

Good Health



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东莞市好康电子科技有限公司
Gongguan City Good Health Electronic Technology Co.,Ltd.

家用医疗器械品牌孵化基地
Home medical equipment Brand Incubation Base



国际品牌 专业制造

臂式全自动电子血压计

腕式全自动电子血压计

压缩式雾化器

红外非接触式额温计

数字电子体温计



国际品牌 专业制造

东莞市好康电子科技有限公司创建于2013年，我们是国内最专业的家用医疗器械OEM/ODM贴牌代加工厂商。好康科技聚集了大陆及台湾半导体、医学工程领域的高科技人才，致力于精准检测人体生命体征参数产品的研发，主要产品有电子血压计、电子体温计、红外额温计、压缩式雾化器和微网雾化器，同时血糖仪和制氧机也在规划日程当中。

在人体血压量测和体温量测方面，好康科技有近二十年的研究开发经验，拥有该领域全球领先的核心技术，我们曾经与台湾研究机构技术与临床合作，十五年的临床实验证，以及完善到最佳状态的技术方案，是我们得以服务好广大客户的最大资本。目前好康科技已通过ISO 13485：2003/ NS-EN- ISO 13485:2012医疗器械质量管理体系认证，产品获得国际上先进的工业化国家通行的欧盟CE0434认证、自由销售证书，以及国家医疗器械生产许可证、医疗器械注册证（SFDA认证）。

好康科技将继续专注于人类健康事业，为成为血压计、体温计、额温计及雾化器专业研发中心及广大客户家用医疗器械品牌孵化基地而努力，致力于成为中国最专业的家用医疗器械代工厂商。目前好康科技产品在市场有很大的市场占有率，产品畅销国内及欧盟国家、东南亚、中东等地区，我们愿携手志同道合的联盟伙伴，一起成长，一起为人类健康事业而努力并作出自己应有的贡献。

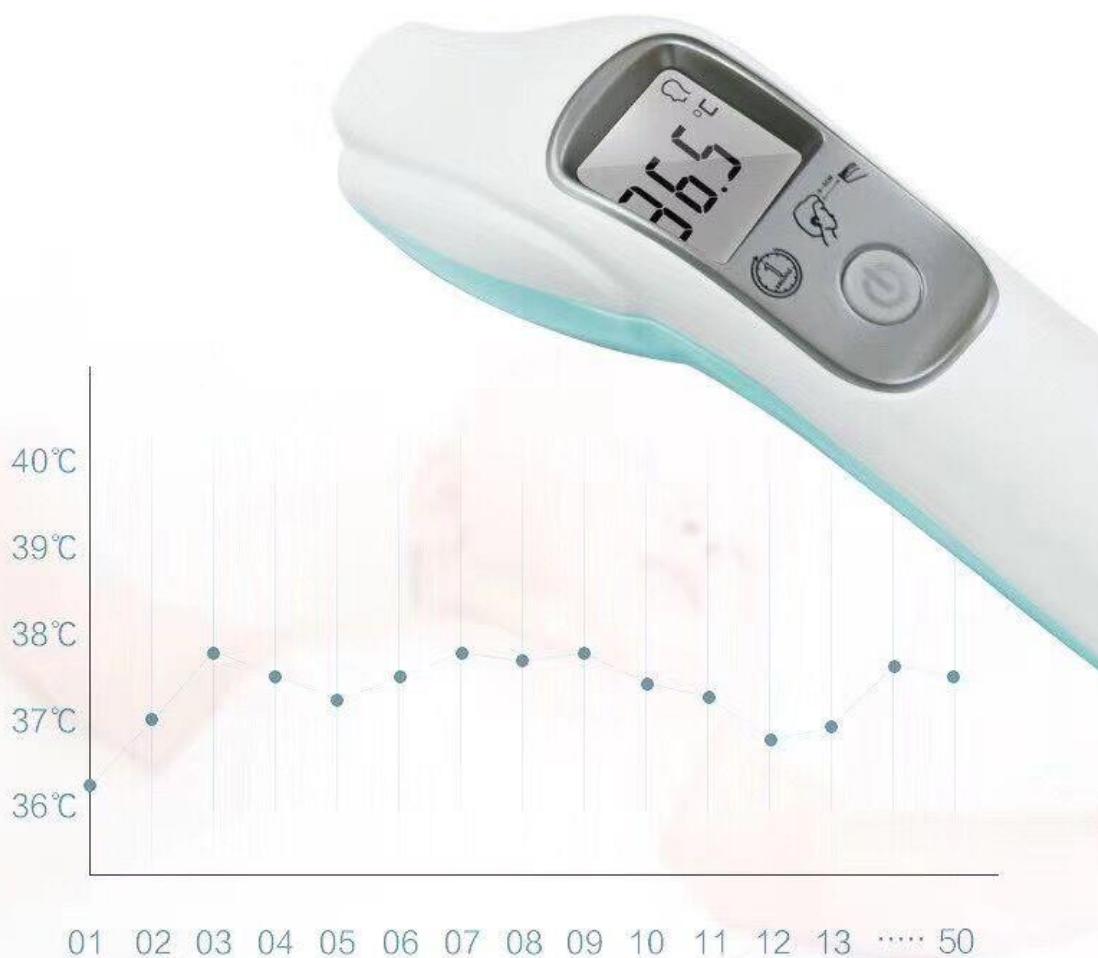


粤制00000934号 2014F224-44



记录体温9组记忆值

时刻记录体温，方便观察体温前后变化。



一键测量无需等待

红外线非接触式快速测量

滴~滴~滴



智能省电自动关机

不使用体温计的情况下，体温计75秒内自动关机



EURO-DePRO

Infrared Thermometer

Specification

Product Model: Rt-101

Measurement Range:

Frontal Temperature Mode: 32.0°C~43.0°C

Surface Mode: 5.0°C~85.0°C

Maximum Allowable Error: 32.0°C~34.9°C±0.3°C

35.0°C~42.0°C±0.2°C

42.1°C~43.0°C±0.3°C

Size: 165x46x47mm

Weight: 85g

Operating Environment Temperature Range:

16°C~35°C ≤85%rh

Transportation And Storage Temperature:

-20°C~55°C ≤93%rh

Power Supply: Dc 3v 2 Knots. 7 Batteries

Attachment: Instruction Manual (including Warranty Card)*1 Battery*2

产品展示

PRODUCT DISPLAY



医用红外额温计
RT-101



两种
测温模式

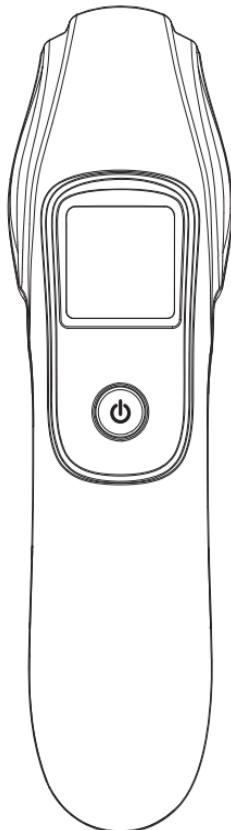
9组
记忆数据



EURO-DePRO

User manual for

Model:RT-101



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EC Certificate Full Quality Assurance System

Certificate No.:
10013-2017-CE-RGC-NA-PS

Project No.:
PRJC-530701-2015-PRC-CHN

Valid until:
10 February 2022

This is to certify that the quality system of:

Shenzhen Youngme Information Communication System Co., Ltd.
3rd Floor, No. A13 building, New Material Industrial Park, Silicon Valley Power,
Guanlan Street, Shenzhen, P.R. China

For design, production and final product inspection/testing of:

Infrared Digital Thermometer

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended
and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 31 May 2017



For:
DNV GL NEMKO PRESAFE AS

Mariann Jeremasson
Certification Manager

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notified Body No.: 2460

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



EC Certificate Full Quality Assurance System

Certificate No.:
10013-2017-CE-RGC-NA-PS

Project No.:
PRJC-530701-2015-PRC-CHN

Valid until:
10 February 2022

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original certificate	2017-05-31

Products covered by this Certificate:

Product Description	Product Name	Class
Infrared Digital Thermometer	YM-668A, YM-668B, YM-668C, YM-668D, YM-668E, YM-668F, YM-668G, YMITF01, YMITF03, YMITF05, YMITF06, YMITF07, YM-6881, YMITE01, YMITE03, YMITE05, YMITE06, YMITE07, YMITE08	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Shenzhen Youngme Information Communication System Co., Ltd.

3rd Floor, No. A13 building, New Material Industrial Park, Silicon Valley Power,
Guanlan Street, Shenzhen, P.R. China

EU Representative

CGI Business Trading and Consulting
Hans-Bethe-Str.1, 60438 Frankfurt am Main, Germany



EC Certificate Full Quality Assurance System

Certificate No.:
10013-2017-CE-RGC-NA-PS

Project No.:
PRJC-530701-2015-PRC-CHN

Valid until:
10 February 2022

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate



EC Certificate Production Quality Assurance System

Certificate No.:
10095-2017-CE-RGC-NA-PS

Project No.:
PRJC-490771-2013-PRC-CHN

Valid until:
09 March 2020

This is to certify that the quality system of:

Dong Guan City Good Health Electronic Technology Co., Ltd.
4 Floor, B Building, Chang Huang Road, Qiaoli Village, Changping Town,
Dong Guan City, P.R. China

For production and final product inspection/testing of:

Electro Medical Devices

Has been assessed with respect to:

**The conformity assessment procedure described in Article 11.2.b
and Annex V (Module D1) of Council Directive 93/42/EEC on
Medical Devices, as amended**
and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 6 November 2017



For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



EC Certificate Production Quality Assurance System

Certificate No.:
10095-2017-CE-RGC-NA-PS

Project No.:
PRJC-490771-2013-PRC-CHN

Valid until:
09 March 2020

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utsyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the certificate 5828-2015-CE-RGC-NA (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460)	2017-11-06

Products covered by this Certificate:

Product Description	Product Name	Class
Digital Blood Pressure Monitor	HK-601, HK-602, HK-603, HK-605, HK-606, HK-607, HK-608, HK-609, HK-610, HK-611 HK-801, HK-802, HK-803, HK-805, HK-806, HK-807, HK-808, HK-809, HK-810, HK-811	IIa
Digital Thermometer	HK-901, HK-902, HK-903, HK-905, HK-906, HK-907, HK-908, HK-909, HK-910, HK-911	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Dong Guan City Good Health Electronic Technology Co., Ltd.,

4 Floor, B Building, Chang Huang Road, Qiaoli Village, Changping Town, Dong Guan City,
P.R. China



EC Certificate Production Quality Assurance System

Certificate No.:
10095-2017-CE-RGC-NA-PS

Project No.:
PRJC-490771-2013-PRC-CHN

Valid until:
09 March 2020

EU Representative

CGI Business Trading and Consulting, Inh. Herr Leizhang, Huegel Str. 73, 60433 Frankfurt am Main, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate



DNV BUSINESS ASSURANCE MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 143648-2013-AQ-RGC-NA

This is to certify that the Management System of:

Dong Guan City Good Health Electronic Technology Co., Ltd.

4 Floor, B Building, Chang Huang Road, Qiaoli Village, Changping Town,
Dong Guan City, P.R. China
Unicode : 9144190007022275X2

has been found to conform to the standard:

ISO 13485:2003 / NS-EN-ISO 13485:2012

This Certificate is valid for the following product or service ranges:

**Design, Manufacture and Sales of
Digital Blood Pressure Monitor and Digital Thermometers.**

Initial Certification date:
8 January 2014

This Certificate is valid until:
28 February 2019

*The audit has been performed under the
supervision of*

Yang Yong Jun
Lead Auditor



Place and date:

Høvik, 5 December 2016
for the Accredited Unit:
DNV GL BUSINESS ASSURANCE
NORWAY AS.

Eugenie Winger Husebye

Eugenie Winger Husebye
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

HEAD OFFICE: Det Norske Veritas AS, Veritasveien 1, 1322 Høvik, Norway. Tel: +47 67 57 99 00 Fax: +47 67 57 99 11 - www.dnv.com
LOCAL REGISTRATION COMPANY NAME AND ADDRESS: DNV GL Business Assurance (China) Co., Ltd. SUITE A, BUILDING 9, NO.1591, HONGQIAO ROAD, CHANGNING DISTRICT, SHANGHAI 200336, P.R.CHINA



第 6059269 号



商 标 注 册 证

欧 德 宝
EURO-DePRO

核定使用商品(第 10 类)

验血仪器; 医用喷雾器; 按摩器械; 医疗器械和仪器; 血压计; 振动按摩器; 医用喷雾器(按钮式); 医用测试仪; 医用体温计; 助听器(截止)

注 册 人 余胜仁 F122927613

注册地址 四川省成都市武侯区共和路新2号2栋2单元8号

注册有效期限 自公元 2009 年 11 月 28 日 至 2019 年 11 月 27 日止

局长签发

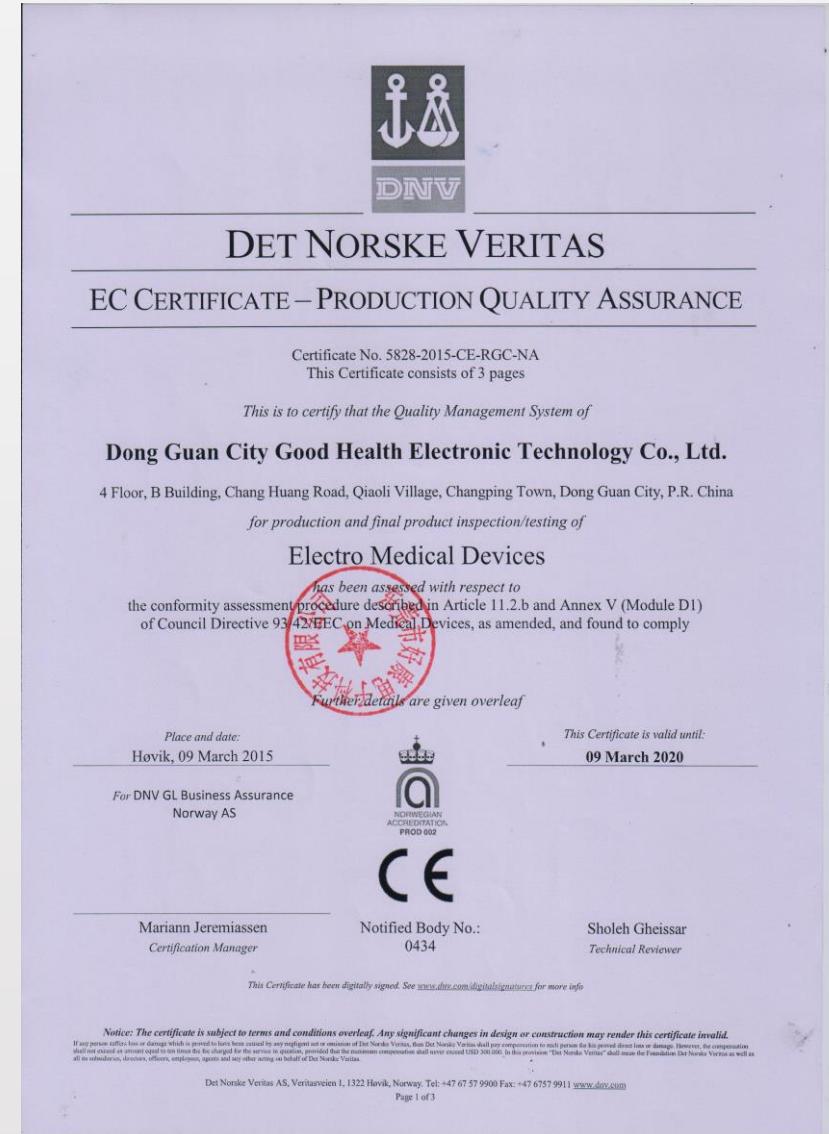
李 建 昌





医疗器械注册登记表
注册号: 粤食药监械(准)字 2014 第 2200292 号

生产企业名称	东莞市好康电子科技有限公司
企业注册地址	东莞市常平镇桥沥村(常黄公路旁)厂房B栋四楼
生产地址	东莞市常平镇桥沥村(常黄公路旁)厂房B栋四楼
产品名称	电子体温计
型号、规格	HK-901, HK-902, HK-903, HK-905, HK-906, HK-907, HK-908, HK-909, HK-910, HK-911
产品标准	GB/T 21416《医用电子体温计》
产品性能 结构及组成	主要由感温探头、控制电路、液晶显示屏和外壳组成。
产品适用范围	供医疗部门或家庭作测量人体体温使用。
产品禁忌症	见说明书备案件。
备注	2014年03月14日





中华人民共和国
制造计量器具许可证



粤制 00000934 号

生产地址：东莞市常平镇桥沥村（常黄公路旁）厂房B栋四楼

东莞市好康电子科技有限公司

根据《中华人民共和国计量法》的规定，对你单位制造下列计量器具的生产条件、产品质量和计量法制管理考核合格，特发此证。

序号 计量器具名称 型号 规格 准确度

臂式语音电子血压计
型号：HK-801、HK-802、HK-803、HK-805、HK-806、HK-807、HK-808、HK-809、
HK-810、HK-811

静态压力测量范围：至少应满足 (0.0~34.7) kPa [(0~260)mmHg]；
静态压力示值最大允许误差：± 0.4kPa (± 3mmHg。)

腕式语音电子血压计
型号：HK-601、HK-602、HK-603、HK-605、HK-606、HK-607、HK-608、HK-609、
HK-610、HK-611

静态压力测量范围：至少应满足 (0.0~34.7) kPa [(0~260)mmHg]；
静态压力示值最大允许误差：± 0.4kPa (± 3mmHg)。

以下空白



发证单位 (盖章)：广东省质量技术监督局

发证日期 2017 年 6 月 14 日

有效日期 2020 年 6 月 13 日止



医疗器械生产许可证

许可证编号：粤食药监械生产许20132351号

企业名称：东莞市好康电子科技有限公司

法定代表人：方晓珍

企业负责人：卢宗家

住 所：东莞市常平镇桥沥村（常黄公路旁）厂房B
栋四楼

有效期限：至 2022 年 10 月 10 日

生产地址：东莞市常平镇桥沥村（常黄公路旁）厂房B
栋三楼、四楼

生产范围：II类6820普通诊察器械



发证部门：广东省食品药品监督管理局



发证日期：2017 年 10 月 11 日

1 Safety information

1.1 Precautions

- The measuring results may vary depending on skin types and thickness. Important notice:
Normal human body temperature varies slightly from person to person and by the time of day. It depends upon the age, exertion, infection, sex, reproductive status of the subject, the place in the body at which the measurement is made, the subject's state of consciousness (waking or sleeping), activity level and emotional state. A rectal measurement is typically slightly higher than oral measurement, and oral measurement is somewhat higher than skin measurement.
- Place the product indoors for 20 minutes before use to avoid inaccurate measurements due to sudden changes of surrounding temperature.
- Please do not measure temperatures near a working electric fan or air conditioner.
- Keep the forehead dry and clean by removing the hair or cleaning the perspiration before
- Do not measure temperatures after precautions such as ice therapy or warm therapy.
- This product is not intended to substitute your doctor's instruction. Consult your physician immediately if you suspect that you have a medical problem.
- This appliance is not designed for use by people (including children) with reduced physical, emotional or mental abilities or those lacking experience or knowledge unless used in the presence of someone responsible for their security, under surveillance or following instructions about how to use the appliance. Children should be supervised around the device to ensure they do not play with it.
- The patient is an intended operator.

1.2 Warning

- Do not expose the product to fire, high temperature, high humidity, direct sunlight or excessive physical shock.

- Do not immerse the product in water, place the product in humid environments, or spill any liquid onto the product.
- Do not expose the product to dust, smoke or steam. Do not allow small particles to get into the product.
- Do not attempt to disassemble the product, or make any modifications to the structure or any parts of it. The product contains no user-serviceable parts.
- Stop using the product if it operates erroneously or shows signs of malfunctioning.
- Remove the batteries and store the product at a cool, dry place if it is not going to be used for a long period of time.
- Keep it out of children's reach.

1.3 Before Use

1. Please place the thermometer in the ambient temperature (16°C-35°C, ≤80%RH) for 30 minutes before use to avoid inaccurate measurements due to possible too cold or too hot environment. Exceeding the specified ambient temperature can result in inaccurate measurement.
2. Please stay inside for at least 20 minutes to keep a stable body temperature.
3. Wait for at least 30 minutes after strenuous exercising before taking a temperature reading.
4. The measuring site is forehead, keep the forehead clean and dry, please wait for 10 seconds for next measurement.

2 Introduction

2.1 General Product Information

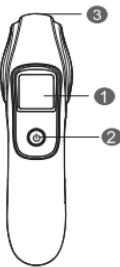
The type RT-101 Infrared Forehead Thermometer mainly consists of LCD display, infrared probe head, PCBA circuit board, plastic shell, button and buzzer.

2.2 Product Function and Intended Use

This product is a high-tech infrared thermometer which is used to measure the temperature of human body by receiving infrared energy from the forehead part of the human body. It can be used in the family and hospital.

2.3 Product Profile

1.LCD screen
2.Switch
3.Infrared detector



2.4 Technical Specifications

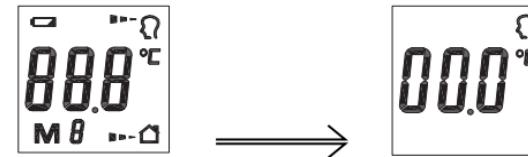
Measurement range	Forehead temperature: 32.0°C–43.0°C
Offset value	32.0°C–34.9°C: ±0.3°C
	35.0°C–42.0°C: ±0.2°C
	42.1°C–43.0°C: ±0.3°C
Display resolution	0.1°C
Measuring distance	0 cm–5 cm
Measurement position	Forehead
Operating environment	Operating temperature: 5°C–40°C
	Relative humidity: ≤ 85%
	Atmospheric Pressure: 700hPa–1060hPa
Storage environment	Storage temperature: –10°C–55°C
	Relative humidity: ≤95%
	Atmospheric Pressure: 700hPa–1060hPa
Power	DC 3V (2x1.5V AAA Battery)
Service life	5 years
Memory function	Stores up to 30groups of measurement values
Indication	If the ambient temperature is not within 5°C–40°C, the LCD screen will display "Err" Measuring temperature: >43.0°C, displays "H °C"; <32.0°C displays "L °C"
Size	165x46x47mm
Weight	85g

3 Operation

3.1 Operating Instructions

- Turn on and prepare for measurement

Press the " " to turn on (with the beep sound and the backlight on), and prepare to test.



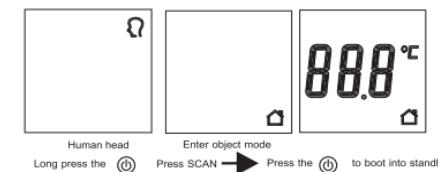
- Body temperature measurement

The forehead thermometer head is aligned with the forehead 0~5 cm, press the scan key, wait for about 2 seconds after you release the beep, read the measurement result.



- Switch object measurement mode

In the off state, press and hold the " " without letting go (about 3 seconds) until the screen displays the " ", in the bottom right part. Press the "Scan" to measure the object temperature. Change to Body temperature mode, In the off state, press and hold the " " without letting go (about 3 seconds) until the screen displays the " ". Press the "Scan" to change to " ", in the upper right part.



- Object temperature measurement

The forehead thermometer's sensor head is aimed at the object 0~5 cm, press the scan button, wait for 2 seconds after releasing it, and the beep will prompt the measurement is completed.



5. Storage / shutdown of measured values

Automatically shut down without re-measurement within 75 seconds, the last measurement result is stored in memory.

6. Memory lookup

In the off state, press "M" for memory look up. Query a group of data each time you can press "M" button



NOTE:

- * Patients and thermometer should stay in steady-state room condition for at least 30 minutes.
- * Don't take a measurement while or immediately after nursing a baby.
- * Don't use the thermometer in high humidity environments.
- * Patients should not drink, eat, or exercise before/while taking the measurement.
- * Don't move the measurement device from the measuring area before hearing the termination beep.
- * Use an alcohol swab to carefully clean the probe and wait for 15 minutes before taking a measurement on another patient.
- * 10 short beeps and a red LCD backlight alert the patient that he/she may have a temperature equal to or higher than 37.5 °C.
- * Always take the temperature in the same location, since temperature readings may vary according to locations.
- * Doctors recommend rectal measurement for newborn infants within the first 6 months, as all other measuring methods might lead to ambiguous results. If using a non-contact thermometer on those infants, we recommend to always verify the readings with a rectal measurement.
- * In the following situations it is recommended that three temperatures are taken and the highest one taken as the reading:
 - * Children under three years of age with a compromised immune system and for whom the presence or absence of fever is critical.
 - * When the user is learning how to use the thermometer for the first time until he/she has familiarized himself/herself with the instrument and obtains consistent readings.

3.2 Symbol Display

Symbol Name	Icon	Instruction	
3-digit display		Measurement results	
Power indication		The batteries can work normally	
		Display	The batteries can only last for a short period and need to be replaced in time
		Flashing	The device cannot work and you need to replace batteries immediately
Temperature unit		Degree Celsius	

4 Cleaning, maintenance and repair

4.1 Cleaning

Use an alcohol swab or cotton tissue moistened with alcohol (70% Isopropyl) to clean the thermometer casing and the measuring probe. Ensure that no liquid enters the interior of the thermometer. Never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the instrument in water or other cleaning liquids. Take care not to scratch the surface of the probe lens and the display. Clean at least once a month. Disabled maintenance equipment without authorization, the user can only replaces the battery, refer to clause 4 Battery.

4.2 Storage

1. Remove the batteries from the device if it is not used for 3 months and above, and store them in the storage box to prevent battery leakage.
2. Never place this product in strong sunlight, dust or pollution environments.

5 Battery

5.1 Use of battery

2 × AAA batteries

5.2 Replacement

Open the battery compartment cover and install two AAA batteries based on their right polarities.

Note: please use disposable alkaline batteries instead of rechargeable batteries.

6 Disposal



Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

7 Warnings and Tips

- (1) The use of this product does not replace the doctor's diagnosis.
- (2) If there is a problem with the product, please contact the distributor and do not attempt to repair it yourself.
- (3) The protective glass outside the LCD frame is very important and also a fragile part of the instrument. Use it with care.
- (4) Do not charge the non-rechargeable battery, do not throw the battery into the fire.
- (5) Please do not expose the product to the sun, nor touch the water.
- (6) The material of the device meets the requirements of ISO10993 series of standards. No Potential allergic reactions.

8 Toxic and hazardous substances or elements in the product and its content

Part Name	Toxic and hazardous substances or elements					
	Pb	Hg	Cd	Cr6+	PBB	PBDE
Printed circuit board assembly	x	o	o	o	o	o
plastic	o	o	o	o	o	o
Metal shell	o	o	o	o	o	o
battery	x	o	o	o	o	o

Remarks:

o : Indicates that the content of the toxic and hazardous substances in all homogeneous materials of the components is below the limit requirement of the SJ / T11363-2006 standard.

x : Indicates that the content of the hazardous material is, at least in a homogeneous material of the part, that exceeds the limit requirement of the SJ / T11363-2006 standard.

9 Troubleshooting

Display symbols	Status	Method of exclusion
Err	Ambient temperature is too cold or too hot, beyond the scope of 5°C~40°C	To the proper ambient temperature, stand for 30 minutes before to start
Err	Ambient temperature changes too fast	Wait until the room temperature is stable, the screen shows "READY" Words, you can start measuring.
Err	System debugging	Please contact the dealer to return to factory repair.
HI LO	The measured temperature is outside the measuring range	This thermometer is designed to measure body temperature only. Do not use the thermometer to measure air or object temperature.
	Insufficient electricity to measure	Please replace the battery immediately
	1) the thermometer has been automatically shut down 2) the battery is not installed 3) The battery is dead 4) If the screen is still blank	1) press the power button to restart 2) Check whether the battery installed backwards 3) replace the new battery 4) Please contact the dealer to return to factory maintenance.

10 Symbols

	Some electrical and electrical equipments forbid to abandon and disposal at will
	Consult Instructions For Use
	Manufacturer's name and address
	Attention consult accompanying documents
	Announcement number institutions
	Type BF equipment
EC REP	Authorized Representative In The European Community

SN	Serial Number
Note: these symbols are on the label.	

11 EMC declaration

⚠ Important Notice

- The Forehead thermometer meets the requirement of electromagnetic compatibility in IEC60601-1-2.
- The user needs to install and use according to electromagnetism compatibility information which is attached with it.
- Portable and mobile RF communication devices may influence the infrared thermometer performance, so The Forehead thermometer should be kept away from them during using.
- Guidance and manufacturer's declaration stated in the appendix.

⚠ Warning:

- The Forehead thermometer should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Forehead thermometer should be observed to verify normal operation in the configuration in which it will be used.
- That operation of the Forehead thermometer below this amplitude or value may cause inaccurate results.

Table 1

Guidance and manufacturer's declaration –electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Forehead 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 B	The Forehead thermometer is suitable for use in all establishments, including domestic establishments 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	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Forehead thermometer requires continued operation during power mains interruptions, it is recommended that the Forehead thermometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity

The Forehead thermometer is intended for use in the electromagnetic environment specified below.

The customer or the user of the Forehead 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	3Vrms 150kHz to 80MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Forehead thermometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <i>a.</i> should be less than the compliance level in each frequency range. <i>b.</i> Interference may occur in the vicinity of equipment marked with the 
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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. 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 field strength in the location in which the Forehead thermometer is used exceeds the applicable RF compliance level above, the infrared thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Forehead thermometer.

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

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity			
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
	0.1	Not applicable	0.38
	1	Not applicable	1.2
	10	Not applicable	3.8
	100	Not applicable	12

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.





中华人民共和国医疗器械注册证

注册证编号：粤械注准 20182200382

注册人名称	东莞市好康电子科技有限公司
注册人住所	东莞市常平镇桥沥村（常黄公路旁）厂房B栋四楼
生产地址	东莞市常平镇桥沥村（常黄公路旁）厂房B栋四楼
产品名称	臂式全自动电子血压计
型号、规格	HK-801、HK-802、HK-803、HK-805、HK-806、HK-807、HK-808、HK-809、HK-810、HK-811
结构及组成	主要由主机和臂带组成。
适用范围	适用于以示波法测量成人的收缩压、舒张压和脉率，其数值供诊断参考。
附 件	产品技术要求。
其他内容	无
备 注	原产品注册证号：粤食药监械（准）字 2014 第 2200293 号 (更)。

审批部门：广东省食品药品监督管理局 批准日期：2018年05月25日
有效期至：2023年05月25日

中华人民共和国医疗器械注册证

注册证编号：粤械注准 20182200302

注册人名称	东莞市好康电子科技有限公司
注册人住所	东莞市常平镇桥沥村（常黄公路旁）厂房B栋四楼
生产地址	东莞市常平镇桥沥村（常黄公路旁）厂房B栋四楼
产品名称	电子体温计
型号、规格	HK-901、HK-902、HK-903、HK-905、HK-906、HK-907、HK-908、HK-909、HK-910、HK-911
结构及组成	主要由感温探测头、控制电路、液晶显示屏和外壳组成。
适用范围	供医疗部门或家庭作测量人体体温使用。
附 件	产品技术要求。
其他内容	无
备 注	原产品注册证号：粤食药监械（准）字 2014 第 2200291 号。

审批部门：广东省食品药品监督管理局 批准日期：2018年05月22日
有效期至：2023年05月22日



商标转让证明

兹核准第 6059269 号商标转让注册。

受让人名称 深圳市瑞尔康科技有限公司

地址 广东省深圳市龙华新区观澜街道凹背社区大富工业区8号汇清科技园
厂房B栋6楼



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注册商标变更证明

兹核准第 6059269 号商标注册人名义/地址变更。

变更后注册人名义 深圳瑞尔康生物科技股份有限公司

地址 广东省深圳市龙华新区观澜街道凹背社区大富工业区8号汇清
科技园厂房B栋6楼



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商标续展注册证明

兹核准第 6059269 号商标第 10 类续展注册。

续展注册有效期至 2029 年 11 月 27 日

发证机关



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