DATREND Systems Inc.

vPad-A3™

Automation Application for vPad-353 Electrical Safety Analyzer

Operating Manual

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Operating Manual

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**

DATREND Systems Inc.

To order this manual, use Part Number 6100-046

Revision	Revision History Description	Date
B	Enable Edits	2013-Dec-12
C	Equipment Info Clear Button	2014-Feb-25
D	Clarified Tablet RAM limits	2014-Aug-21
E	Added Leakage Test Features	2017-Mar-14

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 and Product Support

Software Applications (Apps) for use in conjunction with ES601 and vPad Safety Analyzers and other Datrend Products are supplied subject to the Terms and Conditions agreed to by the act of Activating the App. In the event no Activation is required, the Terms and Conditions published on the Datrend Systems Inc. (DSI) website shall prevail. By using the App, you agree to these terms and Conditions. IN NO EVENT SHALL DATREND SYSTEMS INC. BE LIABLE FOR CONSEQUENTIAL DAMAGES.

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Table of Contents

Abbreviations and Definitions

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

µA	Micro-ampere
A	Ampere
AAMI	American Association of Medical Instrumentation
AP	Applied Parts (patient leads)
App	Software application for a mobile device
Cct.	Abbreviation for circuit (ie. electrical circuit in a power distribution system)
Earth	See GND
EUT	Equipment Under Test. The electrical device being tested.
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
IME	Android input method (e.g. keyboard)
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
NC	Normal Condition of AC supply to EUT: ground and neutral are both connected

PE	Protective Earth. The line (conductor) connected to a place that is maintained at “Ground” or “Earth” voltage.
RA	right arm ECG lead
RL	right leg ECG lead
RMS	Root-Mean-Square measurement of a parameter (eg. V_{rms}, A_{rms}....)
Safety Standard	Standards established by various national and international agencies. The most recognized Standards Organizations include: AAMI - Association for Advancement of Medical Instrumentation IEC - International Electrotechnical Commission
SFC	Single-fault condition of AC supply to EUT: either ground or neutral is disconnected, but not both
Type B (Body)	IEC protection class referring to patient-applied parts (leads) which are not isolated from ground
Type BF (Body Floating)	IEC protection class referring to patient-applied parts (leads) which are isolated from ground
Type CF (Cardiac Floating)	IEC protection class referring to patient-applied parts (leads) which are isolated from ground and also intended for direct cardiac application
V	Volt
V1-V6	Precordial (chest) ECG leads
Vrms	Volts rms

Symbol Definitions

The following symbols may be found on vPad-353, which is used in conjunction with the vPad-A3 App:

CONSULT MANUAL FOR PROPER OPERATION

The operating manual provides valuable information on the proper use of vPad-353. It is highly recommended the operator read the instructions thoroughly before operating the device. It is possible to damage the Equipment Under Test (EUT) and/or cause harm to the operator if vPad-353 is used incorrectly.

Patient Leads: Hazardous Voltage: 264 VAC or 500 VDC max

This warning appears on the label for the patient lead connections, located at the rear of vPad-353. During testing of the isolation of the EUT patient applied parts leads with respect to either ground, or to the power input leads, a voltage of either 100% of the AC line voltage may be present on the (CAT I) lead connectors. This 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 EUT patient leads. The display of vPad-353 will indicate when a hazardous voltage is present at the patient lead connectors.

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

These warnings appear on the serial number label of vPad-353. vPad-353 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 vPad-353. Refer to the Troubleshooting and Maintenance Section of the Operating Manual.

Kelvin Cable

The Kelvin Cable (CAT I) is used to measure the Line Cord Grounding Resistance, using a pulsed 1 amp current (200 mA RMS). The voltage present at these terminals is below 6 volts. Consult the Operating Manual for the proper operation of the Grounding Resistance test.

DO NOT EXCEED THE FOLLOWING CURRENT LOAD ON THE EUT RECEPTACLE:

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

The regulatory requirements for loading a circuit (cct.) in a power distribution system sets a current limit on

any individual receptacle to 80% of the value of the circuit breaker on that circuit. For instance, in a circuit with a 15A circuit breaker (or fuse), the maximum current allowed to be drawn from any individual receptacle is 12A. Allowing 1A for the vPad-353 circuitry, the load current for the Equipment Under Test (EUT) 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 EUT 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 vPad-353.

WARNING: OPENING THE vPad-353 MAY COMPROMISE USER SAFETY. REFER SERVICING TO DATREND AUTHORIZED AGENT.

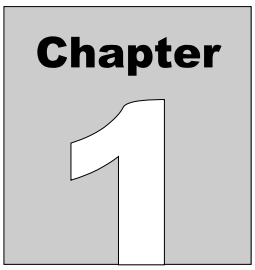
vPad-353 is a complex instrument which contains internally distributed line voltages and other high voltages for specific measurement purposes. Failure to observe appropriate measures when the instrument has been opened, or failure to reassemble correctly may compromise the safety of the user.

WARNING: GROUNDING CIRCUIT CONTINUITY IS VITAL FOR SAFE OPERATION. NEVER OPERATE THE vPad-ES WITH GROUNDING CONDUCTOR DISCONNECTED.

Proper grounding is essential to ensure operator safety. Do not bypass the grounding provisions inherent in the design of vPad-353, 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 EUT, vPad-353 may apply a high voltage (up to 264 VAC) to the EUT. While this voltage is current limited, it does represent a shock hazard to the operator if precautions are not followed. Consult the instructions in this manual regarding Isolation Leakage Current tests (MAP test) for further information.



1 Specifications

vPad-A3 is a software application used in conjunction with the vPad-353 Electrical Safety Analyzer. The following specifications relate to the vPad-353 when used with the vPad-A3 App.

Equipment Performance Specifications

1.1 Electrical Safety Testing Standards

- IEC62353

1.2 Safety Tests

- Line Voltage
- External (point-to-point) Voltage
- External (point-to-point) Micropotential
- Equipment Load Current
- Equipment Power Consumption
- Line Cord Resistance
- External (point-to-point) Resistance
- Chassis Leakage Current (IEC touch current)
- Ground Leakage Current (IEC earth leakage current)
- External (point-to-point) Leakage Current
- Patient Lead Leakage to Ground (earth)
- Patient Lead-to-Lead Leakage (IEC auxiliary leakage)
- Patient Lead Isolation Test (IEC MAP test)

1.3 Instrument Specifications

1.3.1 Voltage Measurement

Line voltage	
Range.....	90 to 264 V rms
Accuracy	±(2 % of reading + 0.2 V)
External (point-to-point) voltage	
Range.....	0 to 300 V rms
Accuracy	±(1 % FS + 0.2 V)
External (point-to-point) micropotential	
Ranges.....	0 to 199.9 mV rms
	200 to 1,999 mV rms
	2000 to 19,999 mV rms
Accuracy	±(1 % of reading + 1 mV)

1.3.2 Load Current Measurement

Ranges	0 to 1.999 A ac rms
	2.00 to 19.99 A ac rms
Accuracy	±(2 % reading + 0.2A)
Duty cycle	0 A to 10 A, continuous
	10 A to 15 A, 7 min. on/3 min. off
	15A to 20 A, 5 min. on/5 min. off

1.3.3 Power Measurement

Range	0 to 2400 watts
Accuracy	±(5 % reading + 5W)

1.3.4 Resistance Measurement

Modes	Four-terminal, fully isolated
Test Current	1A pulsed, 0.2A rms
Range	0.000 to 2.000
Accuracy	±(1 % of reading + 0.015)

1.3.5 Leakage Current Measurement

Modes	AC+DC (True-rms)
	AC only
	DC only
Patient Load Selection	IEC 60601
	AAMI ES1-1993
Crest factor	<=3
Ranges	0.0 to 199.9 µA
	200 to 1,999 µA
	2,000 to 19,999 µA
Accuracy	
DC to 1 kHz	±(1 % of reading + 1 µA)
1 to 100 kHz	±(2 % of reading + 1 µA)
100 kHz to 1 MHz	±(5 % of reading + 1 µA)
Isolation test voltage	100 % ±5 % of AC supply

1.3.6 ECG Simulator

Output	
Amplitude	1 mV QRS into Lead II
Impedance	500 ohms
Accuracy	
Frequency	±1 %
Amplitude	±2 %
Waveforms	
ECG Complex	30, 60, 120, 180, 240 and 300 BPM
Square wave	0.125 Hz, 2 Hz and 1 kHz
Pulse wave	63 msec, 30PPM and 60PPM
Triangle wave	2 Hz
Sine wave	0.5, 10, 40, 50, 60 and 100 Hz
CMRR tests	SQR 2Hz & 1 kHz, PUL 4 sec, SIN 0.5, 50 & 60Hz
Arryhthmias	VFIB, AFIB, SVT, VTACH, PVC and ASYS

1.4 Measurement Terminals

1.4.1 Test Receptacle

Category	CAT II
Maximum Voltage	
North America	132 VAC
Europe/Asia	264 VAC
Maximum Current	
North America	15A AC
Europe/Asia	13A AC

1.4.2 Current Source Terminals (SRC+/-)

Category	CAT I
Maximum Voltage	6V
Maximum Current	200 mA RMS

1.4.3 Meter Input Terminals (EXT+/-)

Category	CAT I
Maximum Voltage	
External µA/mV mode	20V
External voltage mode	300V
Maximum Current	0.2 mA @ 300V

1.4.4 ECG Terminals (APx)

Category	CAT I
Maximum Voltage	264 VAC (Isolation Test)
Maximum Current	14mA AC @ 264 VAC

Connect measurement terminals **ONLY** as instructed in this manual.
See Chapter 4, Operation

1.5 User Interface

Display.....	10.1" colour LCD (1280 x 800)
User Controls.....	Capacitive touchscreen
Wired Connectivity.....	Micro USB 2.0 Type B USB 2.0 Type A XBUS Interface (RJ11-6)
Wireless Connectivity.....	802.11 b/g/n Bluetooth 2.1+ EDR
Memory, Internal.....	16GB Maximum †
Memory, Expansion.....	16GB to 32GB Micro SD Card (optional)
Modes of Operation.....	Manual (standard) Automatic (accessory option)

†16 GB is the maximum amount of internal memory installed in the tablet. The internal memory is formatted similar to a hard disk to facilitate storage and access to data including the Operating System, Programs, and Data. The formatting process reduces that amount of storage available for use by the tablet. Additionally, the Operating System can consume up to 4 GB of storage. The nominal internal storage available for users is approximately 12 GB as shipped from Datrend.

If additional storage is required, an SD card can be installed in the tablet. Upon initial installation of an SD card, check for proper operation and that the correct size is reported. It may be necessary to format your SD card. If so, ensure that the card is formatted for the FAT32 file system, and that the long format mode is used (do NOT use "quick format").

Equipment Technical Specifications

1.6 Electrical Ratings

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

1.7 Externally-Accessible Fuses

20A / 250V AGC

1.8 Environment for Use

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

1.9 Dimensions

Base unit..... 11.8 x 8.9 x 3.3 in. (30 x 23 x 8.4 cm)
Tablet PC (detachable)..... 10.5 x 6.7 x 0.5 in. (27 x 17 x 1.3 cm)

1.10 Weight

5.5 lb (2.5kg)

1.11 Standard Accessories

vPad Kelvin Cable.....	P/N 3140-475
vPad Tablet USB Cable.....	P/N 3140-478
vPad Tablet DC Cable.....	P/N 3140-476 (12V) or -477 (5V), depending on tablet model
Power Cord (country specific)	
North America 15A.....	P/N 3000-009
North America 20A.....	P/N 3000-010
Continental Europe.....	P/N 3000-011
United Kingdom.....	P/N 3000-012
Australia.....	P/N 3000-018

1.12 Optional Accessories

For a complete list of available accessories, visit www.datrend.com or contact Datrend Customer Service (see Chapter 5 for contact details)

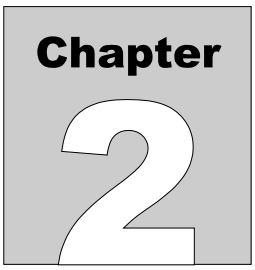
1.13 Compliance With Standards

vPad-353 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

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).



2 Overview

vPad-A3™ is an application (App) which adds automation capabilities to the vPad-353™, a manually-operated electrical safety analyzer providing basic electrical safety testing of medical devices with patient leads. This chapter provides an overview of vPad-A3 features and test modes. This manual assumes the reader has a good understanding of electrical safety principles, and is knowledgeable in the operation of the vPad-353™ Electrical Safety Analyzer.

2.1 Features

2.1.1 Automation Autosequences

The vPad-353 safety analyzer is comprised of an Android™-powered tablet which provides the user interface, and a Base Unit which provides the analyzer instrumentation. vPad-A3 is an accessory App for vPad-353 that adds a basic level of automation to the manual safety analyzer through ***AutoSequences***.

An "AutoSequence" is a user-configurable test template which causes the analyzer to execute a sequence of electrical safety measurements, where each measurement value in the sequence is automatically recorded and may also be compared to a pass/fail acceptance limit. Advantages of AutoSequences are:

- Reduced testing time
- Reduced human error (e.g., forgot to perform a particular measurement; "passed" a measured value when it should have been a "fail"; etc)
- Objective assessment of equipment performance (pass/fail limits are quantitative)
- Increased labour efficiency (technician can do something else while instrument is running a test)
- Automated data recording (Test Record files provide documented evidence that equipment was tested and was found acceptable)

AutoSequences are stored as data files on the tablet. The files are numbered in the order in which they are created, and in addition to the test settings each file will contain both a Title and a Description. Although the Title can have unlimited length, it is generally limited to a few words that summarize the test application. The Description is intended to provide a detailed explanation of the test, and although it can also have unlimited length the Description is generally limited to 2 or 3 lines for ease of reading.

There can be a virtually unlimited number of AutoSequence files stored on the tablet. Existing AutoSequence files can be edited with vPad-AS, or new AutoSequences can be created by editing an existing file and saving the AutoSequence under a new name/number.

2.1.2 Test Instructions

One of the features of vPad-A3 is the ability to present detailed instructions to the user during a test. These instructions can explain how a test is to be performed, how the equipment should be set up, cautions that should be observed during test, and other details of the test that may be relevant. Instructions can combine text with drawings, photographs or video. An Instruction file which is relevant to the device under test may be selected for inclusion in an AutoSequence. If suitable instructions do not exist for the device under test, vPad-A3 enables the user to edit an existing Instruction file or create a new one. Similar to AutoSequence data files, there can be a virtually unlimited number of Instruction files stored on the tablet.

2.1.3 Equipment Inspection

vPad-A3 also provides an option for including an equipment inspection as part of the AutoSequence. In the manual safety analyzer, vPad-E353, the test inspection is a generic 25-point inspection based on the ECRI procedure 438-20081015-01. vPad-A3 expands this capability to include up to 50 steps, with each step fully editable by the user to meet the specific requirements of the device under test. Equipment Inspection files can be saved and re-used in multiple sequences. Similar to AutoSequence data files, there can be a virtually unlimited number of Equipment Inspection files stored on the tablet.

2.1.4 Test Parameters

vPad-A3 provides a test template which lays out all of the electrical safety parameters which can be tested, and allows the user to simply check each parameter which is to be included in the autosequence. The template provides a quick and easy method to see what has been included or excluded from a sequence. Section 2.2 provides an overview of the electrical safety tests specified in the IEC62353 standard.

2.2 IEC62353 Standard

vPad-A3 may be used to automate electrical safety tests of medical devices with patient leads, following the IEC62353 standard. TABLE 2.3-1 relates test nomenclature displayed by vPad-A3 to nomenclature of IEC60601 and IEC62353 standards. TABLE 2.3-2 defines additional terms which pertain in general to electrical safety testing of medical equipment.

TABLE 2.2-1: Safety Test Nomenclature

vPad-A3	IEC60601-1	IEC62353
Mains voltage Hot (L1) Neutral (L2) Protective earth (PE)	Mains voltage Line 1 (L1) Line 2 (L2) Protective earth (PE)	Mains voltage Line 1 (L1) Line 2 (L2) Protective earth (PE)
Protective earth resistance	Protective earth resistance	Protective earth resistance
Equipment leakage current		Equipment leakage current
	Touch current	
	Earth leakage current	
	Patient leakage current	
	Auxiliary leakage current	
Applied Parts Leakage	Mains-on-applied part (MAP) test	Applied Parts Leakage

TABLE 2.2-2: Safety Test Terminology

Term	Definition
EUT	Equipment Under Test
NC	Normal operating condition. AC supply to EUT has ground and neutral both normal (closed).
SFC	Single-Fault Condition. AC supply to EUT has ground *or* neutral disconnected (open).
AP	Applied Part(s). IEC term referring to patient / ECG leads of EUT
Type B	IEC applied part protection class, type "Body" (non-isolated)
Type BF	IEC applied part protection class, type "Body-Floating" (isolated)
Type CF	IEC applied part protection class, type "Cardiac-Floating" (isolated, rated for direct cardiac application)

Leakage current testing is performed by connecting a measuring device, or "***MD***", to the EUT chassis and/or patient leads. The vPad-353 safety analyzer incorporates the measuring device specified by the IEC62353 standard, which is shown in ***Figure 1***. The MD incorporates a low-pass filter between the 1k test resistance and millivoltmeter to compensate for an allowable increase in leakage limits with increasing frequency.

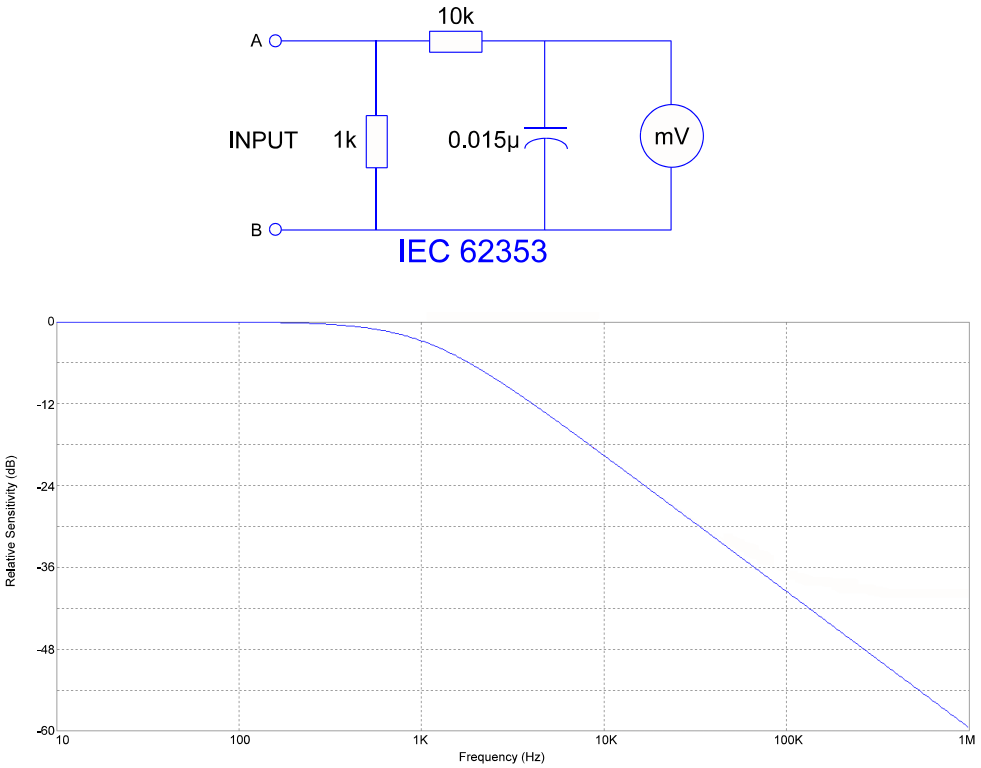


Figure 1 - *Measuring device (MD) for IEC 62353 standard.*

Chapter 3

3 Setup

The following instructions relate to the hardware platform used with the vPad-A3 automation App. Refer to the vPad-353 Operator Manual for any additional information required.

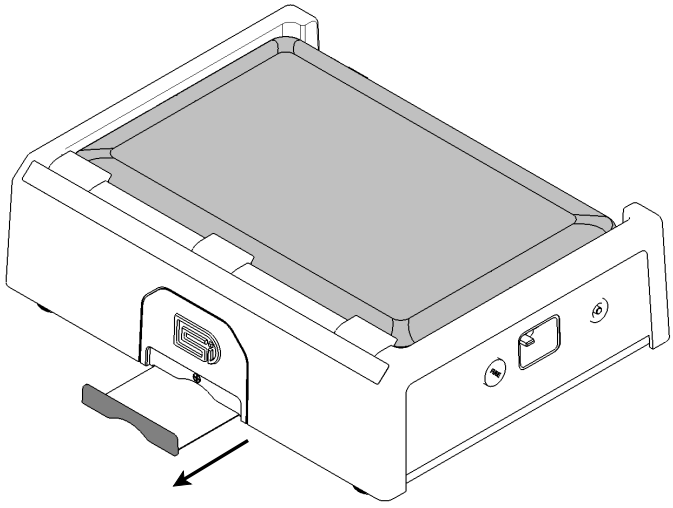


Figure 2

After placing the Analyzer Base Unit on a stable, flat surface, pull out the tablet tray on the front of the unit.

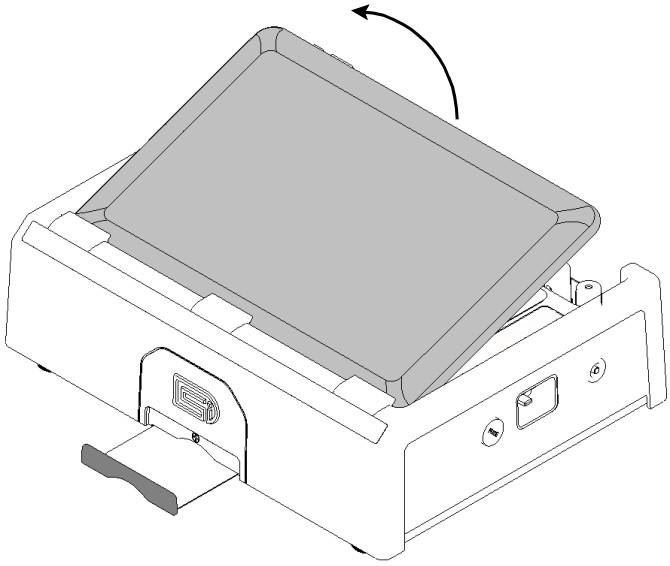


Figure 3

At the back of the Base Unit above the binding posts, grab the tablet and carefully lift it away from the unit.

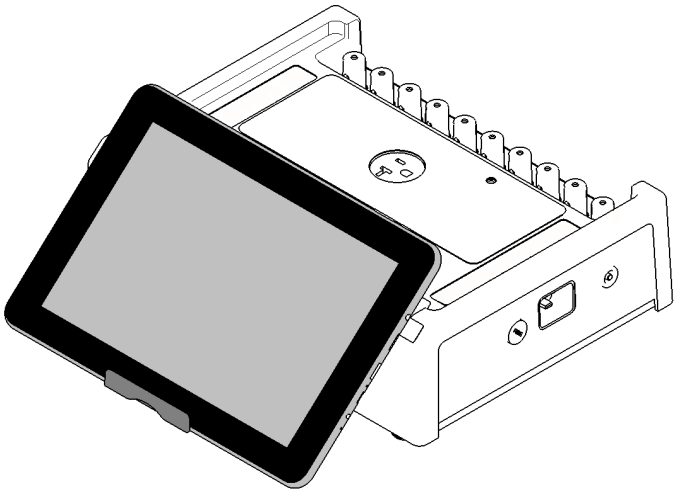


Figure 4

Place the bottom of the tablet on the tray and rest the rear of the tablet on the front of the base unit.

The tablet may also be held in place without the tray, using the inherent 'sticky' characteristics of the labels on the back of the tablet and the front of the base unit.

Connect the power cable from the TABLET DC jack of the Base Unit to the DC IN jack of the tablet. The cable provided with vPad-353 will depend on tablet model: 12V (P/N 3140-476) or 5V (P/N 3140-477).

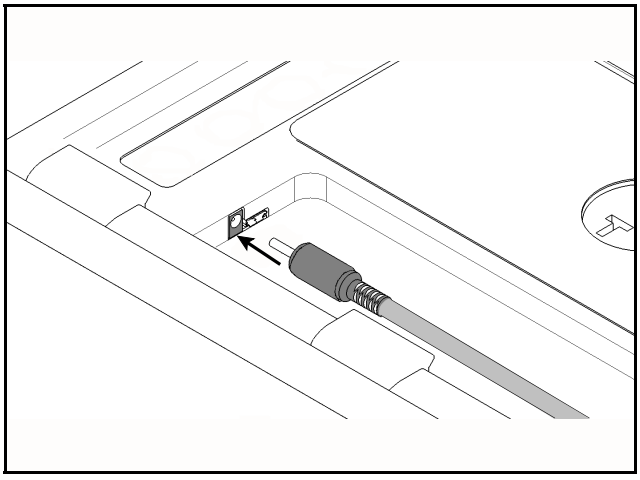


Figure 5

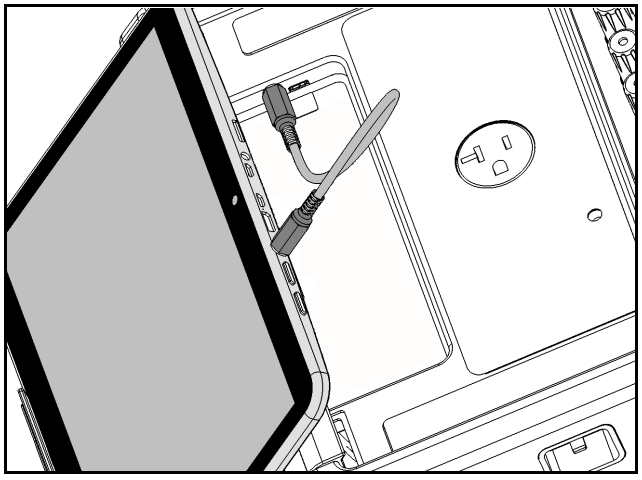


Figure 6

Connect the USB cable provided with vPad-353 (P/N 3140-478) from the TABLET USB jack of the Base Unit to the USB port of the tablet.

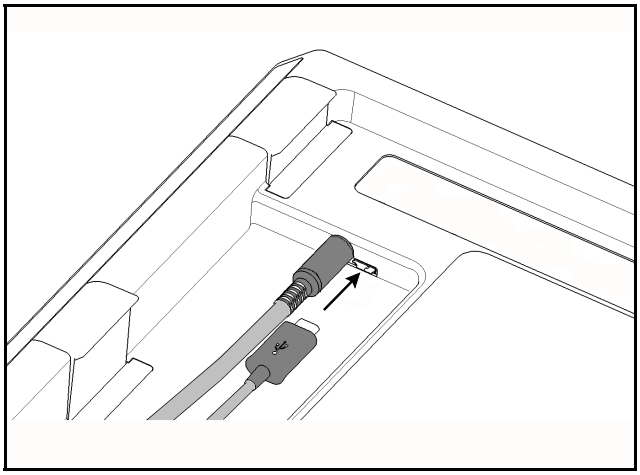


Figure 7

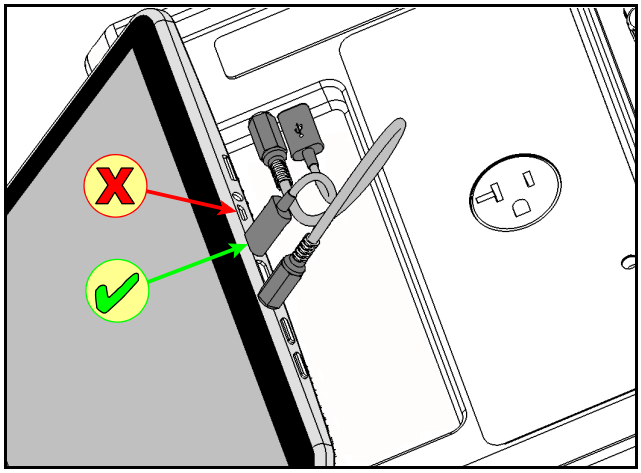


Figure 8

Connect the power cord provided with vPad-353 to the right side panel of the unit, then plug the cord into a power outlet (***Figure 9***). If the AC outlet has power, the indicator lamp on the left panel of the Analyzer Base Unit should now be lit (***Figure 10***).

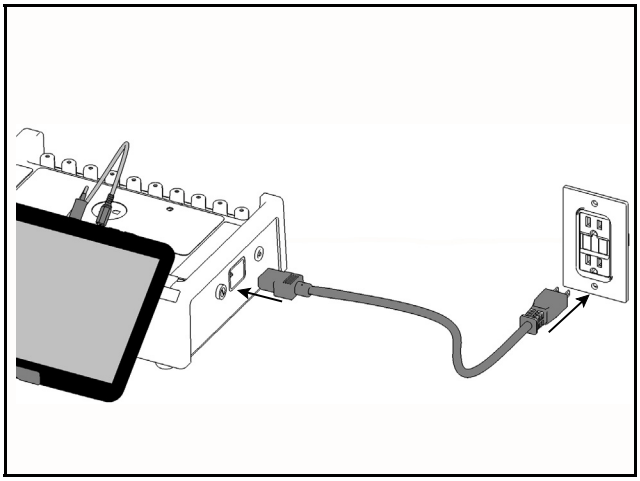


Figure 9

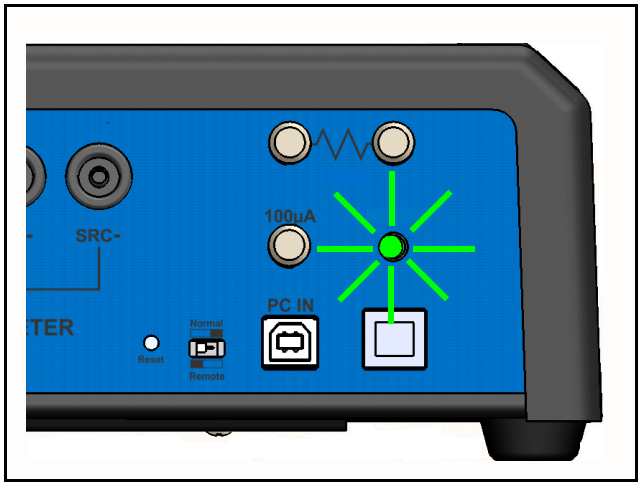


Figure 10

With the Base Unit now powered up, switch the tablet ON by pressing and holding the power button on the top of the tablet until the tablet is felt to vibrate (approx. 5 - 10 sec). Approximately 60 seconds after switching ON, the Android HOME screen should appear on the tablet.

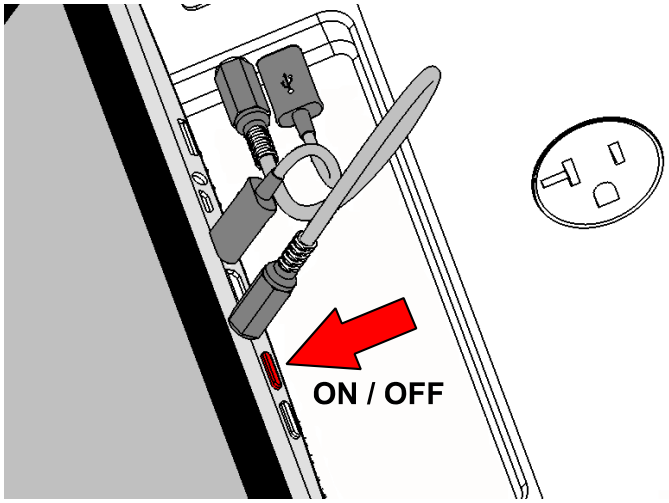


Figure 11

The foregoing instructions are for the standard tablet model. Alternative tablet models may have DC and USB connections and the Power button in different locations; one example is shown in ***Figure 12***. If necessary, refer to the tablet operator manual provided with vPad-353 for further guidance.

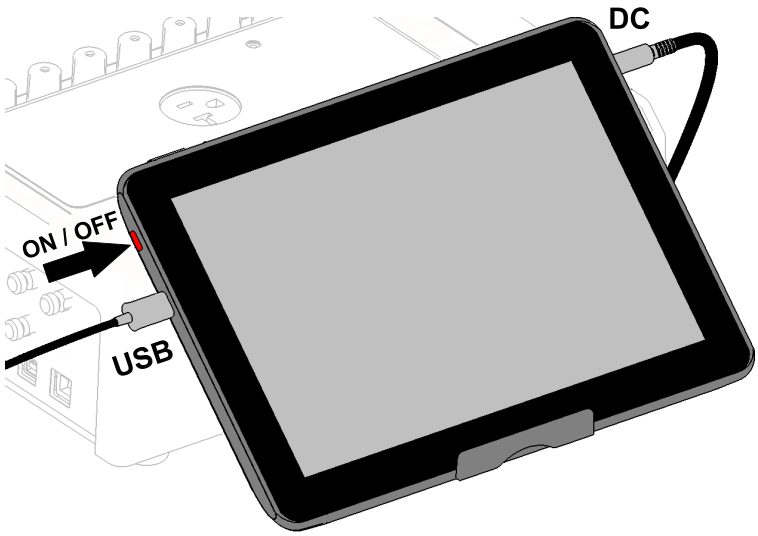


Figure 12

Switch the tablet OFF when vPad-353 is not in use. Press and hold the ON/OFF switch until a confirmation message appears on the tablet screen. Select the appropriate response to complete the Power Off sequence.

Note: Pressing and releasing the Power ON/OFF button momentarily will put the tablet in a 'sleep' mode. Press the ON/OFF button momentarily again to 'wake' the tablet. This is NOT the same as OFF, however it is a good method to extend the battery life if the tablet will be used again in the immediate future.

To store or transport vPad-353, reverse the setup procedure by starting at ***Figure 9*** and proceeding to ***Figure 2*** above.

Note: vPad may be operated wirelessly, via an optional Bluetooth connection between the tablet and the measurement platform. Consult Datrend for further information.

Chapter 4

4 Operation

This chapter explains how to use vPad-A3 to perform electrical safety tests and inspections of medical equipment, following a predefined sequence of steps referred to as an Autosequence. Test Record management is also covered in this chapter.

4.1 HOME Screen

The Android HOME screen (***Figure 13***) is displayed approximately 60 seconds after switching the tablet ON.

Figure 13 - *HOME screen.*

Initiate actions on the tablet by pressing the corresponding icon or button. For example:

Press to launch the vPad-A3 software application, or "***app***". Use this app to perform automated electrical safety testing.

Press to launch the vPad-353 software application, or "***app***". Use this app to perform manual electrical safety testing.

Press to launch the vPad Record Manager app. Use this app to copy, print, convert or delete Test Records saved by vPad-AS.

Press to access Settings. Use this menu to configure sound, display, touchscreen, and wireless setup.

⚠ By default, vPad-AS is supplied with both WiFi and Bluetooth connectivity ***disabled***. Use the Settings menu to enable wireless connectivity, in accordance with policies of your institution or organization.

At bottom middle or top right on the screen*, press this **Apps** icon to access more apps which are installed on the tablet.

On bottom task bar, middle or left on the screen*, press this **Home** icon to return from an app to the Home screen.

On bottom task bar, middle or left on the screen*, press this **Back** icon to navigate back one step, from the app or screen currently being displayed, to a previous one. For some apps, this button's function may be disabled.

On bottom task bar, middle or left on the screen*, press this **Recents** icon to jump from the current app to a different app that was started earlier, but is currently on pause

* Android operating system version dependent, subject to change without notice. For more information on how to use the Android tablet, refer to the tablet operator manual supplied with vPad-353.

4.2 Startup

Press the vPad-A3 icon,  ,on the Android Home screen to start the app. A splash screen will display the product name and the software version.

Figure 14 *- vPad-A3 startup screen.*

As the splash screen is displayed, the app will "connect" to the Analyzer Base Unit and cause it to perform a number of internal self-tests. The AC supply which powers vPad-353 Base Unit is also tested. Normally, all tests will complete successfully and the AutoSequence selection screen of the vPad-353 App will then be displayed.

Faults in the Base Unit or the AC supply may be detected during the self-test, in which case an alarm message is displayed below the software version number. In the event of a Base Unit fault, the app will automatically exit to the Home screen. In the event of an AC supply fault, in addition to the alarm message the App will display an Alert Dialog, which you must then acknowledge by pressing "Continue", "Exit"or "OK" (see ***Figure 15***). Refer to TABLE 4.2-1 for recommended actions in the event of a startup alarm message.

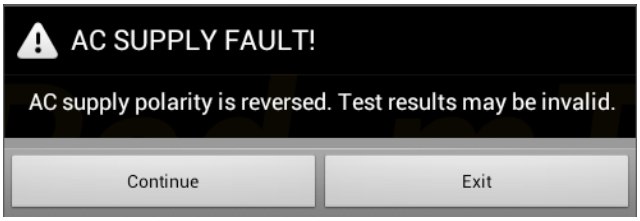


Figure 15 *- Alert Dialog: AC supply fault.*

TABLE 4.2-1: Startup Alarms and Corrective Actions

Alarm Message	Cause	Actions
USB COMM ALERT (safety analyzer not communicating)	App is unable to send messages to one or more instrument systems inside the Base Unit	• Check Base Unit has power (check power indicator, left panel - see ***Figure 10*** on page 15) • Check Base-to-tablet USB connection (see ***Figure 8*** on page 15) • If AC power and USB cables are OK, press and hold RESET button of ***Figure 10*** for 3 seconds, then press RETRY on error dialog • If error persists, contact Datrend Customer Service (see Chapter 5 for contact information)
BLUETOOTH ALERT: (safety analyzer not communicating)	App is unable to send messages to one or more instrument systems inside the Base Unit	• Check Base Unit has power (check power indicator, left panel - see ***Figure 10*** on page 15) • Check Bluetooth is enabled on tablet • If AC power and Bluetooth status are OK, press and hold RESET button of ***Figure 10*** for 3 seconds, then press RETRY on error dialog • If error persists, contact Datrend Customer Service (see Chapter 5 for contact information)
BLUETOOTH ALERT: (Bluetooth not available)	Another app is using the Bluetooth connection to Base Unit	• Quit other Datrend apps running on the tablet, then try restarting vPad-A3
AC SUPPLY FAULT (polarity reversed)	AC outlet incorrectly wired	• Do not use vPad-353 with incorrect or unsafe AC supply • Connect Base Unit to a different outlet
AC SUPPLY FAULT (ground disconnected)	AC outlet incorrectly wired	• Do not use vPad-353 with incorrect or unsafe AC supply • Connect Base Unit to a different outlet
AC SUPPLY FAULT (ground disconnected)	Isolated power system	• Do not perform leakage testing as results will be invalid • Optionally, vPad-353 may be used to perform tests other than leakage (e.g., voltage, resistance or ECG simulator tests) • If possible, change to grounded power outlet
RMS zero calibration failure	Unable to zero voltmeter	• Press RESET button of ***Figure 10*** for 3 seconds, then try restarting app • If problem persists, contact Datrend Customer Service (see Chapter 5 for contact information)

4.3 Test Selection

Following application start-up, vPad-A3 will display the AutoSequence selection screen:

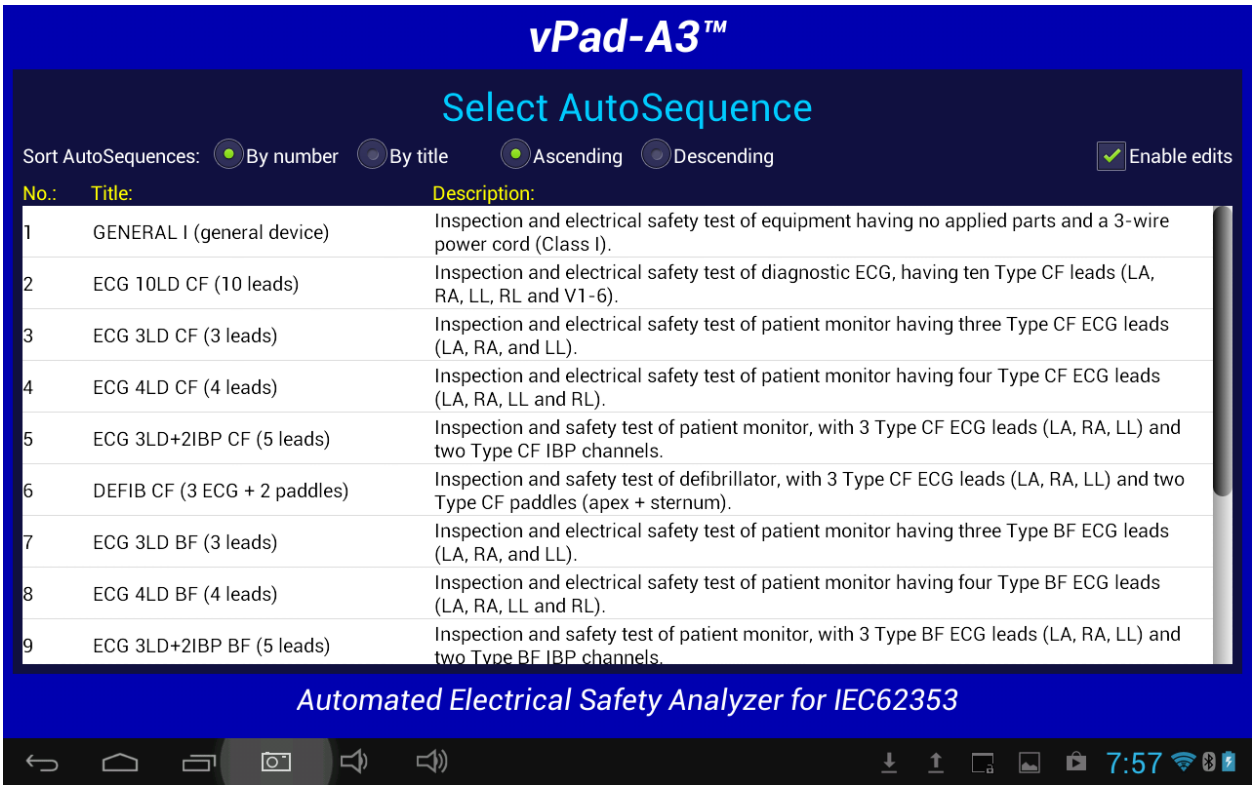


Figure 16 *- AutoSequence Selection Screen.*

When first delivered, vPad-A3 will have a number of sample AutoSequences pre-installed. Each AutoSequence has a title and a description. The Title will normally be reasonably short so that is easy to read. The Title should attempt to indicate the basic test it is intended to perform. The Description can expand on the Title to be much more descriptive of the test, describing differences between Titles that sound similar. The Description can be virtually any length, but generally, keeping the Description to two lines or less is a good idea for readability.

The list of AutoSequences can be sorted by number or by Title, and can be listed in ascending or descending order to assist in location the sequence of interest. Once the list has been created and you have started to use the sequences, it is a good idea not to delete or overwrite existing sequences as it may affect other users' expectations, or their use in other Apps (eg. vPad-Check).

There is a checkbox in the upper right of the display labelled Enable Edits. If checked, vPad-A3 will proceed to the AutoSequence Editor (section 4.4) when a sequence is selected. If not checked, the editor screen(s) will be skipped, and vPad-A3 will proceed directly to running the sequence steps. This setting affects all Apps which can call vPad-A3 (vPad-Check, vPad-mT and vPad-EQM).

4.4 AutoSequence Editing

After an AutoSequence has been selected from the list, the contents of the AutoSequence may be displayed (see ***Figure 17*** through ***Figure 29***), depending on the state of the Enable Edits checkbox in ***Figure 16***. This menu allows the user to review and optionally change the settings and then initiate the testing sequence via the "**Run Test**" button. If changes are made to the AutoSequence, they can be saved to the original file or to a new file. If changes are made but not saved, the changes will apply only to the current test.

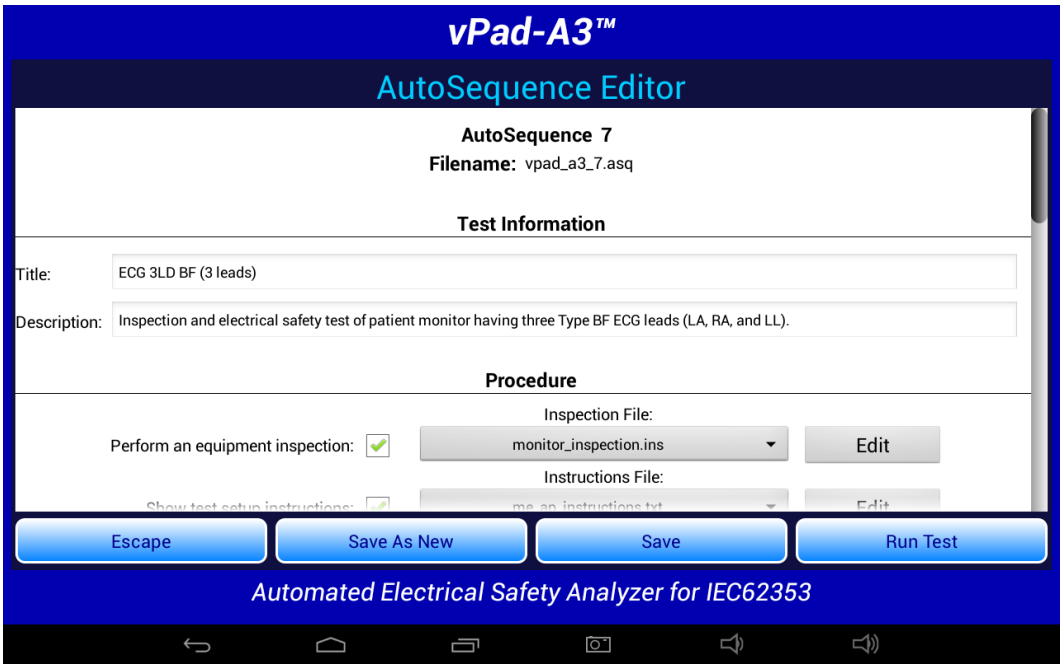


Figure 17

Users can verify all existing test setups with the AutoSequence Editor. This may be useful during the initial learning curve with vPad-A3 to confirm that the AutoSequence selected matches your expectations. It also initially allows the user to adjust settings of the factory-default AutoSequences to match the methods and procedures you normally follow.

The AutoSequence controls are placed within a Vertical ScrollView, allowing the AutoSequence to be viewed in sections. This is done by placing a finger on the screen and simply dragging the ScrollView up or down as required. CheckBoxes, Spinners and other controls will indicate the settings of the AutoSequence which has been selected.

The AutoSequence setup is divided into 5 sections: Test Information; Procedure; Sequencer Control; Voltage, Resistance and Load Tests; and Leakage Current Tests. These are explained in the following sections.

4.4.1 Test Information

The Test Information section of the AutoSequence allows input of a Title and a Description:

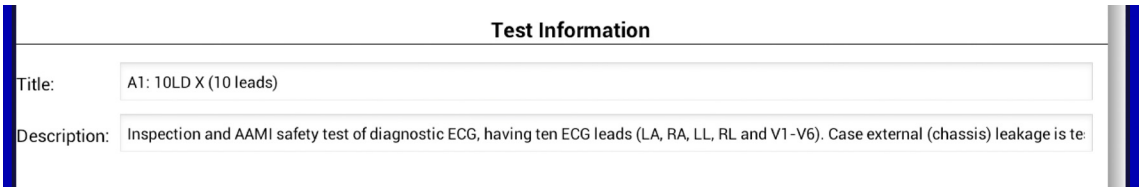


Figure 18

The key to easily finding the AutoSequence you need is to keep the title as short as possible. In the above example, the name of the "A1" autosequence from the legacy medTester system has been used. A1 signifies the link to the medTester and "10LD X" signifies a 10 lead device under test. "X" indicates an external case leakage test. Although a little cryptic, it is short and relatively easy to remember. The Description field provides lots of space to expand upon the meaning of the cryptic title, and can be of any length, although it is recommended to keep it to 2 - 3 lines at most.

4.4.2 Procedure Settings

The Procedure section of the AutoSequence provides settings for performing an inspection, displaying instructions, running a ECG waveform sequence and displaying results at the end of the test.

4.4.2.1 Equipment Inspection

An equipment inspection can be defined in an Inspection File. This is a text file comprised of up to 50 lines, each no longer than 40 characters. The first line is the inspection title, and each additional line is a step in the inspection. The original, fixed Equipment Inspection included with the manual analyzer, vPad-ES, is based on the ECRI *General Devices Acceptance Procedure* (no. 438-20081015-01). With vPad-AS, an inspection file can be tailored for a specific device type, and instructions can be placed in any order.

If **'Perform an equipment inspection'** of the AutoSequence is 'checked', the Equipment Inspection, as defined by a filename shown in the adjacent dropdown selection box, will be performed as part of the AutoSequence.

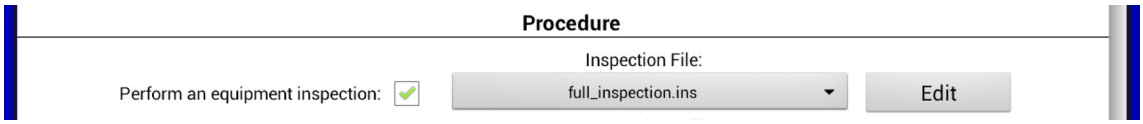


Figure 19

If the file shown is not correct for the device under test, a different file can be selected from the dropdown list, or the current file can be edited by pressing the **'Edit'** button. This displays the Inspection Editor.

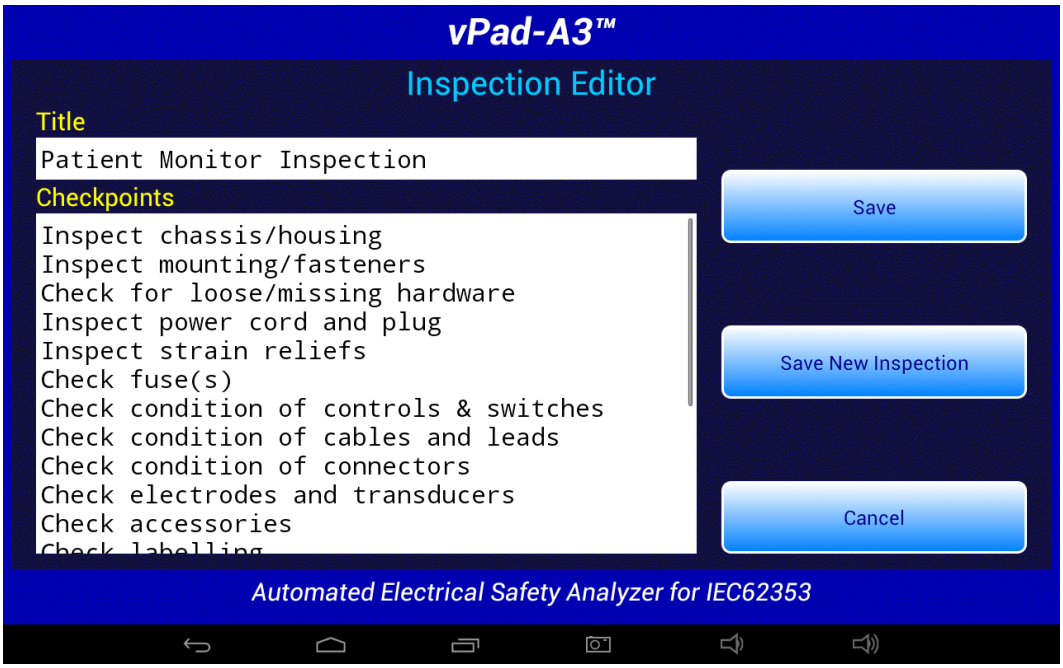


Figure 20

Inspection files have a file format: "Inspection Title", "Task1", "Task2","etc.", ...; with as many as 50 individual tasks. Tasks should be of the form "Do this....", with keywords indicating what to 'do'; such as 'Inspect...', 'Check....', 'Test....', etc. The user will be able to respond to the task with a 'Done' and 'OK' indication, and an optional 'Comment'. The comment can be used for general test explanations or for input of values, such as a battery voltage.

Here is an example, which is called "**default_inspection.ins**":

Inspection of General Equipment	*(Inspection Title)*
Inspect chassis/housing	*(Task #1)*
Check for loose/missing hardware	*(Task #2)*
Inspect power cord and plug	*(Task #3)*
Inspect strain reliefs	*(Task #4)*
Check fuses or circuit breaker	*(Task #5)*
Test controls and switches	*(Task #6)*
Check battery	*(Task #7)*
Test battery charger	*(Task #8)*
Test indicators and displays	*(Task #9)*
Test audible signals	*(Task #10)*
Inspect accessories	*(Task #11)*

The lower text window has cut/copy/paste functions enabled, allowing this window to act as a simple text editor:

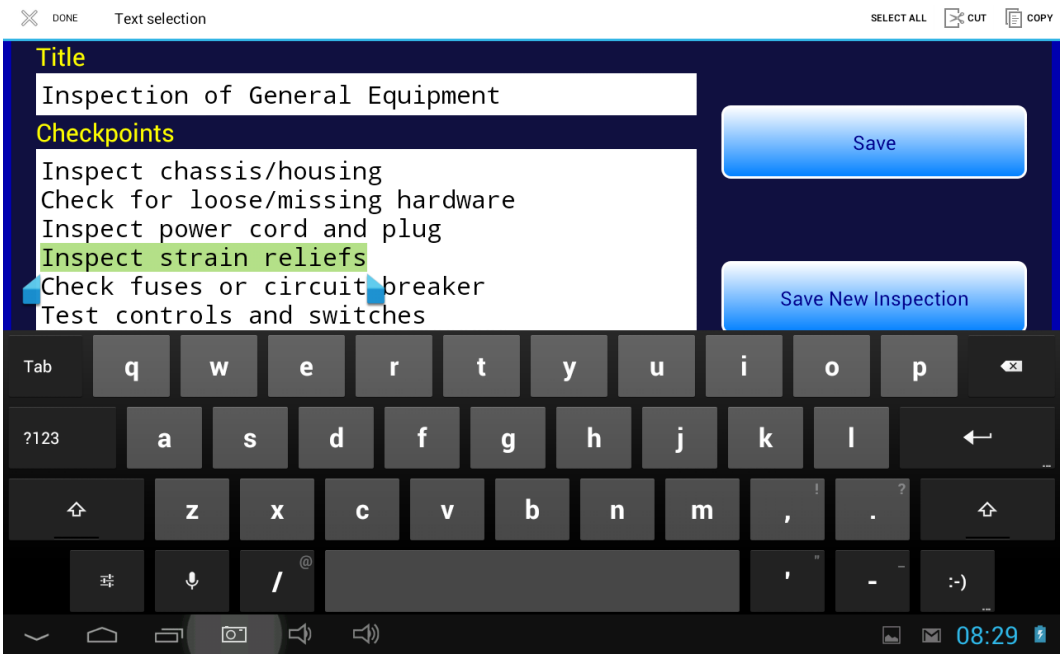


Figure 21

To select text, touch and hold a word until it is highlighted and pointer bars are enabled at the end of the selected word. Move the pointer bars using a touch and drag motion to surround the total text to be selected. Use the icons on the top menu bar to complete the desired action.

Buttons on the right of the Inspection Editor have these functions:

Cancel This button quits the editor and returns to the AutoSequence screen, without updating the **`*.ins`** file.

Save Pressing this button causes an Alert Dialog to be displayed. If the user presses "**No**" on the Dialog, the file is not saved. If "**Yes**" is pressed, the current contents of the screen are saved to the existing file. The activity is finished and display returns to the AutoSequence screen.

Figure 22

Save New Inspection Pressing this button causes a dialog box to be displayed which prompts the user to input an alternative name for the **`*.ins`** file. The "**Cancel**" button on this small dialog aborts the save operation. The "**Save**" button saves the inspection contents to the new file.

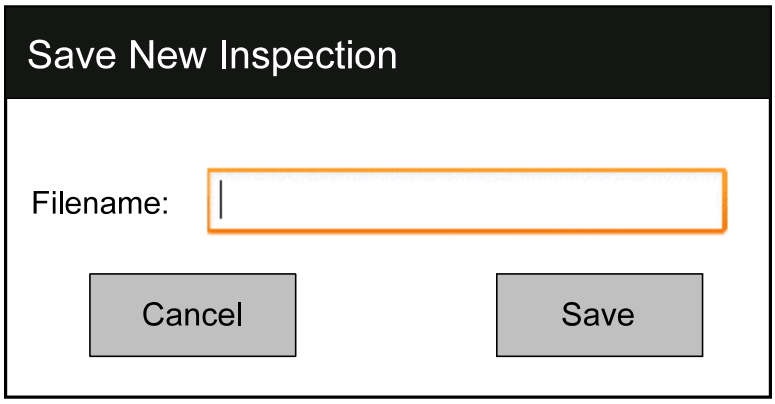


Figure 23

Although the Inspection Editor may be used to modify or create inspections files as described above, **`*.ins`** files are simple text files that can also be viewed or edited with any text editor, for example, Jota. The files are located in the Datrend/vPad-ES/Inspections folder of the tablet. If using a text editor to modify a **`*.ins`** file, be sure to follow the file format as described in this section (title first, followed by up to 50 tasks; title and tasks not exceeding 40 characters in length).

4.4.2.2 Test Setup Instructions

If **'Show test setup instructions'** of the AutoSequence is 'checked', the Instructions File, as defined by the filename shown in the adjacent dropdown selection box, will be performed as part of the AutoSequence.

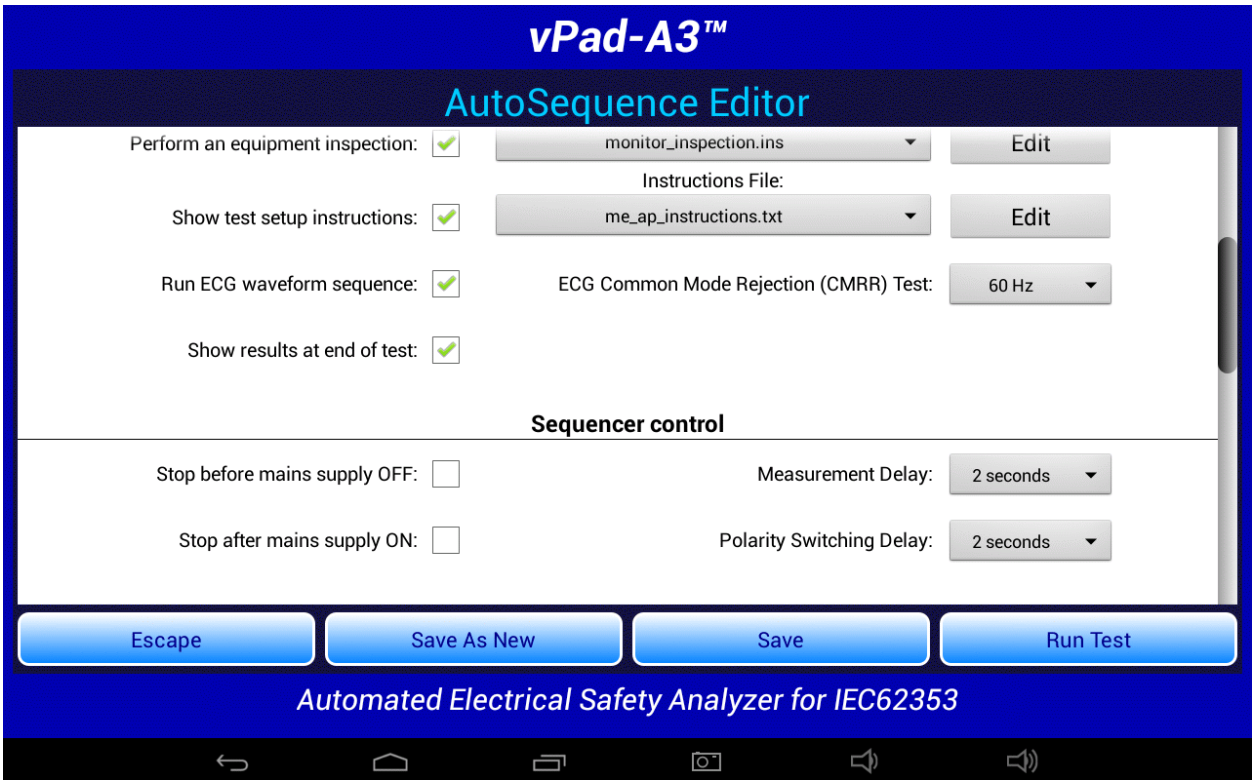


Figure 24

If the filename shown is not correct for the device under test, a different file can be selected from the dropdown list, or the current file can be edited by pressing the **'Edit'** button. This will display the Instruction Editor.

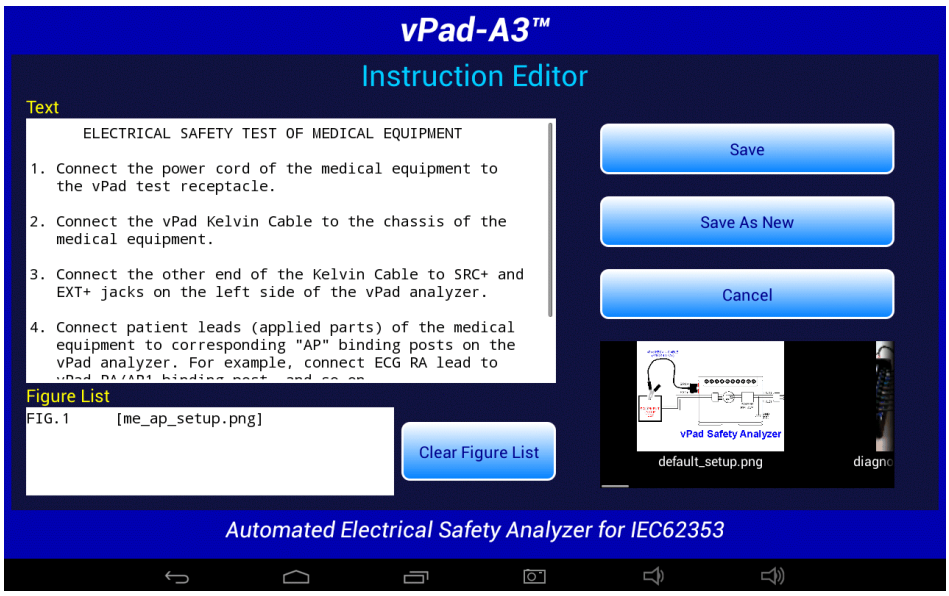


Figure 25

A set of test instructions can be defined in an Instructions file which can be tailored for a specific device type. As shown above, an Instructions file contains descriptive text with optional embedded references to "figures", which are, in fact, filenames of JPG or PNG files. These filenames are included in the Instructions file, surrounded by '[' and ']' characters.

The Instruction Editor consists of a multi-line text box on the upper left where the descriptive text is displayed. Editing functions (cut/copy/paste) of the upper text box are enabled, allowing this window to act as a simple text editor. At the lower left, a list box displays the names of image files which have been embedded in the instructions.

The contents of the lower list may be cleared via the "**Clear Figure List**" button. New figures can then be placed in the list by selecting them from the horizontally-sliding Gallery of thumbnail images on the right. Note the filename of each Gallery image is located underneath its corresponding thumbnail, allowing the user to confirm that the correct file has been selected and appears in the list on the left. Image and Instruction files are located in the Datrend/vPad-353/Instructions folder.

Buttons on the right of the Instruction Editor have these functions:

Cancel	This button quits the editor and returns, without updating the Instructions file.
Save	Pressing this button causes an Alert Dialog to be displayed (see below). If the user presses "**No**" on the Dialog, the file is not saved. If "**Yes**" is pressed, the current contents of the editing screen are saved to the current Instructions file, followed by images (JPG or PNG files, if any).

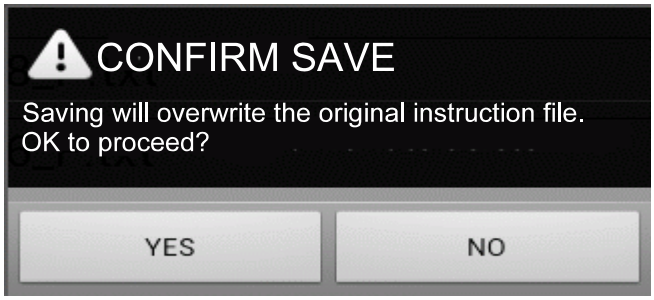


Figure 26

Save As New This button activates a dialog box which prompts the user to input a new name for the Instructions file (see below). The "**Cancel**" button on this screen aborts the save operation. The "**Save**" button saves the edited contents on the screen to a new Instructions file.

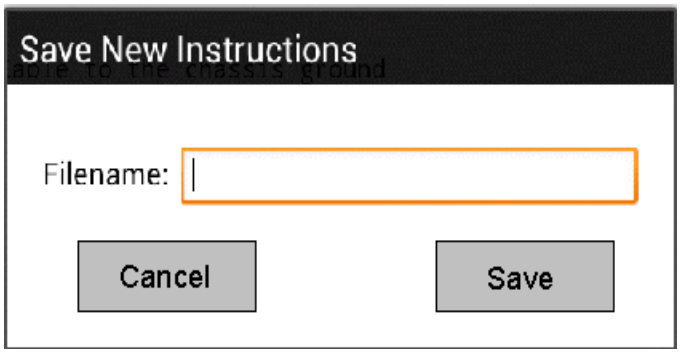


Figure 27

Although the Instructions Editor may be used to modify or create Instructions files as described above, these file are simple **`*.txt`** files that can also be viewed or edited with any text editor, for example, Jota. The files are located in the Datrend/vPad-353/Instructions folder of the tablet. If using a text editor to modify an Instructions file, be sure to follow the file format as described in this section.

4.4.2.3 ECG Waveform Sequence

If **'Run ECG waveform sequence'** of the AutoSequence is 'checked', vPad-A3 will step through each of the waveforms listed below in TABLE 4.4-1. As the ECG waveform is displayed, the user will have an opportunity to Pass, Fail or Skip the waveform. vPad-A3 does not allow you to change the number of steps or the waveforms in the sequence, however, other automation Apps such as vPad-Check will enable you create customized ECG waveform sequences having any number of steps if this should be necessary.

If it is desired to do a Common Mode Rejection test, the AutoSequence provides a pop-up list for selecting a test frequency of 50 or 60 Hz. Selecting 'None' will disable the test.

TABLE 4.4-1: ECG Waveform Sequence

Step	Simulator Waveform Description	vPad-ES Name
1	Square wave, 2 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SQR 2Hz
2	'DC' Pulse, +1 mV for 4 seconds, 0 mV for 4 seconds	PUL 4sec
3	Sine wave, 10 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 10Hz
4	Sine wave, 40 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 40Hz
5	Sine wave, either 50 Hz or 60 Hz (per CMRR test setting), 1 mV p-p (-0.5 to +0.5 mV)	SIN 50 or 60Hz
6	Sine wave, 100 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 100Hz
7	Square wave, 1 kHz, 1 mV p-p (-0.5 to +0.5 mV)	SQR 1KHz
8	Triangle wave, 2 Hz, 1 mV p-p (-0.5 to +0.5 mV)	TRI 2Hz
9	ECG normal sinus rhythm, 60 beats/minute, 1 mV QRS	60 BPM
10	ECG normal sinus rhythm, 30 beats/minute, 1 mV QRS	30 BPM
11	ECG normal sinus rhythm, 120 beats/minute, 1 mV QRS	120 BPM
12	ECG normal sinus rhythm, 240 beats/minute, 1 mV QRS	240 BPM
13	Common Mode Rejection Ratio Test, 50 or 60 Hz (10 mV)	CMRR 50 or 60

4.4.2.4 Show Results at End of Test

If **'Show results at end of test'** of the AutoSequence is 'checked', results acquired during the test will be displayed at the end of the sequence, allowing the user to review and ensure they are complete and accurate, and possibly consider if a final comment should be added to the test record to explain any unusual results.

4.4.3 Sequencer Control

The Sequencer Control settings of the AutoSequence define test conditions of the AC input to the Equipment Under Test (EUT).

4.4.3.1 Stop Before AC Supply OFF

At different points during an electrical safety test, it is necessary to turn the AC power OFF. In some instances it may be detrimental to the equipment to do this without performing some additional action. For instance, if the EUT has an internal personal computer, it may require an orderly shutdown in order to prevent corruption of memory. Stopping to allow the user to follow the correct shutdown procedure is possible when this option is enabled.

4.4.3.2 Stop After AC Supply ON

At different points during an electrical safety test, it is necessary to turn the AC power ON. In some instances, it may be necessary to re-boot the EUT; in others, the ON switch may be a 'soft' key which electronically powers the EUT ON; or in others, it may take some time to get up to operating speed. If this option is enabled, it is possible to allow the EUT to reach operational condition before proceeding.

4.4.3.3 Measurement Delay

The 'measurement delay' setting is the length of time a measurement will be displayed before proceeding to the next measurement. The default setting will be 2 seconds, however this may be extended up to 5 seconds if additional time is deemed useful.

4.4.3.4 Polarity Switching Delay

The 'polarity switching delay' is the length of time between the 'last' measurement in one polarity before switching to the alternate polarity. This can reduce the strain on systems with motors or large inductive loads. The default setting will be 2 seconds, however this may be extended up to 8 seconds if additional time is deemed useful.

4.4.4 Voltage, Resistance and Load Tests

In this section of the AutoSequence setup, the user can define which of the voltage, resistance and load measurements will be enabled for this sequence.

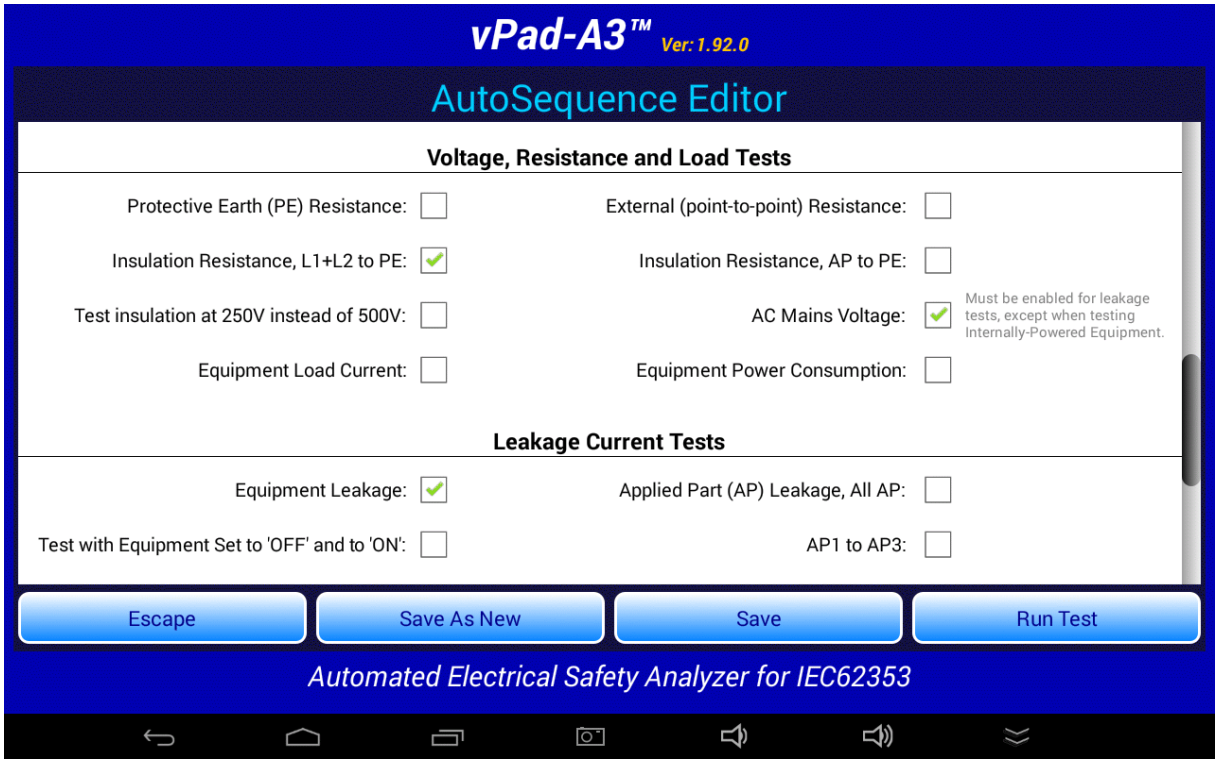


Figure 28

4.4.4.1 Protective Earth Resistance

This selection will enable testing the Protective Earth (Line Cord) resistance, and compare the measured value against the Resistance Limit from the standard (0.300 ohms). During the actual test, multiple readings can be taken.

4.4.4.2 External (point-to-point) Resistance

Where necessary, point-to-point resistance measurements can be enabled. During the actual test, multiple readings can be taken.

4.4.4.3 Insulation Resistance, L1+L2 to PE

In this measurement, the resistance between the transformer primary winding (with L1 and L2 connected together) and PE is measured by applying a DC voltage and measuring the current that flows. The DC voltage can be 250 or 500 volts, as defined later.

4.4.4.4 Insulation Resistance, AP to PE

In this measurement, the resistance between the Applied Parts (with all AP connected together) and PE is measured by applying a DC voltage and measuring the current that flows. The DC voltage can be 250 or 500 volts, as defined later.

4.4.4.5 Test Insulation at 250V Instead of 500V

This sets DC test voltage for insulation resistance to 250 or 500 volts. The default setting is 500V, but can be reduced to 250V by checking this selection.

4.4.4.6 AC Mains Voltage

This setting enables measurement of the three AC mains voltages (L1-L2; L1-PE and L2-PE). The mains voltage test will be automatically enabled by the App if any leakage current test has been enabled in the AutoSequence setup.

During a test, vPad-A3 will analyze the measured mains voltages and will warn of any AC supply fault that may potentially invalidate subsequent measurement of leakage currents. See ***Figure 15*** on page 21 for an example of an AC supply fault Alert Dialog. If users choose to proceed with leakage measurements despite a reverse polarity fault, the App will configure the test receptacle so that test conditions (Normal or Reverse Polarity) are reported correctly.

4.4.4.7 Equipment Load Current

This setting enables measurement of the current drawn from the AC supply by the EUT. Although not a requirement of any standard, it is good practice to measure load current as the value can be used to indicate equipment performance or warn of pending malfunction.

4.4.4.8 Equipment Power Consumption

This setting enables measurement of power (watts) taken from the AC supply by the EUT. It can be considered an alternative to load current measurement and may be useful for monitoring higher-powered equipment.

4.4.5 Leakage Current Tests

There are a large number of leakage current testing options as shown in ***Figure 29***. Tests are enabled by checking the associated box, and measurements are evaluated against the limits set by the IEC62353 standard.

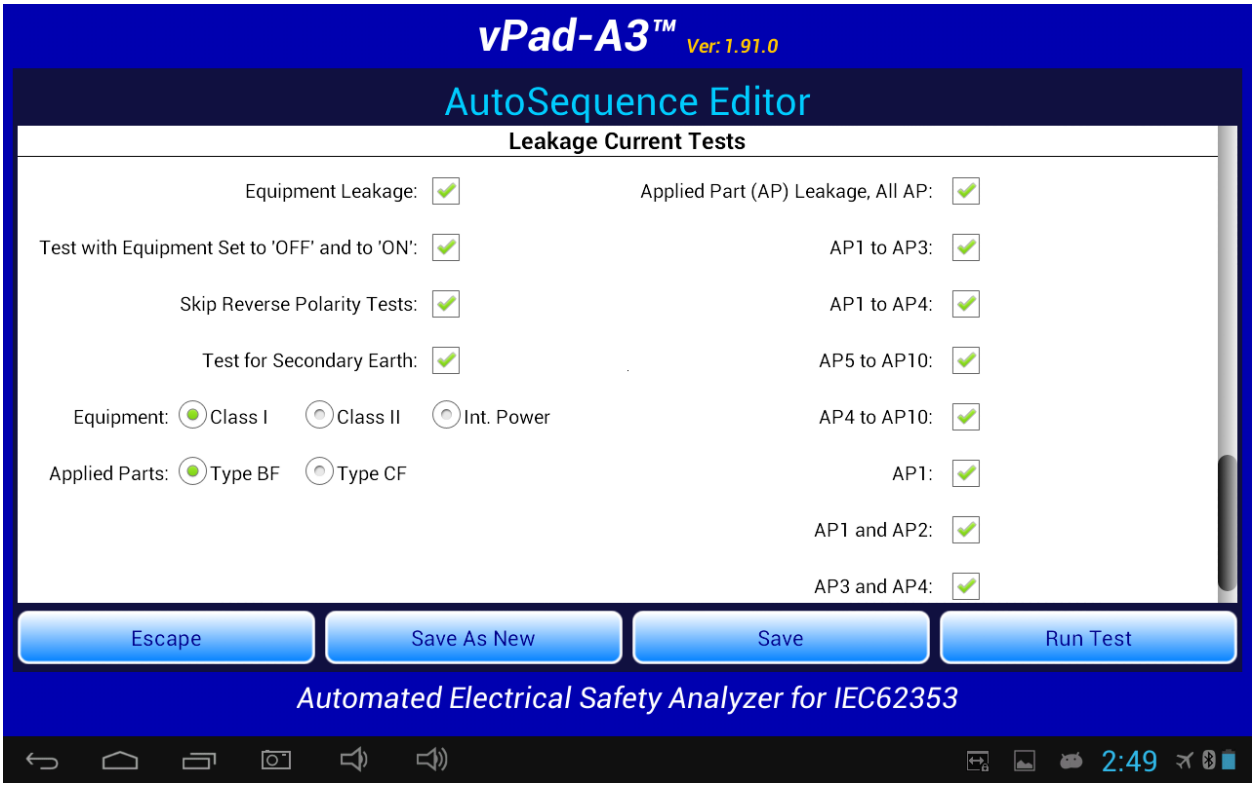


Figure 29

4.4.5.1 Equipment Leakage

Select this option to perform the Equipment Leakage test as defined in the Standard.

4.4.5.2 Equipment ON and OFF

If **'Test with equipment set to 'OFF' and 'ON': '** is 'checked', the leakage current tests will be performed with the EUT turned OFF, and then the user will be prompted the turn the EUT ON.

4.4.5.3 Skip Reverse Polarity Tests

Select this option to skip all leakage measurements that reverse the polarity of the test receptacle.

4.4.5.4 Test for Secondary Earth

Select this option to perform a test for Secondary Earth after the initial Equipment Leakage test. Secondary Earth is an error condition that results in artificially low leakage measurements, specifically when leakage currents bypass the measuring device (***MD***) through alternative pathways to earth ground. It is often caused by erroneous connections in the physical test setup.

The Secondary Earth test is only available for Class I (protectively earthed) devices with **'Equipment Leakage: '** enabled. If the test detects a Secondary Earth, the AutoSequence will pause and display an Alert Dialog so that users can correct the test setup. Choosing "Retry" from the Alert Dialog will repeat both the Equipment Leakage test and the Secondary Earth test. Choosing "Abort" will immediately halt execution of the AutoSequence.

4.4.5.5 Equipment Type

The user can select the type of equipment that is being tested: Class I (protectively earthed); Class II (double-insulated); or, Internally Powered (battery operation). This will affect limits for some measurements, per the standard.

4.4.5.6 Applied Parts Type

The user can select the type of Applied Parts that are on the EUT: BF (Body Floating); or, CF(Cardiac Floating). The leakage current limits will be based on this setting.

4.4.5.7 Applied Parts Selections

Different applied parts (leads) or combinations of applied parts can be selected on the right hand column.

4.4.6 Saving the AutoSequence

If changes have been made to the AutoSequence, the modified setup can be saved to the original file or to a new file. Press the '**Save**' button to overwrite the existing file so the modified setup is available for future use.

If an AutoSequence has been used historically, however, it is best not to modify it arbitrarily since it may become difficult to determine exactly how equipment was tested in 'older' records.

The '**Save As New**' button allows you to save the displayed AutoSequence to a new file. The new AutoSequence will be assigned the next number after the last sequence in the AutoSequence Selector list. This is the preferred way to save a modified test setup. The large memory of the tablet provides virtually unlimited storage for AutoSequence files, allowing you to create and save as many as you like. Note that if saving as '**New**', you should update Title and Description accordingly to reflect the changes you have made.

If you want a modified setup to be temporary, for this test only, do not save the edits, simply '**Run**' the test. The edited values will be used in this test only, and will not be available again without re-entering them.

4.5 Running a Test

To initiate a test sequence from the AutoSequence Editor menu, press the '**Run Test**' button.

The first screen shown is for entering information about the equipment. This screen will always appear.

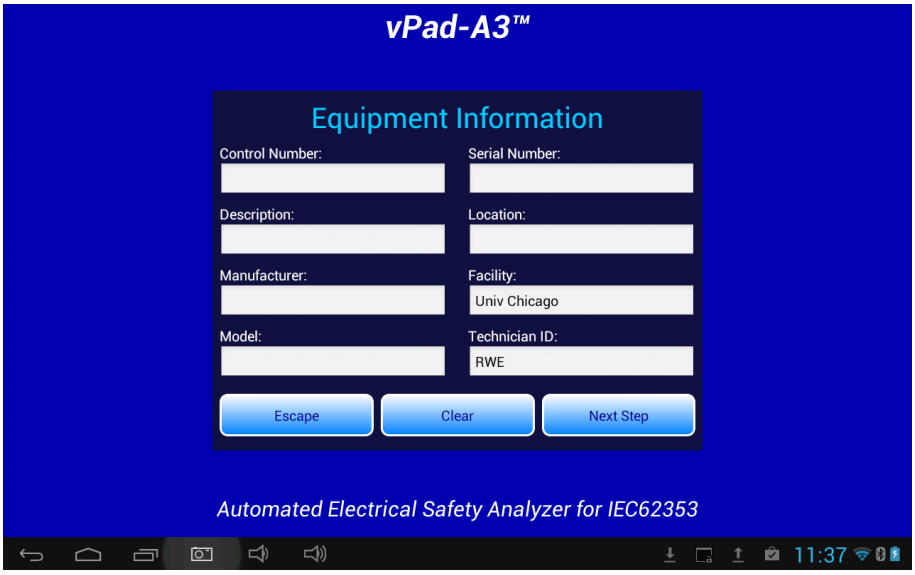


Figure 30 *- Equipment information editor.*

If any information remains on the screen from a previous test, press the **Clear** button to clear the contents of all fields except the **Facility** and **Technician ID.** Tap on a text field to display the Android keyboard and enter information. If an external keyboard or barcode scanner is connected to the tablet, the Android keyboard is not displayed and data entry is then accepted from the external input device. Refer to Section 4.6 for detailed instructions on using the Android keyboard.

Figure 31

Figure 32

Pressing ENTER  on the keyboard advances data input to the next text field on the screen.

Alternatively, use 

to navigate the text fields, or simply tap a field to jump immediately there.

Note: At a minimum, an equipment control number, or other ID, must be entered in the **Control Number** field in order to save a Test Record.

"Facility" and **"Technician ID"** fields are backed up in permanent storage on the Android tablet. These information fields may be modified, but the last values are maintained after power to vPad-ES is switched off, and are restored on subsequent use of the app.

When done entering information, press  to dismiss the keyboard and expose the following buttons at the bottom of the menu:

Escape	Cancel the current AutoSequence and return to the list of available sequences.
Clear	Clear the contents of all fields except Facility and Technician ID. Useful in some instances where data may have been carried over from another test.
Next Step	Press to proceed with the next step of the test.

'Escape' and **'Next Step'** are provided on many screens of the test sequence, where they provide the functions described above.

After **'Next Step'** is pressed, following screens will be displayed, in the following order, IF they have been activated in the AutoSequence:

- Equipment Inspection
- Test Instructions
- Ground/External Resistance Measurements
- Line Voltage Measurements
- Leakage Current Measurements
- Load Current/Power Measurements
- ECG Waveform Sequence
- View Test Results

When the test sequence has completed, you will be prompted to save a test record. The following sections explain each step of the AutoSequence test in detail.

4.5.1 Equipment Inspection

The Inspection file selected in the AutoSequence will be displayed. An Inspection file can contain up to 50 steps which are tailored toward the device being tested. The example AutoSequence shown below is set up to perform a Diagnostic ECG Inspection and will contain steps which are directly related to this device, as opposed to the generic 25 point inspection provided with the manual tester, vPad-353.

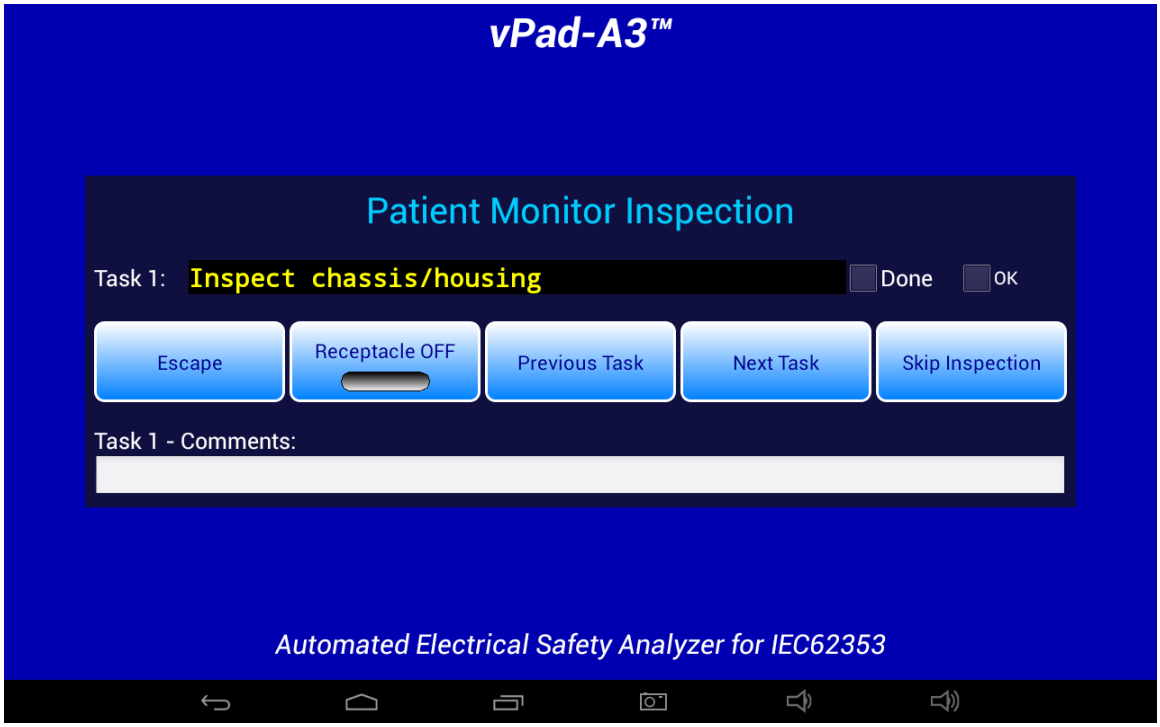


Figure 33 *- Inspection comment entry.*

While doing this Inspection, it is possible to turn the power **ON** or **OFF** to the receptacle, if the inspection step requires the EUT to be powered. To complete a Task, press **'Done'** if the EUT **'Failed'** the task, or **'OK'** if it Passed. Pressing **'OK'** will also check **'Done'** , signifying the task is complete and it **'Passed'**.

Before going on to the **'Next Task'**, the user can enter **'Comments'** to indicate anything important or unusual that was experienced when performing the task.

When a Task is complete, press the **'Next Task'** button to continue. If an error has been made, **'Previous Task'** can be pressed to go back and repeat a Task.

If, for some reason, the Inspection does not need to be done, '**Skip Inspection**' can be pressed.

4.5.2 Test Instructions

If enabled, the Test Instruction screen will appear next. Test setup instructions are displayed on the left and referenced figures or video, if any, will appear in the window on the right. If more than one figure is referenced, navigation buttons will appear below the image window.

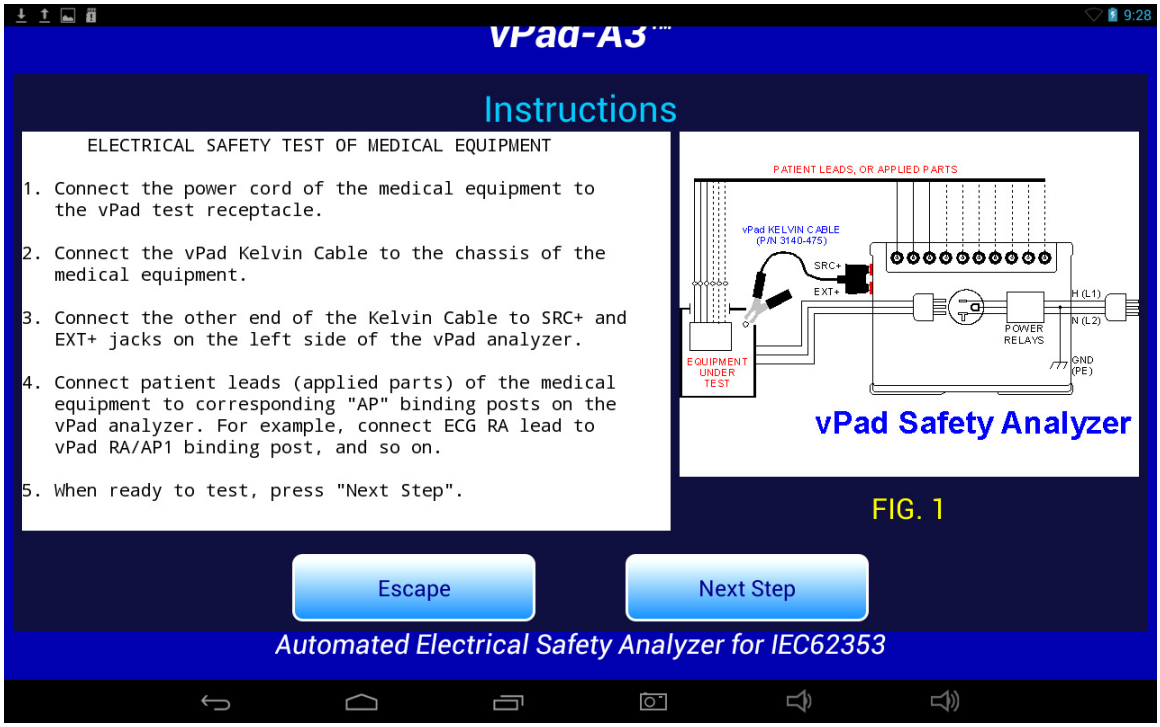


Figure 34 *- Instruction Screen.*

4.5.3 Protective Earth Resistance

Following the Test Instructions, Protective Earth (PE) Resistance will be measured if it has been enabled.

vPad will continuously measure the PE Resistance and display the result on the screen approximately every second. This continuous measurement allows the equipment power cord to be flexed, as necessary, to determine if there are any intermittent faults in the cord. The resistance limit is displayed on the screen, as defined in the IEC62353 standard. The measured value is compared to the limit and a **PASS** or **FAIL** is assigned to the result.

It is possible to make more than one resistance test. On the screen there is an indication of how many results have been recorded (saved). To save a value to the test record, press the **'Save Resistance'** button. The measurement on the display will be recorded to memory and the **'Data Count'** will increment. The number on the screen represents the number of resistance values that have been saved to the test record. The test results that have been recorded can be viewed by pressing the **'View Data'** button.

Figure 35 *- Protective Earth Resistance.*

At least one PE Resistance must be recorded if the test has been enabled, and so the **'Next Step'** button is disabled until a resistance value has been saved. Once a resistance value is saved, the **'Next Step'** button is enabled.

4.5.4 External Resistance

If enabled, the External Resistance measurement screen will appear next. Except for the title, it is identical to the Line Cord Resistance screen. To make external resistance measurements, a second Kelvin Cable is required which is connected to SRC- and EXT- jacks on the vPad Base Unit (refer to vPad-ES operator manual). For ease of measurement, it may be best to have one clamp type cable and one probe type cable. Make the connections between the points of interest, and press the **'Save Resistance'** button. Multiple measurements can be saved.

4.5.5 Mains Voltages

When enabled, vPad will go through a series of three voltage tests: L1 - L2; L1 - PE (earth); and L2 - PE. During each of these three tests, the user will have the opportunity to **'Pause'** the test. When the test is paused, it is possible to **'Repeat'** a test, **'Escape'** completely from the AutoSequence, or **'Continue'** with the next measurement in the sequence. After all three voltage tests, an Alert Dialog similar to ***Figure 15*** on page 21 may be shown in case of an AC mains fault such as a reversed mains or disconnected earth.

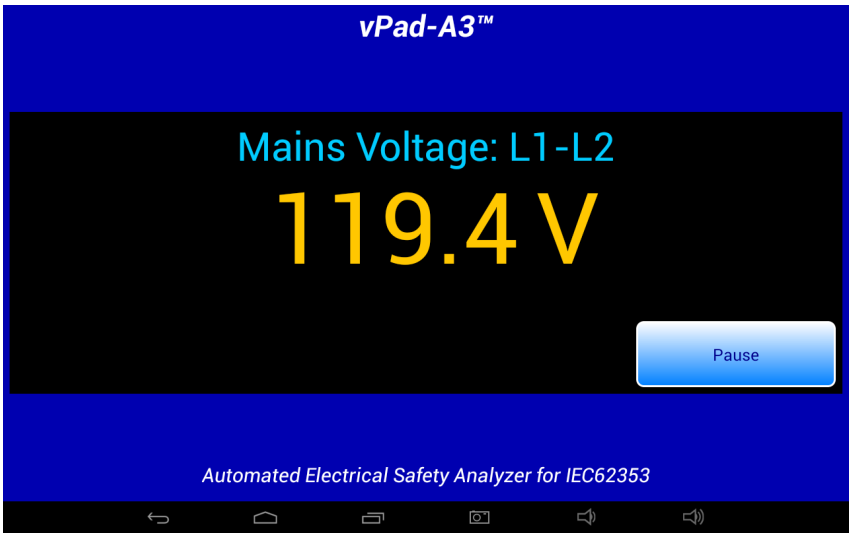


Figure 36 *- Mains Voltage Measurement.*

4.5.6 Insulation Resistance

If enabled in the AutoSequence, insulation resistance measurements will follow the mains voltage measurements. When measuring insulation resistance, it is necessary to set the power switch of the equipment under test to the "ON" position. The user will be prompted to take this action by display of a prompt on the screen. The user will need to acknowledge that the necessary action has been taken prior to proceeding.

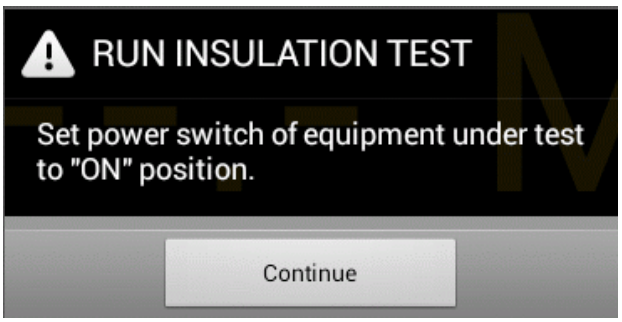


Figure 37 *- Insulation Resistance - power ON prompt.*

In measuring resistance from the EUT primary side to Protective Earth (PE), 500VDC is applied to L1 and L2 (Mains) input lines of the EUT, and the current that flows to the EUT's PE terminal is measured. Using these two parameters, the Mains insulation resistance is calculated. It is possible to use 250VDC instead of 500VDC for this measurement by selection the appropriate option on the AutoSequence setup screen.

During the test, when the high voltage is applied, the screen will display a **'WARNING: HIGH VOLTAGE ON!'** message as shown below. The measurement result is then displayed after a few seconds.

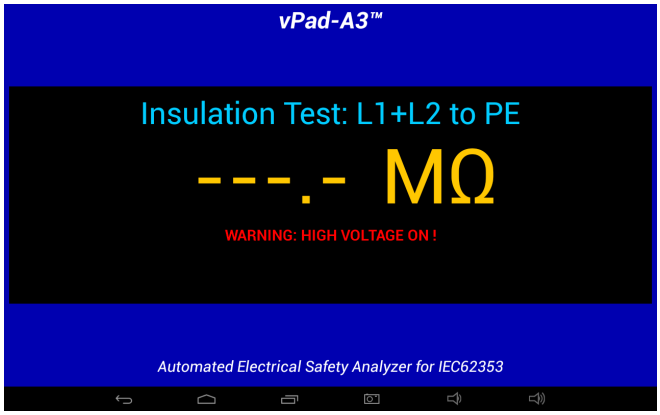


Figure 38 *- High Voltage Warning.*

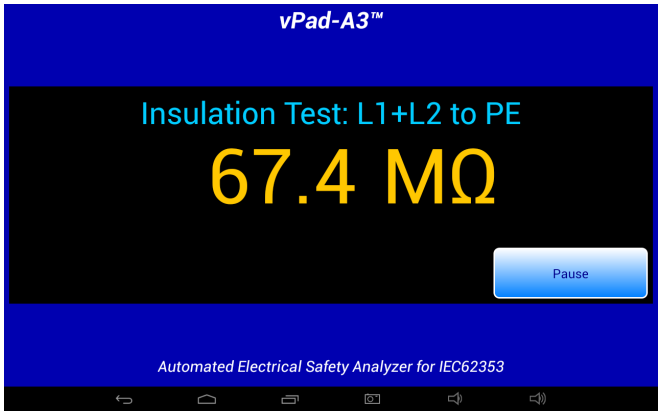


Figure 39 *- Mains Insulation Resistance Measurement.*

The Mains insulation resistance test will be followed by an applied parts (AP) to PE insulation test, if this option been enabled in the AutoSequence setup. The test sequence proceeds as described above for the Mains insulation test, and the same value of test voltage is used (500 or 250 VDC).

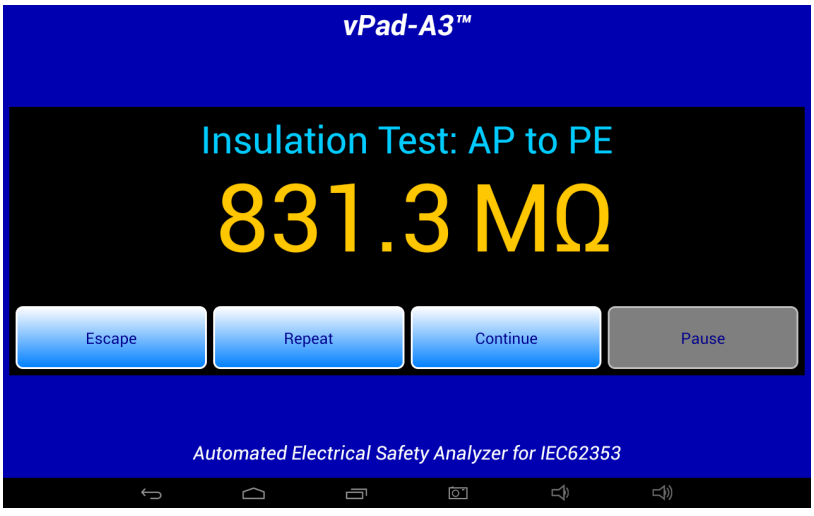


Figure 40 *- AP Insulation Resistance Measurement.*

4.5.7 Leakage Current

If enabled, leakage currents will be measured after insulation resistance. Depending on which test conditions have been enabled in the AutoSequence setup, the leakage test sequence will proceed to measure the Equipment Leakage, followed by various Applied Part (AP) Leakages. Below is the display for the Equipment Leakage measurement.

Figure 41 *- Equipment Leakage.*

Unless "Skip Reverse Polarity Tests" is enabled in AutoSequence settings, Equipment and Applied Part leakages are completed with the AC mains in reverse polarity condition before repeating all leakage measurements in normal polarity condition. AC mains condition (normal or reversed) is displayed below the leakage reading. AutoSequences that skip reverse polarity tests will measure leakages only in normal polarity.

After the first Equipment Leakage test in the sequence, vPad-A3 will perform the Secondary Earth test if it is enabled. If the test fails, users must either correct the Secondary Earth problem in the physical test setup, or abort and restart the AutoSequence. Common causes of Secondary Earth faults include erroneous test lead connections, conductive mounting or fluid supply fixtures, and cables to other devices or accessories.

Each leakage measurement is compared to a corresponding limit defined in the IEC62353 standard. If a measurement is below its limit, a "PASS" result is shown and the test sequence continues automatically. If a measurement exceeds the limit, "FAIL" is shown and the sequence stops. The user is given the option of

escaping the test, repeating the measurement, or continuing the sequence with the "FAIL" result on record.

Time required to complete a leakage measurement is set by the "Measurement Delay" parameter of the AutoSequence. By default, this is set to 2 seconds but may be extended by editing the AutoSequence. During the "Measurement Delay", the user may press the **'Pause'** button to stop the sequence. Then, the user may **'Escape'** the test, **'Repeat'** the measurement, or **'Continue'**.

Applied Part Leakages are measured with L2 (neutral) neutral and protective earth both normal, and with AC mains reversed and then in normal polarity. Individual leads and/or lead groups are tested sequentially (AP1, AP2, AP3... AP1-3 ...) according to the AutoSequence settings. A high-voltage warning is displayed on the screen each time the MAP test voltage is activated during the sequence, as shown below.

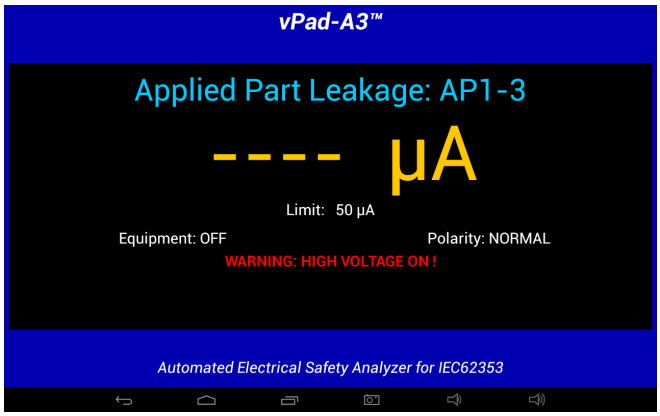


Figure 42 *- Mains Applied Warning.*

Figure 43 *- Applied Part Leakage Measurement.*

Depending on AutoSequence settings, the test sequence may stop periodically and display instructions to the user. One of the more commonly-seen prompts will instruct the user to set the power switch of the equipment under test either 'OFF' or 'ON'. Equipment 'OFF' and 'ON' are test conditions which are required by AAMI and IEC safety standards, although 'OFF' tests may be optionally disabled in the AutoSequence setup to cut the testing time in half.

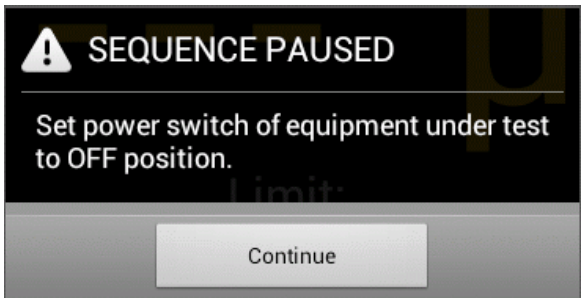


Figure 44 *- Prompt to switch equipment OFF.*

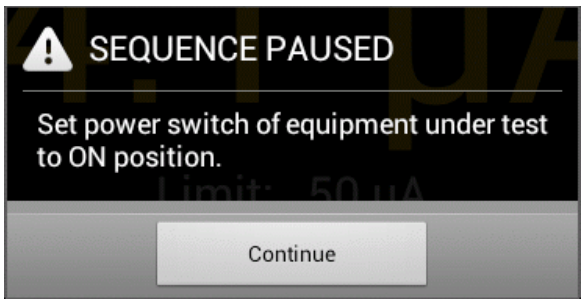


Figure 45 *- Prompt to switch equipment ON.*

An AutoSequence can also be set to stop and prompt the user before a change is made to the AC supply. "Stop before OFF" is an optional setting which is intended to protect equipment that may require a special shut-down procedure before the power can be safely disconnected. "Stop before ON" is another optional setting which is intended for testing equipment that has special startup requirements after AC power has been restored.

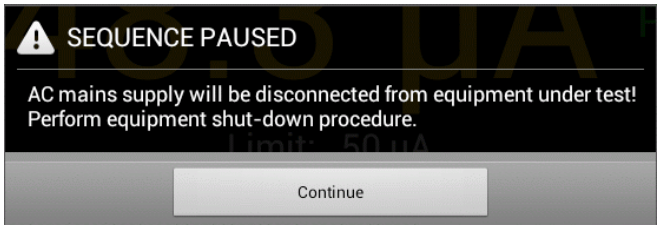


Figure 46 *- "Stop-before-OFF" prompt.*

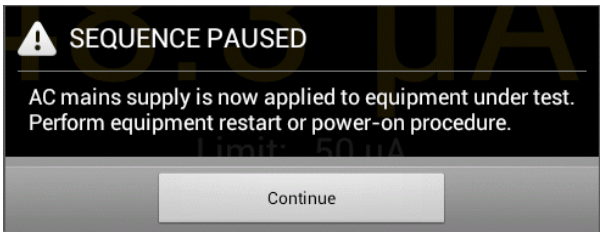


Figure 47 *- "Stop-after-ON" prompt.*

For more information on leakage test settings of the Autosequence, refer to Section 4.4.5.

4.5.8 Load Test

If enabled, the Load Current Test will measure the amount of current drawn by the EUT. If AutoSequence settings are such that AC power has not been previously applied to the EUT, the sequence will stop and prompt you to switch the EUT on. This allows the EUT to reach its operational mode prior to the current measurement. Pressing **'Continue'** enters the current measurement mode.

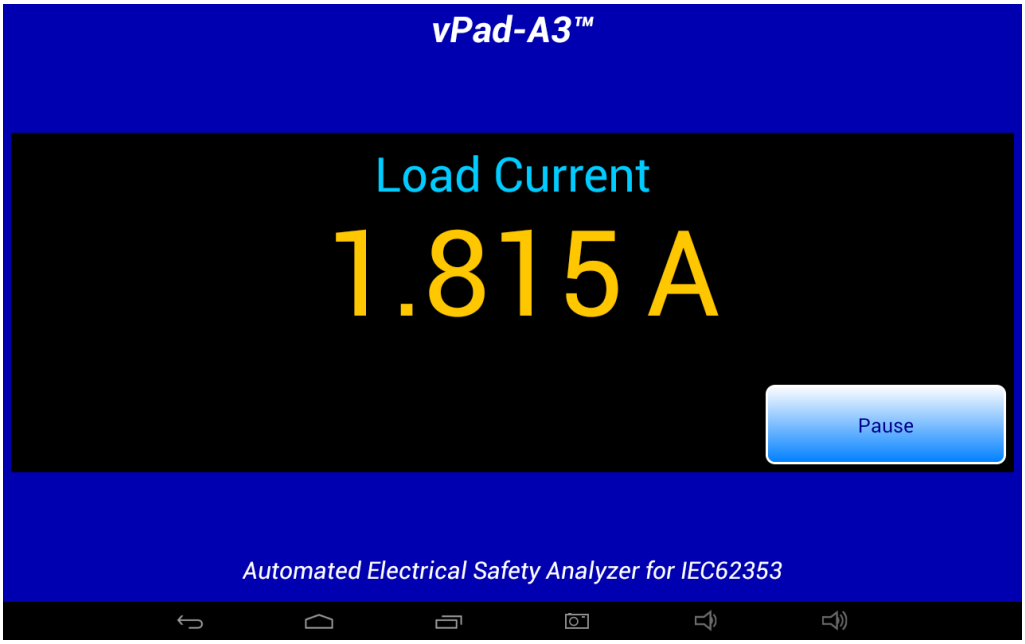


Figure 48 *- Load Current Measurement.*

Measurement of the load current may be optionally followed by a power consumption measurement, if this has been enabled in the AutoSequence.

4.5.9 ECG Waveform Sequence

Following the load tests, the ECG waveform sequence will begin if this function has been enabled. The ECG simulator will output a series of waveforms in the order specified in TABLE 4.4-1.

The **'Skip ECG Test'** button will quit the ECG waveform sequence and go to the next enabled function of the AutoSequence. During the ECG sequence, the user can choose *not* to test a waveform by accepting the default Test Result setting **'Not Tested'**, by pressing either the **'Next Waveform'** button or the **'Skip ECG Test'** button. If it is desired to record a test result for the waveform in use, activate either the **PASS** or **FAIL** radio button, as appropriate, and then **'Next Waveform'** or **'Last Waveform'** button. Pressing the **'Escape'** button will abort the AutoSequence completely, as previously described.

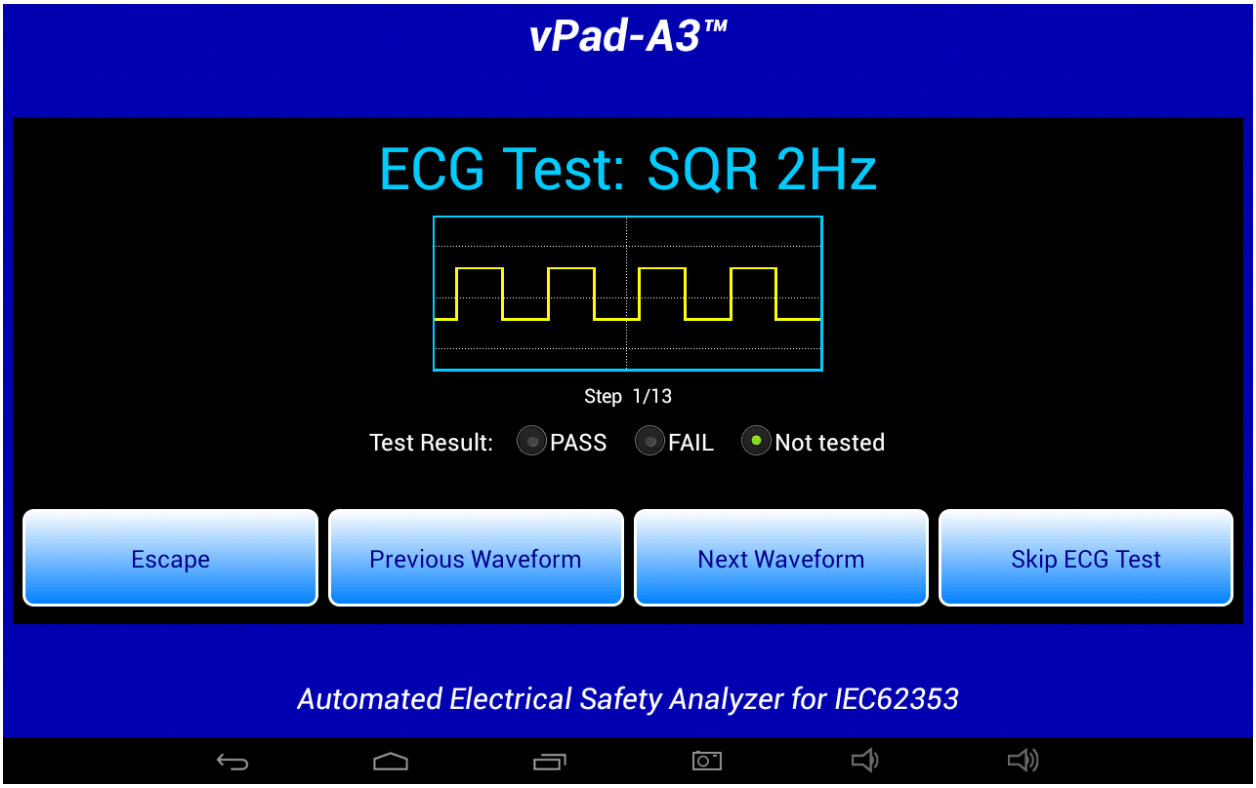


Figure 49 - *ECG Test Waveforms.*

4.5.10 Test Results Preview

When the measurements section of the AutoSequence is complete, a preview of the results will be displayed if the 'Show results at end of test' setting has been enabled. The measurements taken during the test will be displayed in a ScrollView, as shown in the example below.

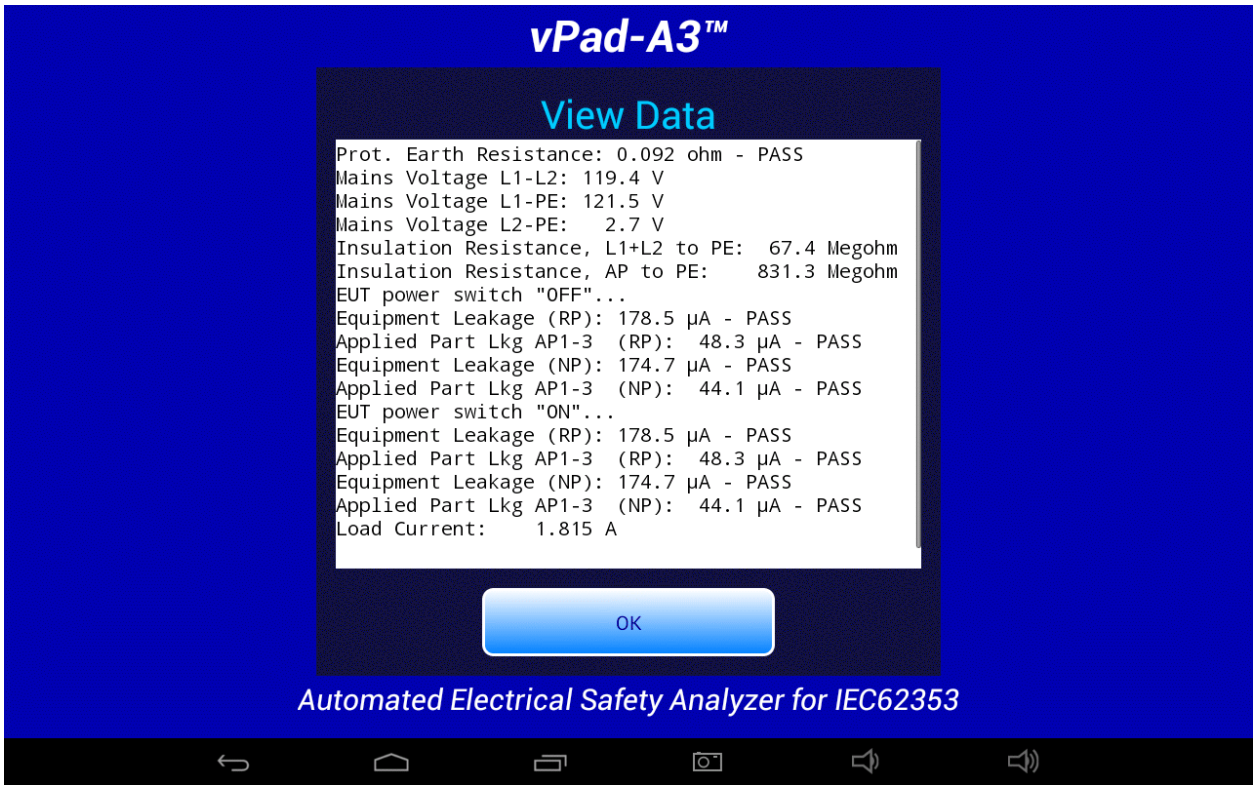


Figure 50 *- Test Result Preview.*

If necessary, the window can be scrolled up or down using a up/down touch-and-drag gesture. When done, press **'OK'** to proceed to the Create Record menu.

4.5.11 Creating a Test Record

When all of the test results have been collected, the final step is to create a record of the test. Test reports are stored in text files which have a name beginning with the EUT Control ID. The remainder of the file name includes a date and time stamp. The general format of the file name is:

```
<control-id>_<yyyymmdd>_<hhmmss>_<r>.txt
```

Where `<r>` can be a **F** for a failed test or **P** for a passed test.

In the event a Control ID has not yet been entered, a reminder warning will be displayed, as shown in ***Figure 51***. Pressing **'Continue'** will return to the Equipment Information screen, ***Figure 30***. Otherwise, the **'Create Test Record'** screen, ***Figure 52*** , will be displayed.

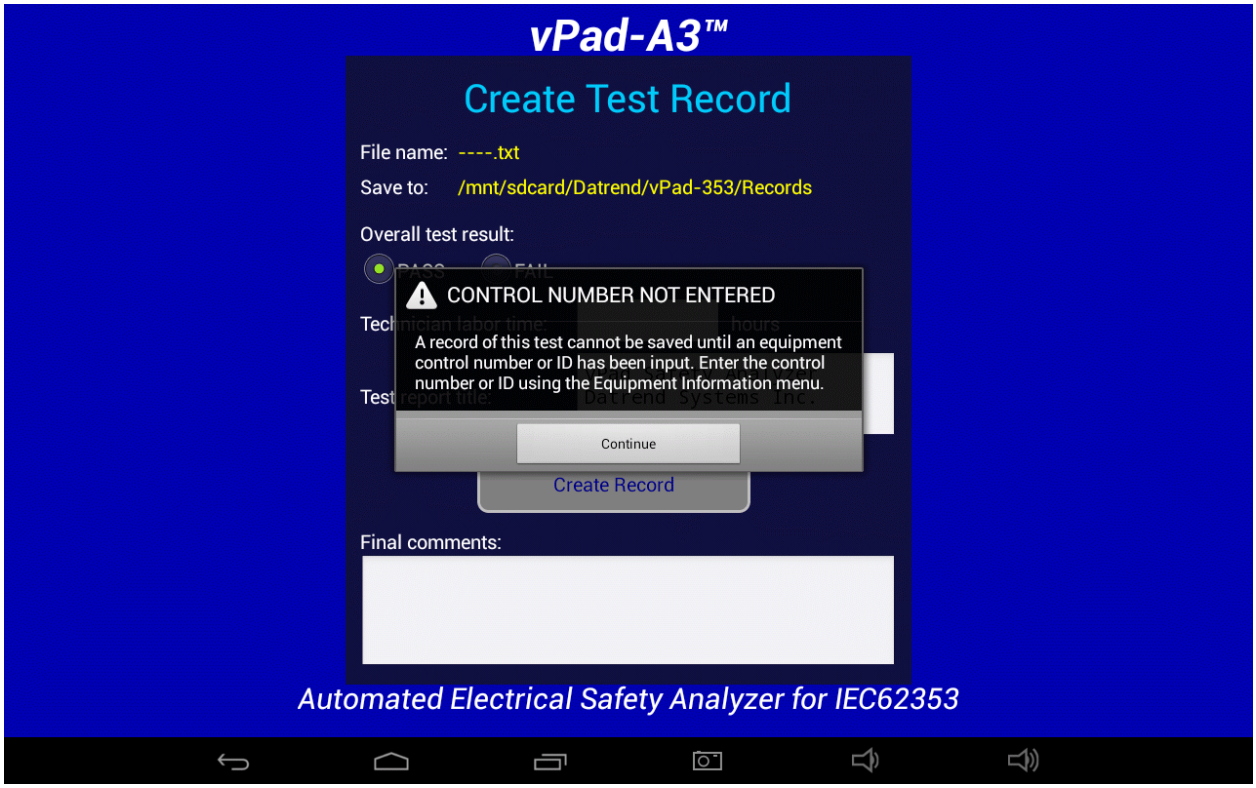


Figure 51 *- Control ID Reminder Screen.*

Once the EUT has been identified by Control Number, it is possible to complete the creation of the Test Record (***Figure 52***). The filename and destination are displayed at the top of the screen and are not user editable.

During the test, certain measurements may have been recorded as a **FAIL** result. If this is true, the **'Overall Test Result:'** will activate the **FAIL** radio button. If there were no failures recorded during the test, the **PASS** radio button will be activated. It is possible to override a **PASS** since there may be circumstances not evident from the test measurements which could recommend a **FAIL** assessment. Reasons for changing a **PASS** to a **FAIL** can be recorded in the **'Comments:'** field.

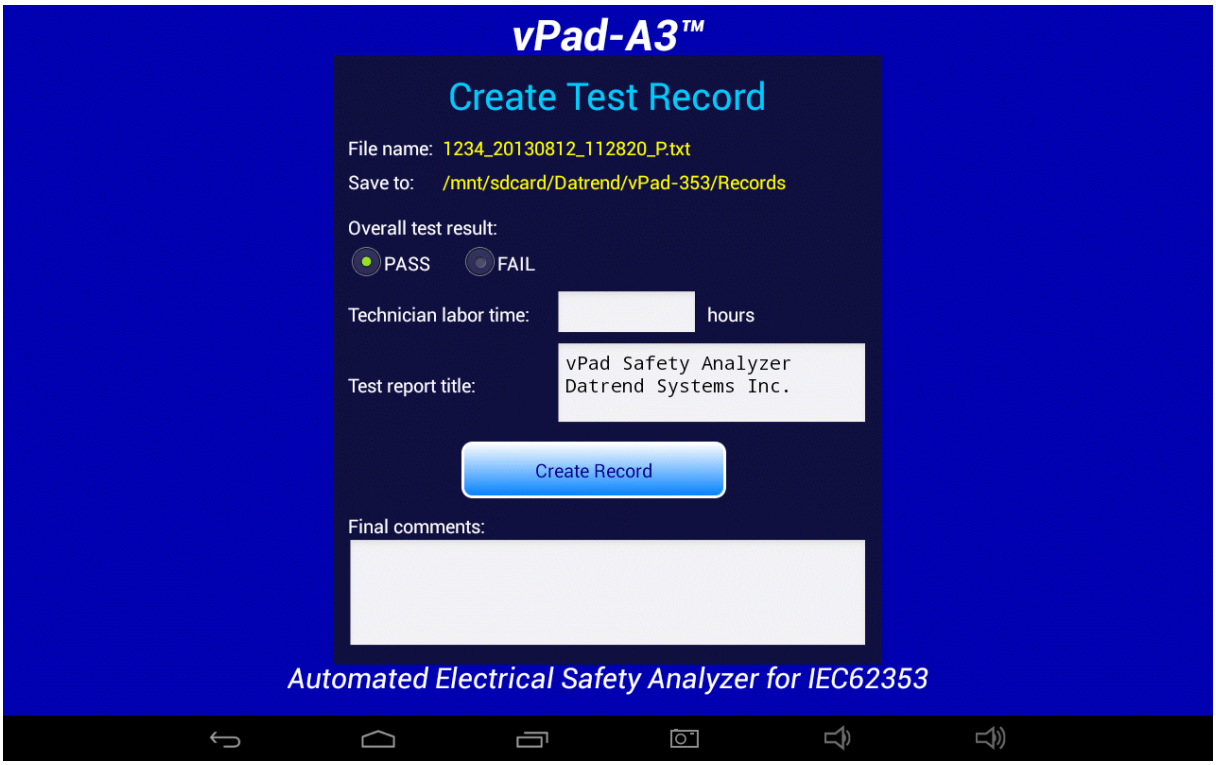


Figure 52 *- Create a Record.*

Time spent by the technician/user can be recorded by entering a value in the **'Technician labor time:'** field. Touching this field space will result in the display of a numeric keypad to allow data entry, per ***Figure 53***. Note that this time is intended to encompass ALL of the time spent by the user in preparing for and completing the requirements of the work order. The actual time spent using vPad-A3 to take and record measurements is recorded separately in the Test Record under the heading 'AutoSequence Run Time'. This is the time from the initial selection of the AutoSequence until the Test Record is created.

Test Record files include a Title at the beginning of the file. This may be modified from default "**`vPad Safety Analyzer`**" after tapping the **Test report title** field. Optionally, enter the name of your institution or business, address, phone number and so on. Up to 16 lines may be entered into this text field, of which the first three lines will be shown when the menu is initially displayed (to view or edit additional lines, scroll the window using a press-and-drag gesture). The **Test report title** is backed up in permanent memory storage on the Android tablet; the title is maintained after power to vPad-353 is switched off, and is then restored on subsequent use of the app.

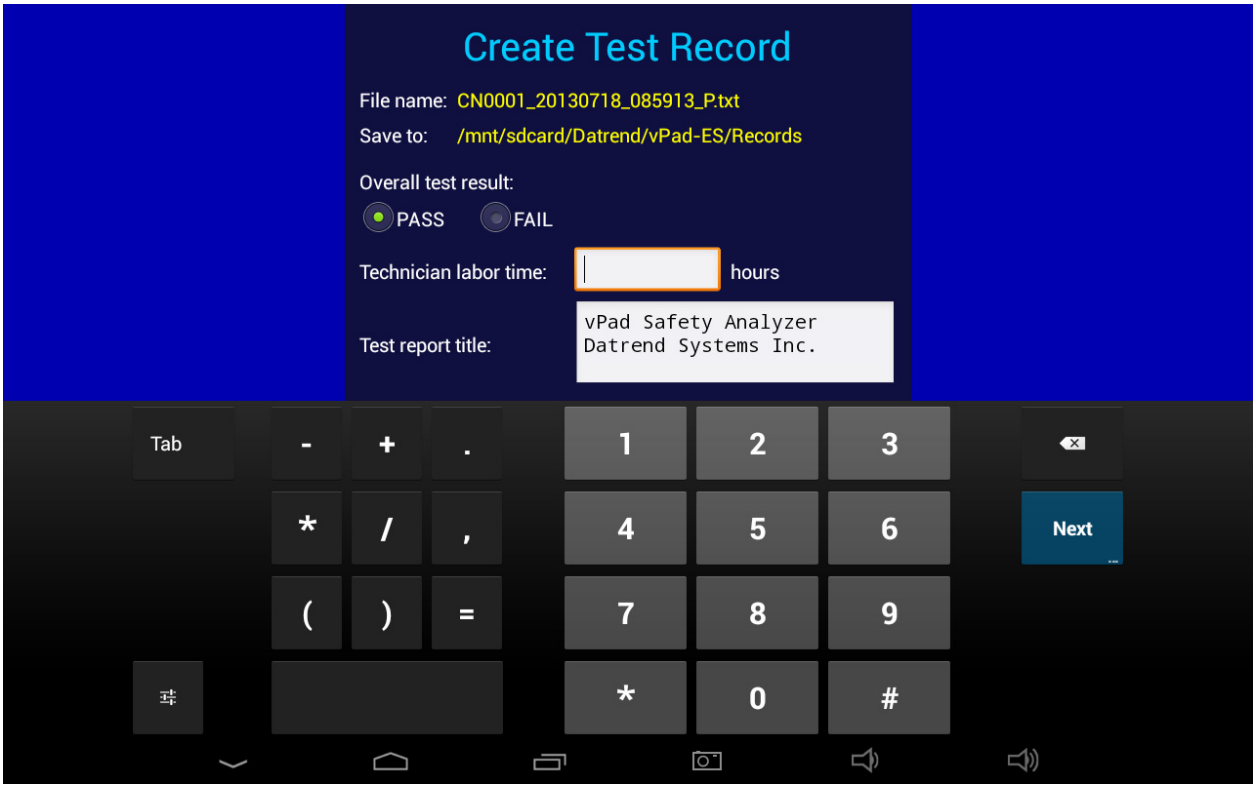


Figure 53 - *Entering Technician Time.*

In the event there is other relevant information concerning the test, the 'Final Comments' field provides a means of recording the information. This could be reasons that a test result was changed from PASS to FAIL, notes regarding additional work that should be done in the future, requirements to order parts, etc.

Once all of the information has been input, press the **'Create Record'** button to save the record to file.

An example of a Test Record file saved by vPad-A3 is given in APPENDIX A.

4.6 Using the Android Keyboard

When you press a text field, the Android keyboard is displayed at the bottom of the screen.

Figure 54 *- Android onscreen keyboard.*

The onscreen keyboard is the default method used by Android to enter information. If you have connected an alternative input device to the tablet (e.g. Bluetooth/USB keyboard or barcode scanner), then the Android keyboard will not appear when a text field is pressed and data entry will then be from the external input device. To switch back to the default keyboard, disconnect the external input device.

The text field which is currently accepting data from the Android keyboard will be highlighted:

Figure 55 *- Single-line text field.*

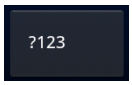
Android text fields may be either single- or multi-line. A practically unlimited amount of text may be typed for either single- or multi-line fields.

Pressing ENTER  (or **Next)** for a single-line text field causes data entry to jump to the next text field on the screen.

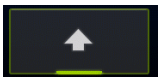
Pressing ENTER  on a multi-line text field inserts a new line. To move from a multi-line field to a different text field on the screen, tap on the desired field.

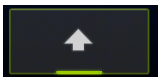
Press 

to navigate forward through multiple text fields on a screen. Press  to navigate backward. You can also jump to a particular field on a screen simply by tapping the field.

Switch the Android keyboard from alpha to numeric modes by pressing 

.

In alpha mode, to activate Caps Lock press and hold  until the indicator lights up: 

Once activated, press  to switch Caps Lock off.

To correct a mistake in typing, tap the text field to the right of the error. This will activate the Android edit cursor. Erase with backspace/correct  then retype.

Figure 56 *- Error correction with edit cursor.*

When done entering text, the Android keyboard may be removed from the screen by pressing  at bottom left.

Note: **`sdcard`** refers to ***internal memory*** of the Android tablet.

`sdcard` is **NOT** a removable "SD Card" memory device, which may be optionally plugged into the external card slot of the tablet.

Any accessory SD Card which may be plugged into the tablet's card slot is referred to as **`extsd`** in the Android file system.

4.7 Record Manager App

vPad Record Manager is an app which is installed on the Android tablet and which may be run independently of, or simultaneously with, the vPad-A3 app.

Record Manager may be used to copy, print, and/or delete Test Record files saved by vPad-A3. Record Manager can also be used to convert Test Records to Adobe PDF documents. Note that PDF is a format which enables vPad Record compatibility with other Android apps, for example, e-book readers and document printing apps.

Press  on the Android HOME screen to launch the Record Manager app.

Figure 57 *- File browser of vPad Record Manager.*

Refer to **MN-087a 6100-081** ***vPad-RM Operators Manual*** for further information on use of the Record Manager.

Chapter 5

5 Calibration and Maintenance

vPad-A3 is a software App designed for the Android operating system and is used in conjunction with the vPad-353 hardware platform. As an App, there are no calibration or maintenance requirements, however, there may from time-to-time be upgrades which provide enhanced features or improvements. Contact Datrend or your local dealer for information on these upgrades.

With regard to the vPad-353 hardware platform, calibration 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 on the Analyzer Base Unit can be extended to a maximum of two (2) 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 vPad-353.

vPad-353 contains no user serviceable parts, other than a 20 Amp/250V AGC fuse located on the right side panel of the Analyzer Base Unit. Any other failure will require return of vPad-353 to an authorized service facility for repair. ***Opening the case of vPad-353 for any reason will void the warranty and may compromise user safety.***

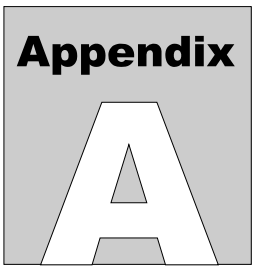
Service must be performed by a factory trained, authorized service agent. This unit contains hazardous voltages which may cause injury if correct service procedures are not followed.

For calibration or service assistance, contact Datrend for a Return Materials Authorization (RMA) number and the location of the nearest Service Facility.

Datrend Systems Inc.
Unit 130 - 4020 Viking Way
Richmond, BC • CANADA • V6V 2L4
Tel 604.291.7747 or 800.667.6557 • Fax 604.294.2355
e-mail customerservice@datrend.com
www.datrend.com

The vPad-353 may be cleaned with the microfiber cloth provided originally with the system (or equivalent type cloth intended for cleaning glass surfaces); or, a soft, lint free, damp cloth using a mild detergent. Use of other cloth materials or cleaning agents on the touchscreen 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 vPad-353 is used for a purpose not specified in this manual.



APPENDIX A. Sample Test Record

This appendix provides an example of a vPad-353 Test Record (created using vPad-A3 automation App), illustrating the data representation for voltage, current, resistance and leakage measurements, as well as ECG waveform data. Inspection data and example notes have been recorded for some measurements to show how these typically appear in a record.

```
                    vPad Safety Analyzer
                    Datrend Systems Inc.

File: cn118_20161123_153024_P.txt
Date: 2016 Nov 23
Time: 15:30:24
vPad ID: My vPad
vPad SN: VPES16060000  Cal Date: 2016-06-30

Equipment Information...
Control Number: CN0118
Description:    ECG Mon
Manufacturer:   PROPAQ
Model:          DN58
Serial Number:  567809832
Location:       PAR
Facility:       St. Joseph's Hospital

Technician ID:   JS
Tech Time (hrs): 0.5

Overall Result:  PASS


Signature:_____________________________  Date:__________


Detailed Test Data...

AutoSequence Filename:   vpad_a3_3.asq
Title of AutoSequence:   ECG 3LD CF (3 leads)
AutoSequence Run Time:   7 minutes
```

```
Elec. Safety Standard:   IEC62353
Earth Resistance Limit:  Maximum 0.300 ohms
Equipment Leakage Limit: Maximum 500.0 µA (Class I)
Applied Part Lkg Limit:  Maximum  5000 µA (Type BF)

Prot. Earth Resistance: 0.174 ohm - PASS
Prot. Earth Resistance: 0.174 ohm - PASS
Prot. Earth Resistance: 0.174 ohm - PASS
Mains Voltage L1-L2: 118.6 V
Mains Voltage L1-PE: 118.1 V
Mains Voltage L2-PE:   0.0 V
Insulation Resistance, L1+L2 to PE:  62.4 Megohm
Insulation Resistance, AP to PE:    209.0 Megohm
EUT power switch "OFF"...
Equipment Leakage (RP):  23.9 µA - PASS
Applied Part Lkg ALL AP (RP):   5.1 µA - PASS
Applied Part Lkg AP1-3  (RP):   6.2 µA - PASS
Applied Part Lkg AP1-4  (RP):   5.8 µA - PASS
Applied Part Lkg AP5-10 (RP):   6.2 µA - PASS
Applied Part Lkg AP4-10 (RP):   6.1 µA - PASS
Applied Part Lkg AP1    (RP):   6.6 µA - PASS
Applied Part Lkg AP1+2  (RP):   6.4 µA - PASS
Applied Part Lkg AP3+4  (RP):   6.2 µA - PASS
Equipment Leakage (NP):  26.7 µA - PASS
Applied Part Lkg ALL AP (NP):   5.0 µA - PASS
Applied Part Lkg AP1-3  (NP):   6.1 µA - PASS
Applied Part Lkg AP1-4  (NP):   5.8 µA - PASS
Applied Part Lkg AP5-10 (NP):   6.2 µA - PASS
Applied Part Lkg AP4-10 (NP):   6.0 µA - PASS
Applied Part Lkg AP1    (NP):   6.5 µA - PASS
Applied Part Lkg AP1+2  (NP):   6.4 µA - PASS
Applied Part Lkg AP3+4  (NP):   6.2 µA - PASS
EUT power switch "ON"...
Equipment Leakage (RP):  23.8 µA - PASS
Applied Part Lkg ALL AP (RP):   5.0 µA - PASS
Applied Part Lkg AP1-3  (RP):   6.1 µA - PASS
Applied Part Lkg AP1-4  (RP):   5.8 µA - PASS
Applied Part Lkg AP5-10 (RP):   6.2 µA - PASS
Applied Part Lkg AP4-10 (RP):   6.0 µA - PASS
Applied Part Lkg AP1    (RP):   6.5 µA - PASS
Applied Part Lkg AP1+2  (RP):   6.4 µA - PASS
Applied Part Lkg AP3+4  (RP):   6.2 µA - PASS
Equipment Leakage (NP):  26.7 µA - PASS
Applied Part Lkg ALL AP (NP):   5.0 µA - PASS
Applied Part Lkg AP1-3  (NP):   6.1 µA - PASS
Applied Part Lkg AP1-4  (NP):   5.8 µA - PASS
Applied Part Lkg AP5-10 (NP):   6.2 µA - PASS
Applied Part Lkg AP4-10 (NP):   6.0 µA - PASS
Applied Part Lkg AP1    (NP):   6.5 µA - PASS
Applied Part Lkg AP1+2  (NP):   6.4 µA - PASS
Applied Part Lkg AP3+4  (NP):   6.2 µA - PASS
```

```
Load Current:    0.272 A
Equipment Power:   32 W

ECG Test: SQR 2Hz - PASS
ECG Test: PUL 4sec - PASS
ECG Test: SIN 10Hz - PASS
ECG Test: SIN 40Hz - PASS
ECG Test: SIN 60Hz - PASS
ECG Test: SIN 100Hz - PASS
ECG Test: SQR 1KHz - PASS
ECG Test: TRI 2Hz - PASS
ECG Test: 60 BPM - PASS
ECG Test: 30 BPM - PASS
ECG Test: 120 BPM - PASS
ECG Test: 240 BPM - PASS
ECG Test: CMRR 60Hz - PASS

END OF RECORD
```


DATREND
Systems Inc.