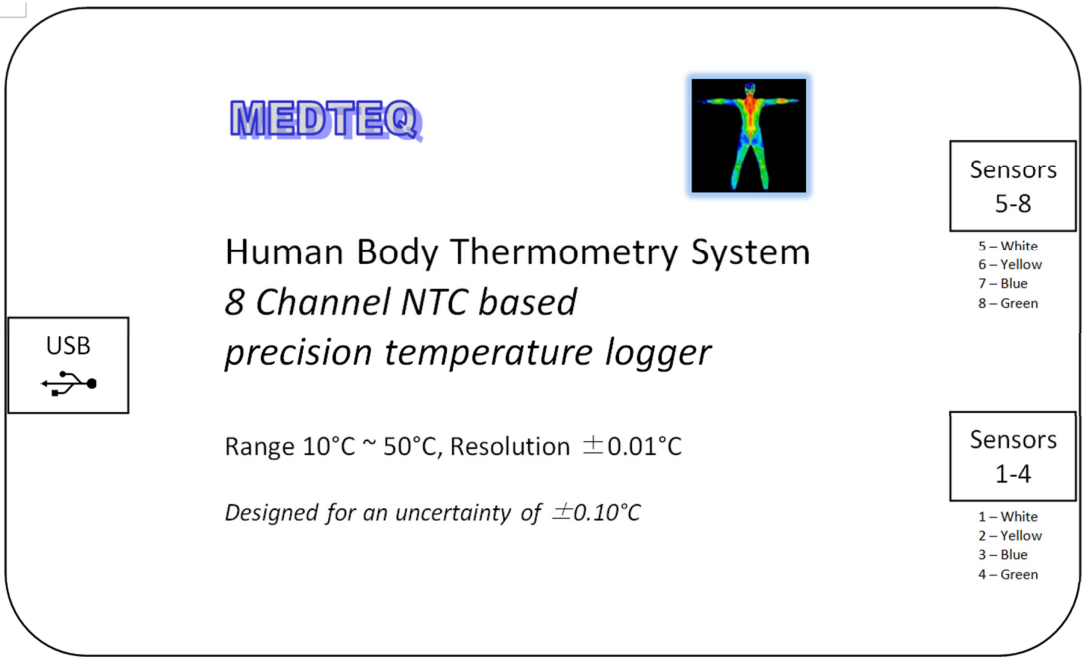
MEDTEQ
Medical Device
Test Equipment
Education
Qualification

MEDTEQ
Human Body Thermometry System
(Model HBTS 1.0)

Operation Manual

Revision 2014-12-24
For use with Software version 1.3.x.x



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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, typically include temperature measurements for performance in normal condition, and protection in fault condition, as well as temperature limits of parts with incidental contact (such as walls, mattresses). In these cases, absolute accuracy of temperature is important for the test.

In other medical devices, unintentional (but unavoidable) heating of applied parts may occur in normal and fault condition. In these cases, limits are often specified in temperature rise.

As the margin between actual test results and allowable limits can often be less than 1°C, it is preferred to use a measurement system which has an uncertainty in the order of 0.2°C. Thermocouples are not suitable for this purpose, being typically ±1°C for the measurement system alone. Pt100 probes are highly accurate but are bulky and have a slow response time.

The MEDTEQ system has been designed to use thin film NTC thermistors which have a small size and are capable of high accuracy in a limited range. The measurement system has a resolution of 0.01°C, repeatability of ±0.05°C, and an overall accuracy of ±0.2°C. A total of 8 channels are provided to allow for tests which require spacial measurements (e.g. incubators, checking mattress temperatures).

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.

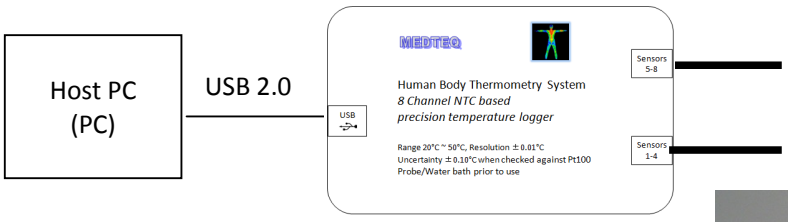
Important notes:

- 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.
- These sensors are not intended for as the “reference meter” used in accuracy tests of patient temperature sensors. A precision Pt100 system should be used as the reference meter for these tests.

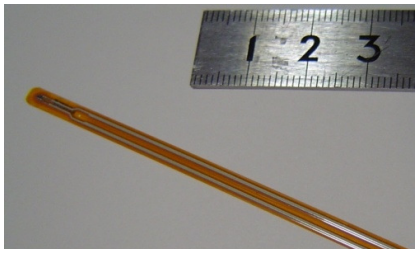
2 System description

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. 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 (10-50°C). The system is typically accurate to ±0.2°C even before calibration offsets are applied.

Using a circulating water bath, the system is then fine tuned by using two adjustment points at the measurement extremes (10°C and 50°C), against the average of two Pt100 “tenth DIN” probes (designed for ±0.03°C). The two probes are confirmed also to be within 0.02°C of each other. Calibration data is stored in the firmware of each unit.

After completing calibration, checks are made at several points between 10°C and 50°C. Typically all 8 sensors remain within ±0.02°C of the reference Pt100 probes.

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.

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	10 - 50°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	0.01°C	Averaging function provide 0.001°C resolution
Overall Accuracy	±0.2°C (absolute) ±0.05°C (relative) ±0.1°C (inter-channel)	Assumed to be calibrated in a water bath against tenth DIN Pt100 as described.
Response time, air	<20s	To 90% of the step change
Response time, water	<10s	To 90% of the step change. Includes software filtering
Power supply	USB (+5Vdc, 0.2A)	USB high powered mode
Environment	+15°C ~ +35°C 35-80% RH Mains noise 50 or 60Hz	By design only, not tested Selectable mains filter of 50 or 60Hz provided.
Warm up time	5 min	

2.4 Updates

As of November 2014, the following updates were made to the software (V1.3.0.6):

- A function is added which calculates absolute and relative humidity from a dry/wet bulb, using CH1 as a dry bulb and Ch2 as the wet bulb. A “wet bulb” can be created with tissue paper over the Ch2 sensor. Contact MEDTEQ for more details.
- Locations and graph option (which items to graph) are stored in memory.
- When the sample button is pressed, the data is automatically copied to the PC’s clipboard

As of December 2014, the following updates were made:

- Additional waterproofing around the joints
- Change to wiring with individual color for each channel; software updated to reflect colors (darker color used for yellow)

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.info/med/HBTSSoftware. Three options are provided which should be used in order of preference. Follow the instructions on the website.

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.info/medteqsoft/mchpcdc.inf. 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.

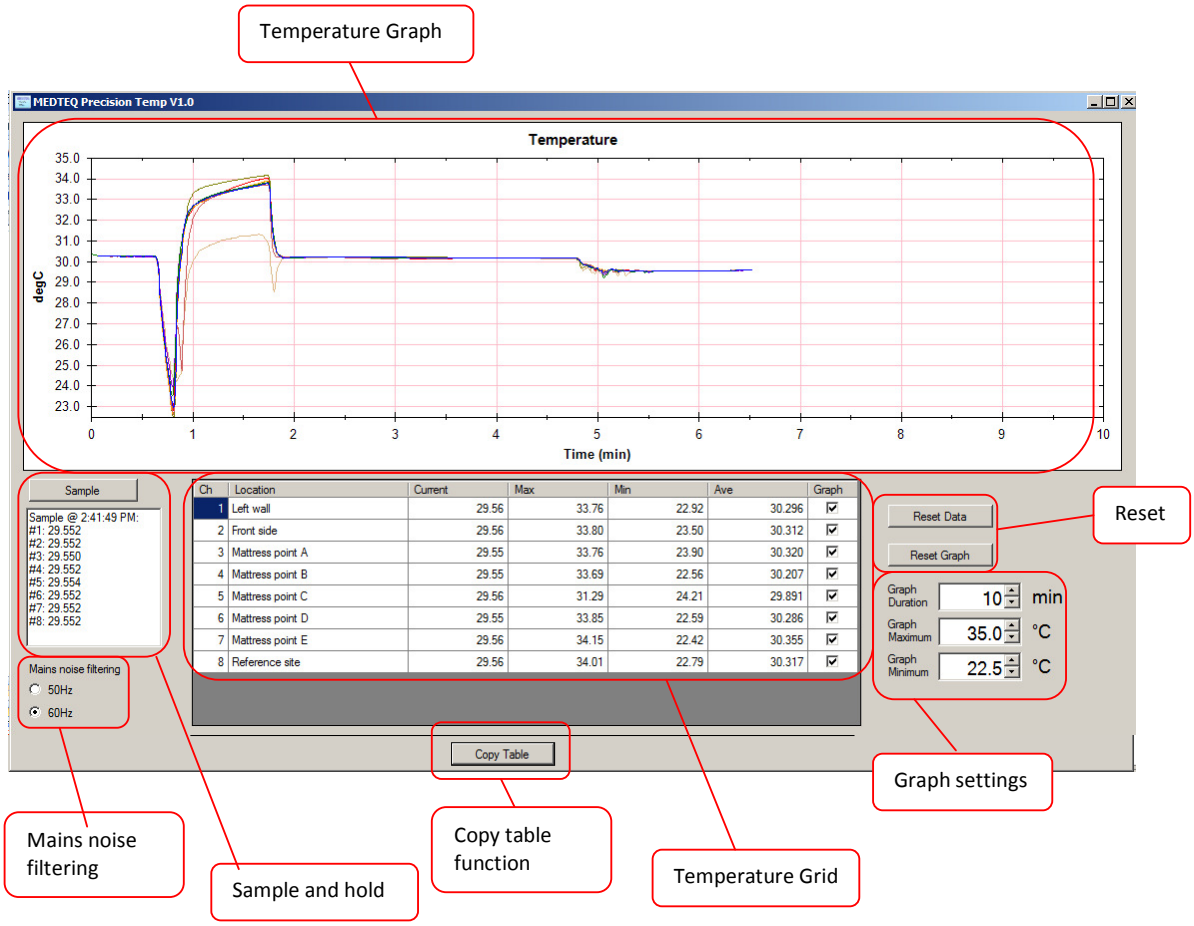
Start the PC software. Select 50Hz or 60Hz for mains filtering depending on the mains frequency in the environment of use.

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.

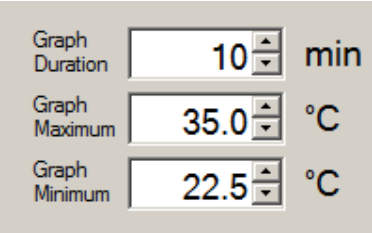
4 Main screen



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).



To adjust the range (min, max °C and time) use the graph settings as shown left. The maximum temperature is limited to 52°C, and the minimum is 8°C. The software ensures there is always at least 1°C between max-min settings.

The time is limited to 600 minutes (10hrs). Note that some older PCs may have problems to record 10hrs of data.

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.

5.2 Table data

The table data shows 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.

Users can edit the “Label” column to provide a description of the Channel.

Pressing the “Reset Data” button will reset all the recorded values for max, min and average. This process takes a few seconds to allow the filtering to provide stable values within 0.02°C.

Pressing the “Copy Table” will copy the contents of the Table to the clipboard, allowing it to be copied to other programs.

5.3 Sample and hold

The sample and hold box allows the user to take a 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.

5.4 Mains filter

The mains filter setting helps the system to reject mains noise through digital filtering. It adjusts the sample rate in the hardware unit so that whole cycles of 50 or 60Hz are sampled.

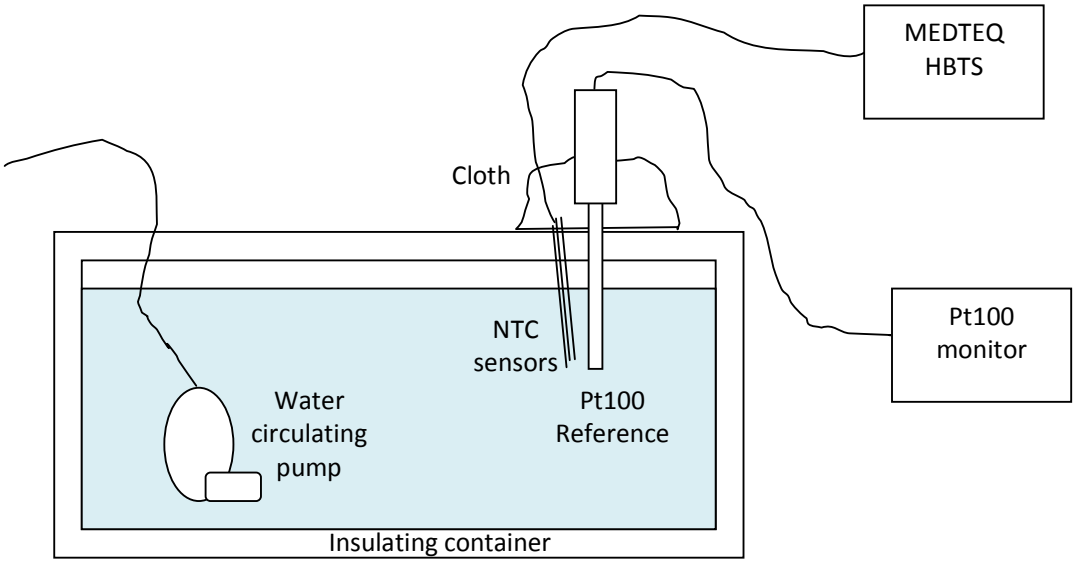
5.5 Humidity calculator (wet/dry bulb)

See Section 2.4 for information on this function.

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, 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 7-8cm[1], with cloth or other insulating material around the point of entry of the probe and thermistors. The water should be allowed to stabilize at the temperatures of interest. The rate of change should be <0.05°C per minute (0.5°C / 10 minutes) to ensure thermal lag in the Pt100 probe does not influence the test.

Experiments indicate that the most critical aspect is the use of a water circulating pump to ensure a uniform temperature around the NTC sensors and the reference probe.

As the NTC sensors are delicate, it is recommended that this test is performed before and after actual use. Contact MEDTEQ if any sensors are damaged.

[1] For highest accuracy, precision Pt100 RTDs are normally recommended to be immersed to 15cm, assuming the remainder of the probe is exposed to air which may be at a substantially different temperature. In order to keep the probe close to NTC sensors it is preferable to reduce this depth. Using a cover and adding cloth around the entry point ensures the part of the Pt100 probe not immersed remains at a temperature close to that of the water. As the temperature difference is not so high (e.g. water at 45°C, ambient at 23°C), the immersion depth is also not as critical.

7 Trouble shooting

Problem	Resolution
USB module not recognized (USB driver is installed correctly)	Recognition of USB devices needs to be done in order: 1) Close MEDTEQ software if open 2) Disconnect the USB module for ~2s 3) Reconnect the USB module 4) Wait for the recognition sound 5) Start MEDTEQ software
USB module stops responding	Disconnect the USB module, reconnect the USB module and re-start the USB module.
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.

8 Contact details

MEDTEQ can be contacted by the following means:

Email: equipment@medteq.info or peter.selvey@medteq.co.jp

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Phone: +81 50 5532 9695