

RWTest

Radiant Warmer Tester

Operating Manual

RWTest *Radiant Warmer 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 60601-2-21

Mid Point Average Temperature	Section 1, clause 2.10.103: the TEST DEVICE AVERAGE TEMPERATURE of the TEST DEVICE at the mid point fo the EQUIPMENT mattress
TEST DEVICE Average Temperature	Section 1, clause 2.10.102: the average temperature reading taken during a STEADY TEMPERATURE CONDITION at regular intervals at the center of a TEST DEVICE

TEST DEVICE	Section 1, clause 2.1.102: the A totally mat blackened disc used as a reproducible receiver of radiant energy during the testing of the INFANT RADIANT WARMER
Control Temperature	Section 1, clause 2.9.104: temperature set at the temperature control (of the RADIANT WARMER as the desired temperature)
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 being tested by RWTest (the RADIANT WARMER)
Graphical User Interface	A display system for the test instrument (IncuTest) which relies on graphics to a large extent to display information. In the case of IncuTest, this is a netbook computer with a Windows type operating system, or equivalent
Radiant Warmer	Section 1, clause 2.2.101: an electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant PATIENT by direct radiation of energy in the infrared region of the electromagnetic spectrum
Incubator Temperature	Section 1, clause 2.9.105: temperature of the air at a point 10 cm above the center of the mattress surface in the BABY COMPARTMENT
NSL Steady Temperature Condition	Noise Sound Level Section 1, clause 2.10.101: the condition reached when the temperature, measured at the center of the TEST DEVICE positioned on the midpoint of the EQUIPMENT mattress, does not vary by more than 1°C over a period of one hour
Skin Temperature Sensor	Section 1, clause 2.9.101: a sensing device including the link with the EQUIPMENT intended to measure the infant's SKIN TEMPERATURE

Chapter

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
- Altitude 2000m (max)

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

User Interface:

RWTest is supplied with a netbook computer which has the RWTest software application pre-installed and ready to run. In some instances, the hardware for RWTest may have been supplied with IncuTest. The software is controlled by right-clicking a function button on the graphical user interface (GUI) or, where applicable, by entering specific data via the keyboard. The netbook has a Microsoft Windows 7^{®†} operating system.

Display (netbook):

1024 x 600 color TFT LCD

[†]Windows and Windows 7 are registered trademarks of Microsoft Corp.

1.2 Data Collection Specifications

Temperature:

• Measurement Range:	0 °C - 50 °C
• Accuracy:	T1: ± 0.05 °C
• Resolution:	0.01 °C
• Convection:	5 'puck' sensors (T6 - T10) - radiant warmer
• Air Conduction:	5 sensors (alternate 'post' T1 - T5) - incubator
• Optional Skin Sensor 'oven' with thermal pad contact:	28 °C to 40 °C in 2 °C increments \pm 0.01 °C resolution, \pm 0.05 °C Accuracy

Airflow:

• Measurement Range:	0.1 to 1 m/s
• Accuracy:	± 0.1 m/s at 50% RH ± 15%

Sound Level:

• Measurement Range:	30 dbA to 90 dbA, Type III
• Accuracy:	\pm 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 / 1700 mA; P/N: 3000-611

And one of the Blade Sets for P/N 3000-611:

North America: P/N: 3000-401 Europe / Schuko: P/N: 3000-402 United Kingdom: P/N: 3000-403 Australia: P/N: 3000-404

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

USB 2.0 Cable (A/B): P/N 3140-440

1.4 Optional Accessories

For a complete list of available accessories, visit <u>www.datrend.com</u> or contact Datrend Customer Service (see Chapter 6 for contact details)

Chapter

2 General Information

2.1 Overview

RWTest is a portable datalogging system for temperature, air flow, and sound level, specifically configured to test infant radiant warmers, and optionally incubators and transport incubators, 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 switchmode AC adapter. The sensors and the data collection system are placed on the mattress of the radiant warmer, and external to the device under test (DUT), a user interface based on a netbook type computer communicates wirelessly to the sensor system and provides the user with the ability to control the test operation and display the results without disturbing the test environment. The size and configuration is defined by the end-user's need to easily carry the instrument from one room, department, or institutional area to another, combined with the physical position the sensors must be placed within the DUT. As such, the tester is not intended to operate hand-held, but occupies a small footprint on a lab bench, table, cart or possibly on top of the DUT itself.

RWTest incorporates all the functionality necessary to meet the requirements of the IEC standards, related to temperature, airflow and sound level tests. The RWTest incorporates a graphical user interface which interfaces wirelessly to 5 temperature sensors, 1 airflow sensor, and 1 sound level meter. The RWTest 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 60601-2-21¹ is a standard which specifies safety and performance requirements for an infant radiant warmer. Some of the parameters that lend themselves to testing are temperature, sound level, and air flow. These parameters are monitored at specific locations within the radiant warmer and are expected to conform to the values defined by the Standard. RWTest provides the mechanical framework to hold the sensors in the appropriate locations, and

¹Throughout this manual, IEC 60601-2-21 is referred to as the "Standard"

provides the ability to adjust the framework to fit warmers of various sizes.

RWTest 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, Incutest provides airflow, and sound level 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, or sound are performed either before or after the temperature tests so that the sensors can be moved about in the radiant warmer without disrupting a temperature test.

2.3 Controls and Interface Connections

Referring to **Figure 1** through **Figure 7**, the following components, controls and interfaces of the RWTest Radiant Warmer Test system are:

Note: the hardware components for RWTest are virtually identical to IncuTest. The differences are in the setup, and which temperatures to measure. If the user has one of the systems (hardware), only the software is needed to do the other EQUIPMENT (incubator).

1.	Sensor Electronics and Wireless Hub (the HUB)	Provides the connection point for all sensors used internally to the incubator or warmer under test.	
2.	Temperature Connectors	Temperature Probes (T1 - T5) are connected on the top of the large, black thermal mass (Puck) to place the thermistor in the correct position above the mattress. T6 - T10, temperature thermistors are embedded in the thermal mass (Puck) for use in radiant warmers.	
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 (T1 - T5)	Bypasses the thermistor in the Puck and places the thermistor at the correct position above the mattress, per the Standard. For use with IncuTest	
5.	Airflow Probe	Measures the flow of air, and can be moved as required. Held in place on the Puck magnetically.	

6. Sound Level Probe		Measures sound level. Can be moved within the device under test (DUT) and can also be connected to the Computer USB Interface for external sound level measurements. Held in place on the Puck magnetically.	
7.	Humidity Probe	Measures Humidity. Can be moved within the device under test (DUT). Held in place on the Puck magnetically. Not required for radiant warmers	
8.	Hub Connections - Left Side	a. T4 Temperature Inputb. T5 Temperature Inputc. Airflow Sensor Inputd. Power Inpute. Power LEDf. Power Switch	
9.	Hub Connections - Right Side	a. T3 Temperature Input b. T2 Temperature Input c. Humidity Sensor Input d. Sound Level Sensor Input	
10.	Computer USB Interface (USBI) Figure 6 and Figure 7	Contains the matching wireless connection to the HUB , and connects to the computer via USB to transfer data to the computer software. Also provides an RS-232 connection to the optional Skin Sensor Oven.	
11.	USBI Connections	a. USB Device Connection to Computer b. RS-232 Connection to Skin Sensor Oven c. Sound Level Sensor Input	
12.	Positioning Frame	Allows T2/7 - T5/10 Pucks to be positioned with respect to T1/6 at the center of the mattress	
13.	Positioning Frame Components	a. longitudinal positioning bar b. horizontal positioning bar c. T bracket	



Figure 1: Wireless HUB - Left Side View





Figure 3: Sound Level Sensor



Figure 4: Air Flow Sensor



Figure 5: Humidity Sensor



Figure 6: USBI Interface to PC and Sensor Oven



Figure 7: USBI Interface - Sound Sensor Input

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**.

2.4 Setup

To test a radiant warmer 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 8.



Figure 8: 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 9**. 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.

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 9: 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 10**.

The RWTest Radiant Warmer test system is now configured mechanically, according to the Standard, to take temperature and other measurements in the center of the radiant warmer 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 radiant 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 10: Sensor Frame Fully Assembled

In the Test Reports generated by the test software, the temperatures are referred to as T1 for the center of the incubator, and T2, T3, T4 and T5 for each of the quadrants as shown in **Figure 11**. If the Probes are removed, to test a radiant warmer for example, the above temperatures are then T6 to T10 respectively.



Figure 11: Temperature Sensor Positions



The cables from the individual **Pucks** will connect to the **HUB** as indicated in **Figure 12**, **Figure 1** and **Figure 2**.

Figure 12: Temperature Sensor Connection Locations

The sensors for Sound and Airflow 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.

At the computer, the USB Interface is connected to any available USB port. The **USBI** provides the data connection to the PC and the wireless connection to the **HUB** in the Test System. When the software application program begins a test, it may take up to a minute to initiate communications between the **USBI** and the **HUB**.

The **USBI** also provides connections to the **Sound Sensor** so that it can be used to test alarm sounds of the radiant warmer; and, connections to the **Skin Sensor Oven** 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 **USBI** to initiate communications.

2.6 RWTest Software

The RWTest software is preloaded on the netbook computer. When turned on, the computer presents the Windows desktop, where selecting the RWTest icon will run the RWTest Application. When you exit the Application, the netbook will return to the desktop. It is recommended no other applications be loaded onto the netbook so as to avoid conflicts with other programs, or accidentally infecting the computer with a virus or other malware. Problems which arise from loading other programs on the netbook are not covered by warranty.

NOTE: The RWTest software is setup to test Infant Radiant Warmers. The large black PUCKs are the required thermal mass for Radiant Warmer testing and have embedded temperature sensors for that purpose. The IncuTest software for Infant Incubators uses the same hardware, with the addition of the temperature probes, and the humidity sensor. IncuTest software may be already loaded on your netbook, or may be purchased as an accessory. Contact your dealer for details.

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 radiant warmer's operation. The Default test protocol includes all of the tests required by Section 8 (Accuracy of Data) and some parts of Section 101(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 warmers and incubators 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 Radiant Warmer Primer

Radiant Warmers 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. Radiant Warmers generally work in one of two modes: 1) manual temperature control, or 2) body (skin) temperature control.

In manual temperature control, the radiant energy from the infrared heating element in the warmer is used to control the infrared energy radiated to the infant on the mattress. The infant's body absorbs the energy, resulting in an increase in body temperature. In this mode the infant's body temperature must be carefully monitored and the energy output of the warmer adjusted constantly to ensure the infant's temperature remains at an acceptable value.

It is generally more effective to control the temperature of the air by monitoring the baby skin temperature directly and automatically adjusting the radiant energy to maintain the infant's skin temperature at the desired temperature.

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

Chapter

3 Configuring a Test

3.1 Overview

The functional performance of infant radiant warmers is defined by the Standard IEC 60601-2-21: Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Infant Radiant Warmers. This standard defines the mechanical and electrical requirements that manufacturers are expected to meet when designing an infant radiant warmer. When testing a warmer after the design has been certified to meet this standard, the most relevant tests are related to the physical parameters of temperature, airflow and sound. The functional specifications for these parameters are contained within section 8 of the Standard - 'Accuracy of Operating Data and Protection Against Hazardous Outputs', and section 101 - 'Additional Requirements'. RWTest has been designed to test these particular requirements.

As temperature tests tend to take a long time, RWTest 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.

3.2 Setting Autosequences

The system and test setups are accessed from the Main Screen of the RWTest program as shown in **Figure 13**. Pressing the **Settings** button will access the display screen of **Figure 14**, which will allow modification of how the system will react 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 radiant warmers or, alternately, the facility doing the testing. Using the mouse, click in either Line 1 or Line 2 and enter the Titles desired. Once a report is created, the Report Title in the report is fixed and will not change if the System Setting is modified.



Figure 13: Start Screen

s	ystem Settings		
Report Title Line 1 Radiant Warmer Test		Language	
Line 2 Datrend Systems Inc.		English	中文
Temperature Control (after STC reached) © 30 minutes 0 2 hours 0 1 hour 0 Continuous 0 1.5 hours	Units © Celsius (°C) © Fahrenheit (°F)	Español 日語	Deutsch Français
	Create/Edit Autosequences	Italiano	
	Done		

Figure 14: System Setup

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, RWTest is designed to recognize a condition called the Steady Temperature Condition (**STC**), which is defined in the Standard, in Section One, clause 2.10.101 as:

Steady Temperature Condition: a condition which is reached when the temperature, measured at the centere of the TEST DEVICE (the 'puck') positioned on the mid point of the EQUIPMENT (radiant warmer) mattress, does not vary by more than 1 °C over a period of 1 hour.

During a particular temperature test, once **STC** is reached the user can optionally set RWTest to continue recording the temperature for an additional 30, 60, 90 or 120 minutes. If a timer is set, RWTest 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 pressing the **Done** button.

Units

The units that the system will use for temperature reporting can be selected as either °C or °F.

Language

RWTest is designed to work in multiple languages. **Figure 14** indicates that, currently, English, German and Simplified Chinese have been implemented. Additional languages are grayed out on the screen. These languages are currently not available, but will be made available as translations are completed. Updating the program language capability will simply require the addition of certain files in the main program folder for RWTest. Contact your dealer for further details.

Create/Edit Autosequences

This button will access the display screen of **Figure 15**, allowing Autosequences to be added, modified or deleted, as described in the next section of this manual.

3.3 Create/Edit Autosequences

Figure 15, 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 filename into the field under 'New Autosequence' and pressing the **Save** button. During an Autosequence, the parameters will be tested in the order in which they appear on the screen. To enable testing of a parameter, right-click in the appropriate check box. Enabled tests will display a check mark in the box.

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

	Skin Sensor Accuracy	Default
Ambient Airflow and Temperature Check	I At 28℃	test
🗹 Manual Temperature Control at 36 🌲 °C	☑ At 30°C	Alarm-o
1 I Dahu Tamparatura Cantral at 26 1 00	☑ At 32°C	ManTemp
Baby Temperature Control at 36	☑ At 34°C	BabyTemp
2. 🗹 Alarm Sound Level - inside	✓ At 36°C	skin34
	✓ At 38°C	
2. 🗹 Alarm Sound Level - outside	☑ At 40°C	
	1. If no skin sensor accuracy tests are enabled, enabling any baby temperature control test automatically enables the "At 36°C" skin sensor accuracy test.	
	2. If any sound level test is enabled, a background sound	Load Delete
	level measurement is	New AutoSequence:
	beginning of the radiant	Default Save
	warmer testing sequence.	
	All North	

Figure 15: Autosequence Parameters

Ambient Air Flow and Temperature Check

The flow of air across the radiant warmer mattress is measured in terms of **Air Velocity** (**AV**) [section 2, clause 10.2.1], and is measured at the midpoint of the mattress. The **AV** at the specified point shall not exceed 0.3 m/s. This test is performed before the (heating) temperature testing is started. During the ambient airflow test the ambient temperature is also tested to be in the range of 18 to 30 °C [per the same clause above].

Manual Temperature Control

The manual temperature test is preset to 36 °C, as recommended by the Standard however, RWTest will allow testing at other temperatures. **STC** has been previously defined. The Mid Point Average Temperature (**MPAT**) is defined in the Standard, section one, clause 2.10.103 as:

The TEST DEVICE AVERAGE TEMPERATURE of the TEST DEVICE at the mid point fo the EQUIPMENT mattress

Where the Test Device Average Temperature (TDAT) is defined in the Standard, section one, clause 2.10.102 as:

The average temperature reading taken during a STEADY TEMPERATURE CONDITION at regular intervals at the center of a TEST DEVICE

With a Control Temperature setting of 36 °C, in Manual Control Mode, the incubator is allowed to reach **STC** and the **MPAT** is calculated. For the temperature measured at the center of the mattress, the difference between the **MPT** and the **TDAT** for each of the other 4 temperature measurement positions T7 - T10 must not exceed 2 °C.

Skin Temperature Control

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

Testing **Servo Controlled Mode or Baby Temperature Control** is described in the Standard in section 8, clause [50.103]. 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 attached to the black metal 'puck' at the center of the mattress. The radiant warmer is allowed to reach **STC**. The difference between the Skin Temperature Sensor and the Control Temperature must not exceed 0.5 °C at any time after **STC** is TRUE.

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 (on the mattress where the infant would be positioned), the requirements are defined in section 101, clause 102.1. The sound pressure level (A weighted) is measured at a position of 5-10 cm above the center of the mattress, with the radiant warmer operating. The sound level at the mattress during an alarm must not exceed 80 dBA.

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 section 101, clause 102.1. The sound pressure level (A weighted) is measured at a position 3 meters perpendicular to the front of the radiant warmer, 1.5 meters above the floor. The sound level during an alarm must be at least 65dBA.

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 section 8, clause 50.101. Testing the accuracy of the **Skin Temperature Sensor** (**STS**) requires the use of a separate 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

All/None

The **All** and **None** buttons on the Autosequence display allow selection of every parameter test (**All**) or no parameter tests (**None**). 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.

3.4 Saving and Editing Autosequences

Once an Autosequence has been defined by enabling the relevant parameters to be tested, it is possible to save the Autosequence for later use. The right side of ? provides the file options available for the Autosequences.

The large panel on the top right of the screen, titled **Saved Autosequences**, provides a list of the Autosequences which have previously been saved. When initially installed, the program will display at least one Autosequence, **Default**, which has all of the parameter tests enabled. Other AutoSequences may be present as examples of other tests. All AutoSequences should be reviewed and adjusted, as necessary, to meet the particular requirements of the user.

Load

Any Autosequence in the list can be loaded for editing by highlighting the Autosequence name and pressing the **Load** button. This will enable each of the parameter tests defined in the Autosequence. This is helpful to review the contents of an Autosequence, and to load an existing Autosequence as a starting point for a new Autosequence. When loaded, the Autosequence name will be displayed in the New Autosequence field. If the Autosequence is modified and is to be saved under the same name, simply press the **Save** button. If this is a new Autosequence, enter a new name in the New Autosequence field and press **Save**.

Delete

An Autosequence can be deleted by selecting it from the list and pressing the **Delete** button.

When all the changes have been made to the Autosequences, press the **OK** button, then the **Done** button to return to the previous screen.



4 Running a Test

4.1 Overview

Once the required Autosequences have been designed and saved, RWTest is ready to run a test on a radiant warmer. This chapter describes the software used to control the test operation and assumes that the hardware has been assembled and is in place on the **mattress** of the radiant warmer, as described in Chapter 2.

4.2 Running a Test

From the Main Screen shown in **Figure 16** below, select the Run Test option, which will activate the Radiant Warmer Test screen of **Figure 17**.



Figure 16: Main Screen

Infant Radiant Warmer Tests								
Please enter test info	ormation							
Equipment ID:	• *	* Mandatory fields: Equipment ID OR						
Make:	•	Serial Numer. Technician Initials is						
Model:	•	always mandatory.						
Serial Number:	• *							
Facility:	•							
Location:	•	1 sec Data						
Technician Initials:	▼ *							
		Demo Data						
Please select an A	COM1 -							
De	fault	•						
	OK	1						

Figure 17: Starting a Test

In order to run a test, it is necessary to provide some basic information so the test results can be identified in the future. Equipment is normally identified by either an asset number (**Equipment ID**) *or* a **Serial Number**. One or the other of these identification marks *must* be entered to run a test. RWTest maintains a small database of equipment information, so once a radiant warmer's information is entered, the information can be recalled by selecting from a list in the **Equipment ID** field. Although it is not mandatory, additional information can be entered for a radiant warmer that may be helpful in the final report. Additional information that can be entered is **Make**, **Model**, **Facility** and **Location**.

A second mandatory field is the **Technician Initials**. This allows tracking of the technician who performed the test. As new initials are entered, they become part of a list from which initials can be selected.

Once the mandatory fields are entered, it is possible to select the Autosequence to be followed. See **Figure 18** for an example of the data input, and the selection of the Autosequence.

When the test has been completely defined, press the **OK** button to activate the test.

Infant Radiant Warmer Tests									
Please enter test inf	ormation								
Equipment ID:	DSI0012	• *	* Mandatory fields: Equipment ID OR						
Make:	GE Medical	•	Serial Numer. Technician Initials is						
Model:	Giraffe	•	always mandatory.						
Serial Number:	AB98A3341	• *							
Facility:	Children's	•							
Location:	NICU	•	1 sec Data						
Technician Initials:	rwe 💌 *								
		Demo Data							
Please select an A		COM1 -							
De									
	ОК	Cancel							
	Figure 18: Minimum Dat	a							

4.3 Ambient Air Flow and Temperature

If an **Ambient Airflow and Temperature** test has been selected, the instruction screen of **Figure 19** will be shown.

Ambient Check 🗺
Place the sound sensor at the mid point of radiant warmer. Place the air flow sensor at the mid point of radiant warmer. Plug in a temperature probe into the center disc.
For this test the radiant warmer should be OFF.
Cancel Probe Test

Figure 19: Ambient Conditions Instructions

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

When all sensors are in place, click on the **Continue** button.

When the measurements have been completed the results will be reported as indicated in **Figure 20** below.



Figure 20: Background Sound Level Measurement

If, during this test, a measurement is found to be outside of the accepted values, the measurement will be shown in a red box and it will be possible to make corrections and retest the ambient values. All ambient values must be acceptable to continue.

Acceptable Ambient Values:	Background Sound Level:	< 50 dbA
	Air Velocity:	< 0.3 m/s
	Temperature:	18 - 30 °C

4.4 Manual Temperature Control Test

A radiant warmer must be able to maintain a constant/consistent radiant infrared energy output so as to able to maintain an infant's body temperature (under ideal conditions). The Standard requires the radiant warmer to be able to sustain a Steady Temperature Condition (**STC**), per section 8, clause 50.102. While the Standard allows testing at any temperature, it generally recommends 36 °C for the temperature test.

When an **Manual Temperature Control** test is initiated by an Autosequence, the test instructions are presented as shown in **Figure 21**. The radiant warmer is then set to Manual

Control mode and 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.

Manual Temperature Control <i>s</i>	DAT
- This test is for radiant warmer with only a manual mode. - Turn on the heater.	
ОК	
Skip Test Cancel All Tests	Probe Test

Figure 21: Manual Temperature Control Instructions

When the test starts, the program will create a graph of the temperature at the center of the mattress from the sensor embedded in the **Test Device** (the 'puck'). As shown in ?, 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** 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.

In addition, the **Mid Point Temperature** will be displayed on a minute to minute basis. The **Mid Point Average Temperature** will not be displayed until **STC** is reached.

During the test, **Figure 22**, all of the data points collected, including those for the temperatures at the other 4 locations, are saved to a Raw Data file. Any event which occurs during the test is also saved as a comment. Typical comments would be: Minute Mode, Manual Temperature Control at 36 °C Started, Waiting for STC, etc. The Raw Data file can be exported and used to recreate the test graphics.



Figure 22: Manual Temperature Control Data Collection



Figure 23: Air Temperature Control After STC Reached



Figure 24: Manual Temperature Control Result Summary

At the end of the test, the **Results** summary will be displayed, **Figure 24**. In addition to the **Mid Point Average Temperature (ATm)** and the length of time that **STC** was true, RWTest will also report other values required by the Standard. The terms **AT7** - **AT10** refer to the **Device 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 **ATm** value, from the temperatures measured at locations T7 - T10. These averages must not differ from the **ATm** by more than 2 °C.

4.5 Baby Temperature Control

In the **Baby Temperature Control** Test the **Skin Temperature Sensor** of the radiant warmer is attached to the **Test Device** at the middle point of the mattress. In this test, the tests performed in the **Manual 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 0.5 °C. The instruction screen shown in **Figure 25**, the parameters on the display for the **Baby Temperature Control** follow the same format as the **Manual Temperature Control**.

	Baby Temperature Control <i>s</i>	DAT A
	- Set radiant warmer to baby controlled mode. - Set the control temperature to 36°C.	
	- Place the center disc on the mid point of the mattress.	
	- Attach the skin temperature sensor to the center disc.	
	ОК	
l	Skip Test Cancel All Tests	Probe Test

Figure 25: Baby Temperature Control Instructions

When running the test and STC is reached, the Skin Sensor Reading button will be enabled, as shown in **Figure 26**.



Figure 26: Baby Temperature Control at STC

Clicking on this button will allow the Skin Sensor temperature, as indicated o the radiant warmer, to be input into the test result. See **Figure 27**, for an example of how this is done.



Figure 27: Entering Skin Sensor Values

As with the manual test, the Baby Temperature ends with a summary of the results of the test, which will be integrated into the test report, **Figure 28**.



Figure 28: Baby Temperature Test Results

Prior to completing the test, the Skin Sensor can be tested for accuracy using the Probe Test. This is covered in the next section.

4.6 Probe Test

If a **Baby Temperature Control** test or a **Skin Sensor Accuracy** Test have been selected in an Autosequence, a **Probe Test** button will appear in the lower right of the screen (as shown previously in **Figure 26**). A **Probe Test** can be initiated at any time when this button is visible, and the test will run in the background. When first activated, the instruction screen for the **Skin Accuracy Test** will be displayed.



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, for instance in the Manual Temperature Control test where the sensor is not needed, and be available when the **Baby Temperature Control** test is ready to begin.

To test the **Skin Sensor**, it must be placed in a tightly controlled temperature environment. RWTest provides an optional **Sensor Oven** to perform this test. The Sensor is removed from the radiant warmer mattress/ **Test Device** and placed in the **Oven**. The Sensor remains plugged into the radiant warmer Control Panel and the radiant warmer must be placed into the **Skin Temperature/ Servo 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 30** with the sensor tip toward the back of the thermal pad in the Oven, to provide good thermal contact.



Figure 30: Sensor Placed in Oven

The Oven is connected to the USBI at the computer via an RS-232 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.

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 RWTest software when connected to the **USBI**. 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** button by clicking on the ∇ icon in the upper right corner of the dialog box.

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 31**. While this screen is displayed, the system is waiting for the Oven temperature to operate consistently within \pm 0.1 °C. If there is a problem at this temperature, or if it is decided to skip the test at this one particular temperature, click on the **Skip** button. To completely abort the **Skin Sensor Accuracy** test click on the **Cancel** button.



Figure 31: 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 32**. On this screen the temperature of the Skin Sensor, as shown by the Control Panel of the incubator, can be entered. If a **Manual Temperature Control** test is in progress when the **Probe Test** requests the Sensor temperature, the warmer can be switched between Manual control and Skin control *momentarily* to read the Skin Temperature, without affecting the **Air Temperature Control** test.



Figure 32: 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.



Figure 33: 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 screen of **Figure 34** will be displayed. Follow the instructions on the screen. Remove the Sensor from the Oven and wait for the Sensor to cool down to <36 °C. The Sensor can then be placed in the radiant warmer to perform the **Baby Temperature Control** test. For further details, see the section on **Baby Temperature Control**.

After the instructions have been followed, click on the **Done** button to complete the **Probe Test**.



Figure 34: Skin Sensor Test Complete

4.7 Alarm Sound Level - Inside

The alarm sounds generated by a radiant warmer have the potential to damage the infant's hearing if they are too loud. The Standard defines in section 101, clause 102.1, that an alarm sound measured at a height of 5 - 10 cm above the center of the mattress must not exceed 80 dBA. Following the instruction screen of **Figure 35**, the **Sound Sensor** is placed on the central Puck, held in place with the magnetic fasteners.

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.

Alarm Sound Level - inside <i></i>	DAT
With sound sensor at the radiant warmer's middle point (Tm), activate the radiant warmer's alarm.	
ОК	
Skip Test Cancel All Tests	Probe Test -1.00°C

Figure 35: Alarm Sound Level Instructions



Figure 36: Inside Alarm Sound Level

When the alarm sound measurement is complete, the result will be displayed as in Figure 36.

4.8 Alarm Sound Level - Outside

In addition to the alarm sounds at the mattress of the radiant warmer, alarms generated by the warmer must be loud enough to be heard by care givers in the area of the warmer. Figure 37 shows the instruction screen for the outside alarm. The alarm sounds outside of the warmer are taken at a distance of 3 meters from the front of the warmer at a height of 1.5 meters above the floor, as defined in the Standard section 101, clause 102.1. The Sound Sensor is unplugged from the Puck in the warmer and removed from the mattress area. The **Sound Sensor** can then be plugged into the **USBI** (Wireless) interface at the computer (GUI). The **Sensor** is then placed at the position defined by the Standard. An alarm is activated on the warmer and the **OK** button is clicked to take a reading.



Figure 37: Alarm Sound Level Instructions - Outside

The Standard requires that the sound level of the alarm is at least 65 dBA at the prescribed position, and at least 10 dBA above the ambient level. When the alarm sound measurement is complete, the result will be displayed as in **Figure 38**.



Figure 38: Alarm Sound Level Instructions - Outside



5 Test Reports

5.1 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.

5.2 Recalling Records

From the Main Screen of **Figure 16**, test records can be recalled for viewing, printing and transfer by clicking on the Review Records button. A list of the test results in memory will be displayed on the screen as shown in **Figure 39**.

Test Records										
Equipment ID	Test Sequence	Test Sequence ▼ Date and Time								
DSI0012	Default	2014-	Jan-24 07:40:57							
DSI0012	Default	2014-	Jan-23 15:13:30							
×[j>]							
View Test Results	View Raw Data	Export Selected Data	Done							

Figure 39: Test Records Listing

The listing will be ordered by Equipment ID and Date. Clicking on the Equipment ID or Date title field will re-order the files in ascending or descending order as appropriate. The types of report available are indicated by checkmarks in the Test Results and Raw Data columns. Both types of files are created during a test and should normally be present. A missing check mark is an indication that the file has been moved or possibly has been deleted.

The options from this screen are to **View Test Results**, **View Raw Data** or **Export Selected Data**. Click on the appropriate button to select one of these options. When complete, click on the **Done** button to return to the Main Screen.

5.3 View Test Results

The **View Test Results** option will display the summary of the test as indicated in **Figure 40**. This test report provides a complete list of the summary results of the tests performed during the Autosequence. The header of the report identifies the date of the test, the Autosequence performed, any data available identifying the equipment, and the technician who performed the testing.



Figure 40: Test Results Summary

Each of the test blocks identified and performed during the Autosequence are reported in the body of the Test Report. This report may be printed to an attached printer by clicking on the **Print Report** button. Printers are installed and setup in the normal manner under Windows[®].

5.4 View Raw Data

The **View Raw Data** option will display the individual data points measured during the test as indicated in **Figure 41**. 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 Incubator Temperature Probe, 10 cm above the mattress. Parameters T6-T10 represent the temperature of the radiant warmer large thermal mass related to the Probes T1 - T5 respectively. RH (relative humidity), SL (sound level) and AF (air flow) are recorded as appropriate to the test. TA is the ambient temperature, LSL is the external sound level, BVL is the battery voltage and V1 - V4 are reserved for future use. The Comments column contains text entries inserted by the program as events occur during the test, relevant parameter values collected during the test, etc. This report may be printed out by clicking the **Print Report** button.

2	T3	T4	T5	T6	T7	Т8	Т9	T10	TA	RH	SL	AF	LSL	BVL	V1	V2	V3	V4	Comments		Drintor Sotup
				23.70			-				-			7.75							Printer Setup
				23.70										7.75					Manual Temperature Cor	1	
				23.73										7.75							Print Report
				23.70										7.75							
				23.70										7.75					Waiting for STC		
				27.13										7.75							
	-		-	29.28							-			7.75			-				
	-		-	31.86							-		30.10	7.75							
				33.10									30.20	7.75							
	-		-	34.74							-		30.40	7.75							
	-			35.98							-		30.50	7.75			-				
				36.44									30.60	7.75							
				36.23									30.70	7.75							
				36.23									30.90	7.75							
				36.26						1			31.00	7.75							
				36.23									31.10	7.75							
				36.23									31.20	7.75							

Figure 41: Test Result Raw Data

5.5 Exporting data

Test result files on the computer may be exported to a USB memory stick using the **Export Selected Data** option. Clicking this button will bring up the dialog box shown in Figure 42. This dialog box will relate to the file(s) selected from the Test Results file list. More than one file may be selected using the standard Shift-click or Ctrl-click keystroke combinations.

ExportWin	×
Test Results	Raw Data
• Unicode Text File	
© PDF	Onicode Text File
Export To USB Stick	Export To USB Stick
	Done

Figure 42 Export Test Record

Test Result Summary files can be exported as either a text file or a PDF file. The Raw Data may only be 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.

The system will store the files on the first USB stick encountered in the filing system. If no USB stick is available, the system will generate an error dialog box.



6 Calibration and Maintenance

Calibration of RWTest/IncuTest by an authorized Datrend Service Facility is required on an *annual* basis to maintain the 5 year factory warranty. Refer to the Calibration Decal applied on the back of the unit to determine calibration status of your RWTest/IncuTest System.

RWTest/IncuTest contains no user serviceable parts. *Opening the case of any RWTest/IncuTest 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 the location of the nearest Service Facility.

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RWTest/IncuTest 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 system , including the netbook computer must be returned, when the system is returned for Calibration.



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