INSTRUCTIONS FOR USE

IRT10

Wireless Tympanic Thermometer

781309EN-6 03/2021

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Notice

Warranty

The information contained in this document is subject to change without notice.
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Revision History

The documentation part number and revision number indicate its current edition. The revision number changes when a new edition is printed in accordance with the revision history of the documentation. Minor corrections and updates which are incorporated at reprint do not cause the revision number to change. The document part number changes when extensive technical changes are incorporated.

Manufactured in the UK by Huntleigh Healthcare Ltd.
As part of the ongoing development programme the company reserves the right to modify specifications and materials without notice.

Contents

1. General Safety Information

This section contains important safety information related to general use of the IRT10 wireless thermometer. Other important safety information appears throughout the manual

Important! Before using this equipment, please study this manual carefully and familiarise yourself with the controls, display features and operating techniques. Ensure each user fully understands the safety and operation of the unit, as misuse may cause damage to the unit or injury to the user or patient.

1.1 Warnings / Cautions

General warning / caution

Refer to Instructions for Use

WARNING: Check the equipment prior to use and ensure its safe and proper use.

WARNING: Before use, carefully read directions for use, including all warnings, cautions, and instructions.

WARNING: If the battery shows any signs of damage, leakage, or cracking, it must be replaced immediately, by a qualified service person, and only with a battery approved by the manufacturer.

WARNING: The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING: It is possible that any radio frequency transmitting equipment and other sources of electrical noise such as cellular phones, due to close proximity or strength of a source, may result in disruption of performance.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

1.2 Service Life

This has been defined as the minimum time period during which the device is expected to remain safe and suitable to meet its intended use, and all risk control measures remain effective. Huntleigh Healthcare Ltd's commitment is that the expected service life for this Device has been defined as 7 years.

2. Introduction

WARNING: The Wireless Tympanic Thermometer is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

This manual contains information about the Wireless Tympanic Thermometer (Order code: IRT10).
It is available as an option for the SC300 and SC500 Vital Signs Monitors.

2.1 Features of the IRT10 Wireless Themometer

Physical

The IRT10 wireless tympanic thermometer is a clinical grade hand held thermometer indicated for the intermittent measurment of body temperature in patients of all ages.

Electrical

The Thermometer is powered by two AAA dry cells.

Display

The Thermometer presents the following information on the integrated display:

- Battery status
- Probe cover indicator
- Wireless pairing status
- Temperature measurment
- Measurement scale °C or °F

2.2 Intended Use

The Thermometer is intended for use by trained healthcare professionals in healthcare settings to measure human body temperature in patients of all ages.

It uses an infra red technique to measure the amount of infrared energy reflected from the tympanic membrane.

2.3 Contraindications

The Thermometer should not be used if the following situations are present:

Do not use the thermometer if there is any blood or drainage in the ear canal.

Do not use the thermometer if the patient presents with inflamatory condition of the ear canal.

Do not use the thermometer if the ear canal is blocked with cerumen.

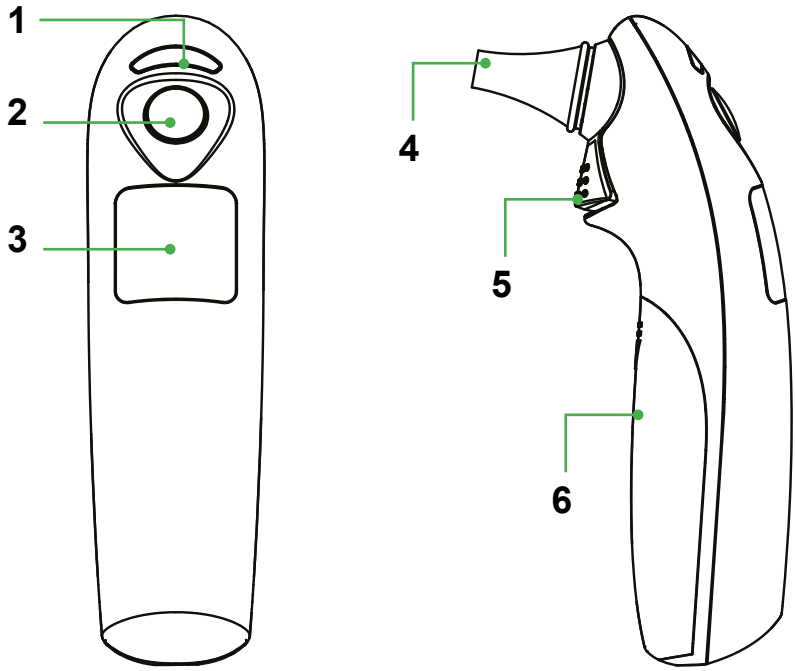
Do not use the thermometer if ear drops or medication has been applied to the ear

2.4 About This Manual

Read the entire manual including the Safety Information section, before you operate the monitor.

3. Description of Controls, Indicators, Symbols and Displays

3.1 Thermometer Controls and Display



1	Status indicator
2	Start measurement
3	Display
4	Infrared sensor
5	Probe cover ejector
6	Battery compartment

Key	Function / Display
	Battery status
	Probe cover status
	Wireless status
°C °F	Scale ºC or ºF
188.8	Measurement

3.2 Description of Symbols/ Indicators

The symbols and Indicators are described as follows:

Symbols	Description
CE 2797	This symbol signifies that this product complies with the essential requirements of the Medical Device Directive (93/42/EEC) - Medical Device Regulation (EU/2017/745)
	This symbol signifies that this product, including its accessories and consumables is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.
Manufactured By:	**Huntleigh Healthcare Ltd.** 35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom T: +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk www.huntleigh-diagnostics.com
	Legal Manufacturer in association with the CE mark in Europe ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden
	Battery charging indicator lamp

Symbols	Description
	Type BF
	Warning
	Attention, consult accompanying documents / Instructions for Use
IPX0	Not protected
SN	Serial number
MD	Medical Device
	Fragile
	Keep dry
	Max stack of x 4 identical boxes
	This way Up

4. Setup

WARNING: The IRT10 Wireless Thermometer is a prescription device and is to be operated by qualified personnel only. It is designed for use by medical clinicians.

WARNING: Discarded battery may explode during incineration. Follow local government ordinances and recycle instructions regarding disposal or recycling of device components, including batteries. Do not dispose of batteries in refuse containers.

4.1 Unpacking and Inspection

The Thermometer is shipped in one carton. Examine the carton carefully for evidence of damage. Contact Huntleigh Healthcare Ltd Service Department immediately if any damage is discovered. Return all packing material and Thermometer. Refer to the Maintenance section for instructions on returning damaged items.

4.2 List of Components

Quantity	Item	Quantity	Item
1	Thermometer	1	Prove Covers
2	AAA dry cells	1	Cradle

4.3 Connecting the Thermometer to the host

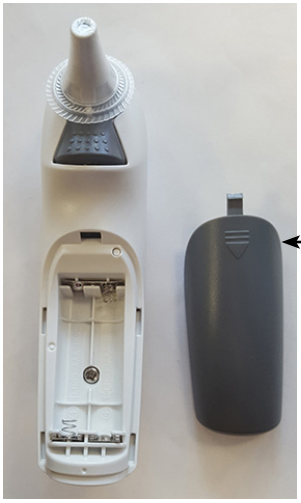
To facilite ease of use, the Thermometer can be fitted to the SC300/SC500 using the cradle supplied.

4.4 Installing the Batteries

WARNING: Dispose of Battery in accordance with local requirements and regulation. Follow local instructions regarding disposal or recycling of batteries.

CAUTION: Measured or displayed data may not be assured in the low battery or the critical low battery condition.

CAUTION: Discarded battery may explode during incineration. Recycle used batteries properly. Do not dispose of batteries in refuse containers.



Remove the battery cover to expose the battery compartment

Place new batteries into compartment paying attention to the polarity, close the compartment ensuring it snaps into place. The system is ready for use

4.5 Pairing the Thermometer and Main Unit

For pairing instructions, refer to the IFU of the Main Unit.

5. Using the Thermometer

The Thermometer must be calibrated at least once every two years, contact your service personnel when calibration is necessary

Use only specified protective probe covers.

The protective probe cover is single-use. Repeated use might give rise to cross infection.

The protective probe cover must be used when measuring, if not, it might cause cross infection or inaccurate readings.

Before use, check whether the cover is free from damage, if not, don't use.

Handle the thermometer with care, it should be stored in the cradle when not in use.

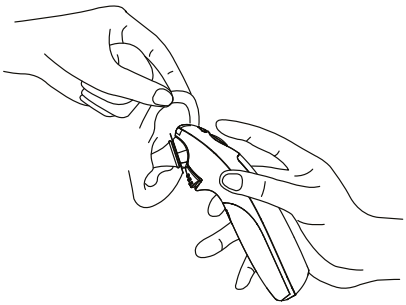
Discard the protective probe cover in accordance with the local regulations.

During the monitoring process, the temperature measuring instrument will automatically check itself once per hour. Self-checking will last 2 seconds, and will not affect the normal working of the temperature monitor.

Measurments are sent via a wireless connection established between the thermometer and the main unit.
Both items (Thermometer and unit) must be paired to enable data transfer.

5.1 Temperature Measurement

1. Install a new probe cover to the thermometer.
2. When correctly fitted, the  icon changes to  .
3. На мгновение нажмите кнопку включения режима ожидания на датчике температуры, чтобы включить прибор, датчик раздаст 2 коротких звуковых сигнала.
4. Расположите пациента, наклонив голову набок, осторожно потяните ухо назад, чтобы выпрямить слуховой проход. Осторожно вставьте кончик датчика температуры в ухо, убедившись, что слуховой проход полностью закрыт.



5. Press and hold down the on/standby button on for 1 second, continue to hold the probe in place until a short beep is heard from the probe when the measurement is complete.
6. Remove the thermometer and read the temperature.
7. The temperature will be displayed on the temperature probe and monitor.

Thermometer display

Monitor display

8. Upon completion press the eject key to remove the probe cover.
9. Place the probe cover in the appropriate waste collection point and replace the thermometer back into its holder

NOTE
The temperature probe will automatically power off after 60 seconds of in activity, if the battery becomes exhausted and the probe shuts down in less than 60 seconds the patient monitor will display “Temp Not connected”.
Manually powering off the device within 60 seconds will also trigger the “Temp Not connected” technical alarm. This is only applicable to units that support technical alarms.

5.2 Wireless Transmission Function

Temperature measurements are transmitted wirelessly to a paired patient monitor. Refer to the IFU of the Main Unit.

6. Care & Cleaning

6.1 General

The probe tip is the most delicate part of the thermometer. It has to be clean and intact to ensure accurate readings.

Gently wipe the surface of the probe tip with a cotton swab or soft cloth moistened with alcohol.

After the alcohol has completely dried, fit a new probe cover and take a temperature measurement.

If the probe tip is damaged, please contact your service agent.

Use a soft, dry cloth to clean the thermometer display and exterior.

Do not use abrasive cleaners.

Never submerge the thermometer in water or any other liquid.

Store thermometer and probe covers in a dry location free from dust and contamination and away from direct sunlight.

6.2 Returning the IRT10 Thermometer and System Components

Contact Huntleigh Healthcare Ltd Service Department for shipping instructions. Pack the accessory items in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect the device during shipping. Return by any shipping method that provides proof of delivery.

6.3 Service

Apart from a 2 year calibration check, the Wireless Thermometer requires no routine service other than cleaning or battery maintenance that is mandated by the user's institution. For more information, refer to Smartsigns® Compact 300 service manual. Qualified service personnel in the user's institution should perform periodic inspections of the equipment. If service is necessary, contact qualified service personnel or Huntleigh Healthcare Ltd Service Department.

If the institution's service personnel cannot correct problems, the equipment should be returned to Huntleigh Healthcare Ltd for service. Contact Huntleigh Healthcare Ltd Service Department for return instructions.

6.4 Periodic Safety Checks

It is recommended that the following checks be performed every 24 months.

- Inspect the equipment for mechanical and functional damage.
- Inspect the safety relevant labels for legibility.

7. Troubleshooting

WARNING: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the monitor is functioning correctly.

WARNING: Only qualified service personnel should remove the cover. There are no user-serviceable parts inside.

7.1 General

If the equipment is unable to perform any of its monitoring functions because of the loss of software control or a detected hardware malfunction, an error code is presented.
In the unlikely event of the unit developing a fault, fault codes will be shown in the corresponding area and the related parameters will flash on the screen

Description	Cause	Solution
Low power	Low power	Replace batteries
Blank Screen	Auto shutdown	Restart the device
	Battery installation incorrectly	Check the correct installation of the batteries
	Low power	Replace batteries
	The screen is still blank	Contact service personnel
Er1	The environment temperature is out of range.	Move the device to appropriate environment and wait 30 minutes prior to taking a temperature.
Er2	The environment temperature is not stable	Do not take measurement until the environment temperature is stable
Er3	Infrared module failure	Contact service personnel
Hi	The measurement is out of range > 42°C (107.6°F)	Make sure the operation method is correct and the probe cover is new and clean. Remeasure.
Lo	The meaurment is out of range <35°C (95°F)	Make sure the operation method is correct and the probe cover is new and clean. Remeasure.

7.2 Obtaining Technical Assistance

For technical information and assistance, or to order a service manual, call Huntleigh Healthcare Ltd Service Department. The service manual includes information required by qualified service personnel when servicing the Smartsigns® Compact 300.

When calling the Huntleigh Healthcare Ltd Service Department, you may be asked to tell the representative the software version number of your equipment. Qualified service personnel or Huntleigh Healthcare Ltd Service Department may help you check the software version installed in your equipment.

8. Electromagnetic Compatibility

Make sure the environment in which the equipment is installed is not subject to strong sources of electromagnetic interference (e.g. radio transmitters, mobile phones).

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause or be subject to interference. Type-tested in a fully configured system, complies with EN60601-1-2, the standard intended to provide reasonable protection against such interference. Whether the equipment causes interference may be determined by turning the equipment off and on. If it does cause or is affected by interference, one or more of the following measures may correct the interference:

- Reorienting the equipment
- Relocating the equipment with respect to the source of interference
- Moving the equipment away from the device with which it is interfering
- Plugging the equipment into a different outlet so that the devices are on different branch circuits

WARNING: The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Smartsigns® Compact 300 as replacement parts for internal components, may result in increased emissions or decreased immunity of the Smartsigns® Compact 300.

WARNING: The Smartsigns® Compact 300 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Smartsigns® Compact 300 should be observed to verify normal operation in the configuration in which it will be used

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Smartsigns® Compact 300 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's declaration - electromagnetic emissions		
The IRT10 infrared ear thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the IRT10 infrared ear thermometer should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	The IRT10 infrared ear thermometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The IRT10 infrared ear thermometer is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's declaration - electromagnetic immunity			
The IRT10 infrared ear thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the IRT10 infrared ear thermometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz outside ISM bands[a] 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the IRT10, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 150 KHz to 80 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in metres (m).[b] and E is the IMMUNITY TEST LEVEL in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range [d]. Interference may occur in the vicinity of the equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3V/m	
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz, to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.
If the measured fi eld strength in the location in which the IRT10 infrared ear thermometer is used exceeds the applicable RF compliance level above, the IRT10 infrared ear thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IRT10 and or the SC300/SC500.

[d] Over the frequency range 150kHz to 80kHz, field strengths should be less than 3V/m.

Guidance and Manufacturer's declaration - electromagnetic immunity			
The IRT10 infrared ear thermometer intended for use in the electromagnetic environment specified below. The customer or the user of the IRT10 infrared ear thermometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not Applicable	Internal battery powered device
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	Internal battery powered device
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_r (>95 % dip in U_r) for 0,5 cycles 40 % U_r (60 % dip in U_r) for 5 cycles 70 % U_r (30 % dip in U_r) for 25 cycles <5 % U_r (>95 % dip in U_r) for 5 s	Not Applicable	Internal battery powered device
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_r is the a.c. mains voltage prior to the application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the IRT10

The IRT10 infrared ear thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. the customer or user of the IRT10 infrared ear thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IRT10 infrared ear thermometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

declaration - IMMUNITY to proximity fields from RF wireless communications equipment

IRT10 is intended for use in an electromagnetic environment in which RF wireless communications equipment is present

Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

9. Specifications

9.1 Equipment Classification

Type of protection against electric shock.	Internally powered equipment
Degree of protection against electric shock 	BF
Mode of operation.	Continuous
Degree of protection against harmful ingress of particles and/or water.	IPX0
Degree of safety of application in the presence of a flammable anaesthetic	Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OXYGEN OR NITROUS OXIDE

9.2 Standards

MDD 93/42/EEC	**MDR 2017/745**
ISO 13485:2016	**ISO 14971:2012**
IEC 60601-1:2012 (reprint)	**IEC 60601-1-2:2014**
IEC 60601-1-6:2012+A1:2013	**ISO 15223-1:2016**
EN 1041:2008+A1:2013	**ISO 10993-1:2018**
ISO 10993-5:2009	**ISO 10993-10:2010**
IEC 62304:2006+A1:2015	**IEC 62366-1:2015**

9.3 General

Battery	2 x Type LR03 AAA1.5VDC
Battery Life	3000 measurements
Size	133 x 63.5 x 36.4 mm
Weight	80g
Automatic Shut down	60s±10s
Service Life	7 years

9.4 Environmental

Operation	
Temperature	15 °C to 36 °C (59 °F to 96.8 °F)
Humidity	≤85% non-condensing
Altitude	700 hPa to 1060hPa
Transport and Storage	
Temperature	–25 °C to 55 °C (-13 °F to 131 °F)
Humidity	≤85% non-condensing
Altitude	700 hPa to 1060 hPa
Note: The system may not meet its performance specifications if stored or used outside the manufacturer's specified temperature and humidity range.	

9.5 Measurement Parameters

Probe Type	Tympanic Infrared
Range	35 °C to 42 °C (95 °F to 107.6°F)
Accuracy	±0.2° C (±0.4° F)
Resolution	0.1°C (0.1 °F)
Measurement interval	≤12s
Measurement duration	<4 seconds
Operating Mode	Direct Mode

10. End of Life Disposal

This symbol signifies that this product, including its accessories and consumables is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.

11. Warranty & Service

Huntleigh Healthcare Diagnostic Products Division standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

11.1 Service Returns

If for any reason the Wireless Thermometer has to be returned, please:

- Clean the product following the instructions in this manual.
- Pack it in suitable packing.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package ‘Service Department ‘

For further details, refer to NHS document HSG(93)26 (UK only).

Huntleigh Diagnostics reserve the right to return product that does not contain a decontamination certificate.

A service manual is available for the Smartsigns® series. It contains service information, parts lists and fault finding guidelines. The service manual can be obtained by contacting your local supplier or:-

Service Department.
Huntleigh Healthcare, Diagnostic Products Division,
35, Portmanmoor Rd.,
Cardiff. CF24 5HN
United Kingdom.

Tel: +44 (0)29 20485885
Fax: +44 (0)29 20492520
Email: sales@huntleigh-diagnostics.co.uk
service@huntleigh-diagnostics.co.uk
www.huntleigh-diagnostics.com

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor.
In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

Manufactured in the UK by Huntleigh Healthcare Ltd on behalf of;

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