

CARE4U INFRARED FOREHEAD THERMOMETER

1 Second Temperature Measurement

Quick & Accurate

Medical Grade







Thermometers comparison



Mercury thermometer

(Long reading time, broken and toxic)





Electronic thermometer (No body temperature storage)



Voice **Prompt**

Tri-color **Backlight**

Fever Reminder

Probe

Care4u Infrared Forehead Thermometer



Product Features



Care4u Infrared Forehead Thermometer is a new generation of infrared forehead thermometer developed and produced by Hunan Zhongliankang Medical Technology Co., Ltd.





Product Parameters





Infrared non-contact Measurement method: 2~5cm Measuring distance: 32°C~42°C Temperature measurement range: Buzzer, 30 dB, Switch control Sound: Temperature measurement accuracy: ±0.2°C Storage: Store temperature data Battery displayed on screen Low battery reminder: Low power consumption: 15s Automatic shutdown without operation Two AAA batteries Battery:









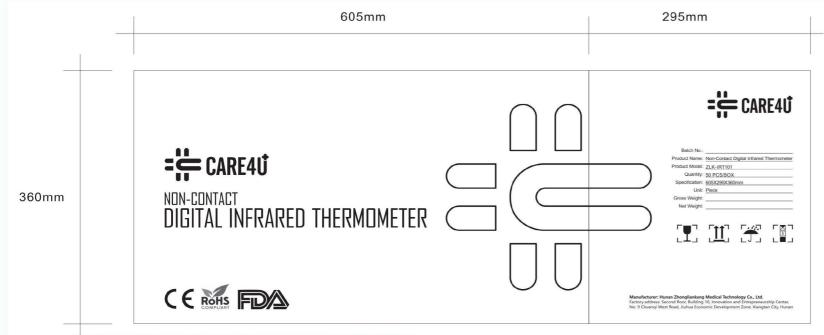


Dimension: 170mm*116mm*55mm



Product Features













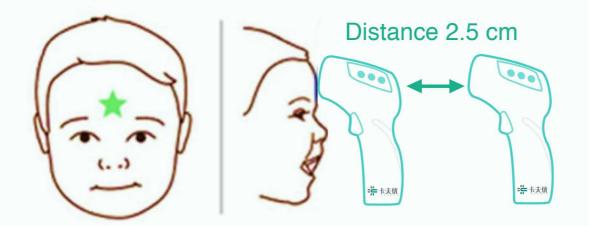


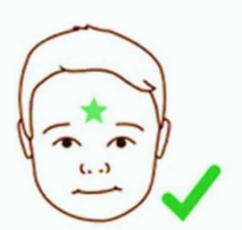


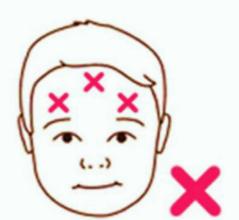
Measurement Method



Place the forehead thermometer within 2-5cm of the forehead, and align it according to the green guide light, The screen displays a horizontal line ("---")









Product Advantages





Non-contact

No contact guarantees the best hygiene, thereby greatly reducing the risk of being tested and the operator being infected by bacterial viruses.



Efficient & Accurate

Simple operation
Non-contact
Sensitive, no need to wait
Accurate measurement



Best Infrared Sensor

Self-developed infrared module accurate to 0.2 °C stable, fast and accurate Strong adaptability 5.5um infrared filter Wide measurement range



Smart Power Saving

Supports automatic shutdown
Two AAA batteries can be
used more than 3000 times



Qualification





Medical Device Business License

经营者中文名称	湖南众连康医疗科技有限公司				
经营者英文名称	Hunan Zhongliankang Medical Technology Co.,Ltd				
组织机构代码	仅供查				
住 所	湖南省湘潭九华经开区传奇西路9号创新创业中心10号楼二层				
经营场所 (中文)	湖南省湘潭九华经	湖南省湘潭九华经开区传奇西路9号创新创业中心10号楼二层			
经营场所 (英文)	Sedond floor, Building 10, Innovation and Entrepreneurship Center, No.9 Chuanqi West Road, Jiuhua Economic Development Zone Xiangtan City, Hunan, PRC				
联系电话	18390222333	联系传真	<u> </u>		
邮政编码	411110	电子邮箱	838333977@qq. com		
工商登记注册日期	2020-2-21	工商登记注册号			
衣法办理工商登记的企	业还须填写以下内容	1013/4	超 4724		
企业法定代表人姓名	戴磊	有效证件号	43030219901010205		
注册资金	登仟万元	453	(折美元)		
依法办理工商登记的外	国 (地区) 企业或个	本工商户(独资经营者	f) 还须填写以下内容		
企业法定代表人/ 个体工商负责人姓名	TO THE STATE OF	有效证件号			
企业资产/个人财产			(折美元)		
备注					
田江					
直表前请认真阅读背面	的条款。并由企业法》	定代表人或个体工商负	责人签字、盖章。		

Export Business License



Qualification







Medical equipment emergency approval notice

Type II medical device business record certificate







中华人民共和国医疗器械注册证

注册证编号: 湘械注准2020207066 77 / # 本

注册人名称	人工 大工 T T
注册人住所	湖南省湘潭市九华经开区传奇西路9号创新创业中心10号楼二层
生产地址	湖南省湘潭市九华经开区传奇西路9号创新创业中心10号楼二层
代理人名称	不适用
代理人住所	不适用
产品名称	额温计
型号、规格	ZLK-IRT101。
结构及组成	产品主要由红外温度传感器、显示单元、供电电路、测量电路组成。
适用范围	适用于采用红外感温方法测量人体额温。
附件	产品技术要求
其他内容	
备注	该产品为应急审批注册。

审批部门:湖南省药品监督管理局

ertificate

CERTIFICATE

Of Conformity

EC Council Directive 2011/65/EU and 2015/863/EU

Certificate No.: SiCT200326105C

Hunan Zhongliankang Medical Technology Co., Ltd.

Second Floor, Building 10, Innovation And Entrepreneurship Center, No. 9 Chuanqi West Road, Jiuhua Economic Development Zone, Xiangtan

SiCTLab

City, Hunan Province

Hunan Zhonglian Kang Marticet Technology Co., Ltd.
Second Floor, Europe Common Addition of Control of Control

City, Hunan Province

Trademark

Test Standard IEC62321-1:2013, IEC62321-3-1:2013, IEC62321-4:2013

IEC62321-5:2013, IEC 62321:6-2015, IEC 62321-7-1:2015 IEC 62321-7-2:2017. IEC 62321-8:2017

The certificate of conformity is based on an evaluation of a sample of the above mentioned product. Technical report is at the applicant disposal. This is to certify the tested sample that is in conformity with all provisions of above RoHS 2.0 Directive (EU) 2015/863 and (EU)2017/2102 amending Annex II to Directive 2011/65/EU . It is only valid in connection with the test report number SiCT200326105R.

The certificate does not imply the assessment of the production and does the SiCT's logo without permission.

RoHS

Shenzhen SiCT Technology Co., Ltd.

4F, Building A, EDerH Industrial District, Fukang Community, Longhua Subdistrict, Longhua District, Shenzhen, Guangdong, P. R. China E-mail: info@sict-lab.com Http:// www.sict-lab.com.cn









墙栗

本次临床试验的目的是使用湖南众连康医疗科技有限公司生产的额温计(型号。 ZLK-IRT101)对成人和小儿及新生儿体温测量,通过对记录结果的统计分析来确认 ZLK-IRT101 临床重复性和临床准确度是否满足以下要求。

1) 临床重复性不应超过±0.3℃ 范围; 2) 临床准确度应符合使用说明书的宣称值。

为了明确其临床重复性和临床准确度是否在标准范围之内,需要进一步的临床试验,参照 GB/T21417-2008 附录 A 推荐的试验方法,制定了科学的临床试验方案,并通过临床试验得出明 确的结论。

本次临床试验受试对象总数共 160 个,年龄最大者 68 岁、最小者 1 个月,使用额温计对 人体额头进行了测试,年龄分布区间:0~1 岁: 55 人:1~5 岁: 50 人:5 岁以上: 55 人: 临床试验开始于 2020 年 03 月 13 日 结束: 2020 年 03 月 16 日

测试对象在临床试验过程中,情况良好,没有一例测试对象因 ZLK-IRT101 的测量而产生不 适症或不良反应。临床试验过程中共测得数据 160 组,经统计后得到的结果如下:

(D)

试验项目	小组			
	0~1岁	1~5岁	5岁以上	
临床重复性 [^] S _R	0.08	0.12	0.05	
临床偏差 Atb	-0.128	7世十	杏素	
临床偏差 Sb	0.188	0.95	里海	

通过临床试验验证,所有年龄组的临床重复性均落在标准要求的范围±0.3°C之内,符合临床 重复性的要求,所有小组的临床准确度(临床偏差和临床标准偏差)均在说明要求的±0.2°C之 由

90 2 00 H 18 00



Export Certification





CE Certificate



FDA Certificate









Forehead thermometer test report



Test Report



Quality Control



By controlling the unstable factors such as operators, equipment, materials, operating methods and test environment, the quality is controlled according to the "three-requires" and "three-checks" principles.

Process control: assembly line, mutual check process

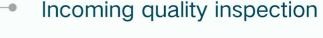
- 1. Process quality management;
- 2. Independent inspection by operators;

Aging test •

Room isolation aging

- 3. Process inspection
- 4. Handling abnormal quality;
- 5. Segmentation and identification of bad products, bad statistics





1 Quality inspection of all assembly and procurement materials according to standards







- Component stress test;
- 2. Hardware reliability test;
- 3. Automated software reliability test;
- 4. Real environment simulation test

Reliability test



Introduction of Industrial Park











The company's production address is the second floor of Building 10, Innovation and Entrepreneurship Center, No. 9 Chuanxi West Road, Jiuhua Economic Development Zone, Xiangtan City, Hunan Province. The building area is about 4,000 square meters, the production workshop area is about 1760 square meters, and the office area is about 980 square meters. The warehouse area is about 486 square meters and the inspection area is about 160 square meters. The company's office area, production workshop and storage space are all independent. The company's workplace and production and inspection equipment are determined to meet the characteristics and processing requirements of the thermometer.





Add: 36F, High-Tech Zone Union Tower, No. 63, Xuefu Road, Nanshan District, Shenzhen, Guangdong, China