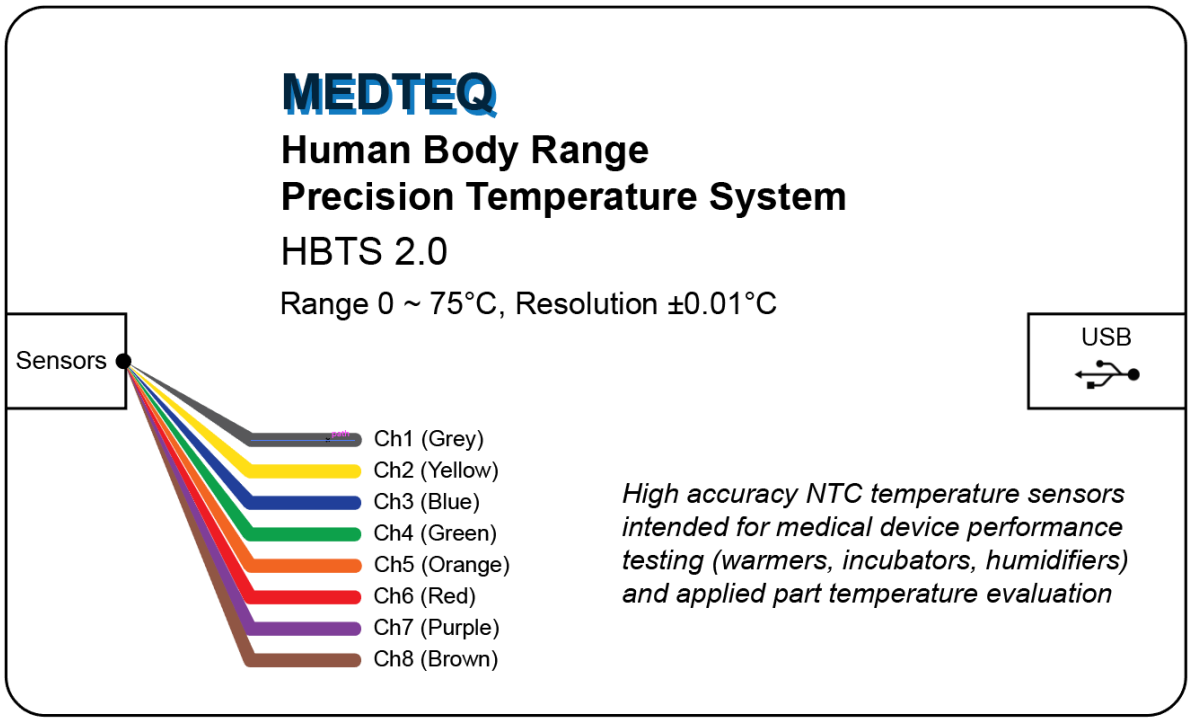
# MEDTEQ
# Human Body Thermometry System
# (Model HBTS 2.0)

## Operation Manual

**Revision 2020-11-25**
**For use with Software version 2.0.1.8**



## Contents

# 1 Introduction

Many medical devices such as patient warmers and infant incubators intentionally control temperature around body temperature. Particular standards such as IEC 60601-2-19 for infant incubators include performance related temperature measurements in normal condition and fault condition, as well as temperature limits of parts with incidental contact (such as walls, mattresses). Other medical devices also have unintentional but unavoidable heating of applied parts again in both normal and fault condition. For these tests, the margin between test results and allowable limits can often be less than 1°C, which implies that equipment accurate to around ±0.2°C is used for tests.

The HBTS 2.0 uses individual 24 bit ADCs for each channel, allowing a range of 0°C ~ +75°C with a resolution of 0.001°C, a specified accuracy of ±0.2°C in the critical range (10-50°C) and a typical accuracy of ±0.05°C in the same range. The use of NTC thermistors allows a sensitivity (µV/°C) around 50-100 times higher than thermocouples, making the system more resistant to noise.

The small sized thin film thermistors can be attached to the object or part being measured or provided with slugs such as used in testing humidifiers to ISO 80601-2-74. The associated PC software records a plot of temperature and a table showing current temperature, maximum, minimum and average for each of the 8 channels. Both the graph and table are easily copied into word processing or other documents.

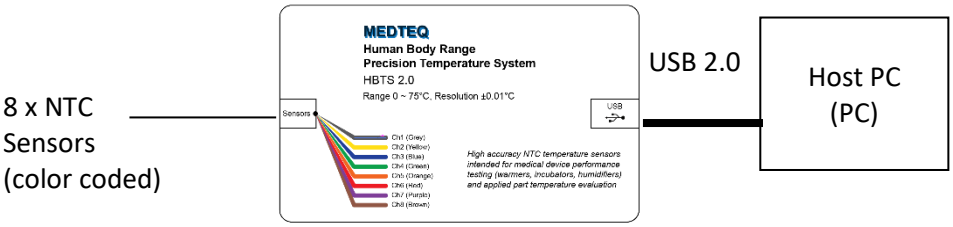
**Important notes**:

- As with all temperature measurements, consideration should be given to errors from the method of attachment and the potential for heating from other energy sources such as radiant heat or ultrasound energy. These issues need to be considered on a case by case basis. The potential for heat sinking, which exists with thermocouples, is not as significant for these sensors being an insulated type.
- These sensors are delicate. Damaged sensor may display an apparently valid temperature. It is recommended to check all sensors indicate the same temperature by bunching all sensors together and placing the sensors approximately 50mm immersed in a medium sized beaker or container of water, which is gently stirred by hand. All sensors should read the same within 0.05°C.
- The sensor part can be immersed in water for long duration. The joint and cable has been provided with a degree of water proofing intended to protect against accidental wetting. The joint is not intended for continuous immersion.
- Although the system provides 0.001 resolution, the production process is targets repeatability of around ± 0.03°C and an overall accuracy claim of ±0.2°C. This accuracy is not sufficient for the “reference meter” for some tests such as ISO 80601-2-56 for clinical thermometers. A precision Pt100 system is recommended for these tests.
- As with all sensitive equipment, the measurements may be affected by electrical noise. Do not connect the sensors to mains parts and keep clear of high current sources. Monitor the graph for unusual indications.

# 2 System description

## 2.1 Overview

The system consists of the host PC (PS), a USB Module and the sensors:




USB module measures sensor data and streams to the PC for further processing and display.

## 2.2 Measurement system details

The measurement system is constructed using accurate NTC (negative temperature co-efficient) thermistors, a network of resistors and analogue electronics, sampling, filtering and finally polynomial curve fitting. Each channel has an individual 24 bit ADC which provides 2 samples/second.

The resistor network has been carefully designed to maximize resolution, provide the first stage of linearization, minimize noise and sensor self heating (<0.05°C in open air). A second stage of curve fitting is designed to match nominal curves to within 0.001°C over the full range (0~ +75°C).

Using a circulating water bath, the system is then checked at two temperature points (typically 10°C and 50°C), against a reference Pt100 probe. The channels are typically accurate to ±0.3°C as assembled.

These two points are then used to calculate a simple span and offset adjustment (y = mx+b) for each individual channel. The adjustment data is stored in the firmware of each unit.

After completing calibration, checks are made at several points between 0°C and 75°C. After this adjustment stage, typically all 8 sensors remain within ±0.03°C of the reference Pt100 probes in the key range of 10-50°C, and ±0.2°C at the extremes of 0°C and 75°C.

The system itself has been designed error budget of ±0.05°C from all sources of error, with the intention of providing high level of confidence in the overall claim of ±0.2°C in the key range.

For the calculating uncertainty in actual measurement situations users should take into consideration the calibration reference, attachment methods, heating from other sources (e.g. radiant heat for infant incubators), and the type of measurement (absolute or relative).

## 2.3 Specifications

| Parameter | Design Specification | Notes |
|---|---|---|
| Range | 0 - 75°C | Considered suitable for both absolute measurements (typically 35-48°C), temperature rise testing (typically 20-35°C) and ambient monitoring (10-40°C) |
| Resolution | 0.001°C | 24 bit ADC |
| Overall Accuracy, core zone, 10-50°C | ±0.2°C (absolute)<br>±0.05°C (relative)<br>±0.1°C (inter-channel) | Assumed to be calibrated in a water bath against tenth DIN Pt100 as described. |
| Overall Accuracy extended zone (0-75°C, excluding the core zone) | ±0.3°C (absolute)<br>±0.1°C (relative)<br>±0.2°C (inter-channel) | Assumed to be calibrated in a water bath against tenth DIN Pt100 as described. |
| Sample interval | 0.5s (2 samples/second) | |
| Response time, air | <10s | To 90% of the step change |
| Response time, water | 2-3s | To 90% of the step change |
| Power supply | USB (+5Vdc, 0.2A) | USB high powered mode |
| Environment | +15°C ~ +35°C<br>35-80% RH<br>Mains noise 50 or 60Hz | By design only, not tested<br><br>24 bit ADC has high 50/60Hz rejection |
| Warm up time | Not significant (<15s) | |

# 3 Set up

## 3.1 Software installation

### 3.1.1 System requirements

The MEDTEQ HBTS uses a normal PC to interface and control the USB module. The PC should meet the following requirements:

- Windows PC (XP or later)
- Microsoft .NET 2.0 or higher
- Administrator access (if necessary for installation of software/driver)
- Free USB port
- Minimum 512MB RAM

### 3.1.2 PC Software installation

Software is available from the MEDTEQ website: http://www.medteq.net/download/.

Three options are provided which should be used in order of preference. Follow the instructions on the website. Note: for the latest version of Windows, the user may need to ignore warnings regarding trusted software.

### 3.1.3 USB driver installation

The system uses a USB mode called “CDC” which emulates a serial COM port for which Microsoft Windows® already has the driver for this installed. However, it is necessary to link the USB Module to this driver, which follows a process similar to installing a driver.

The linking file “mchpcdc.inf” is available at http://www.medteq.net/download/. Copy this file to a known folder. When the USB is first connected, select manual installation, and point to folder containing the above linking file. Continue to follow instruction. There may be a warning that the driver is not recognized by Windows® which can be ignored. This linking file is provided by Microchip® for use with PIC microprocessors having in built USB function.

The same linking file is used for all MEDTEQ equipment, and only needs to be installed one time. Depending on policies of IT departments, installation may require administrator access.

## 3.2 Set up

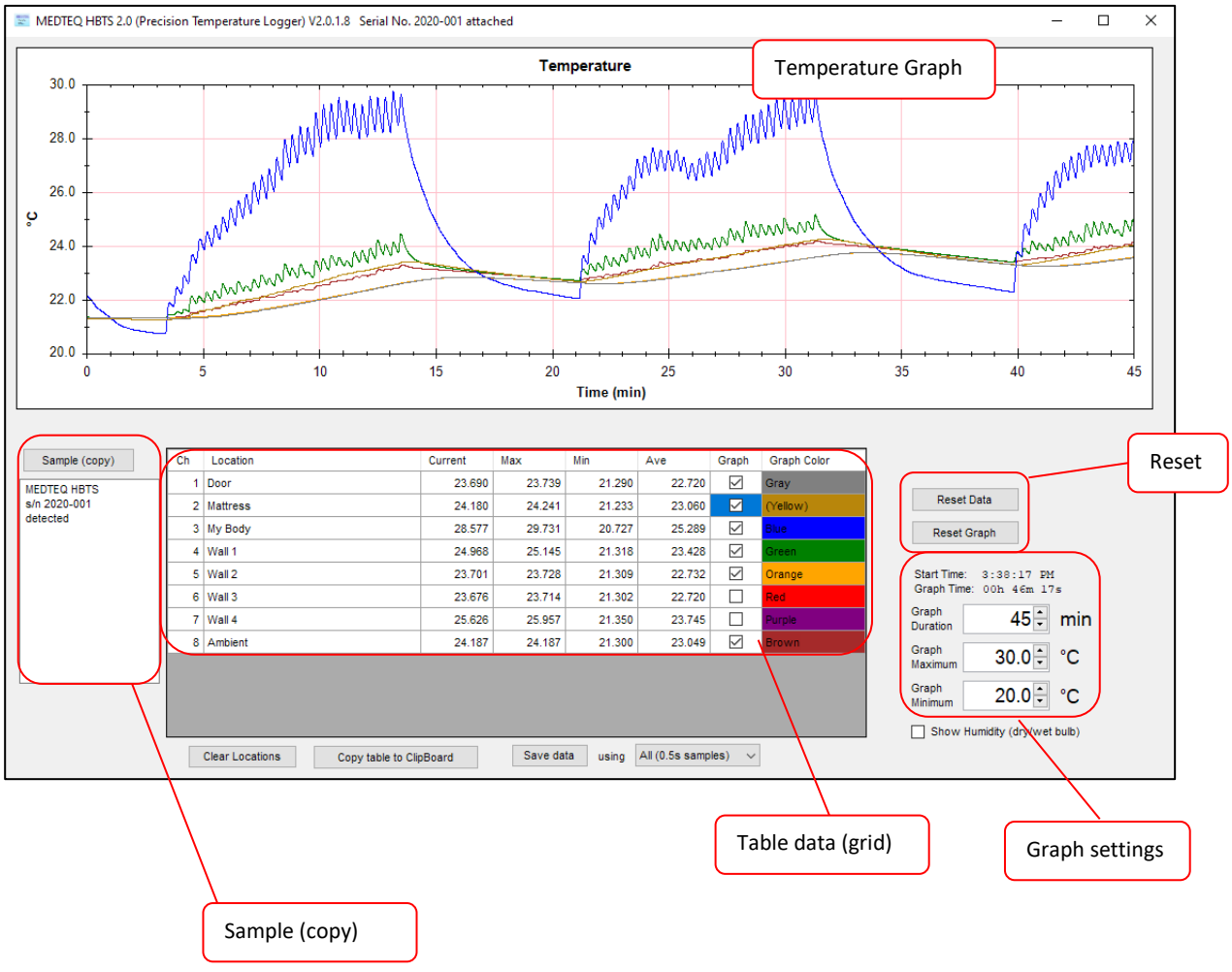
Connect the USB module to the PC, and wait for the normal USB recognition process.

After a short delay, the system will show the temperatures from the 8 channels.

## 3.3 Pre use check

These sensors are delicate. Damaged sensor may display an apparently valid temperature. It is recommended to check all sensors indicate the same temperature by bunching all sensors together and placing the sensors approximately 50mm immersed in a medium sized beaker or container of water, which is gently stirred by hand. All sensors should read the same within 0.05°C.

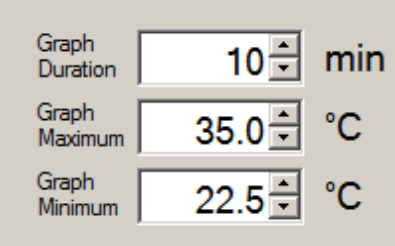
# 4 Main screen



# 5 Functions

## 5.1 Main graph

The main graph keeps a graphical record of the temperatures recorded during the test. This graph can be copied into word processing and similar documents. Use right mouse click when the mouse is over the graph to find a range of additional functionality




To adjust the range (min, max °C and time) use the graph settings as shown left.

The time is limited to 600 minutes (10hrs).

To reset the graph, use “Reset Graph” button. This does not affect the Table data. Users can select which channels are displayed individually using checkboxes in the column marked “Graph” of the Table data. The data is recorded for all channels regardless of the display setting.

## 5.2 Table data

The table data shows a grid with the current value, min, max and average for each channel, a checkbox for determining if the channel is displayed on the graph, and the color of the graph which matches the color of the physical sensor (Yellow color is made darker to ensure it can be easily seen). The min/max and average values are intended for performance testing such as for infant incubators.

Users can edit the “Location” column to provide a description of the channel. The locations are stored with the software, so they will re-appear each time the software is started.

Pressing the “Reset Data” button will reset all the recorded values for max, min and average.

## 5.3 Sample (copy)

The sample and hold box allows the user to take a snapshot sample of all channels at a particular time. The text box shows the system timestamp and data from all 8 channels. The data is also copied to the PC clipboard for transfer to word processing or spreadsheets.

This box is also used to provide notification to the user in case the USB module cannot be found or is disconnected during use, or has other errors.

## 5.4 Other functions

| Button/control | Function |
|---|---|
| Clear Locations | Clears the locations in the above table |
| Copy table to clipboard | Copies the content of the *table* (not the graph) to the PC clipboard which can then be pasted into spreadsheet or word processing applications.<br><br>Note: the column titles are not copied. These are:<br>Channel/Location/Current Temperature/Max/Min/Ave/Graph/Color |
| Save Data | Copies the full data from the graph in to the PC clipboard for all 8 channels at the time resolution selected (default is all data at 0.5s/sample). The data is tab separated and can be can be pasted into spreadsheet or word processing applications. An example is shown below. |
| Show Humidity | This opens a text box that displays temperature, relatively humidity and absolute humidity based on using one channel as dry bulb and another as a wet bulb. The wet bulb can be implemented by wet tissue paper or thin absorbent cloth over the sensor. The algorithm was developed for testing with humidifiers in the range 30~45°C. For critical applications, the humidity values are recommended to be double checked against reference material or webs calculators which are widely available. |

Example output of "Copy Table to clipboard" function (pasted to MS word):

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | Door | 21.459 | 21.567 | 21.448 | 21.518 | False | Gray |
| 2 | Mattress | 20.814 | 21.239 | 20.745 | 20.972 | False | (Yellow) |
| 3 | My Body | 23.884 | 33.620 | 23.809 | 25.939 | True | Blue |
| 4 | Wall 1 | 21.527 | 21.613 | 21.526 | 21.571 | False | Green |
| 5 | Wall 2 | 20.901 | 21.313 | 20.768 | 21.022 | False | Orange |
| 6 | Wall 3 | 20.850 | 21.312 | 20.761 | 20.998 | False | Red |
| 7 | Wall 4 | 21.547 | 21.630 | 21.546 | 21.588 | False | Purple |
| 8 | Ambient | 20.906 | 21.232 | 20.766 | 20.986 | True | Brown |

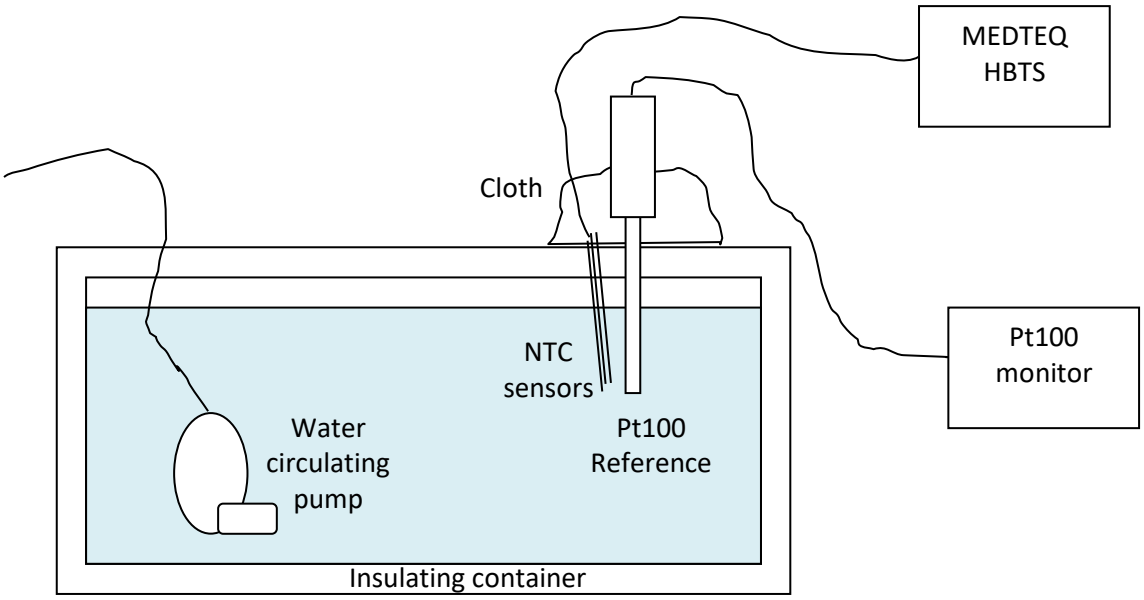
Example output of "Save data" pasted directly to MS Word (15s interval):

| Time (min) | Time (s) | Ch1 Door | Ch2 Mattress | Ch3 | Ch4 My Body | Ch5 | Ch6 Wall 1 | Ch7 Wall 2 | Ch8 Wall 3 | Wall 4 | Ambient |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0.000 | 0.00 | 21.55 | 21.02 | 28.32 | 21.61 | 21.10 | 21.07 | 21.63 | 21.01 | | |
| 0.250 | 15.00 | 21.56 | 20.97 | 26.91 | 21.61 | 21.06 | 21.06 | 21.62 | 21.11 | | |
| 0.500 | 30.00 | 21.57 | 21.04 | 25.96 | 21.61 | 21.13 | 21.12 | 21.62 | 21.15 | | |
| 0.750 | 45.00 | 21.56 | 21.11 | 25.21 | 21.61 | 21.22 | 21.17 | 21.63 | 21.21 | | |
| 1.000 | 60.00 | 21.56 | 21.23 | 30.54 | 21.61 | 21.30 | 21.26 | 21.63 | 21.18 | | |
| 1.250 | 75.00 | 21.55 | 21.17 | 33.30 | 21.60 | 21.24 | 21.22 | 21.62 | 21.14 | | |
| 1.500 | 90.00 | 21.54 | 21.21 | 32.03 | 21.60 | 21.24 | 21.14 | 21.61 | 21.14 | | |
| 1.750 | 105.00 | 21.54 | 21.13 | 30.24 | 21.58 | 21.13 | 21.12 | 21.59 | 21.07 | | |
| 2.000 | 120.00 | 21.56 | 21.08 | 28.78 | 21.58 | 21.11 | 21.10 | 21.59 | 21.00 | | |

# 6 Calibration

For ISO 17025, equipment should be calibrated to provide traceability. This system can be calibrated against a Pt100 probe with an accuracy are required by user.

The recommended system is a moderate sized insulating container with a water circulating pump or manual stirrer, with the sensors placed close to the Pt100 reference probe, as shown in the diagram below:




The Pt100 probe and NTC thermistors should be immersed to a depth of at least 7-8cm, with the opening covered to minimize the ambient influence. Alternately they may be completely immersed for best accuracy.

Users should experiment to confirm their set up has both spatial and temporal variations meet the accuracy needs. The water bath used in MEDTEQ production are at least 7L, use a double container for thermal insulation, and are stabilized at 0.01°C/min and <0.02°C spatial variation around the Pt100 probe, using gentle stirring only. The volume of the water, insulation, stabilization and stirring methods can be adjusted to suit the need of the user, for example, a briskly stirred 2L container may be sufficient for pre-use spot checks or for lower accuracy applications.

Contact MEDTEQ if any sensors are damaged.

# 7 Trouble shooting

| Problem | Resolution |
|---|---|
| USB module not recognized (USB driver is installed correctly) | Recognition of USB devices needs to be done in order:<br>1) Close MEDTEQ software if open<br>2) Disconnect the USB module for ~2s<br>3) Reconnect the USB module<br>4) Wait for the recognition sound<br>5) Start MEDTEQ software |
| USB module stops responding | Try first disconnect the USB module and re-connecting. From Version 2.0.1.8 the software will attempt to re-start without closing the PC software. If this does not work, also close the PC software, reconnect the USB module and re-start the PC software.<br><br>In case the USB module is disconnected during use, the software will wait for re-connection. After re-connection the graph will resume using a straight line connection for the period of missing data. |
| Unstable readings on one channel, or error over 0.1°C in calibration | This indicates that the sensor may be damaged. Contact MEDTEQ for a replacement. |
| Unstable readings or patterns in all or several channels | This indicates the unit may be affected by electrical noise. Route the cables away from any source. Ensure that the sensors are insulated from any mains parts or high current, high frequency parts. |

# 8 Contact details

MEDTEQ can be contacted by the following means:

Email: equipment@medteq.info

Post: 545-56 Tsujikuru-cho, Ise-shi, Mie, Japan 516-0046

Phone: +81 9 9897 2340