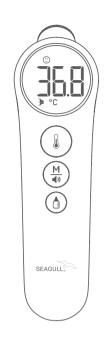
11 Cleaning instructions and product maintenance ------ 9

-- 10

..... 13

Thermometer User Manual FDIR-V12



Please read the guide carefully before use and keep it well. For American please refer to "° F", for European please refer to "° C".

The thermometer will detect the power automatically after boot-up. If the power is low but still sufficient enough for usage, the low power symbol will appear on the screen along with the measurement result. However, when the battery is running too low, the low power symbol will be flashing on the screen, and after 8 seconds, it will automatically shutdown must replace new batteries to ontinue usage

7.5. Battery replacement

1. Press the battery door and slide it down * to open the battery doo Take out the old batteries and replace HE) them with new ones. 3. Insert the new batteries and keep it fixed. Pay attention and follow the polarity symbols to avoid installing reverselv 4. Replace back the battery door to finish. Please follow the related national laws of disposing the abandoned batteries.

Please do not throw the batteries directly to the garbage can Please take out the batteries if the device is not used for long Please do not put the batteries in the fire.

8. Knowledge of body temperature

The temperature of human body belongs in a range and the range may vary among people. Temperature of individuals may also vary from time to time. We recommend that you know your normal temperature measured on the forehead, so that you therefore have a starting point for any temperature lifferences.

Self-diagnosis and self-treatment based on the measurement results could be dangerous, please contact the doctor for advisory and provide him/her the measurement results for

9. Calibration

The thermometer has already been calibrated at the time of manufacture. We suggest to change into new devices after 2 years from purchase, or seek assistance for calibration from professional organizations before usage. If the thermometer is used as prescribed, no further calibration will be necessary. Please consult Seagull Healthcare's quality department for technical questions about measurement results.

10.Trouble-shooting

8



CONTENT

1 Product introduction

2 Product component --

5 Contraindication -

6 Attention -

9 Calibration --

12 Final disposal --

16 Standard list

17 Right of Complaint -

User manual version: V1.2

The batteries type wrong or reversed polarity?

Poor battery connect

mperature range um 32.0 °C ~ 42.9 °

neasured is too high

ured is too

ange of 50 °F ~104 (10°C ~40°C)

irdware damage

11. Please contact distributor for support

1. The probe is the most delicate part of the thermometer

Use soft and dry cloth to clean the screen and them

detergent or place it in water or other liquid.

do not repair the thermometer by yourselves.

soft cloth along with alcohol.

measuring results.

It has to be clean and intact to ensure accurate readings

In order to clean the probe, please follow the way show

below: Wipe the surface of the probe gently using cotton or soft cloth with alcohol (75% Isopropyl).

casing. If the thermometer casing is too dirty, wipe it with

The device is not water-proofed, please do not use

maintain and repair the product. If you suspect that the device might have issues concerning its functions, please

4. We do not authorize any institution or individual to

(89.6 °F ~ 109.2 °F)

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Temperature is

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368

10 Trouble-shooting ----

3 Product specification --

4 Intended use and application -----

7 Installation and instruction ------

8 Knowledge of body temperature

13 Contents and Accessories

14 Explanation of standardized symbol ----

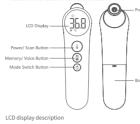
15 Electromagnetic compatibility information ----

Thanks so much for choosing our product. This high-tech infrared thermometer is used to measure the surface temperature of the forehead and convert it to the actual human temperature by an algorithm (adjustment mode). It can help you lear out the health of you and your family quickly at any time and anywhere. Product name: Infrared thermometer Product model: FDIR-V12

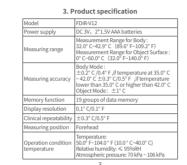
2. Product component eter mainly consists of plastic shell, infrared tem

1. Product introduction

The therm ture sensor, PCBA, buzzer chip, LCD display and battery. roduct front and back view shows belo







Please do not dispose of the product in the invusement waste at the end of it useful life. To protect the envi-ronment, dispose of empty batteries at appropriate Please do not dispose of the product in the household ion sites according to national or local regulations

13. Contents and Accessories	
only use original accessories ow to ensure if the package	
Quantity	Parts
1pcs	FDIR-V12 device
1pcs	User Manual

C € ₁₆₃₉	Complies with the European Medical D Regulation (EU) 2017/745, Notified Boo Belgium NV.
EU REP	Authorized representative in the Europ Union
8	Follow instructions for use.
A	General warning sign.
Ŕ	Type BF applied parts
LOT	Batch code
SN	Serial number
-	Manufacturer
IP22	Level of protection for ingress of water particulate matter into ME equipment
X	Disposal in accordance with Directive 2 EC (WEEE)
MD	Medical device

	EC (WEEE)
MD	Medical device
UDI	Unique device identifier
	Importer

15. Electromagnetic compatibility information

Guidance and manufacturer´s declaration – electromag emission – for all EQUIPMENT AND SYSTEMS
Guidance and manufacturer's declaration - electromagnet

Thermometer is a very precise product, any imprope repair or disassemble will cause inaccuracy of the

oduct issues within the warranty period 9

Transport/Storage condition temperature	Temperature: -13.0°F~131.0°F(-25.0°C~55.0°C) Humidity: ≤ 95%RH, non-condensing Atmospheric pressure: 70 kPa~106 kPa
Grade of waterproof	IP22
Electric shock	Internally powered ME equipment
Applied part	Type BF applied part,including the whole unit
Battery life	2 years/1000 measurements
Product size	145mm*41mm*49mm
Product weight	93g
Service life	5 years

Software version V1.0

4. Intended use and application

This product mainly adopts infrared temperature measure ment method to measure the temperature of forehead and can be used for infants, children and adults. We recommend adults to operate the thermometer instead of babies and children.

5. Contraindication

Measuring inflammation trauma or nostonerative lesions

6. Attention

6.1. related to measurement

6.1.1.The measurement results are for reference only. Please do not make self-diagnosis and treatment according to the neasurement results. If necessary, please go to hospital to e a medical treatment. 6.1.2.There is no absolute standard temperature of human body. In order to make a correct judgment for fever, it is

- important to know your normal body temperature, which is helpful to judge whether you have a fever or not. 6.1.3.Before measuring the forehead temperature, please make sure there is no sweat, cosmetics, oil stain, etc
- 6.1.4.Before measuring, please make sure that the person does not have shower, exercise or eat in past 30 minutes. When human body is in a stable status, the body temperature easured is more referential
- 6.1.5.Please do not measure the temperature near inflamma-tion or scar, which will affect the temperature measurement results
- 6.1.6 Please do not measure the body temperature immediate ly after taking the medicine. The temperature measured at this time is not referential.
- 6.1.7.Please do not measure in the environment where the temperature changes rapidly, such as the air outlet of air conditioner or heater, which will affect the temperature
- neasurement results. 6.1.8.When measuring repeatedly, the measurement results may have small deviation, which is a normal phenomenon. 4

Compliance

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Guidance and manufacturer's declaration – electrom immunity – for all EQUIPMENT and SYSTEMS

IEC 60601

 $2 \text{ kV}, \pm 4 \text{ kV}$

± 8 kV, ± 15 kV air

2 kV for

mode ± 2 kV

0 % U₇; 0,5 cycle U₇ At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°

0 % U₇; 1 cycl

nd 70 % U₁

, 19611 - 250/300

Guidance and manufacturer's declaration – electroma

Compliance level

 $2 \text{ kV}, \pm 4 \text{ k}$

: 8 kV, : 15 kV air

nnly lines

1 kV

0 % U₇; 0,5 cycle U₇ At 0° 45° , 90° , 135 180° , 225° ,

270° and 315

% U₇; 1 cyc

and 70 % U₁;

0 96 U.

250/300 cvr

emissions SPR 11

RF emissio CISPR 11

Harmonic emi: IEC 61000-3-2

/oltage fluctuati

flicker emissions IEC 61000-3-3

nunity test

discharge (ESI EC 61000-4-2

EC 61000-4-4

EC 61000-4-5

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and voltage

Electromagnetic vironment - guida

The FDIR-V12 uses RF energy only for its intern function. There for, its RF

iissions are very low d are not likely to ca

FDIR-V12 suitable

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hospital

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12. Final disposal	
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13. Contents a	nd Accessories
only use original accessorie ow to ensure if the package	
Quantity	Parts
1pcs	FDIR-V12 d
Incs	Liser Man

14. Explanation of standardized symbol

C € 1639	Complies with the European Medical Device Regulation (EU) 2017/745, Notified Body is SGS Belgium NV.
EU REP	Authorized representative in the European Union
8	Follow instructions for use.
\triangle	General warning sign.
Ŕ	Type BF applied parts
LOT	Batch code
SN	Serial number
-	Manufacturer
IP22	Level of protection for ingress of water or particulate matter into ME equipment
X	Disposal in accordance with Directive 2002/96/ FC (WEFF)





Guidance and manufacturer's declaration – electroma
emission



6.2.1.This product belongs to precision equipment. Please put it in the packaging box after use to avoid liquid splashing

- into the device and probe and prevent small foreign matter (such as dust) from falling into the probe, which may affect pasurement results 6.2.2. Avoid falling on the ground or impacted by external force. Plassa do not disass
- ble and assemble by yourself 6.2.3.Avoid touching the probe directly with your finger or blowing it with your mouth. When the infrared probe is damaged or dirty, the measurement results may be inaccu-
- 6.2.4.Please put this product out of reach of the child to prevent the child from swallowing the battery or small parts of
- the thermometer 6.2.5.Do not put the thermometer and battery into the fire to
- 6.2.6.Please take out the batteries if the thermometer will not
- he used for more than 3 months 6.2.7.Self-diagnosis and treatment according to the measurement results are dangerous. Please consult a professional
- doctor for treatment based on the measurement results

7. Installation and instruction

7.1. Installation of product

Put two AAA-batteries into the battery house on the back of the device. At the point the product will start self-inspection, and then turn into power off automatically.(if the battery power is low when starting up, please replace the battery to ensure adequate power supply)

7.2. Measurement process

7.2.1. Forehead temperature measurement A. Put the probe toward the forehead directly at a distance from 1cm to 6cm.



B. Press the [Power/Scan Button] lightly. Testing result can be on display within 1 sec

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequenc magnetic fields should be at lev characteristic of a typical locatio in a typical commercial or hospital environment.
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Guidance and manufacturer 's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM

Guidance and manufacturer imi
The FDIR-V12 is intended for use i

h an environmen	t.
Compliance level	Electromagnetic environment - guida
	Compliance

Conducted RF EC5000-44 RF REAddated RF EC50000-4-3	3 Vms 150 MHz to 80 MHz 6V in ISM and amateur radio Job MHz to 2.7 GHz 30 MHz to 2.7 GHz 355MHz Texts specifications for ENCLOSUBE PORT MMUNITY to RF wireless communication equipmenti equipmenti 0 of 216(0):1 2.2014)	3V 150 kHz to 80 MHz 51 ki IbK and anatiser ratio Job MHz to 2.7 GHZ 00 k/m 385MHz to 2.7 GHZ 385MHz Test specifications for ENCLOSURE CHECTO THE CHECTO THE CH	Pertable and mobile \mathbb{P}^{c} communications \mathbb{P}^{c} communications \mathbb{P}^{c} communications \mathbb{P}^{c} constrained sequation distance actualized from \mathbb{P}^{c} constrained sequation distance actualized from \mathbb{P}^{c} constrained sequation distance \mathbb{P}^{c} constrained sequation distance \mathbb{P}^{c} constrained sequation distance det [$\frac{3.5}{V_{\rm T}}$] \sqrt{P} det [$\frac{12.5}{V_{\rm T}}$] \sqrt{P} det (the transmit manufacture and is the transmit sequence in ach frequency angle. The the following symbol: the i



A. Press the [Mode Switch Button] slightly for object m B. Put the probe towards the object a. At adistance 1-5 cm in a perpendicul ar line When measuring the temperature of food or drink, be careful not to measure on the packaging but close to the





7.2.3. Sound and backlight explanation If infrared thermometer beeps once, it means everything goes well. If the measurement result is 37.6° C or above, the infrared thermometer will been four times. Measurement readings will be displayed on scre

een

Color of backligh uzzer warning ange for body 32.0° C (89.6° I ≪ T ≪ 37.5° C e buzzer warning by nding out a long "beep

he buzzer warning by ending out a "beep" beep" "beep" beep"..."beep" "beep" beep" "beep" ... "beep beep" "beep" "beep" 37.6° C (99.7° F) ≪ T ≪ 42.9° C (109.2° F) < 32.0° C 89.6° F) isplaying Lo ning by een nding out a "beep" een" "been" "been The buzzer warning by sending out a "beep" "beep" "beep" "beep' > 42.9° C reen ange for object uzzer warning 0° C(32.0° F) ≤ T ≤ 60.0° C 140.0° F) sending out a long reen



7.2.4. Memory function

The ISM (industrial, scientific and medical) bands between 11 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz t 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 Hz. The amateur radio bands between 0 5000 MHz. The amateur radio bands between 0.15 MHz and 40,56 MHz to 40, MHz. The amateur radio bands between 0.15 MHz and 80 M are 1,8 MHz to 20, MHz, 35 MHz 40 A O MHz, 53 MHz to 5,4 MH, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz 8,07 MHz to 17,1 7 MHz, 21,0 MHz to 21,4 MHz, 48,8 MHz to 4,99 MHz, 28,0 MHz to 23,7 MHz and 50,0 MHz to 54,0 MHz. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile amateur radio.

be necessary, such as re-orienting or relocating the FDIR-V12. Over the frequency range 150 kHz to 80 MHz, field streng should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS

Recommended separation distant e FDIR-V12 is intended for use in an electromagnetic environm which radiated RF disturbances are controlled. The customer or i

cording to th 150 kHz to 150 kHz to 80

output of transmitter W	80 MHz outside ISM and amateur radio bands $d=\left[\frac{3.5}{\gamma_{1}}\right]\sqrt{p}$	MHz in ISM and amateur radio bands $d=[\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz d=[3.5 €,]√P	800 MHz 1 2.7 GHz d=[7/E;]
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22

 1.2
 2.00
 0.35
 0.70

 3.8
 6.32
 1.10
 2.21
 100 12 20.00 35 70 For transmitters rated at a maximum output power not liste over the recommended separation distance d in metres (m) ca estimated using the equation applicable to the frequency of the nsmitter, where P is the maximum output power rating of the

transmitter in watts (W) according to the transmitte Note 1: At 80 MHz and 800 MHz, the separation dis Note 1: According to the second secon

16. Standard list

FDIR-V12 complies with the following standards dical device –symbols to be used with medical devic els,labeling and information to be supplied –Part 1;

mation supplied by the manufacturer with medical EN 1041 ment Part 1: General requirement 60601-1 for basic safety and essential pe

2. Continue to press [Memory/Voice Button] shortly to a the next group of data. If it exceeds the last group , it will display the first group data again.

3. If there is no operation for 3 seconds, it will exit the me mode display.

After power on, press [Memory/Voice Button] for about 2 sec-

(<u>368</u>)•(<u>368</u>

Once power on, object mode and body mode can be switched by pressing [Mode Switch Button] slightly.

If the device is not in use, it will Power off automatically in 30

A. After power on press and hold the [Mode Switch Button] for

(----) ,, "C

7.4. Battery installation and replacement

B. Then still keep holding the [Mode Switch Button] for 2 more

seconds, the unit ° C and ° F will be switched automatically Release the button when the selected unit appeared, the

device be auto into measure ready status. The unit selected

7

equirements for basic safety and esse Collateral Standard: Requirements fo puipment and medical electrical syste

ASTM E Standard Specification for Infrared Thermometer for

Iedical electrical equipment -- Part 1-2: General equirements for basic safety and essential perfo

- Collateral standard: Electromagnetic compatibility -Requirements and tests

Intermittent Determination of Patient Temperature

IEC Medical devices – Application of usability engineering to 62366 medical devices IEC 62366:2007

17. Right of Complaint

We provide 2 years of Right of Complaint starting from the

date of purchase. Please refer to the followings situations that are excluded from the free repair services within the warranty

1. All damages caused by disassembly and repair of the

device by yourselves.
All damages caused by dropping the device during usage,

All damages caused by improper usage of the device and not following the instructions on the user manual.

Please contact after-sales service and support and enclose

your product purchase receipt while claiming for warranty

ISO Medical electrical equipment – Part 2-56:Particular 80601-2: requirements for basic safety and essential perform clinical thermometers for body temperature meas

10993-1 and testing within a risk management pro

or transport.

Location of purchase

Contact number

Date of purchase:

EU REP

doc Technology Co. 1td

Add.: No. 212 Yilong Road, Changan Town, Dongguan,

Shanghai International Holding Corp. GmbH (Europe

14

Guangdong Province, 523853, P.R. China

Add: Eiffestrasse 80, 20537 Hamburg, Germany

Medical device software - Software life-cycle processes

of medical devices - Part 1: Evaluat

, thcare environment

al equipment - Part 1-11: General

irement system (° C or ° F) automat

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7.2.5. Mute mode function

7.2.7. Power off

seconds.

(<u>3</u>68)

onds to turn on or off the mute mode

7.2.6. Switching measurement modes

7.3. Temperature unit selection

cally appears on the display.

 \rightarrow

10 seconds. The mea

1. This product has 19 groups of data memory function. After

comes the temperature data of this group sequence

power on, press the [Memory/ Voice Button] shortly to que

ry the user's historical test data. During display process, the current data group sequence is displayed first, and then