TP500 PRODUCT MANUALS



PERFORMANCE PARAMETERS

Name	Infrared Thcrmometer		
Model	TP500		
Display range	32.0°C∼43°C		
Max.allowable error	35.0°C~42.0°C:±0.2°C		
Max.allowable clinical repeatability	<±0.3°C		
Resolution	0.1°C		
Power supply	DC 3V(2 AAA batteries)		
Measurement time	<1s		
Display	LCD screen		
Normal working and	16°C~35°C ≤85% (no condensation)		
storage condition	-20°C~+55°C RH≤95% (no condensation)		
Memory 30 groups of data			

BUTTON AND PARAMETER SETTING

- 1) In device off state, pressing the button could turn on the device, and the device performs self-test, after self-test is completed, it enters startup interface and makes a beep sound, if self-test fails, it prompts for failure on the screen.
 - 2) In device on state, short press the button to start measuring.
 - 3) In device on state, long press the button to enter review interface.
 - 4) In review interface, long press the button to enter parameter setting interface. In the setting interface, short press button to switch items, when the cursor moves to the item to be set, long press the button to make it under selected state, then short press button to adjust its parameter. After setting the parameters, long press the button to save and exit.

Parameters in the following can be set

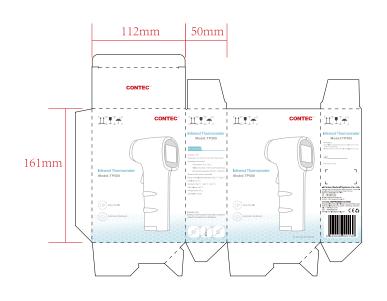
- ① Sound prompt
- ② Unit: °C and °F
- ③ Mode: User can switch the mode to "Obj" (calibration mode). This setting will not be saved, the device automatically enters "Body "mode after restart.

Note: The body temperature is different from the temperature. In "Body" mode, the device measures the uman body temperature, and in "Object"mode, it measures the skin temperature. Please be sure to select the Body mode when measuring body temperature.

NOTE

- Please refer to the maintenance instructions for product inspection before preparing for measureme.
- If the device is not used for a long time, please remove the batteries to prevent battery leakage causing device damage.
- Please pay attention to the polarity of the battery. Wrong installationmay cause device damage.
- Rechargeable battery is not allowed to use on the device. Only single-purpose battery can be used. Do not throw used batteries into fire
- The disposal of waste batteries should follow local environmental protection regulations.

PRODUCT PACKAGING





Positive packaging

Reverse packing

single box: 149.5*96.8*43.5 mm

net weight: 130G/box

sealing: 50/box

box: 58*27*35CM

Gross Weight: 6.5KG/box

PRODUCT IMAGE







DECLARATION OF CONFORMITY

符合性声明

Manufacturer: CONTEC MEDICAL SYSTEMS CO., LTD.

制造商 No.112 Qinhuang West Street,

Economic & Technical Development Zone, 066004,Qinhuangdao,Hebei Province, PEOPLE'S REPUBLIC OF CHINA 康泰医学系统(秦皇岛)股份有限公司

EC- Representative: Shanghai International Holding

欧盟授权代表 Corp. GmbH(Europe)

Eiffestrasse 80, 20537 Hamburg Germany

上海国际(欧洲)集团公司

Product Category/ Model(s): INFRARED THERMOMETER/TP500;TP600

产品型号 红外测温仪/**TP500:TP600**

CE Mark: CE 标志

The product of the declaration described above is in conformity with:

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

The product is non-medical device.

本声明描述的产品符合: 2014/30/EU 指令, 欧洲议会和理事会 2014/2/26 发布的关于协调成员国有关电磁兼容性的法令。

本产品为非医疗器械。

This declaration of conformity is issued under the sole responsibility of the manufacturer. 本声明由制造商负责发布。

Standard(S) applied : IEC60335-1:2010+AMD1:2013+AMD2:2016

适用标准 CISPR 14-1:2016/EN 55014-1: 2017

CISPR 14-2:2015/EN 55014-2: 2015

Signed for and on behalf of: CONTEC MEDICAL SYSTEMS CO., LTD.

签署代表 康泰医学系统 (秦皇岛) 股份有限公司

Place and Date of Issue: Qinhuangdao, CHINA Date: 2020/03/24

签发地点及日期 秦皇岛,中国

Hu kun, CEO (Signature):

胡坤, CEO

市局的

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中华人民共和国 PEOPLE'S REPUBLIC OF CHINA 医疗器械产品出口销售证明 CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: 冀秦药监械出 20200016

Certificate NO.: Certificate of medical device exports made in Qinhuangdao issued by Hebei Drug Supervision Administration No. 20200016

产品名称: 详见附表

Product(s): Details as per attached list.

规格型号: 详见附表

Model: Details as per attached list.

产品注册或备案凭证号: 详见附表

Registration certificate(s): Details as per attached list.

生产企业: 康泰医学系统 (秦皇岛) 股份有限公司 Manufacturer: Contec medical systems co., Ltd

生产企业住所:中国河北省秦皇岛市开发区秦皇西大街 112 号

Address of manufacturer: No. 112 Qinhuang West Street, Economic & Technical Development Zone 066004, Qinhuangdao, Hebei province, P. R. China

生产许可或备案凭证号: 冀食药监械生产许 20150049 号

Manufacturing License(s): Hehei Province Food and Drug Supervision Administration of Medical Device Manufacturing License No. 20150049

兹证明上述产品已准许在中国生产和销售。 This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至: 2021年02月17日 This certification valid until: Feb. 17,2021

备注: 无 Remark: 无





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序号	产品名称 中文	产品。據英獎用	规格型号	规格型号	注册证号	注册证号英文
	/Chinese	/English	中文	英文	中文	/English
			/Chinese	/English	/Chinese	
1	医用红外体温计	Infrared Thermometer	TP500、T P600	TP500、 TP600	冀械注准 20202070 066	Registration of Medical Devices approved by Hebei Food and Drug Supervision Administration No.20202070066

中华人民共和国医疗器械注册证

注册证编号: 冀械注准 20202070176

注册人名称	康泰医学系统 (秦皇岛) 股份有限公司		
注册人住所	秦皇岛市经济技术开发区秦皇西大街 112 号		
生产地址	秦皇岛市经济技术开发区秦皇西大街 112 号		
代理人名称	不适用		
代理人住所	不适用		
产品名称	产品名称 医用红外体温计		
型号、规格	TP500/TP600		
结构及组成	产品主要由外壳、电路板、温度测量部件、显示屏、电源组成。电路板由信号放大部分、MCU 处理单元、显示控制单元组成;温度测量部件温度传感器、传感器隔热部件组成。		
适用范围	用于测量患者额头部位温度。		
附件	产品技术要求		
其他内容			
备 注	以 品监		
	10000000000000000000000000000000000000		

审批部门:河北省药品监督管理局

批准日期: 2020年3月26日

有效期至: 2025年3月25日

授权书

康泰医学系统(秦皇岛)股份有限公司授权深圳市智慧湾科技有限公司经营我公司生产的医用红外体温计,望各方予以协助!

授权时间: 2020年3月9日至2023年3月8日

特此授权!

康泰医学系统(秦皇岛)股份有限公司 2020年3月9日