Test Report issued under the responsibility of:

TEST REPORT
ISO 80601-2-61
Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Report Number. .....:	GZES201103126301
Date of issue .....:	2021-01-21
Total number of pages.....:	54
Name of Testing Laboratory preparing the Report.....:	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch
Applicant's name.....:	Guangdong Biolight Meditech Co., Ltd.
Address .....:	No.2 Innovation First Road, Technical Innovation Coast, Hi-tech Zone, Zhuhai, P.R. China
Test specification:	
Standard .....:	ISO 80601-2-61:2017, COR1:2018 for use IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012
Test procedure .....:	SGS-CSTC
Non-standard test method.....:	N/A
Test Report Form No.....:	ISO80601_2_61C
Test Report Form(s) Originator.....:	CSA Group
Master TRF .....:	Dated 2019-01-22

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing CB Testing Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description ..... :	Fingertip Pulse Oximeter
Trade Mark ..... :	**BLT**
Manufacturer ..... :	Same as applicant
Model/Type reference ..... :	M70, M70A, M70C
Ratings ..... :	3,0 V d.c. (2 × AAA alkaline batteries)

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

☒	**Testing Laboratory:**	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch	
Testing location/ address.....:		198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China	
Tested by (name, function, signature).....:		Nancy Lan Project engineer	
Approved by (name, function, signature)...:		Gary Guo Reviewer	
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address.....:			
Tested by (name + signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

List of Attachments (including a total number of pages in each attachment):

Attachment 1: Photo documentation (from page 33 to page 53);
Attachment 2: Circuit Diagram (page 54).

Summary of testing:

Tests performed (name of test and test clause):

Tests according to the following standard were carried out:
ISO 80601-2-61:2017

The submitted samples fulfilled the requirements of specified standard except for the following:
Clause 201.12.1.101 SpO_2 accuracy of pulse oximeter equipment;
Clause 202 Electromagnetic disturbances;
Clause 206 Usability;
Clause 211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

After technical review, all models were subjected to the full tests.

Testing location:

198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China

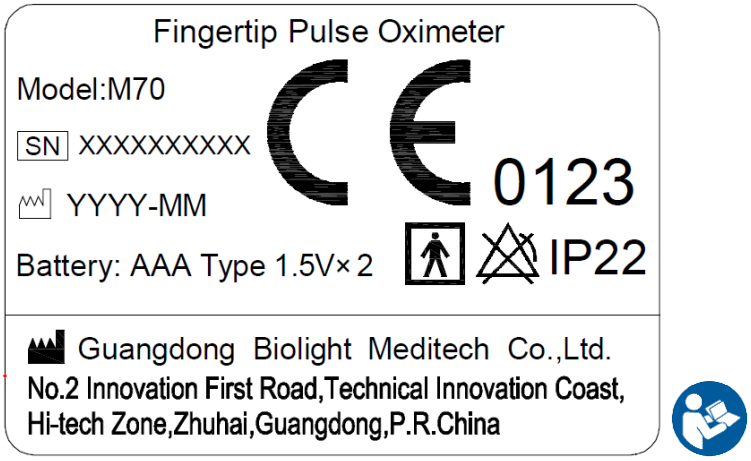
Summary of compliance with National Differences (List of countries addressed):

None.

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 NBs or NCBs that own these marks.

Marking on M70:



Remarks:
The labels of other models are same as above except for the model number;
The height of CE logo shall not be less than 5 mm.

Test item particulars.....:	Fingertip Pulse Oximeter
Classification of installation and use.....:	Hand-held
Supply Connection.....:	Internally powered
.....:	—
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- compliance with the requirement not evaluated..:	N/E (Not Evaluated)
- test object does not meet the requirement.....:	F (Fail)
Testing.....:	—
Date of receipt of test item .....:	2020-11-09
Date (s) of performance of tests.....:	2020-11-09 to 2021-01-08

General remarks:

"(see appended table)" refers to a table appended to the report.

The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.

List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☒ comma / ☐ point is used as the decimal separator.

This Test Report Form is intended for the investigation of the basic safety and essential performance of pulse oximeter equipment ISO 80601-2-61. It can only be used together with the IEC 60601-1 Test Report, IEC 60601-1 wasn't evaluated in this test report.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ **Yes** ☒ **Not applicable**

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) .....:	Same as applicant

General product information:

The Fingertip Pulse Oximeter M70, M70A and M70C are intended to measure functional arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric and adolescent patients in hospital, hospital type facilities, as well as in the home care environment. The oximeters are not suitable to monitor patient continuously for long term.

The SpO2 probe integrated in the device is the applied part of the oximeter and classified as BF type, non-defibrillation-proof.

The oximeter is hand-held equipment.

It is internally powered equipment uses two AAA alkaline batteries.

The IP degree of oximeter is IP22.

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.4	**GENERAL REQUIREMENTS**		—
201.4.3	**ESSENTIAL PERFORMANCE**		P
201.4.3.101	**Additional requirements for ESSENTIAL PERFORMANCE**		P
	Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101. **Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements** Requirement / Subclause: For PULSE OXIMETER EQUIPMENT provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: SpO_2 ACCURACY, pulse rate ACCURACY and limit ALARM CONDITIONS [a] — 201.12.1.101, 201.12.1.104, 208.6.1.2.101 or generation of a TECHNICAL ALARM CONDITION — 201.11.8.101.1, 201.12.4, 201.13.101 For PULSE OXIMETER EQUIPMENT not provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: SpO_2 ACCURACY and pulse rate ACCURACY [a] — 201.12.1.101, 201.12.1.104 or indication of abnormal operation — 201.12.4, 201.13.101 [a] Subclause 202.8.2 indicates methods of evaluating SpO_2 ACCURACY and pulse rate ACCURACY as acceptance criteria following specific tests required by this document.	See appended Table 201.4.3.101	P
201.4.102	**Additional requirements for acceptance criteria**		P
	Many of the clauses and subclauses within this document establish acceptance criteria for performance aspects. These acceptance criteria shall always be met. When the MANUFACTURER specifies in the ACCOMPANYING DOCUMENT performance levels better than those specified within this document, these MANUFACTURER-specified levels become the acceptance levels ..... :		P
201.4.103	**Additional requirements for Pulse Oximeter Equipment, parts and Accessories**		P
	The PULSE OXIMETER EQUIPMENT, as well as all individual parts and ACCESSORIES specified for use with a PULSE OXIMETER MONITOR, shall comply with all requirements specified in this document. This includes all combinations of parts or ACCESSORIES that are specified by a MANUFACTURER for use in PULSE OXIMETER EQUIPMENT ..... :	Inspected pulse oximeter equipment	P
	All specified combinations of PULSE OXIMETER EQUIPMENT, as well as all individual parts and ACCESSORIES specified for use with a PULSE OXIMETER MONITOR, shall be disclosed in the instructions for use... :	No specified combinations	N/A
201.7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		—
201.7.2.3	**Consult Accompanying Documents**		P

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	The PULSE OXIMETER EQUIPMENT shall be marked with the safety sign for the mandatory action: 'follow instructions for use', ISO 7010-M002. .....:		P
201.7.2.9.101	**IP Classification**		P
	The ENCLOSURE of ME EQUIPMENT shall be marked with the IP classification required by 201.11.6.5.101. If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then the degree of protection provided by the ENCLOSURE shall be marked on the ENCLOSURE and the degree of protection provided by the carrying case shall be marked on the carrying case……:	Refer to IEC 60601-1:2005 + AMD1:2012 Test Report, clauses 7.1.2 and 7.1.3 IP22	P
	An ENCLOSURE or a carrying case that is classified IPX0 need not be marked as such. If an ENCLOSURE does not provide the minimum required degree of protection against the ingress of water, it shall be marked 'keep dry' or with ISO 15223-1:2016, Symbol 5.3.4.	No carrying case	N/A
201.7.2.13.101	**Additional requirements for physiological effects**		N/A
	All latex-containing ACCESSORIES shall be marked as containing latex. The marking shall be CLEARLY LEGIBLE. Symbol ISO 7000-2725 (see Table 201.D.1.101, Symbol 5) may be used. All latex-containing components shall be disclosed as such in the instructions for use.	Latex free	N/A
201.7.2.17.101	**Additional requirements for protective packaging**		P
	Packages of ME EQUIPMENT, parts or ACCESSORIES shall be marked a) with the following:		—
	– a description of the contents;		P
	– an identification reference to the batch, type or serial number or Symbol 5.1.5, 5.1.6, 5.1.7 from ISO 15223-1:2016 (see Table 201.D.1.101, Symbol 2, Symbol 3 or Symbol 4); and		P
	– for packages containing natural rubber latex, the word "LATEX", or Symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.1.101, Symbol 5);		N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	b) for those containing parts intended for single use, with the words "SINGLE USE", “DO NOT REUSE”, "NOT FOR REUSE" or Symbol ISO 15223-1:2016, 5.4.2 (see IEC 60601-1:2005 + AMD1:2012, Table D.1, Symbol 28). For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent.		N/A
	These markings shall be CLEARLY LEGIBLE.		P
	Consideration should be given to the disposal of packaging waste.		P
201.7.2.101	**Additional requirements for marking on the outside of ME EQUIPMENT parts**		P
	ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked as follows.		—
	a) The PULSE OXIMETER MONITOR, its parts and ACCESSORIES with any particular storage, handling and operating instructions..:		P
	b) The PULSE OXIMETER MONITOR, its parts and ACCESSORIES with regard to proper disposal, as appropriate.		P
	c) If a PULSE OXIMETER MONITOR is not provided with a low SpO2 ALARM CONDITION, a statement to the effect “No SpO2 Alarms” or Symbol IEC 60417-5319 (DB-2002-10) (see IEC 60601-1-8:2006, Table C.1, Symbol 3)		P
	d) For a REPROCESSED PULSE OXIMETER PROBE, marked as such……:	Not reprocessed	N/A
	These markings shall be CLEARLY LEGIBLE.		P
201.7.4.3	**Unit of measure**		P
	FUNCTIONAL OXYGEN SATURATION shall be expressed in units of per cent *Sp*O2 and shall be marked as % *Sp*O2 or *Sp*O2.....:	%SpO_2	P
	Pulse rate shall be expressed in units of reciprocal minutes (1/min).	/min	P
201.7.9.2	**Instructions for use**		P
201.7.9.2.1.101	**Additional general requirements**		P
	The instructions for use shall indicate the following:		—

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	a) for each PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE, the specified use of the PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE regarding:		P
	– PATIENT population.....:	Refer to user manual “Intended Use”	P
	– part of the body or type of tissue applied to; and.....:	Refer to user manual “Operation Instructions”	P
	– application.....:	Refer to user manual “Intended Use”	P
	b) that the PULSE OXIMETER EQUIPMENT is calibrated to display FUNCTIONAL OXYGEN SATURATION .....:	Refer to user manual “Intended Use”	P
	c) the range of the peak wavelengths and maximum optical output power of the light emitted by the PULSE OXIMETER PROBE and a statement to the effect that information about wavelength range can be especially useful to clinicians.....:	Refer to user manual “Sensors specifications””	P
	d) a description of the effect on displayed and transmitted *Sp*O2 and pulse rate data values by:		P
	– data averaging and other signal processing,		P
	– the DATA UPDATE PERIOD,		P
	– the ALARM CONDITION DELAY, and		N/A
	– ALARM SIGNAL GENERATION DELAY		N/A
	including the effects of any selectable operating mode that affects these properties;		N/A
	e) the DISPLAYED RANGES of *Sp*O2 and pulse rate;		P
	f) if no ALARM SYSTEM that includes the capability to detect an SpO2 or pulse rate PHYSIOLOGICAL ALARM CONDITION is provided, a statement to that effect .....:	Refer to user manual : “This oximeter does not have alarm function; please do not use this product in the environment where alarm is required”	P
	g) for PULSE OXIMETER MONITORS, the PULSE OXIMETER PROBE(S) and PROBE CABLE EXTENDERS with which the PULSE OXIMETER MONITOR has been VALIDATED and tested for compliance with this International Standard (additional information is found in 201.4.103). The list may be made available by electronic means .....:		N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	h) if the PULSE OXIMETER EQUIPMENT or its parts are intended for single-use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the PULSE OXIMETER EQUIPMENT or its parts would be re-used ..... :		N/A
201.7.9.2.2.101	**Additional requirements for warnings and safety notices**		P
	The instructions for use shall include:		—
	a) for each PULSE OXIMETER PROBE and PROBE CABLE EXTENDER, a warning to the effect that probes and cables are designed for use with specific monitors..... :		N/A
	b) a warning to the effect that the responsible organization or operator needs to verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result; and……..…..:		N/A
	c) a warning to the effect that misapplication of a PULSE OXIMETER PROBE with excessive pressure for prolonged periods can induce pressure injury..... :	Refer to user manual “Precautions for use”	P
201.7.9.2.9.101	**Additional requirements for operating instructions**		P
	The instructions for use shall indicate the following:		—
	a) a description of the signal inadequacy indicator and its function. If there is a waveform, a statement as to whether or not it is NORMALIZED shall be provided ..... :	SpO_2 Plethysmogram (normalized) Indication of pulse intensity	P
	b) the recommended maximum application time for each type of PULSE OXIMETER PROBE at a single site ..... :	Every 2 hours	P
	c) the IP classification of the PULSE OXIMETER EQUIPMENT ENCLOSURE and, if applicable, on any carrying case provided with the PULSE OXIMETER EQUIPMENT along with a brief description of that classification's meaning ..... :	IP22	P

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	d) if the PULSE OXIMETER EQUIPMENT is provided with temperature capability such that the PULSE OXIMETER PROBE can operate at greater than 41 °C, specific instructions emphasizing the importance of proper PULSE OXIMETER PROBE application, without excessive pressure. In addition, specific instructions for any changes in recommended maximum application time when using temperatures greater than 41 °C ..... :	Not greater than 41 °C	N/A
201.7.9.2.14.101	**Additional requirements for accessories, supplementary equipment, used material**		**P**
	The instructions for use shall include the following:		—
	a) for PULSE OXIMETER PROBES, the PULSE OXIMETER MONITOR(S) and PROBE CABLE EXTENDERS with which the PULSE OXIMETER PROBES have been VALIDATED and tested for compliance with this document. The list may be made available by electronic means ..... :		N/A
	b) for PROBE CABLE EXTENDERS, the PULSE OXIMETER MONITOR(S) and PULSE OXIMETER PROBES with which the PROBE CABLE EXTENDERS have been VALIDATED and tested for compliance with this document. The list may be made available by electronic means ..... :		N/A
	c) information regarding toxicity or the effect on tissues of materials with which the PATIENT or any other person can come into contact and information on RESIDUAL RISKS for children, pregnant or nursing women and, if applicable, any appropriate precautionary measures ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.7)**	RMF Reference to specific RISKS: Risk Management Report, No. J/M70-073-2011A1, V1.0, chapter 6.4.2.2 and chapter 7, No. H2.1, H2.2, H2.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	P
	d) if a PULSE OXIMETER PROBE is delivered in sterile packaging, a description of how to re-sterilize it, if permissible, in the event of damage to the sterile packaging..... :		N/A
201.7.9.3.1.101	**Additional general requirements**		P
	The technical description shall include a statement to the effect that a FUNCTIONAL TESTER cannot be used to assess the ACCURACY of a PULSE OXIMETER PROBE or a PULSE OXIMETER MONITOR..... :	Refer to user manual : “Pulse oximeter simulator can not be used to access the accuracy of the pulse oximeter”	P

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	The technical description should provide descriptions on how the RESPONSIBLE ORGANIZATION can VERIFY operation of the PULSE OXIMETER EQUIPMENT. If the use of a FUNCTIONAL TESTER is specified, the technical description should indicate the MODEL OR TYPE REFERENCE and its software unique identifier., as applicable, of at least one FUNCTIONAL TESTER that is compatible with the basic functions of the PULSE OXIMETER EQUIPMENT.....:		N/A
201.8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		—
201.8.3.101	**Additional requirements for classification of applied parts**		P
	APPLIED PARTS of PULSE OXIMETER EQUIPMENT shall be TYPE BF or TYPE CF APPLIED PARTS.....:	Type BF	
201.10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		N/A
201.10.4	**Lasers**		N/A
	Depending on the light source used in a PULSE OXIMETER PROBE, the relevant requirements of IEC 60825-1:2014 shall apply to a PULSE OXIMETER PROBE .....:	No laser light source	N/A
	In the case of laser fibre optics, the requirements of IEC 60825-2:2004 + AMD1:2006 + AMD2:2010 shall apply.		N/A
201.11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		—
201.11.1.2.2	**APPLIED PARTS intended to supply heat to a PATIENT**		P
	The PULSE OXIMETER PROBE-tissue interface shall be evaluated when the skin temperature is initially at 35 °C for each PULSE OXIMETER MONITOR and PULSE OXIMETER PROBE indicated in the instructions for use.	See appended Table 201.11.1.2.2	P
	If the surface temperature of the PULSE OXIMETER PROBE at the tissue interface is capable of exceeding 41 °C, then.....:	Not exceeding 41 °C	N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	a) the PULSE OXIMETER EQUIPMENT shall have an OPERATOR-adjustable control for activating any elevated temperature mode that exceeds 41 °C. A deliberate sequence of OPERATOR actions shall be required to activate this mode. The instructions for use shall describe this sequence of OPERATOR actions .....:		N/A
	b) the PULSE OXIMETER EQUIPMENT shall provide a means to limit the duration of an elevated temperature mode in excess of 41 °C. The duration of the elevated temperature mode shall not exceed 4 h at 43 °C or 8 h at 42 °C .....:		N/A
	c) the instructions for use shall include a statement to the effect that the use of temperature settings greater than 41 °C requires special attention in PATIENTS with susceptible skin, such as neonates, geriatric PATIENTS, burn victims.....:		N/A
	d) the PULSE OXIMETER EQUIPMENT shall indicate when it is in the elevated temperature mode.....:		N/A
	e) the technical description shall describe the test method used to measure the maximum temperature at the PULSE OXIMETER PROBE-tissue interface. When performing the temperature measurements for the PULSE OXIMETER PROBE-tissue interface, as specified in IEC 60601-1:2005, 11.1.3, the test method disclosed in the technical description may be utilized .....:		N/A
201.11.6.5.101	**Additional requirements for ingress of water or particulate matter into me equipment or me system**		P
	The ENCLOSURE of a PULSE OXIMETER EQUIPMENT shall provide a degree of protection to the harmful ingress of water of:		—
	at least an IPX2 for PULSE OXIMETER EQUIPMENT.	See appended Table 201.11.6.5.101	P
	For PORTABLE ME EQUIPMENT that is only intended to be used within a protective case, this requirement may be met while the ME EQUIPMENT is inside the case.		N/A
201.11.8.101	**Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT**		N/A
201.11.8.101.1	**TECHNICAL ALARM CONDITION for power supply failure**		N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	If PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects a PHYSIOLOGICAL ALARM CONDITION the ALARM SYSTEM shall provide at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION to indicate when the power supply falls outside the values specified for normal operation	No alarm system	N/A
	If the function of the PULSE OXIMETER EQUIPMENT is maintained by the switchover to an INTERNAL ELECTRICAL POWER SOURCE, the supply failure MEDIUM PRIORITY TECHNICAL ALARM CONDITION shall not be activated. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION		N/A
201.11.8.101.2	**Settings and data storage following short interruptions or automatic switchover**		N/A
	When the SUPPLY MAINS to the PULSE OXIMETER EQUIPMENT is interrupted for less than 30 s or automatic switchover to an INTERNAL ELECTRICAL POWER SOURCE occurs, all settings and all stored PATIENT data shall be preserved unchanged	No any setting and patient data	N/A
201.11.8.101.3	**Operation following long interruptions**		N/A
	The instructions for use shall disclose the operation of the PULSE OXIMETER EQUIPMENT after the SUPPLY MAINS has been interrupted when the “on-off” switch remains in the “on” position and is restored after a period of time that is longer than 30 s . :	Internally powered	N/A
201.12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		—
201.12.1	**Accuracy of controls and instruments**		N/E
201.12.1.101.1	**SpO_2 accuracy of the pulse oximeter equipment – Specification**		N/E
	The SpO2 ACCURACY of PULSE OXIMETER EQUIPMENT shall be a root-mean-square difference of less than or equal to 4.0 % SpO2 over the range of 70 % to 100 % SaO2. The SpO2 shall be indicated as FUNCTIONAL OXYGEN SATURATION and shall not be indicated as FRACTIONAL OXYHAEMOGLOBIN ..... :	SpO2 accuracy of the pulse oximeter equipment was not evaluated in this report	N/E

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	The DECLARED RANGES of SpO2 and SpO2 ACCURACY over those ranges shall be disclosed in the instructions for use. The SpO2 ACCURACY shall be stated over the range 70 % to 100 %. SpO2 ACCURACY information shall be accompanied by a note reminding the reader that, because PULSE OXIMETER EQUIPMENT measurements are statistically distributed, only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER. When a PULSE OXIMETER MONITOR is suitable for use with a variety of PULSE OXIMETER PROBES, SpO2 ACCURACY information shall be made available for each type of PULSE OXIMETER PROBE ..... :		N/E
	A modified Bland and Altman plot (i.e., (*Sp*O2- *Sa*O2) versus *Sa*O2) for each combination of PULSE OXIMETER PROBE and PULSE OXIMETER MONITOR listed in the instructions for use for all subjects pooled, including upper 95 % and lower 95 % limits of agreement shall at a minimum be provided to the RESPONSIBLE ORGANIZATION upon request……..:		N/E
	Additional SpO2 ACCURACY specifications over other ranges may also be provided as long as the range is greater than 15 % *Sp*O2.:		N/E
	If SpO2 ACCURACY claims below 65 % SaO2 are made, SpO2 ACCURACY shall be stated in an additional range over a span of saturation not to exceed 20 % SaO2..... :		N/E
	Additional *Sp*O2 ACCURACY specifications over other ranges may also be provided. ..... :		N/E
201.12.1.101.2	**Data collection for determination of *Sp*O2 ACCURACY**		N/E
	The claims of SpO2 ACCURACY shall be supported by CONTROLLED DESATURATION STUDY measurements taken over the full range of SaO2 values +3 % of the lower value and −3 % of the upper value for which SpO2 ACCURACY is claimed		N/E
	The CONTROLLED DESATURATION STUDY complies with the requirements of ISO 14155:2011		N/E

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	The RESIDUAL RISK inherent in a controlled hypoxia study on healthy adult volunteers, can be reduced to a nonsignificant level by following recommended additional PROCEDURES……..……..: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/E
	The ACCURACY of PULSE OXIMETER EQUIPMENT for paediatric PATIENTS shall be supported via CONTROLLED DESATURATION STUDY measurements on adult subjects. Paediatric subjects are a vulnerable population. Data points should be recorded with comparable density over the full range claimed……..:		N/E
	Any types of interference known to influence or affect the SpO2 ACCURACY need not be stated as part of the SpO2 ACCURACY specification, but shall be disclosed in the instructions for use.....:		N/E
	A summary of the test methods used to establish the SpO2 ACCURACY claims shall be disclosed in the technical description……..:		N/E
	FUNCTIONAL TESTERS or PATIENT simulators shall not be used to VALIDATE the SpO2 ACCURACY of PULSE OXIMETER EQUIPMENT.		N/E
201.12.1.101.3	**Data analysis for determination of *Sp*O2 ACCURACY**		N/E
	For each range specified, *Sp*O2 ACCURACY of the PULSE OXIMETER EQUIPMENT shall be stated in terms of the root-mean-square (rms) difference between measured values (*Sp*O2*i*) and reference values (*Sri*), as given by Equation (1). $$A_{rms} = \sqrt{\frac{\sum_{i=1}^{n} (SpO_{2i} - S_{Ri})^2}{n}}$$		N/E

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	The standard reference for the *Sp*O2 ACCURACY as read by PULSE OXIMETER EQUIPMENT shall be traceable to *Sa*O2 values obtained from CO-OXIMETER analysis of simultaneously drawn arterial blood. The CO-OXIMETER should have a specified *Sa*O2 performance of 1 % (1 standard deviation) or better over the range for which the MANUFACTURER makes *Sp*O2 ACCURACY claims. Quality assurance, including maintenance and calibration, PROCEDURES for assessing CO-OXIMETER performance that are required in laboratories reporting clinical data shall be utilized for the CO-OXIMETER. Particular attention shall be given to the range for which the MANUFACTURER makes *Sp*O2 ACCURACY claims ..... :		N/E
201.12.1.101.4	**Characteristics of the clinical study population for determination of *Sp*O2 ACCURACY**		N/E
	The summary of the clinical study report used to assess *Sp*O2 ACCURACY shall state whether the test subjects were sick or healthy and shall describe their skin colour, age and gender. This information shall be disclosed in the ACCOMPANYING DOCUMENT ..... :		N/E
201.12.1.102	**Accuracy under conditions of motion**		N/A
	If a MANUFACTURER claims that the PULSE OXIMETER EQUIPMENT is accurate during motion, ACCURACY specifications during motion shall be disclosed in the instructions for use ..... :	No such claims	N/A
	A summary of the test methods used to establish the ACCURACY claims during motion shall be disclosed in the technical description. The summary should include the average percentage modulation (of the infrared signal as an indicator of pulsatile signal strength) in quiescent and motion periods during the test ..... :		N/A
201.12.1.103	**Accuracy under conditions of low perfusion**		N/A
	If a MANUFACTURER claims that the PULSE OXIMETER EQUIPMENT is accurate under conditions of low perfusion, ACCURACY specifications under these conditions shall be disclosed in the instructions for use..... :	No such claims	N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	A summary of the test methods used to establish the ACCURACY claims under conditions of low perfusion shall be disclosed in the technical description. The summary should include percentage modulation of the infrared signal as an indicator of pulsatile signal strength ..... :		N/A
201.12.1.104	**Pulse rate accuracy**		P
	If equipped, pulse rate ACCURACY shall be stated as the root-mean-square (rms) difference between paired pulse rate data recorded with the PULSE OXIMETER EQUIPMENT and with a reference method. Pulse rate ACCURACY shall be stated either over the full claimed range of the PULSE OXIMETER EQUIPMENT or as separate pulse rate ACCURACY specifications over segments of that range. The reference method for the computation of pulse rate ACCURACY may be an electronic pulse simulator, ECG heart rate, palpated pulse, thoracic auscultation or a second PULSE OXIMETER EQUIPMENT which has been qualified by comparison to one of these references. The reference method for the determination of pulse rate ACCURACY shall be disclosed in the technical description ..... :	Refer to electronic pulse simulator	P
201.12.4	**Protection against hazardous output**		P
201.12.4.101	**DATA UPDATE PERIOD**		N/A
	There shall be an indication that SpO2 or pulse rate data is not current when the DATA UPDATE PERIOD is greater than 30 s. The DATA UPDATE PERIOD time may be shorter than 30 s. A maximum DATA UPDATE PERIOD for saturation and pulse rate shorter than 30 s is recommended for continuous neonatal monitoring and diagnostic applications ..... :	Less than 30 s	N/A
	SpO2 or pulse rate DATA UPDATE PERIOD (sec)……..:		---
	If the PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITIONS, the ALARM SYSTEM shall provide at least a LOW PRIORITY ALARM CONDITION to indicate when the DATA UPDATE PERIOD exceeds 30 s ..... :		N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	PULSE OXIMETER EQUIPMENT that is not equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITION shall indicate when the DATA UPDATE PERIOD exceeds 30 s. The indication shall be described in the instructions for use.....:		N/A
	If the PULSE OXIMETER EQUIPMENT is equipped with a FUNCTIONAL CONNECTION, an indication that the DATA UPDATE PERIOD exceeds 30 s shall be included in the data stream……:		N/A
201.12.4.102	**Signal inadequacy**		P
	An indicator of signal inadequacy shall be provided to the OPERATOR when the displayed *Sp*O2 or pulse rate value is potentially incorrect. Symbol ISO 7000-0435 (see Table D.2.101, Symbol 6) may be used for this indication. A description of the indicator and its function shall be provided in the ACCOMPANYING DOCUMENT .....:	An indication of pulse intensity; Showed "--" for SpO_2, "---" for pulse rate	P
	If the PULSE OXIMETER EQUIPMENT is equipped with a FUNCTIONAL CONNECTION, then signal inadequacy shall be included in the data stream……:		N/A
201.13	**HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**		—
201.13.101	**Detection of PROBE FAULTS and PROBE CABLE EXTENDER faults**		N/A
	If the PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM to detect any PHYSIOLOGICAL ALARM CONDITIONS, the ALARM SYSTEM shall provide a TECHNICAL ALARM CONDITION to indicate when any wire in the PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER is opened or shorted to any other wire in the PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER that causes other than normal operation	No pulse oximeter probe cable or probe cable extender	N/A
	PULSE OXIMETER EQUIPMENT that is not equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITIONS shall visually indicate the presence of PULSE OXIMETER PROBE FAULTS. The indication shall be described in the instructions for use……:		N/A
201.15	**CONSTRUCTION OF ME EQUIPMENT**		—
201.15.3.5.101	**Additional requirements for rough handling**		N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
201.15.3.5.101.1	**Shock and Vibration**		N/A
	PULSE OXIMETER EQUIPMENT or its parts not intended for use during in the EMERGENCY MEDICAL SERVICES ENVIRONMENT or for use in the HOME HEALTHCARE ENVIRONMENT shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling. STATIONARY EQUIPMENT is exempt from the requirements of this subclause.	Intended for use in the home healthcare environment	N/A
	After the specified tests, the PULSE OXIMETER EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A
201.15.101	**Mode of operation**		P
	PULSE OXIMETER EQUIPMENT shall be suitable for CONTINUOUS OPERATION.....:	Continuous operation	P
201.101	**Pulse oximeter probes and probe cable extenders**		—
201.101.1	**General**		P
	All PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS shall comply with the requirements of this International Standard, whether they are produced by the MANUFACTURER of the PULSE OXIMETER MONITOR, by another entity (“third party manufacturer” or healthcare provider) or are REPROCESSED .....:	The pulse oximeter probe is integrated in the equipment	P
	MANUFACTURERS of REPROCESSED PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS shall perform testing to ensure that all PULSE OXIMETER EQUIPMENT specifications are met with each model of PULSE OXIMETER MONITOR with which the PULSE OXIMETER PROBE or PROBE CABLE EXTENDER is intended to be used. The ACCOMPANYING DOCUMENT of REPROCESSED PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS shall list all PULSE OXIMETER MONITORS with which compatibility is claimed .....:		N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	It is the responsibility of the MANUFACTURER to VALIDATE their PROCESSES to ensure that any new or REPROCESSED product complies with the requirements of this document……..:		P
201.101.2	**Labelling**		P
	The MODEL OR TYPE REFERENCE of at least one PULSE OXIMETER MONITOR shall be included in the ACCOMPANYING DOCUMENT provided with each PULSE OXIMETER PROBE, compliant with 201.101.1 ..... :	The pulse oximeter probe is integrated in the equipment	P
	Statements shall be included in the ACCOMPANYING DOCUMENT of each PULSE OXIMETER PROBE or PROBE CABLE EXTENDER to the effect that:		---
	a) probes are designed for use with specific monitors ..... :		N/A
	b) the operator is responsible for checking the compatibility of the monitor, probe and cable before use..... :		N/A
	c) incompatible components can result in degraded performance..... :		N/A

201.102	**SATURATION OF PULSE INFORMATION SIGNAL**		—
	If a variable-pitch auditory INFORMATION SIGNAL is provided to indicate the detection of a pulse and the relative *Sp*O2 level, the pitch change shall follow the *Sp*O2 reading, e.g. the pitch decreases as the *Sp*O2 reading decreases ..... :	No auditory information signal	N/A

201.103	**FUNCTIONAL CONNECTION**		—
201.103.1	**General**		N/A
	BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained during failure of equipment connected to or the disruptions of connections to SIGNAL INPUT/OUTPUT PARTS of PULSE OXIMETER EQUIPMENT **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.7)**	No functional connection	N/A
201.103.2	**Connection to electronic health record**		N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	PULSE OXIMETER EQUIPMENT should be equipped with a FUNCTIONAL CONNECTION that permits data transmission from the PULSE OXIMETER EQUIPMENT to an electronic health record. If so equipped, the transmission shall comply with Annex HH.		N/A
	The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F2761-09 ..... :		N/A
201.103.3	**Connection to a distributed alarm system**		N/A
	For PULSE OXIMETER EQUIPMENT that is equipped with an ALARM SYSTEM that detects a PHYSIOLOGICAL ALARM CONDITION, the ALARM SYSTEM should be equipped with a FUNCTIONAL CONNECTION that permits connection to a DISTRIBUTED ALARM SYSTEM. The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F2761-09 ..... :		N/A
202	**Electromagnetic disturbances – Requirements and tests**		—
202.4.3.1	**Configurations**		N/E
	– During immunity testing, the PULSE OXIMETER EQUIPMENT shall be tested at an *Sp*O2 reading within the calibrated range that is at least 5 % different from that of a noise-induced value and less than (100 % minus the *Sp*O2 ACCURACY of the PULSE OXIMETER EQUIPMENT) ..... :	Electromagnetic disturbances were not evaluated in this report	N/E
	– The pulse rate shall be different from that of the noise-induced signal frequency and within the specified range of the pulse rate display		N/E
	– The SpO2 and pulse rate signal may be derived from a PATIENT simulator for these tests ..... :		N/E
202.8.1.101	**Additional general requirements**		N/E
	Under the IMMUNITY TEST LEVELS specified in IEC 60601-1-2:2014, 8.9, PULSE OXIMETER EQUIPMENT shall be able to provide BASIC SAFETY and ESSENTIAL PERFORMANCE ..... :		N/E

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	The following degradations, if associated with BASIC SAFETY or ESSENTIAL PERFORMANCE shall not be allowed:		—
	– component failures;		N/E
	– changes in programmable parameters or settings;		N/E
	– reset to default settings; and		N/E
	– change of operating mode.		N/E
	The PULSE OXIMETER EQUIPMENT may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use during IMMUNITY testing) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE providing the PULSE OXIMETER EQUIPMENT recovers from any disruption within 30 s without OPERATOR intervention.		N/E
202.8.2	**PATIENT physiological simulation**		N/E
	During IMMUNITY testing, the PULSE OXIMETER EQUIPMENT shall be tested at an *Sp*O2 reading within the calibrated range that is at least 5 % different from that of a noise-induced value and less than (100 % minus the *Sp*O2 ACCURACY of the PULSE OXIMETER EQUIPMENT).		N/E
	The pulse rate shall be different from that of the noise-induced signal frequency and within the specified range of the pulse rate display.		N/E
	The *Sp*O2 and pulse rate signal may be derived from a PATIENT simulator for these tests.		N/E
206	**Usability**		—
	For PULSE OXIMETER EQUIPMENT, the following shall be considered PRIMARY OPERATING FUNCTIONS:		—
	a) setting the OPERATOR-adjustable controls;	Usability was not evaluated in this report	N/E
	- setting ALARM LIMITS;		N/E
	- inactivating ALARM SIGNALS;		N/E
	- switching between different modes;		N/E
	b) observing monitored parameters;		N/E
	c) applying the PULSE OXIMETER PROBE to the PATIENT;		N/E
	d) starting the PULSE OXIMETER EQUIPMENT from power off; and		N/E

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	e) connecting and disconnecting the DISTRIBUTED ALARM SYSTEM, if provided.		N/E
208	**General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems**		—
208.6.1.2.101	**Additional requirements for ALARM CONDITION priority**		N/A
	If the PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects a PHYSIOLOGICAL ALARM CONDITION, the ALARM SYSTEM shall provide at least a MEDIUM PRIORITY ALARM CONDITION for low *Sp*O2 level.....:	Not equipped with an alarm system	N/A
208.6.5.4.101	**Additional requirements for DEFAULT ALARM PRESET**		N/A
	If the PULSE OXIMETER MONITOR is equipped with an ALARM SYSTEM to detect a low *Sp*O2 level PHYSIOLOGICAL ALARM CONDITION, the ALARM LIMIT in the MANUFACTURER-configured ALARM PRESET for the *Sp*O2 level PHYSIOLOGICAL ALARM CONDITION shall not be less than 85 % *Sp*O2.....:		N/A
	ALARM limit of SpO2 level PHYSIOLOGICAL ALARM CONDITION (%) .....:		—
	Unless the low SpO2 ALARM LIMIT is displayed continuously, the low SpO2 ALARM LIMIT of any OPERATOR configured ALARM PRESET shall not be less than the low SpO2 ALARM LIMIT stored in the DEFAULT ALARM PRESET.....:		N/A
208.6.8.5.101	**Additional requirements for ALARM SIGNAL inactivation states, indication and access**		N/A
	The MANUFACTURER-configured default AUDIO PAUSED or ALARM PAUSED interval of PULSE OXIMETER EQUIPMENT shall not exceed 2 min .....:		N/A
	Time interval of PULSE OXIMETER EQUIPMENT (sec)……..:		---
211	**Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment**		—
	The tests of IEC 60601-1-11:2015, Clause 10, and IEC 60601-1:2005 + AMD1:2012, 15.3, shall be performed on the same sample of the PULSE OXIMETER EQUIPMENT following any REPROCESSING established for this equipment……..:	Refer to IEC 60601-1-11:2015 test report and IEC 60601-1:2005 + AMD1:2012 test report, not evaluated in this report.	N/E
212	**Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment**		N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	The tests of IEC 60601-1-12:2014, Clause 10, and IEC 60601-1:2005+AMD1:2012, 15.3, shall be performed on the same sample of the PULSE OXIMETER EQUIPMENT following any REPROCESSING established for this equipment……..:	Not used in the emergency medical services environment	N/A

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.4.3.101	ESSENTIAL PERFORMANCE		P
Distributed Essential Performance requirements			
Requirements	**Document Ref (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
For PULSE OXIMETER EQUIPMENT provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: *Sp*O2 ACCURACY, PULSE RATE ACCURACY* and limit ALARM CONDITIONS (Sub clause- 201.12.1.101, 201.12.1.104 and 208.6.1.2.101) or	—	—	N/A
Generation of a TECHNICAL ALARM CONDITION (Sub clause – 201.11.8.101.1, 201.12.4 and 201.13.101)	—	—	N/A
For PULSE OXIMETER EQUIPMENT not provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: *Sp*O2 ACCURACY* and PULSE RATE ACCURACY (Sub clause- 201.12.1.101 and 201.12.1.104) or	Risk Management Report, No. J/M70-073-2011A1, V1.0, chapter 4.5	The SpO_2 accuracy and PR accuracy comply the specification	P
or indication of abnormal operation (Sub clause – 201.12.4 and 201.13.101)	Risk Management Report, No. J/M70-073-2011A1, V1.0, chapter 4.5	or not indicate the SpO_2 and PR reading (abnormal operation)	P
*** Note: Subclause 202.6.2.1.7 indicates methods of evaluating *Sp*O2 ACCURACY and PULSE RATE ACCURACY as acceptance criteria following specific tests required by this standard.**			

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.11.1.2.2	TABLE: APPLIED PARTS intended to supply heat to a PATIENT	P
Pulse Oximeter Model No.....:	M70, M70A, M70C	
Test supply voltage/frequency (V/Hz)[4].....	New batteries: 3 V d.c. (2 × AAA alkaline batteries)	
Skin temperature and colour (°C, white/dark)	35,0 °C, SpO_2 simulator	
Thermocouple Type and Size .....: **Note: Type K ≤ 0.25 mm wire**	Type T; 0,25 mm wire	
Measurement expected accuracy .....:	1 °C	
Maximum allowable temperature .....: **Note: All patients 41°C; Patients less than 1 year old 41°C; Adults for up to 8 hours 42°C; Adults for up to 4 hours 43°C**	All patients 41 °C	
Environmental ambient during test (°C, %RH, atmospheric pressure) .....:	35,0 °C; 48% R.H.; 101,1 kPa	

SpO_2 Sensor Model No.	**Thermocouple location[3]**	**Max measured temperature[2], (°C)**	**Remarks**
M70	send light	36,3	
	receive light	36,8	
M70A	send light	36,1	
	receive light	36,6	
M70C	send light	36,1	
	receive light	36,3	

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

This International Standard does not require a particular method of measuring the skin temperature beneath the PULSE OXIMETER PROBE. There are many different widely known and accepted methods of measuring surface temperatures. Different PULSE OXIMETER PROBE MANUFACTURERS have evolved their own methods of measuring temperature, using either human test subjects or thermo-mechanical simulators. It would be impractical today to find a single universally acceptable test method, and the excellent thermal safety record of pulse oximetry suggests that such a method is not necessary. PULSE OXIMETER PROBE designers who wish to take advantage of the higher temperatures should keep the following cautions in mind

– **Measurement tolerances are required to be evaluated carefully. The MANUFACTURER should know the true ACCURACY of temperature measurement when designing PULSE OXIMETER PROBES for use at temperatures above 41 °C since a higher temperature reduces the margin of safety**

– **Temperature sensors are required to be small enough so as not to distort the measurement. The largest temperature sensors that have been found acceptable have characteristic dimensions near 0,5 mm (e.g. the bead of a thermocouple welded from 0,25 mm wire). Often still smaller temperature sensors are used**

– **The temperature sensor is required to not reduce the measured peak temperature by conducting a significant amount of heat away from the measurement region. Thus, it would usually be inappropriate to use the copper-constantan type T thermocouples that are common in medical investigation, since the high thermal conductivity of the copper wire could cause a falsely low temperature measurement**

– **The temperature sensor is required to be located precisely at the warmest point on the interface between the skin and the PULSE OXIMETER PROBE. This is often, but not invariably, a point on the PULSE OXIMETER PROBE that is midway between the two LED chips that are typically used in emitters. The warmest point is found by testing**

– **Experimental methods are required to be adequate to ensure that recommended temperature limits are met under "reasonable worst case" conditions. As an example, reasonable worst case for neonatal PULSE OXIMETER PROBES might include the following conditions**

– **The PATIENT has poor peripheral circulation. There is therefore little forced-convection heat transfer by blood to increase the effective thermal conductivity of surface tissue**

– **The LEDs in the PULSE OXIMETER PROBE are driven at the maximum current which the PULSE OXIMETER MONITOR is capable of providing during normal operation (this condition can occur when the PATIENT has very dark skin or a thick foot)**

– **An active heat source is in use to raise the baby's abdominal skin temperature artificially to 37 °C**

Not every model of PULSE OXIMETER PROBE is required to be tested directly on or representing "worst-case" PATIENTS. The MANUFACTURER should select methods for evaluation of the thermal performance of the PULSE OXIMETER PROBE that lead to confident prediction of thermal safety on such PATIENTS

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.11.6.5.101	TABLE: Ingress of water		P
☒	IPX2	Without protective case	
☐	IPX2	With protective case	

Test Condition/Method	Part under test	Remarks
IP22	M70	Set value: SpO_2: 96%; PR: 75 bpm Measurement value: SpO_2: 96%; PR: 75 bpm
IP22	M70A	Set value: SpO_2: 96%; PR: 75 bpm Measurement value: SpO_2: 96%; PR: 75 bpm
IP22	M70C	Set value: SpO_2: 96%; PR: 75 bpm Measurement value: SpO_2: 97%; PR: 75 bpm
Supplementary information:		

201.11.8.101.1 a)	TABLE: Supply failure technical alarm condition			N/A
Power Supply	**Voltage triggering a Technical Alarm Condition (V)**	**Indication of medium priority technical alarm condition**	**Observed behaviour as voltage continues to decrease**	**Remarks**
Supplementary information:				

201.11.8.101.1 b)	TABLE: Supply failure technical alarm condition			N/A
Automatic switchover to an internal electrical power source	**Voltage triggering a Technical Alarm Condition or Information Signal (V)**	**Indication of Information Signal**	**Indication of Low Priority Technical Alarm Condition**	**Remarks**
Supplementary information: A medium priority technical alarm condition shall not be activated				

201.11.8.101.2	TABLE: Settings and data storage following short interruptions or automatic switchover			N/A
Automatic switchover to an internal electrical power source (Yes/No)	**Settings before power interruption**	**Settings after power interruption**	**Data storage before power interruption**	**Data storage after power interruption**
Supplementary information: A medium priority technical alarm condition shall not be activated				

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.13.101	**TABLE: Detection of pulse oximeter probe faults and probe cable extender faults**	**N/A**
Pulse Oximeter Probe(s) ..... :		
Pulse Oximeter Cable(s)..... :		
Pulse Oximeter probe cable extender(s) ..... :		

Identify active (used) wire in the pulse oximeter (probe, cable and/or extender)	Fault introduced (opened or shorted)	Continues Normal Operation	Technical Alarm Condition	Indication of probe faults

Supplementary information: IFU describes these indications

201.15.3.5.101.1 (Type 1)	**TABLE: Shock test (IEC 60068-2-27:2008) for an Pulse Oximeter Equipment or its parts not intended for use during in the EMERGENCY MEDICAL SERVICES ENVIRONMENT or for use in the HOME HEALTHCARE ENVIRONMENT shall have adequate mechanical strength under the following conditions (Test Type 1):**		**N/A**
	Peak acceleration ..... :	**150 m/s^2 (15 g)**	
	Duration ..... :	**11 ms**	
	Pulse shape..... :	**half-sine**	
	Number of shocks ..... :	**3 shocks per direction per axis (18 total)**	

Applied Shock Direction	Applied Shock Axis	Method	Remarks
Basic Safety Verification:			
Essential performance Verification:			

Supplementary information:

NOTE: This represents Class 7M2 as described in IEC/TR 60721-4-7:2001

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.101.1 (Type 2)	**TABLE: Shock test (IEC 60068-2-27:2008) for an Pulse Oximeter Equipment or its parts not intended for use during in the EMERGENCY MEDICAL SERVICES ENVIRONMENT or for use in the HOME HEALTHCARE ENVIRONMENT shall have adequate mechanical strength under the following conditions (Test Type 2):**		**N/A**
	Peak acceleration .....:	**300 m/s^2 (30 g)**	
	Duration .....:	**6 ms**	
	Pulse shape.....:	**half-sine**	
	Number of shocks .....:	**3 shocks per direction per axis (18 total)**	

Applied Shock Direction	Applied Shock Axis	Method	Remarks
Basic safety Verification:			
Essential performance Verification:			
Supplementary information: **NOTE: This represents Class 7M2 as described in IEC/TR 60721-4-7:2001**			

201.15.3.5.101.1 (Broad-band random)	**TABLE: Vibration Test (IEC 60068-2-64:2008) for a Pulse Oximeter Equipment or its parts not intended for use during in the EMERGENCY MEDICAL SERVICES ENVIRONMENT or for use in the HOME HEALTHCARE ENVIRONMENT shall have adequate mechanical strength under the following conditions (Broad-band random vibration test):**		**N/A**
1	**Acceleration amplitude.....:**	**10 Hz to 100 Hz: 1,0 (m/s^2)^2/Hz**	
2	**Acceleration amplitude.....:**	**100 Hz to 200 Hz: - 3 db per octave**	
3	**Acceleration amplitude.....:**	**200 Hz to 2 000 Hz: 0,5 (m/s^2)^2/Hz**	
	Duration .....:	**30 min per perpendicular axis (3 total)**	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	Method	Remarks
Basic safety Verification:			
Essential performance Verification:			
Supplementary information: **NOTE: This represents Class 7M1 and 7M2 as described in IEC/TR 60721-4-7:2001**			

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.103.1	TABLE: Failure of equipment connected to or disruptions of connections to Signal Input/Output parts			N/A
Signal Input/Output part	**Failure Mode**	**Basic Safety Verification**	**Essential Performance Verification**	**Remarks**
Supplementary information: A medium priority technical alarm condition shall not be activated				

201.103.2	TABLE: Connection to electronic health record			N/A
Identification of Pulse Oximeter Equipment	**SpO_2 Reading**	**Pulse Rate**	**Alarm System Status**	**Remarks**
Supplementary information: The network/data coupling should be provided in accordance with ASTM F2761-09. Alarm systems with physiological alarm conditions should be equipped with a signal input/output part that permits connection to a distributed alarm system.				

208.6.1.2.101	TABLE: Alarm Condition Priority	N/A
SpO_2 Low Alarm Limit Setting	**SpO_2 Low Measurement (% SpO_2)**	**Medium Priority Alarm Condition**
Supplementary information:		

208.6.5.4.101	TABLE: Default Alarm Preset	N/A
SpO_2 Low Alarm Limit Setting – Manufacturer-configured Alarm Preset	**SpO_2 Low Alarm Limit Displayed Continuously (% SpO_2)**	**SpO_2 Low Alarm Limit Operator Configurable Alarm Preset (% SpO_2)**
Supplementary information:		

208.6.8.5.101	TABLE: Alarm Signal Inactivation States, Indication and Access	N/A
Default Audio Paused Interval maximum	**Default Alarm Paused Interval maximum**	**Remarks**
Supplementary information:		

Attachment 1: Photo Documentation

Details of: M70

View:

[ ] general

[ ] front

[ ] rear

[ ] right

[ ] left

[☒] top

[ ] bottom

Details of: M70, marking refer to “copy of marking plate”

View:

[ ] general

[ ] front

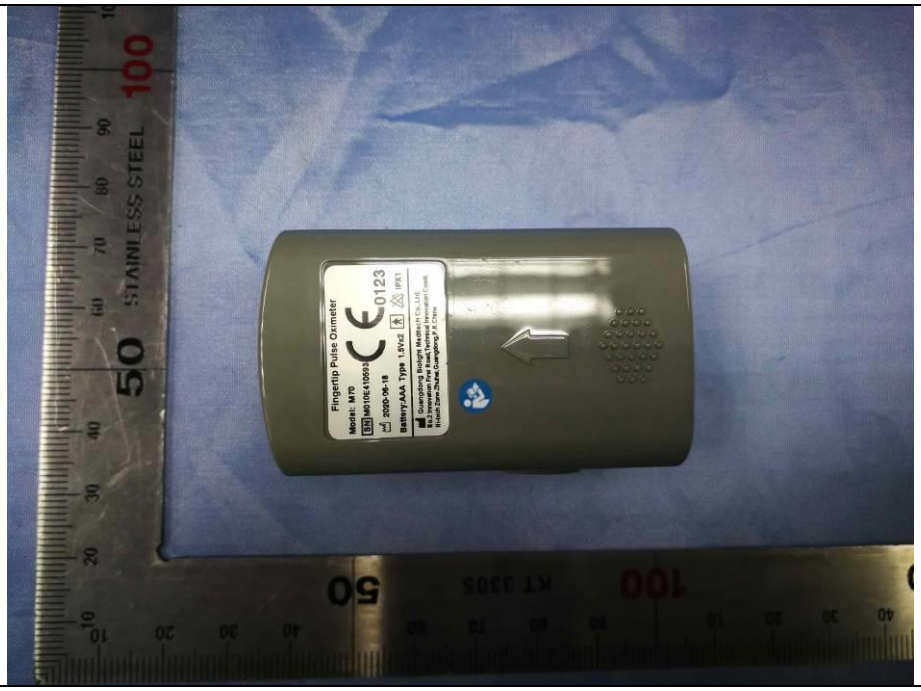
[ ] rear

[ ] right

[ ] left

[ ] top

[☒] bottom



Attachment 1: Photo Documentation

Details of: M70

View:

[ ] general

[ ] front

[ ] rear

[ ] right

[☒] left

[ ] top

[ ] bottom

Details of: M70

View:

[ ] general

[ ] front

[ ] rear

[☒] right

[ ] left

[ ] top

[ ] bottom

Attachment 1: Photo Documentation

Details of: M70

View:

[ ] general

[☒] front

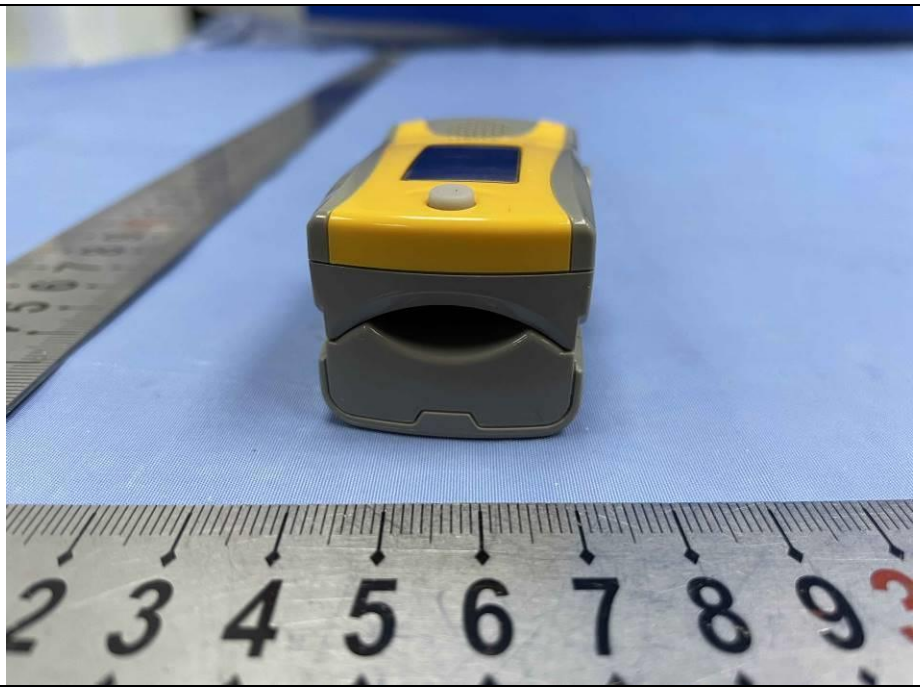
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Details of: M70

View:

[ ] general

[ ] front

[☒] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Attachment 1: Photo Documentation

Details of: M70, display interface

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: M70, applied part

View:

[☒] general

[ ] front

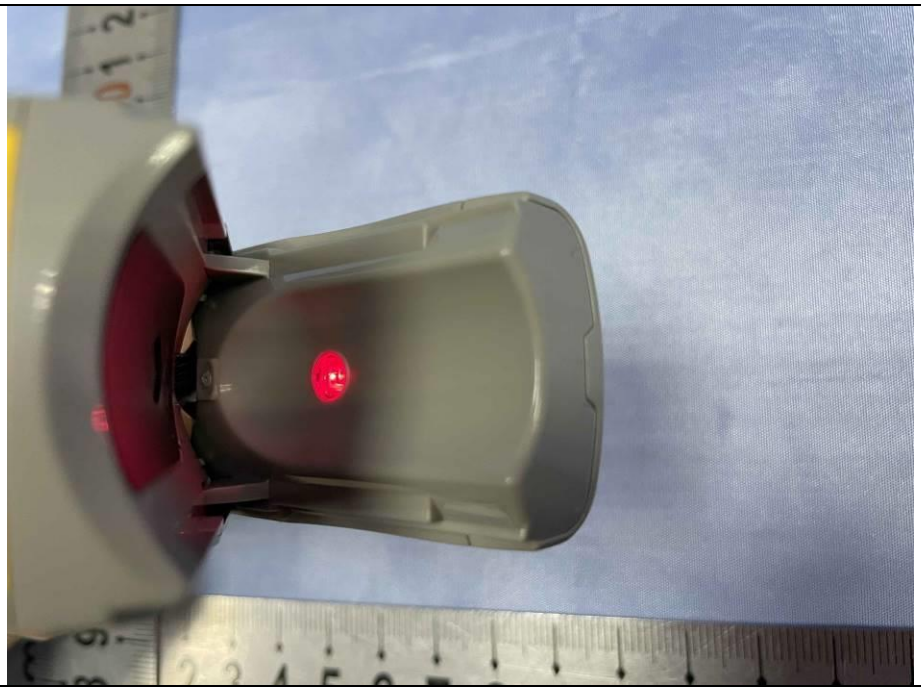
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70, battery compartment

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: M70, internal view

View:

[☒] general

[ ] front

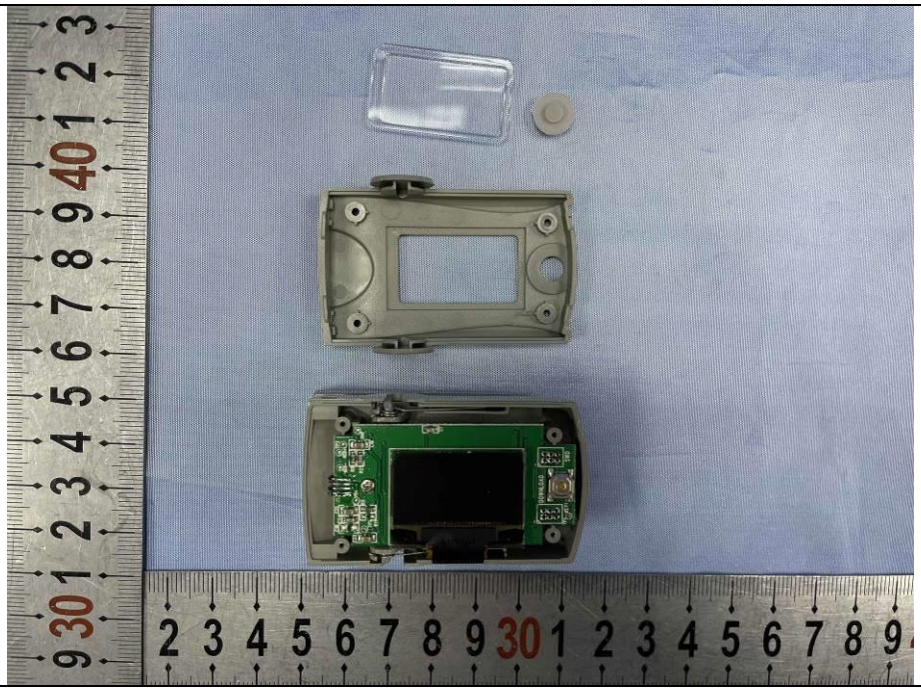
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70, PCB

View:

[☒] general

[ ] front

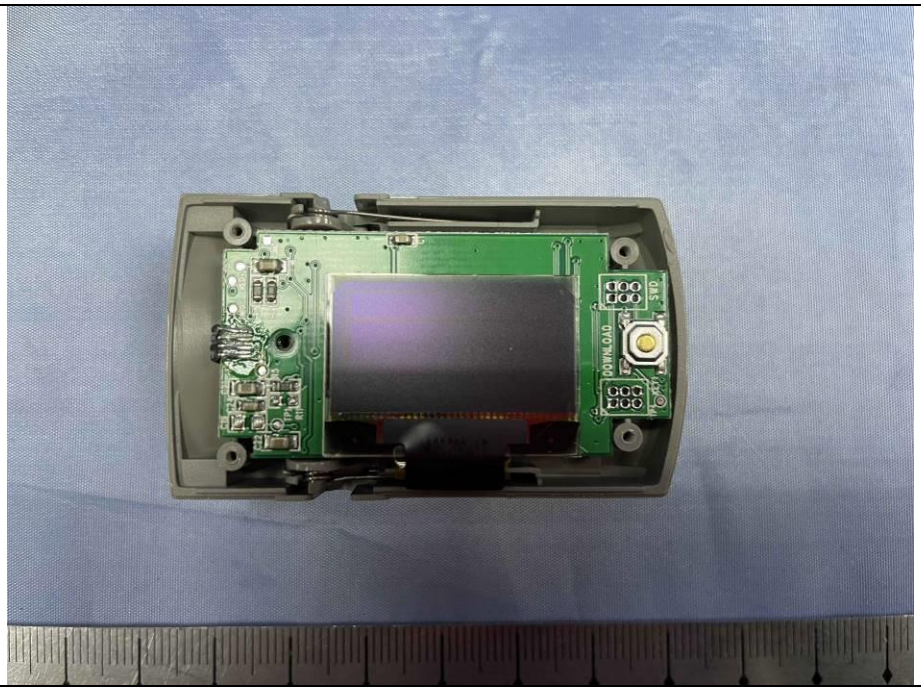
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Details of: M70, PCB

View:

[☒] general

[ ] front

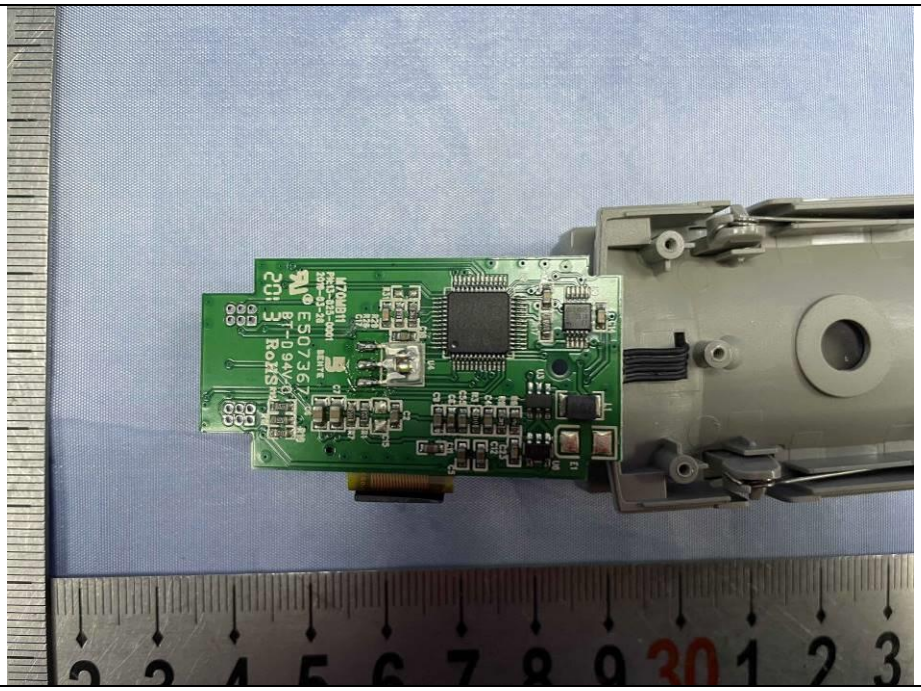
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70, PCB

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: M70, PCB

View:

[☒] general

[ ] front

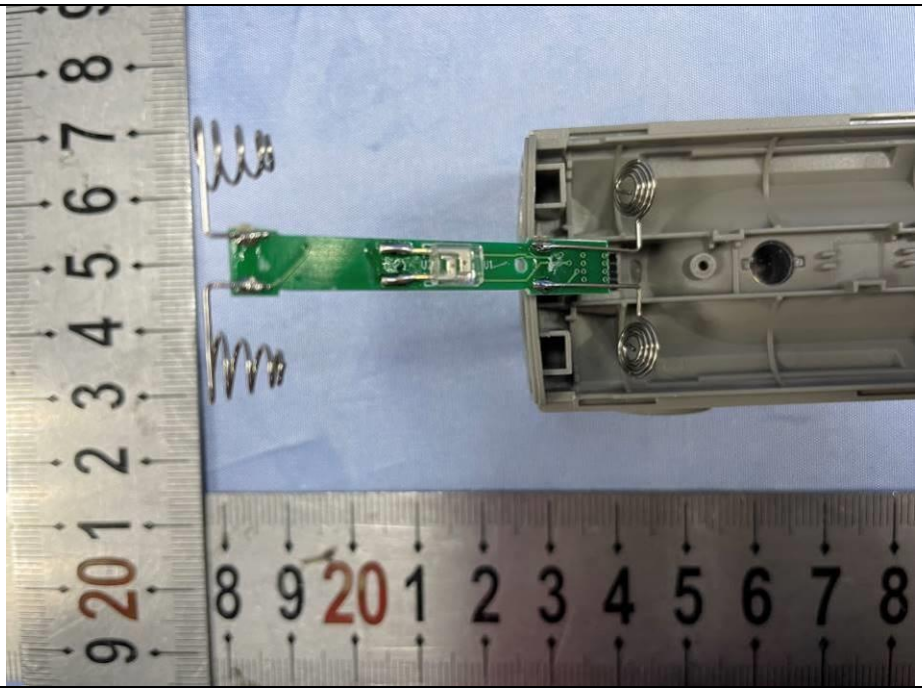
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70A

View:

[ ] general

[ ] front

[ ] rear

[ ] right

[ ] left

[☒] top

[ ] bottom

Details of: M70A, marking refer to “copy of marking plate”

View:

[ ] general

[ ] front

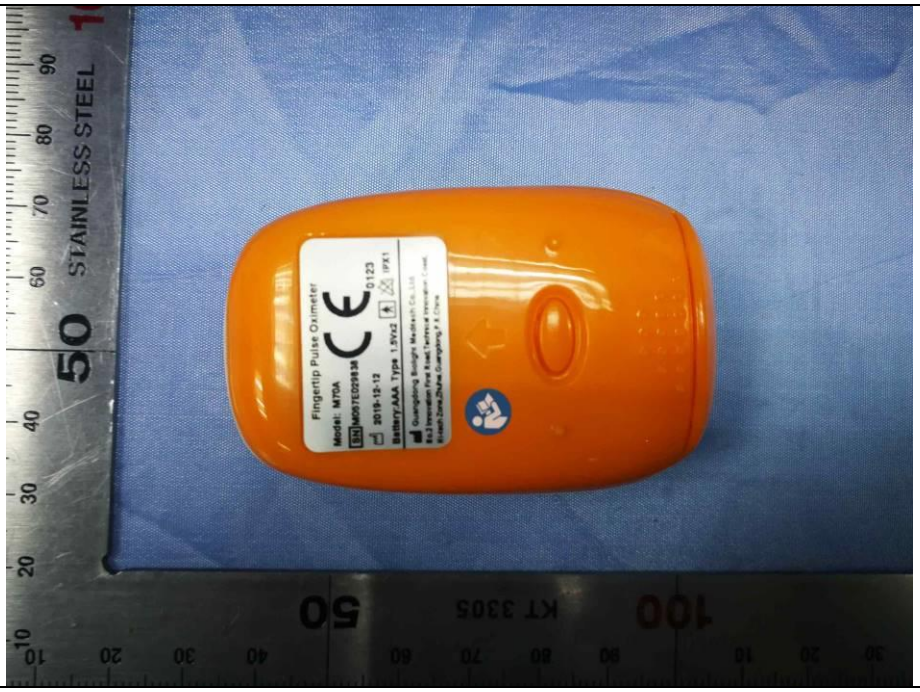
[ ] rear

[ ] right

[ ] left

[ ] top

[☒] bottom



Attachment 1: Photo Documentation

Details of: M70A

View:

[ ] general

[ ] front

[ ] rear

[ ] right

[☒] left

[ ] top

[ ] bottom

Details of: M70A

View:

[ ] general

[ ] front

[ ] rear

[☒] right

[ ] left

[ ] top

[ ] bottom

Attachment 1: Photo Documentation

Details of: M70A

View:

[ ] general

[☒] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: M70A

View:

[ ] general

[ ] front

[☒] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Attachment 1: Photo Documentation

Details of: M70A, display interface

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: M70A, applied part

View:

[☒] general

[ ] front

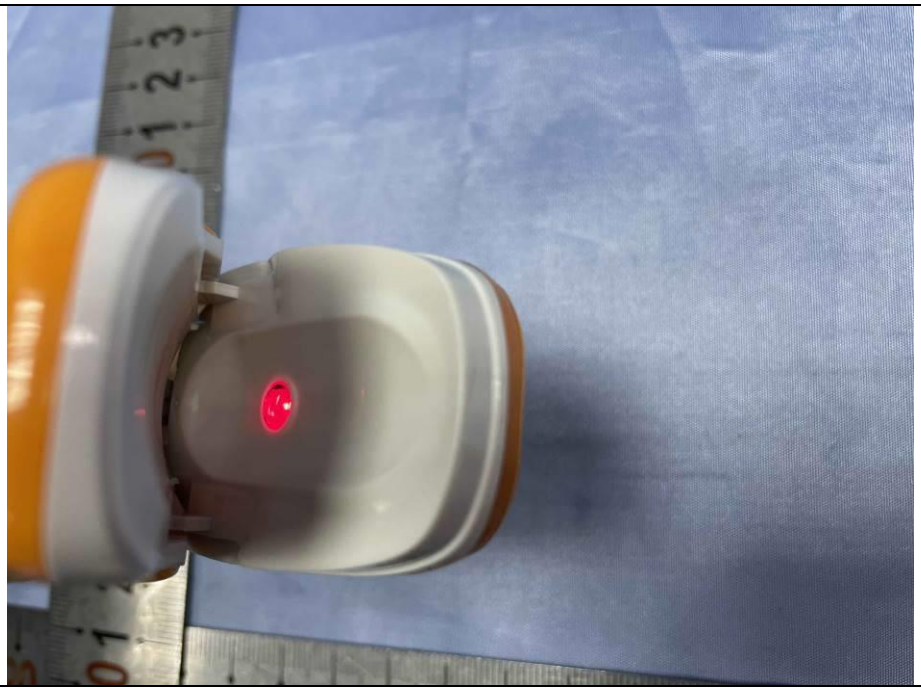
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70A, battery compartment

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: M70A, internal view

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Attachment 1: Photo Documentation

Details of: M70A, PCB

View:

[☒] general

[ ] front

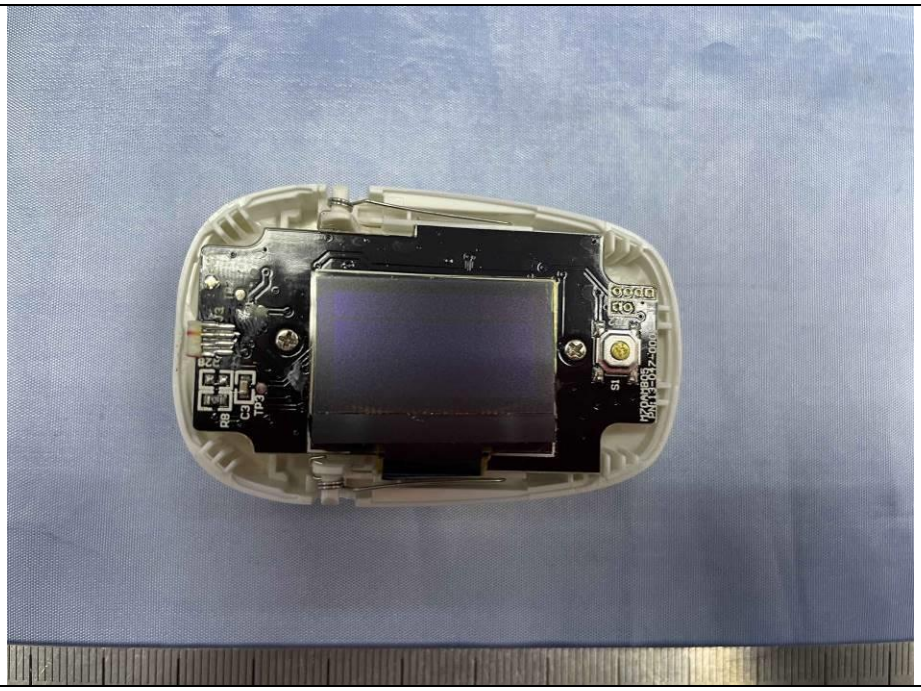
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Details of: M70A, PCB

View:

[☒] general

[ ] front

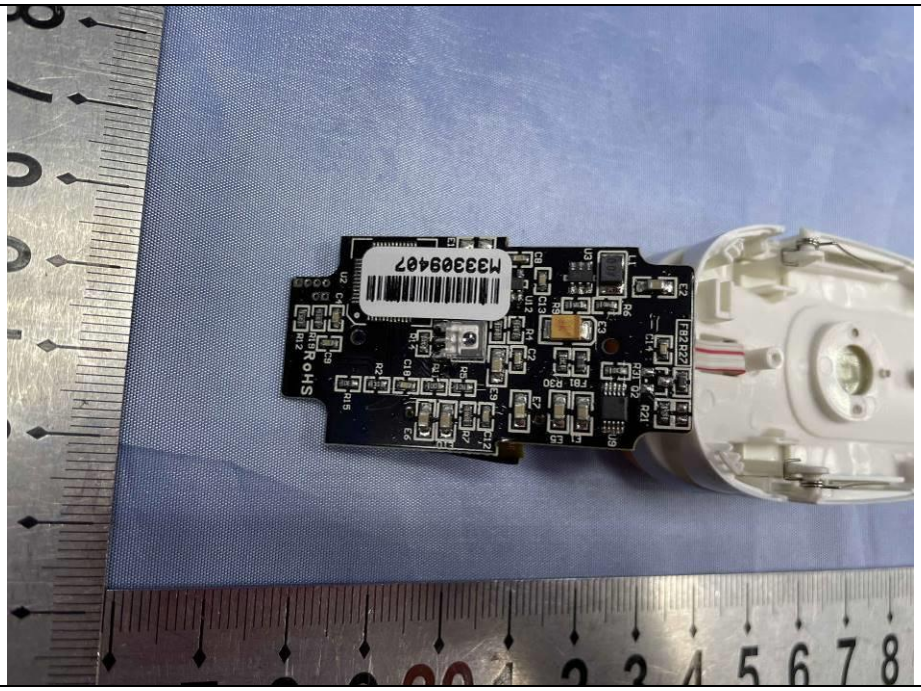
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70A, PCB

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: M70A, PCB

View:

[☒] general

[ ] front

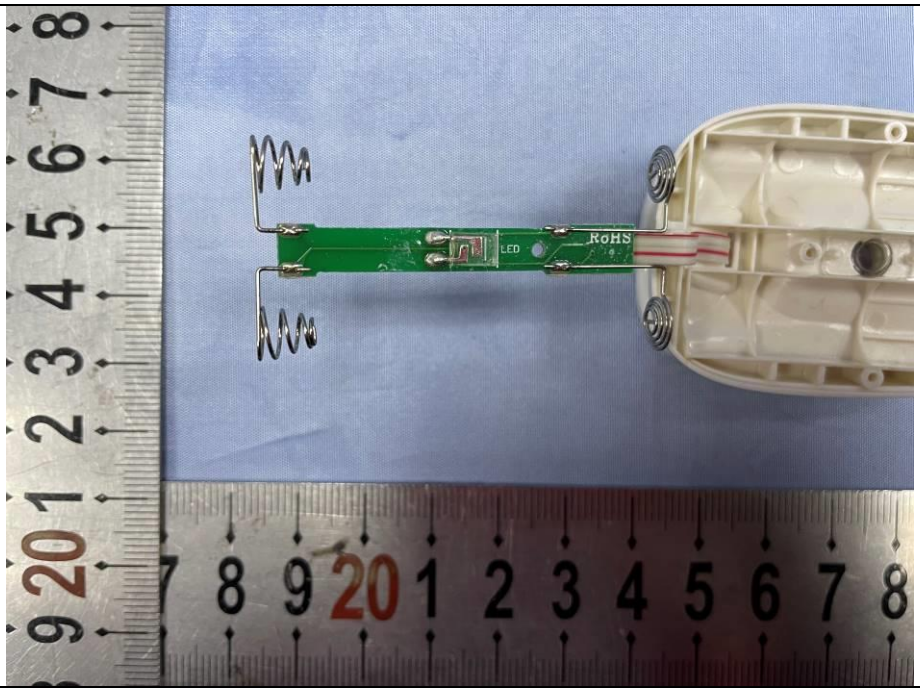
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70C

View:

[ ] general

[ ] front

[ ] rear

[ ] right

[ ] left

[☒] top

[ ] bottom

Details of: M70C, marking refer to “copy of marking plate”

View:

[ ] general

[ ] front

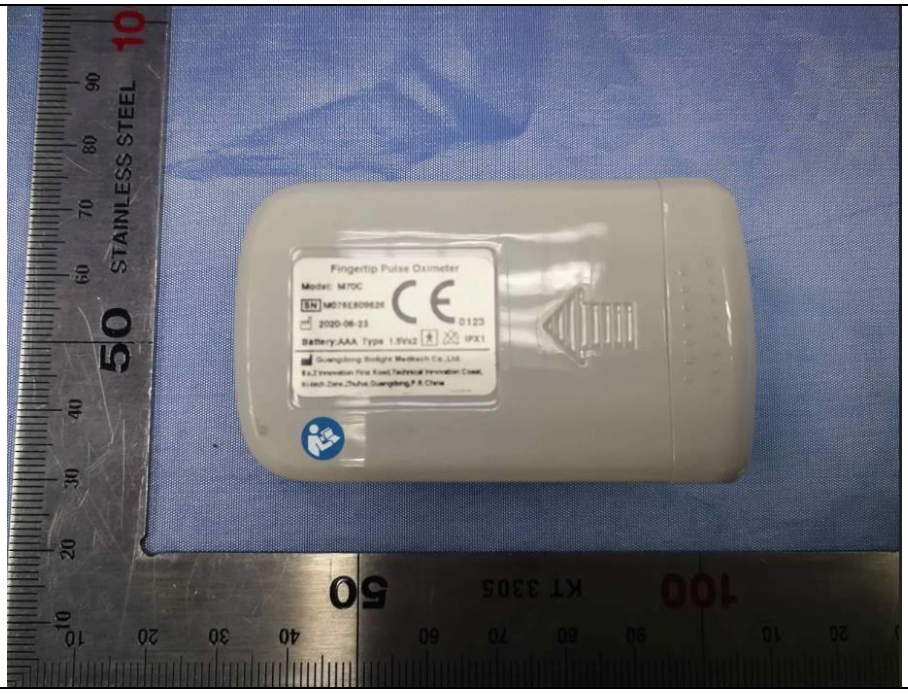
[ ] rear

[ ] right

[ ] left

[ ] top

[☒] bottom



Attachment 1: Photo Documentation

Details of: M70C

View:

[ ] general

[ ] front

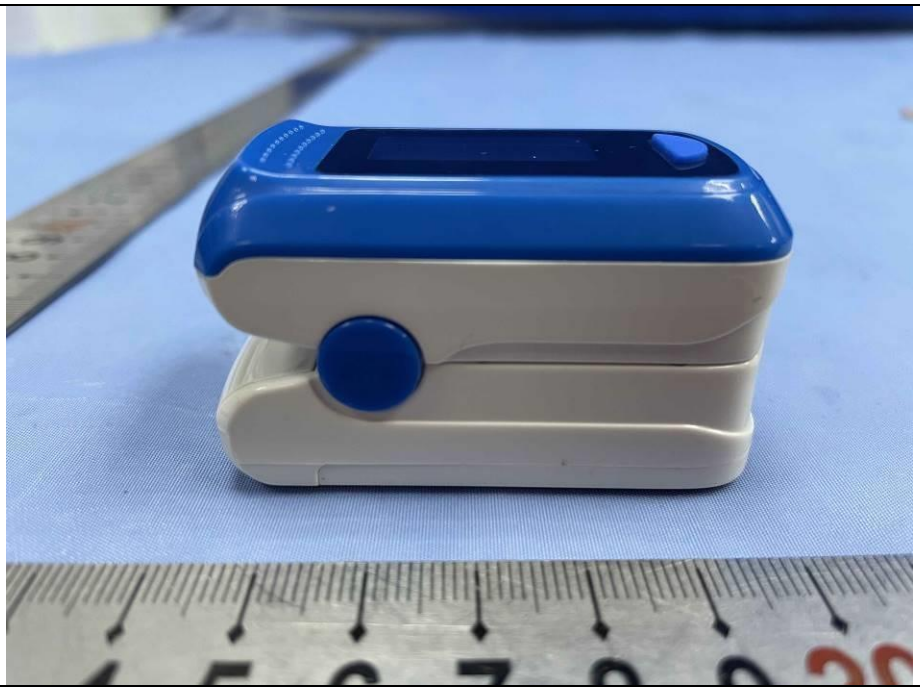
[ ] rear

[ ] right

[☒] left

[ ] top

[ ] bottom



Details of: M70C

View:

[ ] general

[ ] front

[ ] rear

[☒] right

[ ] left

[ ] top

[ ] bottom

Attachment 1: Photo Documentation

Details of: M70C

View:

[ ] general

[☒] front

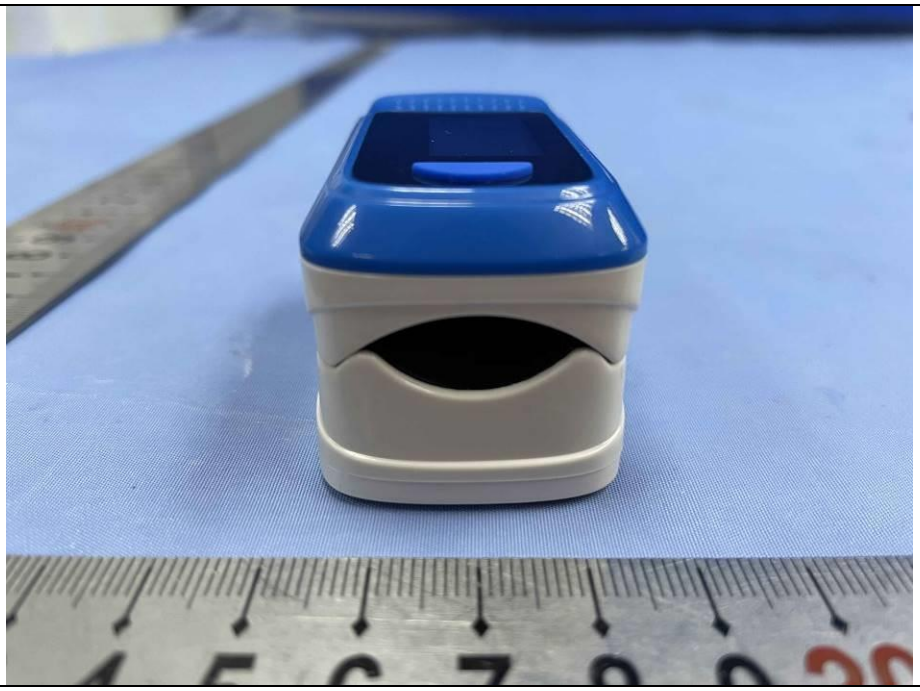
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Details of: M70C

View:

[ ] general

[ ] front

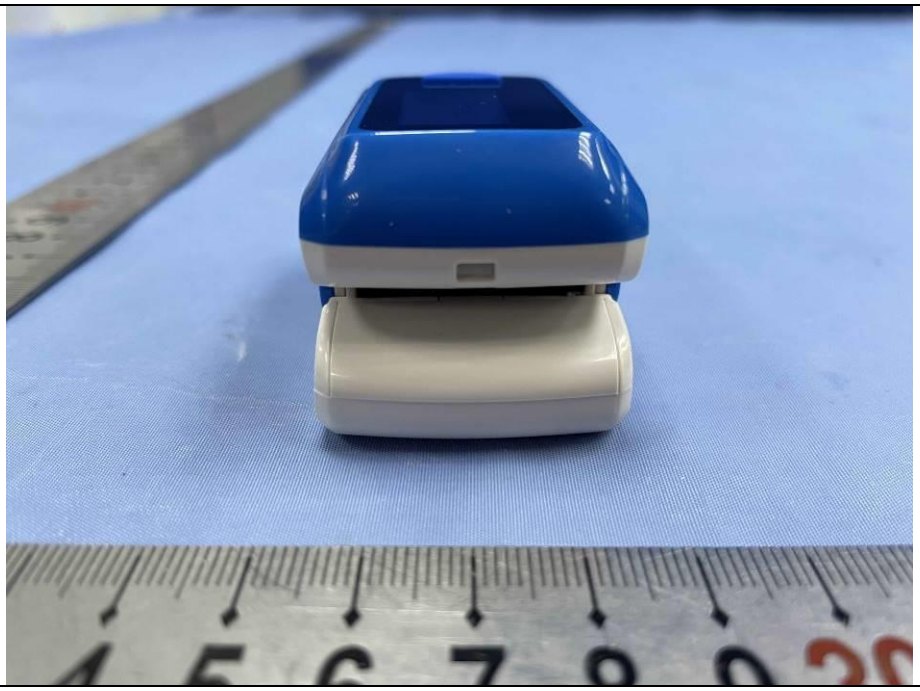
[☒] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70C, display interface

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: M70C, applied part

View:

[☒] general

[ ] front

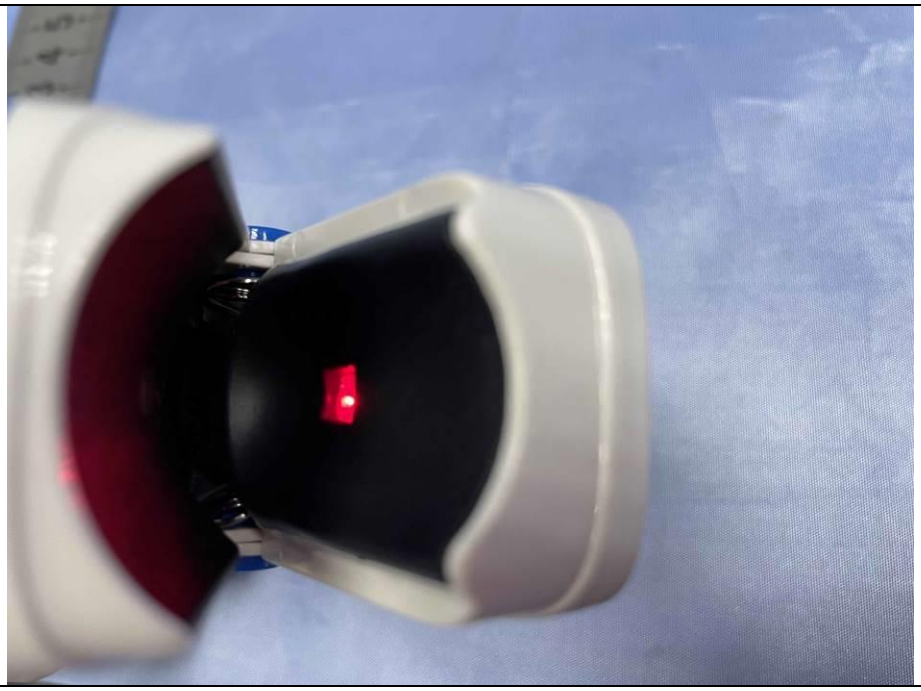
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70C, battery compartment

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Details of: M70C, internal view

View:

[☒] general

[ ] front

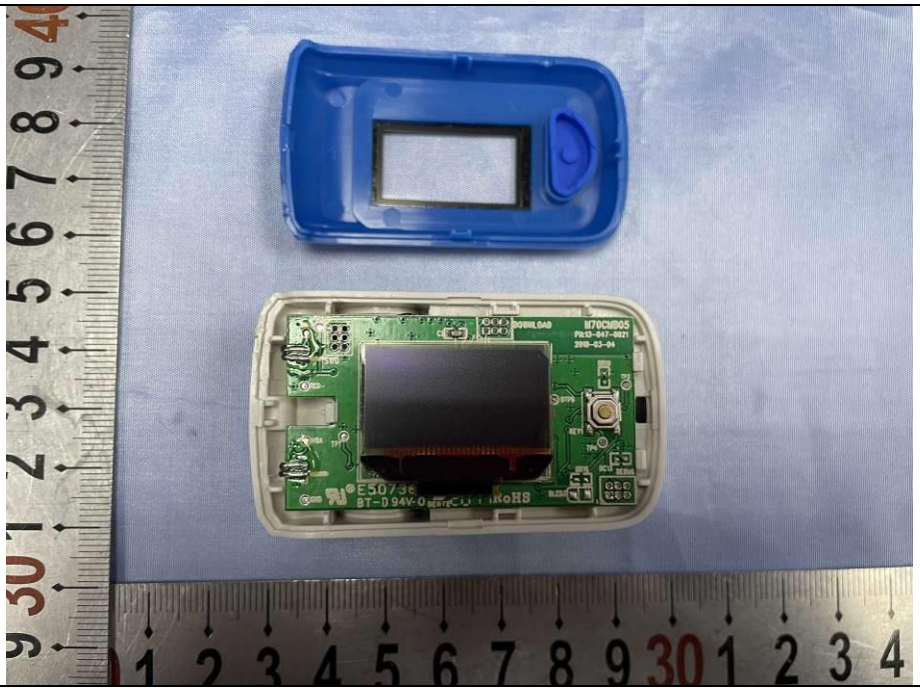
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70C, PCB

View:

[☒] general

[ ] front

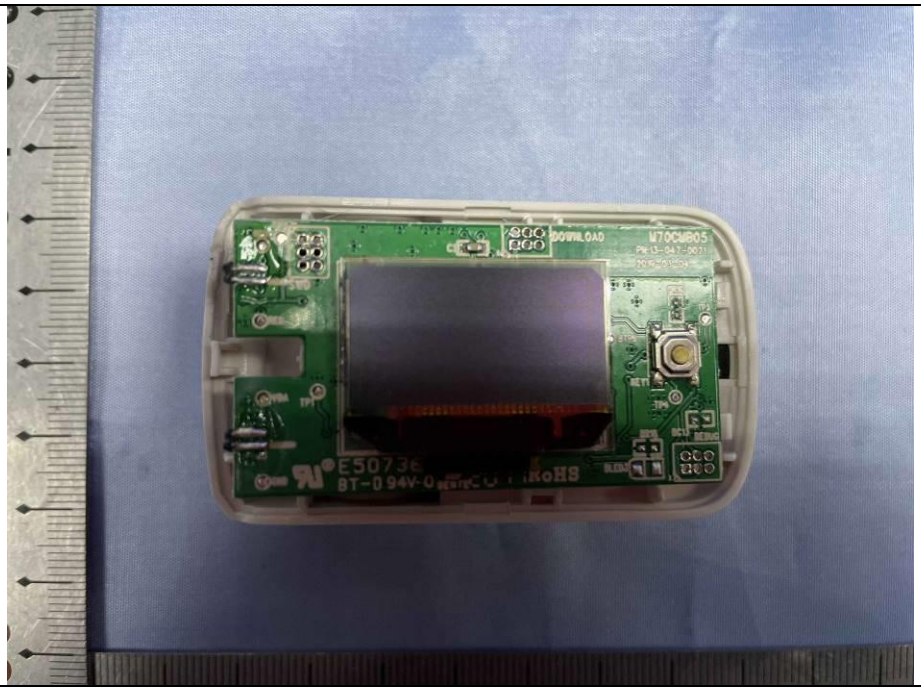
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Details of: M70C, PCB

View:

[☒] general

[ ] front

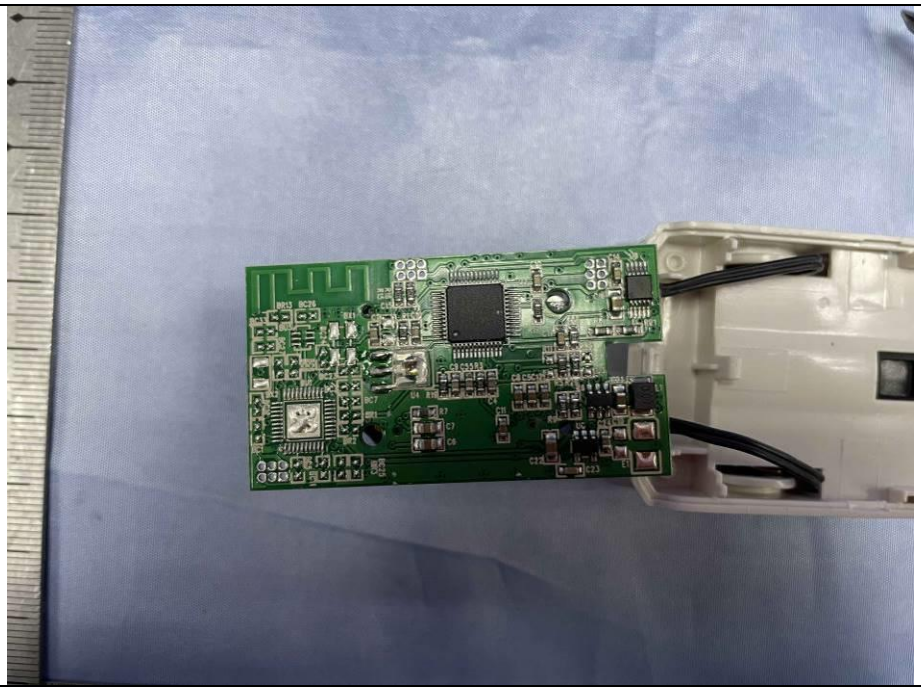
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo Documentation

Details of: M70C, PCB

View:

[☒] general

[ ] front

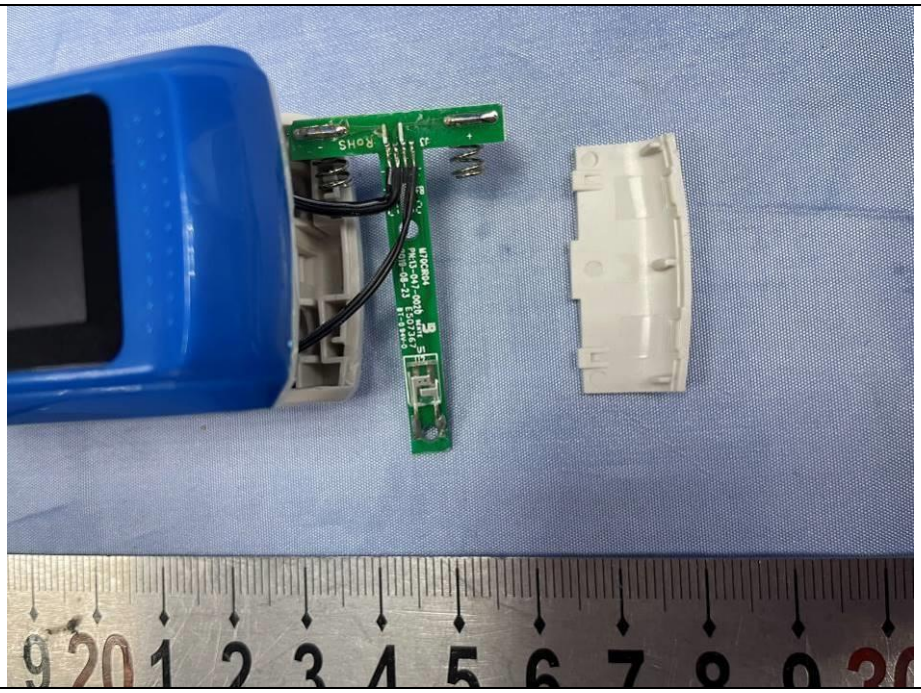
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Details of: M70C, PCB

View:

[☒] general

[ ] front

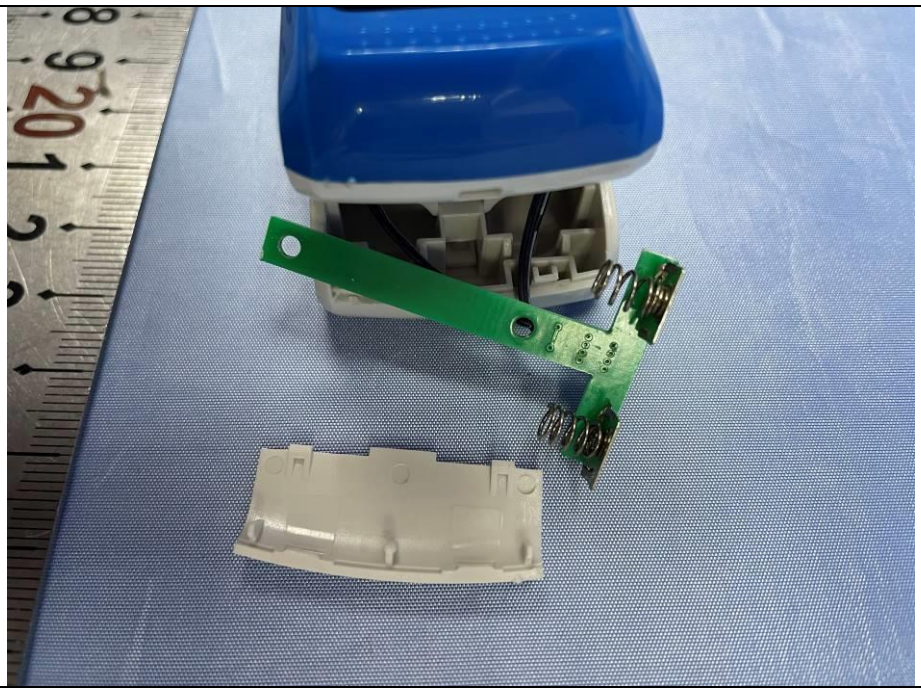
[ ] rear

[ ] right

[ ] left

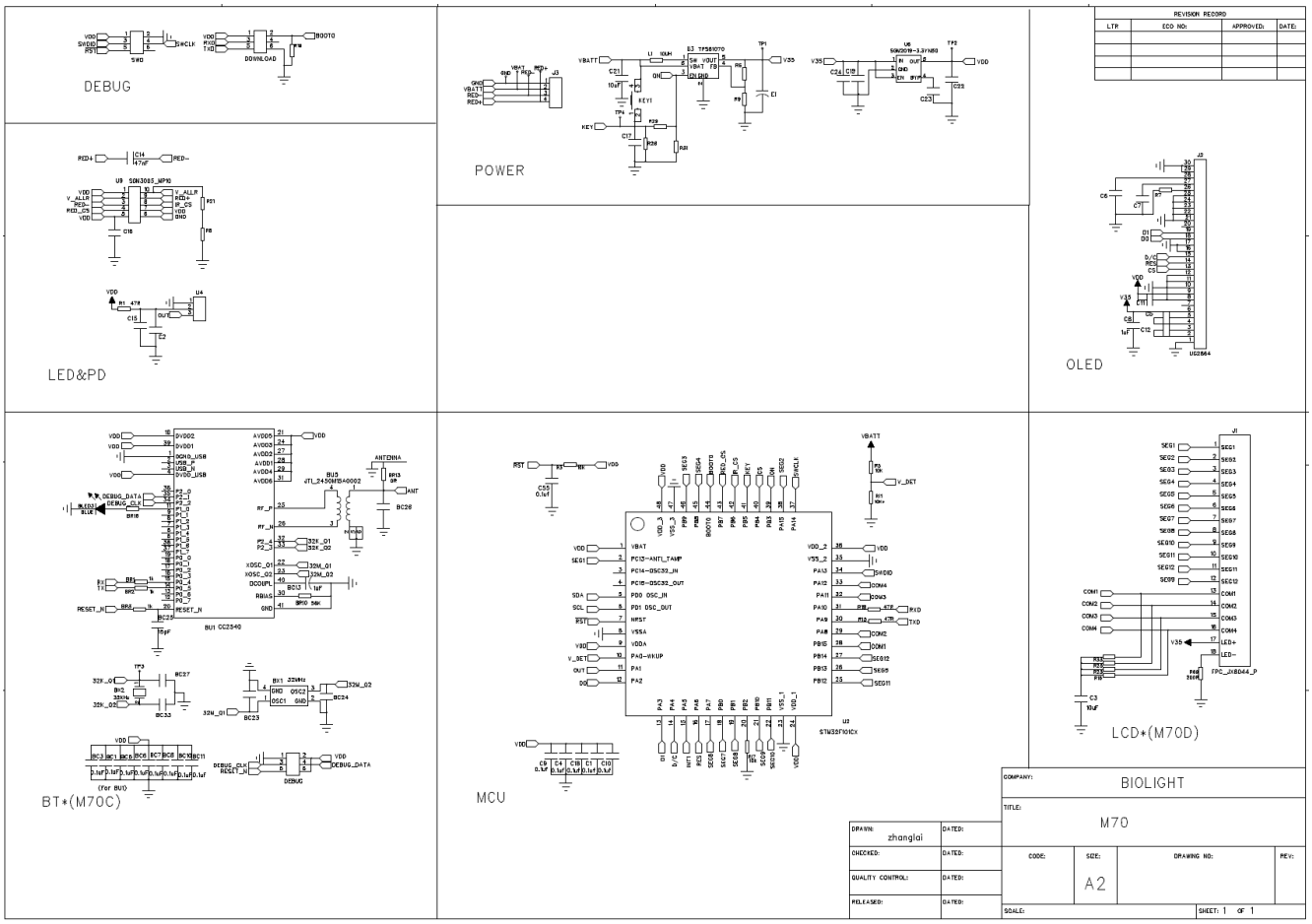
[ ] top

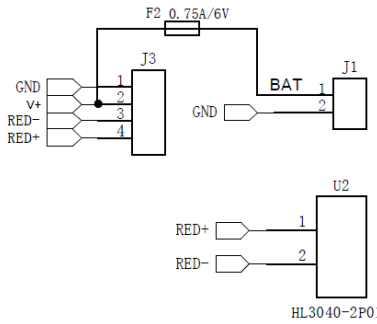
[ ] bottom



Attachment 2: Circuit Diagram

M70, M70A and M70C have the same circuit diagram:





--End of test report--