



DATREND
Systems Inc.

vPad-A6TM

**Automation Application for
vPad-Rugged 2 and vPad-ES 2
Electrical Safety Analyzers**

Software version: 1.01.X

Operating Manual

vPad-A6™
*Automation Application for
vPad-Rugged 2 and vPad-ES 2
Electrical Safety Analyzers*

Operating Manual

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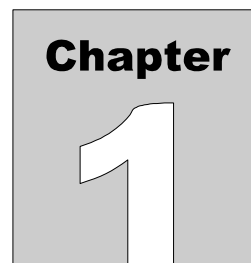
Abbreviations and Definitions

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

µA	Micro-ampere
A	Ampere
AAMI	American Association of Medical Instrumentation
AP	Applied Parts (patient leads)
App	Software application for a mobile device
Cct.	Abbreviation for circuit (ie. electrical circuit in a power distribution system)
Earth	See GND
EUT	Equipment Under Test. The electrical device being tested.
GFCI	Ground fault circuit interrupter. A device that shuts off an electric power circuit when it detects a current flowing along an unintended path.
GND or Ground	The line (conductor) connected to a place that is maintained at "Ground" or "Earth" voltage. Same as Protective Earth.
Hz	Hertz
IEC	International Electrotechnical Commission
IME	Android input method (e.g. keyboard)
kHz	kilohertz
L1 or Line 1	Line 1 of the AC supply voltage, or "mains". In North America, the "Hot" or "Live" line (conductor) of the AC supply.
L2 or Line 2	Line 2 of the AC supply voltage, or "mains". In North America, the "Neutral" line (conductor) of the AC supply.
LA	left arm ECG lead
LL	left leg ECG lead
MAINS	The voltage provided by the building installation, nominally 120 VAC or 230 VAC depending on the country
M.A.P. / MAP	Mains on applied part(s)
Measurement Category I Terminal	Intended for measurements on circuits with no direct connection to MAINS (CAT I)
Measurement Category II Terminal	Intended for measurements on circuits which may have a direct connection to MAINS (CAT II)

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MHz	Megahertz
NC	Normal Condition of AC supply to EUT: ground and neutral are both connected
PE	Protective Earth. The line (conductor) connected to a place that is maintained at “Ground” or “Earth” voltage.
RA	right arm ECG lead
RL	right leg ECG lead
RCD	Residual current device; see GFCI
RMS	Root-Mean-Square measurement of a parameter (eg. V_{rms} , A_{rms})
SA	Electrical Safety Analyzer
Safety Standard	Standards established by various national and international agencies. 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



1 Overview

The vPad-A6™ software application or "app" is intended for use with vPad-Rugged 2™ and vPad-ES 2™ electrical safety analyzers. vPad-Rugged 2 and vPad-ES 2 are test instruments which facilitate electrical safety testing of medical devices with patient leads. Each vPad safety analyzer is comprised of a Base Unit which contains test instrumentation, and an Android™ tablet computer which is equipped with software apps that facilitate inspection and testing of medical equipment.

This manual assumes the reader has some understanding of electrical safety principles, and is knowledgeable in operation of the vPad safety analyzer and in use of the vPad-623™ software application which enables manual testing of electrical safety according to the IEC 62353 standard. For full details on basic operation of vPad safety analyzers, including instrument setup, test connections, and use of the vPad-623 software, refer to **MN-123 6100-099 vPad-623 Operating Manual**.

vPad-A6 is an accessory software app for vPad-Rugged 2 and vPad-ES2 which enables these analyzers to automatically perform tests of medical equipment in accordance with IEC 62353. The remainder of this chapter provides an overview of features provided by the vPad-A6 app.

1.1 Features

1.1.1 Automation Autosequences

vPad-A6 automates IEC 62353 safety tests with ***AutoSequences***. An "AutoSequence" is a user-configurable test template which causes the analyzer to execute a sequence of electrical safety measurements, where each measurement value in the sequence is automatically recorded and may also be compared to a pass/fail acceptance limit. Advantages of AutoSequences are:

- Reduced testing time
- Reduced human error (e.g., forgot to perform a particular measurement; "passed" a measured value when it should have been a "fail"; etc)

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- Objective assessment of equipment performance (pass/fail limits are quantitative)
- Increased labour efficiency (technician can do something else while instrument is running a test)
- Automated data recording (Test Record files provide documented evidence that equipment was tested and was found acceptable)

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

There can be a virtually unlimited number of AutoSequence files stored on the tablet. Existing AutoSequence files can be edited with vPad-A6, or new AutoSequences can be created by editing an existing file and saving the AutoSequence under a new name/number.

1.1.2 Test Instructions

One of the features of vPad-A6 is the ability to present detailed instructions to the user during a test. These instructions can explain how a test is to be performed, how the equipment should be set up, cautions that should be observed during test, and other details of the test that may be relevant. Written instructions can be combined with drawings, photographs or video. An Instruction file which is relevant to the device under test may be selected for inclusion in an AutoSequence. If suitable instructions do not exist for the device under test, vPad-A6 enables the user to edit an existing Instruction file or create a new one. Similar to AutoSequence data files, there can be a virtually unlimited number of Instruction files stored on the tablet.

1.1.3 Equipment Inspection

vPad-A6 also provides an option for including an equipment inspection as part of the AutoSequence. In the vPad-623 manual safety testing app, the test inspection is a generic 25-point inspection based on the ECRI procedure 438-20081015-01. vPad-A6 expands this capability to include up to 50 steps, with each step fully editable by the user to meet the specific requirements of the device under test. Equipment Inspection files can be saved and re-used in multiple sequences. Similar to AutoSequence data files, there can be a virtually unlimited number of Equipment Inspection files stored on the tablet.

1.1.4 Test Parameters

vPad-A6 provides a test template which lays out all of the electrical safety parameters that can be tested, and allows the user to simply check each parameter to be included in the AutoSequence. The template provides a quick and easy method to see what has been included or excluded from a sequence. Section 1.2 provides an overview of the electrical safety tests specified in the IEC 62353 standard.

1.2 IEC 62353 Standard

vPad-A6 may be used to automate electrical safety tests of medical devices with patient leads, following the IEC 62353 standard. TABLE 1.2-1 defines terms which pertain in general to electrical safety testing of medical equipment.

TABLE 1.2-1: 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-Rugged 2 and vPad-ES 2 safety analyzers incorporate the measuring device specified by the IEC 62353 standard, which is shown in **Figure 1**. The MD incorporates a low-pass filter between the 1k test resistance and millivoltmeter to compensate for an allowable increase in leakage limits with increasing frequency.

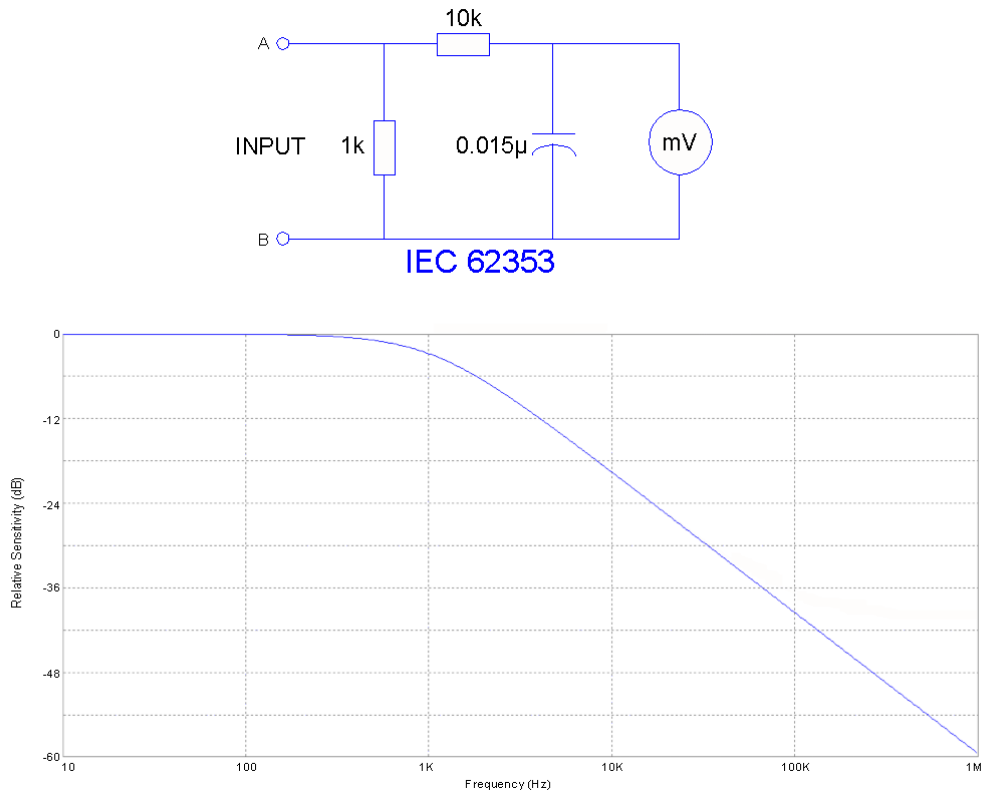


Figure 1 - Measuring device (MD) for IEC 62353 standard.

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 1.2-2. vPad-A6 meets these requirements by providing user-programmable settings that enable automated test sequences to follow the IEC 62353 standard.

TABLE 1.2-2: Leakage Test Requirements of IEC 62353

Test Requirement	Practical Interpretation
When testing by direct or differential method, test 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.	At minimum, test with EUT power switch set to "OFF" position, then repeat tests with EUT power switch set to "ON" position.
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 IEC 62353.</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 IEC 62353 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 IEC 62353 (see TABLE 1.2-3 following).</p>

Acceptance limits according to IEC 62353 are shown in TABLE 1.2-3. These limits are applied by vPad-A6 to determine the pass/fail result of each measurement obtained during an automated test sequence. Note the following with respect to TABLE 1.2-3:

- 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 1.2-3: Measurement Limits

Test	Test Condition	IEC 62353 (Ed. 2)
Protective Earth Resistance		0.3 Ω
	Including RCD/GFCI outlet	0.5 Ω
Equipment Leakage	Direct or differential method	Class I: 500 μ A Class II: 100 μ A
	Alternative method	Class I: 1000 μ A Class II: 500 μ A
Applied Part Leakage	Mains voltage on applied parts (MAP)	Type BF Leads: 5000 μ A Type CF Leads: 50 μ A
Insulation Resistance (Limits are optional)	Mains part to protective earth	2 M Ω
	Mains part to enclosure	7 M Ω
	Mains Parts to applied parts	B Type, Class I: 2 M Ω B Type, Class II: 7 M Ω F Type: 70 M Ω
	Applied parts to protective earth	70 M Ω
	Applied parts to enclosure	70 M Ω

Chapter 2

2 Operation

This chapter explains how to use vPad-A6 to perform electrical safety tests and inspections of medical equipment, following a predefined sequence of steps referred to as an AutoSequence. Test Record management is also covered in this chapter.

2.1 HOME Screen

The Android HOME screen (*Figure 2*) is displayed approximately 60 seconds after switching the tablet ON.



Figure 2 - 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-A6 software application, or "**app**". Use this app to perform **automated** electrical safety testing according to the IEC 62353 standard.



Press to launch the vPad-623 software application. Use this app to perform **manual** electrical safety testing according to the IEC 62353 standard. For full details on vPad-623, refer to **MN-123 vPad-623 Operating Manual**, provided on the Android tablet.



Press to launch the vPad-ES software application. 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 Operating 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-623 or vPad-ES apps.



Press to launch the Datrend Docs app. Use this app to find and read vPad operator manuals and other technical documents stored on the tablet.

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



By default, the tablet 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.



Press the **Apps** button to access more apps that are installed on the tablet.



Press the **Home** button to return from an app to the Home screen.



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.



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

Note: appearance of the last 5 icons shown above may vary, depending on Android OS version.

For more information on how to use the Android tablet, refer to the tablet operator manual supplied with the analyzer.

2.2 Startup


Press the vPad-A6 icon  on the Android Home screen to start the app. A splash screen will display the product name and the software version.



Figure 3 - vPad-A6 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 the vPad safety analyzer is also tested. Normally, all tests will complete successfully and the AutoSequence selection screen of the vPad-A6 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 4**). Refer to TABLE 2.2-1 for recommended actions in the event of a startup alarm message.

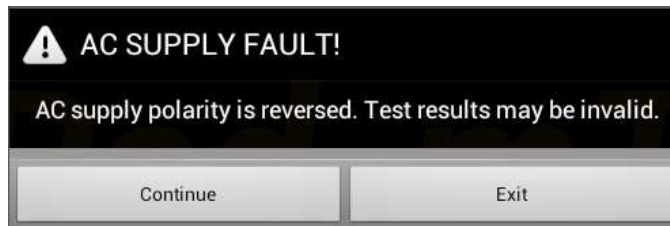


Figure 4 - Alert Dialog: AC supply fault.

TABLE 2.2-1: Startup Alarms and Corrective Actions

Alarm Message	Cause	Actions
USB COMM ALERT (safety analyzer not communicating)	App is unable to send messages to one or more instrument systems inside the Base Unit	<ul style="list-style-type: none"> • Check Base Unit has power • Check Base-to-tablet USB connection • If AC power and USB cables are OK, cycle power to the Base Unit by disconnecting and reconnecting AC power, then try restarting app • If error persists, contact Datrend Customer Service (see Chapter 3 for contact information)
BLUETOOTH ALERT (safety analyzer not communicating)	App is unable to send messages to one or more instrument systems inside the Base Unit	<ul style="list-style-type: none"> • Check Base Unit has power • Check Bluetooth is enabled on tablet • If AC power and Bluetooth status are OK, cycle power to the Base Unit by disconnecting and reconnecting AC power, then try restarting app • If error persists, contact Datrend Customer Service (see Chapter 3 for contact information)
BLUETOOTH ALERT: (Bluetooth not available)	Another app is using the Bluetooth connection to Base Unit	<ul style="list-style-type: none"> • Quit other Datrend apps running on the tablet, then try restarting app
AC SUPPLY FAULT (polarity reversed)	AC outlet incorrectly wired	<ul style="list-style-type: none"> • Do not use analyzer with incorrect or unsafe AC supply • Connect Base Unit to a different outlet
AC SUPPLY FAULT (polarity reversed or ground disconnected)	High voltage two-phase or split-phase power system	<ul style="list-style-type: none"> • Error can be safely ignored provided that users take proper precautions while working with AC outlet adapters • For more information, contact Datrend Customer Service (see Chapter 3 for contact information)

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AC SUPPLY FAULT (ground disconnected)	AC outlet incorrectly wired	<ul style="list-style-type: none">• Do not use analyzer 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">• Perform leakage testing using only the Alternative method; results using other methods will be invalid• Optionally, vPad-623 app 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">• Cycle power to the Base Unit by disconnecting and reconnecting AC power, then try restarting app• If problem persists, contact Datrend Customer Service (see Chapter 3 for contact information)

2.3 Test Selection

Following application start-up, vPad-A6 will display the AutoSequence selection screen:

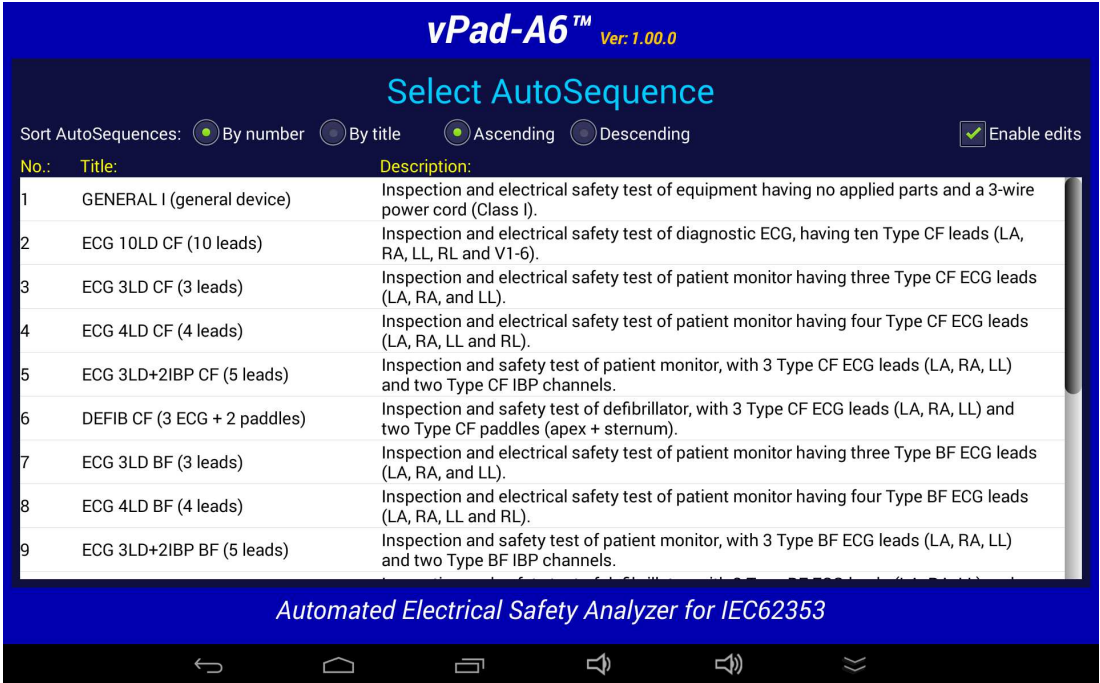


Figure 5 - AutoSequence Selection Screen.

When first delivered, vPad-A6 will have a number of sample AutoSequences pre-installed. Each AutoSequence has a title and a description. The Title will normally be reasonably short so that is easy to read. The Title should attempt to indicate the basic test it is intended to perform. The Description can expand on the Title to be much more descriptive of the test, describing differences between Titles that sound similar. The Description can be virtually any length, but generally, keeping the Description to two lines or less is a good idea for readability.

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

There is a checkbox in the upper right of the display labelled Enable Edits. If checked, vPad-A6 will proceed to the AutoSequence Editor (section 4.4) when a sequence is selected. If not checked, the editor screen(s) will be skipped, and vPad-A6 will proceed directly to running the sequence steps. This setting affects all apps which can call vPad-A6 (vPad-Check, vPad-mT and vPad-EQM).

2.4 AutoSequence Editing

After an AutoSequence has been selected from the list, the contents of the AutoSequence may be displayed (see *Figure 6* through *Figure 18*), depending on the state of the Enable Edits checkbox in *Figure 5*. This menu allows the user to review and optionally change the settings and then initiate the testing sequence via the "Run Test" button. If changes are made to the AutoSequence, they can be saved to the original file or to a new file. If changes are made but not saved, the changes will apply only to the current test.

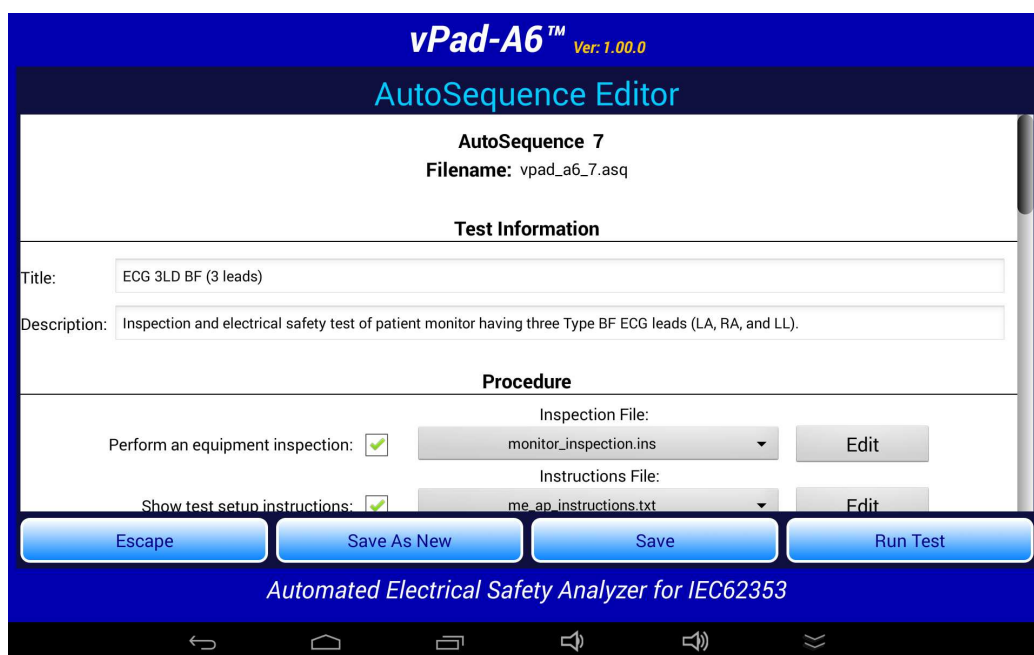


Figure 6

Users can verify all existing test setups with the AutoSequence Editor. This may be useful during the initial learning curve with vPad-A6 to confirm that the AutoSequence selected matches your expectations. It also initially allows the user to adjust settings of the factory-default AutoSequences to match the methods and procedures you normally follow.

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

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

2.4.1 Test Information

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

Test Information	
Title:	A1: 10LD X (10 leads)
Description:	Inspection and AAMI safety test of diagnostic ECG, having ten ECG leads (LA, RA, LL, RL and V1-V6). Case external (chassis) leakage is te

Figure 7

The key to easily finding an AutoSequence on the main menu of the app is to keep the AutoSequence **Title** as short as possible. In the above example, the **Title** is a test name from the legacy medTester system, with “A1” signifying a test ID and “10LD X” signifying a 10-lead device under test. The **Description** field provides additional space to expand upon the meaning of a cryptic or abbreviated title, and can be of any length, although it is recommended to keep it to 2 or 3 lines at most.



The AutoSequence **Title** may be used to optionally enable special limits which are specified by IEC 62353 for certain types of equipment. If the **Title** contains the keyword **defib**, then a higher limit is enabled for specific applied part or "AP" connections which are used for testing the defibrillator paddles (see section 2.4.5.7). Similarly, if the **Title** contains the keywords **mobile x-ray**, then a higher limit is enabled for the equipment leakage test (see section 2.4.5.2). Keywords are not case-sensitive, and they may be placed at the beginning, end, or middle of the **Title** to enable the corresponding special limit.

2.4.2 Procedure Settings

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

2.4.2.1 Equipment Inspection

An equipment inspection can be defined in an Inspection File. This is a text file comprised of up to 50 lines, each no longer than 40 characters. The first line is the inspection title, and each additional line is a step in the inspection. The original, fixed Equipment Inspection included with the manual analyzer app, vPad-623, is based on the ECRI *General Devices Acceptance Procedure* (no. 438-20081015-01). With vPad-A6, an inspection file can be tailored for a specific device type, and instructions can be placed in any order.

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

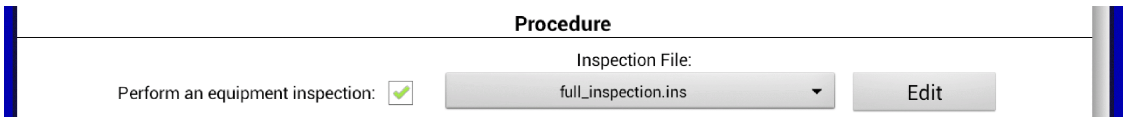


Figure 8

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

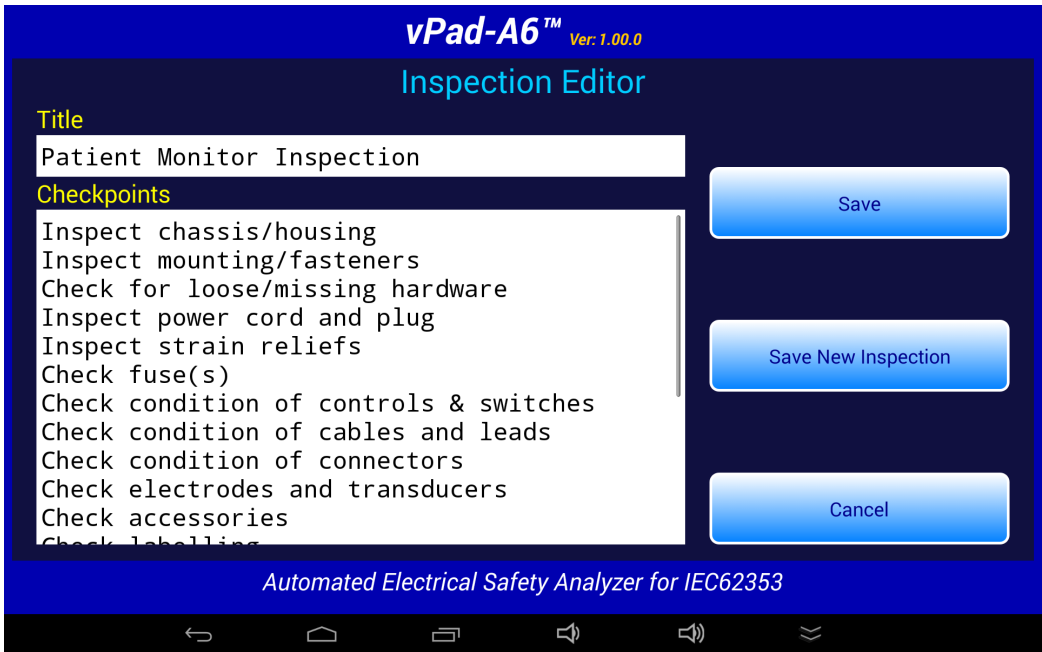


Figure 9

Inspection files have a file format: “Inspection Title”, “Task1”, “Task2”, etc.”,; with as many as 50 individual tasks. Tasks should be of the form “Do this...”, with keywords indicating what to ‘do’; such as ‘Inspect...’, ‘Check...’, ‘Test...’, etc. During the test, the user will be prompted to respond to each task with a ‘Pass’ or ‘Fail’ result and an optional ‘Comment’. The comment can be used for general test explanations or for recording of measured values, such as a battery voltage.

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

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

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

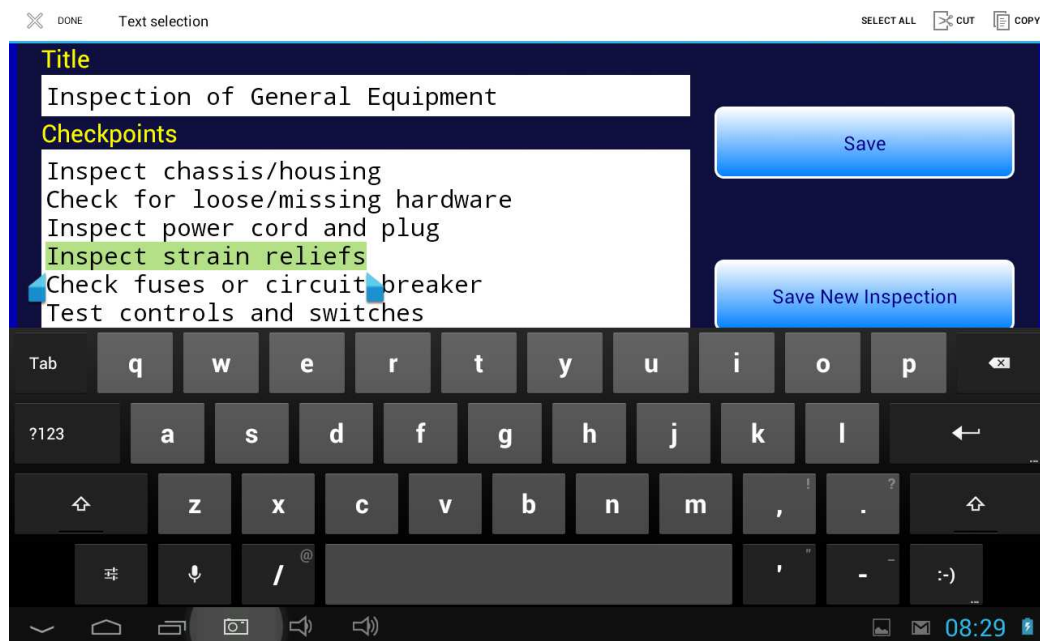


Figure 10

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

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

- Cancel*

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

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



Figure 11

- Save New Inspection*

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

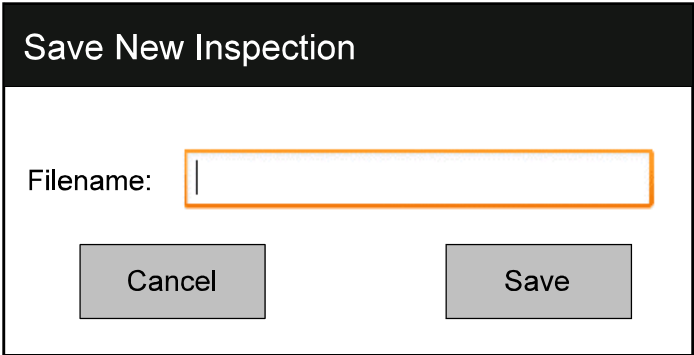


Figure 12

Although the Inspection Editor may be used to modify or create inspection files as described above, *.ins files are simple text files that can also be viewed or edited with any text editor, for example, Jota. The files are located in the Datrend/vPad-623/Inspections folder of the tablet. If using a text editor to modify a *.ins file, be sure to follow the file format as described in this section (title first, followed by up to 50 tasks; title and tasks not exceeding 40 characters in length).

2.4.2.2 Test Setup Instructions

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

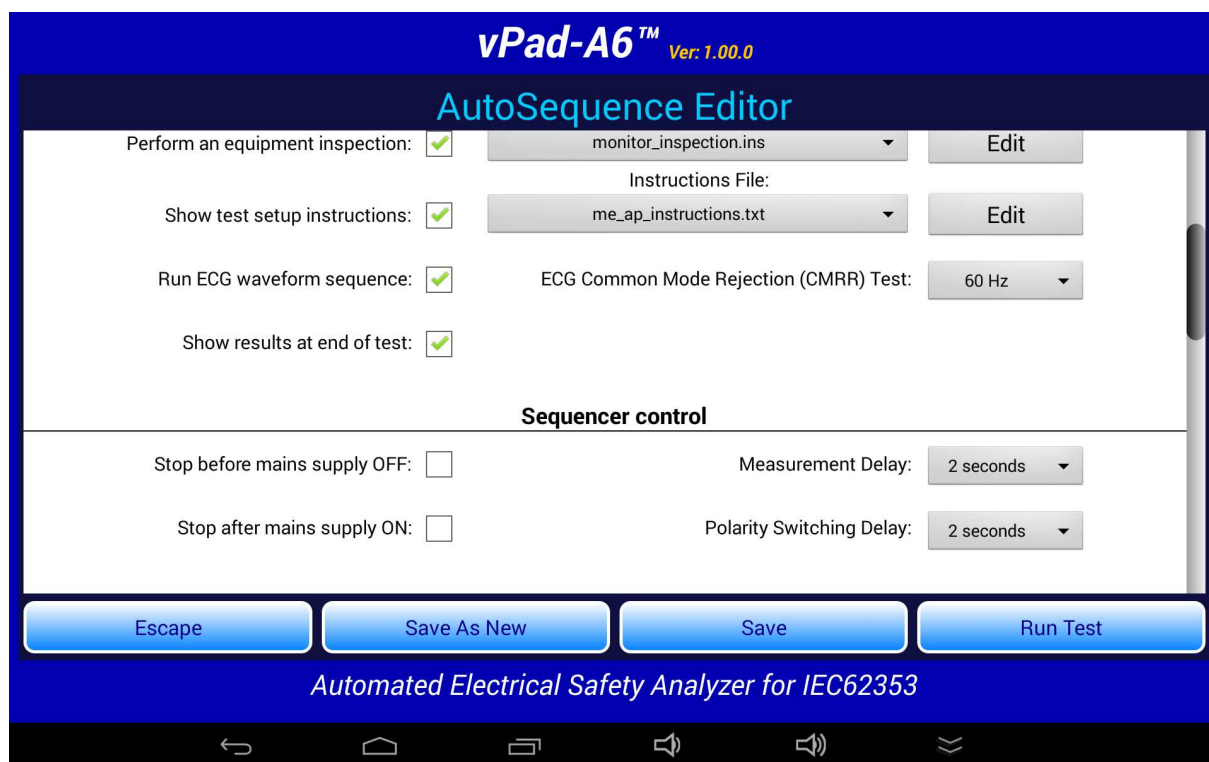


Figure 13

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

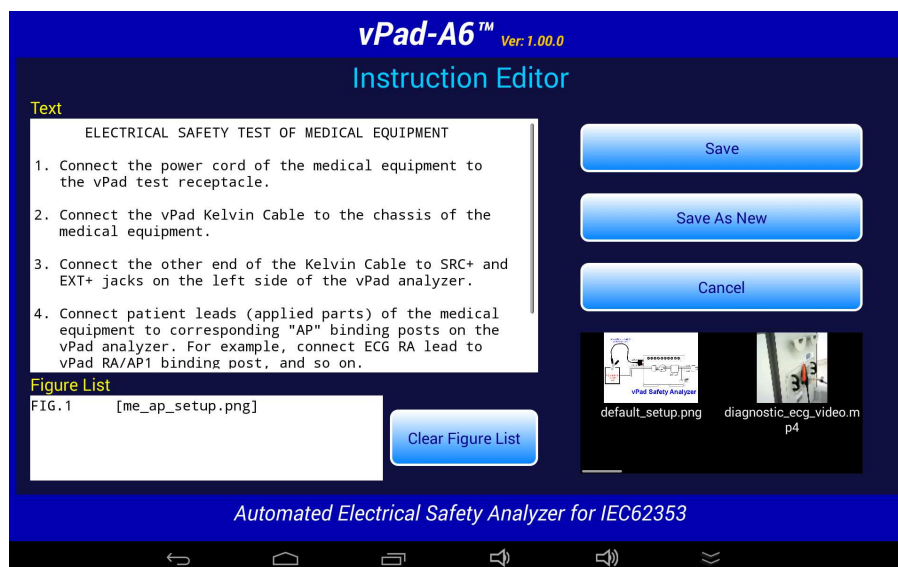


Figure 14

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

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

The contents of the lower list may be cleared via the "**Clear Figure List**" button. New figures can then be placed in the list by selecting them from the horizontally-sliding Gallery of thumbnail images on the right. Note the filename of each Gallery image is located underneath its corresponding thumbnail, allowing the user to confirm that the correct file has been selected and appears in the list on the left. Image and Instruction files are located in the Datrend/vPad-623/Instructions folder.

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

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

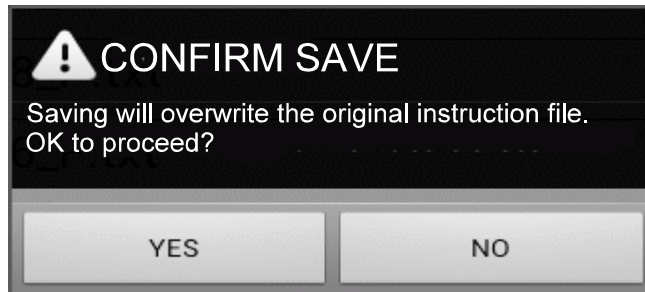


Figure 15

***Save As
New***

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

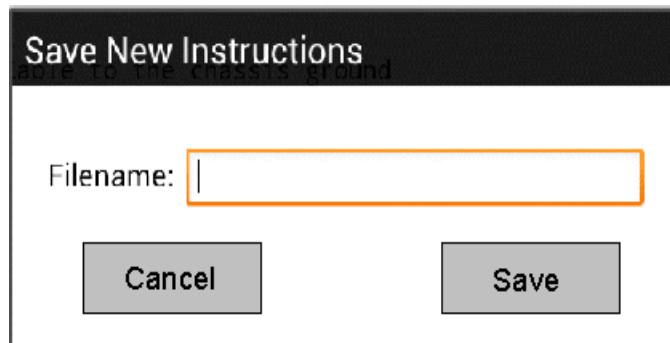


Figure 16

Although the Instructions Editor may be used to modify or create Instructions files as described above, these files are simple ***.txt** files that can also be viewed or edited with any text editor, for example, Jota. The files are located in the Datrend/vPad-623/Instructions folder of the tablet. If using a text editor to modify an Instructions file, be sure to follow the file format as described in this section.

2.4.2.3 ECG Waveform Sequence

If **'Run ECG waveform sequence'** of the AutoSequence is 'checked', vPad-A6 will step through each of the waveforms listed below in TABLE 2.4-1. As the ECG waveform is displayed, the user will have an opportunity to Pass, Fail or Skip the waveform. vPad-A6 does not allow you to change the number of steps or the waveforms in the sequence, however, other automation apps such as vPad-Check will enable you create customized ECG waveform sequences having any number of steps if this should be necessary.

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

TABLE 2.4-1: ECG Waveform Sequence

Step	Simulator Waveform Description	vPad-A6 Name
1	Square wave, 2 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SQR 2Hz
2	'DC' Pulse, +1 mV for 4 seconds, 0 mV for 4 seconds	PUL 4sec
3	Sine wave, 10 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 10Hz
4	Sine wave, 40 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 40Hz
5	Sine wave, either 50 Hz or 60 Hz (per CMRR test setting), 1 mV p-p (-0.5 to +0.5 mV)	SIN 50 or 60Hz
6	Sine wave, 100 Hz, 1 mV p-p (-0.5 to +0.5 mV)	SIN 100Hz
7	Square wave, 1 kHz, 1 mV p-p (-0.5 to +0.5 mV)	SQR 1KHz
8	Triangle wave, 2 Hz, 1 mV p-p (-0.5 to +0.5 mV)	TRI 2Hz
9	ECG normal sinus rhythm, 60 beats/minute, 1 mV QRS	60 BPM
10	ECG normal sinus rhythm, 30 beats/minute, 1 mV QRS	30 BPM
11	ECG normal sinus rhythm, 120 beats/minute, 1 mV QRS	120 BPM
12	ECG normal sinus rhythm, 240 beats/minute, 1 mV QRS	240 BPM
13	Common Mode Rejection Ratio Test, 50 or 60 Hz (10 mV)	CMRR 50 or 60

2.4.2.4 Show Results at End of Test

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

2.4.3 Sequencer Control

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

2.4.3.1 Stop Before AC Supply OFF

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

2.4.3.2 Stop After AC Supply ON

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

2.4.3.3 Measurement Delay

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

2.4.3.4 Polarity Switching Delay

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

2.4.4 Voltage, Resistance and Load Tests

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

The screenshot displays the 'vPad-A6™ Ver: 1.01.0' AutoSequence Editor interface. The title bar is blue with the device name and version. Below it, a dark blue header contains the text 'AutoSequence Editor' in light blue. The main content area is white and titled 'Voltage, Resistance and Load Tests'. It contains several configuration options with checkboxes and radio buttons. The 'Protective Earth (PE) Resistance' checkbox is checked. The 'Resistance Limit (mΩ)' is set to 300 with radio buttons for 300, 500 (RCD/GFCI), and 'Choose at runtime'. The 'External (point-to-point) Resistance' checkbox is unchecked. The 'Insulation Resistance, L1+L2 to PE' checkbox is checked. The 'Insulation Test Voltage' is set to 500 V with radio buttons for 50 V, 100 V, 250 V, and 500 V. The 'Insulation Resistance, L1+L2 to Encl.' checkbox is unchecked. The 'Insulation Limits per IEC62353 Ed. 2' checkbox is unchecked. The 'Insulation Resistance, L1+L2 to AP' checkbox is checked. The 'AC Mains Voltage' checkbox is checked, with a note: 'Must be enabled for leakage tests, except when testing Internally-Powered Equipment.' The 'Insulation Resistance, AP to PE' checkbox is checked. The 'Equipment Load Current' checkbox is checked. The 'Insulation Resistance, AP to Encl.' checkbox is unchecked. The 'Equipment Power Consumption' checkbox is unchecked. At the bottom of the configuration area are four blue buttons: 'Escape', 'Save As New', 'Save', and 'Run Test'. Below these buttons is a blue bar with the text 'Automated Electrical Safety Analyzer for IEC62353'. At the very bottom is a black bar with several white icons for navigation.

Figure 17

2.4.4.1 Protective Earth Resistance

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

2.4.4.2 External (point-to-point) Resistance

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

2.4.4.3 Resistance Limit

The Resistance Limit applies to both Protective Earth and External Resistance tests. The default limit of 0.300 ohms is suitable for most test conditions specified in IEC 62353. Select the 0.500 ohm limit only when testing an EUT that includes a multiple socket outlet with built-in RCD or GFCI protection. Select the “Choose at runtime” option to enable – during execution of the AutoSequence – a pick list from which any test condition for Protective Earth may be selected, as described in the IEC 62353 standard. This allows, for example, a detachable power supply cord to be tested separately from the EUT during the AutoSequence.

2.4.4.4 Insulation Resistance, L1+L2 to PE

In this measurement, the resistance between the transformer primary winding (with L1 and L2 connected together) and PE is measured by applying a user-defined DC voltage to L1+L2 and measuring the current that flows.

2.4.4.5 Insulation Resistance, L1+L2 to Enclosure

In this measurement, the resistance between the transformer primary winding (with L1 and L2 connected together) and non-earthed Accessible Conductive Parts on the EUT is measured by applying a user-defined DC voltage to L1+L2 and measuring the current that flows.

Note: if desired, this test can be paused and repeated while probing different conductive parts on the EUT’s enclosure to find the point at which the resistance is minimum.

2.4.4.6 Insulation Resistance, L1+L2 to AP

In this measurement, the resistance between the transformer primary winding (with L1 and L2 connected together) and the Applied Parts (with all AP connected together) is measured by applying a user-defined DC voltage to L1+L2 and measuring the current that flows.

2.4.4.7 Insulation Resistance, AP to PE

In this measurement, the resistance between the Applied Parts (with all AP connected together) and PE is measured by applying a user-defined DC voltage to all APs and measuring the current that flows.

2.4.4.8 Insulation Resistance, AP to Enclosure

In this measurement, the resistance between the Applied Parts (with all AP connected together) and non-earthed Accessible Conductive Parts on the EUT is measured by applying a user-defined DC voltage to all APs and measuring the current that flows.

Note: if desired, this test can be paused and repeated while probing different conductive parts on the EUT's enclosure to find the point at which the resistance is minimum.

2.4.4.9 Insulation Test Voltage

This sets DC test voltage for insulation resistance to 50, 100, 250 or 500 volts. The default setting is 500V, but lower voltages may be used in accordance with manufacturer's instructions or Standards requirements.

2.4.4.10 Insulation Limits per IEC62353 Ed. 2

This setting enables comparison of insulation test results to optional pass/fail limits which are specified in Edition 2 of the IEC 62353 standard. By default, this selection is disabled and insulation resistance measurements are saved to the Test Record without limits or pass/fail assessment.

2.4.4.11 AC Mains Voltage

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

During a test, vPad-A6 will analyze the measured mains voltages and will warn of any AC supply fault that may potentially invalidate subsequent measurement of leakage currents. See **Figure 4** on page 12 for an example of an AC supply fault Alert Dialog. If users choose to proceed with leakage measurements despite a reverse polarity fault, the app will configure the test receptacle so that test conditions (Normal or Reverse Polarity) are reported correctly.

2.4.4.12 Equipment Load Current

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

2.4.4.13 Equipment Power Consumption

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

2.4.5 Leakage Current Tests

Leakage current test options as shown in **Figure 18**. Tests are enabled by checking the associated box, and measurements are evaluated against pass/fail limits which are defined in the IEC 62353 standard.

The screenshot displays the 'vPad-A6™ Ver: 1.00.0' interface with the 'AutoSequence Editor' title. The 'Leakage Current Tests' section is active, showing various configuration options. The 'Leakage Current Measuring Method' is set to 'Direct' (checked), with 'Alternative' and 'Differential' options available but unchecked. 'Equipment Leakage' is checked, while 'Applied Part (AP) Leakage, All AP' is unchecked. The test sequence is configured to 'Test with Equipment Set to 'OFF' and to 'ON'' (checked), with 'Skip Reverse Polarity Tests' and 'Test for Secondary Earth' unchecked. Equipment is set to 'Class I' (selected), with 'Class II' and 'Internally-Powered' options also visible. 'Applied Parts' are set to 'Type BF' (selected), with 'Type CF' also visible. Specific AP tests are configured: 'AP1 to AP3' is checked, while 'AP1 to AP4', 'AP5 to AP10', 'AP4 to AP10', and 'AP1' are unchecked. The interface includes buttons for 'Escape', 'Save As New', 'Save', and 'Run Test'. The footer identifies the device as an 'Automated Electrical Safety Analyzer for IEC62353'.

Figure 18 - Leakage current testing options; some AP selections not shown.

2.4.5.1 Leakage Current Measuring Method

Select the methodology for measuring Equipment and Applied Part leakage as defined in IEC 62353. The AutoSequence will perform all selected leakage tests using, when possible, each enabled method. Direct method is the default, which can only be disabled once another method has been enabled.

2.4.5.2 Equipment Leakage

Select this option to perform an Equipment Leakage test as defined in IEC 62353. You can optionally enable a special limit for mobile X-ray equipment (either 2 mA or 5 mA, depending on the selected Measuring Method and the Equipment Class), by including the key words "**mobile x-ray**" in the Title of the AutoSequence (see section 2.4.1).

2.4.5.3 Test with Equipment OFF and ON

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

2.4.5.4 Skip Reverse Polarity Tests

Select this option to skip all leakage measurements that reverse the AC mains supply to the EUT.

2.4.5.5 Test for Secondary Earth

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

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

2.4.5.6 Equipment Type

Select the type of equipment being tested: Class I (protectively earthed); Class II (double-insulated); or, Internally Powered (battery operation). This will affect limits for some measurements, in accordance with IEC 62353.

2.4.5.7 Applied Parts Type

Select the type of applied parts that are on the EUT: BF (Body Floating) or CF (Cardiac Floating). The leakage current limit for the applied parts will be based on this setting, as specified in IEC 62353.

You can enable a special 100 μA limit for defibrillator paddles by including the keyword "**defib**" in the Title of the AutoSequence (see section 2.4.1). For the special limit to take effect, applied parts must be set to Type CF and group AP5-AP10 (or alternatively group AP4-AP10) must be enabled in the setup and must be used for connection of the defib paddles. Group AP1-AP4 (or AP1-AP3) may also be enabled and used for connection of the defib's ECG leads, in which case the conventional limit of 50 μA will be used when the ECG leads are tested.

2.4.5.8 Applied Parts Selections

Individual applied parts or "leads", or groups of applied parts, can be selected in the column on the right.

2.4.6 Saving the AutoSequence

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

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

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

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

2.5 Running a Test

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

The first screen shown is for entering information about the equipment. This screen will always appear when an AutoSequence is started in vPad-A6.



Figure 19 - Equipment information editor.

Some equipment information may remain on the screen from a previous test; press the **Clear** button to clear the contents of all fields except the **Facility** and **Technician ID**. Tap on a text field to display the Android keyboard and enter information. If an external keyboard or barcode scanner is connected to the tablet, the Android keyboard is not displayed and data entry is then accepted from the external input device. Refer to Section 2.6 for detailed instructions on using the Android keyboard.

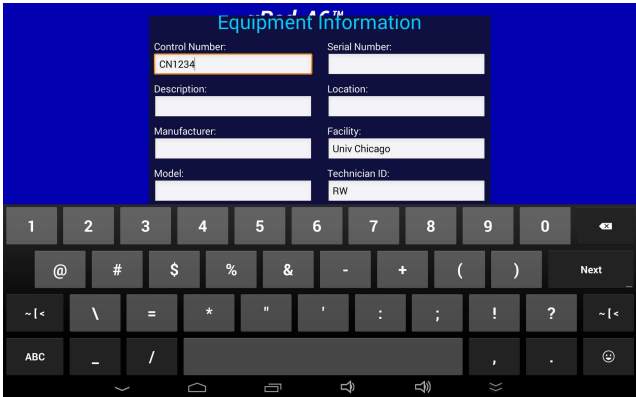


Figure 20

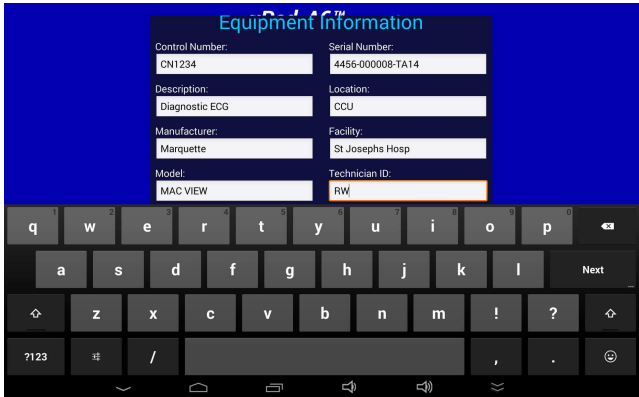


Figure 21


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

Alternatively, simply tap a text entry field to jump immediately there.

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

"**Facility**" and "**Technician ID**" fields are backed up in permanent storage on the Android tablet. These information fields may be modified, but the last values are maintained after power to the vPad Safety Analyzer is switched off, and are restored on subsequent use of the vPad-A6 app.

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

Escape Cancel the current AutoSequence and return to the list of available sequences.

Clear Clear the contents of all fields except Facility and Technician ID. Useful in some instances where data may have been carried over from another test.

Next Step Press to proceed with the next step of the test.

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

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

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

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

2.5.1 Equipment Inspection

The Inspection file selected in the AutoSequence will be displayed. An Inspection file can contain up to 50 steps which are tailored toward the device being tested. The example AutoSequence shown below is set up to perform a Diagnostic ECG Inspection and will contain steps which are directly related to this device, as opposed to the generic 25 point inspection provided with the vPad-623 manual safety testing app.

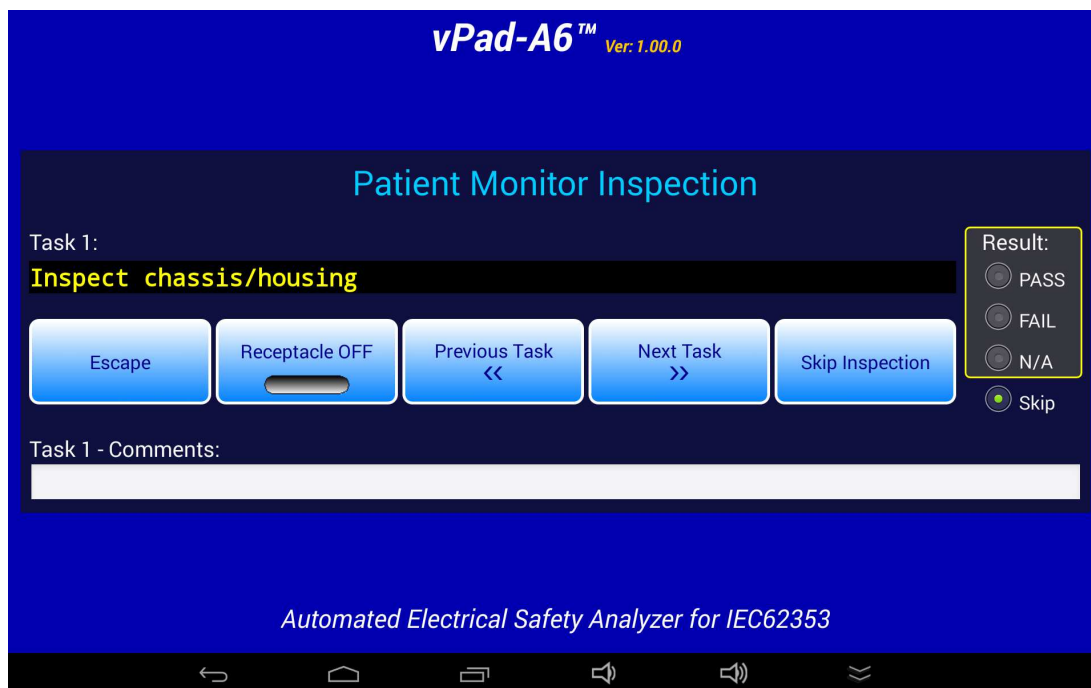


Figure 22 - Inspection comment entry.

While doing an Inspection, it is possible to turn the power to the receptacle **ON** or **OFF** as required for the inspection step. To complete a Task, choose '**PASS**', '**FAIL**', or '**N/A**' for the '**Result**' on the right. All completed Tasks will be added to the final Test Record along with the assigned Result. To skip a Task without recording it, leave the '**Result**' set to '**Skip**', which is the default.

Before going on to the '**Next Task**', the user can enter '**Comments**' to indicate anything important or unusual that was experienced when performing the task. Comments will appear below each completed Task in the Test Record.

Once a Task is completed, or if the Task should be skipped, press the '**Next Task**' button to continue. If an error has been made, '**Previous Task**' can be pressed to go back and repeat a Task.

If an Equipment Inspection is not required, press the '**Skip Inspection**' button without entering any Task Results.

2.5.2 Test Instructions

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

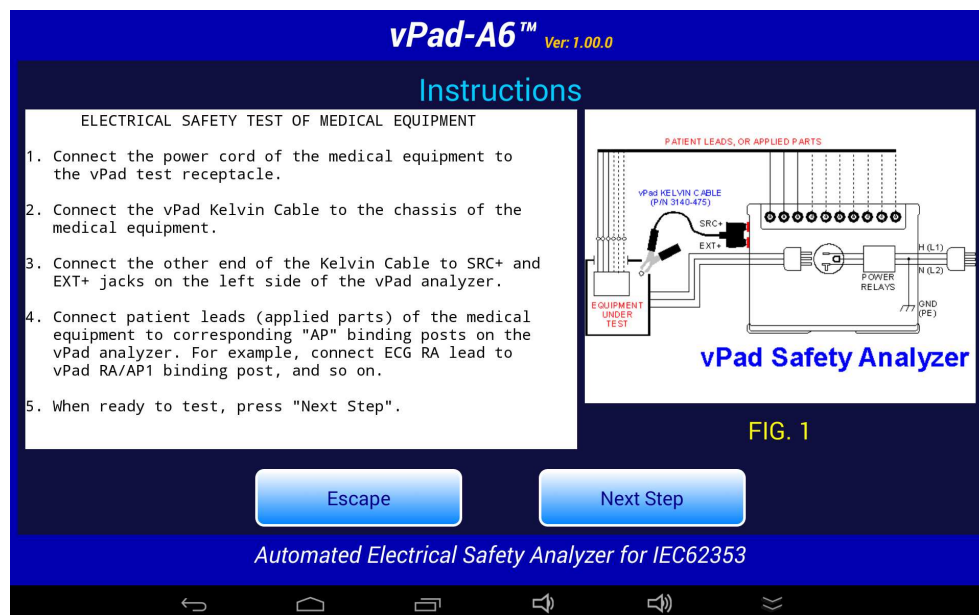


Figure 23 - Instruction Screen.

2.5.3 Protective Earth Resistance

Following the Test Instructions, Protective Earth (PE) Resistance will be measured if it has been enabled. vPad will continuously measure the PE Resistance and display the result on the screen approximately once per second. This continuous measurement allows the equipment power cord to be flexed, as necessary, to determine if there are any intermittent faults in the cord.

The resistance limit is displayed on the screen, as defined in AutoSequence settings and the IEC 62353 standard. The measured value is compared to the limit and a **PASS** or **FAIL** is assigned to the result. Various options are available for setting the resistance limit for a test, including the ability to manually choose a limit while the test is in progress; see Section 2.4.4.3 for further information.

To save a measurement value to the test record, press the **'Save Resistance'** button. The measurement on the display will be recorded to memory and the **'Data Count'** will increment. The number on the screen represents the number of resistance values that have been saved to the test record. The test results that have been recorded can be viewed by pressing the **'View Data'** button.



Figure 24 - Protective Earth Resistance.

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

If the resistance limit has been set to "Choose at runtime", a pick list of test conditions described in the IEC62353 standard will be provided below the measurement result (**Figure 25**). Select the appropriate test condition from the list to suit the equipment or measurement. The "Choose at runtime" mode is enabled through the AutoSequence setup; see Section 2.4.4.3 for further details.

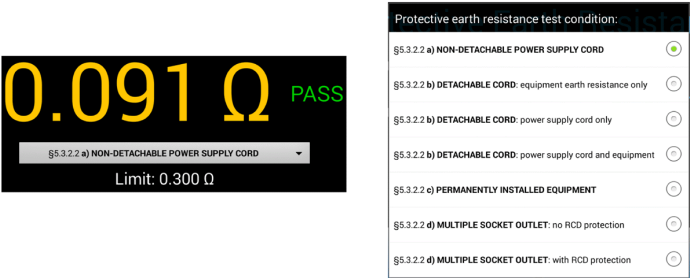


Figure 25 - Choose resistance limit at test runtime.

2.5.4 External Resistance

If enabled, the External Resistance measurement screen will appear next. Except for the title, it is identical to the Protective Earth Resistance screen. To make external resistance measurements, a second Kelvin Cable is required which is connected to SRC- and EXT- jacks on the vPad Base Unit (refer to vPad-623 operating manual). For ease of measurement, it may be best to have one clamp type cable and one probe type cable. Make the connections between the points of interest, and press the **‘Save Resistance’** button. Multiple measurements can be saved.

2.5.5 Mains Voltages

When enabled, vPad will go through a series of three voltage tests: L1 - L2; L1 - PE (earth); and L2 - PE. During each of these three tests, the user will have the opportunity to **'Pause'** the test. When the test is paused, it is possible to **'Repeat'** a test, **'Escape'** completely from the AutoSequence, or **'Continue'** with the next measurement in the sequence. After all three voltage tests, an Alert Dialog similar to *Figure 4* on page 12 may be shown in case of an AC mains fault such as a reversed mains or disconnected earth.

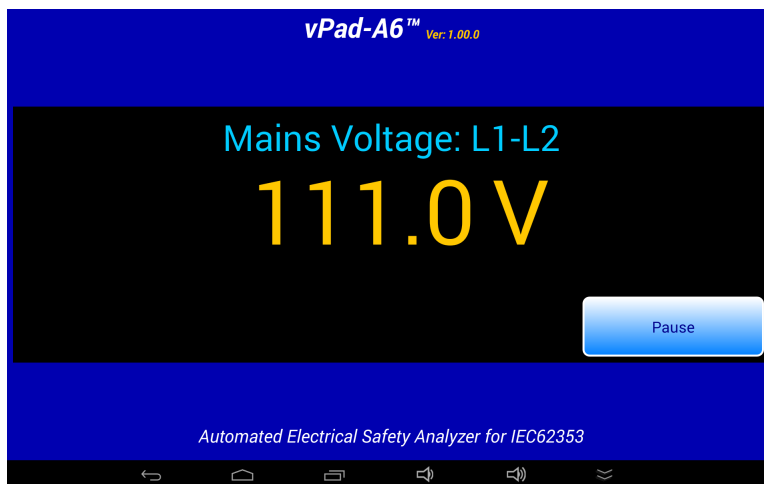


Figure 26 - Mains Voltage Measurement.

2.5.6 Insulation Resistance

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

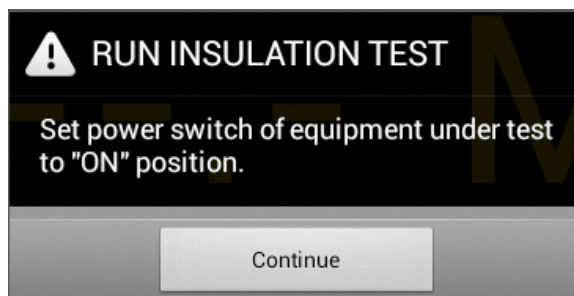


Figure 27 - Insulation test - power ON prompt.

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In measuring resistance from the EUT primary side to Protective Earth (PE), non-earthed Accessible Conductive Parts (Encl.), or Applied Parts (AP), the DC test voltage is applied to L1 and L2 (Mains) input lines of the EUT, and the current that flows to the other test point is measured. Using these two parameters, the Mains insulation resistance is calculated. The insulation test voltage can be set by selecting the appropriate option on the AutoSequence setup screen.

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

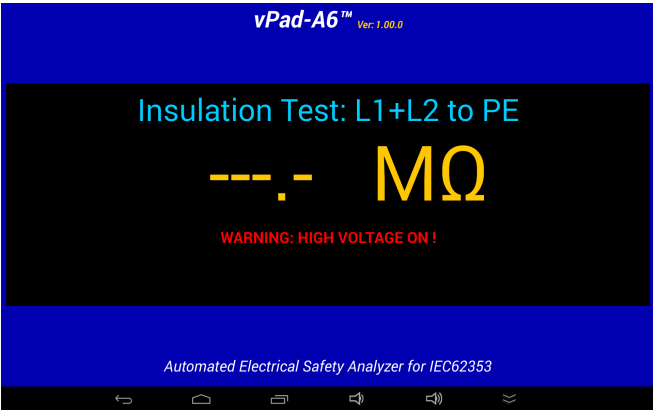


Figure 28 - High Voltage Warning.

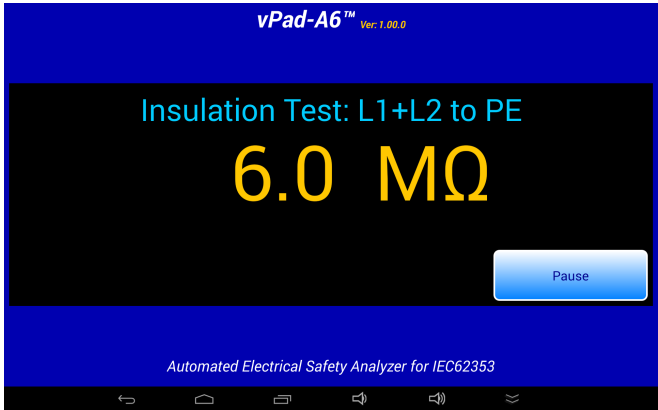


Figure 29 - Mains Insulation Resistance Measurement.

Insulation resistances are measured in the following order, provided they are enabled in the AutoSequence setup: Mains to PE; Mains to Enclosure; Mains to AP; AP to PE; and finally AP to Enclosure. The same test voltage is used for all insulation tests.

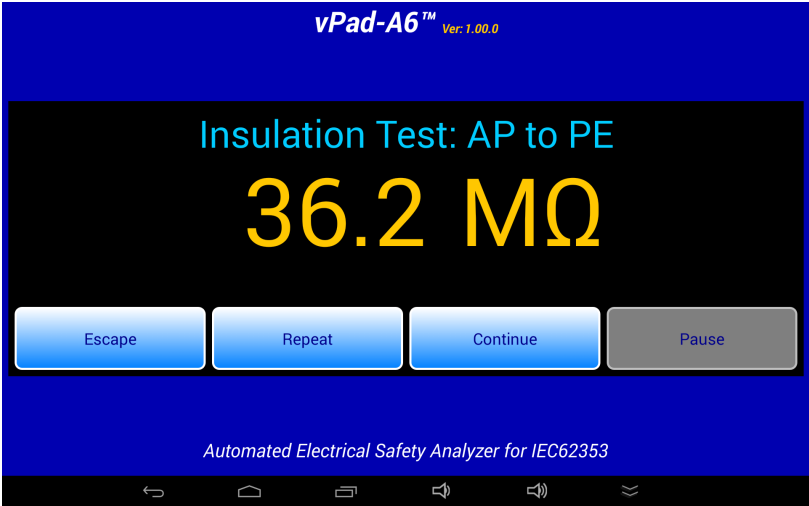


Figure 30 - AP Insulation Resistance Measurement.

2.5.7 Leakage Current

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



Figure 31 - Equipment Leakage.

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

After the first Direct Equipment Leakage test in the sequence, vPad-A6 will perform a Secondary Earth test if it is enabled. If the test fails, users must either correct the Secondary Earth problem in the physical test setup, or abort and restart the AutoSequence. Common causes of Secondary Earth faults include erroneous test lead connections, conductive mounting or fluid supply fixtures, and cables to other devices or accessories.

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Each leakage measurement is compared to a corresponding limit defined in the IEC 62353 standard. If a measurement is below its limit, a "PASS" result is shown and the test sequence continues automatically. If a measurement exceeds the limit, "FAIL" is shown and the sequence pauses. The user is given the option of escaping the test, repeating the measurement, or continuing the sequence with the "FAIL" result on record.

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

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

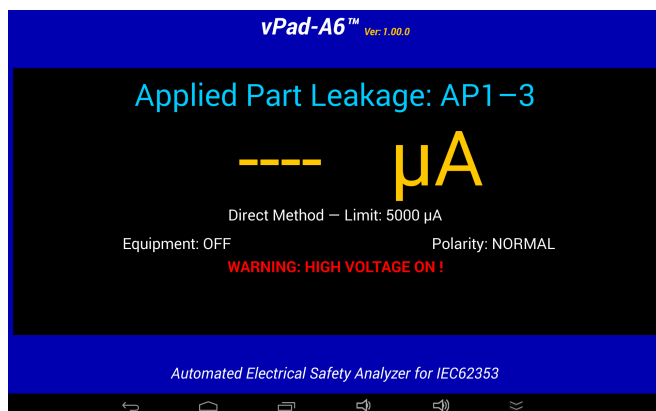


Figure 32 - Mains Applied Warning.

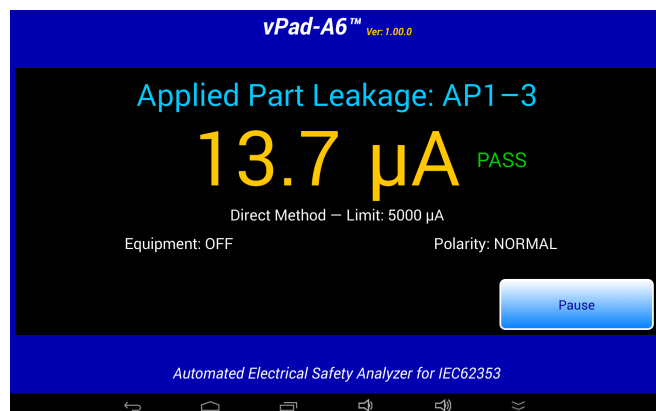


Figure 33 - Applied Part Leakage Measurement.

Depending on AutoSequence settings, the test sequence may stop periodically and display instructions to the user. One of the more commonly-seen prompts will instruct the user to set the power switch of the equipment under test either 'OFF' or 'ON'. Equipment 'OFF' and 'ON' are test conditions which are required by the IEC 62353 standard, although 'OFF' tests may be optionally disabled in the AutoSequence setup to cut the testing time in half.

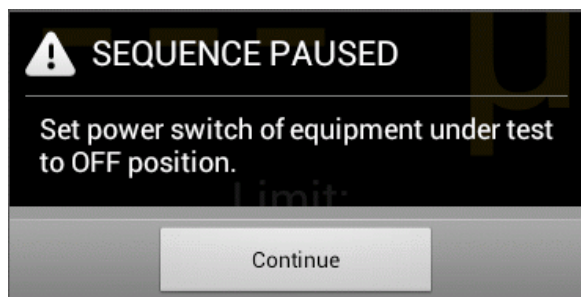


Figure 34 - Prompt to switch equipment OFF.

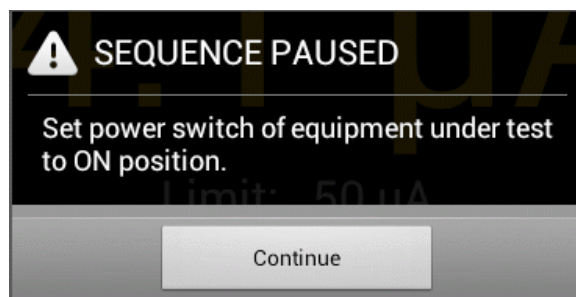


Figure 35 - Prompt to switch equipment ON.

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

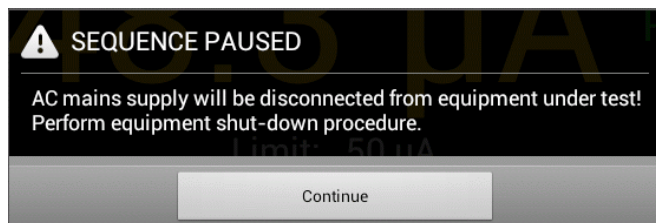


Figure 36 - "Stop-before-OFF" prompt.

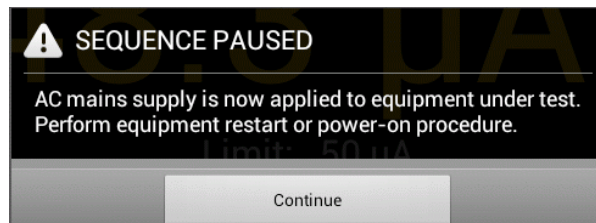


Figure 37 - "Stop-after-ON" prompt.

For more information on leakage test settings of the Autosequence, refer to Section 2.4.5.

2.5.8 Load Test

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



Figure 38 - Load Current Measurement.

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

2.5.9 ECG Waveform Sequence

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

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

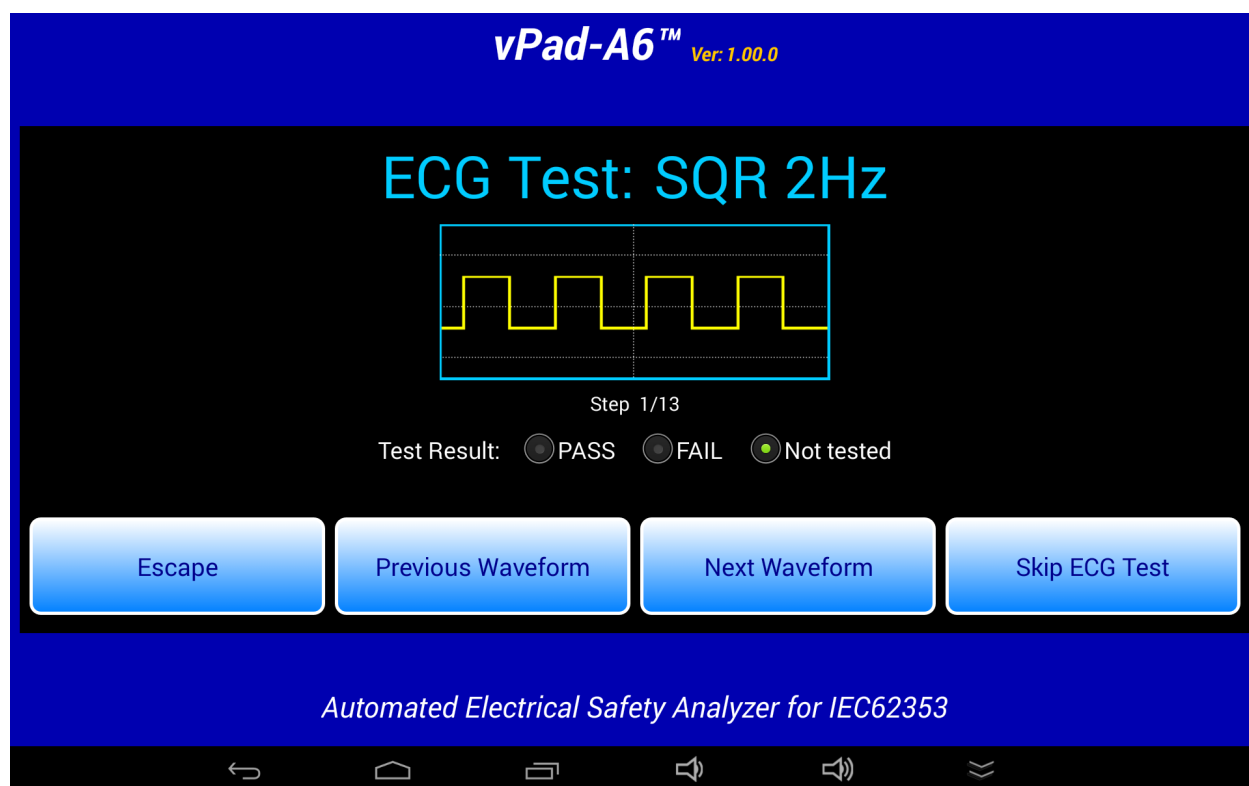


Figure 39 - ECG Test Waveforms.

2.5.10 Test Results Preview

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

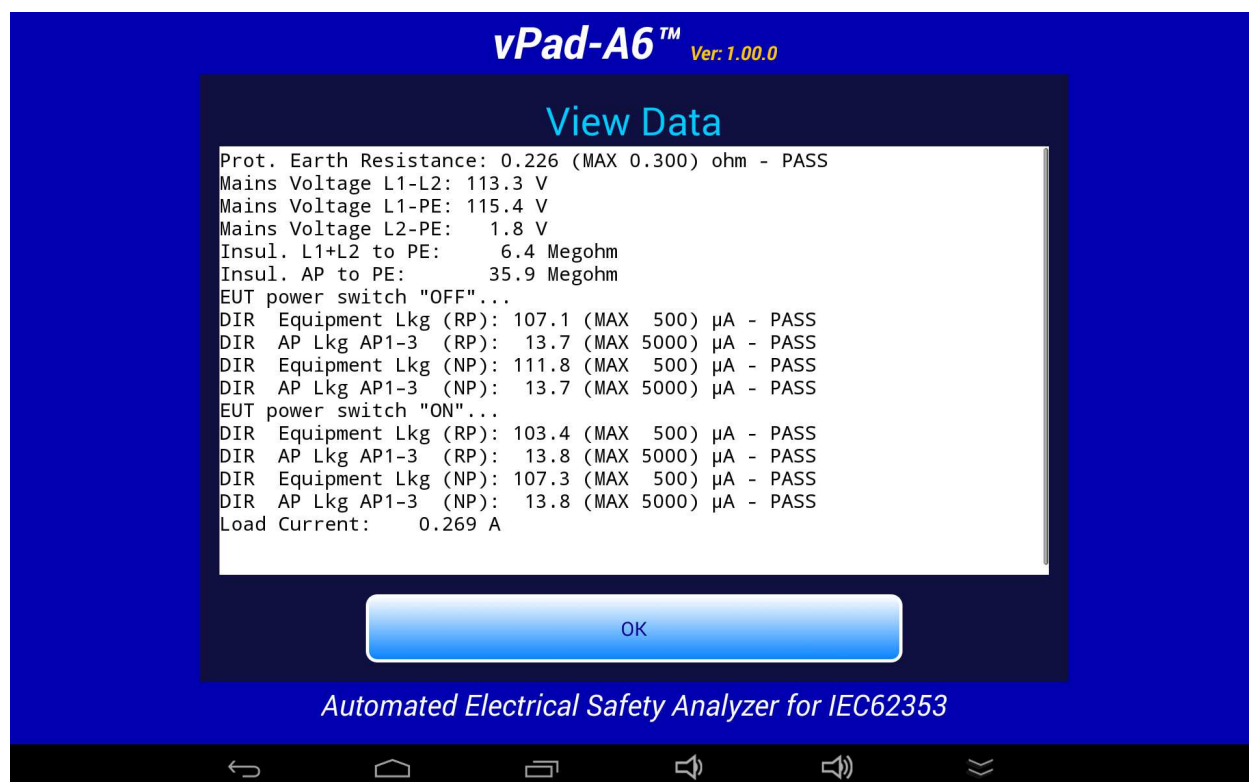


Figure 40 - Test Result Preview.

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

2.5.11 Creating a Test Record

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

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

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

In the event a Control ID has not yet been entered, a reminder warning will be displayed, as shown in *Figure 41*. Pressing **'Continue'** will return to the Equipment Information screen, *Figure 19*. Otherwise, the **'Create Test Record'** screen, *Figure 42*, will be displayed.

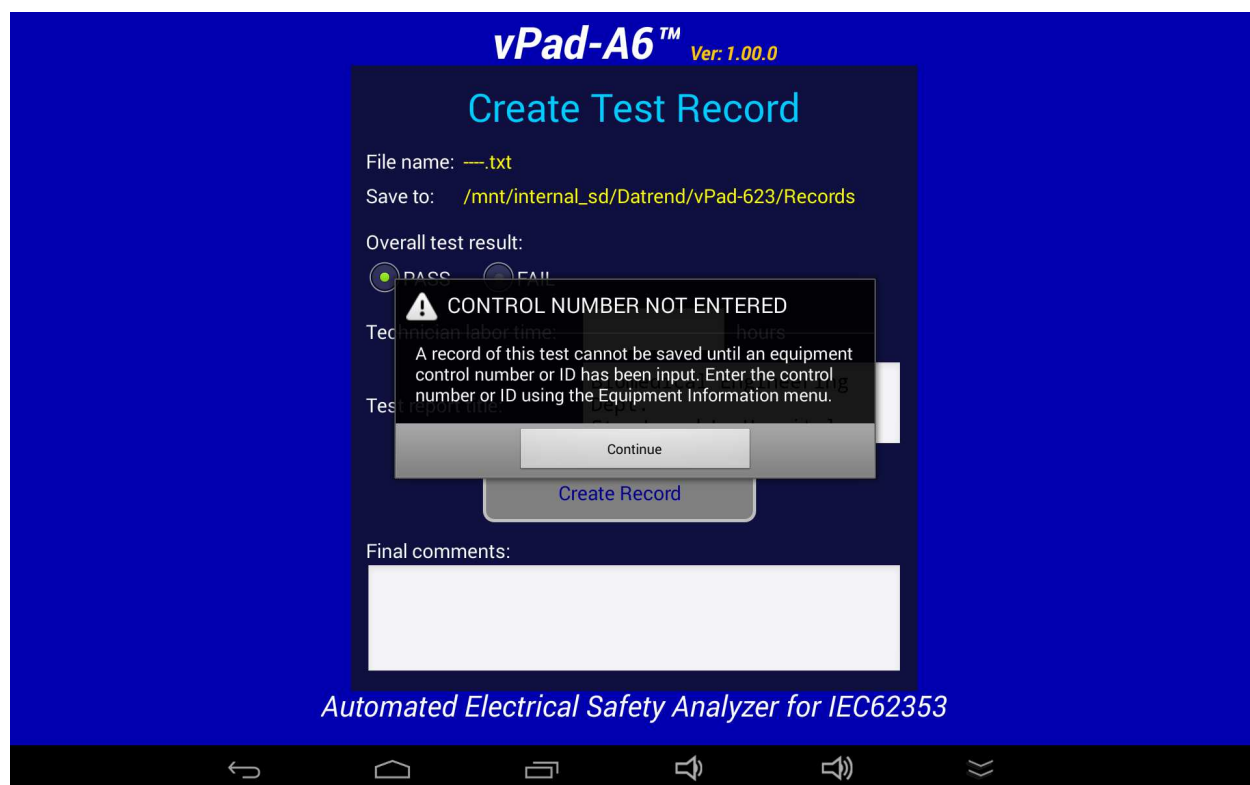


Figure 41 - Control ID Reminder Screen.

Once the EUT has been identified by Control Number, it is possible to complete the creation of the Test Record (*Figure 42*). The filename and destination are displayed at the top of the screen and are not user editable.

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

vPad-A6™ Ver: 1.00.0

Create Test Record

File name: CN1234_20170607_190008_P.txt

Save to: /mnt/internal_sd/Datrend/vPad-623/Records

Overall test result:

☒ PASS ☐ FAIL

Technician labor time: [input field] hours

Test report title: Biomedical Engineering Dept. St. Joseph's Hospital

Create Record

Final comments: [text area]

Automated Electrical Safety Analyzer for IEC62353

Figure 42 - Create a Record.

Time spent by the technician/user can be recorded by entering a value in the '**Technician labor time:**' field. Touching this field space will result in the display of a numeric keypad to allow data entry, per *Figure 43*. Note that this time is intended to encompass ALL of the time spent by the user in preparing for and completing the requirements of the work order. The actual time spent using vPad-A6 to take and record measurements is recorded separately in the Test Record under the heading 'AutoSequence Run Time'. This is the time from the initial selection of the AutoSequence until the Test Record is created.

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

vPad-A6™ Create Test Record

File name: CN1234_20170607_190008_P.txt
Save to: /mnt/internal_sd/Datrend/vPad-623/Records

Overall test result:
☒ PASS ☐ FAIL

Technician labor time: 0.75 hours

Test report title: Biomedical Engineering
Dept.
St. Joseph's Hospital

Next

Figure 43 - Entering Technician Time.

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

Once all of the information has been input, press the '**Create Record**' button to save the record to file. Test Records created by vPad-A6 is saved to **/mnt/sdcard/Datrend/vPad-623/Records** in the tablet.

An example of a Test Record file saved by vPad-A6 is given in APPENDIX A.



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 **external_sd** in the Android file system.

2.6 Using the Android Keyboard

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

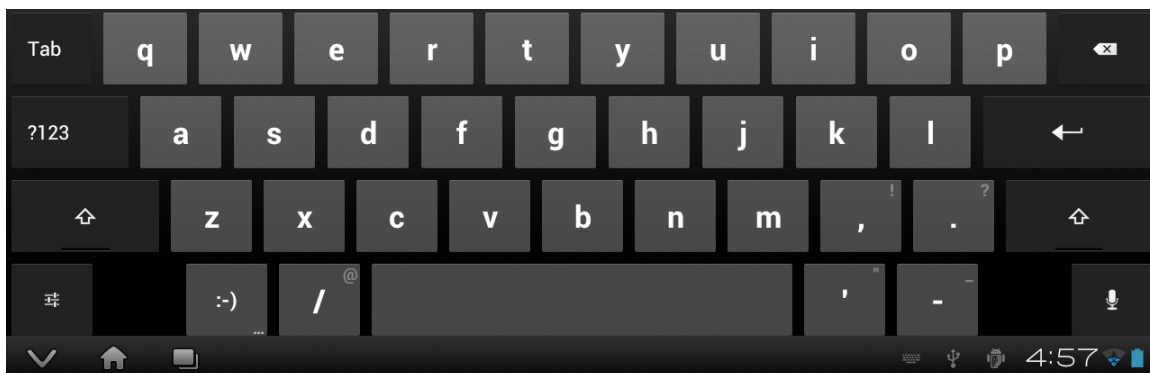


Figure 44 - Android onscreen keyboard.

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

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

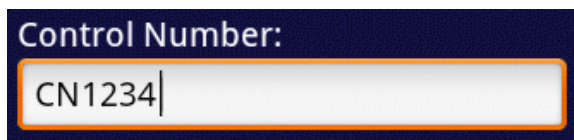
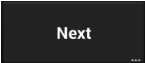
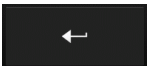


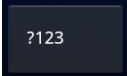
Figure 45 - Single-line text field.

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

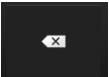
Pressing NEXT  for a single-line text field causes data entry to jump to the next text field on the screen.

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

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Switch the Android keyboard from alpha to numeric modes by pressing .

To activate Caps Lock, double tap or hold SHIFT  until the indicator lights up: . Once activated, press SHIFT again 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.

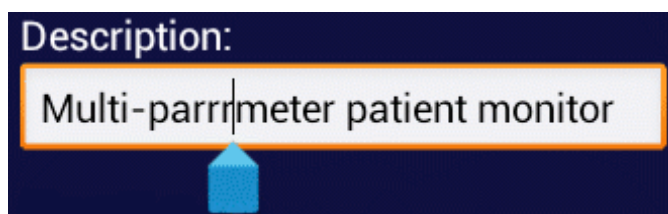
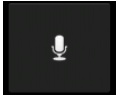



Figure 46 - Error correction with edit cursor.

As an alternative to typing with the keyboard, voice recognition may be used. To enable, press  when the button is available. Note that this will require an active internet connection. 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.

2.7 Record Manager App

vPad Record Manager is an app which is installed on the Android tablet and which may be run independently of, or simultaneously with, the vPad-A6 app.

Record Manager may be used to copy, print, and/or delete Test Record files saved by vPad-A6. 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 47 - 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.

Chapter

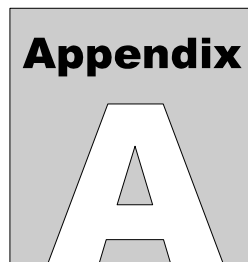
3

3 Upgrades and Maintenance

Software Applications (Apps) may be upgraded from time-to-time to provide enhanced features or improvements. Contact Datrend or your local dealer for information on these upgrades.

In some cases, the changes made to an App may be to correct operational issues that have come to the attention of DSI. These shall generally be referred to as maintenance upgrades. In other cases, the changes may be to improve performance or add features which would enhance the overall functionality of the App. The decision to apply a charge to any upgrade shall be solely at the discretion of DSI.

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APPENDIX A. Sample Test Record

This appendix provides an example of a Test Record that was created with the vPad-A6 app, illustrating the data representation for voltage, current, resistance and leakage measurements, as well as ECG waveform data. Inspection data and example notes have been recorded for some measurements to show how these typically appear in a record.

Biomedical Engineering Dept.
St. Joseph's Hospital
12345 Main Street
MyTown MyState 98765
Phone: 123-456-7890 Ext. 123

File: CN0118_20170609_112536_P.txt
Date: 2017 Jun 09
Time: 11:25:36
vPad ID: vPad Electrical Safety Analyzer
vPad SN: VPS17050001 Cal Date: 2017-05-22

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

Technician ID: RW
Tech Time (hrs): 0.5

Overall Result: PASS

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Signature: _____ Date: _____

Patient Monitor Inspection...

Inspect chassis/housing	PASS
Inspect mounting/fasteners	PASS
Check for loose/missing hardware	PASS
Inspect power cord and plug	PASS
Inspect strain reliefs	PASS
Check fuse(s)	PASS
Check condition of controls & switches	PASS
Check condition of cables and leads	PASS
Check condition of connectors	PASS
Check electrodes and transducers	PASS
Check accessories	PASS
Check labelling	PASS
Test indicators and displays	PASS
Check display focus and intensity	PASS
Check time/date settings	PASS
Updated for daylight savings time.	
Test operation of alarms	PASS
Check operation...overall function OK?	PASS
Test QRS indication	N/A
Test ratemeter accuracy (30...240 BPM)	N/A
Test IBP static pressure (0...300 mmHg)	N/A
Test Temperature(s)	N/A
Test NIBP	N/A
Test SpO2	N/A

Detailed Test Data...

AutoSequence Filename: vpad_a6_3.asq
Title of AutoSequence: ECG 3LD CF (3 leads)
AutoSequence Run Time: 9 minutes

Elec. Safety Standard: IEC62353
Equipment Class: Class I
Applied Part Type: Type CF

Prot. Earth Resistance: 0.093 (MAX 0.300) ohm - PASS
Mains Voltage L1-L2: 119.4 V
Mains Voltage L1-PE: 121.5 V
Mains Voltage L2-PE: 2.7 V
Insul. L1+L2 to PE: 67.4 Megohm
Insul. AP to PE: 831.3 Megohm
EUT power switch "OFF"...

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DIR Equipment Lkg (RP): 177.9 (MAX 500) μ A - PASS
DIR AP Lkg AP1-3 (RP): 49.1 (MAX 50) μ A - PASS
DIR Equipment Lkg (NP): 174.1 (MAX 500) μ A - PASS
DIR AP Lkg AP1-3 (NP): 44.9 (MAX 50) μ A - PASS
EUT power switch "ON" ...
DIR Equipment Lkg (RP): 177.9 (MAX 500) μ A - PASS
DIR AP Lkg AP1-3 (RP): 49.1 (MAX 50) μ A - PASS
DIR Equipment Lkg (NP): 174.1 (MAX 500) μ A - PASS
DIR AP Lkg AP1-3 (NP): 44.9 (MAX 50) μ A - PASS
Load Current: 1.815 A

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

END OF RECORD

