



vPad-TITM

Transport Incubator Tester

Operating Manual

vPad-TI™
Transport Incubator Tester
Operating Manual

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Abbreviations, Definitions and Symbols

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

ACTRE	Air Control Temperature Regulation Error
AIT	Average Incubator Temperature
ATX	Average Temperature of Temperature Sensor X, where X = 2 - 5
AV	Air Velocity
BSL	Background Sound Level
°C	degrees Celsius (centigrade)
°F	degrees Fahrenheit
Autosequence	A series of measurements or test operations that are run automatically in a predefined order, with or without user involvement.
DUT	Device Under Test
GUI	Graphical User Interface
IT	Incubator Temperature
IIT	Independent Incubator Temperature
NSL	Noise Sound Level
STC	Steady Temperature Condition
STS	Skin Temperature Sensor
TC	Temperature Control
TEMP	Temperature
WT	Warm Up Time



CAUTION: Read the instructions for use before operating this device.

Definitions:

Some of the following definitions are paraphrased from the relevant sections and clauses of IEC 60601-2-20, Edition 2

Air Control Temperature Regulation Error	Clause 201.12.1.106: an incubator operating in AIR TEMPERATURE CONTROL shall have an AVERAGE TEMPERATURE that does not differ from the CONTROL TEMPERATURE of 36°C by more than $\pm 1.5^{\circ}\text{C}$ at an ambient temperature between 20°C and 25°C; or, $\pm 2^{\circ}\text{C}$ at an ambient temperature between 10°C and 20°C
Average Transport Incubator Temperature	Clause 201.3.203: the average of the maximum and minimum INCUBATOR TEMPERATURES achieved during STEADY TEMPERATURE CONDITION

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Average Temperature	Clause 201.3.202: the average of the maximum and minimum temperatures at any specified point in the COMPARTMENT achieved during STEADY TEMPERATURE CONDITION
Compartment	Clause 201.3.205: environmentally controlled portion of the INCUBATOR intended to contain a baby
Control Temperature	Clause 201.3.206: temperature selected on the incubator as the desired temperature in the COMPARTMENT
Autosequence	A series of measurements or test operations that are run automatically in a predefined order, with or without user involvement
Device Under Test	The device (the transport incubator) being tested by VPad-TI
Graphical User Interface	A display system for the test instrument (vPad-TI) which relies on graphics to a large extent to display information. In the case of vPad-TI, this is an Android tablet (10") with an Android type operating system (5.1.1), or equivalent
Incubator	Clause 201.3.205: an enclosure, intended to contain a baby and having transparent section(s) which allow(s) for viewing of the baby, provided with means to control the environment of the baby primarily by heated air within the enclosure
Transport Incubator Temperature	Clause 201.3.212: temperature of the air at a point 10 cm above the center of the mattress surface in the COMPARTMENT
Independent Incubator Temperature	A temperature representative of INCUBATOR TEMPERATURE provided by an independent indicator (not powered by the incubator). Commonly an alcohol based thermometer (non-mercury), but may be of an alternate type)
NSL	Noise Sound Level
Steady Temperature Condition	Clause 201.3.211: the condition reached when the INCUBATOR TEMPERATURE does not vary by more than 1°C over a period of one hour
Skin Temperature Sensor	Clause 201.3.210: a sensing device intended to measure the baby's SKIN TEMPERATURE

1 Specifications

1.1 General Specifications

Environment:

- 15 °C to 40 °C (59 °F to 104 °F)
- 10% to 90% Relative Humidity
- Indoor Use Only
- Category II
- Pollution Degree 2

Note: Mains supply voltage fluctuations not to exceed +/- 10% of the nominal supply voltage.

User Interface:

vPad-TI is supplied with a 10" (nominal) Android tablet which has the vPad-TI application pre-installed and ready to run. The software is controlled by touching a function button on the graphical user interface (GUI) or, where applicable, by entering specific data via the keyboard.

Display (10" Android Tablet):

1920 x 1200 color IPS touch screen LCD

1.2 Data Collection Specifications

Temperature:

- Measurement Range: 25 °C - 50 °C
- Accuracy: T_a : ± 0.05 °C
- Resolution: 0.01 °C
- Convection: 5 'puck' sensors (T_6 - T_{10}) - radiant warmer
- Air Conduction: 5 sensors (alternate 'post' T_a - T_e) - incubator
1 mattress temperature
- Optional Skin Sensor 'oven' with thermal pad contact: 28 °C to 40 °C in 2 °C increments ± 0.01 °C resolution,
 ± 0.05 °C Accuracy

Airflow:

- Measurement Range: 0.1 to 1 m/s
- Accuracy: ± 0.1 m/s
at 50% RH $\pm 15\%$

Relative Humidity:

- Measurement Range: 0 - 100%
Non Condensing
- Accuracy: ± 3 %
- Resolution: 0.1% RH

Sound Level:

- Measurement Range: 30 dbA to 100 dbA, Type III
- Accuracy: ± 3 dbA
- Resolution: 0.1 dbA

Data Retention:

- Capacity: up to 48 hours per test
- Sample Rate: 1/min or 1/sec, depending on parameter

1.3 Standard Accessories

AC Adapter (all models): 100-240 VAC 50/60 Hz to 9 VDC (p/n 3000-611)

Blade Sets kit for P/N 3000-611: P/N 7500-490

(Includes: North America; Europe/Schuko; United Kingdom; China/Australia)

AA Battery, 1.2V 2300mAH: P/N 3310-012

1.4 Optional Accessories

For a complete list of available accessories, visit www.datrend.com or contact Datrend Customer Service (see Chapter 7 for contact details)

Chapter
2

2 General Information

2.1 Overview

vPad-TI is a portable data logging system for temperature, air flow, humidity, and sound level; specifically configured to test infant transport incubators and, optionally, incubators and radiant warmers to applicable IEC performance standards. The data collection system is designed to operate for up to 48 hours from a rechargeable 4.8VDC nickel-metal hydride (4 AA cells) battery, or alternatively, from a 5VDC switch mode AC adapter. The sensors and the data collection system are placed on the mattress of the transport incubator, and external to the device under test (DUT), a user interface based on an Android tablet communicates wirelessly to the sensor system via Bluetooth, and provides the user with the ability to control the test operation and display the results without disturbing the test environment.

vPad-TI incorporates all the functionality necessary to meet the requirements of the IEC standard, related to temperature, airflow, humidity, and sound level tests. vPad-TI incorporates a graphical user interface which interfaces wirelessly to 6 temperature sensors, 1 airflow sensor, 1 humidity sensor, and 1 sound level meter. vPad-TI also incorporates a non-volatile memory or "data log" which is used to save test data, such tests typically being conducted by the user over several hours or days.

2.2 Features

IEC 60601-2-20 ed.2¹ is a standard which specifies safety and performance requirements for an infant transport incubator. Some of the parameters that lend themselves to testing are temperature, sound level, air flow and humidity. These parameters are monitored at specific locations within the incubator and are expected to conform to the values defined by the Standard. vPad-TI provides the mechanical framework to hold the sensors in the appropriate locations, and provides the ability to adjust the framework to fit incubators of various sizes.

vPad-TI provides 5 temperature sensors which are positioned according to the standard, with one central sensor and one sensor in the center of each of four quadrants on the mattress. The central sensor is an integral component of the data collection and wireless communication hub of the system. In addition to the 5 temperature sensors, vPad-TI provides mattress temperature, airflow, sound level and humidity sensors in separate packages which connect to the central hub. The test protocols are designed to perform all the temperature tests in one contiguous time block to avoid numerous long heating and cooling cycles. Tests of airflow, sound and/or humidity are performed either before or after the temperature tests so that the sensors can be moved about in the incubator without disrupting a temperature test.

2.3 Controls and Interface Connections

Referring to **Figure 1** through **Figure 5**, the following components, controls and interfaces of the vPad-TI Transport Incubator Test system are:

1. Sensor Electronics and Wireless Hub (the HUB)	Provides the connection point for all sensors used internally to the incubator or warmer under test. Also referred to as the DAT unit.
2. Temperature Connectors	Temperature Probes (Ta - Te) are connected on the top of a large, black thermal mass (Puck) to place the thermistor in the correct position above the mattress.
3. Thermal Mass (the Puck)	Thermal mass to mimic the infant body for convection warming in a radiant warmer. Contains Magnetic Fastener (3.b) for attachment of other sensors
4. Temperature Probe (Ta - Te)	Bypasses the thermistor in the Puck and places the thermistor at the correct position above the mattress, per the Standard.

¹Throughout this manual, IEC 60601-2-20 ed.2 is referred to as the "Standard"

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5. Mattress Temperature	Measures the temperature of the mattress
6. Airflow Sensor	Measures the flow of air, and can be moved as required. Held in place on the Puck magnetically.
7. Sound Level Sensor	Measures sound level. Can be moved within the device under test (DUT) and can also be connected to an extension cable for external sound/alarm level measurements. Held in place on the Puck magnetically.
8. Humidity Sensor	Measures Humidity. Can be moved within the device under test (DUT). Held in place on the Puck magnetically.
9. Hub Connections - Left Side	a. T4 (Td) Temperature Input b. T5 (Te) Temperature Input c. Airflow Sensor Input d. Power Input e. Power LED f. Power Switch
10. Hub Connections - Right Side	a. T3 (Tc) Temperature Input b. T2 (Tb) Temperature Input c. Humidity Sensor Input d. Sound Level Sensor Input
11. Positioning Frame	Allows Tb - Te Pucks to be positioned with respect to Ta at the center of the mattress
12. Positioning Frame Components	a. longitudinal positioning bar b. horizontal positioning bar c. T bracket

Each of the sensors has an internal magnet on the bottom which will hold it in place on the Thermal Mass. Each sensor also has a cable with a miniDIN connection to connect to the **HUB**.

When used, the **Mattress Temperature** sensor connects to the **HUB** in the **Humidity** position, and the **Humidity Sensor** connects to the **Mattress Temperature** module in a daisy chain fashion.

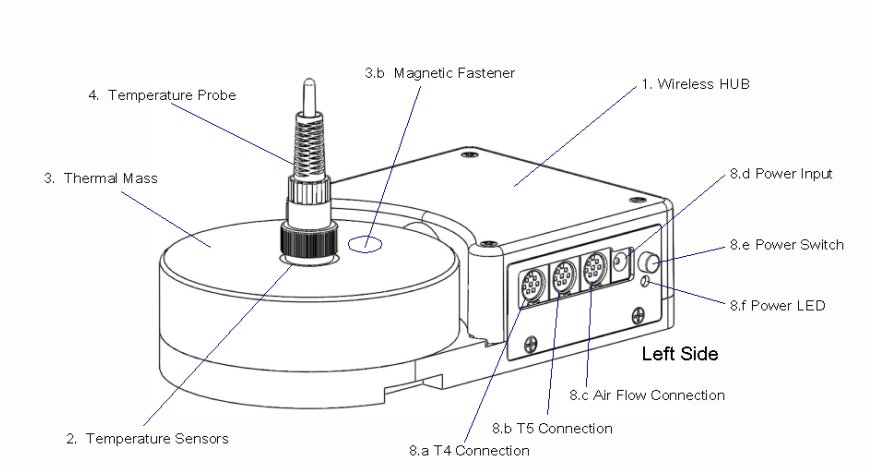


Figure 1: Wireless HUB - Left Side View

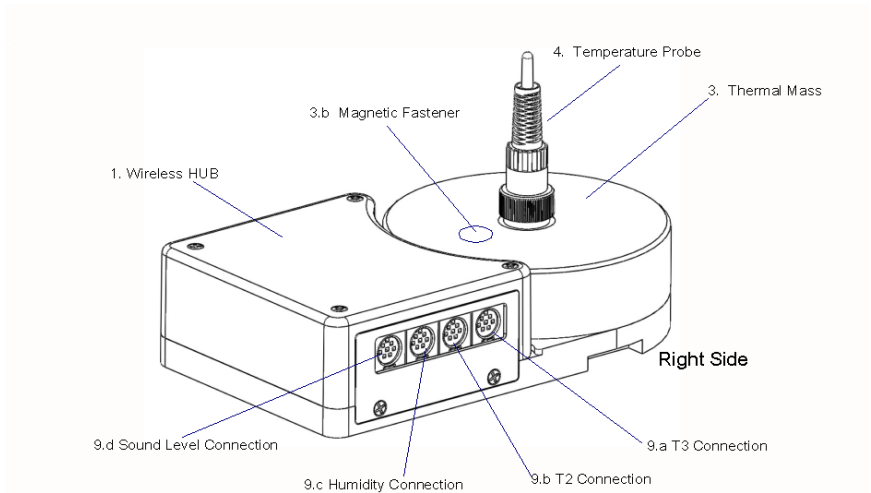


Figure 2: Wireless HUB - Right Side View

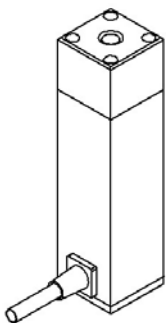


Figure 3:
Sound Level Sensor

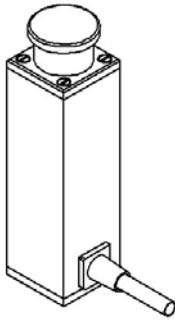


Figure 4:
Air Flow Sensor

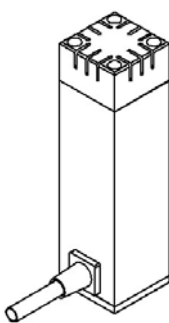


Figure 5:
Humidity Sensor

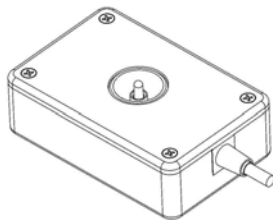


Figure 6:
Mattress
Temperature Sensor

2.4 Setup

To test a transport incubator according to the Standard, the Sensor System must be placed on the mattress of the DUT with the Temperature Probe of the Hub in the center of the mattress, and the Temperature Probes of the remaining 4 Temperature Pucks placed in the center of each of the 4 quadrants of the mattress. The positioning frame is designed to assist in the positioning of the Pucks and to hold them in place during a test.

Measure the mattress to determine its size. For instance, the AirShields C200 has a nominal mattress size of 14 inches wide (36 cm) by 24 inches long (61 cm). Divide the mattress into 4 quadrants, each quadrant being 7 inches (18 cm) by 12 inches (30.5 cm). For this mattress, the center of quadrant Q2 is 3.5 inches above the long axis and 7 inches from the cross axis, see point **C2**, **Figure 7**.



Figure 7: Mattress Quadrants and Center Locations

In setting up the positioning frame, the longitudinal (long) bar would be placed in the body of the **HUB**, with the end having a small hole about 1" from the end sliding into the slot in the **HUB**, as indicated in **Figure 8**. The 'T- bracket' is placed over the long bar and slid into the position marked '6' inches on the long bar. Similarly, the horizontal (cross) bar is slid into the 'T- bracket' and locked in place with the spring plunger. The smaller **Temperature Puck** is then slid into place to the position marked '3.5' inches on the cross bar. If the positioning frame is placed with the temperature probe of the **HUB** in the center of the mattress at C1, then the second temperature probe would be in the center of the mattress quadrant Q2 at position C2 in the diagram. For mattresses of other sizes, the 'small' **Pucks** can be moved along the bars as required to meet the dimensional requirements.

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If the smaller **Temperature Puck** seems too close, it can be rotated 180 degrees, in which case, add 3.5" to the markings on the long bar. In the example above, the 9.5 inch marking ($6" + 3.5" = 9.5"$) would be used.

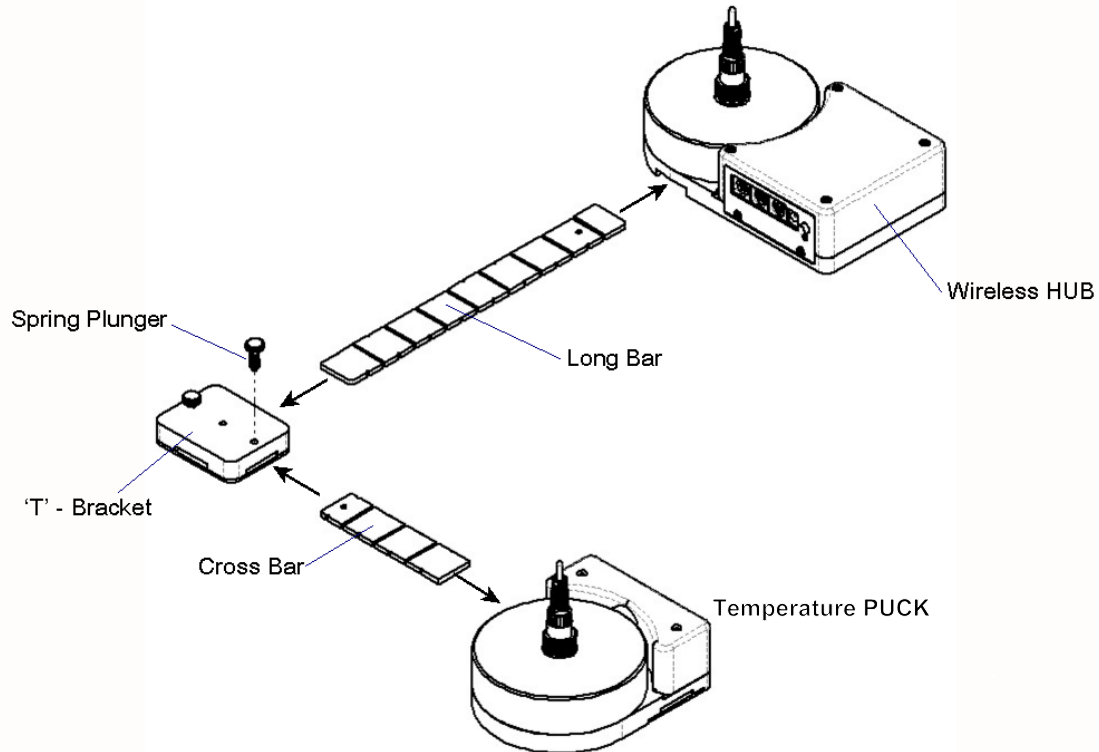


Figure 8: Positioning Frame Assembly

Temperature Pucks for each of the other three quadrants are set up in the same manner. The fully assembled system is shown in Figure 9.

The vPad-TI Transport Incubator test system is now configured mechanically, according to the Standard, to take temperature and other measurements in the center of the incubator and in the center of each of the four quadrants of the mattress. It is now necessary to make the electrical connections for each of the sensors.

As previously described, the large round 'Puck' represents a thermal mass imitating the infant body in a convection warming environment. This 'Puck' is made of aluminum with a black heat absorbing coating, with a temperature sensor embedded in the aluminum block. In this configuration, the temperature measured by the 'Puck' is specifically configured to test **radiant warmers**. For testing **incubators**, a Temperature Probe is inserted into the connector at the center of each Puck. This Temperature Probe bypasses the thermistor in the Puck and elevates the thermistor in the Probe to a position approximately 10 cm above the mattress, in accordance with the Standard.

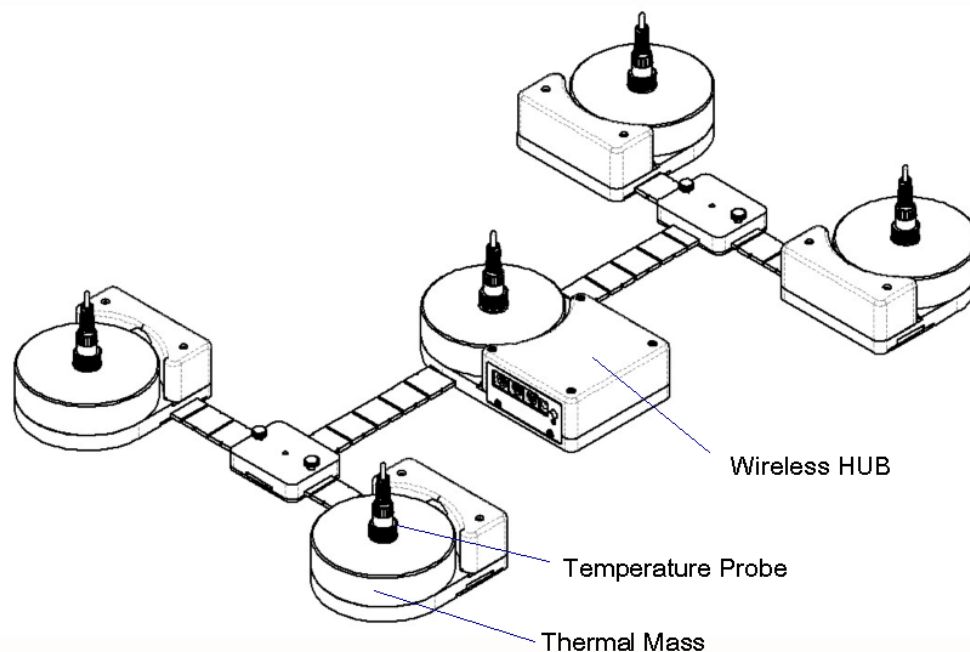


Figure 9: Sensor Frame Fully Assembled

In the Test Reports generated by the test software, the temperatures are referred to as T_a (1) for the center of the incubator, and T_b (2), T_c (3), T_d (4) and T_e (5) for each of the quadrants as shown in **Figure 10**.

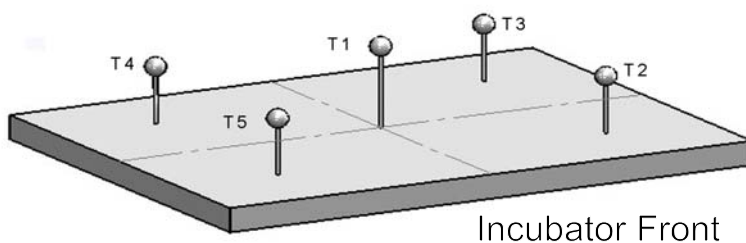


Figure 10: Temperature Sensor Positions

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The cables from the individual **Pucks** will connect to the **HUB** as indicated in **Figure 11**, **Figure 1** and **Figure 2**.

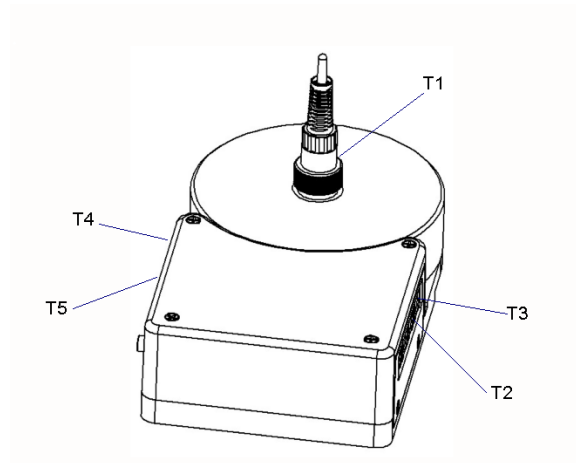


Figure 11: Temperature Sensor Connection Locations

The sensors for Sound, Airflow and Humidity also connect to the **HUB**, as indicated in **Figure 1** and **Figure 2**. These sensors are utilized when the relevant test is selected in the software test setup. When utilized, the sensors are held in place on the Puck by magnets.

The tablet connects wirelessly via Bluetooth to the wireless **HUB**.

The **tablet** also provides connection to the **Skin Sensor Oven** through the USB port so that **Skin Temperature Probes** can be checked for accuracy.

2.5 Power On

After the System has been setup for the required mechanical positions, it may be turned on by pressing the Power On switch on the **HUB**, shown in **Figure 1**. If the **HUB** is being charged, with the AC Adapter plugged into the Power Input connector, a small LED below the Power On switch will illuminate RED, regardless of the position of the Power On switch. If the Power On switch is activated but the AC Adapter is not plugged in, the LED will illuminate YELLOW. If the AC Adapter is not plugged in and the Power On switch is NOT activated, the LED will not illuminate.

The **HUB** may be powered by battery or by AC Adapter.

Once turned ON, the **HUB** will wait for the **tablet** to initiate communications.

2.6 vPad-TI Software

The vPad-TI software is pre-loaded on the tablet. When turned on, the tablet presents the Android Home screen, where selecting the vPad-TI icon will run the vPad-TI Application. When you exit the Application, the tablet will return to the Home screen. It is recommended no other apps be loaded onto the tablet so as to avoid conflicts with other apps, or accidentally infecting the computer with a virus or other malware. Problems which arise from loading other apps on the tablet are not covered by warranty.

NOTE: The vPad-TI software is setup to test Infant Transport Incubators. The large black PUCKs are the required thermal mass for Radiant Warmer testing and have embedded temperature sensors for that purpose. The vPad-RW app is available for Radiant Warmer testing.

The software will allow the user to create different test protocols that may not encompass the complete requirements of the Standard, but which are suitable for testing or verifying different parts of the incubator's operation. The Default test protocol includes all of the tests required by Section 8 (Accuracy of Data) and some parts of Section 11 (Additional Requirements) of the Standard. User defined protocols may be created, saved and recalled for future use.

In addition, the user can create a mini database of the incubators and warmers that have been or are to be tested. In order to do a test, the user must input an identification number (ID) and/or a serial number, so that the test report can be identified. The test technician's initials are also required so the report will show who was responsible for doing the test. Other information can be optionally input to further identify the DUT.

2.7 Incubator Primer

Infant Incubators are a controlled temperature environment which are used to maintain the body temperature of newborns who, for various reasons, are unable to regulate their own body temperature. Incubators generally work in one of two modes: 1) air temperature control, or 2) body temperature control.

In air temperature control, the heater in the incubator is used to control the temperature of the air at a location close to the heater. The air is forced to flow through the incubator chamber by means of a fan. The air circulates through the main chamber of the incubator where the infant lies on a mattress. The air returns to the heating chamber, which normally is located in a mechanical structure below the main chamber. The incubator is designed to create an airflow which is reasonably consistent in the main chamber, normally from back to front. In addition, the main chamber is designed to reduce temperature loss as much as possible through the use of double walls of acrylic.

In many circumstances, keeping the infant surrounded by a blanket of air at a constant temperature is sufficient to keep the infant warm. However, under certain circumstances the infant may continue to lose heat. In these cases it may be more effective to control the temperature of the air by monitoring the baby skin temperature directly and adjusting the air temperature to maintain the skin temperature at the desired temperature. When operating in this mode, the incubator will generally have an air temperature slightly above the skin temperature of the infant.

In addition to controlling the temperature of the air, incubators will also support a number of other features, including but not limited to: alarms for high temperature, humidity control and independent, non-electronic, temperature indicators.

3 Tablet Setup

The following instructions relate to the tablet to be used with the vPad-TI transport incubator test system. The measurement hardware is placed inside the incubator, as described in the previous chapter, and communicates with the tablet via Bluetooth. The tablet will be paired with the measurement hardware and the vPad-TI App will be installed and activated prior to delivery, and should not need any further setup.

Ensure the tablet has been charged before attempting to use it for testing. The tablet battery will typically last for at least 4-6 hours when fully charged, but if power is available, it is advisable to connect the charger to the tablet for the duration of any long tests.

To switch the tablet ON, press and hold the tablet power button (5-10 sec) until the tablet 'HOME screen' appears. The Android operating system will be fully loaded when the screen below is displayed.



Figure 12: Tablet Home Screen

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The Input/Output ports of the tablet are all arranged along the top edge of the tablet. These are:

- SD card: up to 16 Gb
- USB Host: for connection to USB drive, keyboard, barcode scanner, etc.
- USB ADB: Android Developer Bridge, for hardwire control of other devices
- HDMI: Output to HDMI display
- Power Input: 5V, 500mA min
- Power Switch
- Esc: Escape out of the app you are in and return to the Home screen

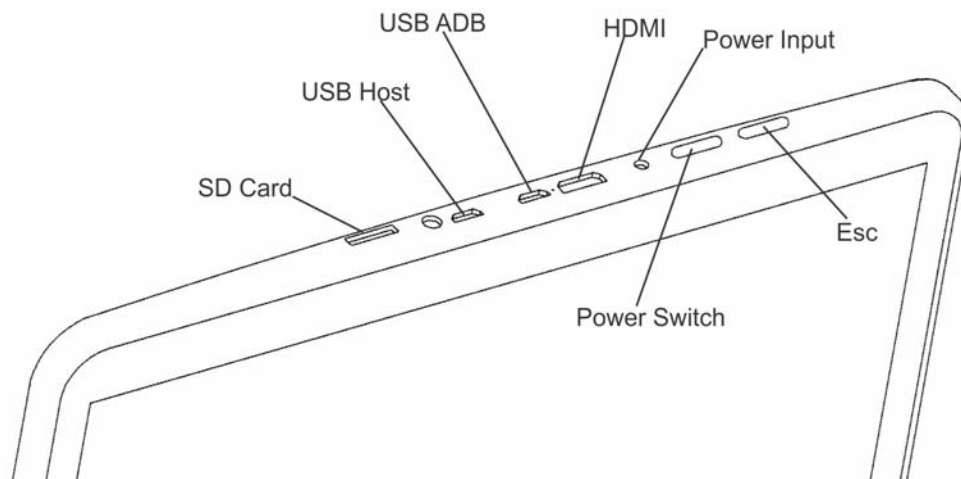


Figure 13: Tablet I/O Ports

Switch the tablet OFF when vPad-TI will not be in use for an extended period of time. Press and hold the ON/OFF switch until a confirmation message appears on the tablet screen. Select the appropriate response to complete the Power Off sequence.

When it is not necessary to have the tablet display on (and you are running from battery power), it is good practice to turn the display OFF temporarily. Pressing and releasing the Power ON/OFF button momentarily will put the tablet in a 'sleep' mode. Press the ON/OFF button momentarily again to 'wake' the tablet. This is NOT the same as OFF, but it will reduce power consumption and extend the usable battery life of the tablet.

4 Operation

This chapter explains how to use vPad-TI to define performance tests and inspections on baby transport incubators, following a predefined sequence of steps referred to as an Autosequence.

This chapter describes the software used to control the test operation and assumes that the hardware has been assembled and is in place in the **Compartment** of the incubator, as described in Chapter 2.

4.1 HOME Screen

The (typical) Android HOME screen, Figure 14 , is displayed approximately 60 seconds after switching the tablet ON.



Figure 14: Android 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-TI software application, or "**app**". Use this app to perform automated transport incubator testing.



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



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



By default, vPad-TI is supplied with WiFi connectivity **disabled**. Use the Settings menu to enable WiFi connectivity, in accordance with policies of your institution or organization.



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



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



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



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

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

4.2 Startup

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



Figure 15: vPad-TI Start up screen

From the splash screen, the user can select one of the four modules that provide vPad-TI with its functionality: 1) Test Settings; 2) AutoSequences; 3) Run Test; and, 4) Review Records. Each of these modules will be discussed in detail in the remainder of this chapter.

4.3 Test Settings

The functional performance of infant transport incubators is defined by the Standard IEC 60601-2-20 edition 2: Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Baby Transport Incubators. This standard defines the mechanical and electrical requirements that manufacturers are expected to meet when designing an infant transport incubator. When testing a transport incubator after the design has been certified to meet this standard, the most relevant tests are related to the physical parameters of temperature, airflow, sound and relative humidity. The functional specifications for these parameters are contained within section 8 of the Standard - 'Accuracy of Operating Data and Protection Against Incorrect Output', and section 11 - 'Additional Requirements'. vPad-TI has been designed to test these particular requirements. (Note: section numbering may change from time to time as the Standard is revised.)

As temperature tests tend to take a long time, vPad-TI has been designed to allow the user to define the particular subset of tests that are desired. This subset can be saved as a Autosequence (protocol) for future use.

4.4 Global Settings

The system and test setups are accessed from the Main Screen of the vPad-TI program as shown in Figure 15. Pressing the **vPad-TI Settings** portion of the screen will access the **System Settings** screen of Figure 16, which will allow modification of how the system will react or perform tests, in a general sense during tests.

Report Title

The Report Title is a 2 line entry which will show up on every report, to identify the facility which owns the incubators or, alternately, the facility doing the testing. Touch in either Line 1 or Line 2 and enter the Title(s) desired. Once a report is created, the Report Title in the report is fixed and will not change if the System Setting is modified (see Figure 16).

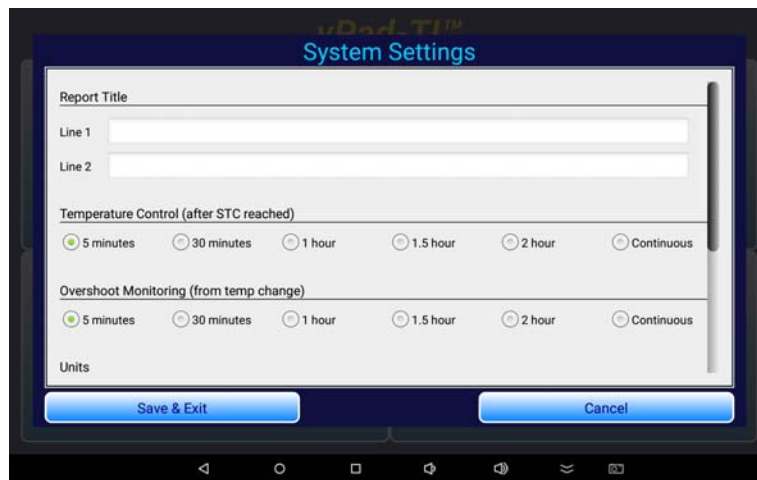


Figure 16: System Settings -1

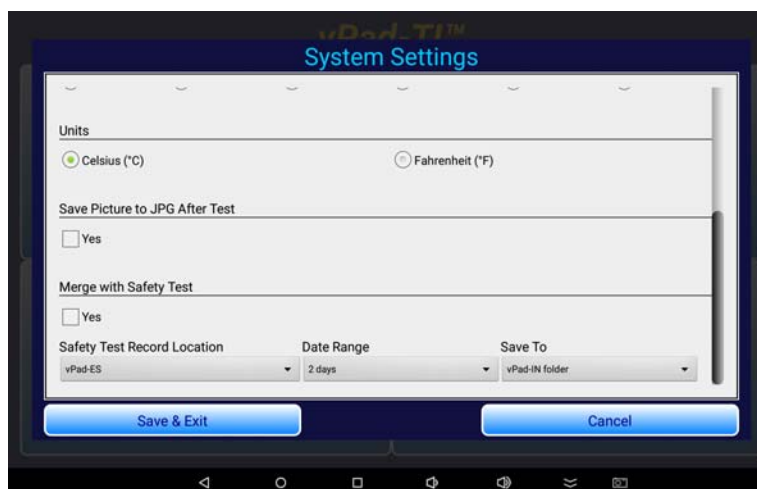


Figure 17: System Settings -2

Temperature Timers

There are two settings that set a limit on the time that particular temperature tests will run, provided a particular condition is met. In accordance with the Standard, vPad-TI is designed to recognize a condition called the Steady Temperature Condition (**STC**), which is defined in the Standard, in Section One, clause 201.3.211 as:

The Steady Temperature Condition is reached when the Incubator Temperature does not vary by more than 1 °C over a period of 60 minutes.

The Transport Incubator Temperature (**IT**) is also defined in the Standard (Section One, clause 201.3.212) as:

The Temperature of the air at a point 10 cm above the centre of the mattress surface in the baby temperature compartment.

During a particular temperature test, once **STC** is reached the user can optionally set vPad-TI to continue recording the temperature for an additional 5, 30, 60, 90 or 120 minutes. If a timer is set, vPad-TI will stop the test the selected number of minutes after **STC** is reached. Alternately, the time can be set to **continuous**, in which case the user can stop the test at any time after **STC** is reached by touching the **Stop Test** button.

The same timer settings can be applied to the Temperature Overshoot test, where vPad-TI will determine when **STC** has been reached after the prescribed temperature change has been detected.

Units

The units that the system will use for temperature reporting can be selected as either **°C** or **°F**. Note that when switching units, the results may not be simple integers; for instance 36 °C will become 96.8 °F. It is best to select one unit of measure and stick with it.

Save Picture to JPG after test

The graph which represents the temperature versus time response of the incubator may be of interest and can be saved to memory. If it is saved, the screen will display the image after the test is accepted, and the filename of the image will be included in the test report.

Merge with Safety Test

The tests performed by vPad-TI can be quite time consuming, therefore it is generally impractical to perform a safety test on an incubator and then do a performance test with the vPad-TI app, all as

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part of one test or AutoSequence (aka. CheckList or Procedure). In order to keep test data together, it is possible to merge the safety test (or even a performance inspection using vPad-Check, vPad-EQM or vPad-mT) with the test results of the vPad-TI app.

If it is desirable to merge the electrical safety test record and vPad-TI performance record, check the **Yes** box under **Merge with Safety Test**. Select the location where the safety test(s) will be found from the list presented under **Safety Test Record Location**. It is expected that the safety test and performance test will be done reasonably close together. Under **Date Range**, select the most appropriate date range to find the most current safety test(s). The default is 2 days, but there are also options for 1 week and All. Finally, in the **Save To** selection, the merged file can be directed to the vPad-TI test records area, or saved back to the original safety test records location.

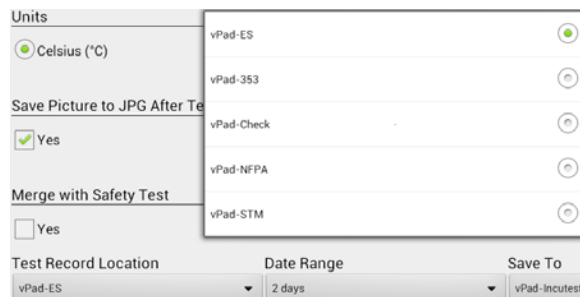


Figure 18. Safety Test Records Location

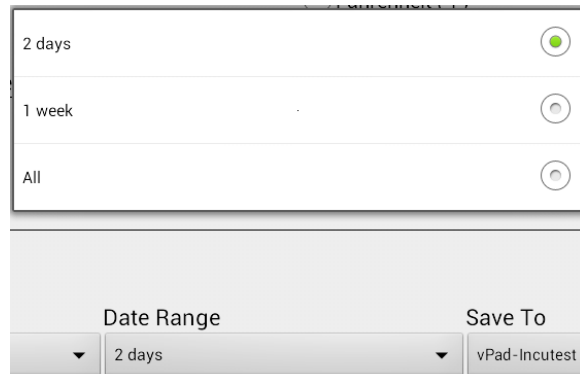


Figure 19. Safety Test Records Date Range

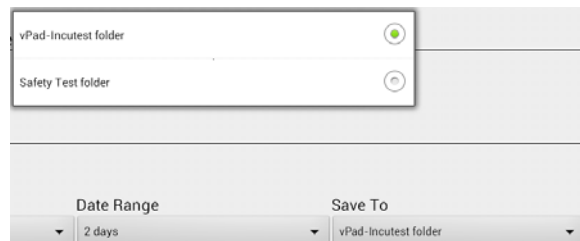


Figure 20. Merge: 'Save To' Location

When the **Merge with Safety Test** option has been selected, and **Save** is pressed at the end of an incubator test, a list of safety tests for the incubator ID, and meeting the above criteria will be displayed. Touching the appropriate filename line will cause the incubator test record data to be appended to the safety test record, and the resulting file will be saved to the designated **Save To** location.

Language

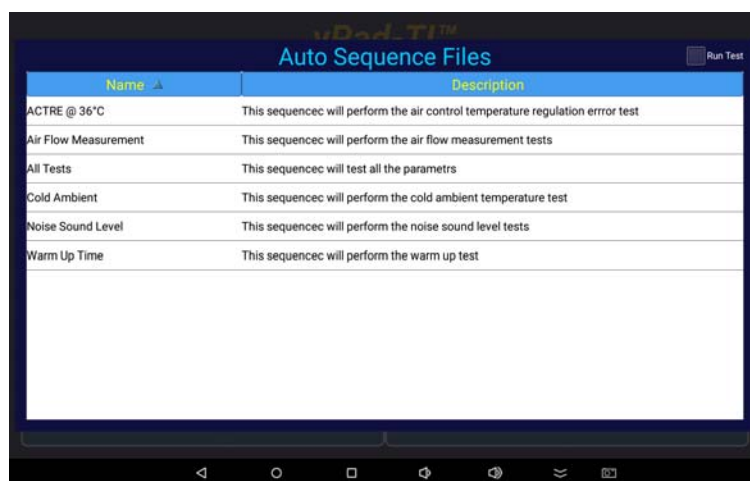
vPad-TI is designed to work in multiple languages. Changing languages is a function of the tablet. If a translation of the App is available, it will be automatically selected by changing the 'native' language of the tablet. Contact your dealer for further details on language availability.

4.5 Create/Edit/Run Autosequences

Autosequences are a defined set of parameters to test during the incubator performance assurance procedure. Touching the **Edit Autosequences** quadrant on the main screen will provide a list of available Autosequences which can either be Edited, used as templates to create new Autosequences, or, be selected to **Run** directly.

The scrollable list of Autosequences provides the sequence name and the sequence description for easy selection. Technically, the Standard expects all the parameters to be tested, however, this is really only true for the type certification test when the manufacturer is seeking regulatory approval. Typically, when doing routine performance assurance testing, a user/owner of an incubator may elect to do a subset of the overall test which reflects the risk level and testing schedule for a given parameter. These various tests or sequences can be created and saved for easy selection when testing is to be done.

In the upper right corner of the Autosequence list screen, there is a check box, **Run Test**. If this box is not checked, selecting an autosequence will allow editing of the selected sequence, or use of the selected sequence as a template for creating a new sequence. If the box is checked, selecting a sequence will actually start running or performing the selected test, without entering the edit screen first.




Name	Description
ACTRE @ 36°C	This sequence will perform the air control temperature regulation error test
Air Flow Measurement	This sequence will perform the air flow measurement tests
All Tests	This sequence will test all the parameters
Cold Ambient	This sequence will perform the cold ambient temperature test
Noise Sound Level	This sequence will perform the noise sound level tests
Warm Up Time	This sequence will perform the warm up test

Figure 21: List of Auto Sequences

Figure 22 and Figure 23, shown below, allows Autosequences to be created, modified, recalled and saved to meet the particular needs of the user. From this screen each test parameter can be enabled as required for a test. If it is expected the test may be needed again, it can be saved as an Autosequence by entering a name into the field **Sequence Name**, entering a **Description**, and pressing the **Save** button. During an Autosequence, the parameters will be tested in the order in which they appear on the screen. This order has been selected to minimize disruption of the temperature tests by opening the incubator doors at inopportune times. To enable testing of a parameter, right-click in the appropriate check box. Enabled tests will display a check mark in the box.

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The **Save** button will save the defined Autosequence to a file with the filename given in the **Sequence Name** field. If the name is the same as the original name (eg. Editing an existing sequence), the existing file will be updated. If the **Sequence Name** has been changed, a new filename will be created. If a file is selected and the **Delete** button is touched, the existing file will be deleted *after* the **Exit** button is pressed. The settings, however, will remain on the screen for further editing, or saving to a new filename.

Some parameters have a small number in front of the selection box. If the  is pressed, a help screen will be displayed, providing information on the numbered parameter.

In this part of the manual, each parameter will be described in reference to the requirements of the Standard.

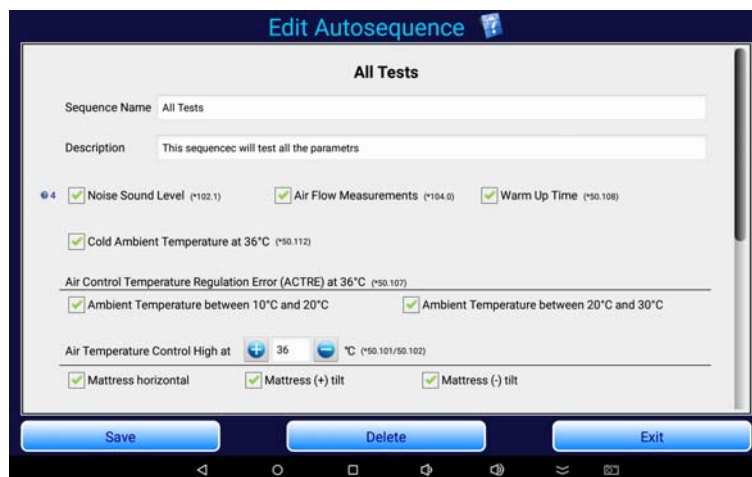


Figure 22: Auto Sequence Parameters -1



Figure 23: Auto Sequence Parameters -2

Noise Sound Level

The **Noise or Normal Sound Level (NSL)** [clause 201.9.6.2.1.101 of the standard] requires that the sound pressure level (A weighted) shall be measured at a position of 10-15 cm above the center of the mattress, with a sound pressure level meter complying with Type III requirements of IEC Publication 651. This test has 2 components, a background sound level (**BSL**) which is recorded at the start of the overall test, before the incubator is powered ON, and the **NSL** measurement which is measured with the incubator operating at a Control Temperature of 36 °C at maximum humidity.

The values of both **NSL** and **BSL** are recorded, with **BSL** at least 10 dB below **NSL**; and, **NSL** should not exceed 60 dB in the baby compartment.

The result of this test generally represents the amount of the noise generated by the incubator's air circulation system.

Air Flow Measurements

The flow of air in the baby incubator is measured in terms of **Air Velocity (AV)** [clause 201.12.1.111], and is measured at positions Tb, Tc, Td and Te. The **AV** at any of the specified points shall not exceed 0.35 m/s. This test is performed before the temperature testing is started. During the test the airflow sensor must be moved to the appropriate position(s) as prompted by the software.

Warm Up Time

It is the expectation that the temperature profile in the infant incubator will generally follow the graph as shown in Figure 24. The first component of the profile is called the **Warm Up Time, (WT)** and the test requirements are defined in the Standard [clause 201.12.1.107].

The Warm-up Time is only relevant if the Incubator Temperature is at least 12°C below the Control Temperature (**CT**) setting at the start of the test. This is best accomplished if the Warm-up Time is the first temperature/heating test performed, with the incubator initially at an ambient temperature less than 25 °C. For other tests to be performed efficiently, it would be best to target a **CT** of 36 °C.

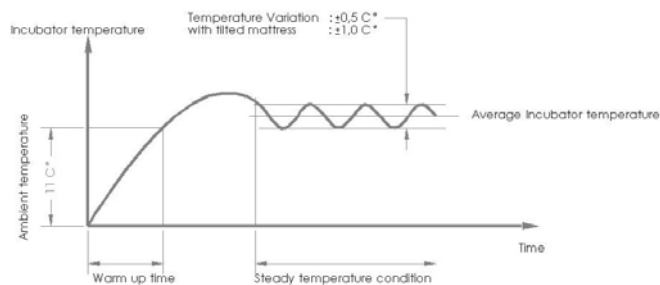


Figure 24: Temperature Profile

To determine the Warm-up Time set the Control Temperature (in Air Controlled Incubator mode) to 12 °C above Ambient Temperature (**AT**).

AT will be measured at the start of the test and the Incubator Temperature (**IT**) will be monitored until the **IT** is 11 °C above **AT**. The software will calculate the Warm-up Time as the time required to make the 11 °C transition.

Cold Ambient temperature at 36 °C

As per clause 201.12.1.113 of the standard, the transport incubator is set to Air Control and connected to an external power source. Once **STC** is established at an ambient temperature within the range of 21 °C to 25 °C and at a control temperature of 36 °C, it is disconnected from the external power source and transferred to an environment where the ambient temperature is between -7 °C and -3 °C and the wind velocity is no more than 1 m/s. After 15 minutes it is returned to an environment where the ambient temperature lies within the range of 20 to 25 °C and reconnected to an external power supply and operated for a further 30 minutes. The incubator temperature shall not differ from the control temperature by more than 3 °C.

Air Temperature Control Regulation Error (ACTRE)

Clause 201.12.1.106 of the standard states that when configured as an Air Controlled Transport Incubator, the Average Transport Incubator Temperature shall not differ from the Control Temperature by more than ± 2 °C at an ambient temperature of between 10 °C and 20 °C and by not more than ± 1.5 °C at an ambient temperature of between 20 °C and 30 °C when the control temperature is set to 36 °C.

Air Temperature Control High

According to the Standard, the ability of the transport incubator to heat to a specific temperature and maintain that temperature must be tested at a high and a low temperature. For the high temperature level, the Standard recommends 36 °C, however, vPad-TI will allow testing at other temperatures. For the purposes of this manual this will be referred to as **Control Temperature Regulation - Air (CTRA)**, and the requirements are described in clause 201.12.1.101 and 102 of

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the Standard. **STC** and **IT** have been previously defined. Average Incubator Temperature (**AIT**) is defined in the Standard as:

The average of the maximum and minimum Transport Incubator Temperatures achieved during **STC**.

With an initial Control Temperature setting of 36 °C, in Air Control Mode, the incubator is allowed to reach **STC** and the **AIT** is calculated. For the temperature measured at the center of the mattress, the difference between the **IT** and the **AIT** shall not exceed 1.5 °C at any time **STC** is TRUE. For each of the other 4 temperature measurement positions T2 - T5, the difference between the Average Temperature (**AT**) and the **AIT** must not differ by more than 1.5 °C.

Average Temperature (**AT**) as defined in the Standard as:

The average of the maximum and minimum temperatures at any specific point in the Baby Compartment achieved during **STC**.

The test may be performed with the mattress horizontal and with the mattress tilted to its maximum angle in the (+) and (-) positions. With a tilted mattress, the difference between the Average Temperature (**AT**) and the **AIT** at each of the four points must not differ by more than 2 °C.

Air Temperature Control Low

The Air Temperature Control Low test is a repeat of the Air Temperature Control High test, at a temperature below the temperature selected for the High test (normally 36 °C). The temperature recommended by the Standard (clause 201.12.1.1072) is 32 °C.

Baby Temperature Control

The ability of the incubator to control the baby's temperature using a skin temperature sensor in Baby (Skin) Control Mode can be tested by selection of Baby Temperature Control at 36 °C. As with the Air Temperature Control, this test can be performed at temperatures other than that recommended by the Standard.

Testing **Control Temperature Regulation - Baby (CTRB)** is described in the Standard in clause 201.12.1.104. With a Control Temperature setting of 36 °C, in Baby (Skin) Control Mode, the pre-tested Skin Temperature Sensor (see Skin Sensor Accuracy test) is freely suspended 10 cm above the center of the mattress, next to the air temperature sensor of vPad-TI, Ta. The incubator mattress is set to the horizontal position and the incubator is allowed to reach **STC** and the **AIT** is calculated. The difference between the Skin Temperature Sensor and the Control Temperature must not exceed 0.7 °C at any time after **STC** is TRUE.

Humidity Checks

The humidity measurement capabilities of the Baby Incubator may be checked by enabling this test. The **Incubator Humidity (IH)** is tested according to the Standard, clause 201.12.1.1079. The Standard requires the indicated value of relative humidity (RH), to have an accuracy of 15% of the actual measured value. vPad-TI will measure the humidity level (normally at the center of the mattress), and allow the manual entry of the incubator's displayed value after **STC** is reached. vPad-TI will compare the manually entered value of humidity to the value measured by the vPad-TI Humidity Sensor. The control temperature should be set at a value between 32 °C and 36 °C for this test.

Temperature Checks

The Standard requires the incubator to have an independent, non-mercury thermometer which can be read without opening the incubator. Enabling the Temperature Check option will allow entry of the value indicated on the independent thermometer after **STC** is reached. The Standard requires the **Independent Incubator Temperature (IIT)** clause 201.12.1.105 to be no more than 1 °C different than the measured **IT**. The sensor should be checked at 32 °C and 36 °C.

Alarm Sound Level - Inside

The Standard requires the alarm sound levels to be tested inside and outside of the incubator to ensure they are not so loud as to injure the infant, and loud enough to be heard by the operator. For the test inside the incubator, the requirements are defined in clause 201.9.6.2.1.103. The sound pressure level (A weighted) is measured at a position of 10-15 cm above the center of the mattress, with the incubator operating at 36 °C. The sound level during an alarm must not exceed 80 dBA. This test is best combined with the Air Temperature Control Low test.

Alarm Sound Level - Outside

The Standard requires the alarm sound levels to be tested inside and outside of the incubator to ensure they are not so loud as to injure the infant, and loud enough to be heard by the operator. For the test outside the incubator, the requirements are defined in clause 201.9.6.2.1.102. The sound pressure level (A weighted) is measured at a position 3 meters perpendicular to the front of the incubator, 1.5 meters above the floor. The test shall be performed with the incubator operating at 36 °C, and at maximum humidity. The sound level during an alarm must be at least 65dBA. This test is best combined with the Air Temperature Control Low test

Temperature Overshoot

The Temperature Overshoot test demonstrates the ability of the temperature control component of the incubator to recover from a drop in temperature as might be experienced when a portal in the incubator is opened. **Air Control Overshoot (ACO)** is defined in clause 201.12.1.108 of the Standard.

With a Control Temperature setting of 32 °C in Air Control Mode, the incubator is allowed to reach **STC**. The Control Temperature is then set to 36 °C. The Incubator Temperature (**IT**) is monitored. The overshoot is the maximum **IT** achieved after reaching 36 °C and must not exceed 2 °C above the set point. After the maximum temperature is reached, an equivalent of **STC** is calculated and must be true within 15 minutes. The time to reach the new **STC** from the first passage of 36 °C shall be measured.

Skin Sensor Accuracy

The sensor used to control the temperature in the **Baby Temperature Control** test must have an accuracy as defined in the Standard under clause 201.12.1.103. Testing the accuracy of the **Skin Temperature Sensor (STS)** requires the use of a separate (optional) temperature-controlled 'oven' module. The 'oven' can be set to a temperature of 28 °C to 40 °C. The **STS** is plugged into the incubator's temperature control module and the temperature sensing element is placed in the 'oven'. The difference between the Skin temperature displayed on the incubator's control module and the oven's temperature must not exceed 0.3 °C

Select All/Clear All

The **Select All** and **Clear All** buttons on the Autosequence display allow selection of every parameter test (**Select All**) or no parameter tests (**Clear All**). These selections can be useful when beginning to set up an Autosequence, depending on whether most of the tests are required or very few tests are required.

4.6 Run Test

In addition to running a test by selecting an autosequence from the Edit Autosequence screen, a test can be run by touching the Run Test quadrant of the main screen. The only difference is whether you select the Autosequence first through the Edit Autosequence list, or you select the Autosequence after you choose the incubator to test through the Run Test option.

Regardless of the way in which a test is 'run', the test requires that the incubator be identified, so that the report can be saved. Running a test will first display the device information input screen shown below.

It is mandatory to enter the Equipment ID, as it will form the core of the test report filename. The Technician Initials (or alternate code) is also mandatory to identify who performed the test. Other information (make, model, location, facility) may be entered, but are not mandatory.

If this screen was entered from the Edit Autosequence option, the correct Autosequence will be included in the AutoSequence field. Otherwise, if this screen was entered from the Run Test screen, it will be necessary to select the desired AutoSequence from the (user defined) list, as shown below.

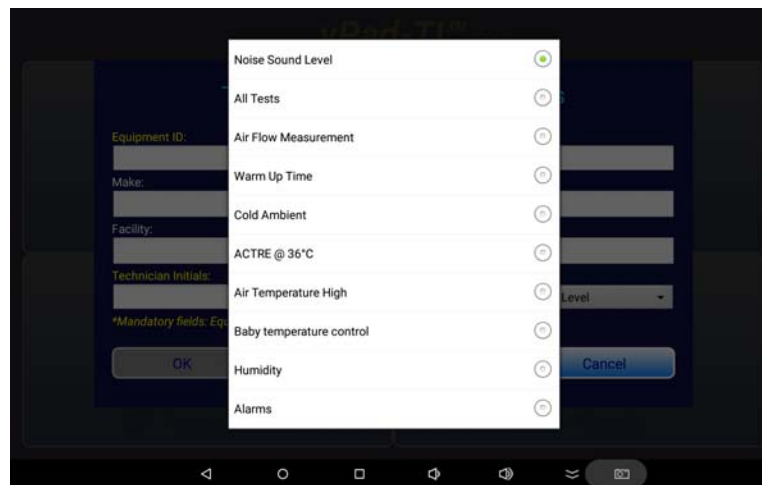


Figure 25: Auto Sequence Selection

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Once the mandatory information is entered, the OK button will be enabled. Touching the OK button will begin the actual test.

Figure 26: Equipment Information Page

As data is entered and accepted (by pressing OK) for the incubator inventory, a small database is created which will allow an incubator to be selected from a list, in the future. To select an incubator from the list, simply touch the Equipment ID field (or Serial Number field), and a list of pre-existing entries will be displayed. Touch the entry which matches the incubator you wish to test, and all of the fields will be populated from the database.

Figure 27

With the equipment information properly entered and the correct Autosequence selected, touch the OK button to run the test. Details of the screens which will be displayed during the various available tests will be covered in the next chapter.

5 Running a Test

5.1 Overview

Once the required Autosequences have been designed and saved, vPad-TI is ready to run a test on an incubator. This chapter describes the software used to control the test operation and assumes that the hardware has been assembled and is in place in the **Compartment** of the incubator, as described in Chapter 2. With the exception of tests performed with the mattress tilted, the description will include all of the parameters.

The process of creating/editing and selecting an Autosequence for processing has been described in the last chapter. Once the equipment information has been input and the OK button pushed, vPad-TI will proceed to perform each of the individual tests enabled in the Autosequence. The tests will proceed in the order shown on the Edit Autosequence screens, which have been determined to be the order which will be least disruptive to the completion of the temperature tests (to minimize temperature loss).

Note: If the wireless hub is running off the battery and the voltage gets low, an alarm will sound every five seconds and a warning sign will be placed on the flashing battery icon:



The mains charger must be connected to ensure no loss of data.

The remainder of this chapter describes the individual tests and the screens that will be encountered during the performance of the test.

5.2 Noise Sound Level Test

The Noise (Normal) Sound Level (**NSL**) test is intended to identify noisy components of the system, such as the fan motors that provide the flow of air within the incubator Baby Compartment. In order to isolate that noise level, it is first necessary to determine the background noise level without the incubator operating. On starting the test, the general instructions and the wireless connection screens will be displayed. These screens will be the first screens displayed, and generally will only be shown once, at the start of any Autosequence.

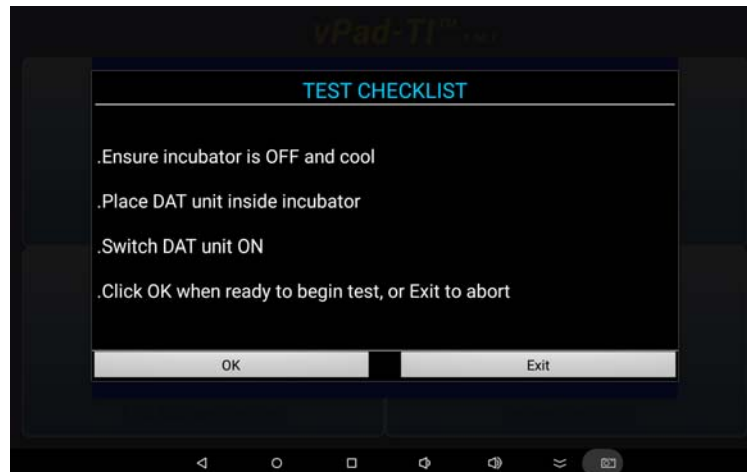


Figure 30

Once the Bluetooth wireless connection is made to the DAT (Data Acquisition Device) the user must press **Continue** to proceed with the actual test. This screen is just to confirm that wireless communications have been established.

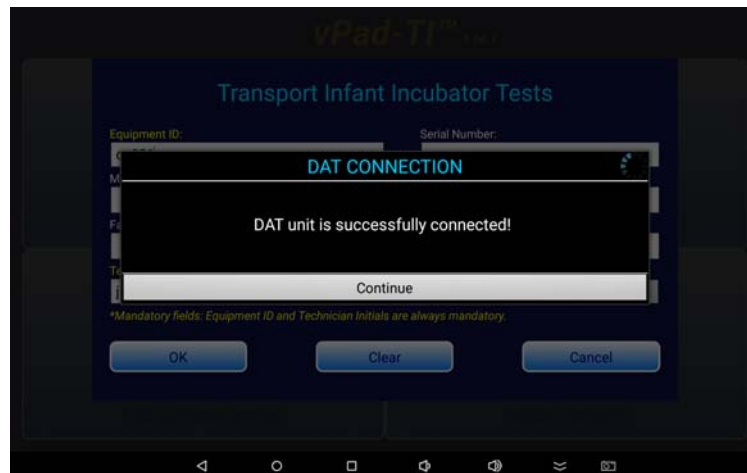





Figure 31

Figure 35 shows the instruction screen for the **Background Sound Level (BSL)** test. On this screen there is a  icon. If this icon is selected, a help screen describing this test will be displayed. In addition, there is a battery icon,  which will indicate the battery level during the test. The battery level is not updated on the instruction screens, only during actual tests. Because certain portions of the test only require data every minute, there may be some uncertainty that the system is operating. An animated activity icon,  is displayed on the screen to show there is activity going on in the background.

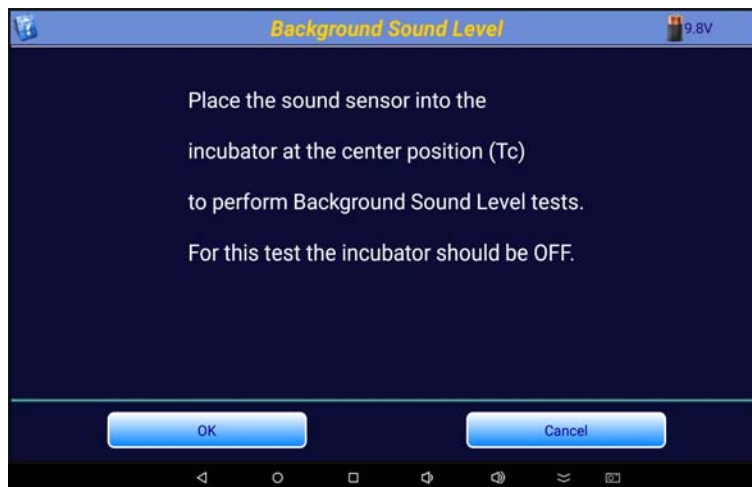


Figure 35

This is a typical instruction screen, indicating any actions that must take place before proceeding. For the **BSL** test, place the sound level accessory module in the center of the mattress, on top of the **HUB**. The module will be held in place with magnets located in the sensor and the **HUB**'s large, black thermal mass. As indicated in the instructions, the incubator should be **OFF** so that the background or ambient noise can be measured.

Note that in some circumstances the term **Tc** may be used instead of **Ta** to indicate the temperature at the center of the incubator mattress.

NOTE: At sound levels below 40 dBA, the HUB must be operated on batteries.

When the instructions have been complied with, click on the **OK** button to activate the test. vPad-IN will measure the sound level and report the value as indicated in Figure 36.



Figure 36: Background Sound Level Management

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After the **BSL** has been measured and displayed, turn the Incubator **ON** at its minimum temperature setting, and press **OK**. The program will proceed to the next step in the **NSL** test.

The Noise Sound Level test instruction screen is shown below in Figure 37. With the sound level sensor in the same position at the center of the mattress, and the incubator operating at minimum temperature, click on the **Get Sound Level** button.

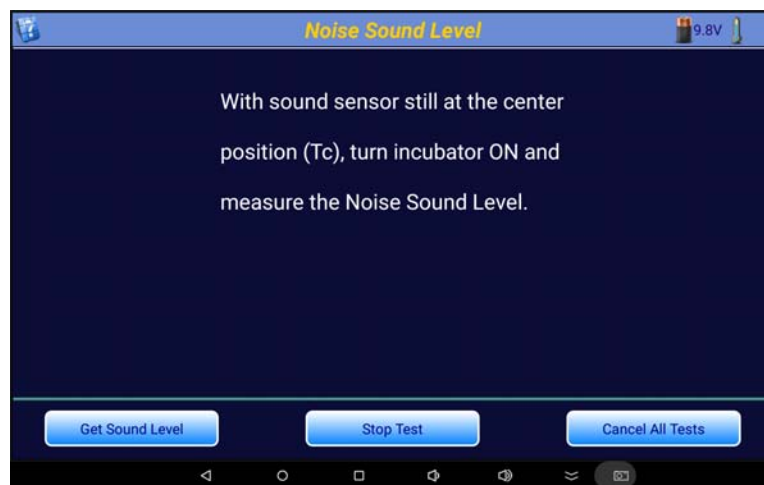



Figure 37: Noise Sound Level Instructions

Note the **Skin Sensor Probe Test** icon, , in the upper right corner of the screen. This indicates that the **Skin Sensor Accuracy** test has been activated. This test may be selected independently of the **Baby Temperature Control** test in the Autosequence. However, if the **Baby Temperature Control** test has been selected, the **Skin Sensor Accuracy** test will minimally include a test at 36 °C. Function of the **Probe Test** will be discussed following the **NSL** test.

The results of the **NSL** test will be shown momentarily, Figure 39, followed by a summary of the results. It can be seen from the results in Figure 40 below that in this particular instance, for example, the **NSL** would be considered to be a pass because there is the minimum 10 dBA difference between the **NSL** and **BSL** values, and **NSL** is less than 60dBA.



Figure 39: Noise Sound Level Measurement

When the test **Results** are displayed, the user has the option of going forward to the **Next Test**, **Repeat** the test, or to **Cancel All Tests**. **Repeat Test** would be used if corrections could be made to the test setup to improve the results. **Next Test** is used to continue on with the Autosequence, and **Cancel All Tests** is used if it is decided to abort the remainder of the Autosequence.

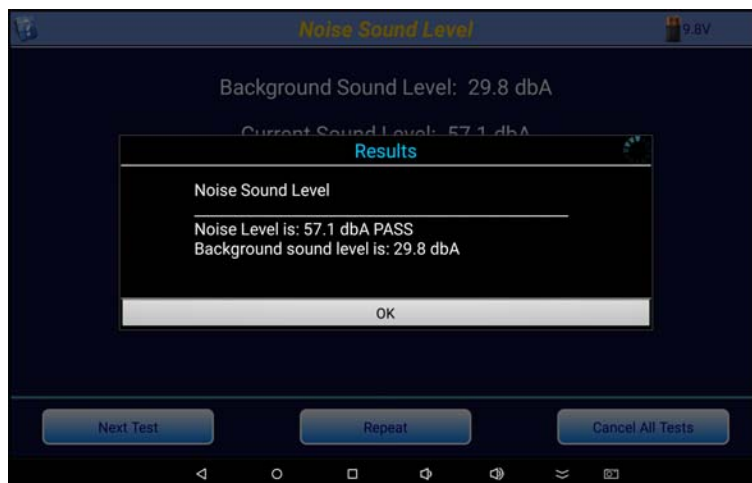



Figure 40: Noise Sound Level Results

5.3 Probe Test

If a **Baby Temperature Control** test or a **Skin Sensor Accuracy** Test have been selected in an Autosequence, a **Probe Test** icon, , will appear in the upper right corner of the screen (as shown previously in Figure 37). A **Probe Test** can be initiated at any time when this button is visible, and the test will (can) run in the background. When first activated, the instruction screen for the **Skin Accuracy Test** will be displayed.

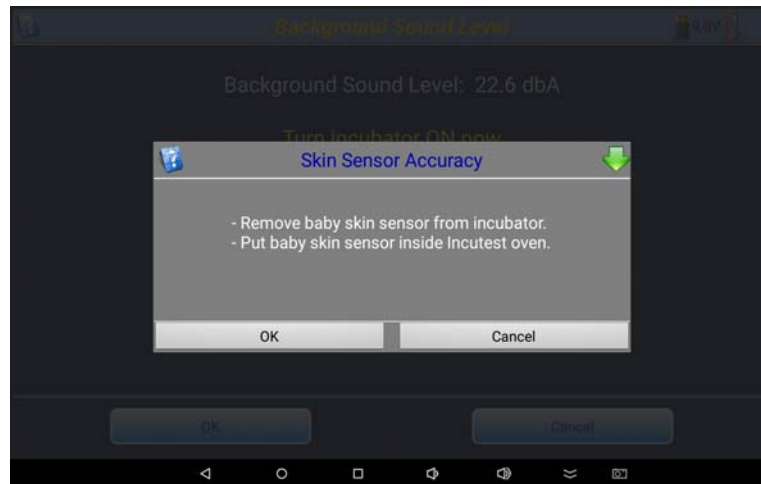


Figure 42

The Skin Sensor must be tested for accuracy before the **Baby Temperature Control** test can be performed. To facilitate this, the **Probe Test** is made available as soon as the Autosequence starts. This allows the Sensor to be tested in the background, and be available when the **Baby Temperature Control** test is ready to begin. Note that the **Probe Test** can be included in any sequence, it is not limited to use with the **Baby Temperature Control** test.

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To test the Skin Sensor, it must be placed in a tightly controlled temperature environment. vPad-TI provides an optional Sensor Oven to perform this test. The Sensor is removed from the incubator Baby Compartment and placed in the Oven. The Sensor remains plugged into the incubator Control Panel and the incubator must be placed into the Skin Temperature Control Mode, with the temperature of the Skin Sensor displayed. The adhesive disk which holds the sensor to the infant's skin must be removed and, if necessary, the sensor should be unrolled so the cable is straight. The sensor should be positioned in the Oven as indicated in **Figure 43** with the sensor tip toward the back of the thermal pad in the Oven, to provide good thermal contact.

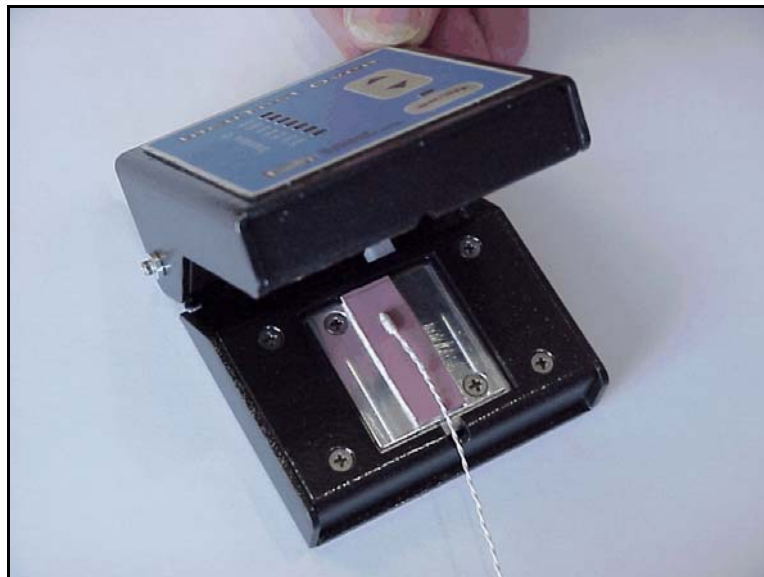



Figure 43: Sensor Placed in Oven

The Oven is connected to the USB Host port of the tablet via a microUSB to microUSB cable, and must be connected to its own 15-18 VDC power supply via the adapter input connection on the back of the Oven. Press the Power ON/OFF switch on the front panel to activate the Oven. When the Probe Test is initiated by touching the Probe Test icon, the app provides an instruction screen on how to make the connection.

The **Skin Sensor Accuracy** Test can be performed at temperatures from 28 °C to 40 °C in increments of 2 °C. The Oven is controlled by vPad-TI software when connected to the **USB Host** port. Once the Sensor has been correctly placed in the Oven, as indicated above, click the **OK** button to initiate the Sensor Test. Alternately, the **Cancel** button can be clicked to abort the **Skin Sensor Accuracy** Test. During a test, the **Skin Sensor Accuracy** dialog box on the screen can be reduced to the **Probe Test** icon by clicking on the  icon in the upper right corner of the dialog box.

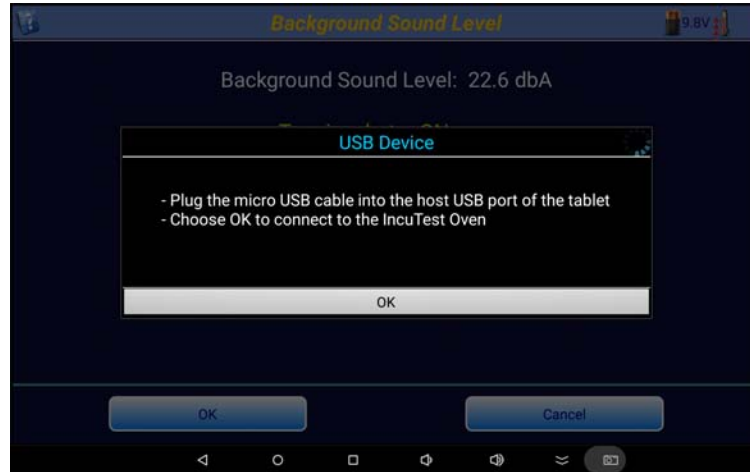


Figure 45

If more than one temperature has been selected on the Autosequence, the test will begin with the lowest temperature value defined in the test. When the test starts, the screen will change to the Temperature Stabilization screen indicated in Figure 46. While this screen is displayed, the system is waiting for the Oven temperature to operate consistently within ± 0.1 °C. To abort the **Skin Sensor Accuracy** test click on the **Cancel** button.

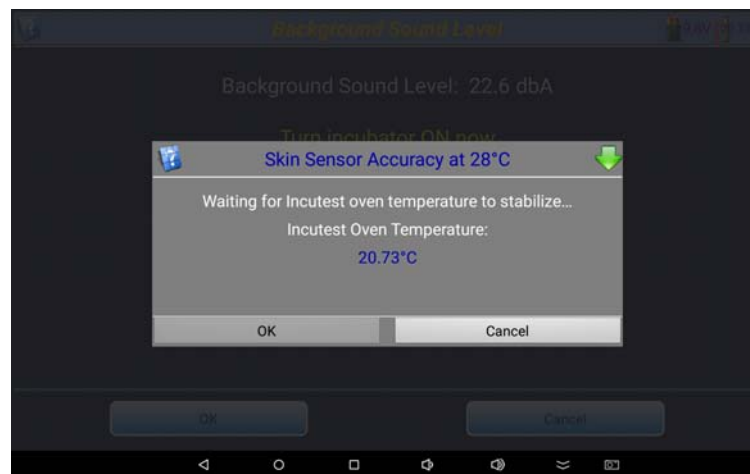


Figure 46: Oven Temperature Stabilization

Once the Oven temperature has stabilized at the set temperature, the program will automatically proceed to the Sensor Temperature Input screen, Figure 47. On this screen the temperature of the Skin Sensor, as shown by the Control Panel of the incubator, can be entered. If another test (air temp, warmup, overshoot, etc.) is in progress when the **Probe Test** requests the Sensor temperature, the incubator can be switched between Air control and Skin control *momentarily* to read the Skin Temperature, without affecting the **Air Temperature Control** test.

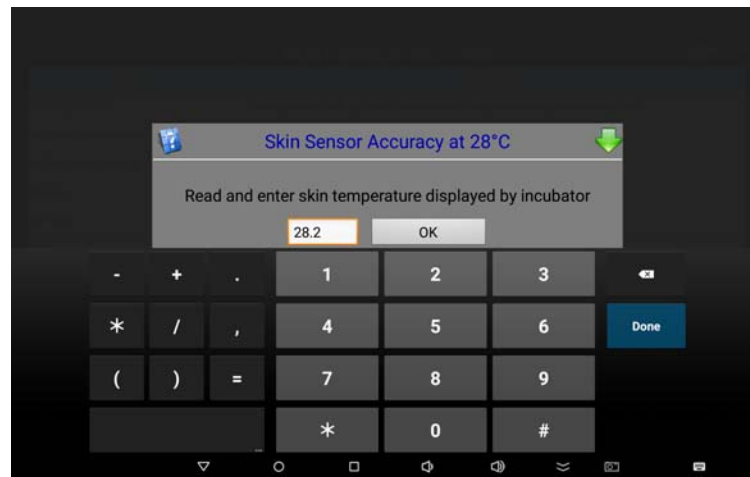


Figure 47: Entering Skin Sensor Temperature

If the Skin Sensor reading from the incubator and the Oven temperature agree to within 0.3°C the Sensor will display a **PASS** indication, otherwise it will display **FAIL**. Clicking the **OK** button will accept the result and continue on to the next temperature, if there is one, in the Autosequence. The **Skip** and **Cancel** buttons will function as previously described.

If you switch back to another test in progress, the Probe Test icon will display the current temperature of the Oven, and will show red arrows moving upwards as the Oven heats:



Figure 49: Skin Sensor Pass Indication

When all of the temperatures indicated in the Autosequence have been tested, the test will be considered to be complete, and the app can return to any other test which was in progress. If no other sensor tests are to be done, the **Probe Test** icon will be removed from the screen. The Sensor can then be placed in the incubator to perform the **Baby Temperature Control** test. For this test, the Skin Sensor is suspended 10 cm above the center of the mattress. For further details, see the section on **Baby Temperature Control**.

5.4 Air Flow/Air Velocity Test

In the **Air Flow** test, the air velocity is measured at four points, at the center of each of the four quadrants of the mattress. This coincides with the positions of Tb - Te for the temperature tests. The **Air Flow Sensor** is held in place on the large black thermal mass (the Puck) using magnets.

Note: Remove the Protective Cap from the Airflow Sensor body to expose the sensor prior to attempting any measurements.

When the test first starts, there is a delay to allow the sensor to acclimatize to the temperature of the incubator, Figure 50. Following the delay, the program will prompt to have the sensor placed at the first position, T2, and the **OK** button will be enabled. When instructed, move the **Air Flow Sensor** to the position indicated in the instruction screen, Figure 51. Note that, in an Autosequence, the **Air Flow** test is performed before any temperature tests. This avoids loss of heat while the Sensor is moved from one position to another. During this test, it is best to operate the incubator at its minimum air temperature so that any temperature tests start with the incubator baby compartment at a temperature as close to ambient as possible.

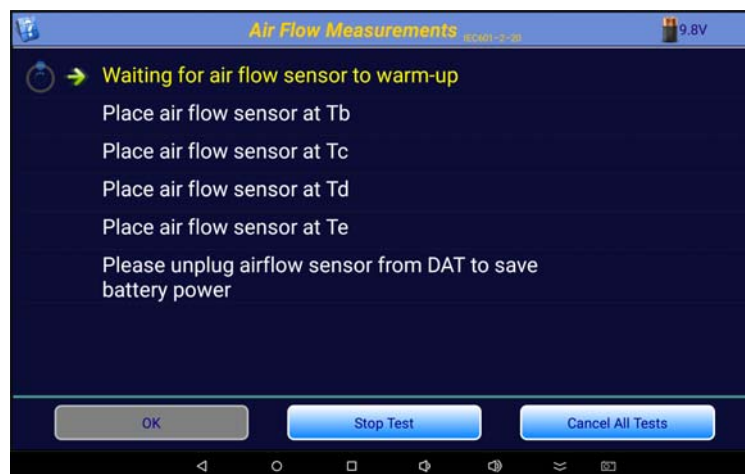


Figure 50

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When one air flow measurement has been completed, you will be prompted to move the sensor to the next position. Once in position, press **OK** to take the measurement. As each air velocity measurement is taken, it is compared to the maximum air velocity allowed by the standard, 0.35 m/s. If the air velocity is less than 0.35 m/s the program will indicate a **PASS**, otherwise it will indicate a **FAIL**.

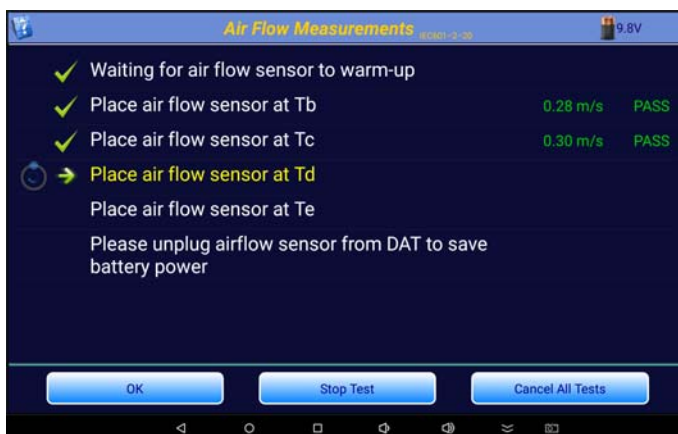


Figure 51

When all four measurements have been acquired, the test **Results** screen will be displayed, summarizing the test, as per Figure 52. At this point the options are: going forward to the **Next Test, Repeat** the test, or to **Cancel All Tests**. As previously discussed, **Repeat** would be used if corrections could be made to the test setup to improve the results. **Next Test** is used to continue on with the Autosequence, and **Cancel All Tests** is used if it is decided to abort the remainder of the Autosequence.

NOTE: the Air Flow Sensor uses a large amount of current relative to the other components, and may significantly reduce battery life if used for prolonged periods of time.



Figure 52

5.5 Warm Up Time Test

According to the standard, the manufacturer should stipulate a nominal warm up time (**WT**) for the incubator in the user manual, and when tested, the warm up time should not differ by more than 20%. To measure the **WT** the incubator should be in a 'Cold Condition', where the ambient temperature is less than 25 °C. The software will measure the start or ambient temperature in the incubator and will add 12 °C to it to determine the target control temperature (**CT**).

Following the instructions presented in Figure 53, the mattress is first set to the horizontal position. A suggested **CT** is calculated from the ambient temperature in the incubator +12 °C, in this case, 37 °C. The **CT** can be set to a value equal to or more than this suggested value. The incubator is then set to Air Control and the incubator is turned **ON**, if it is not already running. When the actions indicated in the instructions are complete, click on the **Continue** button to start the test.

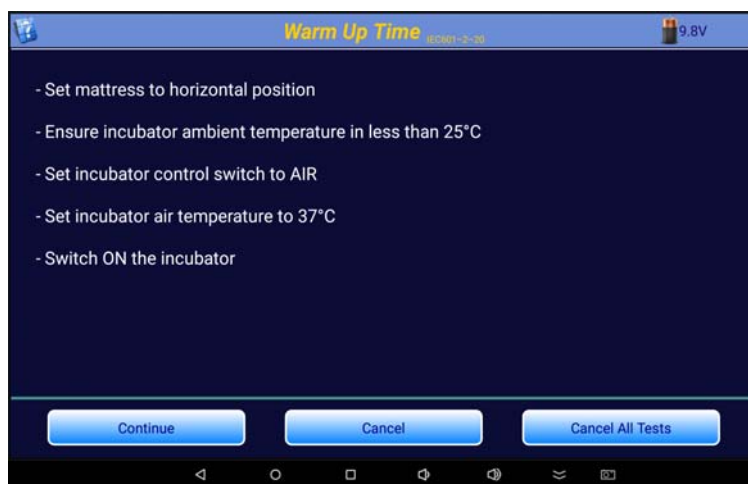


Figure 53: Warm Up Time Instructions

During the **WT** test, the program will display a graph of incubator temperature versus time, along with several key parameters (see Figure 54). Due to the large thermal mass of the air in the incubator, temperature measurements are taken at 1 minute intervals. The Ambient Temperature (**Ta**) is the temperature at which the test started. The Current Temperature is the temperature 10 cm above the center of the mattress, or **IT**. The End Temperature (**Te**) is 11°C above the Ambient Temperature. The Warm Up Time **WT**, is the time it takes to go from the **Ta** to **Te**, and is shown when the test condition is met.



Figure 54

When the **WT** has been determined, the option will be provided to end the test or allow the temperature data collection/graphing to continue, as per Figure 55. At this point the options are: **OK** end the test now, or **Continue Test**.

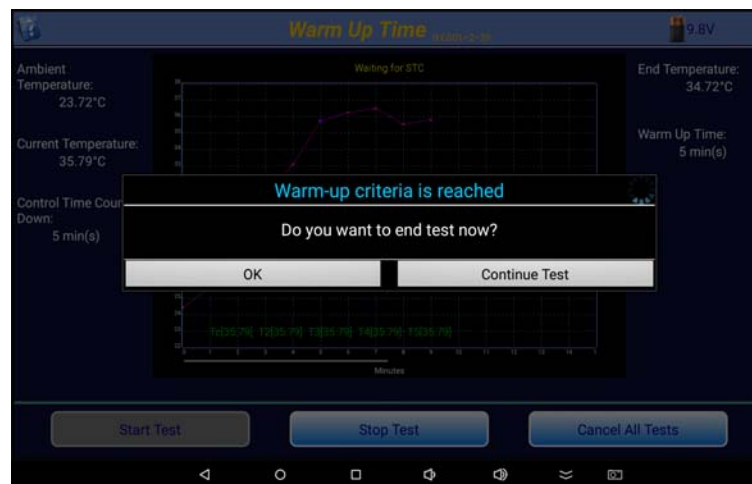


Figure 55: Continue Warm Up Test

If the test is allowed to continue after the initial determination of **WT**, then the data will be analyzed for the **STC**, and green dotted lines will be displayed during the first 60 minutes that the data meets the defined variability condition for **STC**, but has not reached the 60 minute criteria. In the temperature graph, the warm up time is indicated by the blue circle around the data point, which in this case is also the start of **STC**.



Figure 56

At 60 minutes of **STC**, the dotted lines will change to solid lines, indicating that the full criteria for **STC** have been met. At this time, the countdown timer will begin (if it has been set to a value other than Continuous).



Figure 57

When the **WT** test has been completed, the test **Results** screen will be displayed, summarizing the test, as per Figure 58. After pressing OK to acknowledge the results, the options are: going forward to the **Next Test**, **Repeat** the test, or to **Cancel All Tests**. As previously discussed, **Repeat** would be used if corrections could be made to the test setup to improve the results. **Next Test** is used to continue on with the Autosequence, and **Cancel All Tests** is used if it is decided to abort the remainder of the Autosequence.

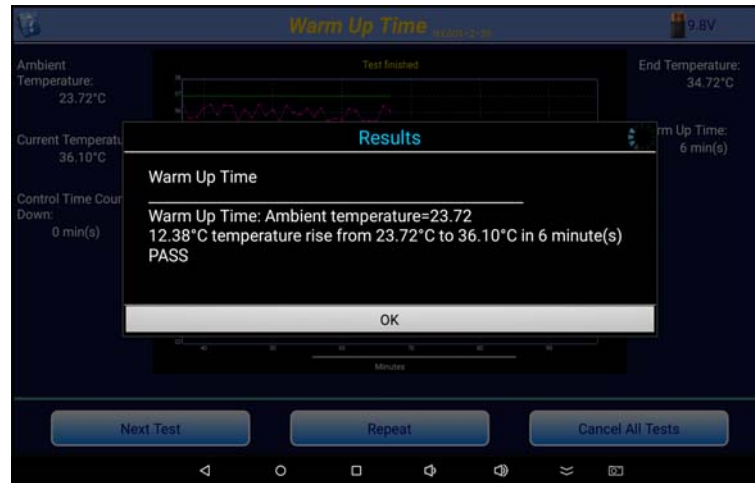


Figure 58: Continue Warm Up Test

If the option to **Save Picture to JPG After Test** has been enabled in the **System Settings**, the **Result** will include a filename of the JPG image of the temperature versus time graph. This filename will be included in the test report for reference.

5.6 Cold Ambient Temperature at 36 °C

The standard states that following changes in ambient temperature, the Transport Incubator Temperature must not differ from the Control Temperature by more than 3°C. To be able to verify this, the ambient temperature must be in the range 21°C to 25°C and the incubator is heated up to 36°C. Once STC has been reached, the external power source is disconnected and the incubator is moved to an environment where the ambient temperature is in the range -5°C ($\pm 2^\circ\text{C}$) and the wind velocity is not more than 1 m/s. After 15 minutes, the incubator is returned to the original environment (ambient temp 20°C to 25°C), external power source reconnected and the incubator run for a further 30 minutes. The Incubator Temperature must not vary by more than 3°C throughout this test.

When initiated from an autosequence, a Test Checklist will be displayed on the screen.

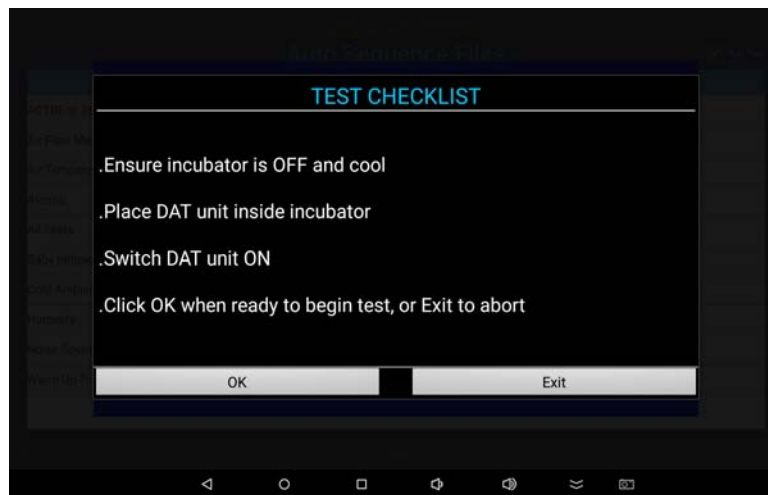


Figure 59: Cold Ambient Temperature Test Checklist

Set up the test environment and on pressing OK, the tablet will initiate communication with the DAT inside the incubator. The tablet will then display the following set up parameters:

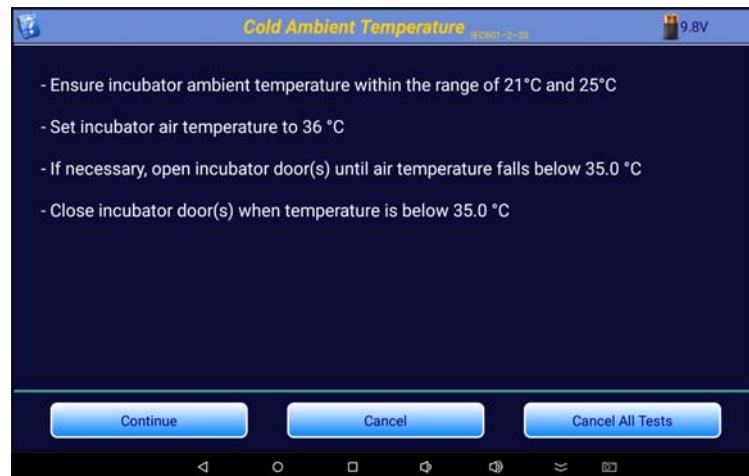


Figure 60: Cold Ambient Temperature Set Up Instructions

Once configured, pressing Continue will start the test by measuring the internal temperatures of the incubator until STC is established

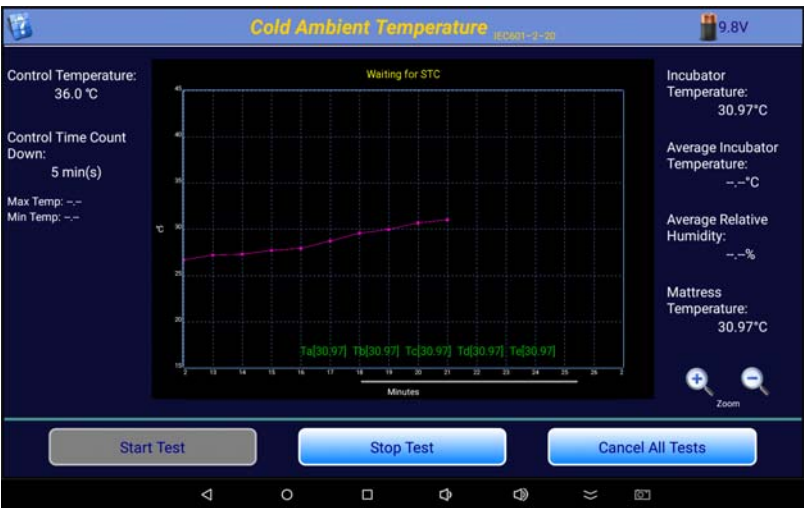


Figure 61

Once STC has been reached, the system will prompt you to disconnect the incubator from the external power supply and move the incubator to an environment where the ambient temperature is -5°C ($\pm 2^{\circ}\text{C}$) and the wind velocity is not more than 1 m/s



Figure 62

The time at which the incubator is moved is marked with a circle on the temperature graph

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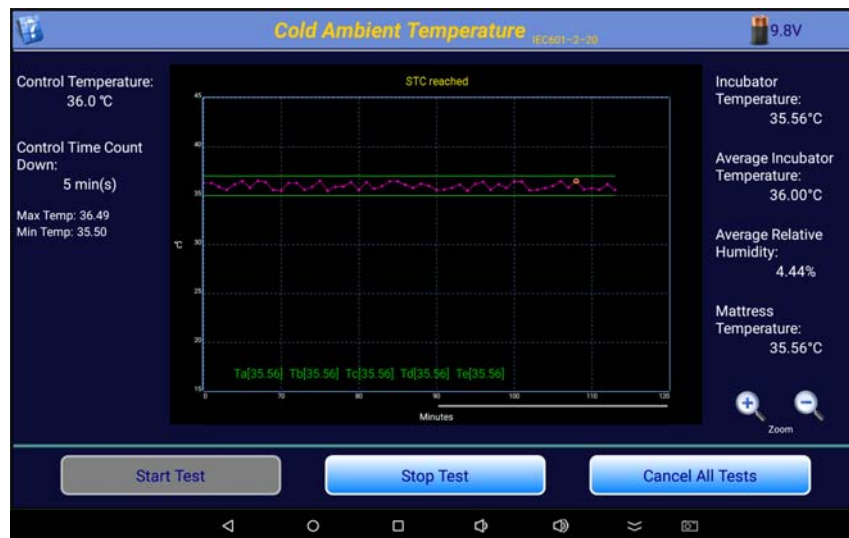


Figure 63

After 15 minutes, the incubator is to be moved back into the original test environment and the external power supply re-connected

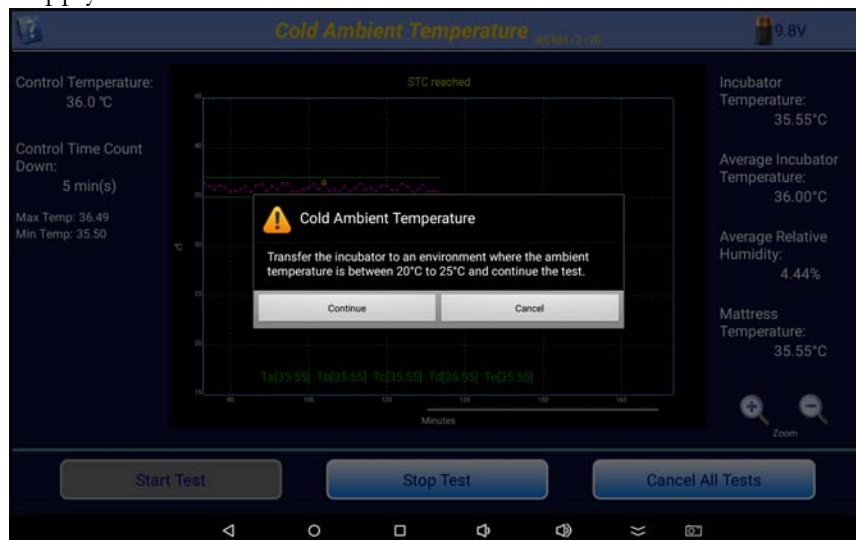


Figure 64

A second circle is placed on the temperature graph indicating the time & temperature of this transition.

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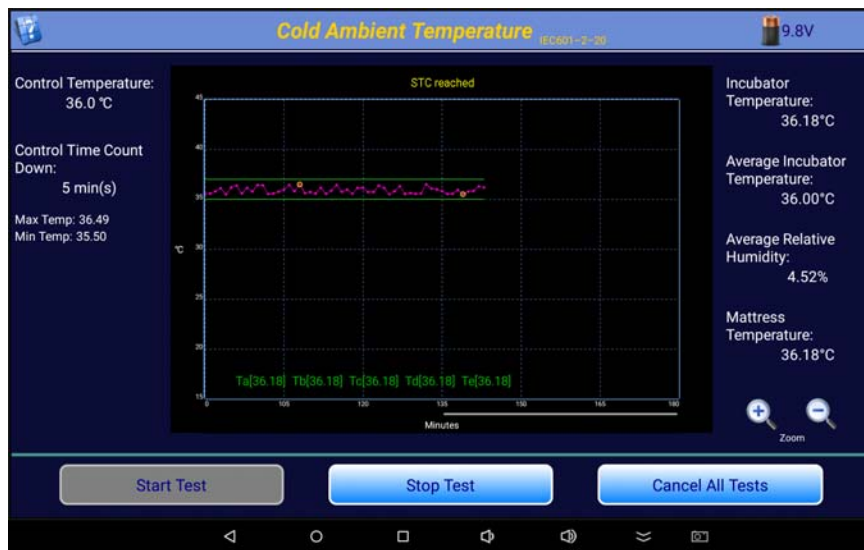
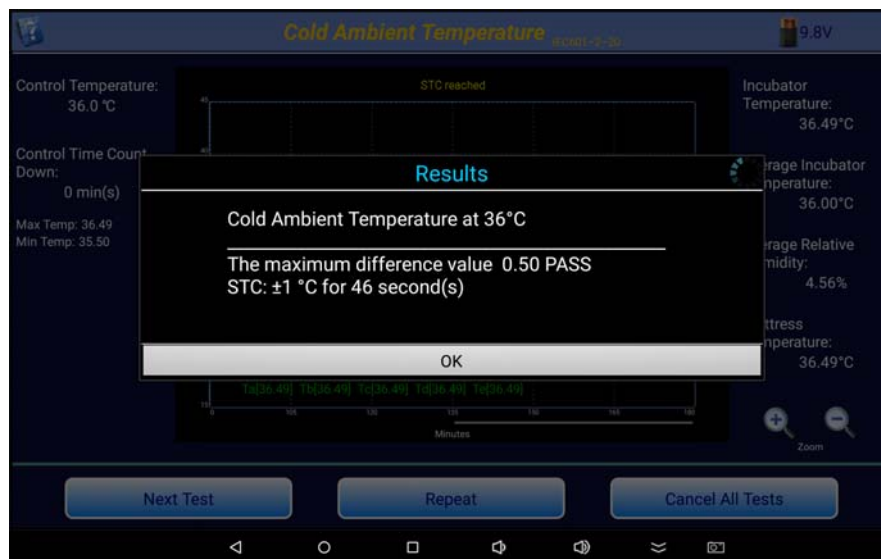


Figure 65

Once the test has finished, the results will be displayed as follows



5.7 Air Temperature Control Regulation Error(ACTRE) at 36 °C

Working as an air controlled Transport Incubator, the average Transport Incubator Temperature must not differ from the control temperature by more than $\pm 2^{\circ}\text{C}$ at an ambient temperature of between 10°C and 20°C and by no more than $\pm 1.5^{\circ}\text{C}$ at an ambient temperature of between 20°C and 30°C .

Once the autosequence is selected and run, the system will display a Test Checklist

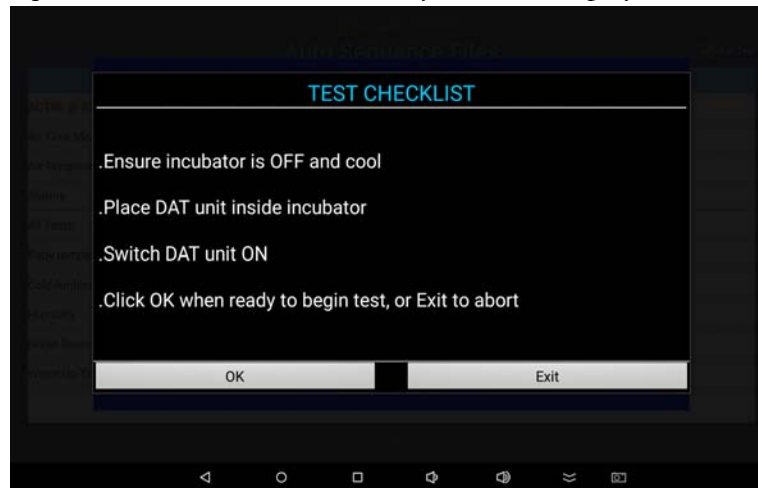


Figure 67: ACTRE Checklist

Set up the test environment and on pressing OK, the tablet will initiate communication with the DAT inside the incubator. The tablet will then display the following set up parameters:

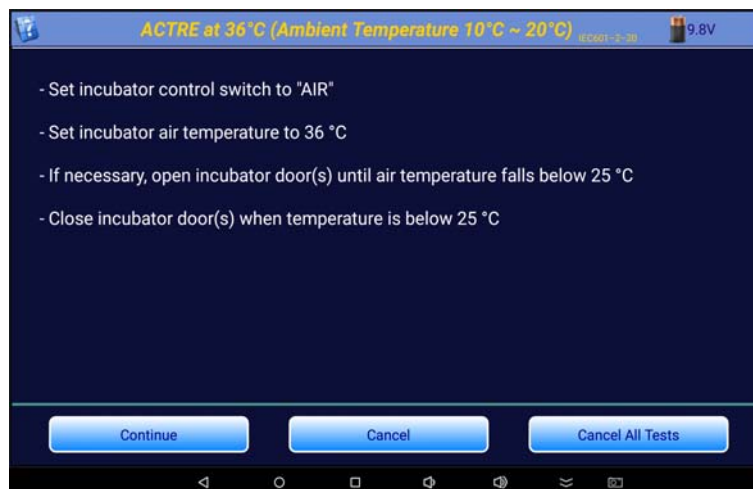


Figure 68: ACTRE Set Up Instructions

Once configured, pressing Continue will start the test by measuring the internal temperatures of the incubator until STC is established

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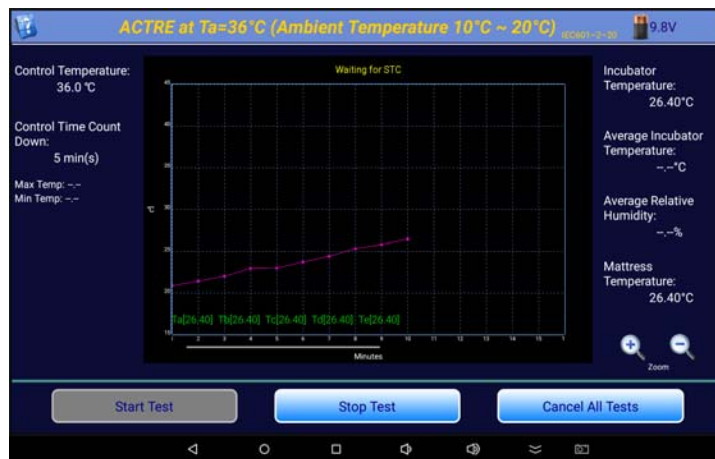


Figure 69

Once STC is achieved the results for the first stage of the test will be presented as follows:

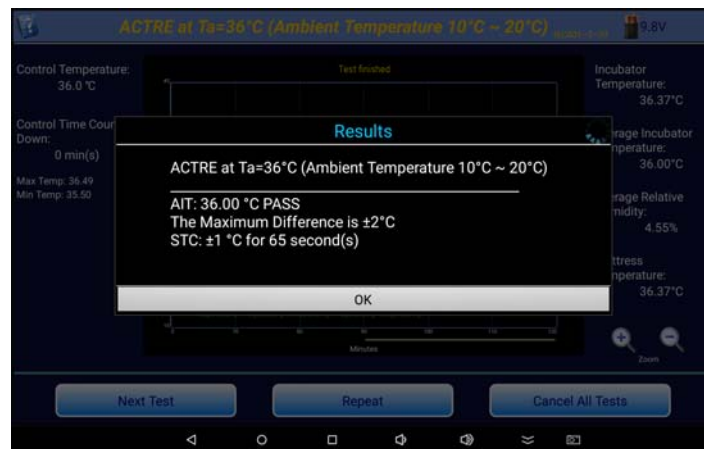


Figure 70

The test will then be repeated for the upper ambient temperature range (20°C ~ 30°C) and the results displayed as follows:

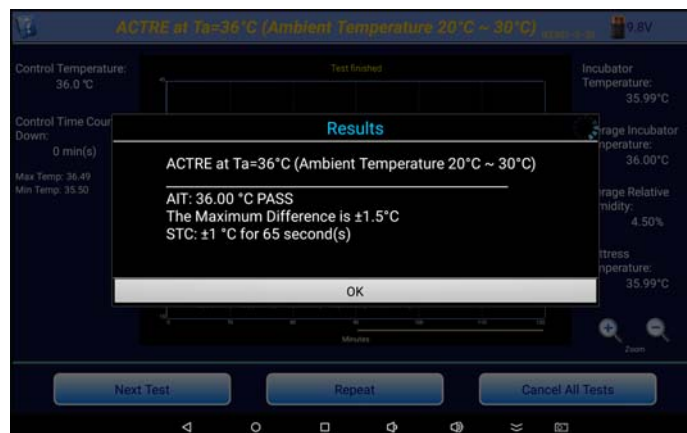


Figure 71

5.8 Air

Temperature Control Test - High

An incubator must be able to maintain a desired air temperature within the Baby Compartment, and the air temperature must be reasonably uniform throughout the space. The Standard requires the incubator to be able to sustain a Steady Temperature Condition (**STC**) after **WT** is reached. In addition, the Average Temperature (**AT**) at 10 cm above the center of the four quadrants of the mattress must not differ from the Average Incubator Temperature (**AIT**) by more than 1.5°C with a horizontal mattress, or 2°C for a tilted mattress. The Standard requires this control test be performed at a high and a low temperature setting. While the Standard allows testing at any temperature, it generally recommends 36 °C for the high temperature test, and 32 °C for the low temperature test.

When an **Air Temperature Control** test is initiated by an Autosequence, the test instructions are presented as shown in Figure 72. The mattress is first set to the horizontal position and the incubator control mode is set to Air. A **CT** target is displayed based on the value set in the Autosequence, in this case 36 °C for the high temperature test. The **CT** can be set to a value equal to or more than this suggested value. The incubator is then set to Air Control and the incubator is turned **ON**, if it is not already running. When the actions indicated in the instructions are complete, click on the **OK** button to start the test.

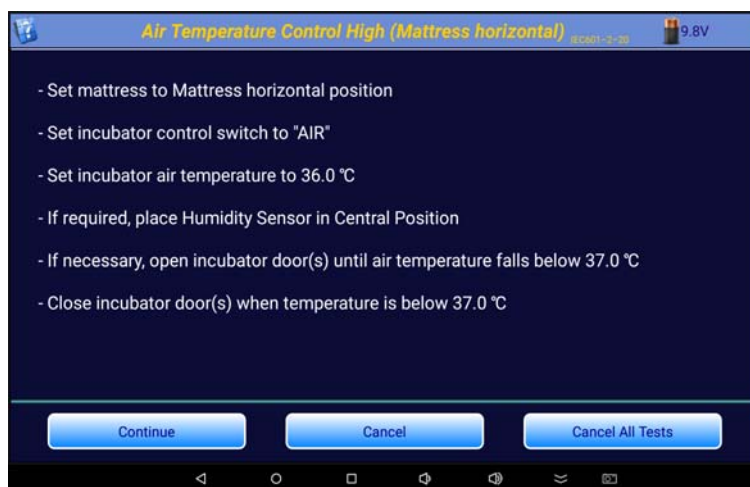


Figure 72: Air Temperature Control Instructions

When the test starts, the program will create a graph of the temperature at the center of the mattress at a height of 10 cm above the mattress. As shown in Figure 73, the display will also indicate the **Control Temperature** defined in the Autosequence, and the length of time the test will continue to run after **STC** is reached. In the example shown, the **Control Time Count Down** has been set to 30 minutes. After **STC** has been reached, the timer will count down to zero, at which time the test will terminate. If the time has been set to **Continuous**, the test will run until the **Done** button is clicked.

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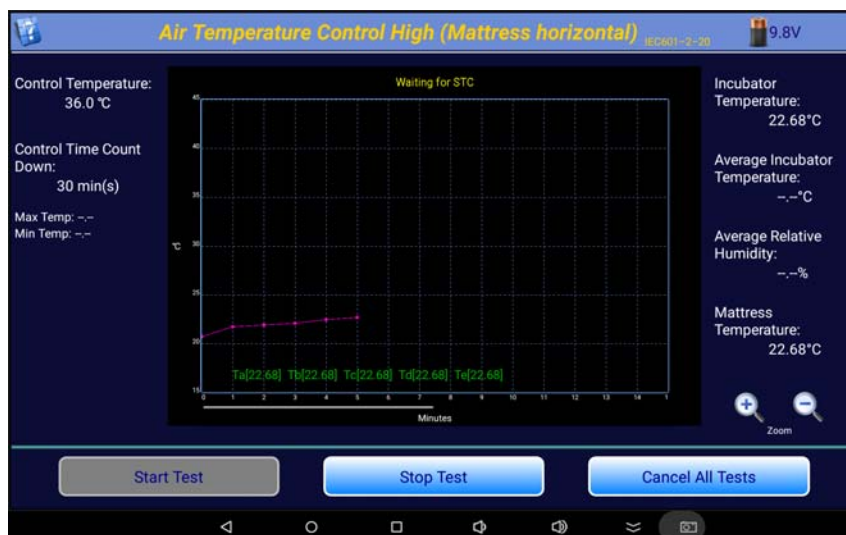


Figure 73

In addition, the **Incubator (air) Temperature** and the **Mattress Temperature** will be displayed on a minute to minute basis. The **Average Incubator Temperature** and the **Average Relative Humidity** will not be displayed until **STC** is reached. During the time before **STC** is true, the buttons labeled **Humidity Check** and **Temperature Check** are also disabled (grayed out). After **STC** is true, these buttons will be enabled for input.

During the test, all of the data points collected, including those for the temperatures at the other 4 locations, are saved to a Raw Data file. All five temperatures for locations Ta through Te are displayed along the bottom of the graph for information purposes. Any event which occurs during the test is also saved as a comment. Typical comments would be: Minute Mode, Air Temperature Control (Mattress Horizontal) at 36 °C Started, Waiting for STC, Humidity Check Pass, etc. The Raw Data file can be exported and used to recreate the test graphics.

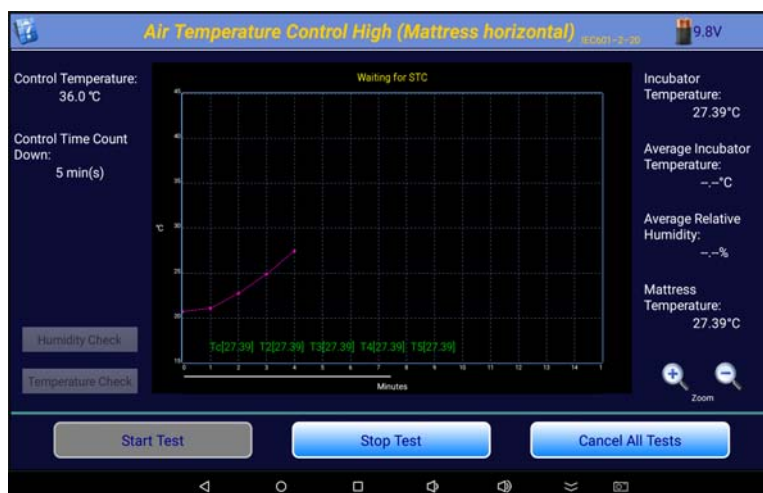


Figure 74

After **STC** is reached, it is possible to enter the Humidity and Temperature values indicated by the incubator. The **Average Relative Humidity** value, as measured by the **Humidity Sensor**, is displayed on the screen. If the incubator has its own indicator of humidity, the **Humidity Check** button can be clicked, enabling the input screen of Figure 75. The relative humidity value displayed by the incubator is input and will be compared to the relative humidity as measured by the **Humidity Sensor**. The value indicated by the incubator must be within 15% of the value measured by vPad-TI's Humidity Sensor.

Figure 75: Relative Humidity Input

Figure 76: Independent Temperature Value Input

Similarly, the incubator is required to have a temperature sensor which is independent of the control system of the incubator. This sensor is typically a non-mercury thermometer mounted within the baby compartment of the incubator. The requirements of the Standard, clause 201.12.1.105, are such that the independent temperature indicator must not differ from the Incubator Temperature by more than 1°C. The indicated value of the independent temperature indicator is input into the appropriate field in Figure 76.

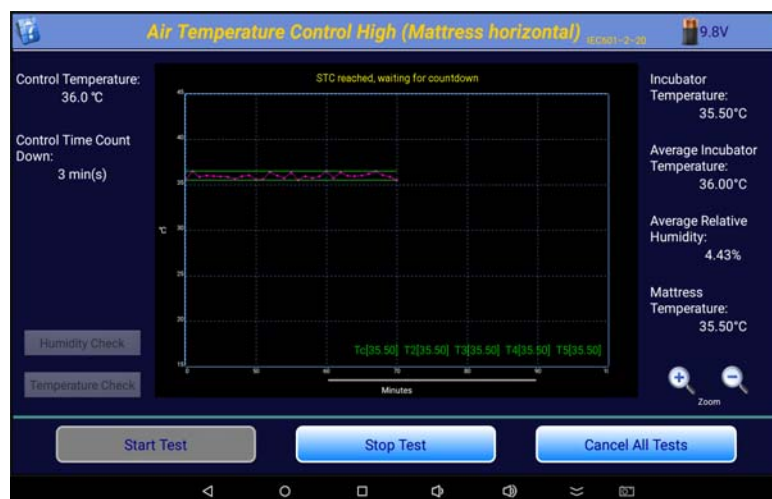


Figure 77

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These two values may be input multiple times after STC has been reached, up to the end of the test. If they have been enabled and no values have been input before the end of the test time, these dialog boxes will appear at the end of the test automatically. Each time a value is entered, a comment is entered in the Raw Data file. The Pass/Fail determination will be based on the last entered value.

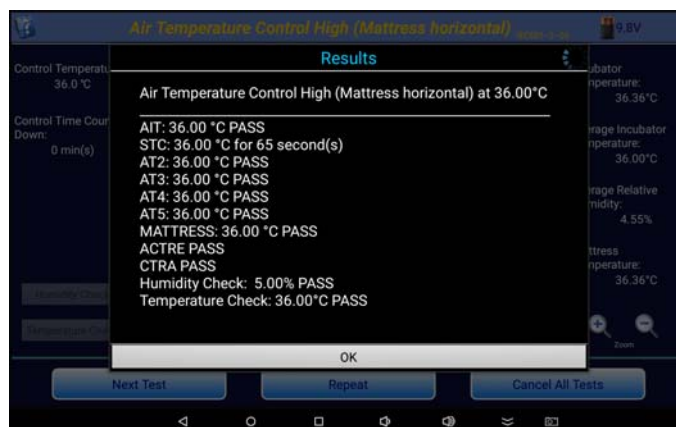


Figure 78: Air Temperature Control Result Summary

At the end of the test, the **Results** summary will be displayed, Figure 78. In addition to the **Average Incubator Temperature (AIT)** and the length of time that **STC** was true, vPad-TI will also report other values required by the Standard. The terms **AT2 - AT5** refer to the **Average Temperature** at each of the locations in the centers of the four quadrants of the mattress. These averages are calculated in a similar manner to the **AIT** value, from the temperatures measured at locations T2 - T5. These averages must not differ from the **AIT** by more than 1.5 °C when the mattress is horizontal, or by more than 2 °C if the mattress is tilted. The Standard requires that difference between the **AIT** and the **CT** be not more than ± 1.5 °C.

When OK is pressed on the Result screen, you are returned to the temperature graph screen and the graph shown is what will be saved to a JPG file if the option to **Save Picture to JPG After Test** has been enabled in the **System Settings**. The **Result** will include a filename of the JPG image of the temperature versus time graph. This filename will be included in the test report for reference.

5.9 Air Temperature Control Test - Low

The **Air Temperature Control - Low** is identical in format to the **Air Temperature Control - High** test, with the exception that it is done at a temperature which is less than that set for the High test. Although the Standard does not dictate a temperature, it does recommend a temperature of 32 °C. vPad-TI will default to the recommended value when setting up the Low temperature value, but other temperatures may be selected. In the event that this test follows a test at a higher temperature, the instructions (see Figure 79) suggest that the doors or portals of the incubator be opened to allow the temperature to fall to at least 33 °C to reduce the time required for the test.

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Figure 79: Air Temperature Control - Low

5.10 Baby Temperature Control

In the **Baby Temperature Control** Test the **Skin Temperature Sensor** of the incubator is suspended approximately 10 cm above the center of the mattress. In this test, the tests performed in the **Air Temperature Control** test are performed, along with a check to ensure the temperature measured by the Skin Temperature Sensor does not differ from the Control Temperature by more than 0.7 °C.

When the test is first started, the user is reminded to test the skin sensor probe for accuracy as shown in the screen of Figure 80. With an accurate skin sensor probe available, the instructions for the **Baby Temperature Control** are then provided.



Figure 80: Skin Sensor Probe Reminder

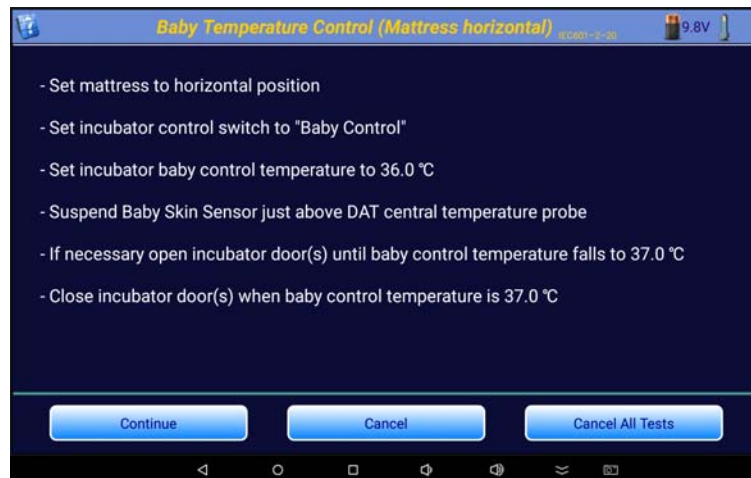


Figure 81: Baby Control Instructions

The **Baby Control Temperature** test functions in the same manner as the **Air Temperature Control** test, with the addition of one more button in the lower left corner next to the graph. This button, **Skin Temperature**, allows for the input of the skin temperature reading from the incubator display, after STC has been reached. The incubator's displayed **Skin Temperature**, as entered on

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the **Skin Temperature Check** dialog box, will be compared to the **Control Temperature**. If the difference is less than 0.7°C, the **Control Temperature Regulation - Baby (CTRB)** will be considered a Pass.



Figure 82: Baby Control Test - STC reached

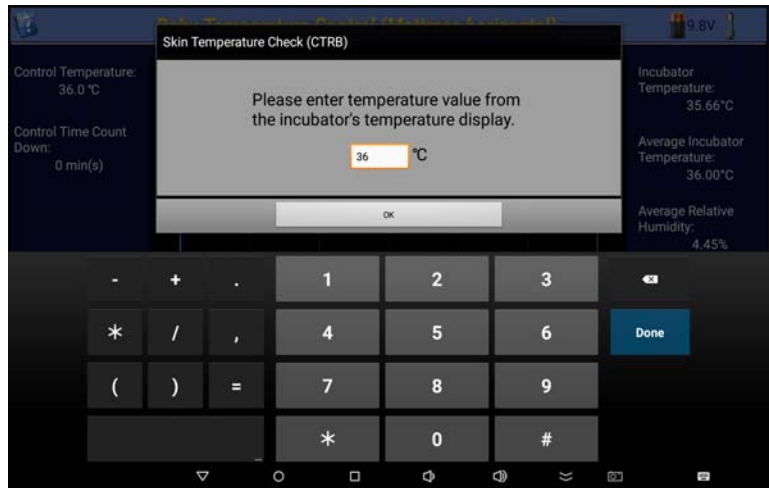


Figure 83: Incubator Skin Temperature Input



Figure 84: Baby Temperature Control results Summary

If the Humidity Check and/or the Temperature Check options have been selected in the definition of the Baby Temperature Control test, they will be enabled after STC is reached and values for these parameters can be input.

The results screen provides a summary of the test just completed.

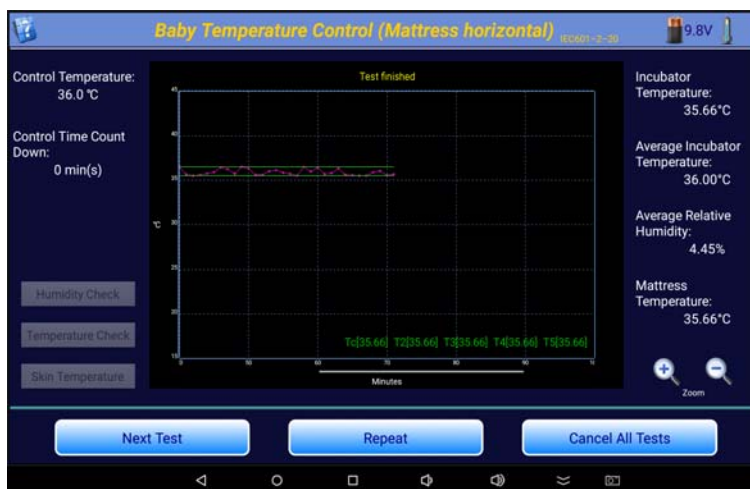


Figure 85: Baby Temperature Control Test Complete

After accepting the **Results**, the graph of the saved test is displayed. The user may now **Repeat** the test or go on to the **Next Test**.

5.11 Humidity and Temperature Checks

See the sections on **Air** and **Baby Temperature Control**.

5.12 Temperature Overshoot

It is inevitable that, during operation at **STC**, a care giver will be required to open a portal or a door in the incubator and the incubator will lose temperature. The Standard prescribes how the incubator should be able to recover from this problem in the **Temperature Overshoot** test in section 8, clause 50.109. To simulate the problem described above, the incubator is operated at 32 °C until **STC** is reached (Figure 87). Once the temperature reaches **STC** (60 min+) at 30 °C the program prompts the user to set the **Control Temperature** to 36 °C degrees, and the **Incubator Temperature** is monitored (see Figure 88).

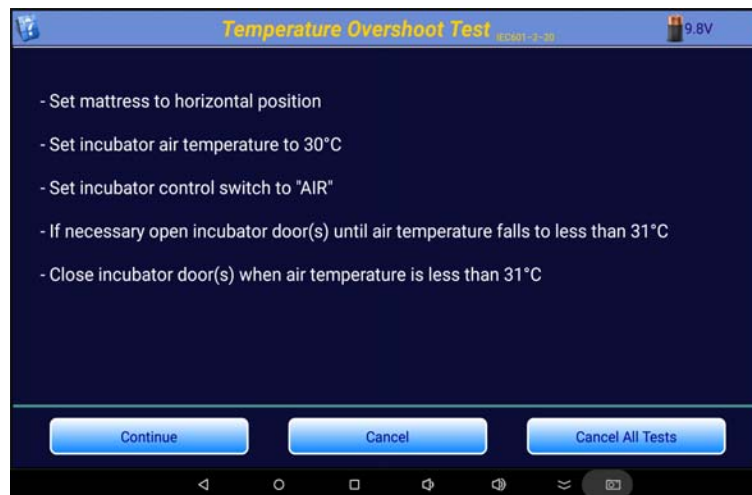


Figure 86: Temperature Overshoot Instructions

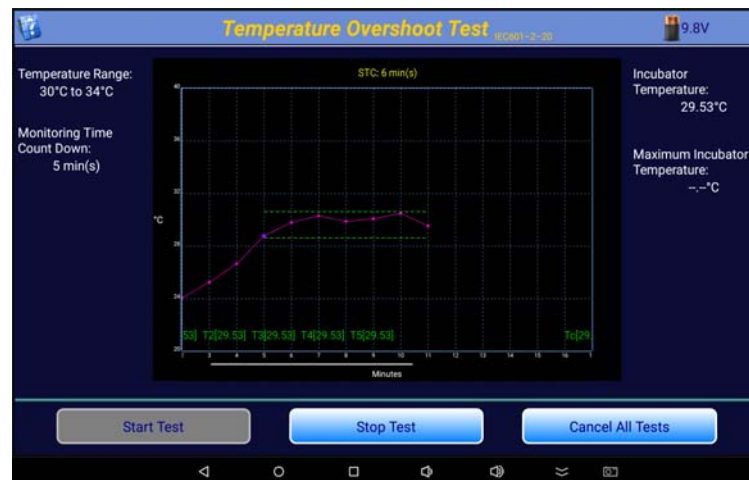


Figure 87: Initial Temperature Operation Prior to STC Complete

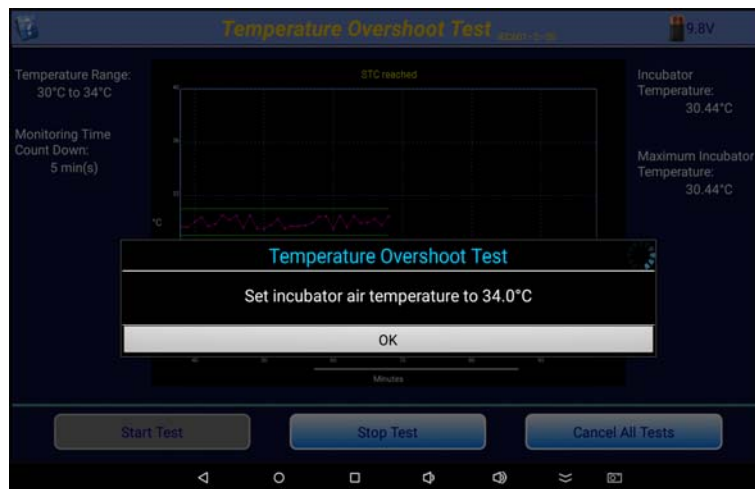


Figure 88: Initial Temperature STC Complete

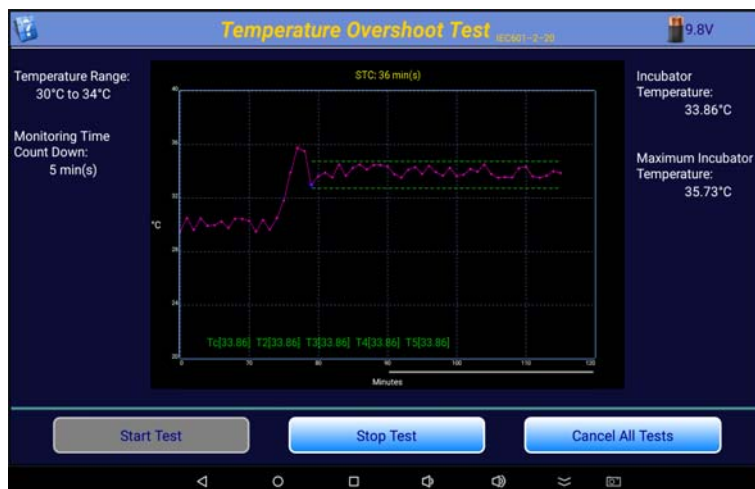


Figure 89: Upper Temperature STC in Progress

The Standard prescribes that the **Incubator Temperature** must not exceed 38 °C (36 °C + 2 °C). In addition, the incubator must return to a **Steady Temperature Condition** within 15 minutes of first reaching 36 °C. This last requirement is a little unclear in the Standard, since **STC** is already defined as a condition that exists for 60 minutes. vPad-TI interprets the requirement of the Standard to mean the incubator must return to a condition that meets the requirements of **STC**, except for the 60 minute minimum time frame. If the temperature variability conditions are met for at least 5 minutes, the display will indicate **STC XX min(s)**, and green, dotted lines will appear showing the upper and lower **STC** limits. If **STC** persists for over 60 minutes, the green lines will become solid and the display will indicate “**waiting for count down**”. The test will continue until the count down timer reaches zero, and then the test will terminate.

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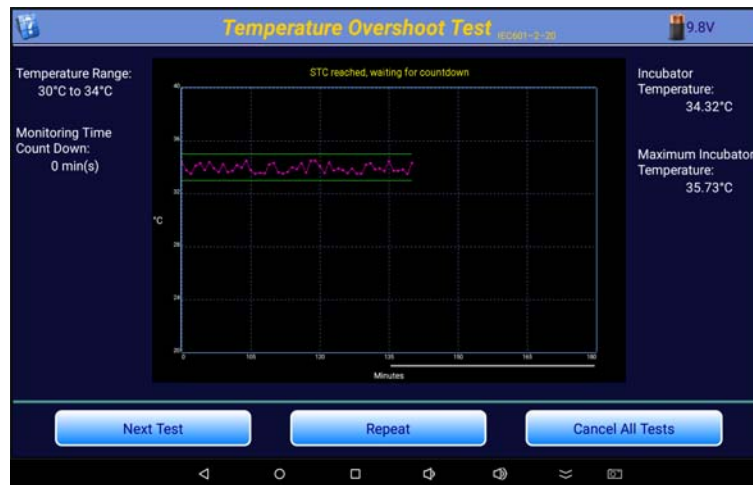


Figure 90: Higher Temperature STC Complete, Countdown in Progress

vPad-TI monitors the **Average Incubator Temperature (IT)** and checks to see that the **Incubator Temperature** does not differ from **IT** by more than 1.5°C. vPad-TI will display the length of time **STC** has been true using dashed green lines on the display. If this **STC** measurement is true within 15 minutes of first reaching 36 °C, the incubator passes the test requirements. The **Results** will be shown in the dialog box as shown in Figures 91.

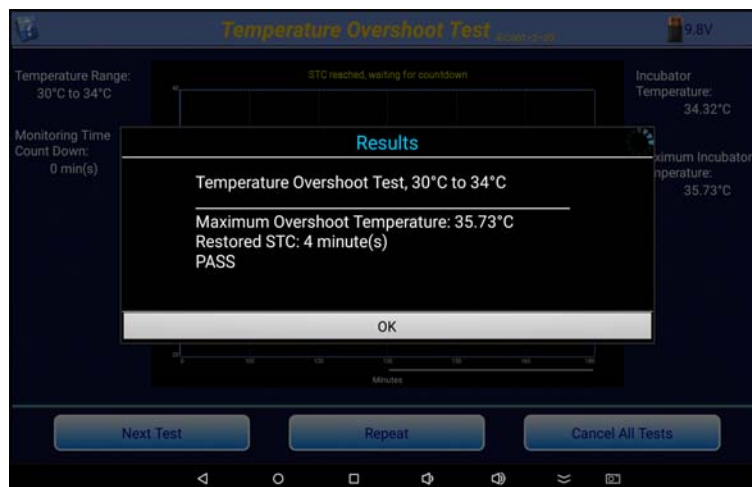


Figure 91: Temperature Overshoot Test Results

When the test is complete, the display will show the graphical result, from the start of the test. This graph will be saved as a JPG image if the setting **Save Picture to JPG After Test** is checked. The filename for the image will also be referenced in the test report.

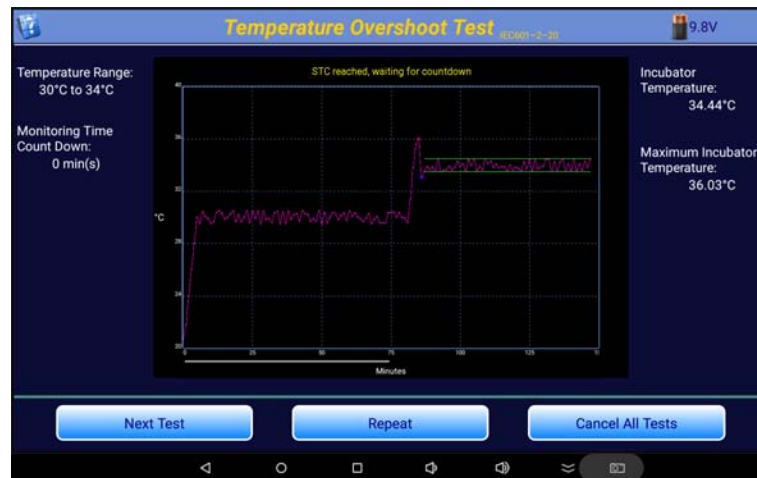


Figure 92: Temperature Overshoot Test Graph

5.13 Alarm Sound Level - Inside

The alarm sounds generated by an incubator have the potential to damage the infant's hearing if they are too loud. The Standard defines in clause 201.9.6.2.1.103, that an alarm sound measured at a height of 10 - 15 cm above the center of the mattress must not exceed 80 dBA. Following the instruction screen of Figure 96, the **Sound Sensor** is placed on the central Puck, held in place with the magnetic fasteners.

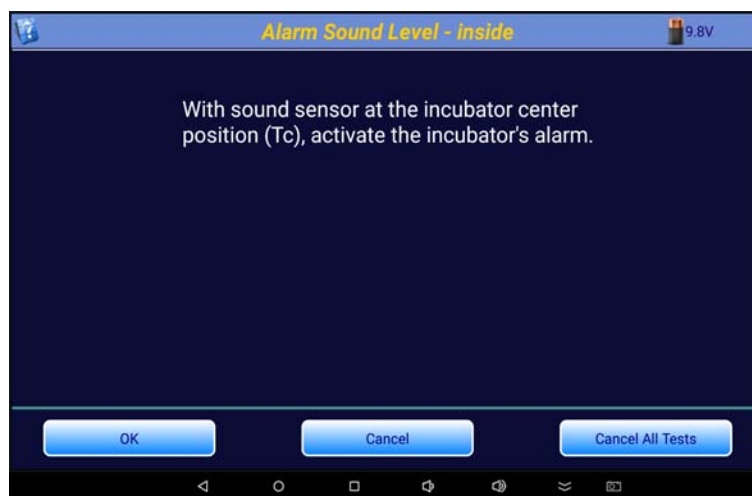


Figure 93: Alarm Sound Level Instructions

Once in place, an alarm is initiated by the user. The alarm can be generated in any manner the user sees fit. While the alarm is sounding, click on the **OK** button to take the measurement. While the alarm sound is processed, a progress indicator screen is displayed.



Figure 94

When the alarm sound measurement is complete, the result will be displayed as in Figure 95.

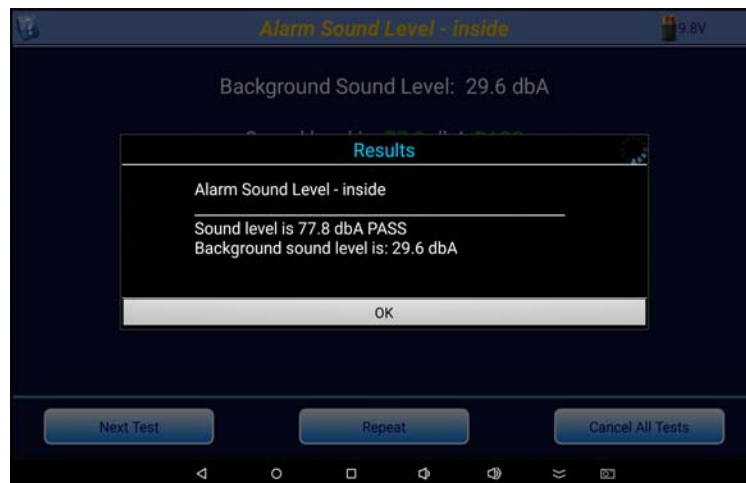


Figure 95: Inside Alarm Sound Level

5.14 Alarm Sound Level - Outside

In addition to the alarm sounds inside the incubator, alarms generated by the incubator must be loud enough to be heard by care givers outside of the incubator. Figure 96 shows the instruction screen for the outside alarm. The alarm sounds outside of the incubator are taken at a distance of 3 meters from the front of the incubator at a height of 1.5 meters above the floor, as defined in the Standard clause 201.9.6.2.1.102. The Sound Sensor is unplugged from the **Puck** in the incubator and removed from the Baby Compartment. The **Sound Sensor** can then be plugged into an extension cable to allow it to be moved around outside the incubator. The **Sensor** is then placed at the position defined by the Standard. An alarm is activated on the incubator and the **OK** button is clicked.

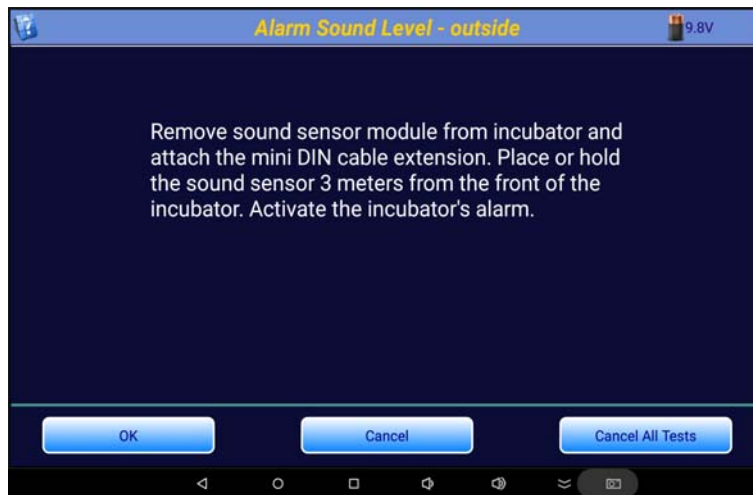


Figure 96: Alarm Sound Level Instructions - Outside

The Standard requires that the sound level of the alarm is at least 65 dBA at the prescribed position. When the alarm sound measurement is complete, the result will be displayed as in Figure 97.



Figure 97: Alarm Sound level - Outside

5.15 Saving Test Reports

When **Next Test** is pressed during an autosequence, the particular parameter test is considered to be complete. If this is the *last* or *only* test being performed, the content of the **Test Report** is shown on the screen. If it is decided that the report need not be saved, press **Cancel**. If it would be helpful to add a comment regarding any aspect of the test, press **Add Comment**. To save the report press **Save**.



Figure 98: Test Report

Pressing **Add Comment** will display a Text Input window, and touching anywhere in the window will bring up a keyboard to allow a comment to be created. This comment will form part of the final test report.



Figure 99: Test Report Comment

If the option to **Merge with Safety Test** has been enabled in the **System Settings**, a list of electrical safety test reports relevant to the **Equipment ID** being tested will be displayed. This list will be extracted from the **Records** folder of the vPad app specified in the **System Settings/Test Record Location**. The list will be trimmed to meet the **Date Range** specified. If there are no

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electrical safety test reports that match the criteria, a message will be displayed at the bottom of the screen, and the test report will be saved to the **vPad-TI test/Records** folder.

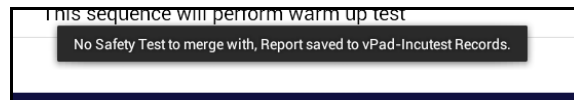


Figure 100: Test Report

If one or more appropriate electrical safety test reports are found, the filenames will be presented in a dropdown list to allow selection of the correct report. Select a safety test and press **OK** to proceed, or press **Cancel** to abort the merge and simply save the incubator test report.

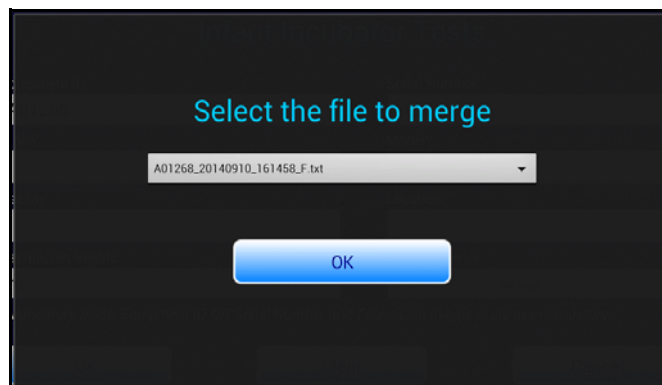


Figure 101: Test Report

The merged file will be saved to the original safety test report location or to the **vPad-TI/Records** folder, as per the choice made in the **System Settings**.

6 Test Reports

6.1 Overview

Test results are saved in two formats after the tests are completed, a summary report and a file containing all measured data points and comments collected during the test.

6.2 Recalling Records

From the Main Screen test records can be recalled for viewing, printing and transfer by clicking on the Review Records image. A list of the test results in memory will be displayed on the screen as shown in Figure 102.



The screenshot shows the 'vPad-TI' interface with a 'Test Records' screen. At the top, it says 'vPad-TI 1.00.1' and 'Test Records'. Below this is a table with three columns: 'Equipment ID', 'Test Sequence', and 'Date and Time'. The table contains ten rows of test data. At the bottom left, there are two radio buttons: 'Test Result' (selected) and 'Raw Data'. At the bottom right, there is a blue 'Exit' button. The screen is framed by a dark border with navigation icons at the bottom.

Equipment ID	Test Sequence	Date and Time
CN002	Overshoot	2017 Mar 23 15:50:18
cn001	Warm Up Time	2017 Mar 22 13:56:31
cn001	Air Flow Measurement	2017 Mar 22 13:41:38
cn001	Alarms	2017 Mar 17 18:53:54
cn001	Humidity	2017 Mar 17 18:08:19
cn001	Baby temperature control	2017 Mar 17 17:54:45
cn001	Air Temperature High	2017 Mar 17 17:43:20
cn001	ACTRE @ 36°C	2017 Mar 17 17:16:51
cn001	Cold Ambient	2017 Mar 17 16:35:21

Figure 102: Test Records Listing

The listing can be ordered by Equipment ID, Test Sequence or Date. Clicking on the title of the field and the list will be re-ordered in ascending or descending order as appropriate, using multiple touches. The types of report listed are indicated by checkmarks in the **Test Results** or **Raw Data** check boxes. Both types of files are created during a test and should normally be available for each test.

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From this screen it is possible to View the Test Results by touching on a filename. This will open vPad-RM (Record Manager) to display the contents of the selected file. Once in **Record Manager**, other files may also be viewed, transferred or printed (see the Record Manager manual). Printing will be processed according to the setting in **Record Manager**, and can be set using the **Copy To External Device** function from within **Record Manager**.

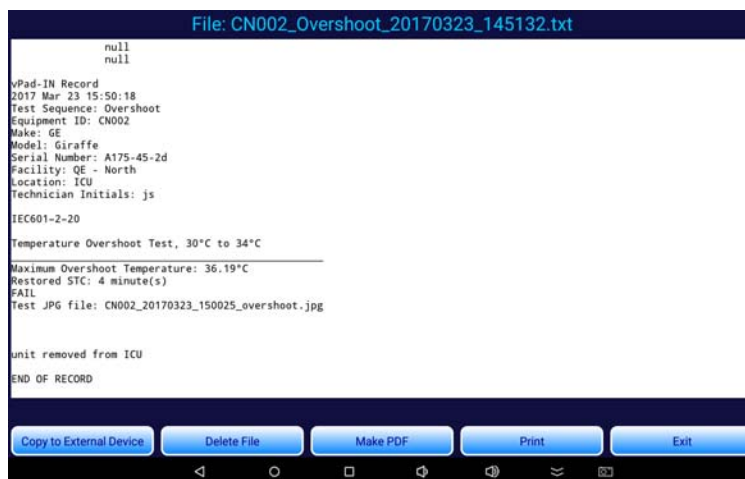


Figure 103: Test Results Summary

Raw Data may be viewed in the same way, after first checking the **Raw Data** checkbox. Select **Export Files** to move files to another device - see the next section. When complete, click on the **Exit** button to return to the Main Screen.

6.3 View Raw Data

The view **Raw Data** option will display the individual data points measured during the test as indicated in Figure 104. This test report provides measurement data for each of the parameters measured along with a time stamp, in seconds. The parameters T1 - T5 represent the temperatures at the end of the Temperature Probe, 10 cm above the mattress. Parameters T6-T10 represent the temperature of the large thermal mass related to the Probes T1 - T5 respectively. TA is the ambient temperature reading. RH (relative humidity), SL (sound level), AF (air flow) and BVL (battery voltage) are recorded as appropriate to the test. LSL and V1 - V4 are reserved for future use. The Comments column contains text entries inserted by the program as events occur during the test. The Comments may include indications of the data sample rate, the start or end of a test, relevant parameter values collected during the test, etc. This report may be printed out by clicking the **Print** button.

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Figure 104: Test Result Raw Data

6.4 Exporting data

Test result files on the tablet may be exported to a USB memory stick, Dropbox™ or to another device via Bluetooth file transfer using the **File Transfer Utility** option. To select this, click on Copy to External device button and this will open the utility as shown below in Figure 105. Refer to the vPad-RM manual for instructions on selecting and moving files. Press **Exit** to return to the file list in vPad-TI.

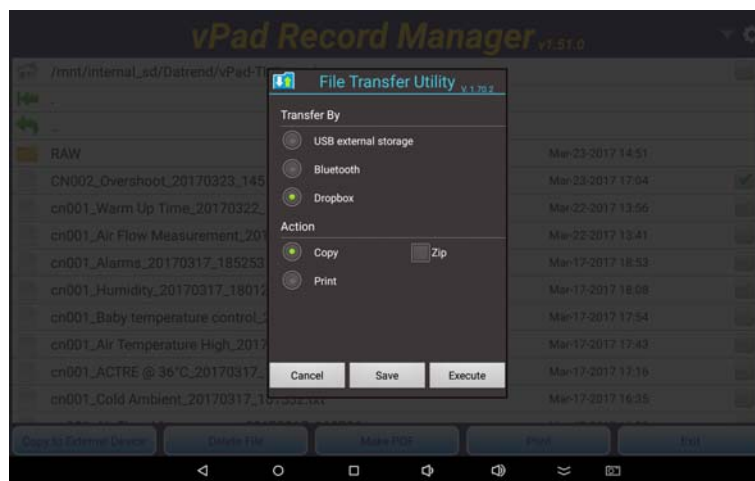


Figure 105: Exporting Data

The Raw Data is exported as a comma separated unicode text file. Unlike the ordinary CSV format, the unicode text file supports international language and can be imported into a spreadsheet. This text file may be used to recreate graphs that were seen during the test, or to create detailed reports which include graphs.

Chapter

7

7 Calibration and Maintenance

Calibration of vPad-TI by an authorized Datrend Service Facility is required on an **annual** basis to maintain the factory warranty. Refer to the Calibration Decal applied on the back of the unit to determine the calibration status of your vPad-TI System.

vPad-TI contains no user serviceable parts. ***Opening the case of any vPad-TI component or module, for any reason, will void the warranty.***

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

130 - 4020 Viking Way
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Tel: 800.667.6557 (North America Only) or
604.291.7747 • Fax 604.294.2355
e-mail: customerservice@datrend.com

vPad-TI should be cleaned with a soft, lint free, damp cloth. Use of cleaning agents may result in scratching, discoloration, or streaking.

NOTE: ***All components of the vPad-TI system, including the tablet must be returned with vPad-TI, when the system is returned for Calibration.***



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