DataTherm®II

**24h TEMPERATURE MONITOR
CONTINUOUS TEMPERATURE MONITOR**

USER INSTRUCTIONS

Model KD-2300   CE 0118

Contents

Introduction

The DataTherm®II is a lightweight, portable, continuous temperature monitor that provides three functions:

1. "Display" of current temperature in Fahrenheit or Celsius.
2. "Alert" with visual and/or audible alarms that are automatically activated when the patient's temperature rises above or falls below user adjustable levels.
3. "Store" up-to 140 temperature/time/date data records at regular intervals to allow for recall and assessment of temperature trends.

The DataTherm® II uses disposable probes, which significantly reduce the risk of cross contamination. The instrument may be connected to a PC (Personal Computer) for the purpose of archiving, display of data, graphic representation, or emailing of one or more temperature series that may have been taken from different patients or at different times.

Indications for Use

The DataTherm® II Continuous Temperature Monitor is used to measure human body temperature and store data at adjustable preset time intervals. The DataTherm® II can continuously monitor and store up to 140 temperature readings. The DataTherm® II features both high and low adjustable temperature alarm settings, manifested by a beeping sound and flashing light when the measured temperature exceeds the high

temperature setting or falls below the low temperature setting. The DataTherm® II allows the patient or doctor to view and email stored temperature information.

! NOTE !:

1. Only a qualified individual should use this device.
2. Do not use this monitor as a substitute for a physician's advice.

This device complies with Part 15 of the FCC Rules and is subject to the following conditions:

(1) This device does not emit harmful electromagnetic (RF) interference.
(2) This device resists electromagnetic (RF) interference, including interference that may cause undesirable operation.

Precautions

1. The DataTherm® II probes are intended to be disposable. The manufacturer does not recommend reuse. Should they be reused, do not boil, heat or auto clave the probe. Clean by wiping with a cloth dampened with mild detergent and water. Disinfect the probe with ethyl or isopropyl (rubbing) alcohol.
2. Do not drop the temperature monitor or expose it to heavy shock.
3. Do not store the unit under direct sunlight, at high temperature, high humidity or in dusty conditions. Performance may be degraded.
4. Do not use the monitor if it operates erratically or if the display window malfunctions.
5. Keep out of the reach of children.
6. Always clean the monitor before storing.
7. Do not attempt to disassemble the unit except when replacing the batteries.
8. If the monitor has been stored in a sub-freezing environment for any length of time, allow it and its components to slowly warm to room temperature prior to using.
9. In case of a discharged battery or complete failure of the device for another reason, there will be no warning when body temperature is abnormal.
10. To ensure accurate and consistent temperature measurement, proper probe position should be checked periodically by the caregiver.

About the Device

Probe
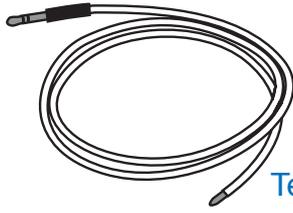
Temperature probe

USB cable

DataTherm®Ⅱ   KD-2300 Unit

Display Window

▲ button

▼ button

on/off button

mode button

LED

Battery cover

lock button, on/off & mode function

Sensor plug

USB plug

The LCD

Temperature

Temperature Scale

Mode selection

Date/Time

Lock/Unlock

Low Battery
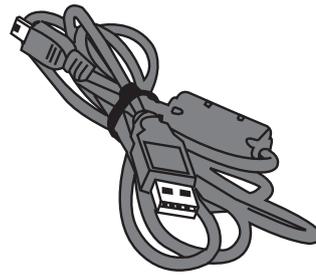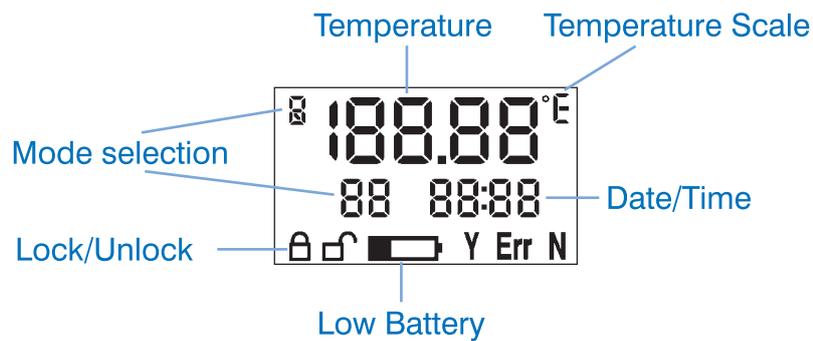
Battery installation / replacement

1.	2.	3.

1. Remove battery cover by sliding the lock to the open position and lift the battery cover open.
2. Install/replace two new 1.5 V Size-AAA batteries into the battery compartment.

Note: *Be sure that the batteries are installed with the correct polarity.*

3. Do not store the unit under direct sunlight, at high temperature, high humidity or in dusty conditions. Performance may be degraded.

Note: *Re-set the date and time after battery removal or replacement.*
Battery removal will erase the memories.

DataTherm® II Programming

Note: *The probe must be connected to the DataTherm® II before setting-up the device.*

Program the operating parameters according to the following steps:

Press the "On" Button

There are 10 modes used to set the operating parameters of the DataTherm® II. Press "mode" button once, to advance through each of the 10 set-up modes. Press "▲" or "▼" button to make the changes in the values for each mode. Confirm all changes.

1. High temp alarm setting: press mode key once (Figure 1).
2. Low temp alarm setting: press mode key 2 times (Figure 2).
3. Hour setting mode: press mode key 3 times. Hour will flash (Figure 3).
4. Minute setting mode: press mode key 4 times. Minute will flash (Figure 4).
5. Memory data capture interval - hour selection: press mode key 5 times. Hour will flash (Figure 5).
6. Memory data capture interval - minute selection: press mode key 6 times. Minute will flash (Figure 6).
7. Celsius and Fahrenheit scale selection mode: press mode key 7 times (Figure 7).
8. Visible "LED" alarm On/Off mode: press mode key 8 times (Figure 8).
9. Audible "buzzer" alarm On/Off mode: press mode key 9 times (Figure 9).
10. Delete memory and accept changes mode: press mode key 10 times (Figure 10). Y = accept new settings and deletes memory, N = retain existing data

Note: *Changes in the Memory Data Capture Interval, Modes 5 and 6 above require the user to advance to mode 10 and press (▲) "Y" button (Caution: This will erase any stored data).*

(Figure 1)
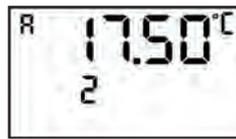
(Figure 2)

(Figure 3)

(Figure 4)

(Figure 5)

(Figure 6)
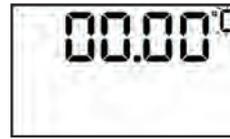
(Figure 7)

(Figure 8)

(Figure 9)
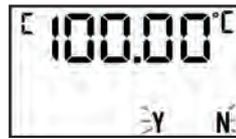
(Figure 10)

Connecting the DataTherm® II to PC

Be sure to install the software prior to connecting the DataTherm® II to the PC.
When first connected, the DataTherm® II LCD will display Figure 11 first, then display Figure 12. The DataTherm® II control buttons are automatically locked when it is connected to the PC.
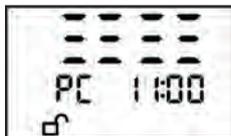
(Figure 11)

(Figure 12)

Software Instructions

The DataTherm(r) II software is compatible with Windows XP and Windows Vista.

1. Download the DataTherm® II software program from the mini-disc to the PC. Follow the instructions on the screen to complete the installation. To start the program, either double click the icon found C:\Program Files\DataTherm\ as seen below,

or, the DataTherm® II shortcut icon found on the "Desk Top."

2. The initial window display will look like Figure 13 (pg. 8). The DataTherm® II must be turned On and your PC must be "linked" before current temperature is displayed or data downloaded. Activate "Link" of computer screen tab definitions/ functions. Once linked, the screen will look like Figure 14.

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3. To change the temperature scale from "°C" to "°F" or "°F" to "°C", click the **UNIT: °F** button on the computer screen

Computer Screen Tab Definitions/Functions

- **Open:** Opens previously archived data (.dat) files.
- **Link:** Links PC to the DataTherm®II unit. (See Figure14)
  -- displays current temperature. DataTherm II must be turned "On."
- **Download:** Downloads DataTherm®II stored data to the PC and asks if you want to save the file as the existing PID (Patient ID) name displayed or a new PID (See figure 15).
  -- The download feature copies data stored in the DataTherm®II to the archived data folder as a new .dat file. All data is retained in the DataTherm®II until:
  - memory is manually erased using mode 10
  - batteries are changed
  - time (24 hour clock) is updated from the PC (See Figure 16) or, manually changed in modes 3 or 4 (See Figures 3 & 4).
- **Update:** Updates DataTherm®II time; allows memory reading interval change; patient ID change. (See Figure 16).
- **Export:** 1. Exports the data (.dat) file to *.txt or *.xls (Excel) format and/or
  2. Accesses previously stored .txt and .xls files.

Note: *An existing .dat file must be be active on the main screen before Export tab will function – After clicking the Export tab, select either .txt or .xls file choices at the bottom of the export file window and manually "Name" and "Save" a new file in either .txt or .xls formats.*

To open previously saved records for each of the archived file types, select the format and "Right Click" the file. Then select among the options in the drop-down window to "Open," "Send To," "Rename," etc. Additionally, the text Excel files may be accessed directly from the DataTherm program by opening Windows "Notepad" for .txt or Excel for .xls files.

- **Help: Help.**

(Figure 13)

(Figure 14)

(Figure 15)

! WARNING !

"Y" (Yes) will overwrite any file stored with the same PID name.

(Figure 16)

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Accessing Stored Data

1. The DataTherm® II provides 140-memory sets that include temperature/sequential day/time information. Click the "▲" or "▼" button to scroll, by time sequence, through the data. The maximum number of data sets that can be stored is 140. When the data bank is full, the oldest record will be erased automatically.

Note: *The memory data will be erased when the batteries are replaced. Be sure to transfer the data before replacing batteries.*

Turning Off the DataTherm® II

Turn off the measurement and storage functions by clicking the On/Off key. (Actually, the device is always on.) When turned "Off," the monitor goes into standby mode and the display shows the time, only. Pressing the "On/Off" button once, while in standby, begins a self-test of internal circuitry and all LCD displays. The circuit test lasts no more than 2 seconds.

Creating a patient file and downloading temperature readings to your PC

1. Activate the DataTherm® II Program on the PC.
2. Turn DataTherm® II **"ON"** with the sensor probe attached to the unit.

Note: *the DataTherm® II will continue to display the current patient or room temperature on the PC screen every 4 seconds.*

3. Connect the USB cable to the port on the top of the DataTherm® II and connect the opposite end into USB port on the PC.

Using the tabs at the top of the menu bar

4. Click **"Link"** tab (*note it will now convert to unlink).
5. Click on **"Download"** tab (*if there are existing files saved in the program you will see a prompt to **"save new data with this existing PID file name"** click "**NO**," enter a new file name, click "OK."

Emailing downloaded files by changing to Excel or text formats

1. Click on **"Export"** tab.
2. Note **"Save as type"** and select format **text** or **Excel**® at the bottom of the window.
3. Enter the file name you previously selected (without the .dat file designation)
4. Click **"Save"** to close the window
5. Click the **"Export"** tab and **"right click"** on desired file to **"Open."**
6. **"Send to:"** mail recipient (if desired you may now use the Excel® Graph function to represent data in a graphic format)
7. The download is complete. Disconnect the USB cable from your DataTherm® II and PC.

Deleting stored readings and Saving New Settings

Go into the 10th (or last) set mode on the DataTherm II, see a flashing "Y" and "N" and press the ▲ **"Y"** button to **"delete"** data <u>and</u> **"save"** mode setting changes. **"N"** will retain old settings and stored data.

Maintenance

	Do not drop the unit.
	Do not modify or disassemble the unit or probe.
	Do not twist or pull the probe.
	Use a cloth moistened with water or neutral detergent to clean the body of the unit and then wipe it dry. To disinfect the body use ethyl or isopropyl instead of water.
	Avoid petroleum-based solvents or other harsh cleaners.
	Avoid storing at high temperature, in direct sunlight, high humidity or dust.
	Remove the batteries for long-term storage.

Error Indicators	Interpretation
HI	The temperature measured was higher than the specified operating range. Please measure again.
LO	The temperature measured was lower than the specified operating range. Please measure again.
Err	**Probe connection error.** Please ensure the probe is connected
EEP Err	**The memory function error.** The unit has a circuit error, **DO NOT USE.** Contact customer service.
▮ or, "No display"	**Low Battery Symbol.** Replace two 1.5V (AAA) size batteries.

Specifications

Power Source	2 - AAA size batteries
Measuring range	17.0~45.0 °C (62.6~113 °F) Below 17.0 °C (62.6 °F) displays "L" °C (°F) Above 45.0 °C (113 °F) displays "H" °C (°F)
Display Resolution	0.01 °C (0.1 °F)
Accuracy	±0.1°C (±0.2°F): 34.0 ~ 42.0°C (93.2~107.6°F) ±0.2°C (±0.4°F): for other ranges
Dimensions	80.2mm x 60.2mm x 18.0mm (3.16" x 2.37" x 0.71")
Weight	69 grams (2.4 oz) including batteries
Alarm (Audible and Visual)	Alarms are activated when temperature reaches the Hi/Low alarm setting.
Operating Conditions:	Temperature: -26°C ~50 °C, -14.0°F ~122°F Humidity: 10%~83%
Storage Conditions:	Temperature: -26 °C ~60 °C, -14.0 °F ~140 °F Humidity: 10%~83%
Memory	140 memories
Low battery	Replace the batteries if the low battery symbol appears
Standards Conformity	CE 0118 DIN EN ISO 13485:2003 DIN EN 12470-4 (Clinical thermometers – Part 4: Performance of electrical thermometers for continuous measurement). EN 60601-1-2 (2006) (harmonized) "Electromagnetic Compatibility" ASTM E1112-00 (2006) "Electronic Thermometer for Intermittent Determination of Patient Temperature"

Testing and Calibration

We recommend that the accuracy of your DataTherm® II is checked every two years (this is a legal requirement in Germany). Geratherm Medical AG is able to provide calibration services for a fee.

Guarantee

Geratherm Medical AG provides a guarantee that is restricted to two years (from the date of sale) on manufacturing defects for the DataTherm® II unit.

Geratherm Medical AG or its authorised representatives will repair or replace faulty DataTherm® II units, which have material or manufacturing faults. This guarantee does not cover any damage, which has been caused by misuse, improper treatment or failure to obey written instructions or any damage caused by unauthorised persons of damage occurring during transportation. Guarantee work does not prolong the guarantee period of two years from the original date of sale. The guarantees provided by the various manufacturers cover the accessories found in the DataTherm® II kit. Any direct or indirect liability claims are excluded from this guarantee. The manufacturer does not make any explicit or implicit assurances that go beyond what is written here.

In the case of guarantee claims, please get in touch with the service department of Geratherm Medical AG by phoning 0049-36205-98-205 in order to obtain a transaction number.
Please pay attention to the current rules and regulations when disposing of the unit or the batteries.

Manufactured by:
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