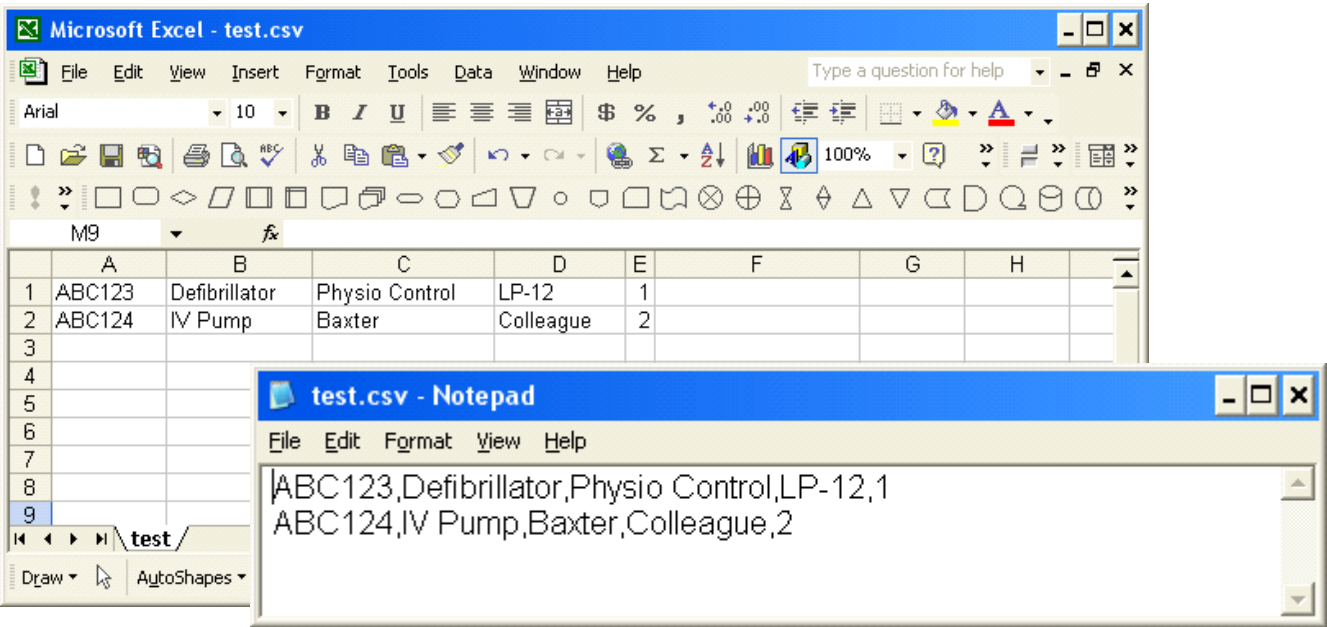
The preceding is an example of a short equipment list. There can be more fields, but this will demonstrate the function. In this case, Column E is the test procedure number - This can be added or changed later. Be sure to save the file as ".CSV".
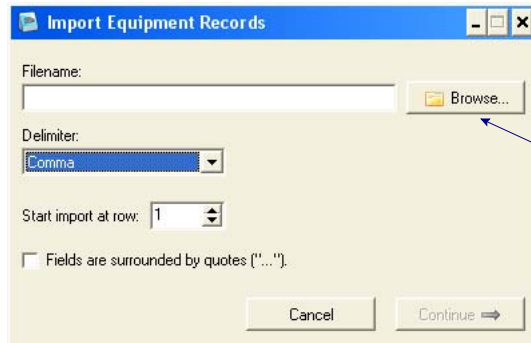
Press Browse to locate the file you wish to import.
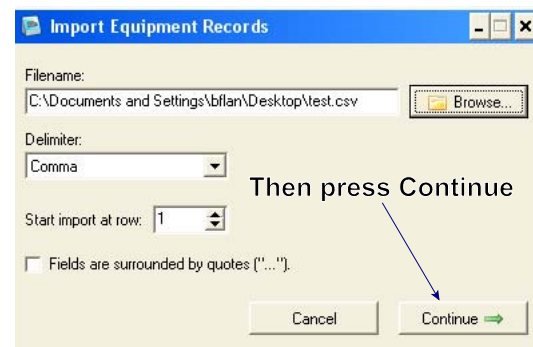
Then press Continue

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.

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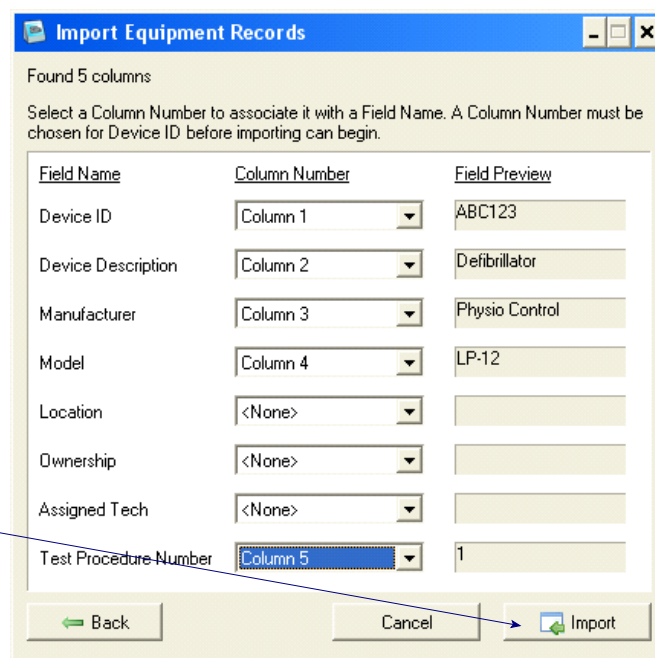
For this simple example, the import process will run very quickly. The amount of time required to import will depend of the number of records in the input CSV file. Press OK when the import completes.
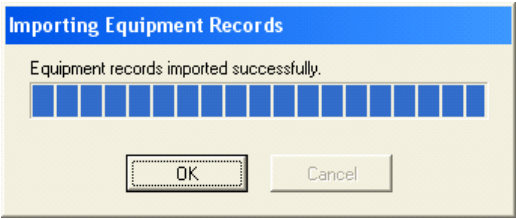
You will notice that the default equipment records have been replaced by the new data.

Double-click a record to view/edit.
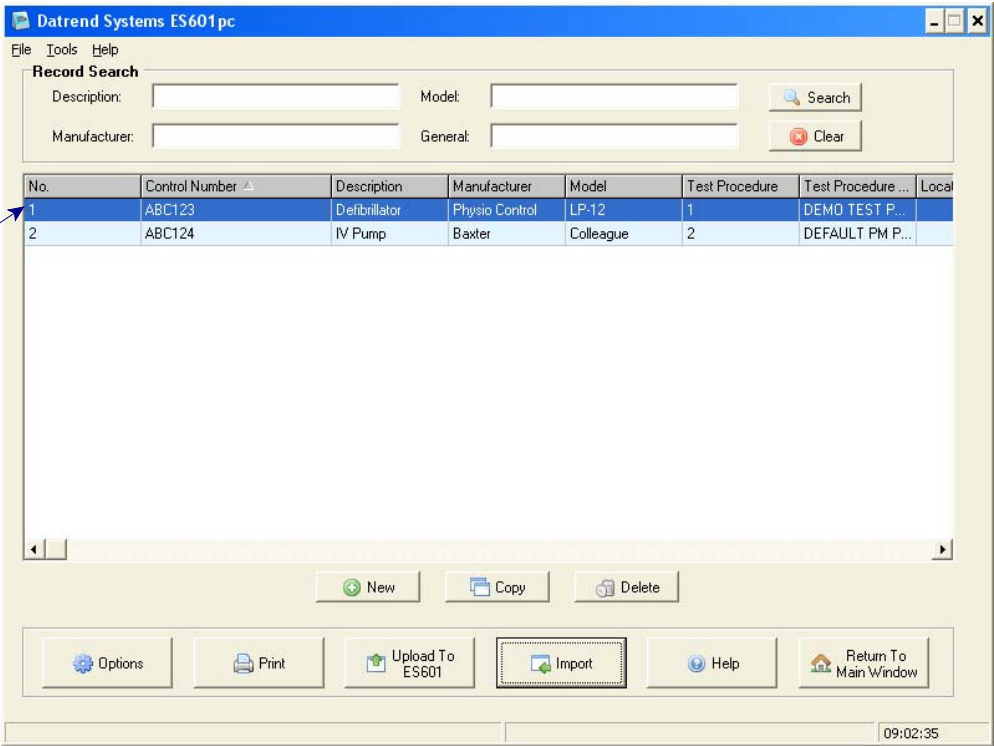
If not already assigned, test procedures can be assigned now, and custom fields can be added or edited.

Ensure that the USB Driver for ES601*Plus* is installed and the unit connected to the PC as per section 8.2; then upload the data to the ES601*Plus*, and the equipment records and associated test procedures will be ready.

Refer to manual MN-049 (6100-428) on the ES601 product CD for more details on the Equipment Record Editor.