



DATREND
Systems Inc.

vPad-STMTM

**Safety Test MultiSequencer App
for vPad Safety Analyzers**

Software version: 1.92.X

Operating Manual

vPad-STMTM
Safety Test MultiSequencer App
for vPad Safety Analyzers
Operating Manual

© 2017 Datrend Systems Inc.
Unit 130 - 4020 Viking Way
Richmond, BC • CANADA • V6V 2L4
Tel: 800.667.6557 (North America Only) or
604.291.7747 • Fax 604.294.2355
e-mail: customerservice@datrend.com



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1 Overview

vPad-STM™ is a software application (App) which may be installed on vPad Safety Analyzers, including vPad-ESTM, vPad-353™, vPad-ES 2™, and vPad-Rugged 2™. The vPad-STM App may be used in conjunction with multiple standards-specific Apps to create automated electrical safety tests of arbitrary complexity. Such tests may be required when evaluating electrical safety of medical devices in full conformance with IEC standards.

vPad-STM provides these benefits when combined with the test capabilities of Datrend's electrical safety testing Apps:

- perform IEC electrical safety tests of equipment providing a variety of medical functions, where each medical function may have a differing number of applied parts (patient leads) and protection class (Type B, BF or CF)
- perform tests which combine measurements from different IEC safety standards, for example, perform leakage testing per IEC60601 in combination with insulation resistance testing per IEC62353
- perform electrical safety tests in accordance with Edition 2 of IEC60601, instead of Edition 3 which is the default used by vPad-AS when the "limits per standard" setting is enabled.

1.1 MultiSequences

1.1.1 Description

vPad-STM™ implements safety test automation through **MultiSequences**. A typical MultiSequence will be comprised of two or more AutoSequences, where each AutoSequence is specified by a list of measurements that is passed to vPad-ASTM, vPad-A3™ or vPad-A6™ for execution. In addition to the measurements, a MultiSequence may optionally include a description of the equipment and test setup which will be displayed to the user during the test.

As far as the software is concerned, there is no limit to the complexity or number of steps that a MultiSequence may have, although in practice the complexity of any test will be limited by the number of applied part connections that are provided by the vPad analyzer unit. These are terminals AP1 to AP4 which are suitable for independent Type CF leads such as ECG, and AP5 through AP10 which are shorted together and are thus suited to testing Type B and Type BF functional groups.

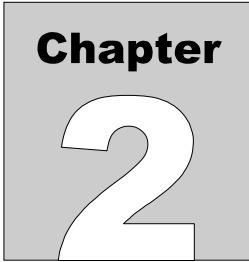
A MultiSequence is written in a descriptive language using a specific format. MultiSequences are contained in files having a **".stm"** extension, which are plain text files that can be viewed or edited with any text editor. MultiSequence programming is covered in Section 3.5 of this manual.

1.1.2 Operation



To perform an electrical safety test, the technician begins by selecting the required MultiSequence from a scrollable list. In the list, MultiSequences are typically named according to the test application, for example, by safety standard, the number of applied parts, and the protection class of the parts.


When a test is selected from the list, a detailed description is displayed which will enable the technician to confirm the test's suitability to the medical device under test. Following the description, the technician is prompted to input information about the equipment such as control number, make, model and so on. Instructions are then displayed which explain the electrical connections that must be made for the test. Lastly, the MultiSequence is executed by launching vPad-AS, vPad-A3 and/or vPad-A6 to perform the required measurements, as specified by the STM script.

After all steps of the script have been executed, a record of the test including inspections and measurements with pass/fail results will be saved in the vPad filing system. In order to create a Test Record, at minimum an equipment control number or other ID must be entered. Test Record files are named according to this entered ID or control number.



2 Installation

vPad-STM may already be installed on the vPad tablet, though the icon for the App  may not have been placed on the Home screen  .

Go to the Apps menu by pressing the icon  on the Home screen. If the vPad-STM icon is in the Apps menu, press and hold the icon for a few seconds. You will then be able drag and drop the icon onto the Home screen. In order to use the App it will need to be activated. When the App is started for the first time, the activation screen will be presented. Enter the activation code provided by your dealer to allow the App to run.

In the event that vPad-STM is not on the tablet, contact your dealer who will provide an installation package for the App via download.

The table below shows the relationship between electrical safety standards, corresponding vPad Apps which can test to those standards, and the safety analyzer models which are compatible with the corresponding Apps. In order to use vPad-STM, you must have at least one of the test automation Apps (vPad-AS, -A3 and/or -A6) shown below installed on the vPad tablet.

Testing Standard	Software Apps Required	Compatible Safety Analyzer Models
AAMI-ES1 and/or IEC60601	vPad-ES and vPad-AS	vPad-ES safety analyzer vPad-353 safety analyzer vPad-ES 2 safety analyzer vPad-ES Rugged safety analyzer vPad-Rugged 2 safety analyzer
IEC62353 Edition 1	vPad-353 and vPad-A3	vPad-353 safety analyzer vPad-ES 2 safety analyzer vPad-ES Rugged safety analyzer vPad-Rugged 2 safety analyzer
IEC62353 Edition 2	vPad-623 and vPad-A6	vPad-ES 2 safety analyzer vPad-Rugged 2 safety analyzer

3 Operation

This chapter covers operation of the vPad-STM app and safety test execution.

3.1 Startup



Press the vPad-STM icon to start the App. A splash screen will display the product name and the software version.



Figure 1 - vPad-STM startup screen.

As the splash screen is displayed, the app will "connect" to the Analyzer Base Unit of the vPad and cause it to perform a number of internal self-tests. The AC supply which powers the Analyzer Base Unit is also tested. Normally, all tests will complete successfully and the main menu 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” to accept the fault and continuing using the app, or “Exit” to close the app (see **Figure 2**). Refer to TABLE 3.1-1 for recommended actions in the event of a startup alarm message.

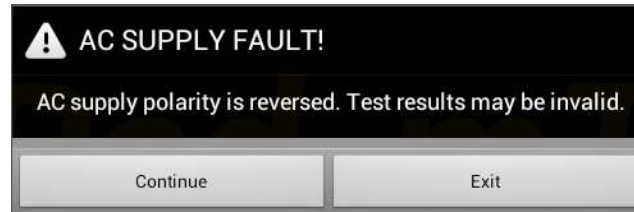


Figure 2 - Alert Dialog: AC supply fault.

TABLE 3.1-1: 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, press and hold RESET button on left side of Base Unit, then try restarting the app• If error persists, contact Datrend Customer Service (see Chapter 4 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, press and hold RESET button for 3 seconds, then press RETRY on error dialog• If error persists, contact Datrend Customer Service (see Chapter 4 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 vPad-STM
AC SUPPLY FAULT (polarity reversed)	AC outlet incorrectly wired	<ul style="list-style-type: none">• Do not use vPad with incorrect or unsafe AC supply• Connect Base Unit to a different outlet

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AC SUPPLY FAULT (ground disconnected)	AC outlet incorrectly wired	<ul style="list-style-type: none">• Do not use vPad 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 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 on left side of Base Unit for 3 seconds, then try restarting app• If problem persists, contact Datrend Customer Service (see Chapter 4 for contact information)

3.2 Main Menu



Following a successful start-up, vPad-STM will display the main menu of the App:




Figure 3 - Main menu of vPad-STM.

Some example MultiSequences are supplied with the App and will appear in the scrollable list as shown above. To scroll the window, press and drag on the *center of the list* (not the scrollbar at right) until the desired test is found. To start a safety test, tap anywhere along the desired row to select it.

On startup, the App defaults to '**Run**' mode as indicated by the radio buttons above the list. '**Edit**' mode may be selected by tapping the corresponding radio button. This mode is explained in Section 3.5.

To return to the Android Home screen, press the  icon on the navigation bar. Note this will only pause the App temporarily and will not actually terminate or close vPad-STM. To fully close the App, press the Android "BACK" navigation button  when viewing the main menu.

3.3 Settings Menu

The Settings button  on the main menu shows the available user settings.

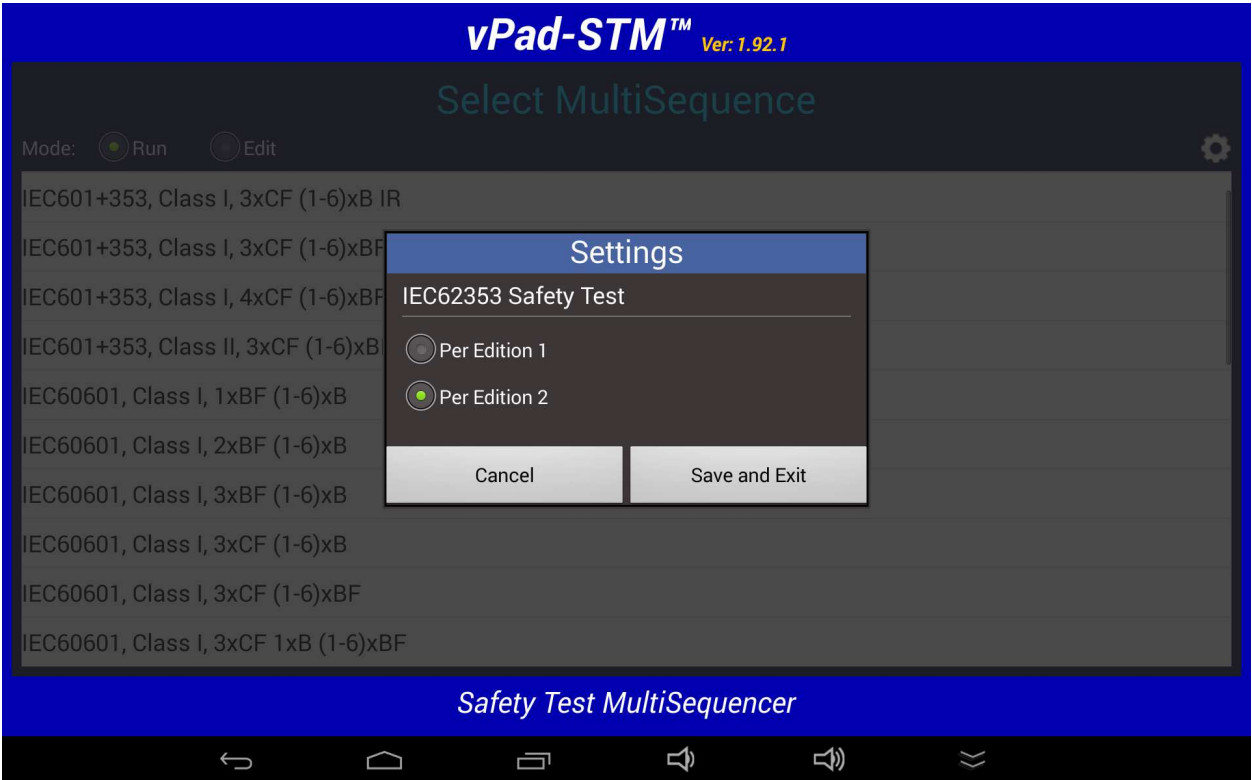


Figure 4 - vPad-STM settings menu.

When a MultiSequence test includes a IEC62353 safety test, vPad-STM uses the above setting to determine the App to be launched:

<u>IEC62353</u>	Automated Safety Test App	Manual Safety Test App
Per Edition 1	vPad-A3	vPad-353
Per Edition 2	vPad-A6	vPad-623

The **IEC62353 Safety Test** setting should typically be chosen based on the Apps which have been installed and activated. If an App required for the MultiSequence is not installed, vPad-STM will display an error message as shown in *Figure 12* on page 14, or *Figure 20* on page 20.

3.4 Running a Safety Test

3.4.1 Test Description

When a test is selected from the main menu, the first screen shown will present a detailed description of the test:

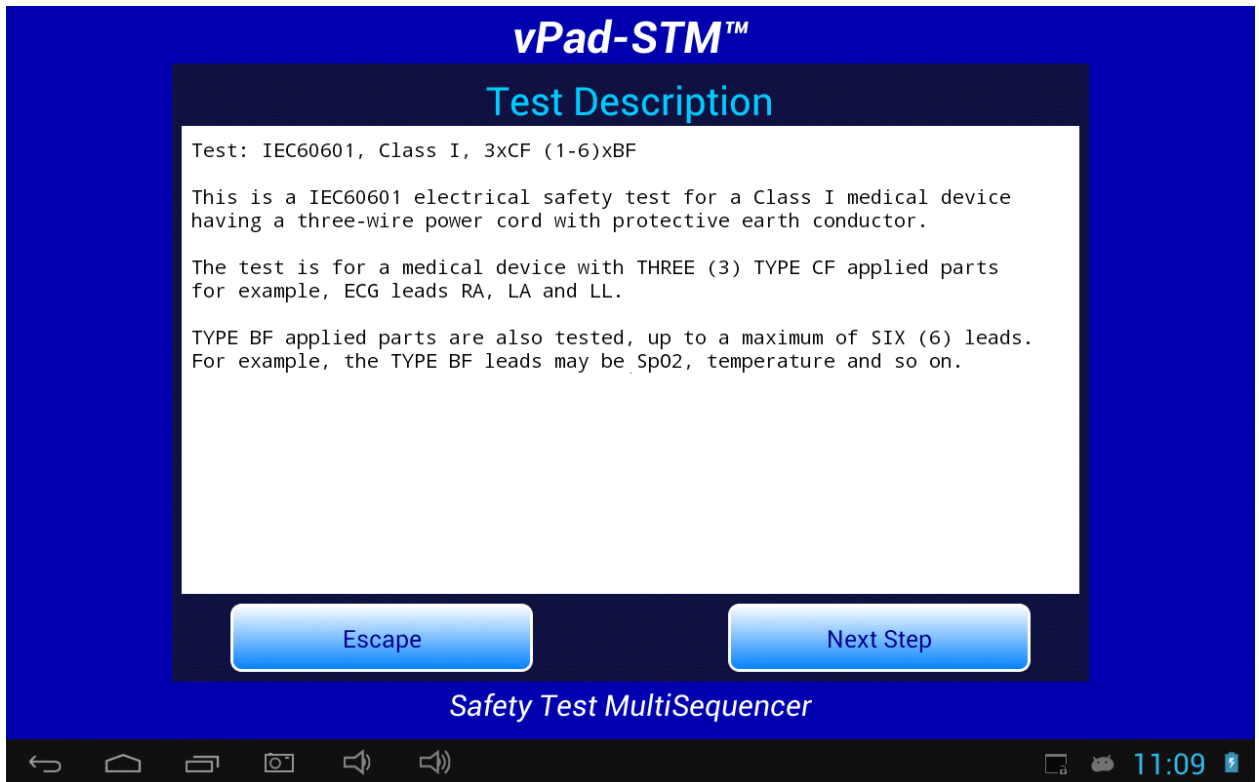


Figure 5 - Test Description menu.

Review the description. If the safety test is applicable to the medical device under evaluation, press '**Next Step**' to continue with the test. Otherwise, press '**Escape**' to return to the main menu and choose a different test.

A test description is optional and will not be shown if the selected MultiSequence program does not include a **Description** block. For more information on MultiSequence programming, refer to Section 3.5.2.

3.4.2 Equipment Information

After the test description, the next screen will be for entering information about the equipment:



Figure 6 - Equipment Information menu.

Tap on a text field to display the Android keyboard and enter information. If an external keyboard is connected to the tablet, the Android keyboard is not displayed and data entry is then accepted from the external input device. A barcode scanner can also be used for data entry. Refer to Section 3.6 for detailed instructions on using the Android keyboard.



Figure 7

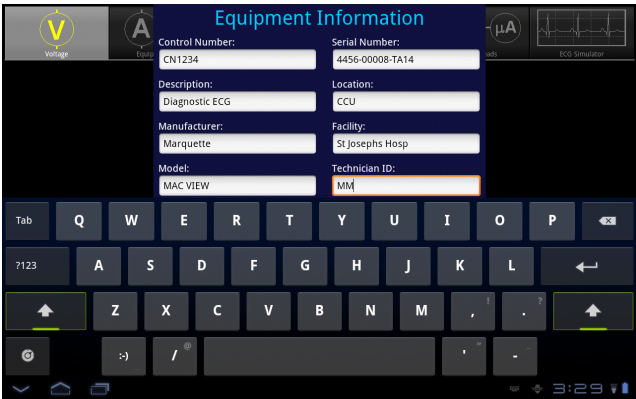
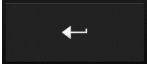



Figure 8


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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.

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 is switched off, and are restored on subsequent use of the App.

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

- | | |
|------------------|--|
| Escape | Cancel the safety test and return to the main menu. No test results are saved. |
| Clear | Clear all fields on the menu, except for Facility and Technician ID. |
| Next Step | Press to proceed with the next step of the test sequence. |

3.4.3 Test Connections

After equipment information has been entered, the next screen will present instructions for connecting the device under test to the vPad safety analyzer:

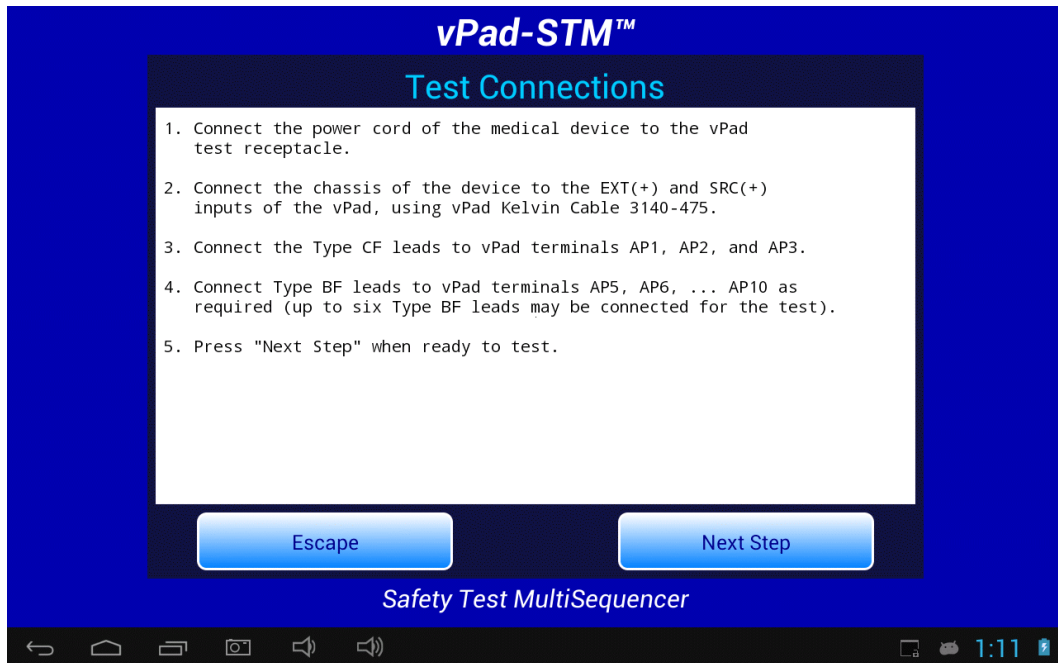


Figure 9 - Test Connections menu.

Make the required connections then press '**Next Step**' to initiate the electrical safety measurements. If you press '**Escape**', you will be asked to confirm the abort before you are returned to the main menu:

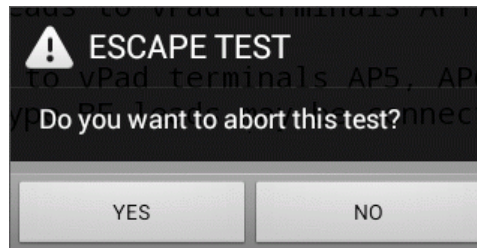


Figure 10 - Abort test confirmation.

Test connections are optional and will not be shown if the selected MultiSequence program does not include a **Connections** block. For more information on MultiSequence programming, refer to Section 3.5.2.

3.4.4 Test Sequence

As each step of the STM script is executed, vPad-STM launches either the vPad-AS App, the vPad-A3 App, or the vPad-A6 App to perform the electrical safety measurements. vPad-STM passes the **Test** specifications defined in the STM script to the appropriate App, which then runs the AutoSequence.

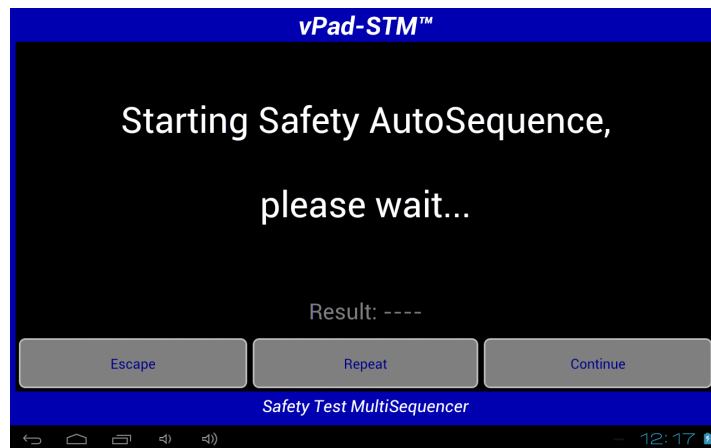


Figure 11 - vPad-STM launches safety testing App.

If the targeted App is not installed on the tablet, then the following error message is shown.



Figure 12 - vPad safety testing App is not installed.

In the above situation, you may press '**Continue**' to skip the current step and proceed to the next step of the MultiSequence. In this case, "test skipped" status will be saved to the Test Record. Alternatively, you may press '**Escape**' to abort the MultiSequence in progress and discard results which have been saved up to this point.

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When successfully launched, the vPad-AS, vPad-A3 and vPad-A6 Apps each provide an '**Enable Edits**' checkbox on their respective main menus. If this box is checked, the AutoSequence Editor of the App will be shown when the App is launched by vPad-STM. In this case, review the test settings and make changes if necessary, then press '**Run Test**' to begin the AutoSequence.

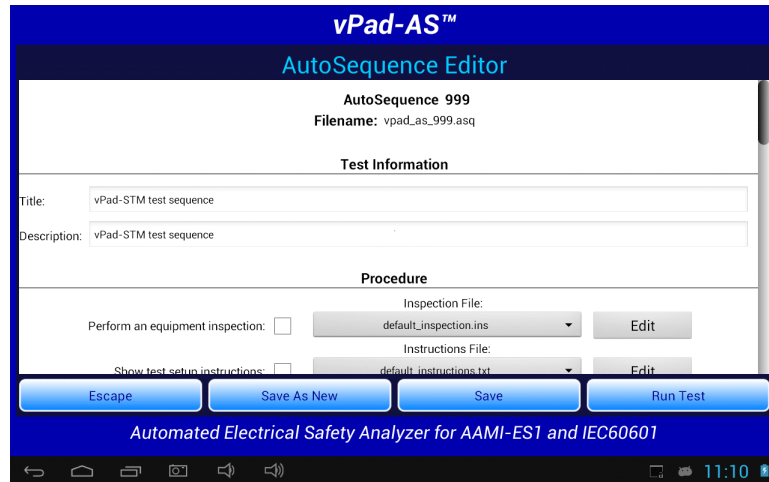


Figure 13 - Review test settings with AutoSequence Editor.

Note: As shown in the figure above, AutoSequence #999 is used by vPad-STM to convey the **Test** specifications to vPad-AS, vPad-A3 or vPad-A6. It is a temporary AutoSequence which is deleted after the safety test has been completed. AutoSequence #999 is reserved for use by vPad-STM and will not conflict with the other AutoSequences used or created by vPad-AS, -A3 and -A6.

While it is possible to modify sequence #999, it is not recommended, as it negates the advantage of using pre-defined, well considered multisequences. The exception might be the Inspection and Instruction files, which may be generically defined as the 'default_....', but could benefit by changing to a more specific file during the test.

The 'Show Results' checkbox is disregarded since the results will be displayed by vPad-STM as part of its function. This aspect of vPad-STM cannot be modified.

If the '**Enable Edits**' checkbox of vPad-AS, vPad-A3 or vPad-A6 has not been checked, the AutoSequence Editor will be skipped and the test will begin with the first enabled inspection or safety measurement of the AutoSequence.

If the AutoSequence includes an equipment inspection, the Inspection menu will be shown next. Select an inspection task using the **'Next Task'** or **'Previous Task'** button, perform the specified inspection and select **'Done'**. If the inspection result is acceptable, press **'OK'**. For each task, comments or data may be optionally recorded by tapping the **'Comments'** field, which will then display the Android keyboard. Power to the equipment may be switched ON or OFF via the **'Receptacle'** button. Pressing the **'Run Safety Test'** button (which is initially a **'Skip Inspection'** button until an inspection result is saved) will initiate the electrical safety measurements of the AutoSequence. The **'Escape'** button may be pressed at this step or a subsequent step to abort the AutoSequence in progress.

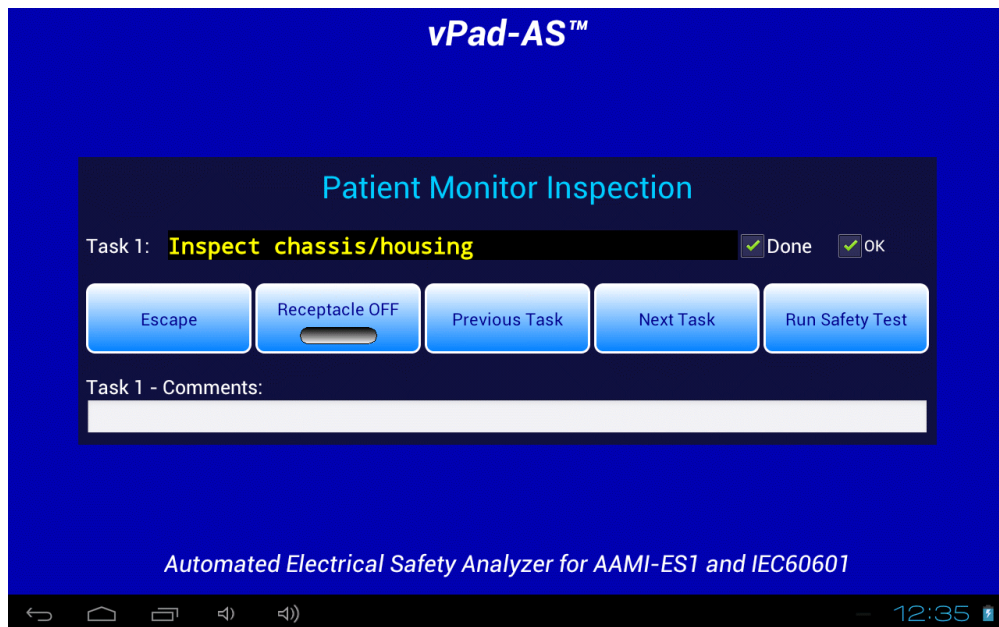


Figure 14 - Perform equipment inspection.

Note: Example MultiSequences installed with the vPad-STM App do not have equipment inspections enabled by default. Inspections may be enabled through MultiSequence programming as described in Section 3.5.

Following the optional inspection, the AutoSequence will proceed automatically through a number of electrical safety measurements. Each measurement is compared to a limit which is defined in the AutoSequence setup.

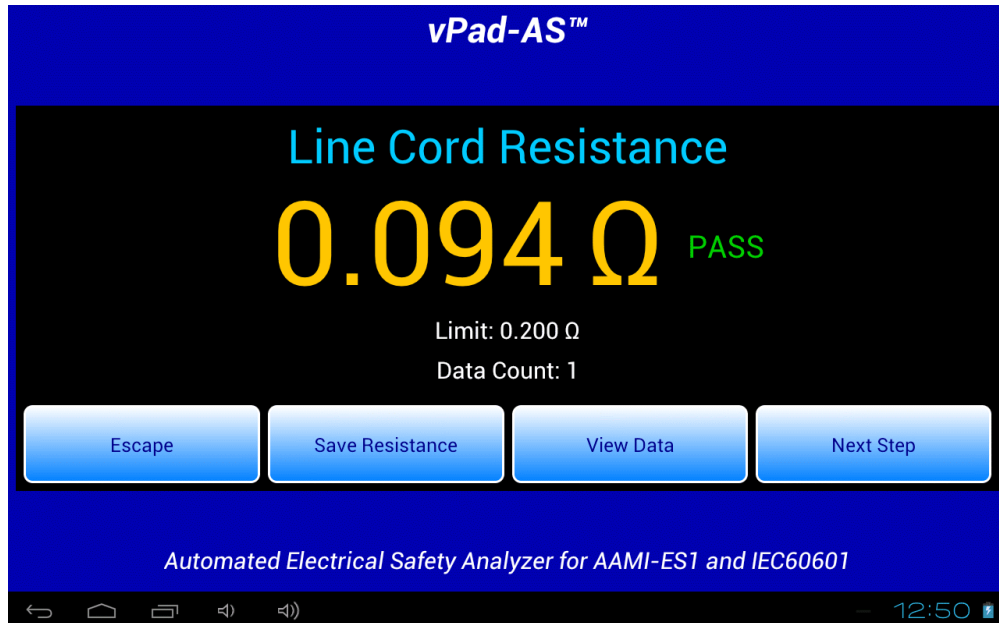


Figure 15 - Line cord resistance measurement.

The AutoSequence may stop at certain steps and you may be required to respond to prompts or alarms displayed by the safety testing App. If necessary, refer to **MN-079 (6100-045) vPad-AS Operators Manual**, **MN-080 (6100-046) vPad-A3 Operators Manual** or **MN-124 (6100-098) vPad-A6 Operators Manual** for further information on electrical safety testing and use of these Apps.

Note these operator manuals are provided on the Android tablet, and may be viewed with the **Datrend Docs App** which is on the Home screen.



After all measurements of the AutoSequence have been completed, you are presented with a menu for saving the acquired results in the Test Record. The result of the AutoSequence test is shown as "PASS" or "FAIL"; if the result is a "PASS" and you wish to change it to a "FAIL" you may do so by pressing the radio button. If the result is a "FAIL", you cannot modify the overall result.

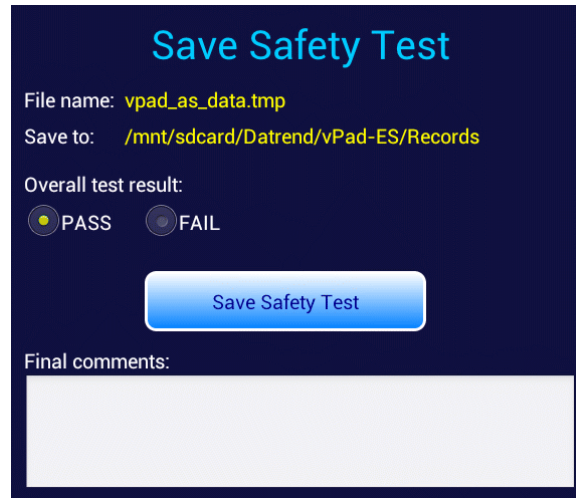


Figure 16 - Save AutoSequence test results.

If desired, enter concluding comments about the safety test by tapping the **'Final comments'** box, which will display the Android keyboard. When ready to exit the safety testing App and return to vPad-STM, press the **'Save Safety Test'** button.

After the safety testing App is closed, measurement values and the result obtained by the AutoSequence are then displayed by vPad-STM. Results are displayed in a scrollable view; to see all values, move the view by press-and-drag gesture.



Figure 17 - AutoSequence results displayed by vPad-STM.

While an AutoSequence is running, you may press the **'Escape'** button to interrupt or abort. The safety testing App (vPad-AS, vPad-A3, or vPad-A6) will close and execution will return to vPad-STM.



Figure 18 - AutoSequence aborted while in-progress.

If you interrupt an AutoSequence in progress, you can restart the AutoSequence by pressing the **'Repeat'** button, or you can press **'Continue'** to skip to the next step of the MultiSequence without completing the current AutoSequence. In this case, "test skipped" status will be saved to the Test Record. To abort the MultiSequence entirely and discard all results, press **'Escape'** on the screen of *Figure 18*.

3.4.5 Manual Safety Test

MultiSequences can include manual safety tests which are performed with one or more of these Apps: vPad-ES for AAMI-ES1 or IEC60601 tests; and/or vPad-353 or vPad-623 for IEC62352 tests. Manual tests provide flexibility and enable users to perform certain electrical measurements which are not easily automated, however, manual tests may require additional instructions to be displayed to the user. For details on how to add such instructions to a MultiSequence program, refer to Section 3.5.2.7.

Manual testing Apps are launched by vPad-STM in a similar way to automated testing Apps.

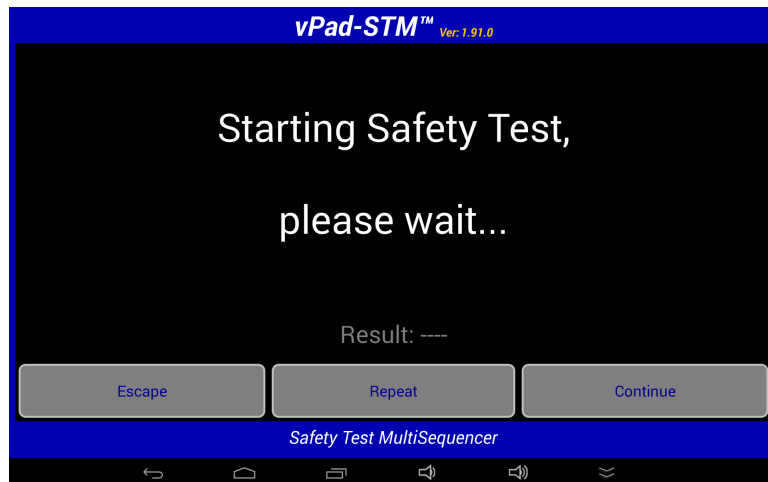


Figure 19 - vPad-STM launches App for manual safety testing.

If the targeted App is not installed on the tablet, then the following error message is shown.



Figure 20 - vPad safety testing App is not installed.

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In the above situation, you may press **'Continue'** to skip the current step and proceed to the next step of the MultiSequence. In this case, "test skipped" status will be saved to the Test Record. Alternatively, you may press **'Escape'** to abort the MultiSequence in progress and discard results which have been saved up to this point.

To perform a manual test, vPad-STM passes the measurement type (voltage; resistance; or leakage) as defined in the Multisequence to the safety testing App. When testing leakage currents with vPad-ES, configuration of the measuring device (AAMI; IEC; AC; DC) may be selected via the **'Settings'** button on the leakage menu.

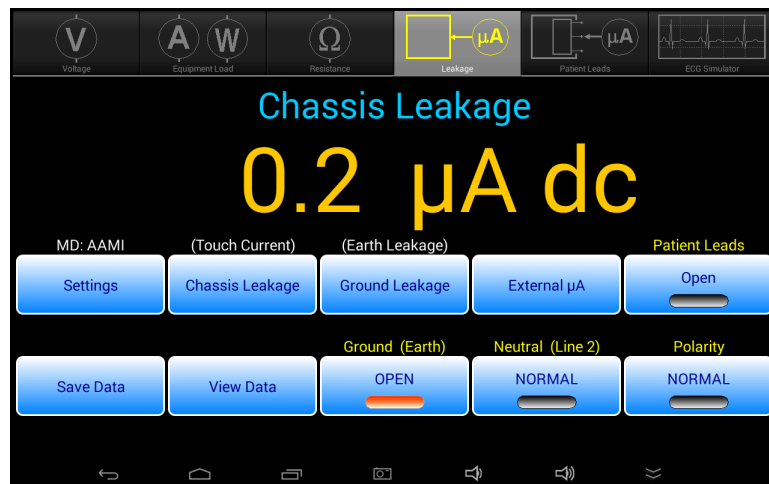


Figure 21 - Select safety test measurement.

Perform the required measurements and save each result with the **'Save Data'** button.

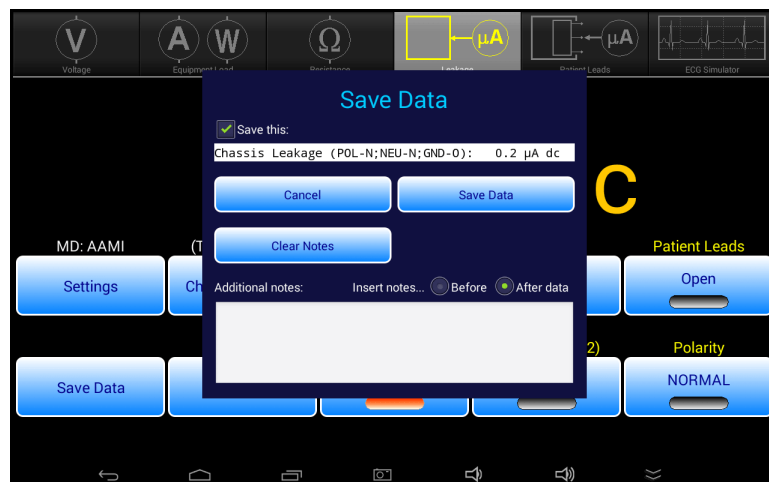


Figure 22 - Save measurement result to memory.

When all required measurements have been stored, press the **'View Data'** button to recall the recorded values, then press the **'Save Data'** button to prepare the results for return to vPad-STM.



Figure 23 - View recorded measurement results.

On the **'Save Safety Test'** dialog, select either "PASS" or "FAIL" for the overall result with the corresponding radiobutton, then press **'Save Test'** to quit the manual test and return the data to vPad-STM. Note that "PASS" is the default result on entry to the **'Save Safety Test'** dialog; "FAIL" must be chosen by the user manually, when desired.

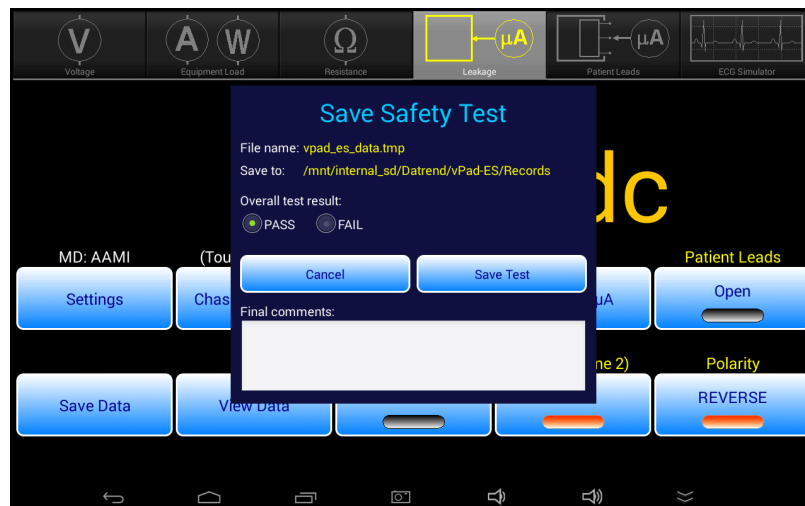


Figure 24 - Select pass/fail and return to vPad-STM.

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After the manual testing App has been closed, the recorded measurement values and the overall result as selected by the user are displayed by vPad-STM. Results are displayed in a scrollable view; to see all values, move the view by press-and-drag gesture. Press **'Next Step'** when ready to proceed to the next step of the MultiSequence.



Figure 25 - Results of manual safety test.

If you wish to repeat the manual tests that have just been completed, press the **'Repeat'** button. Alternatively, to proceed to the next step of the MultiSequence, press **'Continue'**.



While a manual test is running, you may press the Android **'Back'** button  to interrupt or abort. The safety testing App in use (vPad-ES, vPad-353, or vPad-623) will close and execution will then return to vPad-STM.



Figure 26 - Manual tests aborted while in-progress.

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If you interrupt manual tests in progress, you can restart the test by pressing the **'Repeat'** button, or you can press **'Continue'** to skip to the next step of the MultiSequence without completing the current step. In this case, "test skipped" status will be saved to the Test Record. To abort the MultiSequence entirely and discard all results, press **'Escape'** on the screen of *Figure 26*.

If necessary, refer to **MN-074 (6100-040) vPad-ES Operators Manual**, **MN-041 (6100-041) vPad-353 Operators Manual** or **MN-123 (6100-099) vPad-623 Operators Manual** for further information on manual safety testing and use of these Apps. Note these operator manuals are provided on the Android tablet, and may be viewed with the **Datrend Docs App**  which is on the Home screen.



3.4.6 Creating a Test Record

On completion of the MultiSequence, the **'View Data'** menu is then shown. This menu is always shown regardless of test settings and displays a compilation of inspections and measurements as acquired by the constituent AutoSequences and manual tests. Results are shown in a scrollable view; to see all values, move the view by press-and-drag gesture. Press **'Next Step'** when ready to proceed to the **'Create Test Record'** menu.

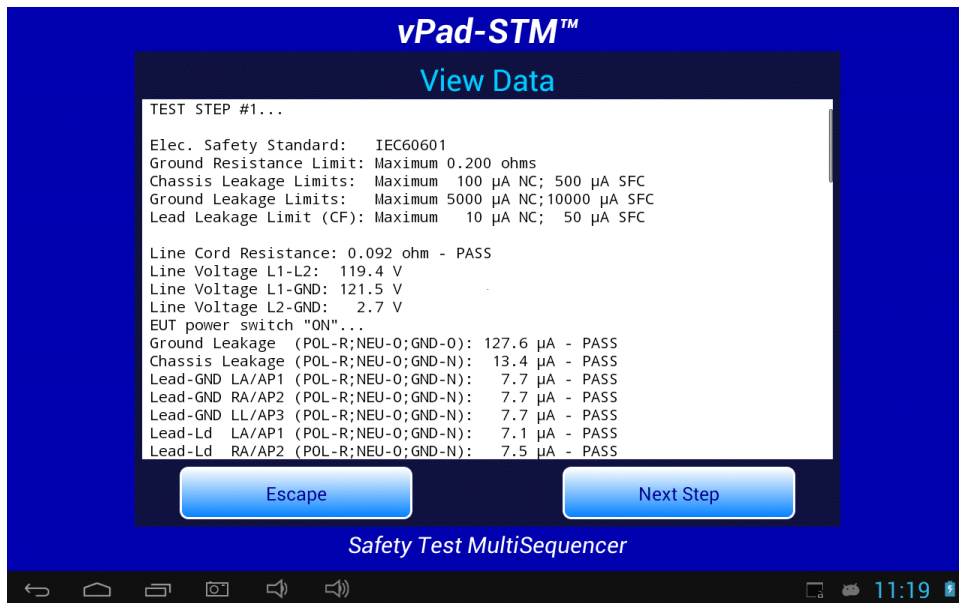


Figure 27 - Comprehensive view of results from all AutoSequences.

When all 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. vPad-STM test records are saved to the "external storage" of the Android tablet, in the **Datrend/vPad-STM/Records** directory.

In the event a Control ID has not yet been entered, a reminder will be displayed, as shown in *Figure 28*. Pressing '**Continue**' will return to the Equipment Information screen, *Figure 6*. Otherwise, the '**Create Test Record**' screen, *Figure 29*, will be displayed.



Figure 28 - 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 29*). The filename and destination are displayed at the top of the screen and are not user editable.

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

Figure 29 - 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 30*. 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-STM to take and record measurements is recorded separately in the Test Record under the heading 'MultiSequence Run Time'. This is the time from the initial selection of the MultiSequence until the Test Record is created.

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

Create Test Record

File name: CN0001_20130718_085913_P.txt
Save to: /mnt/sdcard/Datrend/vPad-ES/Records

Overall test result:
☒ PASS ☐ FAIL

Technician labor time: hours

Test report title:
vPad Safety Analyzer
Datrend Systems Inc.

Tab - + . 1 2 3
* / , 4 5 6
() = 7 8 9
* 0 #
Next

Figure 30 - 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 a file. The file is in TXT format and is saved to directory **mnt/sdcard/Datrend/vPad-STM/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.

3.5 MultiSequence Programming

A Safety Test MultiSequence is a script which is contained in a file with a ".stm" extension. The ".stm" files are stored in directory `mnt/sdcard/Datrend/vPad-STM`. The Select MultiSequence menu of vPad-STM displays the MultiSequence files in ascending order by filename, but without the ".stm" extension. Arbitrary filenames can be used, but ideally should be chosen to describe the test in terms of safety standard, medical device, and the number and class of applied parts.

This section explains how MultiSequence files are edited or created, and the syntax of the MultiSequence script.

3.5.1 Editor App

MultiSequence files are edited using a text editor App. New MultiSequence scripts can be created by opening an existing ".stm" file with a text editor and then saving the file with a different filename.

To edit a MultiSequence, set vPad-STM to "edit" mode by pressing the 'Edit' radio button on the Select MultiSequence menu.



Figure 31 - Set vPad-STM to "edit" mode.

When a test is selected from the menu, vPad-STM will then call an App to open the MultiSequence file. If you have not already chosen a favourite App for working with text files, you will be prompted to select one.

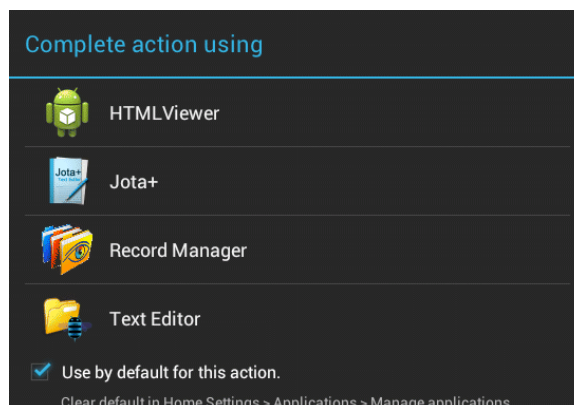


Figure 32 - Select text editor App.

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Apps shown in the list of **Figure 32** will be able to open text files for display, although only some of them may be capable of editing a file. Select "Jota+" if it appears in the list, or an alternative text editor if you have installed one. To avoid being prompted with this screen again, check the box for **'Use by default for this action'** *before* selecting the editor App.

The text editor will display the contents of the selected **".stm"** file. An example file appears in **Figure 33**.

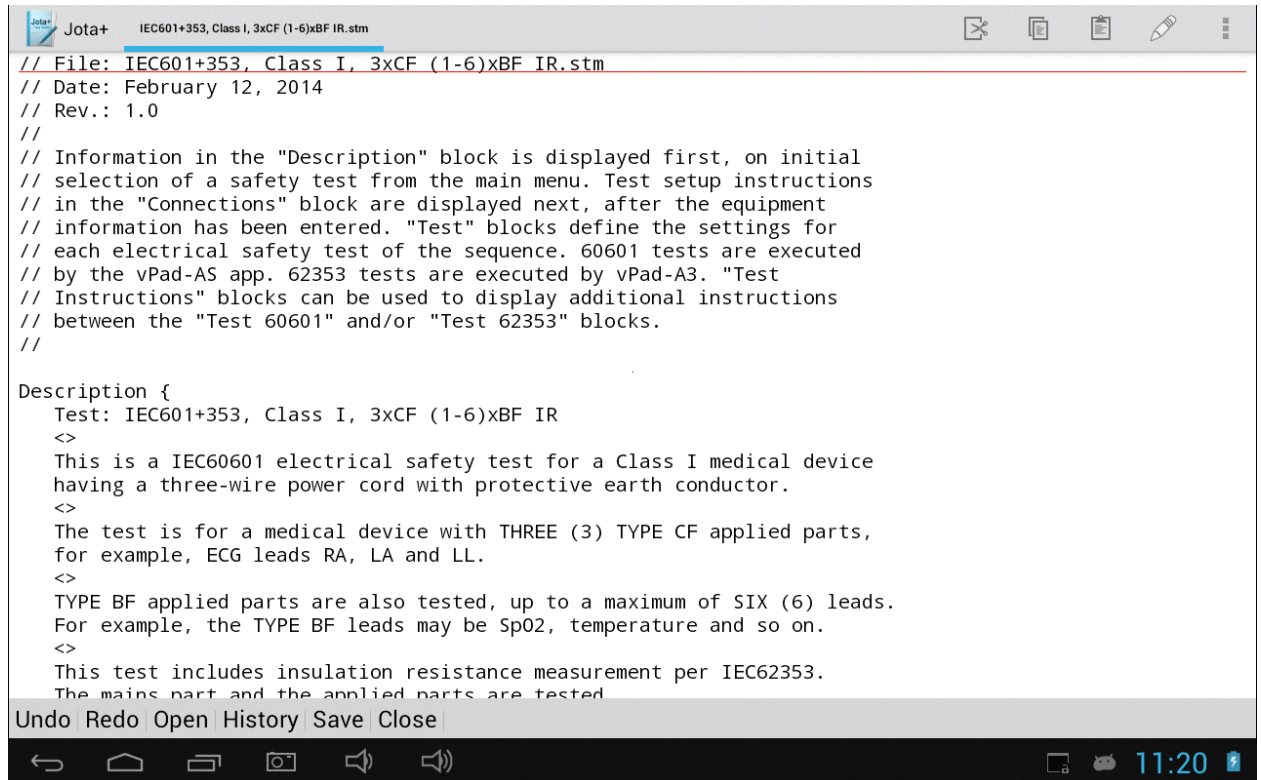



Figure 33 - Example of a **".stm"** file.

Edits can be made to the script and the result saved under the same or different filename. If using Jota+, saving the file may be done after pressing the menu icon  at upper right, which will reveal the menu drop-down (see **Figure 34**). If saving as a new file, choose a filename that adequately describes the safety test and remember to keep or add the **".stm"** extension.

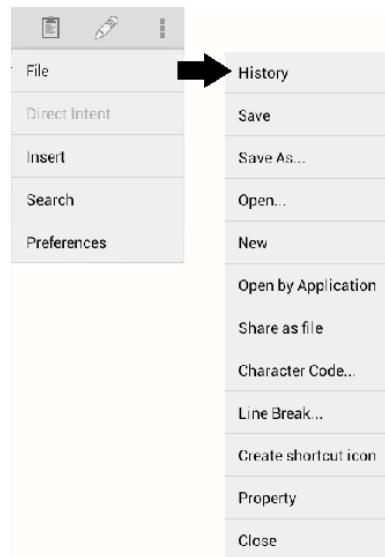


Figure 34 - Jota File menu.

Most editors implement cut/copy/paste and other common functions, but use of such functions will depend on the App chosen. Specific instructions for the text editor are outside the scope of this manual; consult help menus of the editor App or on-line documentation for details.

3.5.2 Programming Language

Each ".stm" file contains a program or script that is organized as a number of discrete sections or "*blocks*".

The **Description** block contains information which will be displayed by the Test Description menu at the start of a test (see Section 3.4.1 and *Figure 5*). The **Connections** block contains instructions which will be displayed by the Test Connections menu after equipment information is input (see Section 3.4.3 and *Figure 9*). **Test** blocks contain AutoSequence settings which are passed to vPad-AS, vPad-A3 or vPad-A6 for execution. **Test** blocks may also be used to display additional instructions to the user, in between calls to vPad-AS, vPad-A3 or vPad-A6. The ".stm" file can contain an unlimited number of **Test** blocks, enabling safety tests of arbitrary length and complexity to be programmed.

In addition to **Description**, **Connections**, and **Test** blocks, the ".stm" file may optionally include blank lines and comments to improve readability of the code. { and } characters are used to delimit blocks within the file. Additional special characters are used to format text as displayed by Description, Connections and Instructions menus.

Further details of the MultiSequence programming language are explained in the following sections.

3.5.2.1 Blank Lines

Blank lines may be placed anywhere in a MultiSequence program and will be ignored by vPad-STM when the MultiSequence is executed. Blank lines are useful for separating a MultiSequence into logical sections.

3.5.2.2 Comments

Comments may be placed within a MultiSequence program to explain what the program does or how it works. Any line that begins with a double-slash `//` is considered a comment by vPad-STM and will be ignored when the MultiSequence is executed. A comment must be placed on its own line.

```
// This is an example of a comment
// And here is another comment following the first comment
```

3.5.2.3 Description Block

Text to be displayed by the Test Description menu (see Section 3.4.1 and *Figure 5*) is contained in a **Description** block. This block can appear anywhere in the `".stm"` file, although normally it is placed near the beginning. The block begins with **Description {**, with subsequent lines being interpreted as the text to be displayed by the menu. The block is terminated by **}**, which must be placed on its own line.

By default, whitespace at the beginning and end of lines is removed prior to display by the menu. This default can be overridden by special character sequences.

`<>` may be used to insert a blank line and thereby separate displayed text into paragraphs. If a line begins with a backslash `\`, whitespace is not removed on the left and so paragraph indenting may be preserved as it appears in the `".stm"` file.

Example:

```
Description {
  Test: IEC60601, Class I, 1xBF (1-6)xB
  <>
  This is a IEC60601 electrical safety test for a Class I medical device
  having a three-wire power cord with protective earth conductor.
  <>
  The test is for a medical device with ONE (1) TYPE BF applied part.
  <>
  TYPE B applied parts are also tested, up to a maximum of SIX (6) leads.
}
```


3.5.2.4 Connections Block

Text to be displayed by the Test Connections menu (see Section 3.4.3 and *Figure 9*) is contained in a **Connections** block. This block can appear anywhere in the ".stm" file, although it makes most sense to place it after the **Description** block. Text formatting for **Connections** is the same as for **Description**. The only real difference between **Connections** and **Description** is the step at which the text is displayed during the test sequence.

Example:

```
Connections {
  1. Connect the power cord of the medical device to the vPad
    \ test receptacle.
  <>
  2. Connect the chassis of the device to the EXT(+) and SRC(+)
    \ inputs of the vPad, using vPad Kelvin Cable 3140-475.
  <>
  3. Connect the Type BF lead to vPad terminal AP1.
  <>
  4. Connect Type B leads to vPad terminals AP5, AP6, ... AP10 as
    \ required (up to six Type B leads may be connected for the test).
  <>
  5. Press "Next Step" when ready to test.
}
```

3.5.2.5 Test Blocks

Test blocks are executed sequentially as they are encountered in the ".stm" file. There are five types of **Test** block, as follows:

Safety Test	Mode	Start of Test Block	App Launched for Execution
IEC60601	Auto	Test 60601 {	vPad-AS
IEC62353	Auto	Test 62353 {	vPad-A3 (per Edition 1) vPad-A6 (per Edition 2)
IEC60601	Manual	Test 60601 Manual {	vPad-ES
IEC62353	Manual	Test 62353 Manual {	vPad-353 (per Edition 1) vPad-623 (per Edition 2)
Instructions only	--	Test Instructions {	--

The IEC62353 Edition, and thus the Apps which are used to perform IEC62353 testing, is specified by means of the Settings menu of vPad-STM. Refer to Section 3.3 for more information.

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Blocks beginning with **Test Instructions** { will contain text that is to be displayed to the user via a Test Instructions menu, similar to Test Description or Connection menus. Refer to specifications of **Description** or **Connections** blocks for text formatting rules.

Like other blocks, a **Test** block is terminated by a **}** character, which must be placed on its own line.

When a **Test 60601** or **62353** block is encountered during MultiSequence execution, vPad-STM creates a default vPad-AS, vPad-A3 or vPad-A6 AutoSequence with all parameters set to default values (usually *disabled* except for "Limits per Standard" which is always enabled). Measurements and other settings listed in the **Test** block then selectively *enable* the corresponding settings in the AutoSequence. The AutoSequence setup described by the **Test** block is handed to vPad-AS, vPad-A3 or vPad-A6, which then executes the AutoSequence.

Each line in the **Test** block conveys one setting of the AutoSequence. Settings are not case sensitive and may be listed in any order. The **Test** block will list only those settings which need to be enabled, or those parameters which need to be changed from the default initial value.

TABLE 3.4-1 lists the available test settings for automated test blocks. Settings that are incompatible with the test standard (i.e. settings without a check mark) will simply be ignored by vPad-STM.

TABLE 3.4-1: AutoSequence Test Settings

Test Setting	Test 60601	Test 62353 (per Ed. 1)	Test 62353 (per Ed. 2)	Default
Mains Voltage	✓	✓	✓	disabled
Load Current	✓	✓	✓	disabled
Equipment Power	✓	✓	✓	disabled
Earth Resistance	✓	✓	✓	disabled
External Resistance	✓	✓	✓	disabled
Use RCD Limit			✓	disabled
Mains Insulation to PE		✓	✓	disabled
Mains-Encl Insulation			✓	disabled
Mains-AP Insulation			✓	disabled
AP Insulation to PE		✓	✓	disabled

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Test Setting	Test 60601	Test 62353 (per Ed. 1)	Test 62353 (per Ed. 2)	Default
AP-Encl Insulation			✓	disabled
Test at 250V		✓		disabled
Test Insulation at: <volts>			✓	500 (NOTE 1)
Use Insulation Limits			✓	disabled
Direct Leakage Method			✓	(NOTE 2)
Alternative Leakage Method			✓	disabled
Differential Leakage Method			✓	disabled
Touch Current	✓			disabled
Earth Leakage	✓			disabled
Device Leakage		✓	✓	disabled
AP1 Leakage	✓	✓	✓	disabled
AP2 Leakage	✓			disabled
AP3 Leakage	✓			disabled
AP4 Leakage	✓			disabled
AP1+2 Leakage	✓	✓	✓	disabled
AP3+4 Leakage	✓	✓	✓	disabled
AP1-3 Leakage	✓	✓	✓	disabled
AP1-4 Leakage	✓	✓	✓	disabled
AP1-10 Leakage	✓	✓	✓	disabled
AP4-10 Leakage	✓	✓	✓	disabled
AP5-10 Leakage	✓	✓	✓	disabled
Auxiliary Leakage	✓			disabled
MAP Leakage	✓			disabled
Use B Limits	✓			(NOTE 3)
Use BF Limits	✓	✓	✓	(NOTE 3)
Use CF Limits	✓	✓	✓	(NOTE 3)
Use Class I Limits		✓	✓	(NOTE 4)

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Test Setting	Test 60601	Test 62353 (per Ed. 1)	Test 62353 (per Ed. 2)	Default
Use Class II Limits		✓	✓	(NOTE 4)
Internally Powered Device		✓	✓	disabled
Test OFF and ON Conditions	✓	✓	✓	disabled
Measurement Delay: <seconds>	✓	✓	✓	2
Polarity Delay: <seconds>	✓	✓	✓	2
Skip Reverse Polarity Tests	✓	✓	✓	disabled
Test for Secondary Earth	✓	✓	✓	(NOTE 5)
Stop Before OFF	✓	✓	✓	disabled
Stop After ON	✓	✓	✓	disabled
ECG Test Sequence	✓	✓	✓	disabled
ECG CMRR Test: <test_mode>	✓	✓	✓	0
Equipment Inspection	✓	✓	✓	disabled
Inspection File: <filename>	✓	✓	✓	default_ inspection.ins

- NOTE 1:** 62353 The **Test Insulation at:** parameter for IEC62353 Edition 2 may be set to 500, 250, 100, or 50
- NOTE 2:** 62353 The **Direct Leakage Method** for IEC62353 Edition 2 will be **enabled** if no leakage method is indicated in the **Test** block.
- NOTE 3:** 60601 If **AP Leakages** are specified, **B Limits** will be used by default unless **MAP Leakage** is specified, in which case **CF Limits** are then used. Therefore, explicitly identifying the applied part Type in the AutoSequence setup is not always necessary, but is recommended to make the test description more clear. To test Type BF AP, specify **MAP Leakage** and also **Use BF Limits**.
- 62353 If **AP Leakages** are specified, BF limits are used by default. It is not necessary to specify **Use BF Limits**, but doing so is recommended as it will make the AutoSequence description more clear. To test Type CF AP, specify **Use CF Limits**. Per IEC62353, Type B AP are not tested.

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NOTE 4: 62353 If **Device Leakage** is specified, Class I limits are used by default. It is not necessary to specify **Use Class I Limits**, but doing so is recommended as it will make the AutoSequence description more clear. To test a Class II device, specify **Use Class II Limits**.

NOTE 5: 60601 **Test for Secondary Earth** is not performed unless **Touch Current** is also **enabled**.

62353 Ed.1 **Test for Secondary Earth** is not performed unless **Device Leakage** is also **enabled**.

62353 Ed.2 **Test for Secondary Earth** is not performed unless **Device Leakage** and **Direct Method** are also **enabled**.

When a **Test 60601 Manual** or **62353 Manual** block is encountered during MultiSequence execution, vPad-STM launches vPad-ES, vPad-353 or vPad-623 with the specified tab ready to perform the manual test.

There should be only one line inside the manual **Test** block indicating the desired test tab. TABLE 3.4-2 lists the available tabs and their functions. Any unrecognized keywords will cause Apps to default to the **Voltage** tab.

TABLE 3.4-2: Manual Test Tabs and Functions

Test Tab	Test 60601 Manual	Test 62353 Manual (per Ed. 1)	Test 62353 Manual (per Ed. 2)	Functions
Voltage	✓	✓	✓	Mains and External Voltages
Equipment Load	✓	✓	✓	Load Current and Equip. Power
Resistance	✓			Line Cord and Ext. Resistance
Earth Resistance		✓	✓	Prot. Earth and Ext. Resistance
Insulation Resistance		✓	✓	Insulation Tests
Leakage	✓			Chassis and Ground Leakage, External Current Meter
Patient Leads	✓			Lead Leakages, Isolation Tests
Leakage Current		✓	✓	Equipment and AP Leakages
ECG Simulator	✓	✓	✓	ECG Performance Test


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Example:

```
// Test Class I medical device with 3 Type BF AP's and from one to six Type B AP's
// Test earth resistance, touch current, earth leakage, and the Type BF AP's first
Test 60601 {
    Earth Resistance
    Load Current
    Mains Voltage
    Stop After ON
    Touch Current
    Equipment Inspection
    Inspection File: defib_inspection.ins
    Earth Leakage
    AP1-3 Leakage
    Auxiliary Leakage
    MAP Leakage
    Use BF Limits
    External Resistance
}
// Note that order inside the block is not important

// Next, test the Type B AP's (maximum 6 leads)
Test 60601 {
    AP5-10 Leakage
    Auxiliary Leakage
    Use B Limits
}
```

For more information on the AutoSequence settings listed in TABLE 3.4-1, refer to refer to manuals **MN-079 (6100-045) *vPad-AS Operators Manual***, **MN-080 (6100-046) *vPad-A3 Operators Manual***, and **MN-124 (6100-098) *vPad-A6 Operators Manual***.

Note these manuals are provided on the Android tablet, and may be viewed with the **Datrend Docs App**  which is on the Home screen.

Test blocks that refer to a manual safety test app should include only one tab setting. TABLE 3.4-1 lists the available tabs for manual test blocks.

3.5.2.6 IEC60601 Edition 2 Tests

vPad-AS performs electrical safety tests according to IEC60601 Edition 3. vPad-STM enables testing to Edition 2 of the standard.

Note that this **NOT** the same as the IEC62353 Edition 2 option described in **Section 3.3**.

As far as the vPad analyzer is concerned, IEC60601 Edition 2 differs only in limits used for the earth leakage test. This is done through a slight change to the earth leakage specification in the **Test 60601** block, as follows:

Ed.2 Earth Leakage

When earth leakage per Edition 2 is enabled, other leakages should not be measured by the same **Test** block since the default leakage limits have been modified. If necessary, touch current and AP leakages may be measured by prior or subsequent **Test** blocks.

Below is an example of a complete electrical safety test for a medical device with patient leads that includes earth leakage per Edition 2 of IEC60601. This example is installed with vPad-STM and is called **IEC60601-Ed.2, Class I, 3xCF (1-6)xBF**

```
Test 60601 {  
    Earth Resistance  
    Load Current  
    Mains Voltage  
    Ed.2 Earth Leakage  
}
```

```
Test 60601 {  
    Touch Current  
    AP1 Leakage  
    AP2 Leakage  
    AP3 Leakage  
    Auxiliary Leakage  
    MAP Leakage  
    Use CF Limits  
}
```

```
Test 60601 {  
    AP5-10 Leakage  
    Auxiliary Leakage  
    MAP Leakage  
    Use BF Limits  
}
```

3.5.2.7 Test Instructions

During the course of a test, it may be necessary to display additional instructions, for example, to disconnect, change or add applied part connections. This may be done with one or more **Test Instructions** blocks, which may be placed in between the **Test 60601** and **Test 62353** blocks of the MultiSequence.

The following example is installed with the vPad-STM App and is called **IEC601+353, Class I, 3xCF (1-6)xB IR**. This example is for a medical device in which Type CF and Type B applied parts are tested per IEC60601. The test also includes insulation resistance of the mains part and applied parts per IEC62353. Before the insulation resistance is tested, a **Test Instructions** block informs the user to disconnect the Type B applied parts so that the medical device is not damaged by the insulation test voltage.

```
// Test earth resistance, touch current, earth leakage and 3 x CF leads
Test 60601 {
    Earth Resistance
    Load Current
    Mains Voltage
    Touch Current
    Earth Leakage
    AP1 Leakage
    AP2 Leakage
    AP3 Leakage
    Auxiliary Leakage
    MAP Leakage
    Use CF Limits
}

// Test BF leads
Test 60601 {
    AP5-10 Leakage
    Auxiliary Leakage
    Use B Limits
}

Test Instructions {
    <>
    <>
    <>
    <>
    <>
    \
    <>
    \
        Disconnect Type B leads for insulation test!
}

// Perform insulation resistance tests
Test 62353 {
    Mains Insulation
    AP Insulation
}
```


When the above MultiSequence is executed, the Test Instructions menu will be displayed after the Type B applied part leakage tests and before the insulation resistance tests:

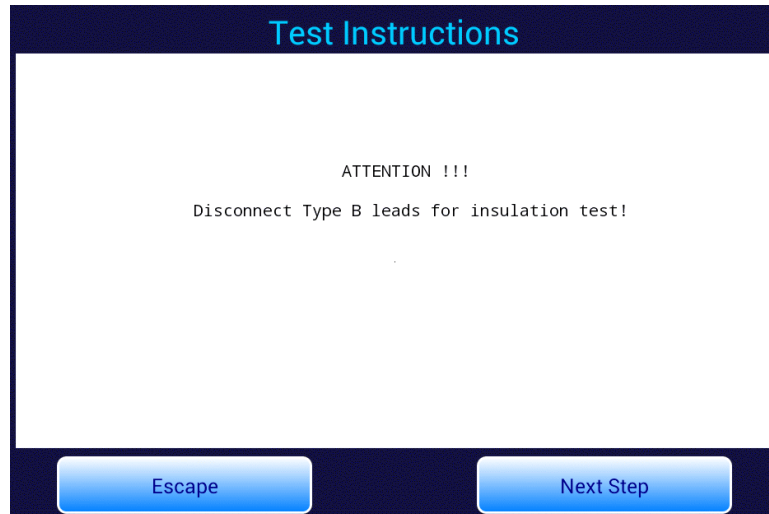


Figure 35 - Test Instructions menu.

This menu operates similarly to Test Description and Connection menus described in Sections 3.4.1 and 3.4.3 respectively.

3.6 Using the Android Keyboard

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



Figure 36 - 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:

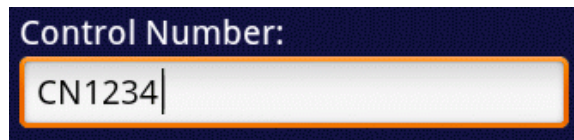
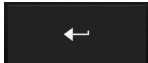



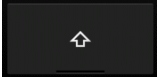

Figure 37 - Single-line text field.

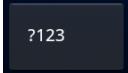
Android text fields may be either single- or multi-line. A practically unlimited amount of text may be typed for either single- or multi-line fields.

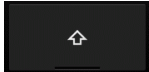


Pressing ENTER  (or **Next**) for a single-line text field causes data entry to jump to the next text field on the screen.

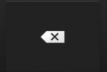
Pressing ENTER  on a multi-line text field inserts a new line. To move from a multi-line field to a different text field on the screen, tap on the desired field.

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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.

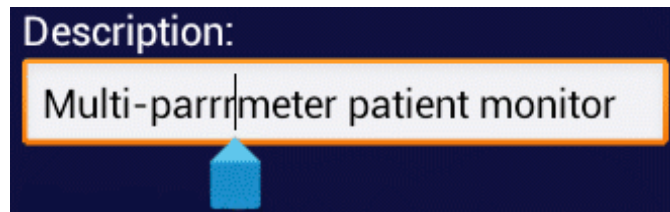



Figure 38 - Error correction with edit cursor.

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

3.7 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-STM app.

Record Manager may be used to copy, print, and/or delete Test Record files saved by vPad-STM to directory **mnt/sdcard/Datrend/vPad-STM/Records**. 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 39 - 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. MN-087 and other Datrend manuals can be read using the **Datrend Docs App** on the Android tablet.

4 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.

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

