



DATREND
Systems Inc.

vPad-353TM

**Electrical Safety Analyzer
for IEC 62353**

Operating Manual

vPad-353TM
Electrical Safety Analyzer
Operating Manual

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Revision	Revision History Description	Date
B	Update figures for PiPO tablet	2013-June-13
C	AC Fault, address	2013-Dec-12
D	Clarified Tablet RAM limits	2014-Aug-21

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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.

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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.

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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.

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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 the Analyzer Base Unit of vPad-353 (the "Datrend product") 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 to **two (2) 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 Datrend 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:

- Tablet PC: per tablet manufacturer's original 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 5 of this manual) to obtain an RMA number and receive help with shipping/customs documentation.

* Subject to some exclusions, based on sales territory. Contact Datrend for details.

Warranty Disclaimer

Should you elect to have your instrument serviced and/or calibrated by someone other than Datrend Systems or an Authorized Service Centre, 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 or an Authorized Service Centre 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 1-604-291-7747. You will be required to provide us with the serial number for your instrument as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your instrument without interruption.

WARNING

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

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Note: Calibration of Datrend products typically involves adjustment of parameters stored in firmware by proprietary software. Parties other than Datrend and its Authorized Service Centers are limited to verification of the status of the accuracy of the instrument. Do not confuse verification with calibration.

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Abbreviations and Definitions

The following abbreviations, terms and acronyms are 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, Line 1 or Hot	Line 1 of the AC supply voltage, or "mains". In North America, the "Hot" or "Live" line (conductor) of the AC supply.
L2, Line 2 or Neutral	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

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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. Vrms, Arms....)
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
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:



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 or 500 VDC may be present on the (CAT I) lead 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 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)

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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-353 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.

Chapter

1

1 Specifications

Equipment Performance Specifications

1.1 Electrical Safety Testing Standards

- IEC62353
- IEC60601 (via vPad-ES application, included)
- AAMI-ES1 (via vPad-ES application, included)

1.2 Safety Tests

- Mains Voltage
- External (point-to-point) Voltage
- External (point-to-point) Micropotential
- Equipment Load Current
- Equipment Power Consumption
- Protective Earth Resistance
- External (point-to-point) Resistance
- Equipment Leakage Current
- Applied Part Leakage
- Insulation Resistance

1.3 Instrument Specifications

1.3.1 Voltage Measurement

Mains voltage	
Range.....	90 to 264 V rms
Accuracy	$\pm(2\% \text{ of reading} + 0.2 \text{ V})$
External (point-to-point) voltage	
Range.....	0 to 300 V rms
Accuracy	$\pm(1\% \text{ FS} + 0.2 \text{ V})$
External (point-to-point) micropotential	
Ranges.....	0 to 199.9 mV rms
	200 to 1,999 mV rms
	2,000 to 19,999 mV rms
Accuracy	$\pm(1\% \text{ of reading} + 1 \text{ mV})$

1.3.2 Load Current Measurement

Ranges	0 to 1.999 A ac rms
	2.00 to 19.99 A ac rms
Accuracy	$\pm(2\% \text{ reading} + 0.2\text{A})$
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	$\pm(5\% \text{ reading} + 5\text{W})$

1.3.4 Earth Resistance Measurement

Modes	Four-terminal, fully isolated
Test Current	1A pulsed, 0.2A rms
Range	0.000 to 2.000 Ω
Accuracy	$\pm(1\% \text{ of reading} + 0.02 \Omega)$

1.3.5 Insulation Resistance Measurement

Ranges.....	0.5 to 5 MΩ 5 to 50 MΩ 50 to 999.9 MΩ
Range Selection.....	Automatic
Accuracy	
5 MΩ Range	±(1 % of reading + 0.1 MΩ)
50 MΩ Range	±(2 % of reading + 0.2 MΩ)
50 to 100 MΩ.....	±(5 % of reading + 0.2 MΩ)
Test Voltage	
Selections.....	500V or 250V
Accuracy.....	±5 % for 0 to 1 mA load
Maximum load capacitance....	1 μF

1.3.6 Equipment and Applied Part Leakage Tests (vPad-353)

Measurement.....	True RMS
Method.....	Direct method
Patient Load.....	Per IEC62353
Functional Group Selections.....	AP1; AP1 and AP2; AP3 and AP4; AP1 to AP3; AP1 to AP4; AP5 to AP10; AP1 to AP10

1.3.7 Chassis and Lead Leakage Tests (vPad-ES)

Measurement.....	AC+DC (True RMS) AC only DC only
Patient Load Selections.....	IEC60601 AAMI-ES1

1.3.8 Leakage Current Measurement

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

1.3.9 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
Arrythmias.....	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 μ A/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 (shareable with base unit) USB 2.0 Type A (premium tablet only) 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 \pm 10%, 60 Hz, 16A in 20A circuit
 120 VAC \pm 10%, 60 Hz, 12A in 15A circuit
 230 VAC \pm 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).

Chapter

2

2 Overview

vPad-353™ is a manually-operated electrical safety analyzer providing basic electrical safety testing of medical devices with patient leads. This chapter provides an overview of vPad-353 features and test modes. A summary of testing requirements specified by the IEC 62353 safety standard (Medical Electrical Equipment - Recurrent test and test after repair of medical electrical equipment) is included at the end of this chapter.

2.1 Features

2.1.1 Analyzer Base Unit

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. Referring to **Figure 1**, controls, interfaces and features of the Analyzer Base Unit are:

Item	Description/Function
1. AC supply input	Connect to AC power supply using line cord provided with vPad-353
2. Line fuse	Main supply fuse; replace with AGC 20A / 250V
3. AUX test jack	Use when testing applied part leakage current of Class II medical equipment
4. Test receptacle	Connect to AC power input of Equipment Under Test (EUT)
5. Receptacle Active indicator	Lights when power is applied to/available at test receptacle (4)
6. Tablet tray	Supports tablet when safety analyzer in use
7. TABLET DC	Connect to DC power input of tablet, using cable provided (either 12V (P/N 3140-476) or 5V (P/N 3140-477), according to tablet model)
8. TABLET USB	Connect to USB port of tablet, using cable provided (P/N 3140-478)
9. Cable storage bay	Store tablet USB and Power cables here when transporting or storing vPad-353

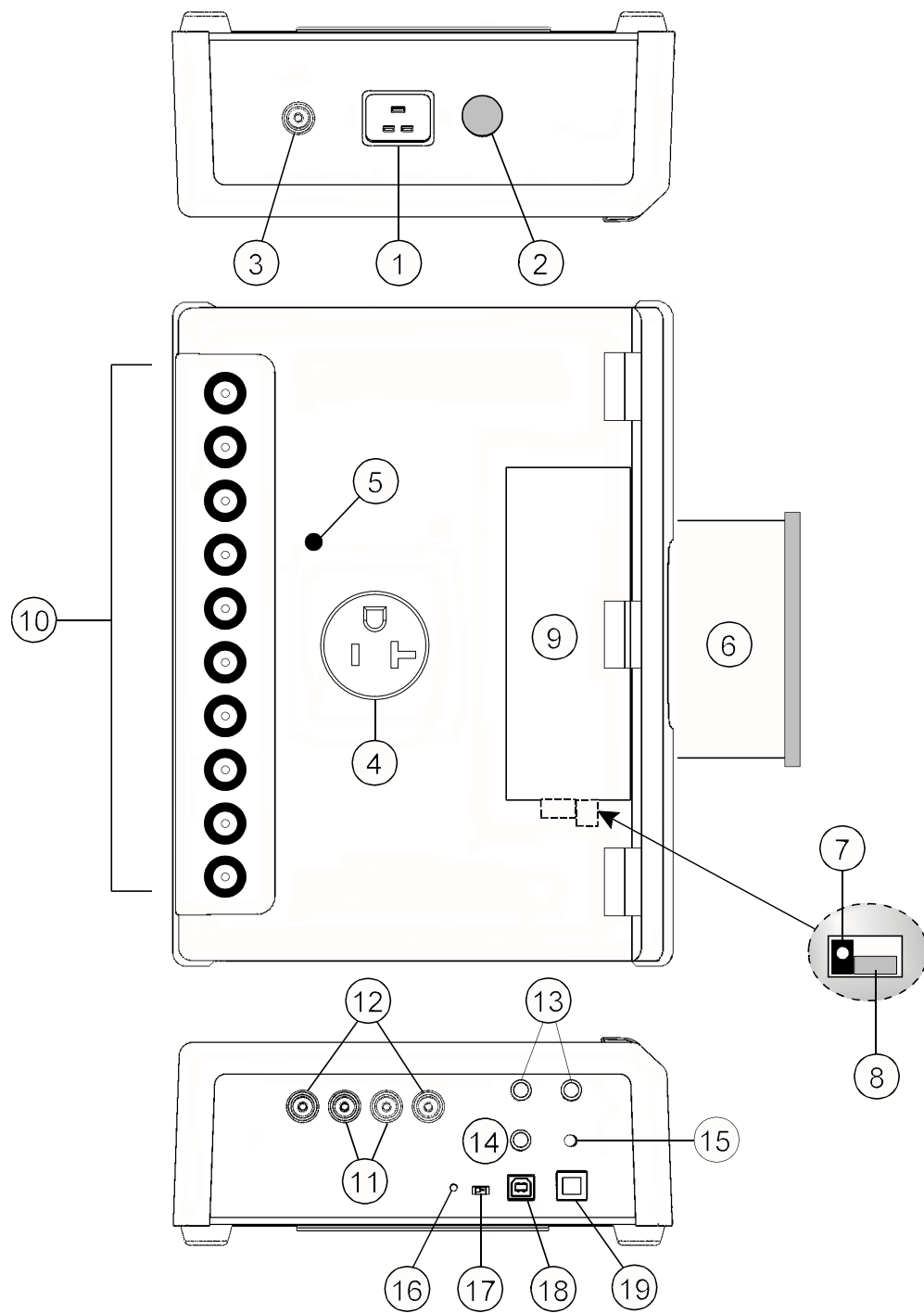


Figure 1 - vPad-353 Analyzer Base Unit.

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Item	Description/Function
10. Binding posts	Connect to EUT patient leads or applied parts, for example, ECG leads
11. Meter input, EXT+/-	Input to voltmeter or leakage measuring device
12. Current source, SRC+/-	Current source output for four-wire resistance measurement
13. Test resistor, 1.0 Ω	Use to verify function of ohmmeter
14. Test current, 100 μ A	Use to verify function of leakage measuring device
15. AC supply indicator	Lights when AC supply is connected to Base Unit
16. Reset button	Press to reset Base Unit
17. Normal/remote switch	Set to "normal" for operation by Android tablet; set to "remote" for operation via remote control from PC running Microsoft Windows® (Android tablet is bypassed)
18. PC IN	USB Type B (Device) - connect to PC for remote control operation
19. XBUS Port	Connect to Vision-Pad Technology™ accessory devices

2.1.2 Test Receptacle Configuration

vPad-353 may be equipped with one of these test receptacles, but other receptacles may be substituted to satisfy customer requirements. For additional configurations, please contact Datrend Customer Service (see Chapter 5 for contact details).

North America



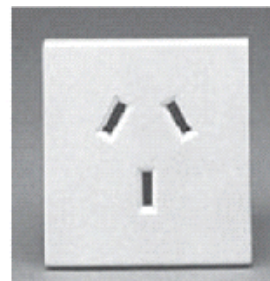
Western Europe



United Kingdom



Australia/China



2.1.3 User Interface

The user interface of vPad-353 is based on an Android™-powered tablet computer. Android provides numerous features which make vPad-353 unique as a biomedical test instrument:

- High Definition (HD) colour display with capacitive touchscreen
- 4 to 16GB of internal memory (depending on tablet model), expandable via accessory SD Card
- WiFi for wireless connectivity to printers, PC's and the Internet
- Bluetooth for wireless connectivity to PC's and hardware add-ons (keyboard; barcode scanner; etc.)
- USB Host Port on premium Vision-Pad tablets supports hardwired accessories such as flash drive, keyboard, barcode scanner, etc.
- Still-image camera and audio/video recorder (tablet dependent)
- Full-size (8½ x 11") document printing
- Pre-installed software applications ("apps"): file manager; Internet browser; PDF and e-book reader; e-mail; calendar; notepad; plus many others
- More Android apps easily installable via direct download from Google Play, GetJar, and other sources

The vPad-353 app for Android drives the Analyzer Base Unit. In addition to large, easy-to-read indicators and pushbutton controls necessary for analyzer operation, Datrend's vPad apps provide data recording and other features which are unprecedented in a safety analyzer in this price range:

- Save tens of thousands of Test Records on the safety analyzer, with each Record storing a practically unlimited number of measurement values in combination with in-line notations
- Save equipment information to Test Records, including control number, description, make, model, serial number and more
- Perform and record equipment inspections following the *General Devices Acceptance Procedure* published by the ECRI Institute (USA)
- Manage vPad Test Records: copy; delete; convert to PDF; and print to full-size (8½ x 11") pages - on an individual basis or on multiple selected Records at once

More information on the many features of the user interface and apps may be found in Chapter 4 of this manual.

2.2 Test Modes

vPad-353 provides a variety of test modes which are useful for performing electrical safety measurements on medical equipment.

<i>Mains Voltage</i>	Use this mode to test the AC supply which powers vPad-353. Measure voltages from AC mains Line 1 (L1) to Line 2 (L2); from L1 to Protective Earth (PE); and from L2 to PE.
<i>External Voltage</i>	Use this mode to check larger voltages between two arbitrary points, up to 300V RMS maximum.
<i>External Micropotential</i>	Use this mode to observe small voltages in the millivolt range between two arbitrary points. In this mode, the voltmeter has a low input resistance (1 kohm). vPad-353 auto-ranges to suit the potential being measured (200, 2000 or 20000 mV RMS full scale).
<i>Load Current</i>	Use this mode to measure current drawn from the AC mains supply by the equipment under test (EUT). vPad-353 auto-ranges to suit the current being measured (2A or 20A AC full scale).
<i>Power</i>	Use this mode to measure the power consumption of the EUT. Power is calculated from the product of the line voltage and load current. This test mode is useful for monitoring power consumption of loads over 50W.
<i>Protective Earth Resistance</i>	Use this mode to test the resistance of the EUT's power supply cord, up to a maximum of 2 Ω . In this test mode, vPad-353 uses an isolated, four-wire ohmmeter with a pulsed 1 amp current source.
<i>External Resistance</i>	Use this mode to measure resistance between two arbitrary points, up to 2 Ω . A four-wire ohmmeter is used.

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Equipment Leakage

Use this mode to check for leakage current that may flow from the chassis or enclosure of the EUT to ground of the AC supply when the PE connection is open.

The leakage measuring device (MD) is configured for true-rms measurement, per the standard. The test receptacle may be set to normal or reverse polarity. As required, vPad-353 auto-ranges to suit the leakage being measured (200, 2000 or 20000 μ A full scale).

Applied Part Leakage

Use this mode to check for leakage current from EUT "Applied Parts" or patient leads to Earth of the AC mains supply, when an isolated voltage equal to the mains is connected to one or more leads.

Applied Parts (AP) may be tested in various combinations or groups, according to their medical function.

Insulation Resistance

Use this mode to measure the insulation resistance between the Mains Part and the PE of the EUT; and, the insulation resistance between the EUT AP and PE.

ECG Simulator

Use this mode to produce calibrated test signals such as pulse, square, sine and physiological waveforms which are useful in testing patient monitoring systems.

In addition to measurements required by the IEC 62353 standard, the vPad-353 analyzer can be used to perform electrical safety testing in accordance with IEC 60601 and AAMI-ES1 standards.

IEC 60601 and AAMI-ES1 safety tests are implemented in the vPad-ES software "app", which is installed on the Android tablet of the vPad-353 analyzer. Refer to **MN-074 vPad-ES Operator's Manual**, included with vPad-353, for instructions on using the analyzer to perform IEC 60601 and AAMI-ES1 tests.

2.3 Safety Test Standards

vPad-353 may be used to perform electrical safety tests of medical devices with patient leads, following the IEC62353 standard. TABLE 2.3-1 defines terms which pertain in general to electrical safety testing of medical equipment.

TABLE 2.3-1: Safety Test Terminology

Term	Definition
EUT	Equipment Under Test
NC	Normal operating condition. AC supply to EUT has PE (ground) and L2 (neutral) both normal (closed).
SFC	Single-Fault Condition. AC supply to EUT has ground 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. vPad-353 incorporates the measuring device specified by the IEC62353 standard, which is shown in **Figure 2**. 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.

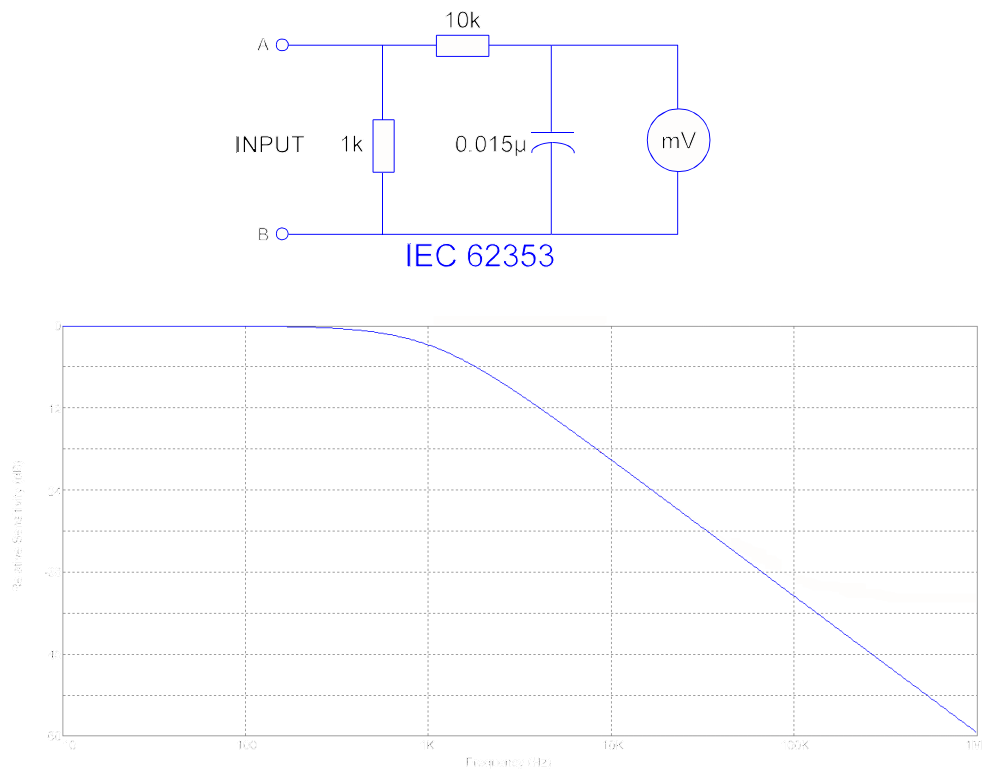


Figure 2 - Measuring device (MD) for IEC 62353 standard.

In addition to specifying the measuring device circuit, the IEC 62353 standard also specifies test conditions under which leakage current must be measured. The requirements of the standard and the practical interpretation of these requirements are summarized in TABLE 2.3-2. vPad-353 meets these requirements by providing the necessary test settings that enable you to follow the IEC 62353 standard.

TABLE 2.3-2: Leakage Test Requirements of IEC 62353

Test Requirement	Practical Interpretation
Test by the direct method at mains voltage and in either position of the mains plug, if applicable.	Measure leakage with normal AC mains polarity, and with reversed mains polarity.
Test leakage with equipment in all intended functional conditions (i.e. switch positions) that influence the leakage current. The highest value and the related condition, if relevant, shall be documented.	Unless a specific functional condition is known a priori to produce the highest leakage, test with EUT power switch set to "OFF" position, and with EUT power switch set to "ON" position. Testing with equipment set to additional functional states may be necessary to find the highest leakage.
Test applied part leakage with all patient connections of a single function of the Applied Part connected together. When testing equipment with multiple Applied Parts, test each Applied Part in turn. Applied Parts which are not part of a measurement shall be left floating.	<p>When patient connections of a common medical function are shorted together, the shorted leads will then form a single "Applied Part" per the definition of IEC62353.</p> <p>For example, in testing leakage current of a portable patient monitor which provides three ECG leads and two invasive blood pressure (IBP) channels, the IEC62353 standard requires that the ECG leads must be shorted together and measured, while leaving the two IBP connections floating. Then, the two IBP connections are shorted together and measured, while leaving the three ECG leads floating.</p> <p>Leakage current is measured and recorded for each medical function separately. According to additional requirements above, test with normal/reverse mains polarity and with EUT on/off.</p> <p>All leakage values must be less than the maximum limit specified in IEC62353 (see TABLE 2.3-3 following).</p>

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Acceptance limits according to IEC 62353 are shown in TABLE 2.3-3. These limits are applied by vPad-353 to determine the pass/fail result of a measurement. Note the following with respect to TABLE 2.3-3:

- EUT ON or OFF and supply polarity reversed are normal operating conditions and have no bearing on limits specified.
- Equipment Class affects the limit for Equipment Leakage. Cord-connected equipment without protective earth connection, designated as Class II, must have lower leakage than Class I equipment, which has a three-wire power cord.
- Applied Part Type affects the limit for Applied Part Leakage. Applied Parts intended for direct cardiac application, designated as Type CF, must have lower leakage than Type BF Applied Parts, which are sufficiently isolated for body application but are not for application near or on the heart.

TABLE 2.3-3: Maximum Limits

Test	IEC62353 (Ed. 1)
Protective Earth Resistance	0.3 Ω
Equipment Leakage	Class I: 500 μ A Class II: 100 μ A
Applied Part Leakage	Type BF Leads: 5000 μ A Type CF Leads: 50 μ A
Insulation Resistance	No limits specified

Chapter

3

3 Setup

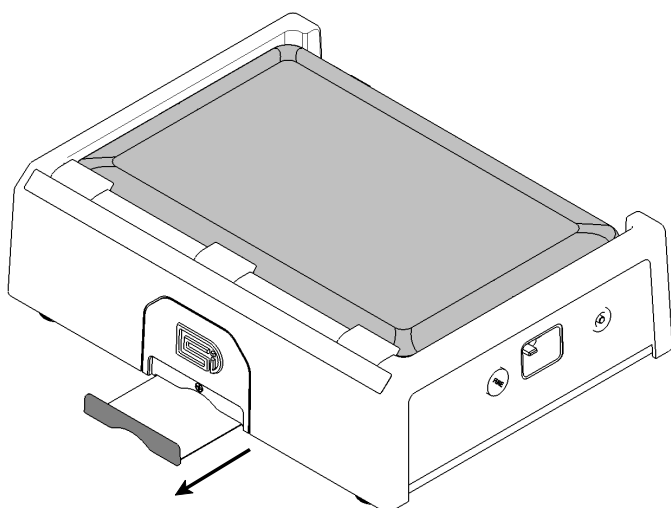


Figure 3

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

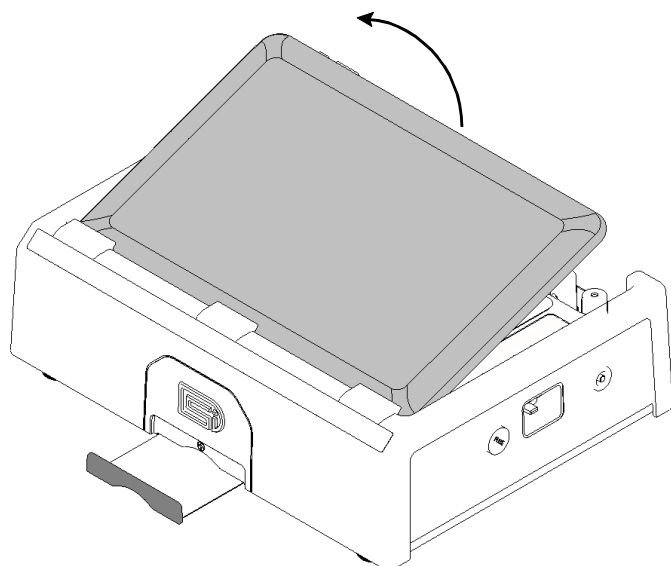


Figure 4

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

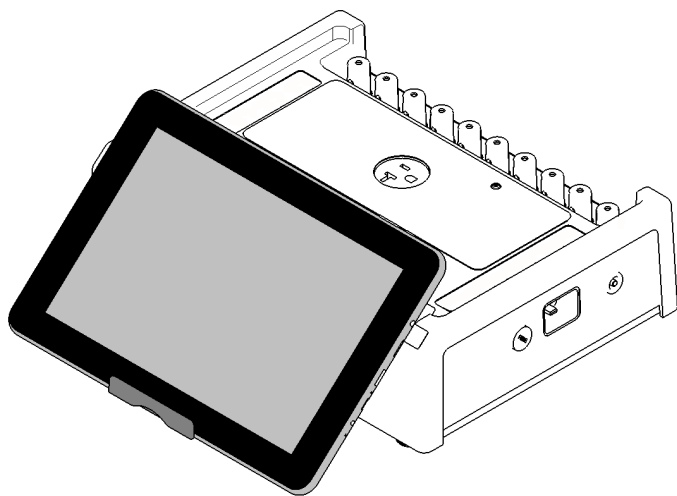


Figure 5

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).

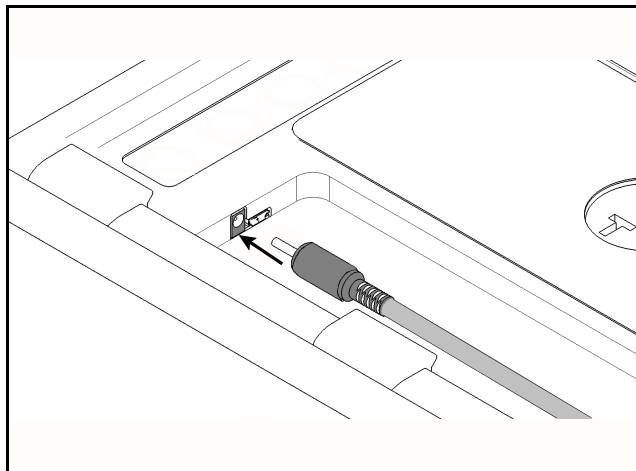


Figure 6

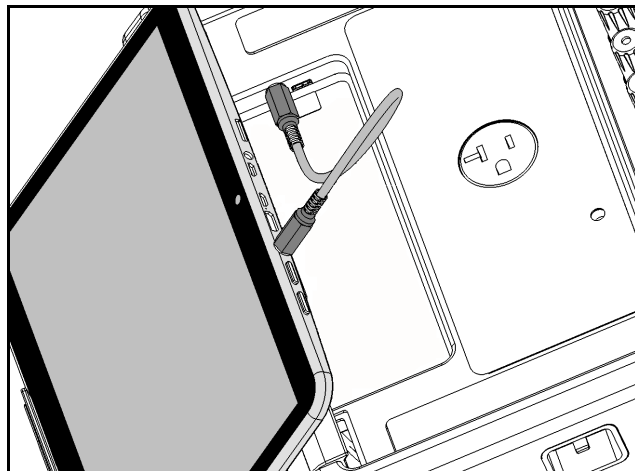


Figure 7

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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.

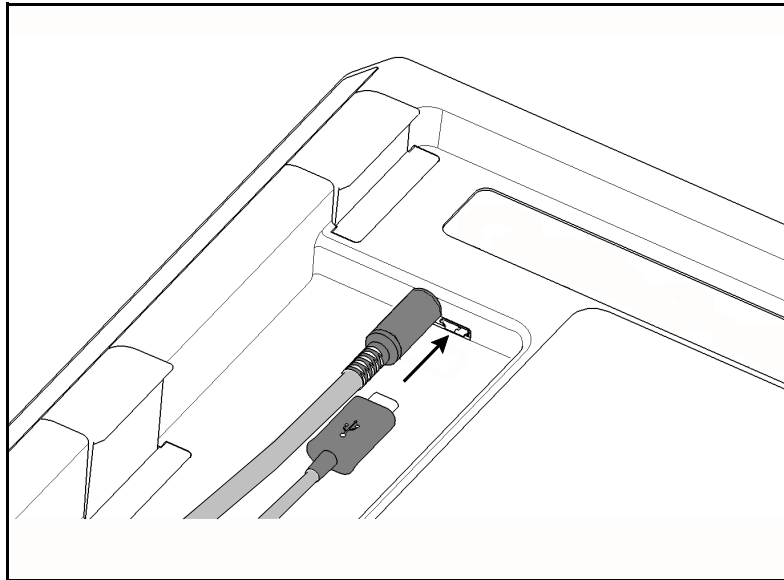


Figure 8

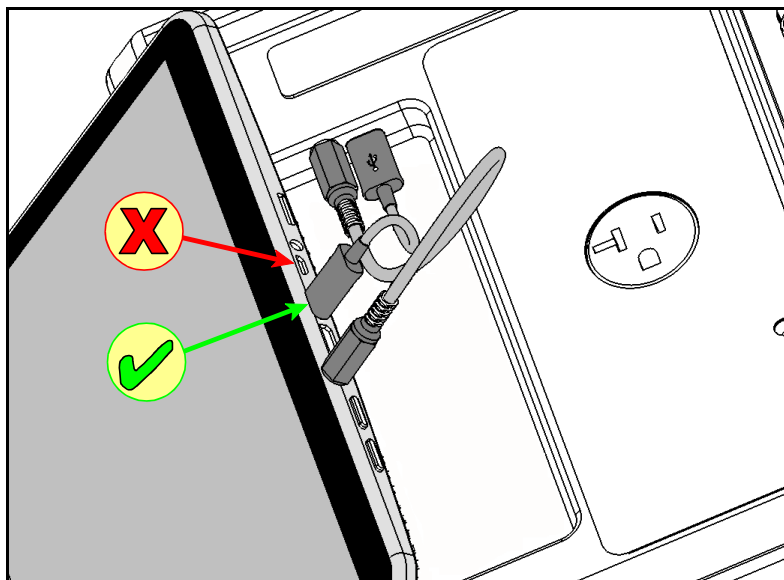


Figure 9

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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 10*). If the AC outlet has power, the indicator lamp on the left panel of the Analyzer Base Unit should now be lit (*Figure 11*).

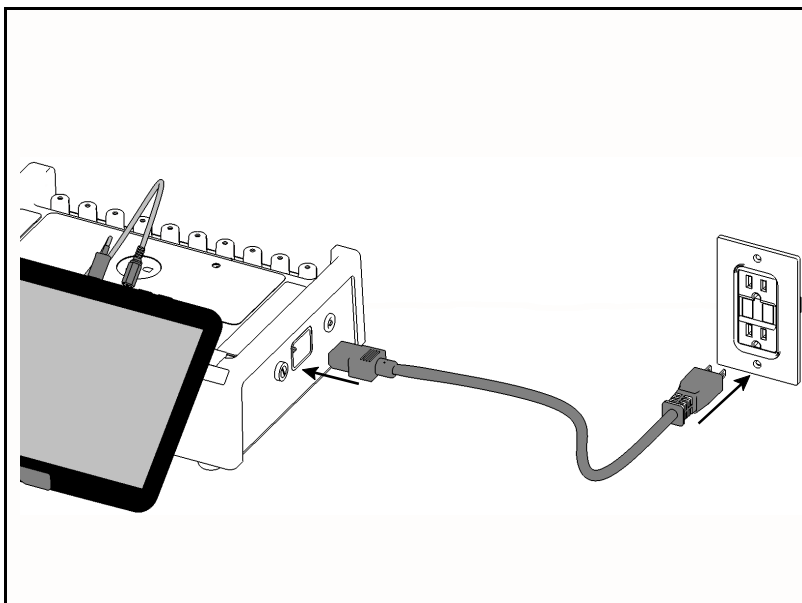


Figure 10

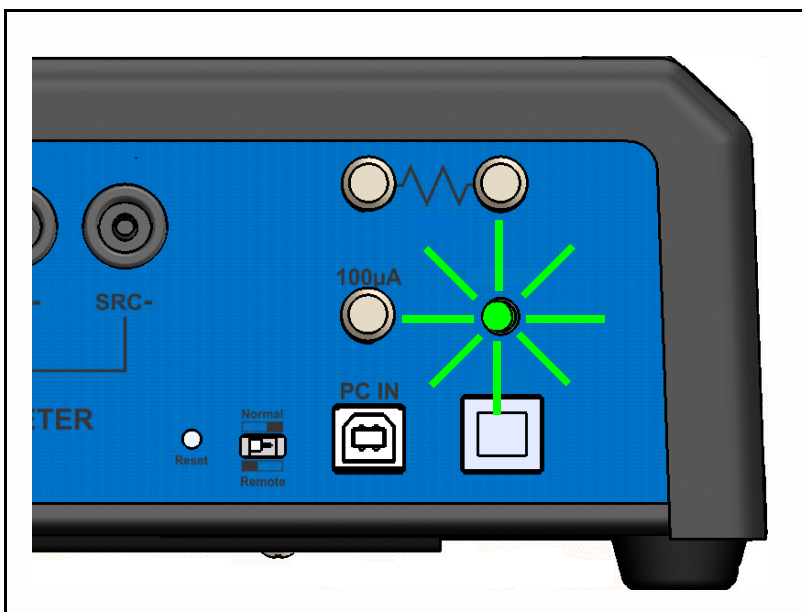


Figure 11

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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.

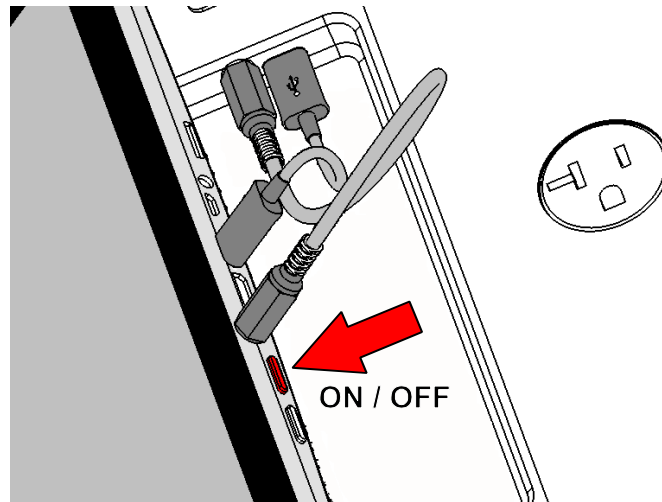


Figure 12

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 13*. If necessary, refer to the tablet operator manual provided with vPad-353 for further guidance.

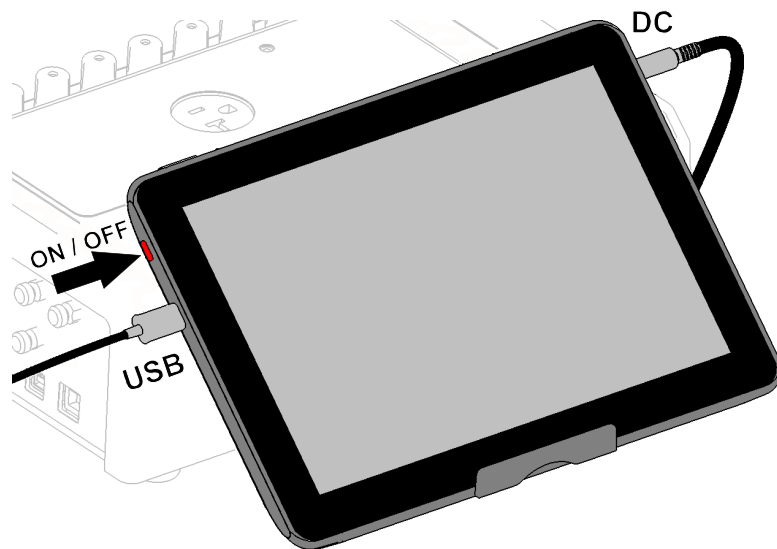


Figure 13

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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. This mode is useful when moving the vPad-353 between locations, and avoids the delay in starting from the Power OFF state.

To store or transport vPad-353, reverse the setup procedure by starting at ***Figure 10*** and proceeding to ***Figure 3*** above.

Chapter

4

4 Operation

This chapter explains how to use vPad-353 to perform electrical safety tests and inspections of medical equipment. Test Record management is also covered in this chapter.

4.1 HOME Screen

The Android HOME screen (*Figure 15*) is displayed approximately 60 seconds after switching the tablet ON.



Figure 15 - HOME screen.

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



Press to launch the vPad-353 software application, or "**app**". Use this app to perform electrical safety testing according to the IEC 62353 standard.



Press to launch the vPad-ES app. Use this app to perform electrical safety testing according to the IEC 60601 standard, or AAMI-ES1 standard. For full details on vPad-ES, refer to **MN-074 vPad-ES Operator Manual**, provided on the Android tablet.



Press to launch the vPad Record Manager app. Use this app to copy, print, convert or delete Test Records saved by vPad-353.



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



By default, vPad-353 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 top right on the screen, press the **Apps** button to access more apps which are installed on the tablet.



At bottom left on the screen, press the **Home** button to return from an app to the Home screen.



At bottom left, press the **Back** button 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.



At bottom left, press the **Recents** button to jump from the current app to a different app that was started earlier, but is currently on pause.

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-353 icon on the Android Home screen to start the app. A splash screen will display the product name and the software version.



Figure 16 - vPad-353 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 is also tested. Normally, all tests will complete successfully and the main activity of the 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 17**). Refer to TABLE 4.2-1 for recommended actions in the event of a startup alarm message.

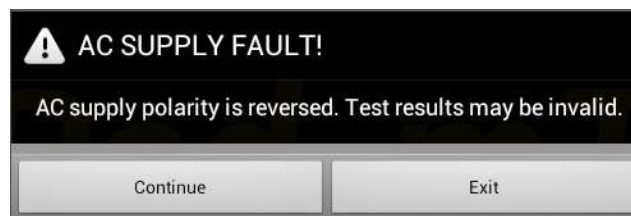


Figure 17 - Alert Dialog: AC supply fault.

TABLE 4.2-1: Startup Alarms and Corrective Actions

Alarm Message	Cause	Actions
ERROR: cannot communicate with Base Unit	App is unable to send messages to one or more instrument systems inside the Base Unit	<ul style="list-style-type: none"> • Check Base Unit has power (check power indicator, left panel - see Figure 1 on page 10) • Check Base-to-tablet USB connection (see Figure 9 on page 21) • If AC power and USB cables are OK, press and hold RESET button of Figure 1 for 3 seconds, then try restarting app • If error persists, contact Datrend Customer Service (see Chapter 5 for contact information)
AC SUPPLY FAULT (polarity reversed)	AC outlet incorrectly wired	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Press RESET button of Figure 1 for 3 seconds, then try restarting app • If problem persists, contact Datrend Customer Service (see Chapter 5 for contact information)

4.3 Test Navigation

After startup, the main menu of vPad-353 is displayed. Tabs the top of the screen navigate test modes provided by vPad-353. By default, vPad-353 selects the Voltage tab after startup. To select a different test mode, press the corresponding tab.

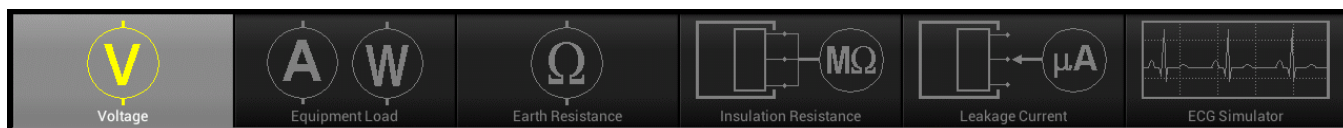


Figure 18 - Test Tabs.

4.4 Receptacle Control



This section contains important information which relates to operator safety. Read and follow all instructions.

Voltage, Resistance and Simulator test modes provide a button which you may press to switch the test receptacle ON or OFF as required. The Equipment Inspection menu also provides this control.



Figure 19 - Test receptacle power button.

For convenience, vPad-353 automatically switches the receptacle **ON** when you select the **Equipment Load** or **Leakage Current** mode.

By default, vPad-353 automatically switches the receptacle **OFF** if you change test mode to Voltage, Resistance, Insulation or ECG Simulator. If desired, this default behaviour can be overridden for the ECG Simulator mode via the vPad-353 Settings menu; refer to Section 4.10 for details.


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Android navigation buttons override the app display but do not necessarily **stop** what an app may be doing. If the test receptacle is **ON**, and you navigate away from vPad-353 by pressing:

Home  , or


Recent 

the test receptacle will remain **ON**. A characteristic of Android is that once an app such as vPad-353 is launched, the app *may keep running*, even if the app's display is partly or completely obscured by another app or the Android Home screen.

While viewing Voltage, Leakage and other test displays of vPad-353, the Android "Back" button  may be pressed to completely close the application. Since unsaved measurement data will be lost if vPad-353 is closed, a warning dialog is displayed which will allow you to exit or otherwise keep the application running. When vPad-353 is closed, the test receptacle is switched **OFF** automatically. Note the Android "Back" button is enabled on the test displays, but is disabled when viewing smaller pop-up menus such as Save Data, which typically have a dedicated "Cancel" button for exiting the pop-up.

For safest operation of vPad-353, follow these instructions:



- Before connecting or disconnecting equipment, observe the **Receptacle Active** lamp (*Figure 1*, page 10). Use caution when the **Receptacle Active** lamp is lit.
- Switch the test receptacle **OFF** when not in use
- Do not disable the Receptacle Auto-OFF setting unless the EUT or test requires that the AC supply must be continuously ON
- Before launching a new application, press the Android "Back" button  and respond "YES" to the displayed message. This will close vPad-353 and switch the test receptacle **OFF**.

4.5 Voltage Tests

Following application startup, vPad-353 defaults to measurement of the AC supply or "Mains Voltage", from Line 1 (L1) to Line (L2).

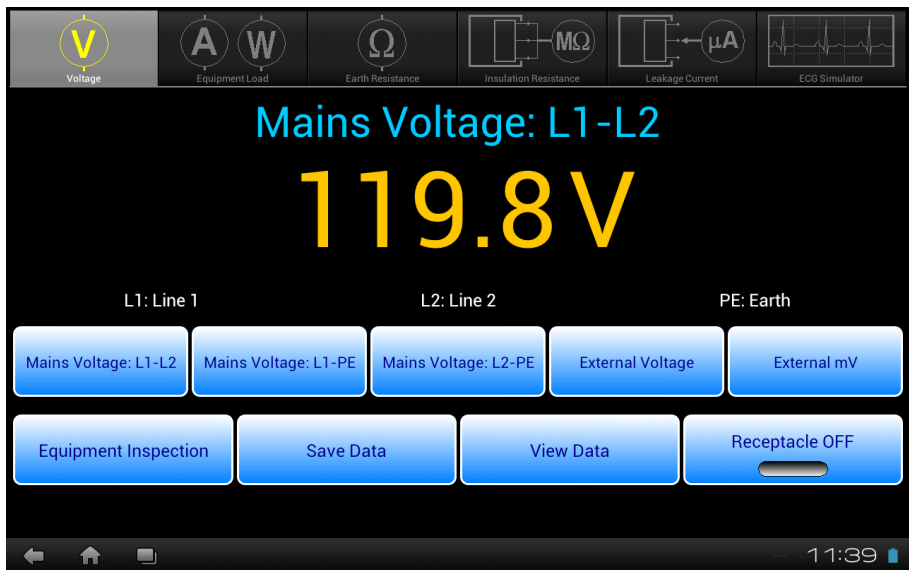


Figure 20 - Voltage test mode.

This test mode enables measurement of three different voltages associated with the AC supply, and two external or point-to-point voltages. As selected by the upper row of buttons, the voltage currently under test is indicated immediately above the numeric readout. Voltage is continuously measured and displayed until a different test mode is selected. The bottom row of buttons provides these functions:

<i>Equipment Inspection</i>	Press to launch the equipment inspection procedure. See Section 4.12 for instructions.
<i>Save Data</i>	Press to save the voltage measurement currently being displayed. Refer to Section 4.13 for instructions on data recording.
<i>View Data</i>	Press to review measurement data recorded during testing.
<i>Receptacle ON/OFF</i>	Press to switch the test receptacle ON or OFF as desired. Refer to Section 4.4 for important information and instructions concerning operation of the test receptacle.

Sections 4.5.1 to 4.5.3 provide instructions for the Voltage test mode.

4.5.1 Mains Voltage

Press the corresponding **Mains Voltage** button to measure the desired potential per *Figure 21* to *Figure 23*. No external test leads are necessary. Voltages are measured over a range of 90-264 VAC.

With respect to the illustrations, note the following:

- Line 1 (L1) = AC supply Hot (H)
- Line 2 (L2) = AC supply Neutral (N)
- Earth (E) = AC supply Ground (G)

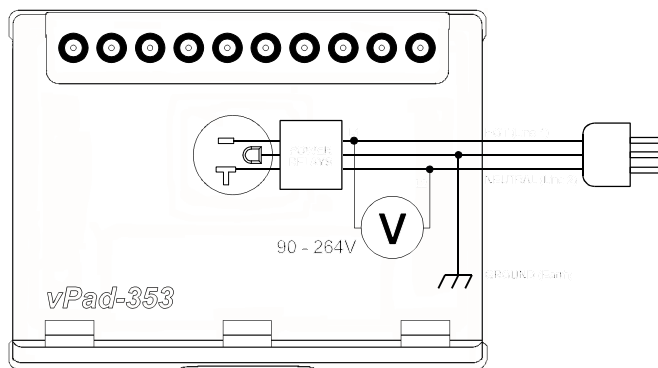


Figure 21: Line voltage test, L1-L2 (hot-neutral).

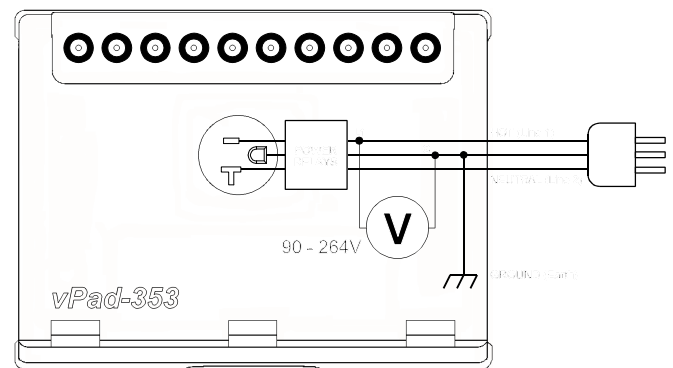


Figure 22: Line voltage test, L1-PE (hot-ground)

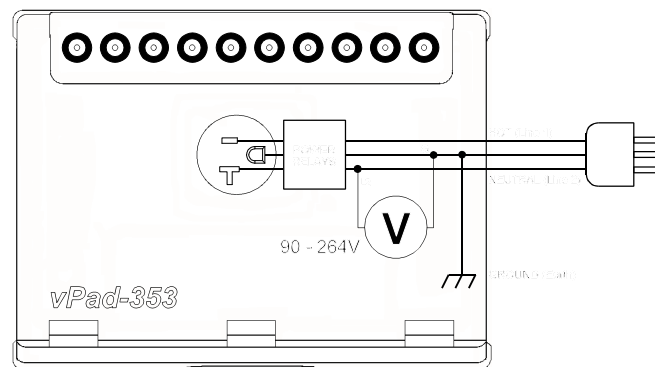


Figure 23: Line voltage test, L2-PE (neutral-ground)

If the AC supply which powers vPad-353 is correctly wired and is not connected to an isolated power distribution, potentials L1-L2 and L1-PE should be approximately equal, and potential L2-PE should be substantially smaller than L1-L2.

4.5.2 External Voltage

Press the **External Voltage** button to measure large voltages, typically greater than 20 Volts, between two arbitrary points, up to a maximum of 300V.

Connect test leads to the voltmeter at **EXT+** and **EXT-** jacks on the left panel of the Analyzer Base Unit. You may use standard multimeter (DMM) probes, or alternatively two vPad Kelvin Cables as respectively shown in *Figure 24* and *Figure 25* following.

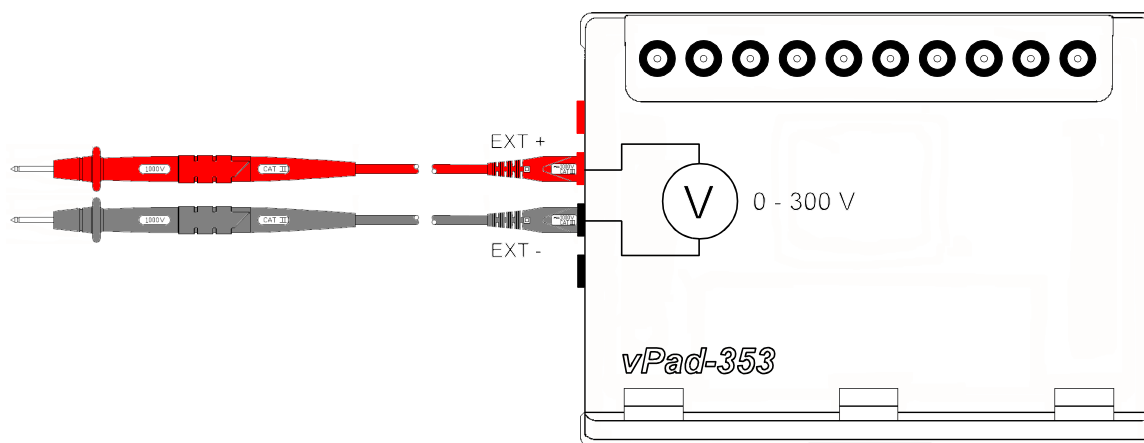


Figure 24: External voltage with two DMM probes

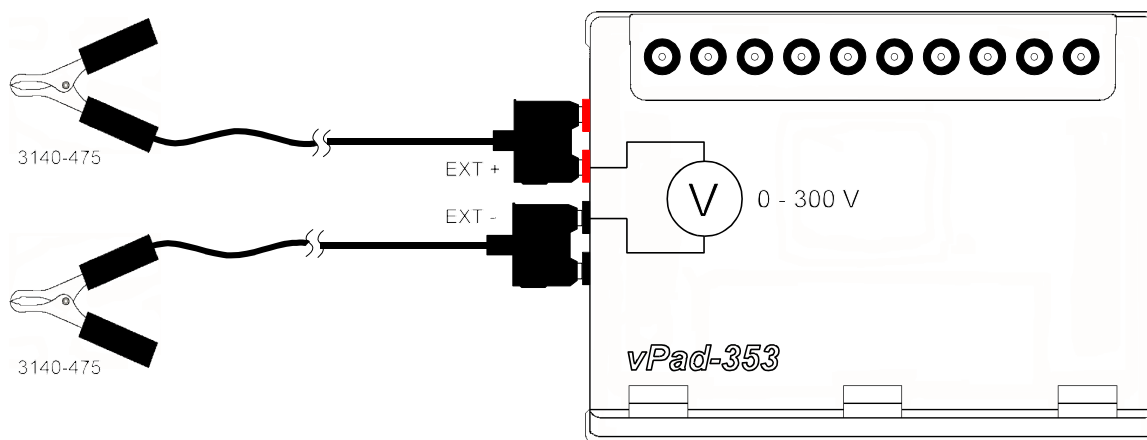


Figure 25: External voltage with two Kelvin Cables

4.5.3 External Micropotential

Press the **External mV** button to measure small potentials in the millivolt range between two arbitrary points, up to a maximum of 20V.

When you select this test, an Alert Dialog is displayed to remind you of vPad-353 maximum ratings. Press "OK" to clear the Alert Dialog and begin testing, or "Cancel" to abort and return to the previous test mode.

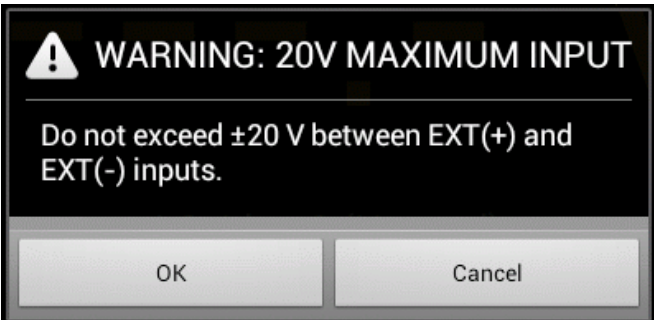



Figure 26 - Alert Dialog - maximum input 20V.



Exceeding specified maximum ratings may result in damage to vPad-353 and is not covered by warranty.

Connect test leads to the voltmeter at **EXT+** and **EXT-** jacks on the left panel of the Analyzer Base Unit. You may connect to external points using two standard multimeter (DMM) probes, or two vPad Kelvin Cables as shown in **Figure 27**. If points are less than 1" (2 cm) apart, a single Kelvin Cable may optionally be used, as shown in **Figure 28**.

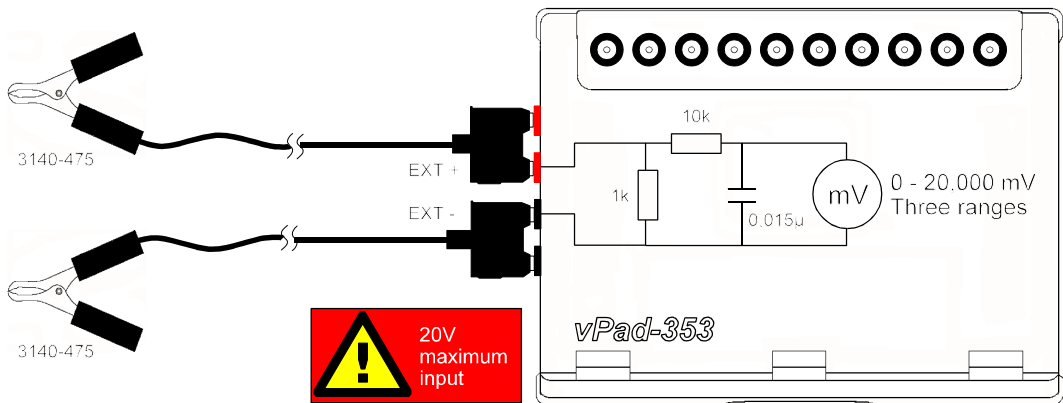


Figure 27: External micropotential with 2 × Kelvin Cable

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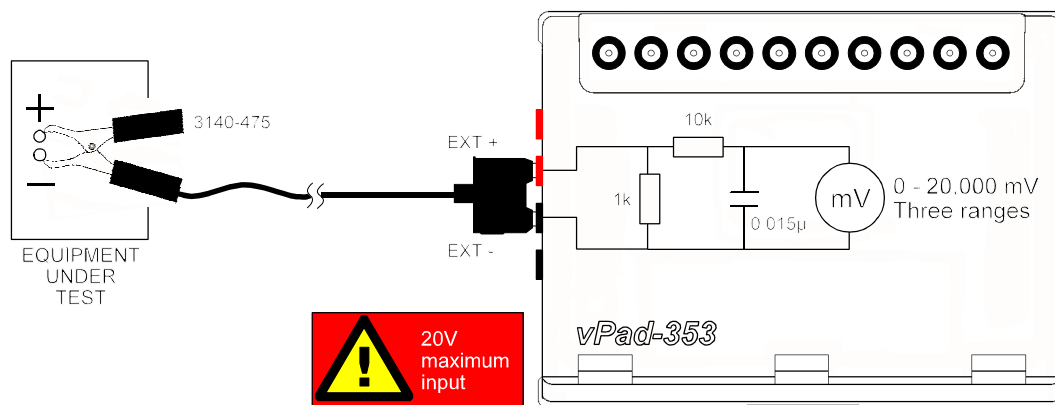


Figure 28: External micropotential test with one Kelvin Cable

According to the above schematics, external micropotential is measured with an IEC measuring device. Range is automatically selected by vPad-353 to suit the voltage being measured (200, 2000 or 20000 mV full scale).

4.6 Equipment Load Tests

Select the **Equipment Load** test mode by pressing the corresponding tab at the top of the screen. When this mode is selected, the test receptacle is switched **ON** automatically. Refer to Section 4.4 for important information and instructions concerning operation of the test receptacle.

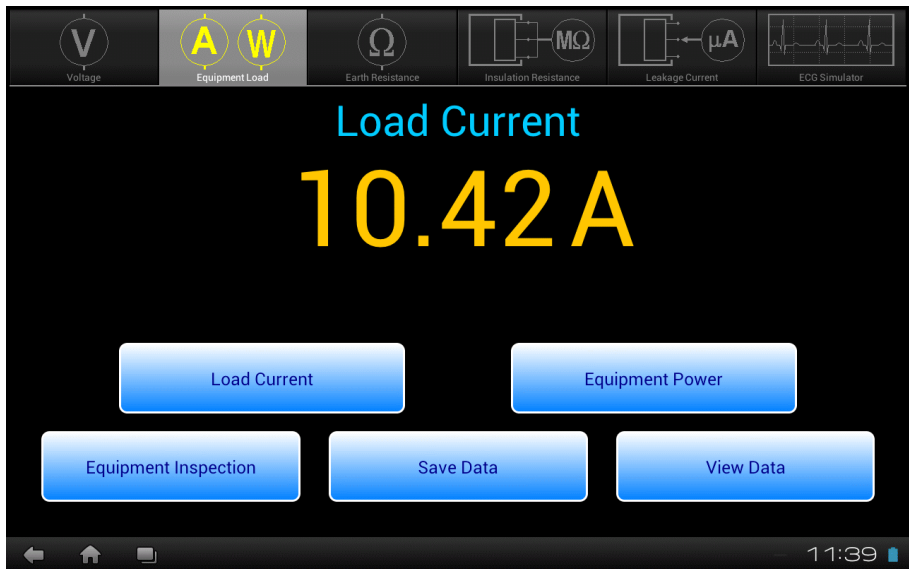


Figure 29 - Load test mode.

This test mode enables you to measure the AC supply current of the equipment under test (EUT), and the power consumption. The upper two buttons select the test, which is indicated immediately above the numeric readout. AC current or power is continuously measured and displayed until a different test mode is selected. The bottom row of buttons provides these functions:

<i>Equipment Inspection</i>	Press to launch the equipment inspection procedure. See Section 4.12 for instructions.
<i>Save Data</i>	Press to save the measurement value currently being displayed. Refer to Section 4.13 for instructions on data recording.
<i>View Data</i>	Press to review measurement data recorded during testing.

Sections 4.6.1 and 4.6.2 provide instructions for the Equipment Load test mode.

4.6.1 Load Current

Connect the EUT to the test receptacle and press the **Load Current** button to place an AC ammeter in series with the EUT (**Figure 30**). No external test leads are necessary. AC current is measured up to 2A or 20A, with the range being automatically selected by vPad-353 as required.

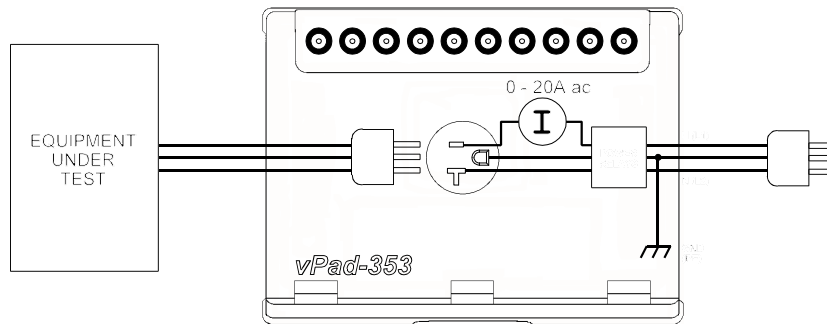


Figure 30: Load current test

4.6.2 Power Consumption

With the EUT connected to the test receptacle, press the **Equipment Power** button to measure EUT power consumption (**Figure 31**). No external test leads are necessary. vPad-353 derives power by measuring the load current, then the line voltage L1-L2, and multiplying the results: power = voltage x current.

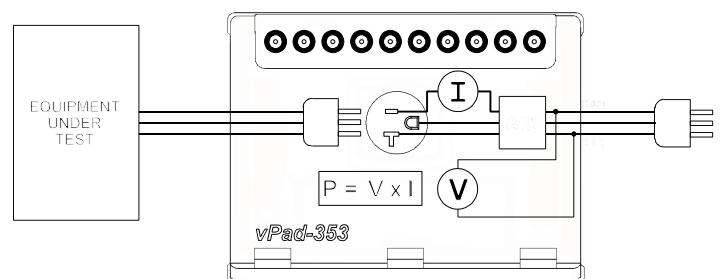


Figure 31: Power consumption test

Considering specified tolerances of voltage and current measurements, this test mode is most useful when measuring loads which draw 50W of power or higher. Examples would include lamps, heaters, ovens, fans and other equipment incorporating larger induction motors or pumps.

4.7 Earth Resistance Tests

Select the **Earth Resistance** test mode by pressing the corresponding tab at the top of the screen.



Figure 32 - Resistance test mode.

This mode enables measurement of the resistance of the line cord which conveys AC power to the equipment under test (EUT). Point-to-point (External) resistance may also be measured. The upper two buttons select the resistance test mode, which is then indicated immediately above the numeric readout. Resistance is continuously measured and displayed until a different test mode is selected. The bottom row of buttons provides these functions:

Equipment Inspection	Press to launch the equipment inspection procedure. See Section 4.12 for instructions.
Save Data	Press to save the resistance value currently being displayed. Refer to Section 4.13 for instructions on data recording.
View Data	Press to review measurement data recorded during testing.
Receptacle ON/OFF	Press to switch the test receptacle ON or OFF as desired. Refer to Section 4.4 for important information and instructions concerning operation of the test receptacle. For safety, this button is disabled when measuring resistance of the EUT power cord.

Sections 4.7.1 and 4.7.2 provide instructions for the Resistance test mode.

4.7.1 Protective Earth Resistance

Press the **Protective Earth Resistance** button to measure the resistance of the line cord, from the EUT chassis to the ground pin on the plug of the EUT's line cord. This test is the default on entry to the **Earth Resistance** mode.

An Alert Dialog is displayed if the test receptacle is **ON** when this test is selected. Press "**OK**" when you are ready to power down the EUT and proceed with the resistance test.

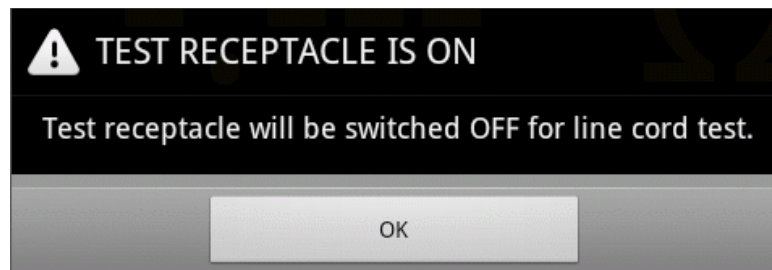


Figure 33 - Alert Dialog - EUT will be powered OFF for test.

Connect the EUT line cord to the test receptacle. Plug the vPad Kelvin Cable into **SRC+** and **EXT+** jacks on the left panel of the Analyzer Base Unit, then connect the Kelvin Cable to a protectively earthed terminal or conductive point on the EUT chassis (*Figure 34*).

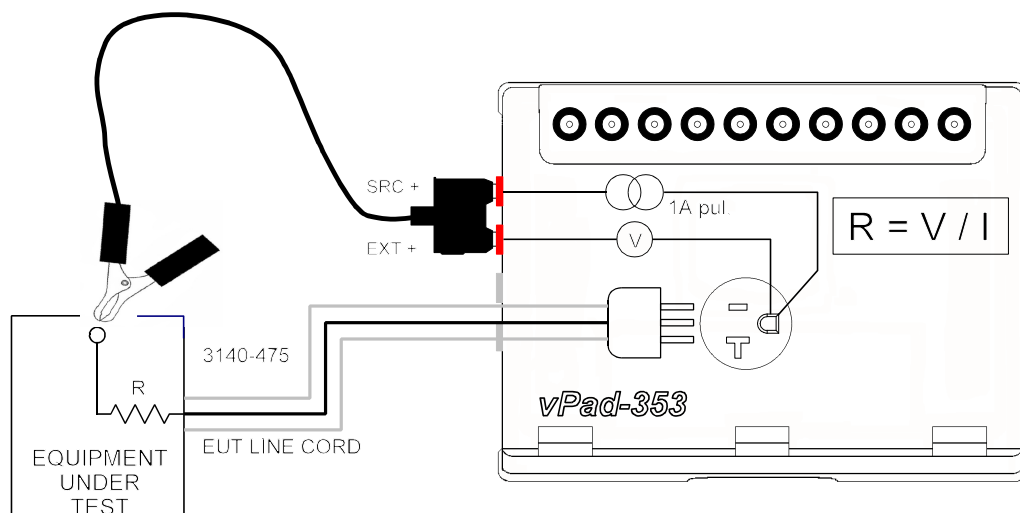


Figure 34: Protective earth resistance test

Resistance is measured up to 2 Ω . If vPad-353 indicates **X.XX**, the resistance exceeds 2 Ω and may be open-circuit. When the display shows **X.XX**, a poor connection to the EUT chassis may be the problem; inspect the attachment of the Kelvin Cable or move the cable to a different point on the chassis.

Note: all exposed metal is not necessarily connected to protective earth.

Avoid connecting the Kelvin Cable to "functional earth" (FE) terminals on the EUT. FE terminals are zero-reference points for EUT input/output signals, and are not intended to provide protective grounding of medical equipment. Examples of FE include the grounded shell or frame of connectors used for computer interface (e.g. RS-232 Port; USB Port; etc.)

4.7.2 External Resistance

Press the **External Resistance** button to measure resistance between two arbitrary points. In this mode, the receptacle ON/OFF button is enabled so that the EUT may be powered up, if desired.



Figure 35 - External Resistance test

This test requires two vPad Kelvin Cables, connected as shown in **Figure 36**. Resistance up to 2 Ω may be measured. As with the line cord test, high resistance or open-circuit conditions are represented by **X.XX** on the display; inspect the attachment of the Kelvin Cables in this case.

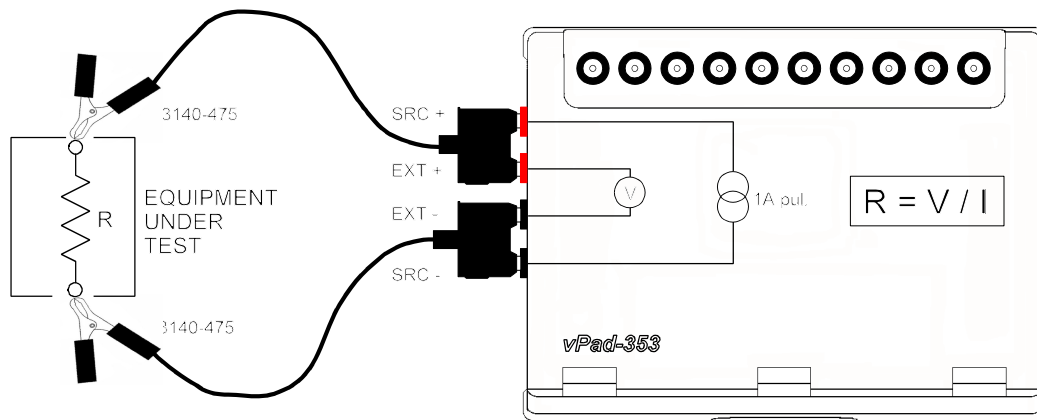


Figure 36: External (point-to-point) resistance test

4.7.3 Measurement Method

Referring to **Figure 34** and **Figure 36**, vPad-353 uses a "four-wire method" when measuring line cord or point-to-point resistance. Not apparent from the schematics are two separate insulated conductors in the Kelvin Cable, one conductor conveying a current (I) to the resistance under test (R), and the other conductor conveying voltage (V), caused by the current (I), to a voltmeter. For a known or measured current (I) and a measured voltage (V), resistance can then be calculated as $R = V / I$. The four-wire method is preferred for measurement of small resistance values, since error caused by internal resistance of the test leads is eliminated.

The four-wire ohmmeter of vPad-353 uses a pulsed 1A (200 mA rms) current source. Both the current source and the voltmeter of vPad-353 are "floating", that is, isolated from the ground of the AC supply. This permits vPad-353 to be used for measuring resistance between any two points, grounded or otherwise.

4.7.4 Test Application

If medical equipment is not double-insulated (IEC Class II), resistance of the line cord should be tested to at least one point of contact, or preferably to several different points, on the equipment chassis. Additionally, it may be necessary to test continuity from one conductive part of the equipment to another, for example, across the articulation points of a hospital bed.

The maximum protective earth resistance permitted by the IEC 62353 standard appears in TABLE 2.3-3 of Section 2.3, and is represented on the test display as "Limit: 0.300 Ω". Resistance measurements which exceed this limit will cause a "FAIL" indication to be displayed to the right of the measurement. Indications of "X.XX" are assumed to be open-circuit and so are also assigned a "FAIL". Otherwise, the measurement is assigned a "PASS" as shown in the example figures above.

4.8 Insulation Resistance Test

Select the **Insulation Resistance** test mode by pressing the corresponding tab at the top of the screen. When this mode is selected, the test receptacle is switched **OFF** automatically. Refer to Section 4.4 for important information and instructions concerning operation of the test receptacle.

Note: Set the power switch of the EUT to the "ON" position when performing insulation tests. A reminder will be displayed on the screen when this test mode is initially selected.

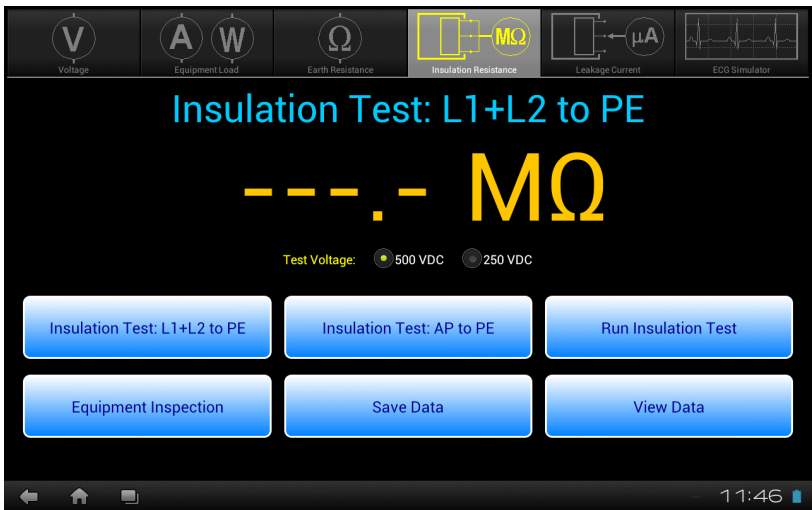


Figure 37- Insulation test mode.

This test mode enables measurement of the insulation resistance between EUT Line 1 and Line 2 to Earth (L1+L2 to PE), or alternatively all Applied Parts (AP) to PE. The test may be performed at 500 VDC or 250 VDC, as selected by the radio buttons on the display, just above the test buttons. The measurement is performed when the **Run Insulation Test** button is pressed. The bottom row of buttons provides these functions:

Equipment Inspection	Press to launch the equipment inspection procedure. See Section 4.12 for instructions.
Save Data	Press to save the resistance value currently being displayed. Refer to Section 4.13 for instructions on data recording.
View Data	Press to review measurement data recorded during testing.

4.8.1 Insulation Test: L1+L2 to PE

Press the **Insulation Test: L1+L2 to PE** button to measure insulation resistance between the Mains Part of the EUT (L1+L2) and the EUT's protective earth terminal (PE). A test voltage of either 500V or 250V may be used, with 500V being the default upon selection of the Insulation Test mode.

To prepare for the test, simply connect the EUT to the test receptacle. No external test leads are necessary.

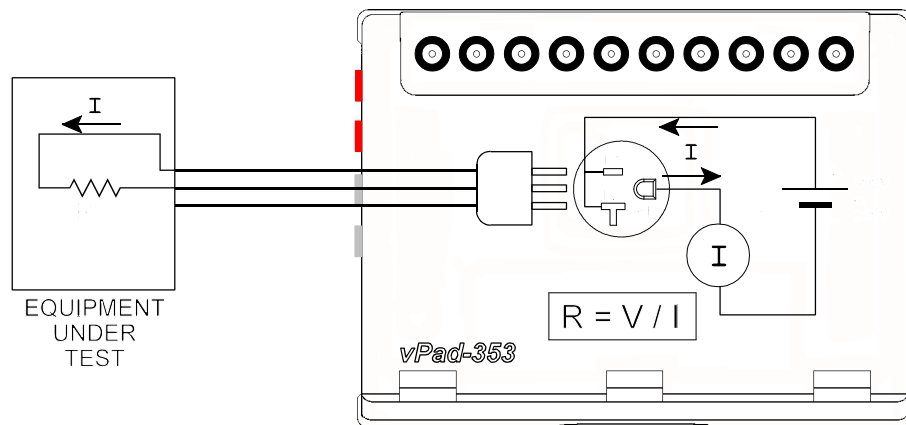


Figure 38 - Insulation Resistance test - Mains Parts to Protective Earth

With the EUT connected to vPad-353, press the **Run Insulation Test** button to make the measurement. During the measurement, the screen of **Figure 39** will be displayed, indicating the High Voltage (250 or 500 VDC) has been applied.

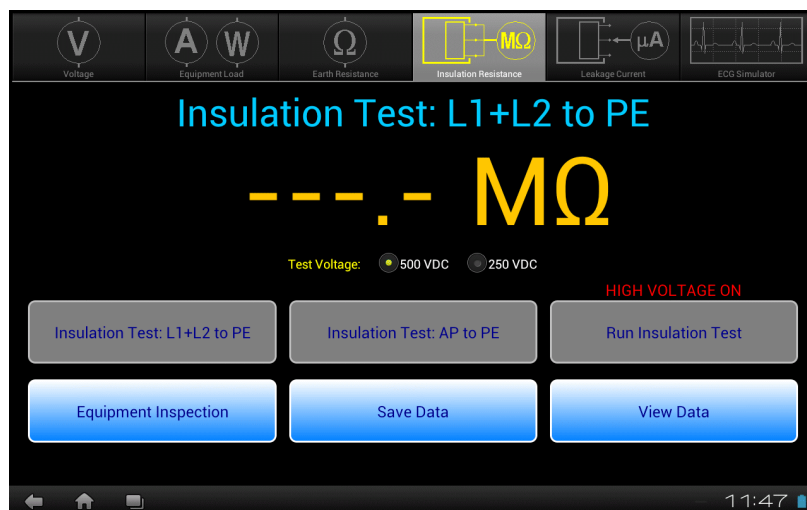


Figure 39 - Insulation Resistance test - RUN

After 2 to 3 seconds, the measured result will be displayed on the screen, as in *Figure 40*.

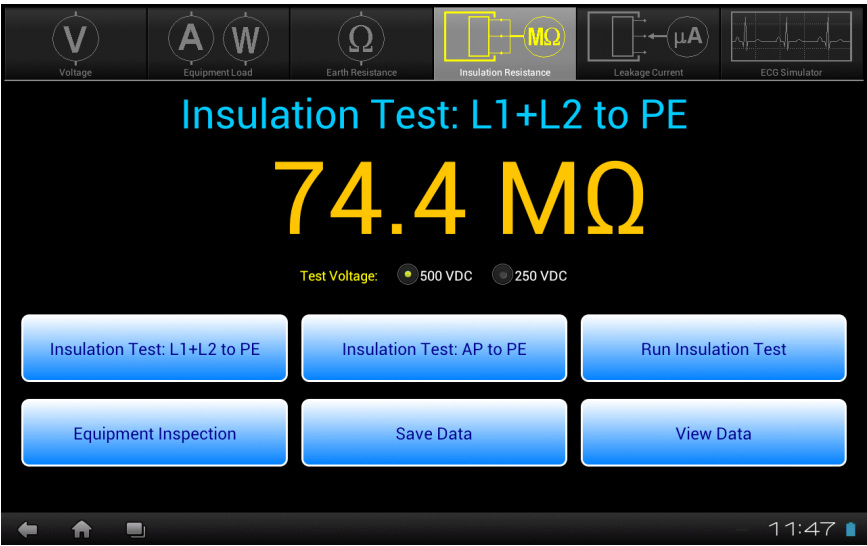


Figure 40 - Insulation Resistance test result

4.8.2 Insulation Test: AP to PE

Referring to the display screen shown in *Figure 37*, the **Insulation Test: AP to PE** button may be used to enable measurement of resistance between the EUT's Applied Parts (AP) and its protective earth terminal (PE). This is represented in the schematic of *Figure 41*.

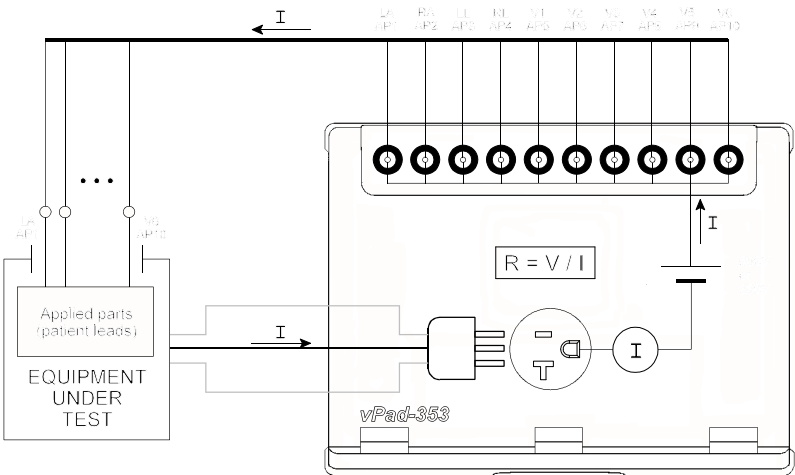


Figure 41 - Insulation Resistance test - Applied Parts to Protective Earth

vPad-353 OPERATORS MANUAL

To prepare for the test, connect the EUT power cord to the test receptacle and connect all Applied Parts of the EUT to the corresponding binding posts of vPad-353 (refer to Section 4.9.2 for details on connecting EUT patient leads to the binding posts). When the **Run Insulation Test** button is pressed, vPad-353 will apply the high voltage to the Applied Parts and measure the resistance to PE of the EUT, as described earlier for the L1+L2 to PE measurement.

4.8.3 Test Application

Before IEC standards were published, some countries had standards for testing the insulation of medical equipment. At the time, it was not possible to measure leakage current with acceptable accuracy, and so resistance of the equipment insulation was measured instead of current through the insulation.

The IEC 62353 standard does not specify an acceptance limit for insulation resistance, although some other standards do. Insulation resistance measurement is included in IEC 62353 since the test may be helpful in addition or instead of leakage current measurement for certain components or equipment, such as heating elements which may show changes in insulation characteristics with temperature.

The IEC 62353 standard recommends that insulation resistance should be checked periodically. Over time, a significant decrease in the resistance would then provide a rationale for further investigation of the equipment or a reduction in test interval.

4.9 Leakage Current Tests

Select the **Leakage Current** test mode by pressing the corresponding tab at the top of the screen. When this mode is selected, the test receptacle is switched **ON** automatically, in the **NORMAL** condition. Refer to Section 4.4 for important information and instructions concerning operation of the test receptacle.



Figure 42 - Leakage test mode.

Note that prior use of the External Voltage test function (Section 4.5.2) will cause a warning to be displayed when Leakage test mode is initially selected. This warning prompts to user to confirm that a source of high voltage, which could have been under test by the External Voltage function and which could damage the safety analyzer if still active, has been disconnected from the EXT(+) input jack. The leakage meter of vPad-353 is not activated until the user acknowledges this warning with the "Continue" button.

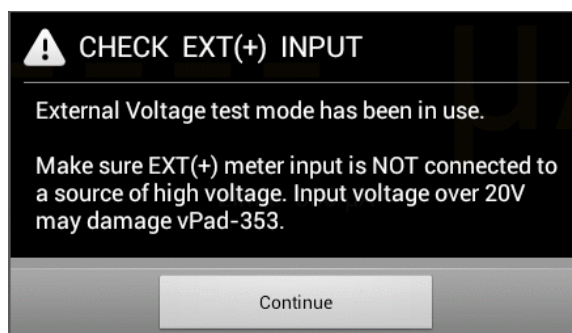


Figure 43 - Warning - check EXT(+) input.

The Leakage test mode enables measurement of Equipment and Applied Part Leakage currents. As selected by the upper row of buttons, the leakage under test is indicated immediately above the numeric readout. The selected leakage current is continuously measured and displayed until a different test mode is selected. The bottom row of buttons provide these functions:

<i>Equipment Inspection</i>	Press to launch the equipment inspection procedure. See Section 4.12 for instructions.
<i>Save Data</i>	Press to save the leakage value currently being displayed. Refer to Section 4.13 for instructions on data recording.
<i>View Data</i>	Press to review measurement data recorded during testing.
<i>Polarity</i>	Press to toggle the polarity of the test receptacle between "Normal" and "Reverse" conditions.

Sections 4.9.1 and 4.9.2 provide instructions for the **Leakage Current** test mode.

4.9.1 Equipment Leakage

Press the **Equipment Leakage** button to measure leakage current from the enclosure and the applied parts of the EUT to earth of the AC mains supply. **Equipment Leakage** is the default upon selection of the Leakage test mode.

To prepare for the test, connect the power cord of the EUT to the test receptacle, and use the vPad Kelvin Cable to connect a conductive, protectively earthed point on the EUT chassis to the **EXT+** jack on the left of the Base Unit (see *Figure 44*). If the EUT has applied parts or patient leads, connect them to the corresponding binding posts of vPad-353 as shown in the figure (refer to Section 4.9.2 for details on connecting EUT patient leads to the binding posts). If the EUT has unearthed conductive parts, use a test jumper lead to connect such unearthed parts to the point where the Kelvin Cable is attached to the EUT, or alternatively to AP10 or other unused applied part binding post on the vPad-353 (for more information, see Section 4.9.3). During the test, leakage current is measured over three ranges (200, 2000 or 20000 μ A full scale), with range being automatically selected by vPad-353 as required.

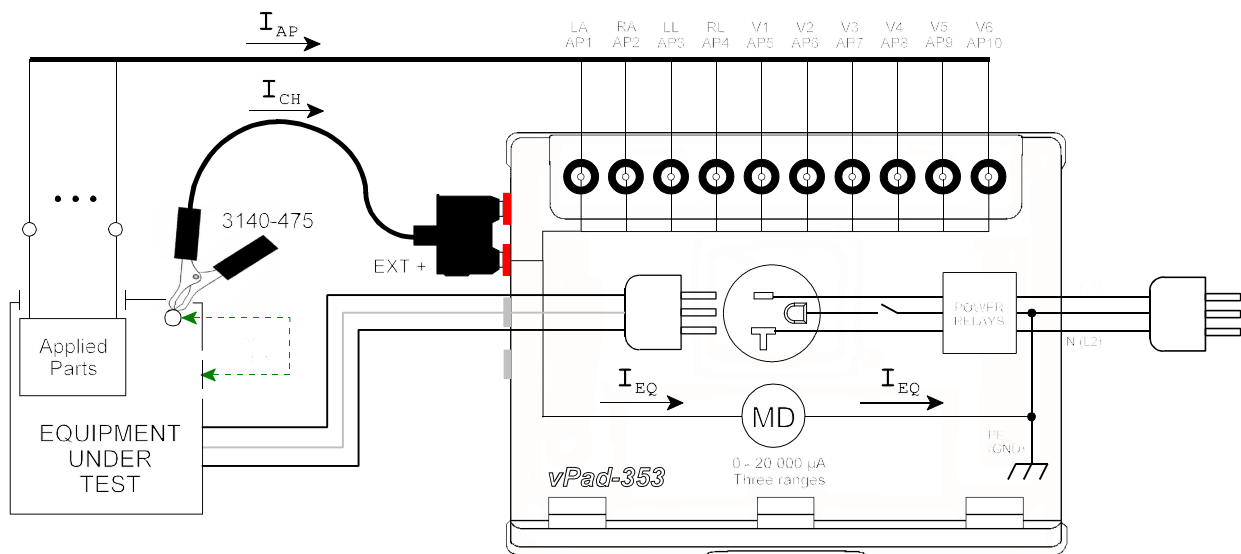


Figure 44 - Equipment leakage test.

During measurement of **Equipment Leakage**, the **MAP Voltage** button is disabled, as this test setting is applicable only to the **Applied Part Leakage** test. **Equipment Leakage** may be measured with the test receptacle in Normal condition and in Reverse Polarity condition. When **Polarity** is changed, the test receptacle is switched OFF for a period of time, after which the receptacle is then re-activated at the new polarity (see **Figure 45**). During the delay, the **Polarity** control is disabled. This time delay is necessary to prevent surges in supply current which could potentially damage the EUT and/or the vPad-353. When **Polarity** is changed, a user-selectable delay applies which may be set, using the **Settings** function, over a range of 2 to 8 seconds; refer to Section 4.10 for details.

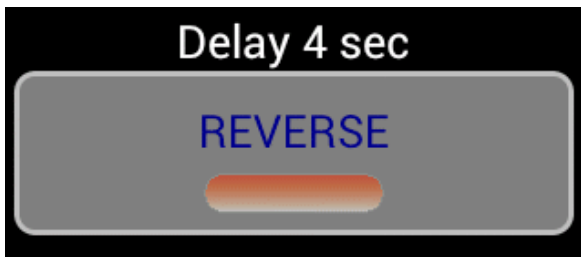


Figure 45 - Polarity change in progress.

4.9.2 Applied Part Leakage

Referring to the display screen shown in **Figure 46**, the **Applied Part Leakage** button may be used to enable testing of EUT patient leads or "Applied Parts" in various combinations or groups, according to the medical functions provided by the EUT. In this test, leakage is produced by applying an isolated AC voltage to the selected patient leads, where the voltage is equal to the mains supply.

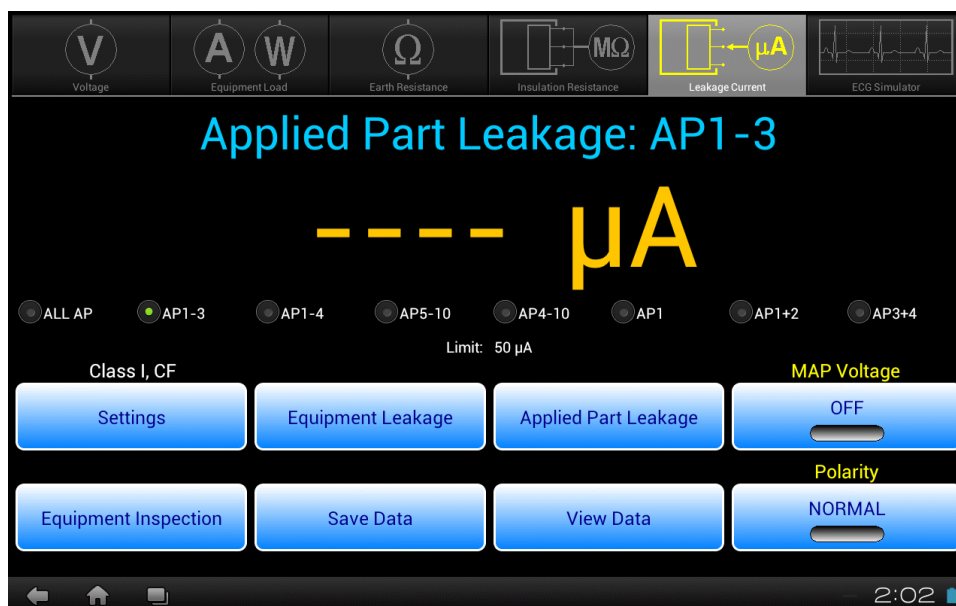


Figure 46 - Applied Part leakage display.

The test setup is represented in the schematic of **Figure 47**, in which switches S_1 through S_5 correspond to the Applied Part (AP) radio buttons on the menu of **Figure 46**. Pressing the **Settings** button of **Figure 46** allows you to choose the Type of Applied Parts (BF or CF), which then affects the leakage limit that is indicated below the Applied Part radio buttons.

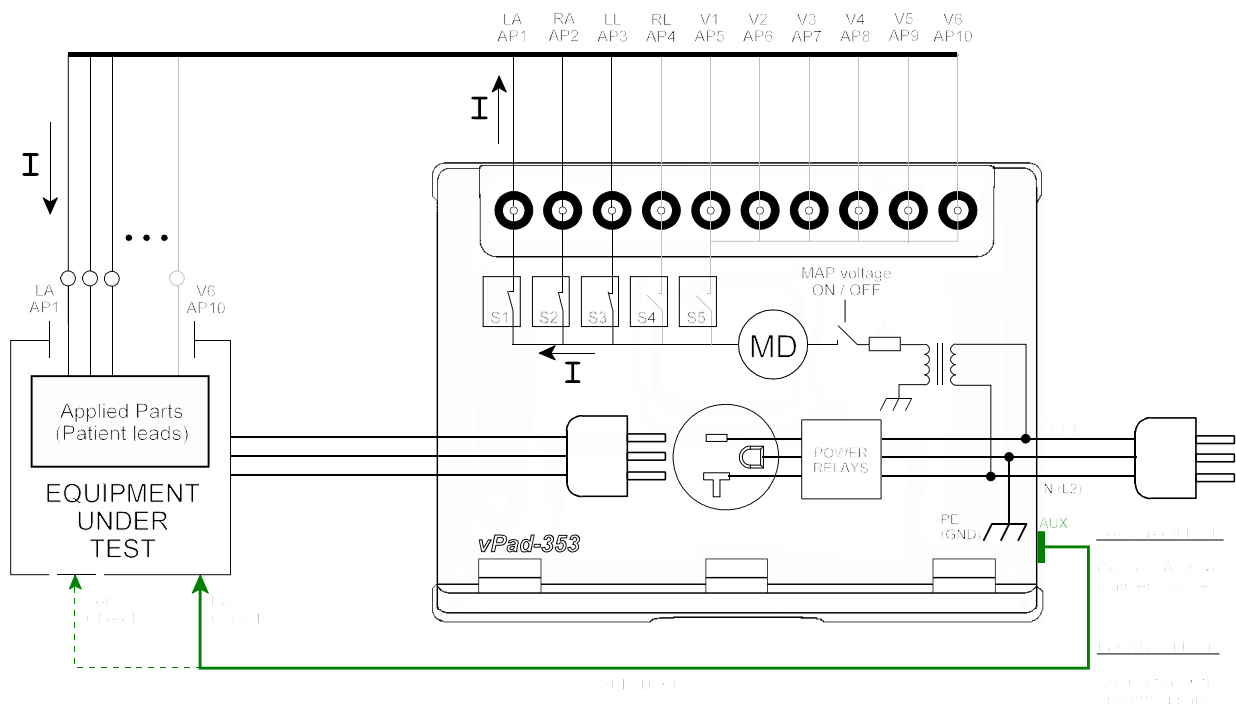


Figure 47 - Applied Part leakage test (AP1 to AP3).

To prepare for the test, connect the power cord of the EUT to the test receptacle, and connect the EUT patient leads to the corresponding binding posts of vPad-353 as shown in **Figure 47**. If the EUT is Class II (two-wire power cord), use a jumper lead to connect the green "AUX" test jack on the right side of the Base Unit to the EUT enclosure. If the EUT is Class I (three-wire power cord), and the EUT has unearthed conductive parts, use a jumper lead to connect the "AUX" jack to these unearthed parts. See Section 4.9.3 for more information.

Binding posts of vPad-353 operate according to **Figure 48**: for patient leads terminated in a 3 mm or 4 mm banana plug, press the spring-loaded collar of the binding post down to expose the receptacle inside, insert the plug, then release to secure the plug in place (**Figure 48 - (b)**). If testing ECG snap on leads, press the collar of the binding post down then rotate clockwise to lock in place, exposing the male button (**Figure 48 - (c)**). ECG snap connectors may then be attached to the buttons. Follow the markings on the vPad-353 label when connecting ECG leads (LA; RA; LL; RL and V1-V6).

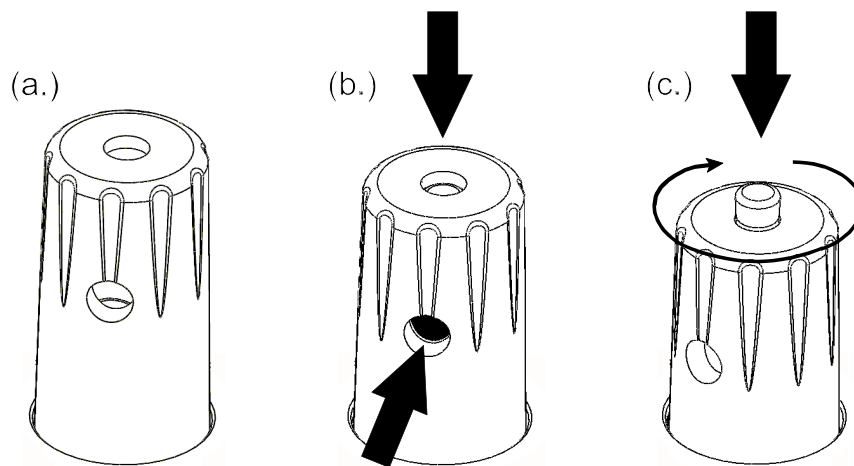


Figure 48 - Operation of binding post.

Press the **MAP Voltage** button on the display of *Figure 46* to initiate a leakage test of the selected Applied Parts. Leakage current is measured over three ranges (200, 2000 or 20000 μA full scale) while the test voltage is being applied, with the range being automatically selected by vPad-353 as required. This test may be performed with the mains polarity in either Normal condition or Reverse condition.

For the user's safety, the AC test voltage will be applied for a maximum of 20 seconds, after which the voltage will then be switched off. To continue testing, simply press the **MAP Voltage** button after the 20 second timeout. Different Applied Part groups may be selected while the test voltage is active. While the Leakage Current is displayed, it may be saved using the **Save Data** button.

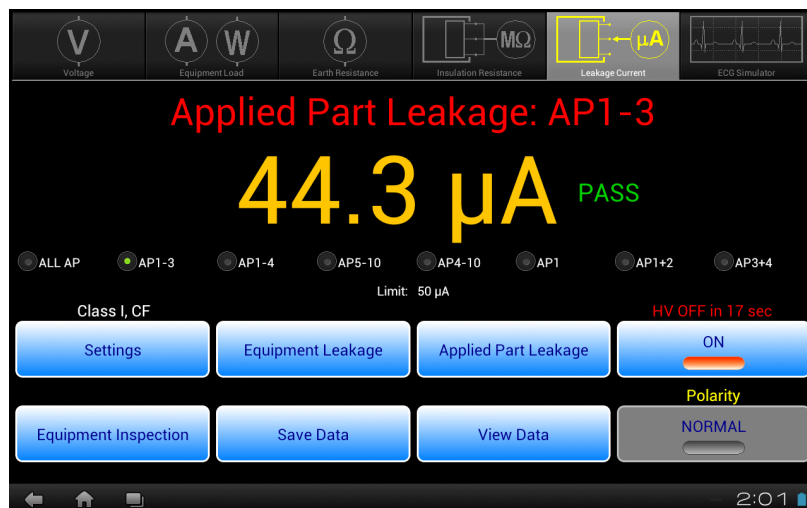


Figure 49 - Applied Part leakage - MAP voltage ON.

4.9.3 Test Application

At a minimum, equipment leakage of medical equipment should be tested with the equipment ON and the AC mains in normal polarity and in reverse polarity. In this case, the number of measurements performed will be two. Test leakage with equipment in all intended functional conditions (i.e. switch positions) that influence the leakage current. If the functional condition that produces the highest leakage is not known, test with the EUT power switch set to OFF position, in addition to the equipment-ON tests. For non-conductive equipment enclosures, apply tin foil onto the enclosure and attach the Kelvin Cable to the foil.

If the equipment has conductive parts which are not earthed, but which could contact a person, such parts should be included in the equipment leakage test. To do so, use a test jumper lead to connect such conductive parts to the same point on the equipment enclosure where the Kelvin Cable is attached. Alternatively, it may be more convenient to connect unearthed conductive parts to an unused applied part binding post of the vPad-353 (e.g., AP10). Referring to **Figure 44**, leakage from unearthed parts is then combined with chassis and applied part leakages to produce the total equipment leakage.

Applied Parts leakage tests will depend on the EUT, and the number and type of applied parts it has. Per IEC 62353, each medical function provided by the EUT is to be tested separately, with all patient leads or connections of the medical function tested as a group.

For example, a portable patient monitor may provide three ECG leads (LA; RA; and LL) and two invasive blood pressure channels (IBP-1 and IBP-2). To test this patient monitor, LA, RA and LL are respectively connected to binding posts AP1, 2 and 3 of vPad-353, and IBP-1 and -2 are respectively connected to AP4 and 5. ECG leakage is measured by pressing the **AP1-3** radio button on the display of **Figure 49**, and IBP leakage is measured by pressing the **AP4-10** radio button. Per IEC 62353, each group of applied parts should be tested with AC mains in normal polarity and in reverse polarity, with equipment power switch set to ON position and to OFF position.

If the equipment is Class II (two-wire power cord), a test jumper lead must be used to connect the enclosure of the equipment to the "AUX" jack of the vPad-353, as shown in **Figure 47**. If the "AUX" connection is omitted when testing applied parts of Class II equipment, then no leakage current will be measured.

If the equipment is Class I (three-wire power cord), and the equipment has unearthed conductive parts which may contact a person, then such parts should be connected to the earth when measuring leakage of the applied parts. A convenient way to accomplish this is to use a test jumper lead to connect such unearthed parts to the "AUX" jack of the vPad-353, according to **Figure 47**.

The limits for leakage current tests are defined in the IEC 62353 standard, per TABLE 2.3-3 of Section 2.3. The measured values will be assessed according to those limits, and a PASS or FAIL assessment will be recorded with the measurements.

4.10 Leakage Settings

Press the **Settings** button on the **Leakage Test** mode screen to enter the Leakage Settings menu, shown below.

Leakage Settings

Equipment Specification

ME Class
Specify shock protection by PE conductor (Class I)
or by double-insulation (Class II)

Applied Parts
Specify body floating (BF) or cardiac floating (CF)

Test Receptacle

Polarity Delay
Select polarity switching delay

Receptacle Auto-OFF
Switch receptacle OFF when changing test
to Voltage, Resistance or ECG Simulator ☒

Exit

Figure 50 - Leakage settings menu.

At the bottom of the menu, the **Receptacle Auto-OFF** setting determines behaviour of the test receptacle when changing test modes. For convenience, vPad-353 automatically switches the test receptacle ON when Equipment Load, Leakage or Patient Lead test mode is selected. When changing to Voltage, Resistance or Simulator mode, the test receptacle will be automatically switched OFF if **Auto-OFF** is checked, as shown in **Figure 50**. If Auto-OFF is not checked, when changing modes the test receptacle will be switched OFF only if the receptacle is in reverse polarity condition, otherwise the receptacle will remain ON as modes are changed.

The default is **Auto-OFF** enabled; disable **Auto-OFF** only for special situations where repeated application and removal of power to the EUT must be avoided.

To view or change a setting other than **Auto-OFF**, press the corresponding row on the menu (**ME Class**; **Applied Parts**; or **Polarity Delay**).

The **ME Class** setting (*Figure 51*) allows you to choose the Class (I or II) of the EUT. This will affect the pass/fail limit which is applied to Equipment Leakage measurements. Press the radio button corresponding to the desired Class, or **Cancel** to exit without changing the setting. Note the selected Class is indicated above the **Settings** button on the Leakage display.

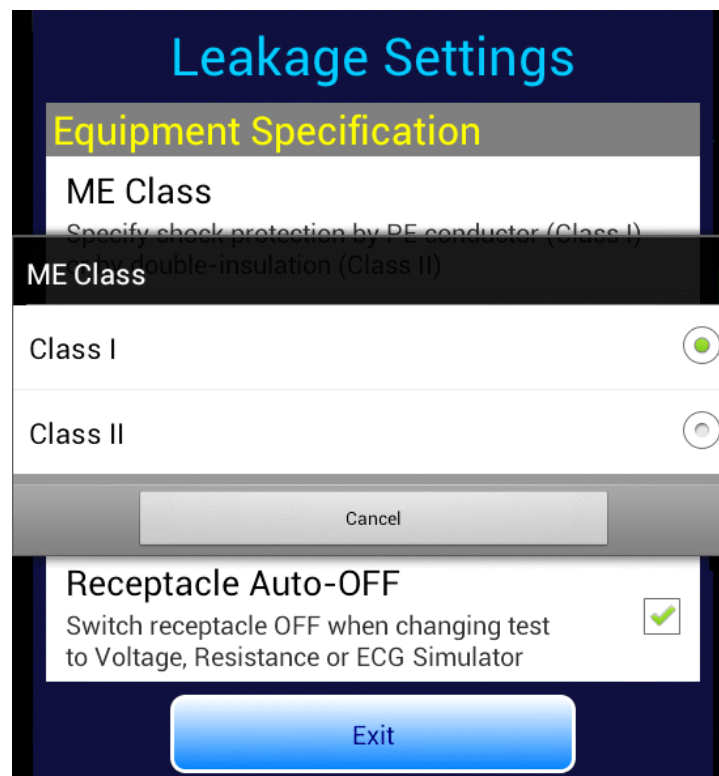


Figure 51 - Set medical equipment class.

The **Applied Parts** setting (*Figure 52*) allows you to select a part Type (BF or CF). This will affect the pass/fail limit which is applied to Applied Part leakage measurements. Press the radio button to select the applicable part Type, or **Cancel** to exit without changing the setting. Note the selected part Type is indicated above the **Settings** button on the Leakage display.

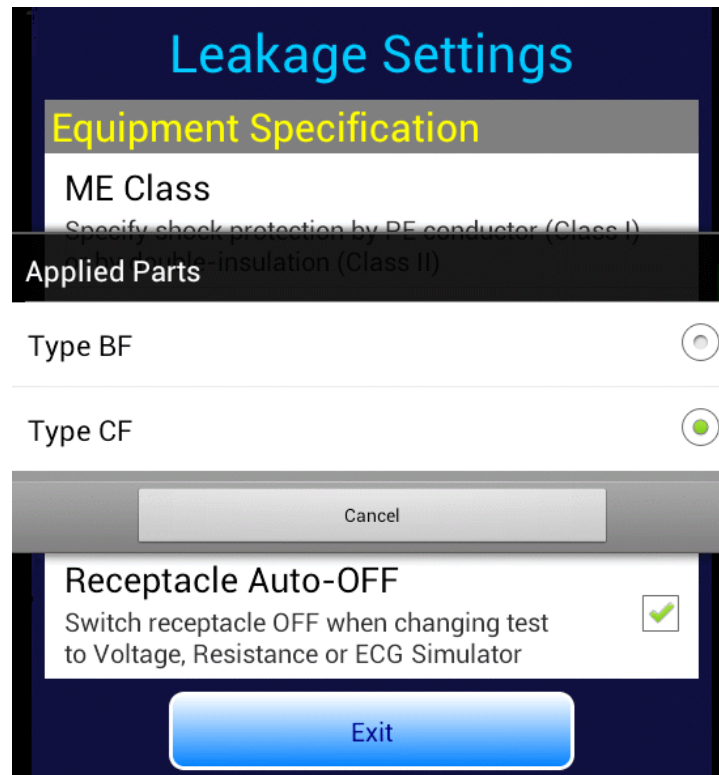


Figure 52 - Set applied part type.

When test receptacle polarity is changed during a test, the receptacle is switched OFF for a period of time, after which the receptacle is then re-activated at the new polarity. This time delay is necessary to prevent surges in supply current which could potentially damage the EUT and/or vPad-353. When polarity is changed, a user-selectable delay then applies which may be set over a range of 2 to 8 seconds (see **Figure 53**).

The default delay is 2 seconds. Delays of 2 or 3 seconds may be used with low-powered equipment which will not suffer ill effects from cycling of the AC power. Longer delays of up to 8 seconds should be used for higher-powered equipment, particularly if the equipment presents a reactive load such as an induction motor.

Press the radio button to select the desired delay time, or **Cancel** to exit without changing the setting.

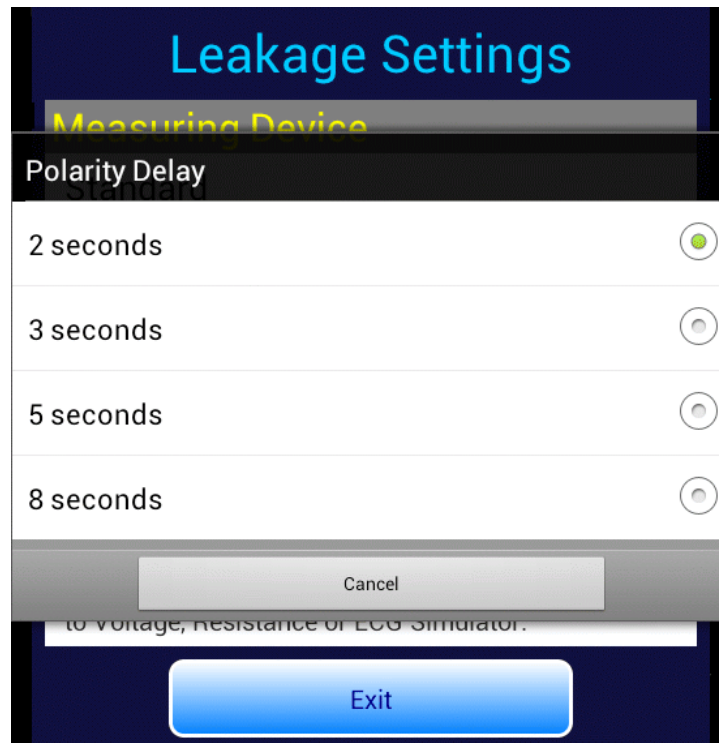


Figure 53 - Set polarity switching delay.

4.11 ECG Simulator

Select ECG Simulator mode by pressing the corresponding tab at the top of the screen. vPad-353 will default to outputting a 2 Hz square wave to the ECG binding posts.

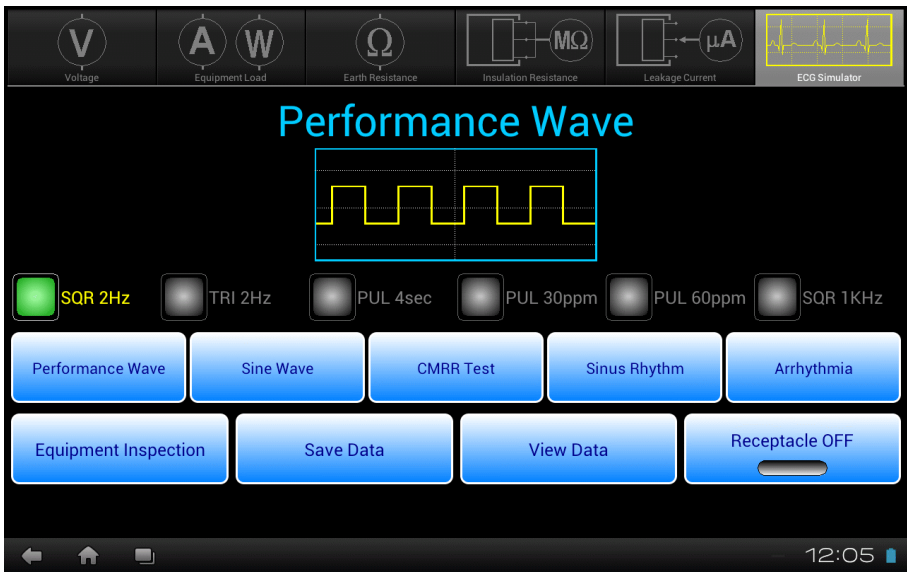


Figure 54 - ECG simulator mode.

Test signals and physiological simulations are organized in five general categories such as Performance Waves or Sinus Rhythm. Under each category, six waveforms may be selected via radio buttons. Upon selecting a waveform, a simplified illustration of the signal is displayed on-screen above the radio buttons. The bottom row of buttons provides these functions:

Equipment Inspection	Press to launch the equipment inspection procedure. See Section 4.12 for instructions.
Save Data	Press to save the name of the ECG waveform in use. In addition to the waveform, test notations may be saved. Refer to Section 4.13 for instructions on data recording.
View Data	Press to review measurement data recorded during testing.
Receptacle ON/OFF	Press to switch the test receptacle ON or OFF as desired. Refer to Section 4.4 for important information and instructions concerning operation of the test receptacle.

TABLE 4.11-1 describes the waveforms which may be selected via the menu. Amplitudes are specified for ECG Lead II connection at the patient monitor.

TABLE 4.11-1: ECG Simulator Waveforms

Simulator Menu	Simulator Waveform Description	vPad-353 Name
Performance	Square wave, 2 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SQR 2Hz
Performance	Triangle wave, 2 Hz, 1 mV p-p (-0.5 to +0.5 mV)	TRI 2Hz
Performance	'DC' Pulse, +1 mV for 4 seconds, 0 mV for 4 seconds	PUL 4sec
Performance	Pulse, +1 mV for 63 msec, rate = 30 pulses/minute	PUL 30ppm
Performance	Pulse, +1 mV for 63 msec, rate = 60 pulses/minute	PUL 60ppm
Performance	Square wave, 1 kHz, 1 mV p-p (-0.5 to +0.5 mV)	SQR 1KHz
Sine wave	Sine wave, 0.5 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 0.5Hz
Sine wave	Sine wave, 10 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 10Hz
Sine wave	Sine wave, 40 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 40Hz
Sine wave	Sine wave, 50 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 50Hz
Sine wave	Sine wave, 60 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 60Hz
Sine wave	Sine wave, 100 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 100Hz
CMRR test	Square wave, 2 Hz, 10 mV common-mode	SQR 2Hz
CMRR test	DC Pulse, 10 mV common-mode	PUL 4sec
CMRR test	Sine wave, 0.5 Hz, 10 mV common-mode	SIN 0.5Hz
CMRR test	Sine wave, 50 Hz, 10 mV common-mode	SIN 50Hz
CMRR test	Sine wave, 60 Hz, 10 mV common-mode	SIN 60Hz
CMRR test	Square wave, 1 kHz, 10 mV common-mode	SQR 1KHz
NSR	ECG normal sinus rhythm, 30 beats/minute, 1 mV QRS	30 BPM
NSR	ECG normal sinus rhythm, 60 beats/minute, 1 mV QRS	60 BPM
NSR	ECG normal sinus rhythm, 120 beats/minute, 1 mV QRS	120 BPM
NSR	ECG normal sinus rhythm, 180 beats/minute, 1 mV QRS	180 BPM
NSR	ECG normal sinus rhythm, 240 beats/minute, 1 mV QRS	240 BPM
NSR	ECG normal sinus rhythm, 300 beats/minute, 1 mV QRS	300 BPM

Simulator Menu	Simulator Waveform Description	vPad-353 Name
Arrhythmia	Arrhythmia, ventricular fibrillation, coarse	VFIB
Arrhythmia	Arrhythmia, atrial fibrillation, coarse	AFIB
Arrhythmia	Arrhythmia, supraventricular tachycardia at 200BPM	SVT
Arrhythmia	Arrhythmia, monomorphic ventricular tachycardia at 190 BPM	VTACH
Arrhythmia	Arrhythmia, unifocal preventricular contraction following 5 normal ECG beats	PVC
Arrhythmia	Arrhythmia, asystole, random baseline	ASYS

4.11.1 ECG Test

To test a patient monitor, connect ECG leads to the binding posts of vPad-353 as shown in *Figure 55*. Specific instructions for connecting patient leads to binding posts are given in Section 4.9.2. Optionally, the EUT may be connected to the test receptacle and powered from there. According to *Figure 55*, the ECG simulator outputs three independent signals for the limbs (LA, RA, LL) and a fourth signal which is common to all chest leads (V1-V6). RL provides the zero reference for the circuit which, as indicated, is isolated with respect to ground of the AC supply.

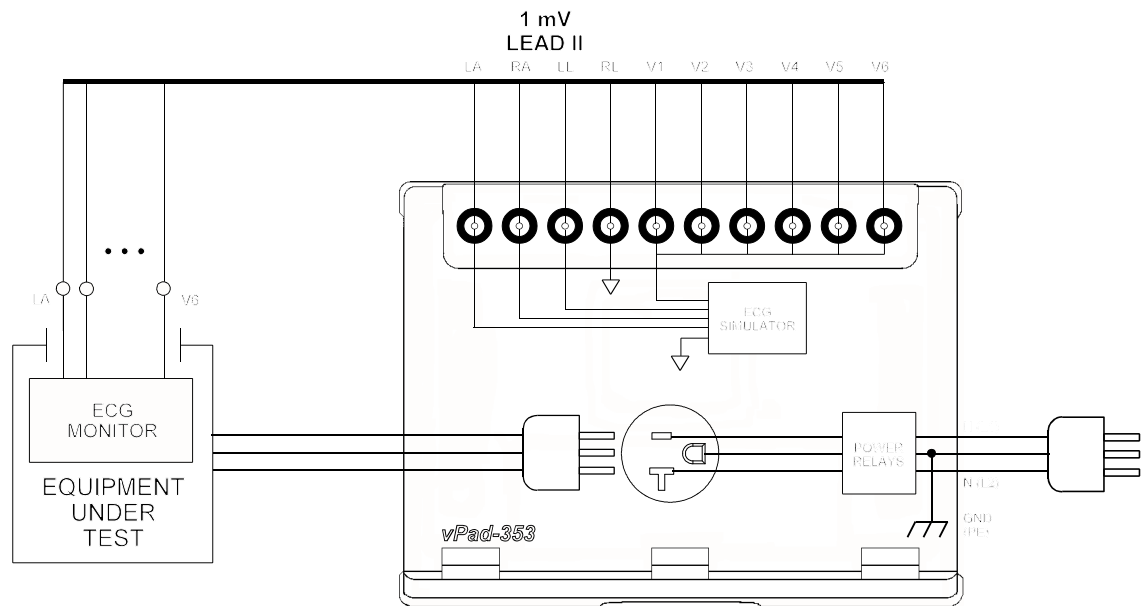


Figure 55 - Connection to ECG simulator.

4.11.2 Common-Mode Test

When a Common-Mode Rejection Ratio (CMRR) test is selected, the ECG simulator is internally configured as shown in **Figure 56**. Limb and chest leads are connected together and driven with a common 10 mV signal with respect to RL.

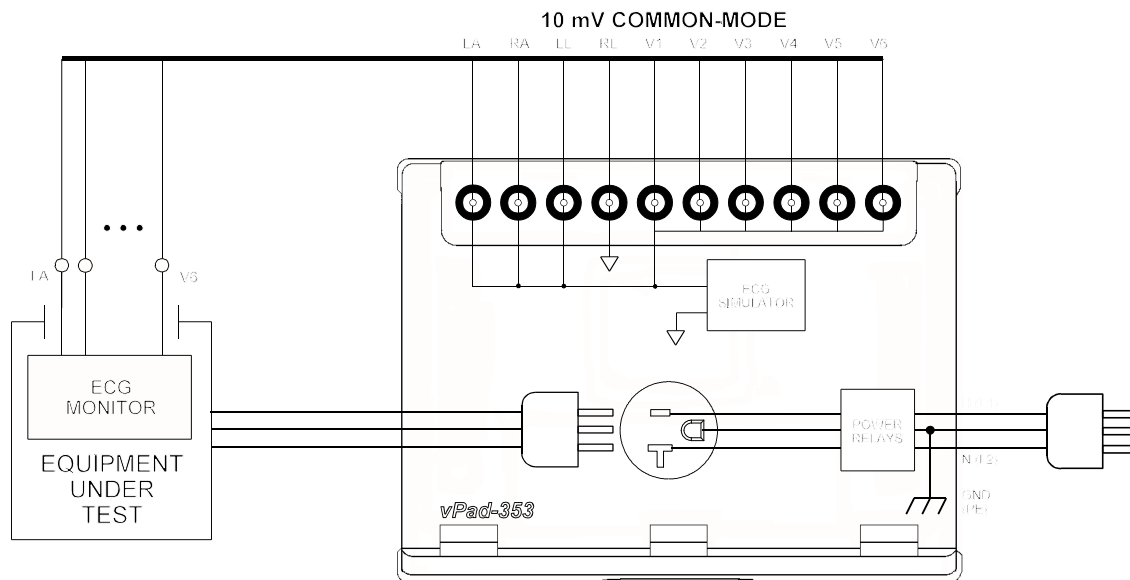


Figure 56 - Common-mode rejection test.

Provided differential amplifiers in the patient monitor are operating correctly, the common-mode signal should be cancelled and there should be no indication on the monitor display for Lead I, II or III. Different waveforms are provided for the CMRR test, allowing common-mode performance to be verified for a range of frequencies and waveshapes.

4.12 Equipment Inspection

4.12.1 Inspection Tasks

All test modes provide an **Equipment Inspection** button. Pressing this button displays a dialog for performing and recording an inspection.

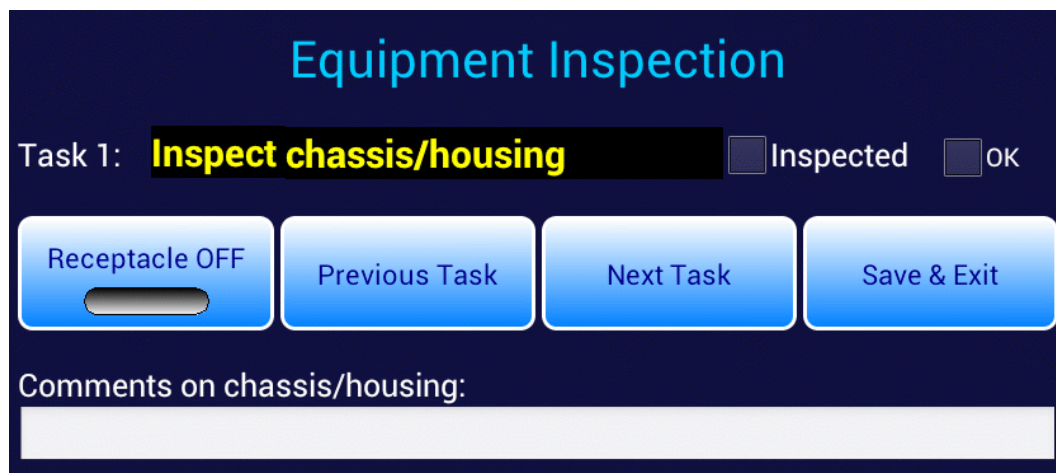
The image shows a screenshot of the 'Equipment Inspection' dialog box. The title 'Equipment Inspection' is at the top in a large, light blue font. Below the title, 'Task 1:' is followed by a text field containing 'Inspect chassis/housing' in yellow. To the right of the text field are two checkboxes: 'Inspected' and 'OK', both of which are currently unchecked. Below these elements is a row of four buttons: 'Receptacle OFF' (which has a small graphic of a receptacle below the text), 'Previous Task', 'Next Task', and 'Save & Exit'. At the bottom, there is a label 'Comments on chassis/housing:' followed by a large, empty text area for input.

Figure 57 - Equipment Inspection dialog.

The Equipment Inspection is based on a list of checkpoints or tasks, which are explained in the *General Devices Acceptance Procedure* (no. 438-20081015-01), published by the ECRI Institute (USA). This guidance document is in the public domain and may be downloaded from this URL:

https://www.ecri.org/Documents/General_Devices_USA_Acceptance.pdf

The IEC version of the procedure may be obtained from this URL:

https://www.ecri.org/Documents/General_Devices_IEC_Acceptance.pdf

The *General Devices Acceptance Procedure* was developed by ECRI to be generically applicable to medical equipment undergoing incoming inspection, installation or repair service. The procedure includes a number of qualitative checks and maintenance steps which are routinely performed on a wide range of medical devices. Specific electrical safety tests are also described in the ECRI document.

This inspection is provided to meet the requirements of the IEC62353 standard with respect to 'Reporting of Results'. The Standard only indicates that results of visual INSPECTIONS be recorded, but does not suggest any specific inspection details.

The **Next Task** button on the dialog of *Figure 57* increments the displayed "Task" through a list of items to be inspected or serviced, following the ECRI procedure as summarized in TABLE 4.12-1.

TABLE 4.12-1: Equipment Inspection Tasks

Task	Inspection Activity (perform as applicable)	Summary
1	Chassis/housing	Check for shipping damage; cleanliness; general physical condition.
2	Mounting/fasteners	Check stability (unit won't tip); check security of wall-mount equipment.
3	Casters/brakes	Check casters are correct size; check casters roll freely; check brakes. Repair/replace as necessary.
4	Plug/receptacle(s)	Check plug for damage; ensure blades and/or blade screws are not loose. Replace if necessary.
5	Power cord	Ensure power cord is long enough; for detachable cord, check for capture device/cleat; check for wear; replace if necessary.
6	Strain reliefs	Verify strain reliefs hold power cord securely and are not damaged; check both ends.
7	Circuit breaker/fuses	Check correct fuses are installed, per equipment labelling or instructions.
8	Tubes and hoses	Check condition; repair/replace as necessary.
9	Cables	Check condition; check continuity while twisting; repair/replace as necessary.
10	Fittings/connectors	Check fittings are correct type; check labelling is correct; check for leaks; check for wear/damage; repair/replace as necessary.
11	Electrodes/transducers	Check required electrodes/transducers are with the equipment; check condition of reusable transducers.
12	Filters	Check condition; clean or replace as required.

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Task	Inspection Activity (perform as applicable)	Summary
13	Controls and switches	Verify software setup parameters accessible through hidden or service menus are correctly set; check physical condition, secure mounting and range of motion for mechanical controls/switches.
14	Heater	Examine for damage; verify heater controls function correctly.
15	Motor/pump/fan	Check shaft alignment; check wear; lubricate as required.
16	Fluid levels	Check and fill as required.
17	Battery/charger	Replace battery if necessary or per schedule; check rechargeable battery can hold sufficient charge; check battery charger function.
18	Indicators/displays	During inspection activities, check operation of all lights, indicators, meters, gauges, waveform displays and numeric display segments. Repair/replace as required.
19	Cal/self-test function	Check calibration due label; check self-calibration function; activate self-test or service-mode functions for basic performance verifications.
20	Time/date settings	Check settings are correct.
21	Network setup/security	Document device, operating system, version, IP address; verify passwords and virus protection; verify data backup processes.
22	Alarms and interlocks	Verify alarm settings; induce alarm condition(s) and verify alarm function.
23	Audible signals	During inspection activities, check audio tones/alarms; check volume control function.
24	Labelling	Check required placards, labels, charts and instruction cards are present, legible and easy to understand.
25	Accessories	Verify required accessories are with the equipment.

4.12.2 Performing an Inspection

To use the Equipment Inspection dialog of *Figure 57*:

- a.) Select the task to be performed, using the **Next / Previous Task** buttons. Per the ECRI document, tasks can be performed in any order; some tasks may not be applicable to the equipment and would therefore be skipped.
- b.) Perform the inspection task, following the specific instructions of the ECRI document. If necessary, connect the EUT to the test receptacle and apply AC power via the **Receptacle ON / OFF** button on the dialog.
- c.) On completion of the task, press the **Inspected** checkbox. Checking this box adds the inspected item to the Test Record, combining it with safety test measurement data which may be recorded either before or after the inspection (refer to Section 4.13 for full details on saving test results and vPad-353 Test Records). Inspection Tasks which do not have the **Inspected** box checked will not appear in the Test Record.
- d.) If the inspected item meets requirements, press the **OK** checkbox. This assigns a "**PASS**" to the inspected item in the Test Record.
- e.) If an inspected item is not acceptable, and you are not able to correct the problem, do not press the **OK** checkbox. In this case, a "**FAIL**" will be assigned to the inspected item in the Test Record.
- f.) While inspecting, you may wish to record comments about what you find, and any repairs or modifications you may have made to the EUT. To do so, press the **Comments on...** text field, located below the buttons. This will display the Android onscreen keyboard (*Figure 58*). Although the text field is displayed as a single line, you may enter as many characters or sentences as you wish. Comment data entry is reformatted as paragraphs later, when the Test Record is saved.

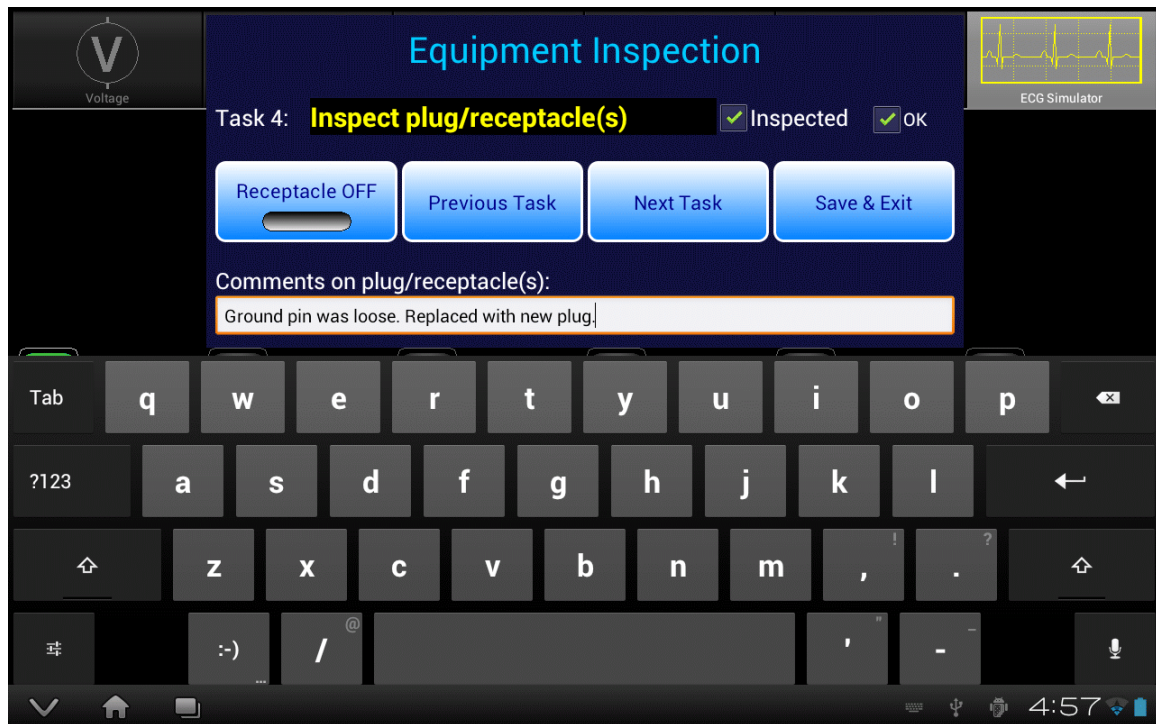
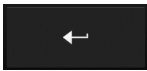



Figure 58 - Inspection comment entry.

- g.) Other inspection items may be selected via **Next** / **Previous Task** buttons while the Android keyboard is being displayed. Alternatively, once a comment has been input the keyboard can be dismissed, by pressing the ENTER button , or alternatively the "dismiss keyboard" button  at bottom left on the screen. More information on using the Android keyboard is given in Section 4.13.1.
- h.) Once all pertinent items have been inspected, press **Save & Exit** to return to the previous test mode. The Equipment Inspection dialog can be re-opened anytime prior to saving of the Test Record, allowing you to view, modify or add inspection results as needed.

4.13 Data Recording

Each test mode of vPad-353 provides means for recording and viewing measurement data during the course of a test. Once sufficient data has been collected and information about the equipment under test (EUT) has been entered, results may then be saved as a file in a designated folder on the "internal SD card" (internal non-volatile memory) of the Android tablet.

This section provides instructions for recording measurements and notes during a test, and creating Test Records.

4.13.1 Using the Android Keyboard

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

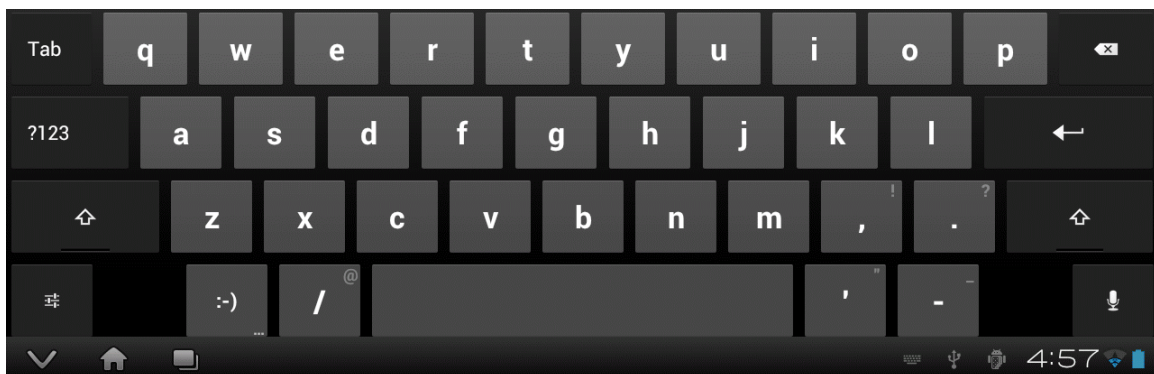


Figure 59 - Android onscreen keyboard (default IME).

Android permits use of various input methods, called "**IME**". The onscreen keyboard is the default IME. 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 IME, disconnect the external input device.

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

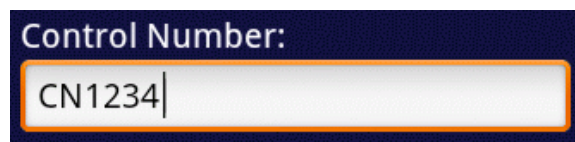
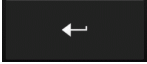
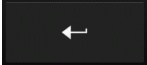





Figure 60 - Single-line text field.


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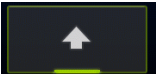
Android text fields may be either single- or multi-line. A practically unlimited amount of text may be typed for either single- or multi-line fields.

Pressing ENTER  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.

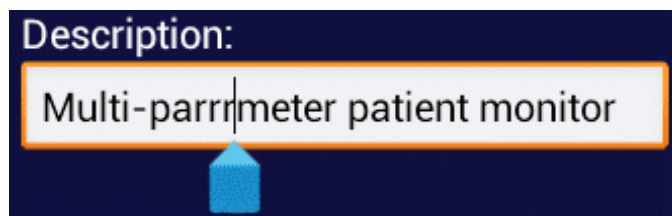




Figure 61 - Error correction with edit cursor.

As an alternative to typing with the keyboard, voice recognition may be used. Note that this will require an active internet connection. To enable, press . Android voice recognition technology has good performance, particularly when entering numbers.

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

4.13.2 Recording Measurements and Notes

While safety testing, press the **Save Data** button to capture the reading currently being displayed on the screen. The captured reading is combined with a description of the measurement and is forwarded to the Save Data menu, which appears as pop-up over the test activity. The measurement, with optional notes, may then be saved to a temporary holding buffer located in (volatile) memory.

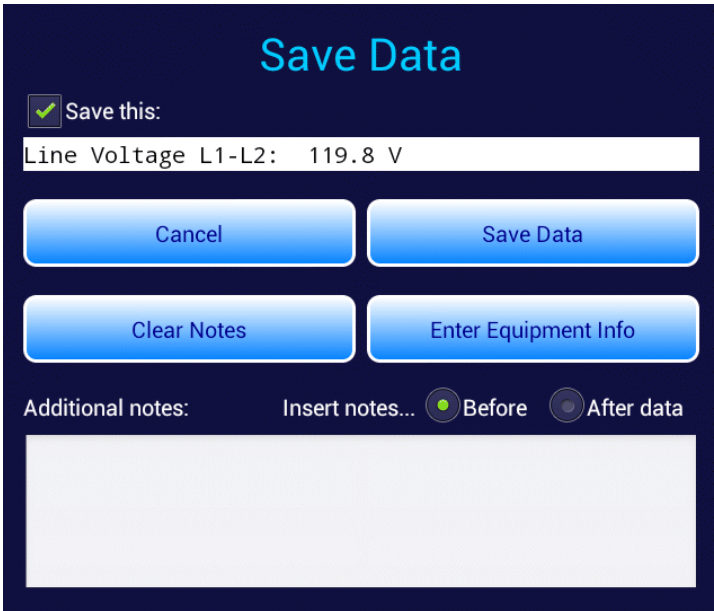


Figure 62 - Save Data pop-up menu.

Tap on the **Additional notes** text field to enter notations or comments, which will then be attached to the measurement being saved. Tapping the text field causes the Android keyboard to be displayed (*Figure 63*). 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 4.13.1 for detailed instructions on using the Android keyboard.

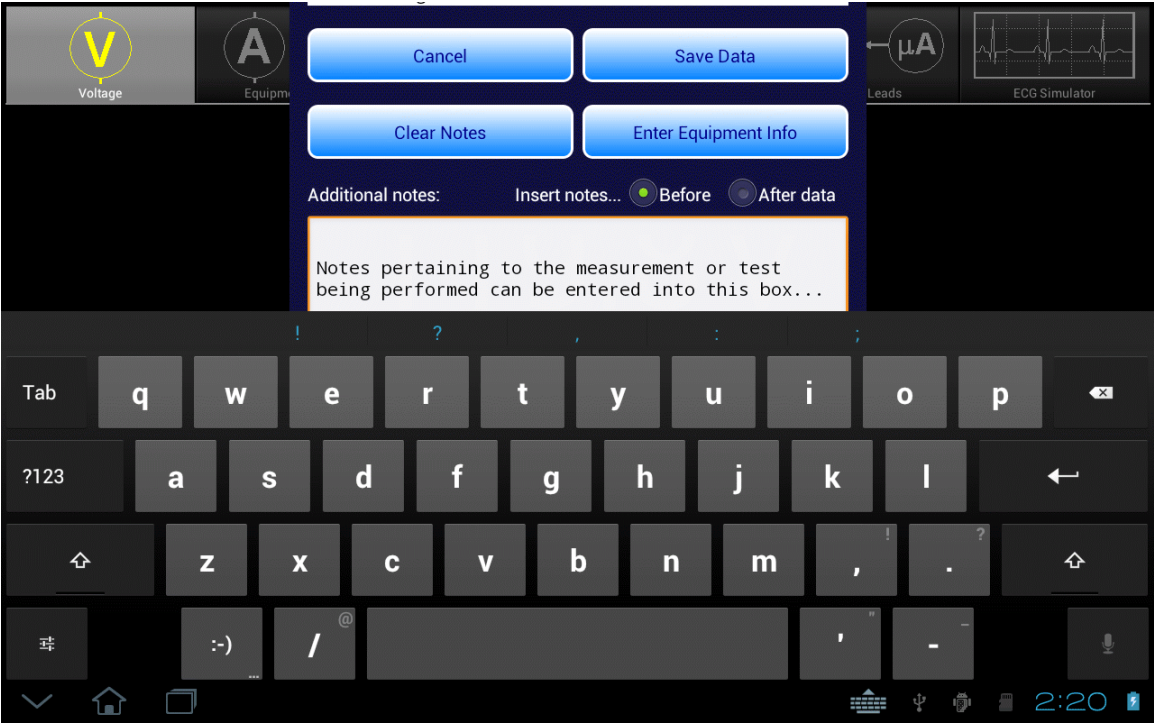


Figure 63 - Enter additional notes or comments.

By default, notes are inserted into the test data *before* the measurement value. Alternatively, to place notations after the measurement value, press the **Insert note... After data** radio button (see *Figure 62*).

To save notations only, without any measurement data, uncheck the **Save this** checkbox near the top of *Figure 62*.

Other buttons on the menu of *Figure 63* provide these functions:

- | | |
|------------------------------------|---|
| <i>Save Data</i> | Press to add the measurement data and notations (if any) to the holding buffer, then return to the test activity. This button can be pressed anytime to save and exit the menu, even while the keyboard is being displayed. |
| <i>Cancel</i> | Press to return to the test activity without saving. |
| <i>Clear Notes</i> | Press to erase the Additional notes test field. |
| <i>Enter Equipment Info</i> | Press to display the equipment information editor (see Section 4.13.4 for instructions on using the editor). |

4.13.3 Viewing Measurements and Notes

Via the Save Data menu of Section 4.13.2, measurements and notes may be saved to a holding buffer while testing is in progress. To view contents of the buffer, press the **View Data** button. If the amount of data exceeds the length of the window, scroll it into view by means of a press-and-drag gesture on the window.

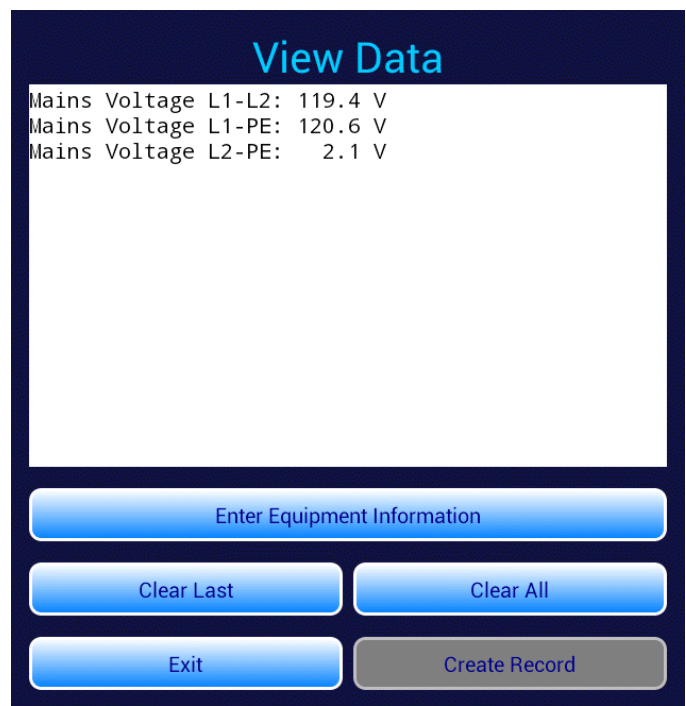


Figure 64 - View Data menu.

Buttons on the View Data menu provide these functions:

- | | |
|-----------------------------|---|
| Enter Equipment Info | Press to display the equipment information editor (see Section 4.13.4 for instructions on using the editor). |
| Clear Last | Press to erase the last line of text saved to the holding buffer. |
| Clear All | Press to erase all data currently stored in the holding buffer. An Alert Dialog will be displayed which will prompt you to confirm the erasure. |
| Create Record | Press to save recorded measurement values, notes, equipment information and inspection results as a Test Record file on the Android tablet. This button remains disabled until an Equipment Control Number has been input. See Sections 4.13.4 and 4.13.5 for instructions. |
| Exit | Press to close the View Data menu and return to the test activity. |

4.13.4 Recording Equipment Information

Press **Enter Equipment Info** on the Save Data or View Data menu to pop-up the equipment information editor.

Equipment Information

Control Number:

Serial Number:

Description:

Location:

Manufacturer:

Facility:

Model:

Technician ID:

Clear Control+Serial No.

Clear All

Cancel

Save Info

Figure 65 - Equipment information editor.

Tap on a text field to display the Android keyboard. 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 4.13.1 for detailed instructions on using the Android keyboard.

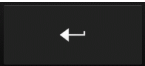



Figure 66



Figure 67


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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.

At minimum, you must enter an equipment control number or other ID 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 are maintained after power to vPad-353 is switched off, and are restored on subsequent use of the app, but may be changed as necessary.

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

- Clear Control+Serial No.*** Press to erase **Control Number** and **Serial Number** fields.
- Clear All*** Press to erase all text fields on the menu.
- Cancel*** Press to return to Save or View Data menu without saving changes.
- Save Info*** Press to save information as displayed, and then return to Save or View Data menu.

4.13.5 Creating a Test Record

Press the **Create Record** button on the View Data menu to save recorded measurement values, notes, equipment information and inspection results as a Test Record file. You must save at least one measurement and an equipment control number/ID before the View Data menu will permit you to create a Test Record (see Sections 4.13.2 through 4.13.4 respectively).

Create Test Record

File name: **CN1234_20130104_121414_P.txt**

Save to: **/mnt/sdcard/Datrend/vPad-353/Records**

Overall test result:

☒ **PASS** ☐ **FAIL**

Technician labor time: hours

Test report title:

Final comments:

Figure 68 - Create Record menu.

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The filename and path of the Test Record are shown at the top of the Create Record menu (*Figure 68*). The filename is derived automatically by vPad-353, in the following format:

```
<control_number>_<date_code>_<timestamp>_<result>.txt
```

where:

control_number is the **Control Number** field from the Equipment Information menu (see Section 4.13.4).

date_code represents the date of the Record, format YYYYmmDD (year-month-day)

timestamp represents the time of the Record, format hhMMss (hours-minutes-seconds)

result represents the overall result of the test: pass (P) or fail (F)

Test Record files are saved in TXT format, with character encoding that is compatible with both Android (Linux) and Microsoft Windows® operating systems.

Test Records are saved to this location in the Android file system:

```
/mnt/sdcard/Datrend/vPad-353/Records
```



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.

The **Overall test result** shown in *Figure 68* will be set to **PASS**, unless a failing result was recorded during an Equipment Inspection (see Section 4.12) or as a result of a test measurement. The Pass/Fail indication that has been automatically applied may be over ridden by selecting either the **PASS** or **FAIL** radio button to reflect the result you wish to store in the Test Record file.

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Optionally, time spent working on the EUT may be entered after tapping on the **Technican labor time** field. This causes the Android numeric keypad to be displayed. Enter the labor time in hours.

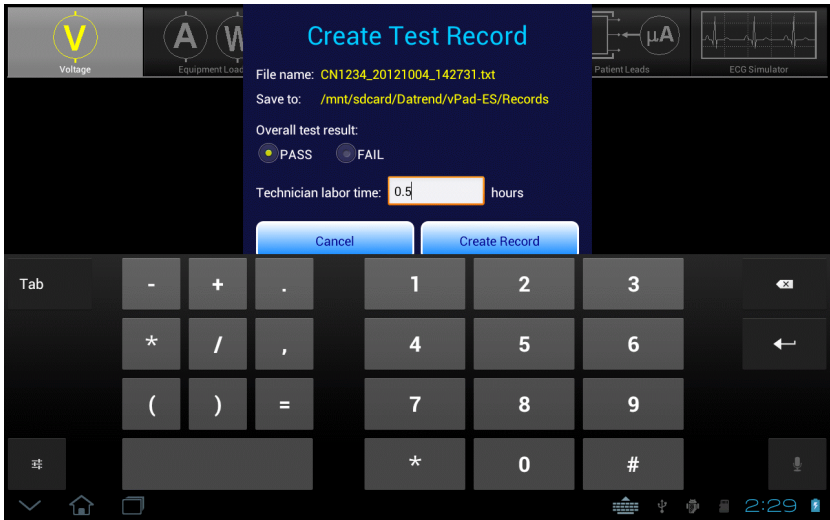


Figure 69 - Optionally, enter technician labor time (hours).

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 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 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.

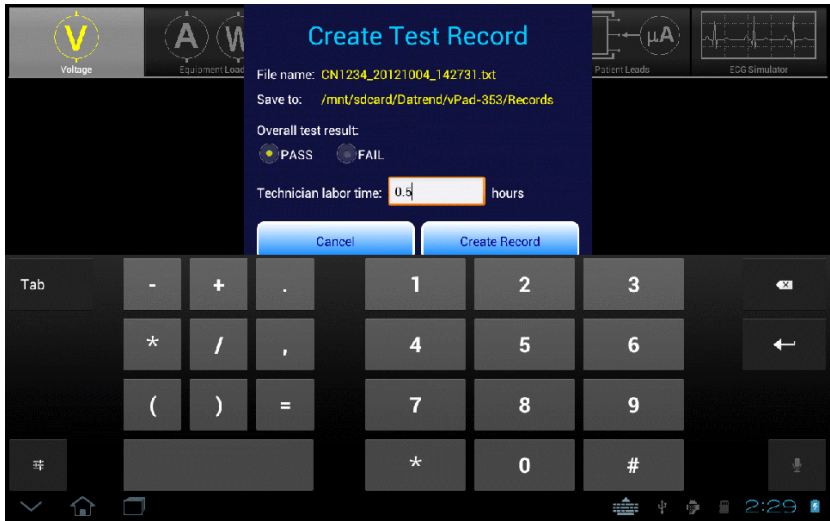


Figure 70 - Optionally, enter report title.

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Optionally, concluding comments about the EUT or test results may be entered after tapping the **Final comments** field. Information entered in this text field will appear at the end of the Test Record file. Any number of lines may be entered into the text field.

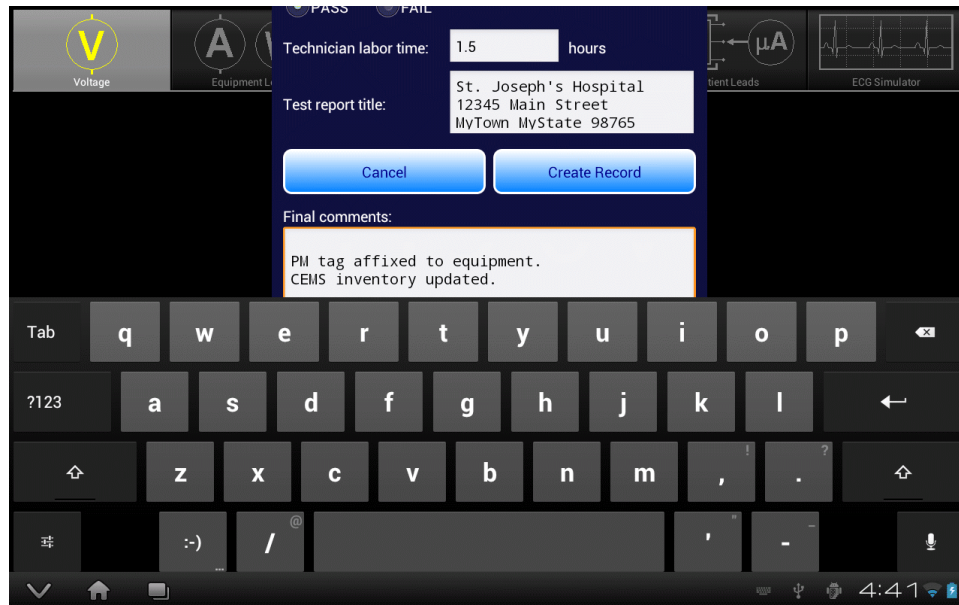


Figure 71 - Optionally, enter final comments about EUT or test.

Press the **Create Record** button at any time to save the Test Record file, whether or not the Android keyboard is active. Alternatively, press **Cancel** to exit the menu without saving a file. On cancelling, measurements and other data stored in the temporary holding buffer are retained.

When **Create Record** is pressed:

- The Test Record file is saved to `/mnt/sdcard/Datrend/vPad-353/Records` in the tablet;
- The temporary holding buffer is erased, clearing all recorded measurement values, notes, and equipment inspection results;
- **Control Number** and **Serial Number** fields of the Equipment Information are erased;
- Other fields of the Equipment Information (**Description**, **Manufacturer**, **Model** and so on) are *not* erased. This is intended as a time-saving feature when performing acceptance tests and inspections on multiple EUT of the same type.

An example of a Test Record file saved by vPad-353 is given in APPENDIX A.

4.14 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-353 app.

Record Manager may be used to copy, print, and/or delete Test Record files saved by vPad-353. 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 72 - File browser of vPad Record Manager.

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

5 Calibration and Maintenance

Calibration of vPad-353 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-ES 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.

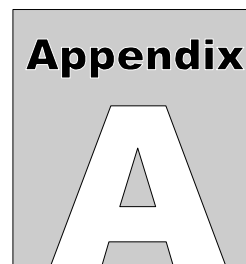
For calibration or service assistance, contact Datrend for a Return Materials Authorization (RMA) number and the location of the nearest Service Facility.

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

vPad-353 may be cleaned with a soft, lint free, damp cloth using a mild detergent. Use of other 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, 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. This is an example of a file where most available measurements and inspections have been recorded.

Biomedical Engineering Dept.
St. Joseph's Hospital
1234 Main Street
MyTown MyState 98765
Phone: 123-456-7890 Ext. 123

File: CN123456_20120618_173835.txt
Date: 2012 Jun 18
Time: 17:38:35
vPad-353: VPES12010001

Equipment Information...
Control Number: CN123456
Description: Diagnostic ECG
Manufacturer: Marquette
Model: MAC VIEW
Serial Number: 4459-712-50-DE
Location: CCU
Facility: St Josephs Hosp

Technician ID: MEM
Tech Time (hrs): 0.5

Overall Result: PASS

Signature: _____ Date: _____

Equipment Inspection...
Chassis/housing: PASS
Small dent at the rear of the unit.
Acceptable.
Mounting/fasteners: PASS
Casters/brakes: PASS

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Plug/receptacle(s): PASS
Power cord: PASS
Line cord insulation was split. Replaced the cord.
Strain reliefs: PASS
Circuit breaker/fuses: PASS
Wrong fuse was installed. Replaced with correct fuse.
Tubes and hoses: PASS
Cables: PASS
Fittings/connectors: PASS
Electrodes/transducers: PASS
Filters: PASS
Controls and switches: PASS
Heater: PASS
Motor/pump/fan: PASS
Fluid levels: PASS
Battery/charger: PASS
Replaced the clock backup battery.
Indicators/displays: PASS
Cal/self-test function: PASS
Time/date settings: PASS
Network setup/security: PASS
Alarms and interlocks: PASS
Audible signals: PASS
Labelling: PASS
Accessories: PASS

Detailed Test Data...

Elec. Safety Standard: IEC62353
Earth Resistance Limit: Maximum 0.300 ohm
Equipment Leakage Limit: Maximum 500.0 μ A (Class I)
Applied Part Lkg Limit: Maximum 50 μ A (Type CF)

This test begins with some voltage measurements although any test data may come first in a file. This paragraph is an example of "additional notes". By default, notes are inserted BEFORE the data.
Mains Voltage L1-L2: 120.2 V
Mains Voltage L1-PE: 121.3 V
Mains Voltage L2-PE: 2.2 V
External Voltage: 3.2 V

The notes text box can also be used to insert a blank line, as immediately above this note.
Load Current: 10.49 A
Equipment Power: 1256 W

Here are the IEC62353 safety test measurements...
Prot. Earth Resistance: 0.093 ohm - PASS
Insulation Resistance, L1+L2 to PE: 74.4 Megohm
Insulation Resistance, AP to PE: 672.7 Megohm
Equipment Leakage (NP): 174.4 μ A - PASS
Equipment Leakage (RP): 178.7 μ A - PASS
Applied Part Lkg ALL AP (NP): 44.4 μ A - PASS
Applied Part Lkg ALL AP (RP): 48.4 μ A - PASS
Applied Part Lkg AP1-3 (NP): 32.4 μ A - PASS
Applied Part Lkg AP1-3 (RP): 33.4 μ A - PASS

Additional AP combinations can also be measured here....

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Now run a quick check on the ECG monitor with some
standard waveforms...
ECG Test: SQR 2Hz
ECG Test: TRI 2Hz
ECG Test: PUL 4sec
ECG Test: 30 BPM
ECG Test: 60 BPM
ECG Test: 120 BPM
ECG Test: 240 BPM
All BPM within 1 count ok.
Finish off by entering some final comments here...
PM tag affixed.
Parts inventory updated.

END OF RECORD

