CE认证发证机构为 ECM

Form QAT_10-M05, version 00, effective since March 25th, 2020

Certificate of Compliance

No. 0H200404.HHEDO66



Certificate's Holder:

Hunan Honggao Electronic Technology

Co., Ltd.

Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park, Nanxian Economic Development Zone, Yiyang, Hunan Province.

Certification ECM Mark:



Product: Model(s):

Infrared Forehead Thermometer

HG01, HG02, HG03, HG04, HG05, HG06, HGB01, HGB02, HGB03, HGB04, HGB05, HGB06, F101,

F102, F103

Verification to:

Standard:

EN 60601-1:2006+A11:2011+A1:2013+A12:2014, EN 55011:2016+A1:2017, EN 60601-1-2:2017, EN 61000-3-2:2014, EN 61000-3-3:2013

related to CE Directive(s): 2014/35/EU (Low Voltage)

2014/30/EU (Electromagnetic Compatibility)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 04 April 2020 Expiry date: 03 April 2025

> Reviewer Technical expert Amanda Payne

Approver ECM Service Director Luca Bedonni

Ente Certificazione Macchine Srl

Via Castello, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) → ALY 3 +39 051 6705141
4 +39 051 6705156
info@entecerma.it
www.entecerma.it

美国FDA认证





Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

HUNAN HONGGAO ELECTRONIC TECHNOLOGY CO., LTD

Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park, Nanxian Economic Development Zone Yiyang, Hunan, 431200, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10064921

Listing No.

Product Code:

Device Name:

D380324

PXH

Thermometer kit

Medical infrared thermometer HG01 HG02、HG03、HG04、HG05、HG06 HGB01、HGB02、HGB03、HGB04、HGB05、HGB06

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder,

for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S.Food and Drug Administration does not issue a certificate of registration, nor does the U.S Food and Drug Administration recognize a certificate of registration, UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.



UCL-REGSERVICE INC.
602 ROCKWOOD ROAD, WILMINGTON,
NEW CASTLE DE 19802 USA

UCL-REG SERVICE INC

suchorites Skensture(s)

Cert. No.: M20710 Issued Date: 27 March 2020 Expiration Date: 31 December 2020



SDoC's Compliance Information Statement

No.: PTC20031812401E-FC01

Applicant : Hunan Honggao Electronic Technology Co., Ltd

Address : Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park,

Nanxian Economic Development Zone, Yiyang, Hunan Province

Manufacturer : Hunan Honggao Electronic Technology Co., Ltd

Address : Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park,

Nanxian Economic Development Zone, Yiyang, Hunan Province

Trade Mark : N/A

Product : Infrared Thermometer

Model No. : HG01; HG02; HG03; HG04; HG05; HG06; HGB01; HGB02; HGB03;

HGB04; HGB05; HGB06; F101; F102; F103

The submitted sample of the above equipment has been tested and found to comply with the following requirement of 47 CFR of PART 15.

The assessment of compliance of the product with the requirements relating to FCC rules was based on the following standards and procedure:

Applicable Standard(s)	Test Report(s) Number
FCC Part 15, Subpart B ANSI C63.4:2014	PTC20031812401E-FC01

This verification is part of the full test report(s) and should be read in conjunction with it. This verification is based on an evaluation of one sample of above mentioned product. It does not imply assessment of the production of the product. Without the written approval of Precise Testing & Certification (Guangdong) Co., Ltd., this verification is not permitted to be reproduced, except in full. It is not permitted to use the test lab's logo.





Jacky Ou Manager

Date: March 25, 2020

Precise Testing & Certification (Guangdong) Co., Ltd. Building 1, No.6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China

Tel: 86 769 38808222 Web:www.ptc-testing.com

Mail: inquiry@ptc-testing.com









CERTIFICATE OF CONFORMITY

No.: PTC20031202601C-CP01

Applicant : Hunan Honggao Electronic Technology Co., Ltd

Address : Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park,

Nanxian Economic Development Zone, Yiyang, Hunan Province

Manufacturer : Hunan Honggao Electronic Technology Co., Ltd

Address : Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park,

Nanxian Economic Development Zone, Yiyang, Hunan Province

TradeMark : /

ProductName : Infrared thermometer

ModelNo. : HG01、HG02、HG03、HG04、HG05、HG06、HGB01、HGB02、

HGB03、HGB04、HGB05、HGB06、F101、F102、F103

The submitted sample of the above equipment has been tested and found to comply with the following European Directive:

RoHSDirective2011/65/EU&EUNo.2015/863

Thestandard(s)usedforshowingcompliancewiththeessentialrequirements:

Applicable Standard(s)	Test Report(s) Number	
IEC 62321-1:2013, IEC 62321-2:2013		
IEC 62321-3-1:2013, IEC 62321-3-2:2013		
IEC 62321-4:2013, IEC 62321-5:2013	PTC20031202601C-CP01	
IEC 62321-6:2015, IEC 62321-7-1: 2015		
IEC 62321-7-2: 2017, IEC 62321-8:2017		

Thiscertificate is part of the full test report (s) and should be read in conjunction with it. This certificate is based on an evaluation of one sample of above mentioned product. It does not imply assessment of the production of the product. Without the written approval of Precise Testing & Certification (Guangdong) Co., Ltd., this certificate is not permitted to be reproduced, except in full. It is not permitted to use the test lab's logo.

RoHS



JackyOu Manager Date:Mar.23,2020

Precise Testing & Certification (Guangdong) Co., Ltd. Building 1, No.6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China

Tel: 86 769 38808222 Web:www.ptc-testing.com

Mail: inquiry@ptc-testing.com





Certificate of Registration



The Governing Board of ARES INTERNATIONAL CERTIFICATION CO., LTD. hereby grants to:

Hunan Honggao Electronic Technology Co., Ltd.

(Organization Credit Code: 91430921MA4R0CBE69)

Building 5, Tenghui Pioneer Park Comprehensive Industrial Park, Nanxian Economic Development Zone, Yiyang City, Hunan Province, P.R. China

Has been assessed and found to be in accordance with the requirements of standard detailed below

YY/T0287-2017/ISO13485:2016

Scope

The Design and Production of Infrared Thermometer

Authorized by : Chions Junean



Certificate Number: ARES/CN/G2003073M Initial Certificate Date: 2020-04-15

Registration Expiration Date: 2023-04-14

Note: The time interval between each surveillance audit and the last on-site audit shall not exceed 12 months, and the organization must obtain "surveillance audit approval notification" issued by ARES to ensure the validity of the certificate



ARES INTERNATIONAL CERTIFICATION CO., LTD.

No.12-2, Ln.187, Wenping Rd., Anping Dist., Tainan City 708, Taiwan

TEL: +886-6-2959696 FAX: +886-6-2959667

www.ares-registration.com

Check the validity of certificate at www.cnca.gov.cn or www.

ares-china.cn



Certificate of Registration



The Governing Board of ARES INTERNATIONAL CERTIFICATION CO., LTD. hereby grants to:

> 湖南泓高电子科技有限公司 (统一社会信用代码: 91430921MA4ROCBE69)

中国湖南省益阳市南县经济开发区 腾辉创业园综合产业园 5号栋

医疗器械质量管理体系符合

YY/T0287-2017/ISO13485:2016

认证范围 红外测温仪的设计和生产

批准: Chiors powon



证书编号: ARES/CN/G2003073M 证书签发日期: 2020年04月15日

注册有效日期: 2023年04月14日

注: 每次监督审核时间与上次现场审核时间间隔不得超过12个月,且必须取得ARES签发的监督审核通过证明以确保证书有效性。



ARES INTERNATIONAL CERTIFICATION CO., LTD.

No.12-2, Ln.187, Wenping Rd., Anping Dist., Tainan City 708, Taiwan

TEL: +886-6-2959696 FAX: +886-6-2959667

www.ares-registration.com

Check the validity of certificate at www.cnca.gov.cn or www.

ares-china.cn









中国认可 国际互认 检测 **TESTING CNAS L0095**

共 37 页 第 1 页

No. WTS2020-3934-1

检测报告 TEST REPORT

产品名称: NAME OF SAMPLE	医用红外体温计	
受检单位: CLIENT	湖南泓高电子科技有限公司	
检测类别: CLASSIFICATION OF TEST	委托检测	







Soupethe



中国认可 国际互认 检测 TESTING CNAS L5772

EN 60601-1: 2006

Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Report Reference No. PTC20031202601S-LD01

Date of issue...... March 17, 2020

Tested by Soap Hu

(name + signature).....:

Approved by (name + signature).....: Chris Du

Testing Laboratory Precise Testing & Certification (Guangdong) Co., Ltd.

Address....... Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan,

Guangdong, China.

Applicant's name Hunan Honggao Electronic Technology Co., Ltd

Address...... Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park,

Nanxian Economic Development Zone, Yiyang, Hunan Province

Test specification:

Standard EN 60601-1: 2006 + A11:2011 + A1:2013 + A12:2014

Test procedure...... IEC Report

Non-standard test method...... N/A

Test Report Form No...... IEC60601_1P

Test Report Form(s) Originator: UL(US)

Master TRF...... 2019-10-11

Test item description: Infrared Thermometer

Trade Mark.....: N/A

Manufacturer: Same as Applicant

Address..... Same as Applicant

HGB03, HGB04, HGB05, HGB06, F101, F102, F103

Ratings.....: Battery: DC 3.0V

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: 湘药监械出 20200050 号 Certificate NO.: HNMPA 20200050

产品名称: 医用红外额温计

Product(s): Medical infrared thermometer

规格型号: HG01, HG02, HG03

specification and type: HG01, HG02, HG03

产品注册或备案凭证号: 湘城注准 20202070605

Registration certificate(s): Hunan Medical Devices Registration

Certificate No. 20202070605

生产企业: 湖南泓高电子科技有限公司

Manufacturer: Hunan Honggao Electronic Technology Co., Ltd

生产企业住所: 湖南省益阳市南县经济开发区腾辉创业园综合产业园 5 号栋 Address of manufacturer: Building No. 5, Tenghui business park, Economic Development Zone, Nanxian County, Yiyang City, Hunan Province, China

生产许可或备案凭证号: 湘食药监械生产许 20200041 号 Manufacturing License(s): Hunan CFDA production permit NO. 20200041

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: 2022年3月31日

This certification valid until: Mar. 31, 2022

湖南省药品监督管理局 HUNAN MEDICAL PRODUCTS ADMINISTRATION

> 2020年4月1日 Apr. 1, 2020

泓高营业执照副本 统一社会信用代码91430921MA4R0CBE69



国家企业信用信息公示系统网址: http://www.gsxt.gov.cn

家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监

海关进出口货物收发货人备案回执

企业名称	湖南泓高电子科技有限公司
统一社会信用代码	91 430921 MA4ROCBE69
海关备案日期	2020-03-20
海关编码	43099609CE
检验检疫备案号	4354500048
有效期	长期

益阳海关 2020年3月20日

自然人、法人或者非法人组织可通过"中国海关企业进出口信用信息公示平台" (http://credit.customs.gov.cn) 或者 "互联网+海关" (http://online.customs.gov.cn) 查询海关公示的企业信息。

泓高医疗器械生产许可证 湘食药监械生产许20200041

医疗器械生产许可证

DESENDED DE SONDE SE DE SE DE

许可证编号:

湘食药监械生产许20200041号

企业名称:

湖南泓高电子科技有限公司

生产地址:

湖南省益阳市南县经济开发区腾辉创业

园综合产业园5号栋

法定代表人: 聂永富

生产范围:

II类: 07-03 生理参数分析测量设备

企业负责人: 聂文芳

住

F. 湖南省益阳市南县

发证部门:

()

有效期限:至

2025

03日

发证日期:

2020年

03月 23 日

中国海关企业进出口信用信息公示平台



企业名称或统一社会信用代码

搜索

湖南泓高电子科技有限公司

统一社会信用代码: 91430921MA4R0CBE69 海关编码: 43099609CE 注册海关: 益阳海关

经营类别:进出口货物收发货人

白名单企业

尺寸: 70X60mm

QUALIFIED CERTIFICATE

合格证

Product Name: 产品名称	Medical infrared thermometer
Item NO 型号	医用红外额温计 HG01
Brand 品牌	DIKANG 滴康
制造商 Manufacturer	Hunan Honggao Electronic TechnologyCo.,Ltd 湖南泓高电子科,有效公司
地址 Address	Block 5,Comprehensive Industrial Park, lenghuiPioneer Park,Nanxian Economic Development Zone,Yiyang, Hunan Province 世南省益四 南县祭交升发区腾辉创业园综合产业园5号
Medical device registration number: 注册证号	湘械注准2020207605
Medical device manufacturer license number: 生产许可证号	湘食药监械生产许20200041
Executive Standard: 执行标准	GB/T 21417. 1-2008; GB 9706. 1-2007; YY 0505-2012
Batch No.: ク ク ク ク ク ク ク ク ク ク	202004-16
mix号 202051 Date of manufacture 20051 生产日期	DACC
Preservative Period: 有效期	2 years
Inspector: 检验员	02

A fter inspected, confirm the product meets quality requirements of the standard.经检查,产品符合标准规定的质量要求。

中国国际贸易促进委员会

China Council for the Promotion of International Trade China Chamber of International Commerce

证明书

CERTIFICATE



号码 No. 204300B0/001196

兹证明: 所附由湖南省药品监督管理局颁发的第湘药监械出 20200050号中华人民共和国医疗器械产品出口销售证 明的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS OF THE PEOPLE'S REPUBLIC OF CHINA NO. HNMPA20200050 issued by HUNAN MEDICAL PRODUCTS ADMINISTRATION is in conformity with the original.

China Council for the Promotion of International Trade

授权签字:

Authorized Signature:

ZHANG XIAOLING

日期: 2020年05月19日 (Date: May. 19, 2020)

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: 湘药监械出 20200050 号 Certificate NO.: HNMPA 20200050

产品名称: 医用红外额温计

Product(s): Medical infrared thermometer

规格型号: HG01, HG02, HG03

specification and type: HG01, HG02, HG03

产品注册或备案凭证号: 湘械注准 20202070605

Registration certificate(s): Hunan Medical Devices Registration

Certificate No. 20202070605

生产企业: 湖南泓高电子科技有限公司

Manufacturer: Hunan Honggao Electronic Technology Co., Ltd

生产企业住所: 湖南省益阳市南县经济开发区腾辉创业园综合产业园 5号栋 Address of manufacturer: Building No. 5, Tenghui business park, Economic Development Zone, Nanxian County, Yiyang City, Hunan Province, China

生产许可或备案凭证号: 湘食药监械生产许 20200041 号

Manufacturing License(s): Hunan CFDA production permit NO. 20200041

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: 2022年3月31日

This certification valid until: Mar. 31, 2022

湖南省药品监督管理局 HUNAN MEDICAL PRODUCTS ADMINISTRATION

> 2020年 4月1日 Apr. 1, 2020





FI-45054

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

CB TEST CERTIFICATE

Product

Name and address of the applicant

Name and address of the manufacturer

Name and address of the factory

Note: When more than one factory, please report on page 2

Ratings and principal characteristics

Trademark / Brand (if any)

Customer's Testing Facility (CTF) Stage used

Model / Type Ref.

Additional information (if necessary may also be reported on page 2)

A sample of the product was tested and found to be in conformity with

As shown in the Test Report Ref. No. which forms part of this Certificate

Medical Infrared Forehead Thermometer

Hunan Honggao Electronic Technology Co., Ltd. Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park, Nanxian Economic Development Zone, Yiyang, Hunan, China

Hunan Honggao Electronic Technology Co., Ltd. Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park, Nanxian Economic Development Zone, Yiyang, Hunan, China

Hunan Honggao Electronic Technology Co., Ltd.

Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park, Nanxian Economic Development Zone, Yiyang, Hunan, China

☐ Additional Information on page 2

DC 3,0 V (powered by 2 x AAA batteries); IP22

DIKANG

HG01 V1, HG01 V2, HG02 V1, HG04, HG05, HG06

☐ Additional Information on page 2

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012

IEC 60601-1-11:2015

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013

SGS Fimko Ltd.

ISO 80601-2-56:2017,

ISO 80601-2-56:2017/AMD1:2018

National Differences:

US

GZES200501813401, GZES200501813402, GZES200501813403, GZES200501813404

This CB Test Certificate is issued by the National Certification Body

SGS Fimko Ltd.
Takomotie 8
FL-00380 Helsinki, Fin

FI-00380 Helsinki, Finland

Date: 2020-06-05 Signat

Signature:

Jason Hoo Certification Manager

Issued 2018-06-05

1/1

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.



Test Report No.: GZES200501813405

Date: 2020-06-05

The following sample(s) was/were submitted and identified on behalf of the client as:

Applicant: Hunan Honggao Electronic Technology Co., Ltd

Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park, Nanxian

Economic Development Zone, Yiyang, Hunan, China

Manufacturer: Same as applicant

Factory: Same as applicant

Testing Laboratory: SGS-CSTC Standards Technical Services Co. Ltd. Guangzhou Branci

198 Kezhu Road, Science City, Economic & Technology Development Area,

Guangzhou, Guangdong, China

The standards: ASTM E 1965-98 (Reapproved 2009)

Test item description: Medical Infrared Forehead Thermometer

Model/Type reference: HG01 V1, HG01 V2, HG02 V1, HG04, HG05, HG06

Ratings: DC 3,0 V (powered by 2 x AAA batteries); IP22

Test result: In the opinion of SGS – CSTC the presented appliance was found to be in

compliance with the test specification as indicated in the details on the

following pages.

Remark: None

Gary Guo

Project Reviewer

George Gu

Project Engineer

Medical Electrical Equipment Laboratory



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M. Birgischi volta strate hat, Garagita Strate hat Garagita (Dire 510663 1 (86-20) 82155555 † (86-20) 82075058 www.sgsgroup.com.ci 中国・广州・経済技术开发区科学域科珠路198号 邮線: 510663 1 (86-20) 82155555 † (86-20) 82075058 sgs.china@sgs.com



Report No.: GZES200501813405

Date: 2020-06-05

Summary of testing:

Tests according to the following standard were carried out:

ASTM E 1965-98 (Reapproved 2009)

The submitted sample fulfilled the requirements of specified standard except the following clauses were not evaluated in this test report according to applicant's requirement:

Clause 5.5 Special Requirements about clinical Accuracy, clause 6.2 Clinical Accuracy Tests and clause 7.4 Accuracy determination;

Clause 5.2.2 Displayed Temperature Range;

Clause 5.6.4 Storage Conditions and clause 6.1.6 Storage Test;

Clause 6.5 Electrostatic Discharge Tests;

Clause 7.2.1.3 Body site(s) used as a reference;

Clause 5.9.1 Housing Materials.

Model HG01 V1, HG01 V2 and HG02 V1 were subjected to full tests.

The remaining models were subjected to construction check only

TRF No.: ASTM E 1965-98(Reapproved 2009)b



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is 19kath Rod. Santah Pat, Garaphu Einning 1 Technisg Developer District, Gangstou, Orins 510663 1 (88-20) 82155555 † (86-20) 82075056 www.sgs.group.com.cr 中国・广州・经济技术开发区科学城科琼路198号 鄭錦: 510863 1 (86-20) 82155555 1 (86-20) 820750568 sgs.chlina@sgs.com



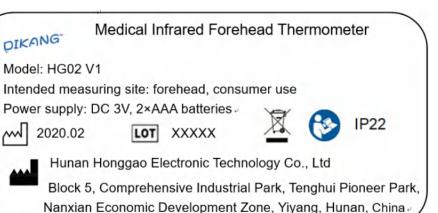
Report No.: GZES200501813405

Date: 2020-06-05

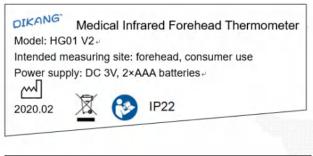
Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs or NBs that own these marks.

HG02 V1 Label



Remark: the marking of HG02 V1 and HG05 are indentical except the model number HG01 V2 Label





Remark: the marking of HG01 V1, HG06, HG04 and HG01 V2 are indentical except the model number

TRF No.: ASTM E 1965-98(Reapproved 2009)b



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Report No.: GZES200501813405

Date: 2020-06-05

Battery compartment marking for HG01 V2



Battery compartment marking for HG01 V1



Battery compartment marking for HG02 V1



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Test Report No.: GZES200501813405

Date: 2020-06-05

Test item particulars	Medical Infrared Forehead Thermometer
Classification of installation and use	Hand-held equipment
Supply connection	Internally powered equipment
Possible test case verdicts:	
- test case does not apply to the test object:	N/A
- test object does meet the requirement:	P (Pass)
- test object does not meet the requirement:	F (Fail)
- test object was not evaluated for the requirement:	N/E
Testing	
Date of receipt of test item	2020-05-21
Date (s) of performance of tests	2020-05-21 to 2020-06-05

General remarks:

The test results presented in this report relate only to the object tested.

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Throughout this report a comma is used as the decimal separator.

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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Report No.: GZES200501813405

Date: 2020-06-05

General product information:

Infrared thermometer is intended to measure forehead temperature at home and in public. The thermometer can be used for infants, children and adults.

It has two measurement modes: Body mode and object mode, Body mode is an adjusted mode and object mode is direct mode.

Object mode is not intended for clinical use, which was not evaluated in this report.

Measuring site: forehead. Reference body site: axilla.

Infrared thermometer is non-contact thermometer, it has no applied part.

The IP degree of enclosure is IP22.

The measuring rated output range is from 32,0 °C to 43,0 °C.

Operating ambient temperature of this product is:

Temperature: +15 °C to +40 °C Relative Humidity: ≤ 95%

Atmospheric pressure: 70 kPa -106 kPa

According to the declaration of applicant and construction check,

HG01 V2 and HG04 are identical except for model name; HG02 V1 and HG05 are identical except for model name; HG01 V1 and HG06 are identical except for model name

HG01 V2, HG01 V1 and HG02 V1 are identical in critical components, with differences being that the electric circuit, PCB layout, construction, shape of enclosure, control button and LCD displayer.

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ASTM E 1965-98 (2009)			
Clause	Requirement	Remarks	Verdict
4	Classification		Р
4.1	IR thermometers may be classified into two types: "ear canal IR thermometers" and "skin IR thermometers."	skin IR thermometers	Р
4.1.1	The ear canal IR thermometer is intended for assessing the internal temperature of a subject		N/A
4.1.2	The skin IR thermometer is intended for assessing the outer surface temperature of a subject		Р
5	Requirement		Р
5.1	The following requirements shall apply to any IR thermometer that is labeled to meet these specifications		Р
5.2	Displayed Temperature Range:		Р
5.2.1	In any display mode, an ear canal IR thermometer shall display a subject's temperature over a minimum range of 34.4 to 42.2 °C (94.0 to 108.0 °F)		N/A
5.2.2	A skin IR thermometer shall display a subject's temperature over a minimum range of 22 to 40.0 °C (71.6 to 104.0 °F)	Only for forehead with the range: 32,0 °C to 43,0 °C	N/E
5.3	Maximum Permissible Laboratory Error (for an Ear Canal IR Thermometer):		N/A
5.3.1	Within the manufacturer's specified operating ambient conditions (see 5.6), laboratory error δ as measured according to 6.1.4 shall be no greater than values specified below:	(see clause 6.1.4 and appended table 5.3.1)	N/A
5.3.1.1	For blackbody temperature range from 36 to 39 °C (96.8 to 102.2 °F) 0.2 °C (0.4 °F)		N/A
5.3.1.2	For blackbody temperatures less than 36 °C (96.8 °F) or greater than 39 °C (102.2 °F) 0.3 °C (0.5 °F).		N/A
5.4	Maximum Permissible Laboratory Error (for a	Skin IR Thermometer):	Р
5.4.1	Within the manufacturer's specified operating ambient conditions (see 5.6) over the display temperature range as specified in 5.2.2, laboratory error d as measured according to 6.1.5 shall be no greater than 0.3 °C (0.5 °F)	(see clause 6.1.5 and appended table 5.4.1)	Р



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	ASTM E 1965-98 (2009)	
Clause	Requirement	Remarks	Verdict
5.5	Special Requirements:	,	N/E
5.5.1	Clinical Accuracy:		N/E
5.5.1.1	The clinical accuracy requirement is applicable only to an ear canal IR thermometer system and the corresponding age groups of subjects for which such thermometer is labelled or implied to be used	Clinical Accuracy was not evaluated in this report.	N/E
5.5.1.2	Clinical accuracy shall be determined separately for each of the following conditions: for each device model, for each adjusted display mode, and for every age group of febrile and afebrile subjects on which the IR thermometer is intended to be used.		N/E
5.5.1.3	Any disclosure of clinical accuracy claims shall be accompanied by disclosure of methodology and procedures. Such information shall be made available on request		N/E
5.5.1.4	Clinical accuracy should be determined in form of two characteristics—clinical bias with stated uncertainty and clinical repeatability, as defined in 3.2.8		N/E
5.6	Ambient Conditions:		Р
5.6.1	Operating Temperature Range:		Р
5.6.1.1	The system shall meet laboratory error requirements as specified in 5.3 or 5.4, or both, when operating in an environment from 16 to 40 °C (60.8 to 104.0 °F).	15°C to 40°C (50 °F to 104 °F)	Р
5.6.1.2	If the operating temperature range is narrower than specified in 5.6.1.1, the device shall be clearly labeled with a cautionary statement of the maximum or minimum operating temperatures, or both		N/A
5.6.1.3	Under no circumstances may the upper limit of operating temperature range be less than 35 °C (95 °F).	The upper limit: 40°C (104 °F)	Р
5.6.2	Operating Humidity Range—The relative humidity range for the operating temperature range as specified in 5.6.1 is up to 95 %, noncondensing		Р
5.6.3	Shock		Р



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	ASTM E 1965-98 (2009)	
Clause	Requirement	Remarks	Verdict
5.6.3.1	The instrument with batteries installed (if applicable) without a carrying (storage) casing shall withstand drops with controlled orientation of the device without degradation of accuracy as specified in 5.3 or 5.4, or both, for a blackbody temperature of or near 37 °C (98.6 °F), when tested according to 6.3	(see clause 6.3 and appended table5. 6.3)	Р
5.6.3.2	If an IR thermometer does not meet requirement of 5.6.3.1, a means of detecting and informing the user of its inoperable state, after being subjected to shock, shall be provided	Can meet requirement of 5.6.3.1	N/A
5.6.4	Storage Conditions—The instrument shall meet the accuracy requirements of 5.3 or 5.4, or both, after having been stored or transported, or both, at any point in an environment of – 20 to + 50 °C (– 4 to + 122 °F) and relative humidity up to 95 %, noncondensing, for a period of one month. The test procedure is specified in 6.1.6	Not evaluated in this report	N/E
5.6.5	Cleaning and Disinfection—Instrument performance shall not be degraded by using the manufacturer's recommended procedures for cleaning and disinfection provided in the instruction manual. Such procedures are part of the required documentation in 7.2.2	Cleaning	Р
5.6.6	Electromagnetic Immunity—An IR thermometer that is intended for professional use shall meet the accuracy requirements of 5.3 or 5.4, or both, for temperature ranges of 6.3.2, during and after exposure to electromagnetic interference	Non-professional use	N/A
5.6.7	Electrostatic Discharge—An IR thermometer shall meet the accuracy requirements of 5.3 and 5.4, or both, for temperature ranges of 6.3.2, after 5 s from being subjected to electrostatic discharge	(see appended table 5.6.7)	Р
5.7	Low Power Supply Operation—The instrument shall operate at power supply voltage lower by no less than 0.1 V than that required for indication of low power supply sign as specified by 5.8.3. The test of operation is defined in 6.3.2 and 6.3.3	(see appended table 5. 7)	Р



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	ASTM E 1965-98 (2009)	
Clause	Requirement	Remarks	Verdict
5.8	Display and Human Interface:		Р
5.8.1	Resolution—The resolution of a display shall be 0.1 °C (0.1 °F).	0,1 °C/0,1 °F	Р
5.8.2	Modes:		Р
5.8.2.1	An IR thermometer shall indicate in what mode the instrument is set	On the LCD display	Р
5.8.2.2	Unadjusted Mode—The unadjusted mode shall be accessible by the user either by setting the instrument into that mode directly or by a conversion technique from adjusted mode.	Setting the instrument into that mode directly	Р
5.8.2.3	Adjusted mode sets an IR thermometer to represent a reference body site, such as core, oral, rectal, etc.	Axilla	Р
5.8.3	Warning Signs—The instrument shall have means to inform the operator when the following are outside the operating ranges specified by the manufacturer: power supply, subject temperature, and ambient temperature		Р
5.9	Construction:		N/A
5.9.1	Housing Materials—All materials that may come in contact with the operator or a subject shall be nontoxic.	Not evaluated in this report	N/E
5.9.2	Probe Covers:		Р
5.9.2.1	To provide a sanitary barrier between a subject and the probe, a probe cover that comes in contact with a subject, if such a probe cover is required by the manufacturer, shall maintain its physical integrity while being placed on the probe and during temperature measurement		N/A
5.9.2.2	A probe and a probe cover of the system shall have shape and dimensions that prevent injury to a subject of any age.		N/A
5.9.2.3	A probe cover shall not increase laboratory errors whose limits are set in 5.3.1		N/A
5.10	Labeling and Marking (Instruments and Acce	ssories):	Р
5.10.1	Thermometer and Accessories:		Р
5.10.1.1	A thermometer shall clearly indicate the units of its temperature scale.	On the LCD display	Р



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ASTM E 1965-98 (2009)			
Clause	Requirement	Remarks	Verdict
5.10.1.2	An IR thermometer housing shall be clearly marked with:	See "Copy of marking plate"	Р
	the trade name or type of the device, or both	Trade name	Р
	model designation	See "Copy of marking plate"	Р
	name of the manufacturer or distributor	See "Copy of marking plate"	Р
	and lot number or serial number	See "Copy of marking plate"	Р
5.10.1.3	An IR thermometer intended for professional use shall be conspicuously labeled with indication of the unadjusted or adjusted mode(s), or both, that correspond to the temperature value(s) capable of being displayed by the instrument	Consumer use	N/A
	Such labeling is optional for IR thermometers that display only one mode and are intended for non-professional use		N/A
	However, as required in 7.2.1.3, the instruction manual for both professional and non-professional use IR thermometers shall specify the body site(s) (that is, oral, rectal, core) used to reference the adjusted temperature value(s) displayed	Not evaluated in this report	N/E
5.10.2	Probe Covers Package:		N/A
5.10.2.1	The package shall state the name and type of the enclosed products, name of the manufacturer or distributor, lot number or serial number, and expiration date (if the probe covers have limited shelf life).		N/A
5.10.2.2	The thermometer model(s) for which the covers are intended for use shall be specified on the probe cover package.		N/A
5.10.2.3	The package shall state whether the probe cover is intended for single use or multiple use.		N/A
5.10.2.4	Any probe cover handling, application, storage, or cleaning procedures which impact the ability of an IR thermometer to meet the requirements for maximum permissible laboratory error specified in 5.3 shall be stated	Not impact the ability	N/A



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	ASTM E 1965-98 (2009)	
Clause	Requirement	Remarks	Verdict
6	Test Methods		Р
6.1.4	Ear Canal Type IR Thermometer		N/A
6.1.4.1	Tests shall be repeated for three blackbody temperatures, t_{BB} set within \pm 0.5 °C (\pm 1 °F) from the following temperatures: 35, 37, and 41 °C, (95, 98.6, and 105.8 °F). At each blackbody temperature, the tests shall be repeated under the ambient conditions stated in Table 1.	All models	N/A
	TABLE 1 Conditions of Ambient Temper Testing an IR Thermometer with a Black Blackbody Setting	body for Each of Three	N/A
	Operating Temperature F	Relative Humidity (%)	
	16 to 18 °C (60 to 65 °F) [*] 16 to 18 °C (60 to 65 °F) [*] 24 to 26 °C (75 to 80 °F) 38 to 40 °C (100 to 104 °F) [*] 38 to 40 °C (100 to 104 °F)	less than 50 90 to 95 40 to 60 less than 25 75 to 85	
	Note: marked with an asterisk shall be chang such specified operating temperature range	ed for the respective limits of	
6.1.4.2	Prior to the measurements, the IR thermometer shall be stabilized at given conditions of ambient temperature and humidity for a minimum of 30 min or longer if so specified by the manufacturer		N/A
6.1.4.3	At each combination of operating temperature and humidity in Table 1, at least six measurements shall be taken for each blackbody temperature, tbb. The number of readings shall be the same for all combinations.		N/A
	A new disposable probe cover (if applicable) must be used for each test reading. The rate and method of temperature taking shall be in compliance with the manufacturer's recommendations.	No probe cover used	N/A



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ASTM E 1965-98 (2009)					
Clause	Requirement	Remarks	Verdict		
6.1.4.4	The requirements of 5.3 demand that no individual error δj exceeds the specified limits for laboratory error. The individual measurement error is: $\delta j = l t_j - t_{Bd} $ (1)		N/A		
	t_j = displayed or calculated value of unadjusted temperature, t_{BB} = true temperature of the blackbody, j = sequential number of a reading, \parallel = signifies taking an absolute value.				
6.1.4.5	In each mode, three data sets shall be formed. Each data set is comprised of values δ_j obtained at the same blackbody temperature setting by pooling together values for all combinations of operating temperature and humidities obtained at that blackbody temperature. The largest δ_j is a measure of the laboratory error of a system.		N/A		
6.1.4.6	The correction method to arrive at unadjusted temperature tj from readings in adjusted mode(s) shall be used according to the manufacturer's recommendation. Such recommendations shall be available from the manufacturer on request and provided in the service and repair manual, if any (see 7.3).		N/A		
6.1.4.7	To comply with this standard, the greatest calculated error $\delta_{\rm j}$ from all data sets measured and calculated for all display modes shall conform with requirements set forth in 5.3.	(see appended table 5.3.1)	N/A		
6.1.5	Skin Type IR Thermometer:		Р		
6.1.5.1	Testing is as specified in 6.1.4 except that blackbody temperatures shall be set within ± 1°C (± 2 °F) from the following temperatures: 23, 30, and 38 °C (73, 86, and 100 °F)		Р		
6.1.5.2	The greatest calculated error δ_j from all data sets shall conform with requirements set forth in 5.4.		Р		



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ASTM E 1965-98 (2009)				
Clause	Requirement	Remarks	Verdict	
6.1.6	Storage Test—To test compliance with storage conditions, an IR thermometer shall be maintained in an environmental chamber at temperature –20 °C (–4 °F), relative humidity below 50 %, for a period of 30 days and at 50 °C (122 °F), relative humidity no less than 75 % noncondensing, for a period of 30 days. After each exposure the IR thermometer shall be tested according to 6.3.2 and 6.3.3	itions, an IR thermometer shall d in an environmental chamber re –20 °C (–4 °F), relative bw 50 %, for a period of 30 50 °C (122 °F), relative ess than 75 % noncondensing, of 30 days. After each exposure ometer shall be tested		
6.2	Clinical Accuracy Tests	Not evaluated in this report	N/E	
6.3	Shock Test:		Р	
6.3.1	To test the ability of an IR thermometer to comply with 5.6.3, it shall be subjected to a fall from a height of 1 m (39 in.) onto a 50 mm (2 in.) thick hardwood board (hardwood of density higher than 700 kg/m3) that lies flat on a rigid base (concrete block). The test shall be performed with a controlled orientation of the device once for each of two axes (see Fig. 1) where the IR thermometer probe faces down. Axis A is defined as an optical axis of the probe. Axis B passes through the IR thermometer center of gravity and the point where the window of the probe crosses axis A		P	
	A center of gravity probe window			



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ASTM E 1965-98 (2009)					
Clause	Requirement	Requirement Remarks			
6.3.2	The IR thermometer's operation shall be tested by measuring the temperature of a blackbody that is set within ± 0.5 ° C (± 1 °F) from 37 °C (98.6 °F), at ambient temperature in the range from 20 to 26 °C (68 to 79 °F) and relative humidity in the range from 40 to 70 %. A total of at least five measurements shall be performed by using a new disposable probe cover (if applicable) for every measurement. The IR thermometer shall be set in an unadjusted mode as specified in 5.8.2.2.	P			
6.3.3	The unadjusted temperature value shall be subtracted from the blackbody setting. The absolute value of the largest error shall be no greater than the error limit set forth in 5.3 (or 5.4, whichever is applicable) for the blackbody temperature range from 36 to 39 °C (96.8 to 102.2 °F)	(see appended table 5.6.3)	P		
6.4	Electromagnetic Susceptibility Test	N/A			
6.5	Electrostatic Discharge Tests Not evaluated in this report		N/E		
7	Documentation	Р			
7.1	Identification:		Р		
7.1.1	In order that purchasers may identify products conforming to requirements of this specification, producers and distributors may include a statement of compliance in conjunction with their name and address on product labels or associated printed materials, or both, such as invoices, sales literature, and the like. The following statement is suggested: "This infrared thermometer meets requirements established in ASTM Standard (E 1965-98). Full responsibility for the conformance of this product to the standard is assumed by (name and address of producer or distributor)." In the event one or more provisions of this standard are not met, a cautionary statement shall be included.	Instructions for use Version: 1.0	P		
7.1.2	The IR thermometer shall be identified as intended for professional or consumer use, or both, as applicable	Only consumer use	Р		
	Instruction Manual	•	Р		



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	ASTM E 1965-98 (2	2009)			
Clause	Requirement Remarks				
7.2.1	Specifications—An instruction manual shall b system specifications, including but not limite	Р			
7.2.1.1	Displayed temperature range		Р		
7.2.1.2	Maximum laboratory error		Р		
7.2.1.3	Body site(s) used as a reference for adjusting the displayed temperature value		Р		
7.2.1.4	Applicable subject categories for each display mode		Р		
7.2.1.5	Required period of recalibration or reverification, if applicable		N/A		
7.2.1.6	Environmental characteristics (operating and storage ranges for temperature and humidity)		Р		
7.2.1.7	Statement informing that clinical accuracy characteristics and procedures are available from the manufacturer on request		Р		
7.2.2	Detailed instructions—The instruction manual instructions for use with sufficient detail for transpolication, care, and biological and physical and accessories. The instruction manual shall performance of the instrument may be adversing or the following occur:	Р			
7.2.2.1	Operation outside of the manufacturer specified subject temperature range		Р		
7.2.2.2	Operation outside of the manufacturer specified operating temperature and humidity ranges		Р		
7.2.2.3	Storage outside of the manufacturer specified ambient temperature and humidity ranges		Р		
7.2.2.4	Mechanical shock		Р		
7.2.2.5	Manufacturer defined soiled or damaged infrared optical components.		Р		
7.2.2.6	Absent, defective, or soiled probe cover (if applicable)		Р		
7.2.2.7	Use of unspecified probe covers		N/A		





ASTM E 1965-98 (2009)					
Clause	Requirement	Remarks			
7.2.3	Blackbody—The instruction manual shall indicate the type and availability of a blackbody recommended for verifying laboratory or clinical accuracy, or both, if only such type is required by the manufacturer as addressed in 6.1.3.3				
7.2.4	The instruction manual shall specify whether the probe cover is intended for single use or multiple use. If multiple use is allowed, cleaning instructions and criteria for determining when a probe cover should be discarded shall be specified. Cleaning instructions shall be adequate to prevent cross-contamination between patients.				
7.2.5	The instruction manual shall inform the user of differences in the accuracy of measurements obtained with IR thermometers versus contact thermometers (that is, mercuryin-glass and electronic thermometers). Such differences shall include, whenever applicable, a description of the anticipated error sources associated with disposable or reusable probe covers and sleeves, operators' technique, anatomical variations, earwax buildups, subject cooperation, etc. In addition, this section of the instruction manual that explains differences in the accuracy of measurements obtained with IR thermometers versus contact thermometers shall conspicuously include the following statement: "ASTM laboratory accuracy requirements in the display range of 37 to 39 °C (98 to 102 °F) for IR thermometers is ± 0.2 °C (± 0.4 °F), whereas for mercuryinglass and electronic thermometers, the requirement per ASTM Standards E 667-86 and E 1112-86 is ± 0.1 °C (± 0.2 °F)."		P		
7.3	Service and Repair Manual:		N/A		
7.3.1	A detailed service manual shall be made available if user service or repair is permitted by the manufacturer	Not user service or repair is permitted by manufacturer	N/A		
7.3.2	A service manual shall disclose values of instrumentation or combined site offsets, or both		N/A		



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ASTM E 1965-98 (2009)						
Clause	Requirement	Verdict				
7.3.3	A service manual shall provide a method of arriving to unadjusted readings from temperatures displayed in an adjusted mode		N/A			
7.4	Accuracy Determination—A manufacturer shall make available upon request specific instructions for tests to determine the laboratory error, clinical bias and clinical repeatability of an IR thermometer.	Clinical Accuracy was not evaluated in this test report	N/E			
	When describing how clinical tests are performed, the manufacturer shall disclose the profile of subject groups tested, including age and febrile status. A detailed procedure for taking reference temperatures also shall be disclosed		N/E			



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Test data table:

5.3.1	Laboratory accuracy test (Ear Canal Type IR Thermometer)						N/A
Operating Temperature Relative Humidity (%) 16 to 18°C (60 to 65°F					C (60 to 65°F), I	ess than 50	
Measur ement	t _{вв} set: 23,0°С/73,4 °F		t _{BB} set: 30,0°C/86,0 °F		t _{BB} set: 38,0°C/100,5°F		Verdict / remark
No.	t _j °C/°F	Error (t _j – t _{BB}) Limit 0,3°C/0,5°F	t _j °C/ °F	Error (t _i – t _{BB}) Limit 0,2°C/0,4°F	t _j °C/°F	Error (t _j – t _{BB}) Limit 0,3°C/0,5°F	
1							
2							
3							
4							
5							
6							

Supplementary information:

t_{BB}: Temperature of blackbody

t_{j:} Displayed value of unadjusted temperature (test mode)

Remark:

5.3.1	Laboratory accuracy test (Ear Canal Type IR Thermometer)						N/A
Operating Temperature Relative Humidity (%) 16 to 18°C (60 to 65°F					F), 90-95		
Measur ement		_{вв} set: °C/73,4 °F	t _{BB} set: t _{BB} set: 30,0°С/86,0 °F 38,0°С/100,5°F		Verdict / remark		
No.	t _j °C/°F	Error (t _j – t _{BB}) Limit 0,3°C/0,5°F	t _j °C/°F	Error (t _j – t _{BB}) Limit 0,2°C/0,4°F	t _j °C/°F	Error (t _j – t _{BB}) Limit 0,3°C/0,5°F	
1							
2							
3							
4							
5							
6							

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t_{j:} Displayed value of unadjusted temperature (test mode)



Supplementary information: t_{BB:} Temperature of blackbody

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Remark:

5.3.1	Laborator		N/A				
Operating Temperature Relative Humidity (%) 24 to 26°C (75 to 80°F							
Measur ement		_{вв} set: °C/73,4 °F		вв set: °C/86,0 °F		вв set: C/100,5°F	Verdict / remark
No.	t _j °C/ °F	Error (t _j — tвв) Limit 0,3°C/0,5°F	t _j °C/°F	Error (t _i — tвв) Limit 0,2°C/0,4°F	t _j °C/ °F	Error (t _j — tвв) Limit 0,3°C/0,5°F	
1							
2							
3							
4							
5							
6							

Supplementary information: tbb: Temperature of blackbody tj: Displayed value of unadjusted temperature (test mode)

Remark:

5.3.1	Laborator	Laboratory accuracy test (Ear Canal Type IR Thermometer)							
Operating Temperature Relative Humidity (%)					38 to	40°C (100,4 to less than 25	,		
Measur ement	t _{вв} set: 23,0°С/73,4 °F			вв set: °C/86,0 °F		B set: Verdict / C/100,5°F remark			
No.	t _j °C/°F	Error $(t_j - t_{BB})$ Limit 0.3° C/ 0.5° F	t _j °C/ °F	Error (t _j – t _{BB}) Limit 0,2°C/0,4°F	t _j °C/ °F	Error (t _i – t _{BB}) Limit 0,3°C/0,5°F			
1									
2									
3									
4									
5									
6									

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t_{BB}: Temperature of blackbody

t_{j:} Displayed value of unadjusted temperature (test mode)

Remark:

5.3.1	Laborator	Laboratory accuracy test (Ear Canal Type IR Thermometer)						
Operating Temperature Relative Humidity (%) 38 to 40°C(100,4 to 104								
		_{вв} set: °C/73,4 °F		BB set: C/86,0 °F		BB set: C/100,5°F	Verdict / remark	
No.	t _j °C/°F	Error (t _j — tвв) Limit 0,3°C/0,5°F	t _j °C/ °F	Error (t _j — tвв) Limit 0,2°C/0,4°F	t _j °C/ °F	Error $(t_j - t_{BB})$ Limit 0.3° C/ 0.5° F		
1								
2								
3								
4								
5								
6								

Supplementary information: t_{BB} : Temperature of blackbody

t_{j:} Displayed value of unadjusted temperature (test mode)

Remark:

TRF No.: ASTM E 1965-98(Reapproved 2009)b



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5.4.1	.4.1 Laboratory accuracy test (Skin Type IR Thermometer)						
O	perating Tem	nperature Rela	tive Humidit	y (%)	16 to	o 18°C, less tha	an 50
Measur	t _{BB} set	: 23,0°C	t _{BB} set	t: 30,0°C	t _{BB} set:	: 38,0°C	Verdict /
ement No.	No. $ \begin{array}{c cccc} t_j & Error & t_j & Ei \\ & (t_j - t_{\text{BB}}) & & (t_j - t_{\text{BB}}) \\ & Limit~0,3^{\circ}\text{C} & Limit \\ \end{array} $	Error (t _j – t _{BB}) Limit 0,3°C	t _j	Error (t _j – t _{BB}) Limit 0,3°C	remark		
HG01 V1							
1	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
2	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
3	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
4	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
5	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
6	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
HG01 V2							
1	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
2	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
3	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
4	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
5	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
6	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
HG02 V1							
1	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
2	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
3	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
4	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
5	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
6	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р

t_{BB}: Temperature of blackbody

t_{j:} Displayed value of unadjusted temperature (surface temp mode)

Remark:

TRF No.: ASTM E 1965-98(Reapproved 2009)b



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5.4.1	Laboratory	Laboratory accuracy test (Skin Type IR Thermometer)						
0	perating Tem	nperature Rela	tive Humidit	y (%)	16	to 18°C, 90 to	95	
Measur	t _{BB} set	: 23,0°C	t _{BB} set	:: 30,0°C	t _{BB} set	: 38,0°C	Verdict /	
ement No.	t _j	Error (t _j – t _{BB}) Limit 0,3°C	t _j	Error (t _j – t _{BB}) Limit 0,3°C	tj	Error (t _j – t _{BB}) Limit 0,3°C	remark	
HG01 V1								
1	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
2	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
3	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
4	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
5	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
6	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
HG01 V2								
1	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
2	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
3	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
4	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
5	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
6	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р	
HG02 V1								
1	22,9	-0,1	30,0	0	38,1	+0,1	Р	
2	22,9	-0,1	30,0	0	38,1	+0,1	Р	
3	22,9	-0,1	30,0	0	38,1	+0,1	Р	
4	22,9	-0,1	30,0	0	38,1	+0,1	Р	
5	22,9	-0,1	30,0	0	38,1	+0,1	Р	
6	22,9	-0,1	30,0	0	38,1	+0,1	Р	

t_{BB}: Temperature of blackbody

t_{j:} Displayed value of unadjusted temperature (surface temp mode)

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5.4.1	Laboratory	accuracy test	(Skin Type I	R Thermometer	er)		Р
0	perating Tem	perature Rela	tive Humidit	y (%)	24	to 26 °C, 40 to	60
Measur	t _{BB} set	: 23,0°C	t _{BB} set	:: 30,0°C	t _{BB} set	: 38,0°C	Verdict /
ement No.	t _j	Error (t _j – t _{BB}) Limit 0,3°C	t _j	Error (t _j – t _{BB}) Limit 0,3°C	t _j	Error (t _j – t _{BB}) Limit 0,3°C	remark
HG01 V1							
1	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
2	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
3	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
4	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
5	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
6	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
HG01 V2							
1	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
2	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
3	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
4	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
5	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
6	23,1	+0,1	30,1	+0,1	38,1	+0,1	Р
HG02 V1							
1	22,9	-0,1	30,0	0	38,0	0	Р
2	22,9	-0,1	30,0	0	38,0	0	Р
3	22,9	-0,1	30,0	0	38,0	0	Р
4	22,9	-0,1	30,0	0	38,0	0	Р
5	22,9	-0,1	30,0	0	38,0	0	Р
6	22,9	-0,1	30,0	0	38,0	0	Р

t_{BB}: Temperature of blackbody

t_{j:} Displayed value of unadjusted temperature (surface temp mode)

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5.4.1	Laboratory accuracy test (Skin Type IR Thermometer)						
0	perating Tem	perature Rela	tive Humidit	ty (%)	38 to	40 °C, less tha	an 25
Measur	t _{BB} set	: 23,0°C	t _{BB} se	t: 30,0°C	t _{BB} set	: 38,0°C	Verdict /
ement No.	t _j	Error (t _j – t _{BB}) Limit 0,3°C	tj	Error (t _j – t _{BB}) Limit 0,3°C	t _j	Error (t _j – t _{BB}) Limit 0,3°C	remark
HG01 V1							
1	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
2	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
3	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
4	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
5	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
6	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
HG01 V2							
1	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
2	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
3	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
4	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
5	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
6	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
HG02 V1							
1	22,9	-0,1	30,0	0	38,0	0	Р
2	22,9	-0,1	30,0	0	38,0	0	Р
3	22,9	-0,1	30,0	0	38,0	0	Р
4	22,9	-0,1	30,0	0	38,0	0	Р
5	22,9	-0,1	30,0	0	38,0	0	Р
6	22,9	-0,1	30,0	0	38,0	0	Р

t_{BB}: Temperature of blackbody

t_{j:} Displayed value of unadjusted temperature (surface temp mode)

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5.4.1	Laboratory	accuracy test	(Skin Type I	R Thermometer	er)		Р
Ο	perating Tem	perature Rela	tive Humidit	y (%)	38	to 40 °C, 75 to	85
Measur	t _{BB} set:	23,0°C	t _{BB} set	t: 30,0°C	t _{BB} set	: 38,0°C	Verdict /
ement No.	t _j	Error (t _j – tвв) Limit 0,3°С	t _j	Error (t _j – t _{BB}) Limit 0,3°C	tj	Error (t _j – t _{BB}) Limit 0,3°C	remark
HG01 V1							
1	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
2	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
3	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
4	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
5	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
6	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
HG01 V2							
1	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
2	23,2	+0,2	30,1	+0,1	38,2	+0,2	Р
3	23,2	+0,2	30,1	+0,1	38,2	+0,2	Р
4	23,2	+0,2	30,2	+0,2	38,2	+0,2	Р
5	23,2	+0,2	30,1	+0,1	38,2	+0,2	Р
6	23,2	+0,2	30,1	+0,1	38,2	+0,2	Р
HG02 V1							
1	22,9	-0,1	30,0	0	38,0	0	Р
2	22,9	-0,1	30,0	0	38,0	0	Р
3	22,9	-0,1	30,0	0	38,0	0	Р
4	22,9	-0,1	30,0	0	38,0	0	Р
5	22,9	-0,1	30,0	0	38,0	0	Р
6	22,9	-0,1	30,0	0	38,0	0	Р

t_{BB}: Temperature of blackbody

t_{j:} Displayed value of unadjusted temperature (surface temp mode)

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5.6.3	Shock Test	Р	
0	perating Temperature Relative Humidity ((%) 20 to 26 °C (68 to	78,8°F), 40 to 70
Measur ement	t _{BB} : 37,		Verdict / remark
No.	t _j °C	Error (t _j — t _{вв}) Limit 0,2°С	
HG01 V1			•
1	37,1	+0,1	Р
2	37,1	+0,1	Р
3	37,1	+0,1	Р
4	37,1	+0,1	Р
5	37,1	+0,1	Р
HG01 V2			•
1	37,1	+0,1	Р
2	37,1	+0,1	Р
3	37,1	+0,1	Р
4	37,1	+0,1	Р
5	37,1	+0,1	Р
HG02 V1			
1	37,0	0	Р
2	36,9	-0,1	
3	36,9	-0,1	
4	37,0	0	
5	37,0	0	

Supplementary information:

t_{BB}: Temperature of blackbody

t_j: Displayed value of unadjusted temperature (test mode)

Remark:

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5.6.4	Storage Test			N/E			
0	perating Temperature Relative Humidity (%)	20 to 26 °C(68 to 78,8°F), 40 to 70			
	30d storage in chamber at temperature –	20 °C (–4 °F	relative humidity below 50	%			
Measur ement	t _{вв} s 37,0°С/9	Verdict / remark					
No.	t _i °C/ °F	Error (t _j – t _{BB}) Limit 0,2°C/0,4°F					
1							
300	d storage in chamber at temperature 50 °C	C (122 °F), r	elative humidity no less than	75 %			
Measur ement	t _{BB} s 37,0°C/9			Verdict / remark			
No.	t _j °C/ °F	Error (t _j – t _{BB}) Limit 0,2°C/0,4°F					
1							
t _{BB:} Tempe	Supplementary information: Not evaluated in this report tbb: Temperature of blackbody tj: Displayed value of unadjusted temperature (test mode)						
iveillaik.							

5.6.6	Electromagnetic Immunity Tests	N/A				
0	Operating Temperature Relative Humidity (%) 20 to 26 °C(68 to 78,8°F					
Measur ement	ement 37,0°C/98,6 °F					
No.	t _i °C / °F	$\begin{array}{c} t_{j} & \text{Error} \\ \text{°C / °F} & (t_{j}-t_{BB}) \\ \text{Limit 0,2°C/0,4°F} \end{array}$				
1						

t_{BB}: Temperature of blackbody

t_{j:} Displayed value of unadjusted temperature (test mode)

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5.6.7	Electrostatic Discharge Tests	Р	
С	operating Temperature Relative Humidity (%) 20 to 26 °C (68 to	78,8°F), 40 to 70
Measur ement	t _{вв} s 37,0°С/9		Verdict / remark
No.	t _j °C/ °F	Еrror (tյ – t _{ВВ}) Limit 0,2°С/0,4°F	
HG01 V1			1
1	37,1	+0,1	Р
2	37,1	+0,1	Р
3	37,1	+0,1	Р
4	37,1	+0,1	Р
5	37,1	+0,1	Р
HG01 V2			
1	37,0	0	Р
2	37,0	0	Р
3	36,8	-0,2	Р
4	36,8	-0,2	Р
5	36,9	-0,1	Р
HG02 V1			
1	37,0	0	Р
2	36,9	-0,1	Р
3	36,9	-0,1	Р
4	37,0	0	Р
5	37,0	0	Р

Supplementary information: $t_{BB:}$ Temperature of blackbody $t_{j:}$ Displayed value of unadjusted temperature (test mode)

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5.7	Low power supply operation			Р
Operating Temperature Relative Humidity (%) 20 to 26 °C (68 to 78,8			8,8°F), 40 to 70	
Measur ement No.	t _{вв} set: 37,0°С/98,6 °F			Verdict / remark
	t _j °C/ °F	Error (t _j — t _{вв}) Limit 0,2°С/0,4°F		
HG01 V1				•
1	36,9	-0,1		Р
2	36,9	-0,1		Р
3	36,9	-0,1		Р
4	36,9	-0,1		Р
5	36,9	-0,1		Р
HG01 V2				
1	37,1	+0,1		Р
2	37,1	+0,1		Р
3	37,1		+0,1	Р
4	37,1		+0,1	Р
5	37,1	+0,1		Р
HG02 V1				
1	37,0		0	Р
2	36,9		-0,1	Р
3	36,9		-0,1	Р
4	37,0		0	Р
5	37,0		0	Р

Supplementary information: t_{BB}: Temperature of blackbody t_j: Displayed value of unadjusted temperature (test mode)

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Attachment 2: Photo Documentation

Details of: HG01 V1

Marking refer to copy of marking plate



Details of: HG01 V1

View:

[x] general

[] front

[] rear

[] left

[] lop

[] bottom

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Details of: HG01 V1



Details of: HG01 V1



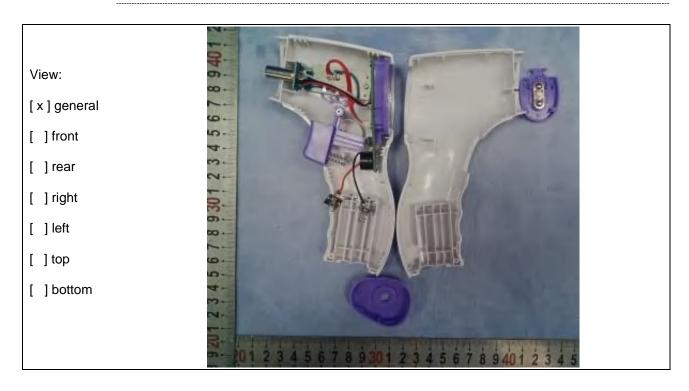
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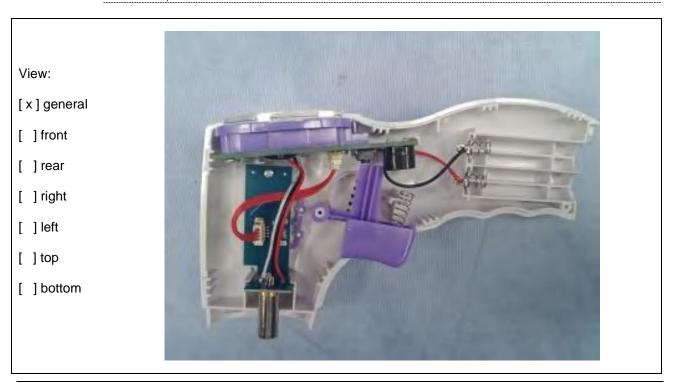
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Details of: HG01 V1, Internal view



Details of: HG01 V1, Internal view



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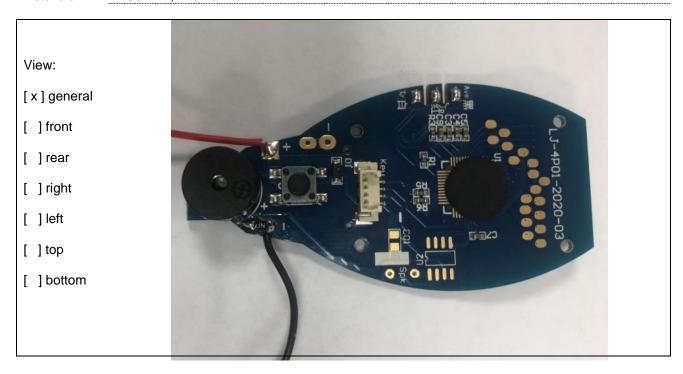
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Details of: HG01 V1, internal view



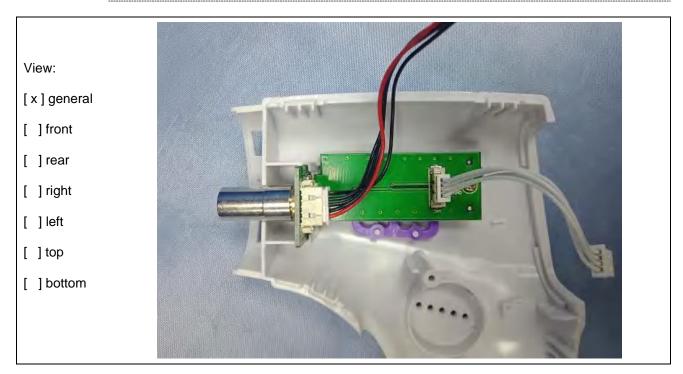
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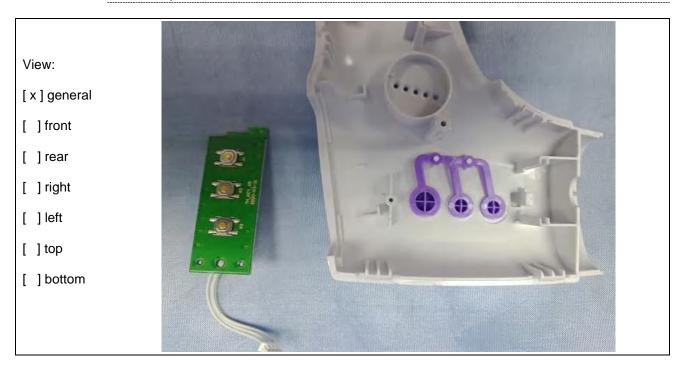
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Details of: HG01 V1, internal view



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Details of: HG01 V1, Battery compartment



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Details of: HG01 V2

View:

[x] general

[] front

[] rear

[] left

[] top

[] bottom

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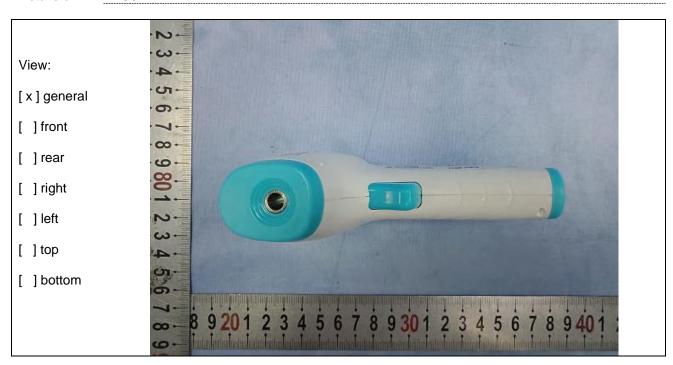
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Details of: HG01 V2



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Assertion: To check the authorized of testing inspection report a certification provided the situation of the common services.

Details of: HG01 V2, Battery compartment

View:	
[x]general	
[] front	
[] rear	3
[] right	
[] left	
[] top	
[] bottom	

Details of: HG01 V2, Internal view



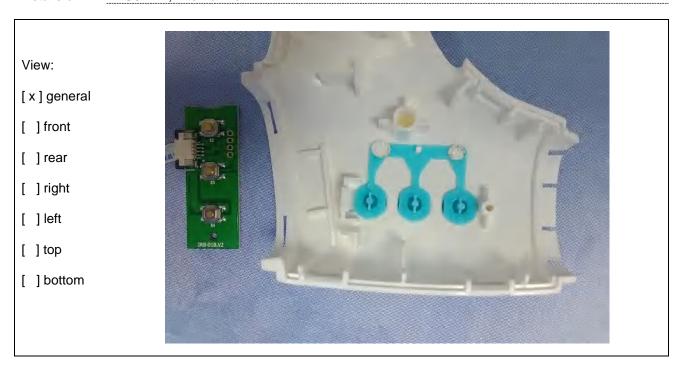
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Details of: HG01 V2, Internal view



Details of: HG01 V2, Internal view



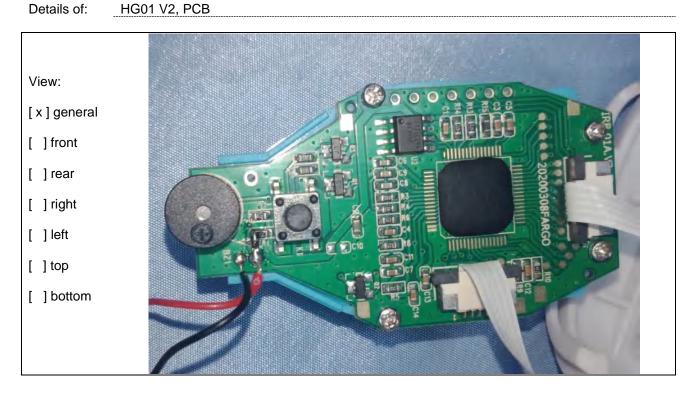
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Attachment 2: Photo Documentation



Details of: HG01 V2, Temperature sensor



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Details of: HG02 V1



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Details of: HG02 V1



Details of: HG02 V1, Battery compartment



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Details of: HG02 V1, Internal view



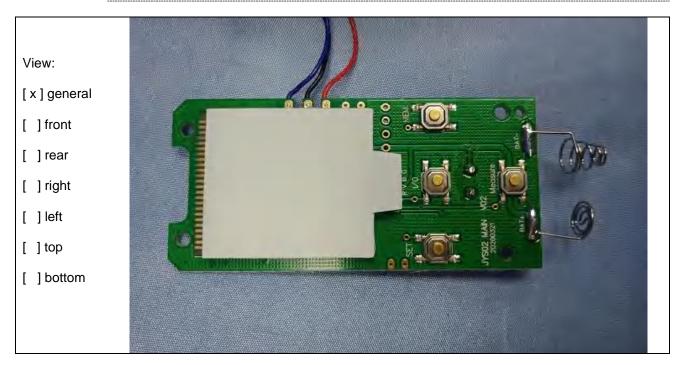
Details of: HG02 V1, Internal view



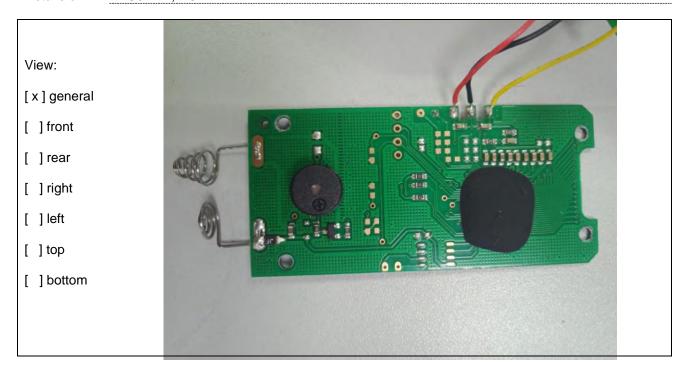
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Details of: HG02 V1, PCB



Details of: HG02 V1, PCB



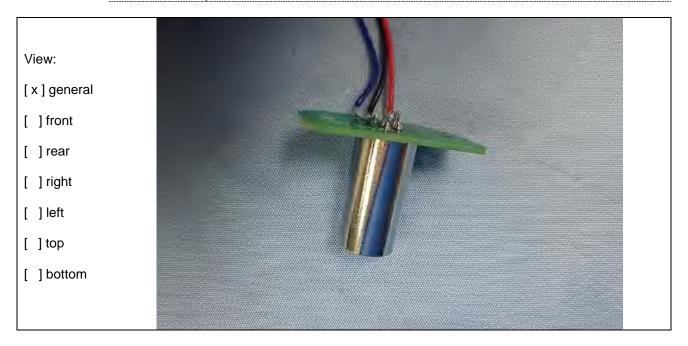
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