Direct Supply® Infrared Thermometer

Owner's Manual

Thank you for purchasing a Direct Supply® Infrared Thermometer. Please read this entire guide carefully and keep it for future reference. This guide provides instructions, warnings, warranty information and other important information about your Direct Supply® Infrared Thermometer. Share this information with your nursing, housekeeping and maintenance staff to help ensure the Infrared Thermometer is cared for properly. Please keep and refer to this owner's manual.

Intended Use

The Direct Supply® Infrared Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in a homecare environment and doctors/clinicians in a hospital or hospital-like environment. It is intended for measuring human body temperature of people 3 months of age and older by detecting infrared heat from the center of the forehead. This device is an adjusted-mode clinical thermometer that is user-maintainable.

Package Contents

- Direct Supply® Infrared Thermometer
- Owner's Manual

Cautions and Warnings

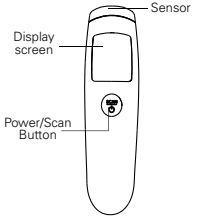
- Do not use the thermometer in extreme ambient temperatures (below 60.8°F/16°C or above 95°F/35°C) or extreme humidity (below 15% RH or over 80% RH). Failure to do so may result in inaccurate readings.
- Do not store the thermometer in extreme ambient temperatures (below -4°F/-20°C or over 131°F/55°C) or extreme humidity (below 15% RH or over 93% RH). Failure to do so may result in inaccurate readings.
- Do not drop the thermometer. If the thermometer is dropped, discontinue use and contact Direct Supply.
- It is dangerous for patients to perform self-evaluation or self-treatment. Follow the instruction of a physician.
- Do not touch or blow on the infrared sensor. A dirty or broken sensor may give inaccurate readings.
- Only gently clean a dirty infrared sensor using a soft cloth. Using any other type of material may scratch the infrared sensor, which may result in inaccurate readings.
- Install the batteries in the correct orientation. Incorrect installation may cause batteries to overheat, resulting in potential damage to the thermometer or injury to the user.
- Do not immerse the thermometer in liquids.
- Portable and mobile RF communications equipment can affect medical equipment. Using the thermometer in the presence of a mobile phone may cause inaccurate readings.
- If you notice any damage to the sensor, stop using the thermometer immediately and contact Direct Supply.
- Do not modify this thermometer. If you suspect that this thermometer has been modified, stop using the thermometer immediately and contact Direct Supply.
- This thermometer is not repairable and contains no user serviceable parts. If there are any problems with this thermometer, contact Direct Supply.
- This thermometer does not require calibration. If you suspect that the thermometer is not giving accurate readings, contact Direct Supply.
- Keep this thermometer out of the reach of children. Some parts are small enough to be swallowed. If any parts of the thermometer are accidentally swallowed, contact a physician immediately.
- If the thermometer is stored in an area where the ambient temperature is different than the temperature where the thermometer will be used, wait 30 minutes before taking the first temperature reading.
- Do not service or perform maintenance on the thermometer while in use.
- Follow the instructions in this manual when taking measurements.
- Maintain the device following the instructions in this manual.

Explanation of Marks and Symbols

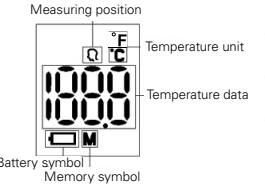
The following symbols may appear in this manual, on the thermometer or on its accessories:

	Must observe
	Follow instructions for use.
	Type-BF applied part.
	CAUTION: Consult accompanying documents
	Do not dispose of this thermometer in household waste – follow all local laws for disposing of electronic devices
	Do not expose to rain or moisture
	Do not expose to sunlight
	Indicates correct upright position of the transport package
	Fragile – handle with care
	Temperature limitation
	Non-ionizing electromagnetic radiation
	Do not roll
LOT	Lot number
	Production date
	Do not use after the date printed on the thermometer
IP22	Resistant to liquid ingress
	Manufacturer

Appearance and Key Functions of the Thermometer



Display Information



- **Measurement mode icon:** Indicates the current temperature measurement mode
- **Temperature unit:** Indicates whether the thermometer is measuring temperature in Fahrenheit or Celsius
- **Battery icon:** Indicates if the batteries are low and need to be replaced
- **Memory icon:** Indicates that the user is viewing stored temperature readings

Before Taking a Measurement on a Resident

- Try taking a measurement on yourself prior to using on a resident to familiarize yourself with the thermometer.
- The thermometer must be at room temperature for a minimum of 30 minutes before use.
- If the resident being measured had recently been in a cold or hot environment, allow a minimum of 20 minutes for their skin temperature to return to normal.
- Wait at least 30 minutes before taking the temperature of a resident who recently exercised.
- If repeated temperature measurements are required, move the thermometer away from the resident and wait at least 5 seconds before making another measurement.
- Normal body temperature can vary between 95.9°F and 100.0°F. In order to assess a resident's normal temperature range, take a series of temperature readings over an extended period of time to establish a baseline. Consult a physician if any abnormalities are discovered.
- Verify that the infrared sensor is clean before each measurement to ensure accurate readings.

Instructions for Use

- Turn on the thermometer by pressing and releasing the "Scan" button. The thermometer will beep, followed by the screen displaying - - - °F, indicating that the thermometer is ready to use.
- Place the thermometer sensor near the forehead and press and release the "Scan" button. The thermometer will beep when the measurement is complete and display the temperature reading on the screen. Whenever consecutive readings are required, wait at least 5 seconds between measurements.
- If the temperature reading is below 89.6°F, the display will read "Lo" followed by 2 quick beeps.
- If the temperature reading is above 100.0°F, the display will show the measured temperature followed by 6 quick beeps.
- If the temperature reading is above 108.0°F, the display will read "Hi" followed by 2 quick beeps.
- To turn off the thermometer, press and hold the "Scan" button for at least 5 seconds until the thermometer beeps. The thermometer will also automatically shut off if not used for 12 seconds.

Recalling Readings from Memory

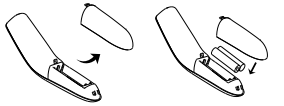
- Ensure that the thermometer is switched off.
- Press and hold the "Scan" button for at least 4 seconds until the display turns on. The most recent reading will be displayed.
- Press and release the "Scan" button to view the next most recent reading.
- The thermometer stores up to 32 readings.
- When you are done reviewing stored readings, wait for 12 seconds. The thermometer will automatically shut off. When the "Scan" button is pressed and released, the thermometer will turn back on and be ready to take a new measurement.

Changing Units from °F to °C

- Ensure that the thermometer is switched off.
- Press and hold the "Scan" button for at least 8 seconds. The display will show - - - and °F will be blinking. Press and release the "Scan" button to change the units to Celsius. The °C will now blink on the display. Press and release the "Scan" button again to convert back to Fahrenheit.
- When finished, wait for 4 seconds. The thermometer will turn off. When the "Scan" button is pressed and released, the thermometer will turn back on and take measurements with the newly selected units.

Replacing the Batteries

- When the low battery icon is lit, replace the batteries.
- Place pressure on the battery door and slide it down and away from the thermometer.
- Remove the old batteries from the thermometer.
- Insert the new batteries into the battery compartment, making sure to following the polarity indicators.
- Replace the battery door on the thermometer.



Error Messages

Error Message	Problem	Solution
Hi:	Temperature is higher than 108°F	• Operate the thermometer within the specified ambient temperature range • If you continue to see this error message, contact Direct Supply
Lo:	Temperature is lower than 89.6°F	• Operate the thermometer within the specified ambient temperature range • If you continue to see this error message, contact Direct Supply
Err:	Sensor disconnected	• Contact Direct Supply
ErE:	EEPROM is abnormal	• Contact Direct Supply
Battery Icon:	Low battery	• Replace the batteries
ErH:	Ambient temperature is too high	• Ensure that the thermometer is used within the specified ambient temperature range • If you continue to see this error message, contact Direct Supply
ErL:	Ambient temperature is too low	• Ensure that the thermometer is used within the specified ambient temperature range • If you continue to see this error message, contact Direct Supply.

Maintenance

- Remove any dirt or stains from the body of the thermometer with a soft and dry cloth
- Clean the sensor lens using a cotton swab or soft cloth lightly moistened with 70% alcohol. If the sensor is damaged, contact Direct Supply
- Do not wash the thermometer with water containing abrasive detergents or benzene
- Do not immerse the thermometer in liquids

Storage

- Do not store the thermometer in excessively high or low temperatures or humidity, in sunlight, in dusty locations or in the presence of electrical currents. Doing so may cause damage to the thermometer, resulting in inaccurate readings.
- Remove the batteries from the thermometer if it will be stored for an extended period of time

Technical Specifications

Parameter	Specification
Measurement mode	Forehead mode
Measuring site	Forehead
Measurement units	Fahrenheit (°F) and Celsius (°C)
Operating conditions	60.8°F-95°F (16°C-35°C) with a relative humidity of 15%-80%
Storage conditions	-4°F to 131°F (-20°C-+55°C) with a relative humidity of 15%-93%
Measurement distance	0.6" to 2.0" from the measuring point
Forehead temperature measurement range and accuracy	Measurement range: 89.6°F-108°F (32°C-42.2°C) Measurement accuracy: ±0.4°F(95.0°F-107.6°F)\±0.2°C (35.0°C-42.0°C); ±0.5°F (±0.3°C) other range
Memory	32 measurements
Dimensions	1.57" x 1.73" x 6.46" (40mm x 44mm x 164mm)
Weight	2.2 oz. without batteries (61g)
Battery	2 AAA batteries (DC 3V)
Auto-shutoff	Automatically shuts off after 1 minute
Battery life	1,000 measurements

Standards

This thermometer is manufactured under ISO 80601-2-56.

Electromagnetic Compatibility

This thermometer is suitable for home healthcare, long-term care, hospital and hospital-like environments.

⚠ **WARNING:** Don't use near active HF surgical, MRI equipment or any other environment where EM disturbances are high

⚠ **WARNING:** Use of this thermometer adjacent to or stacked with other equipment should be avoided, as it could result in improper operation. If such use is necessary, this thermometer and the other equipment should be observed to verify that they are operating normally.

If any: a list of all cables and maximum lengths of cables (If applicable), transducers and other accessories that are replaceable by the responsible organization and that are likely to affect compliance of the ME Equipment or ME System with the requirements of Clause 7 (Emissions) and Clause 8 (Immunity). Accessories may be specified either generically (e.g., shielded cable, load impedance) or specifically (e.g., by Manufacturer and equipment or type reference).

If any: the performance of the ME equipment or ME system that was determined to be essential performance is lost or degraded due to EM disturbances (the defined term "Essential performance" need not be used).

1. All necessary instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration – electromagnetic emissions and immunity.

Table 1

Guidance and manufacturer's declaration – electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR11	Class B
Harmonic emissions IEC 61000-3-2	N/A
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2kV Input/output lines: ±1 kV	N/A
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV. line(s) to earth: ±2 kV.	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle and 70% 25/30 cycles Single phase: at 0 0% 300 cycle	N/A
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz/60 Hz	30 A/m 50 Hz/60 Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	N/A
Radiated RF IEC61000-4-3	10 V/m 80 MHz - 2,7 GHz 80% Am at 1kHz	10 V/m 80 MHz - 2,7 GHz 80% Am at 1kHz
NOTE: UT is the AC mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	Immunity Test Level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	380-390	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
	710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	810 870 930	800-960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	1,720 1,845 1,970	1,700-1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	2,450	2,400-2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5,240 5,240 5,785	5,100-5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9

Distributed by Direct Supply Manufacturing, Inc. 6635 W. Champions Way, Milwaukee, WI 53223.

Manufactured by Alicn Medical (Shenzhen), Inc., 4/f, B Building, Shefubao Modern Optical Factory, Kengzi Street, Pingshan District, Shenzhen City, China, 518122

Limited Warranty

We offer to you, as the original purchaser, a warranty for the Infrared Thermometer. Our warranty applies for the limited warranty period stated below. If any product or product part listed below is defective in material or workmanship during the applicable limited warranty period, we will repair or replace it at our cost. Please note that the decision to repair or replace a product or product part will be at our discretion. Our warranty applies only if the product is properly maintained by the original purchaser for normal, indoor use and does not cover normal wear and tear, modification of the product or damage caused by abuse, improper use, failure to maintain, use which exceeds the published product limitations or the combination of any product with another product. In certain cases, we may provide you repair or adjustment instructions and/or replacement parts, and ask you to perform a repair or adjustment or replace a defective part. Our warranty gives you specific legal rights, and you may also have other rights, which vary from state to state. Please note that our limited warranty period begins when we ship the product to you. The limited warranty period and our obligations under the warranty end once you transfer the product to someone else or at the end of the applicable limited warranty period identified below, whichever is earlier.

	Warranty Period (Parts)	Anticipated Usable Product Life
Infrared Thermometer	1 year	5 years

Anticipated Usable Product Life is based on normal use with proper maintenance, cleaning and storage. You should still inspect, monitor and care for the product as described in this guide, as the product may need to replaced sooner than anticipated in particular situations.

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