Prüfbericht - Nr.: *Test Report No.:*	**17004174 001**		**Seite 1 von 19** *Page 1 of 19*
Auftraggeber: *Client:*	**Unimed Medical Supplies, Inc** *The 5th floor, No. 6 Nanshui Industrial Zone, No. 5 Industrial Road, Shekou, Shenzhen 518067, P.R. China*		
Gegenstand der Prüfung: *Test item:*	**Compatible SpO2 sensor**		
Bezeichnung: *Identification:*	**Uab-cde series (see page 3 for description of variables a, b, c, d, and e)**	**Serien-Nr.:** *Serial No.:*	Engineering sample w/o serial number
Wareneingangs-Nr.: *Receipt No.:*	**163018789**	**Eingangsdatum:** *Date of receipt:*	Dec-12-05
Prüfort: *Testing location:*	**TÜV Rheinland (Shenzhen) Co., Ltd** *34/F., World Finace Centre, 4003 Shennan East Road, Luohu District, 518001 Shenzhen, P. R. China*		
Prüfgrundlage: *Test specification:*	IEC 60601-1:1988 + A1:1991 + A2:1995, clauses 3, 5, 6, 48 and 56. EN 60601-1 : 1990 + A1:1993 + A2:1995 + A13: 1996, clauses 3, 5, 6, 48 and 56.		
Prüfergebnis: *Test Result:*	**Der vorstehend beschriebene Prüfgegenstand wurde geprüft und entspricht oben genannter Prüfgrundlage.** *The a. m. test item passed*		
Prüflaboratorium: *Testing Laboratory:*	**TÜV Rheinland (Shenzhen) Co., Ltd**		

geprüft/ *tested by:*			**kontrolliert/** *checked by:*		
31-Mar-2006	Kevin Shao	Kevin Shao	31-Mar-2006	Chris Reeves	C.D Reeves
Datum *Date*	**Name** *Name*	**Unterschrift** *Signature*	**Datum** *Date*	**Name** *Name*	**Unterschrift** *Signature*

Sonstiges/ Other Aspects:

This report approves the construction and documentation for the above mentioned products, since they are external terminal devices, only clauses 3, 5, 6, 48 and 56 are considered as applicable.

The completed test report includes the following documents:

- EN/IEC 60601-1 report (16 pages including this cover page)
- Attachment: Photo documentation (pages 17-19)

Abkürzungen:	***ok / P***	= ***entspricht Prüfgrundlage***	***Abbreviations:***	***ok / P***	= ***passed***
	fail / F	= ***entspricht nicht Prüfgrundlage***		***fail / F***	= ***failed***
	n.a. / N	= ***nicht anwendbar***		***n.a. / N***	= ***not applicable***

TEST REPORT

IEC 60601-1

Medical electric equipment
Part 1: General requirements for safety

TÜV

Report

Reference No. ..... : **17004174 001**

Compiled by (+ signature) ..... : See cover page .....

Approved by (+ signature) ..... : See cover page .....

Date of issue ..... : See cover page

Contents ..... : See cover page

This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator (see below).

Testing laboratory

Name ..... : See cover page

Address ..... : See cover page

Testing location ..... : See cover page

Client

Name ..... : **Unimed Medical Supplies, Inc**

Address ..... : *The 5th floor, No. 6 Nanshui Industrial Zone, No. 5 Industrial Road, Shekou, Shenzhen 518067, P.R. China*

Test specification

Standard ..... : IEC 60601-1 : 1988 + A1:1991 + A2:1995
EN 60601-1 : 1990 + A1:1993 + A2:1995 + A13: 1996

Test procedure ..... : Test Report

Procedure deviation ..... : N.A.

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

Test Report Form/blank test report

Test Report Form No. ..... : I601-1_C/97-07

TRF originator. ..... : UL

Master TRF ..... : Dated 97-04

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Test item

Description ..... : Compatible SpO2 Sensor

Trademark ..... : UniMed

Model and/or type reference ..... : Uab-cde series (see page 3 for description)

Manufacturer ..... : Same as client

Factory ..... : Same as client

Rating(s) ..... : N.A.

Particulars: test item vs. test requirements

Classification of installation and use ..... : External Terminal Device

Supply connection..... : N.A.

Test case verdicts

Test case does not apply to the test object..... : N(.A.)

Test item does meet the requirement..... : P(ass)

Test item does not meet the requirement..... : F(ail)

..... :

Testing

Date of receipt of test item ..... : Dec-12-2005

Date(s) of performance of test ..... : Dec-27-2005

..... :

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.

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

"(see remark #)" refers to a remark appended to the report.

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

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

Brief description of device under test

Uab-cde series, where

a = Application, can be 1 (used for children), 2 (used for infants), 3 (used for neonatal), or 4 (used for adults)

b = Length of the lead cable, can be 03 (length = 3 inch), 05 (length = 5 inch) , or 10 (length = 10 inch)

c = Customer code, can be any 2-digit number

d = Technology applied, can be M (Maximum), O (Optimum) or blank (ordinary)

e = Clip type, can be S (Soft clip) or blank (rigid clip)

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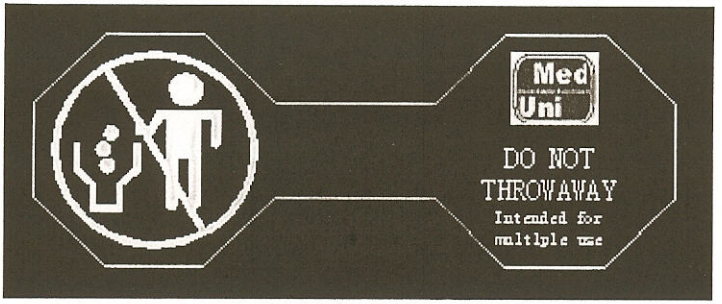
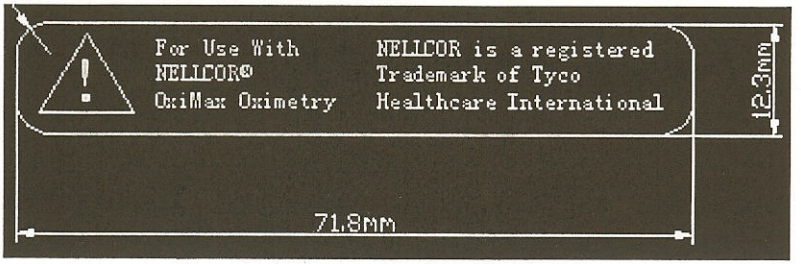
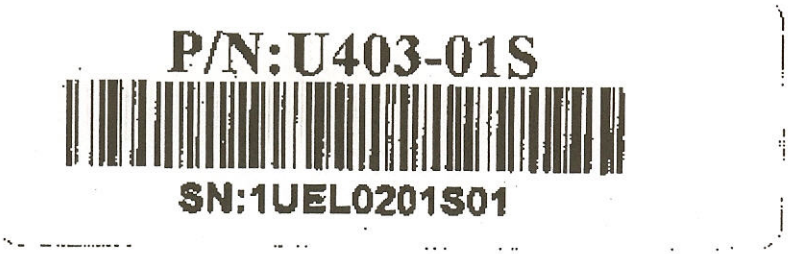
Copy of marking plate



Label wrapped on cable



Label wrapped on cable



Label wrapped on cable and package bag

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
3.	GENERAL REQUIREMENTS		P
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)	Compatible SpO2 Sensors only for transducing the arterial oxygen saturation and pulse rate signal from patient to current signal and transferring the signal to particular oximeters, no hazard	P
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained		N
5.	CLASSIFICATION		P
5.1	Type of protection against electric shock		N
	Class I equipment	External terminal device only, protection against electric shock relies on the final equipment on which the sensor is installed, and should be evaluated in final system.	N
	Class II equipment		N
	Internally powered equipment		N
5.2	Degree of protection against electric shock	External terminal device only, degree of protection against electric shock should be evaluated in final system.	N
	Type B applied part		N
	Type BF applied part		N
	Type CF applied part		N
	Not classified, no applied parts	External terminal device	P
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 60529 (see 6.1.1) .....:	Ordinary protection: IPX0	N
5.4	Methods of sterilization or disinfection	Cleaning with isopropyl alcohol	
5.5	Equipment not suitable for use in the presence of flammable mixtures	Not AP or APG category equipment.	
	Category AP equipment		N
	Category APG equipment		N
5.6	Mode of operation:		N

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	continuous operation	Designed for continuous operation	P
	short-time operation, specified operation; period ...:		N
	intermittent operation, specified operation; rest period .....:		N
	continuous operation with short-time, stated permissible loading time .....:		N
	continuous operation with intermittent, stated permissible loading/rest time .....:		N
	Table: insulation diagram		—
	Protection against electric shock - Block diagram of system		—

INSULATION DIAGRAM

No diagram is needed because the product is component (external terminal device) which contains SELV only after installation, no safety insulation boundaries were considered, therefore, no insulation diagram was deemed necessary

	Table: to insulation diagram	N

area	insulation type: operational/basic/ supplementary/ double/reinforced	reference voltage (V)	required creepage (mm)	required clearance (mm)	measured creepage (mm)	Measured clearance (mm)	Remarks

INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.

2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional.

3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.

4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

5. Blocks containing the letter "Z" indicate protective impedance.

6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with requirements of Cl. 17., 20. and 57.

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Note: The component will not contain any live parts or protectively earthed metal enclosure, it is only used
- to transfer the oxygen saturation signal from patient to pulse oximeter monitor, no dielectric strength test has been considered to be necessary.

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
6.	IDENTIFICATION, MARKING AND DOCUMENTS		P
6.1	Marking on the outside of equipment or equipment parts		P
	c) Markings of the specific power supply are affixed	The sensors are specially designed for particular equipment which is specified on the body of sensor, label is wrapped on the cable.	N
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N
	e) Name and/or trademark of the manufacturer or supplier .....:	Trademark: UniMed	P
	f) Model or type reference .....:	Model number "Uab-cde" marked, label is wrapped on the cable and protected by clear tube, see page 4 for details	P
	g) Rated supply voltages or voltage range(s)	Not necessary	N
	Number of phases .....:		N
	Type of current .....:	Not applicable	N
	h) Rated frequency or rated frequency range(s) (Hz) .....:		N
	j) Rated power input (VA, W or A) .....:		N
	k) Power output of auxiliary mains socket-outlets	No auxiliary mains socket-outlets.	N
	l) Class II symbol	External terminal device only	N
	Symbol for degree of protection against ingress of water provided .....:	The equipment with IPX0. Therefore no marking required.	N
	Symbol for protection against electric shock .....:		N
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets	The applied part is of insulation material, no hazard.	N
	Symbol for protection of defibrillation-proof applied parts .....:	No defibrillation-proof applied parts	N
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable	No defibrillation-proof applied parts	N
	m) Mode of operation (if no marking, suitable for continuous operation)	Suitable for continuous operation	N

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	n) Types and rating of external accessible fuses ...:	No external accessible fuses.	N
	p) Ratings of external output .....:	No external output	N
	q) Symbol for physiological effect(s):		P
	attention, consult accompanying documents	Not possible to cause physiological effects	N
	non-ionizing radiation, or symbols as adopted by ISO or IEC 60417	No such radiation	N
	r) Anaesthetic-proof symbol: AP or APG .....:	Not of category AP or APG	N
	s) Dangerous voltage symbol	Not applicable	N
	t) Special cooling requirements	No special cooling requirements	N
	u) Limited mechanical stability	Not applicable	N
	v) Protective packing requirement(s)	Not applicable	N
	Marking(s) for unpacking safety hazard(s)		N
	Equipment or accessories supplied sterile, marked as sterile		N
	y) Potential equalization terminal	No earth terminal	N
	Functional earth terminal	Not applicable.	N
	z) Removable protective means	No such means.	N
	Durability of marking test	Label withstands rubbing test: Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit at ambient temperature and then for 15 s with a cloth rag soaked with isopropyl alcohol.	P
6.2	Marking on the inside of equipment or equipment parts		N
	a) Nominal voltage of permanently installed equipment	Not applicable.	N
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements or holders for heating lamps.	N
	c) Dangerous voltage symbol	No High Voltage parts. Not applicable.	N
	d) Type of battery and mode of insertion	No battery used	N
	Marking referring to accompanying documents used for battery not intended to be changed by the operator		N

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	No fuses	N
	f) Protective earth terminal	No protective earth terminal	N
	g) Functional earth terminal		N
	h) Supply neutral conductor in permanently installed equipment (N)	Not permanently installed equipment	N
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed	Not applicable	N
	Markings comply with IEC 60445		N
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	As above	N
	l) Statement for suitable wiring materials at temperatures over 75 °C	Not intended to connect to external wiring	N
	n) Capacitors and/or circuit parts are marked as required in Cl. 15. c)	No capacitor or circuit parts	N
6.3	Marking of controls and instruments *No controls or instruments provided.*		N
	a) Mains switch clearly identified	No mains switch	N
	ON and OFF positions marked according to Symbols 15 and 16 of Table D1 or indicated by an adjacent indicator light		N
	b) Indications of different positions of control devices and switches	No such control device and switch.	N
	c) Indication of the direction in which the magnitude of the function changes, or an indicting device	No indicating device or function change	N
	f) The functions of operator controls and indicators are identified	No such control or indicator	N
	g) Numeric indications of parameters are in SI units except for units listed in A2	No numeric indication	N
6.4	Symbols		N
	Symbols used comply with Appendix D or IEC 60417 and/or IEC 60878 or ISO publications (if applicable)	No symbol used	N
6.5	Colours of insulation of conductors		P
	a) Protective earth conductor has green/yellow insulation	No protective earth conductor	N

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		N
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		N
	d) Colour of neutral conductor .....:	No neutral conductor	N
	e) Colours of phase conductors .....:	No phase conductor	N
	Compliance with IEC 60227 and IEC 60245		N
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors	No such conductor	N
6.6	Medical gas cylinders and connections		N
	a) In accordance with ISO/R 32	No medical gas cylinders and connections used.	N
	b) Identification of connection point		N
6.7	Indicator lights and push-buttons *No indicator lights and push-buttons*		N
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N
	Yellow used to indicate caution or attention required		N
	Green used to indicate ready for action		N
	b) Colour red used only for push-buttons by which a function is interrupted in case of emergency		N
6.8	Accompanying documents		P
6.8.1	Equipment is accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Provided in instruction manual	P
	Classifications specified in Cl. 5. are included in both the instructions for use and the technical description	External terminal device only, compliance should be evaluated in final system	N
	Markings specified in 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Permanently affixed to the equipment	N
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Warning statement provided, see chapter "Warnings and Precautions" in instruction manual	P
6.8.2	Instructions for use		P

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	a) General information provided in instructions for use:		P
	- state the function and intended application of the equipment	See chapter "Indications" in instruction manual	P
	- include an explanation of: the function of controls, displays and signals	No controls, displays or signal	N
	- the sequence of operation	See chapter "instructions for use" in instruction manual	P
	- the connection and disconnection of detachable parts and accessories	See chapter "instructions for use" in instruction manual	P
	- the replacement of material which is consumed during operation	No material consumable	N
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	See chapter "Warnings and Precautions" in instruction manual, using with MRI or CT system is not recommended	P
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	No accessories and detachable parts	N
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	See chapter "Cleaning or Disinfecting the Sensor" in instruction after each use	P
	General information provided in instructions:		P
	- information for the safe performance or routine maintenance	Specified in instruction manual chapter "Cleaning and disinfecting the Sensor"	P
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	Not safety relevant	N
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	Not used	N
	c) Signal output or signal input parts intended only for connection to specified equipment described	No signal input or signal output parts	N
	d) Details about acceptable cleaning, disinfection or sterilization methods included	Specified in instruction manual chapter "Cleaning and Disinfecting"	P
	e) Warning statement for mains operated equipment with additional power source	No additional power source	N
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	No primary batteries used.	N
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	No rechargeable batteries used.	N

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 60601-1	Not applicable.	N
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	No waste products, no environmental risks.	N
	Advice in minimizing these risks		N
6.8.3	Technical description		P
	a) All characteristics essential for safe operation provided	Provided in instruction manual	P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	No fuses	N
	Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	No such interchangeable or detachable parts	N
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	Availability of technical data is stated in the instruction, contact information provided.	P
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Not relevant to safety	N
48.	BIOCOMPATIBILITY		P
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	All the plastic parts have been evaluated by Testing Center of Radiological Medical Research Institute, Soochow University Report Number: SDFY-2005-*2337-2, SDFY-2006-2031 and* SDFY-2005-2337-1according to ISO 10993-1, ISO 10993-5 and ISO 10993-10 respectively for cytotoxicity, Sensitization and Skin Irritation test.	P
56.	COMPONENTS AND GENERAL ASSEMBLY		P
	List of critical components	See appended table.	P
56.1	b) Ratings of components not in conflict with the conditions of use in equipment	The components are used according to their ratings.	P
	Ratings of mains components are identified	No such components.	N

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	d) Components, movements of which could result in a safety hazard mounted securely	No component movements could result in a safety hazard	N
	f) Conductors and connectors are secured and/or insulated to prevent accidental detachment resulting in a safety hazard	No accidental detachment will cause safety hazards.	P
56.3	a) Connectors provide separation required by Cl. 17. g)	No live part in the equipment	N
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	Special plug provided, not possible to be connected to other outlets	P
	Medical gas connections not interchangeable	No medical gas connections used.	N
	b) Accessible metal parts cannot become live when detachable interconnection cord between different parts of equipment is loosened or broken		P
	c) Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages	No leads with conductive connection to a patient	N
56.4	Connections of capacitors	*No capacitor used*	N
	Not connected between live parts and non-protectively earthed accessible parts		N
	If connected between mains part and protectively earthed metal parts, comply with IEC 60384-14		N
	Enclosure of capacitors connected to mains part and providing only basic insulation is not secured to non-protectively earthed metal parts		N
	Capacitors or other spark-suppression devices are not connected between the contacts of thermal cut-outs	No thermal cut out used.	N
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	No such device used.	N
56.6	Temperature and overload control devices		N
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment	No thermal cut out used.	N
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	Not applicable.	N
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	Not applicable.	N

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N
	Non-self-resetting over-current releases operated 10 times		N
	b) Thermostats with varying temperature settings clearly indicated	No thermostat used.	N
	Operating temperature of cut-outs is clearly indicated		N
56.7	Batteries	*No battery used*	N
	a) Battery compartments are:		--
	- adequately ventilated		N
	- accidentally short-circuiting is prevented		N
	b) Incorrect polarity of connection prevented		N
56.8	Indicators, unless indication is provided by other means (from the normal operation position), indicator lights are used (colour see 6.7)	*No indicator used*	N
	- to indicate that equipment is energized		N
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N
	- to indicate when output exists if a safety hazard could result	No output	N
	- charging mode indicator is provided	No battery charging mode.	N
56.10	Actuating parts of controls	No controls	N
	b) Actuating parts are adequately secured to prevent them from working loose during normal use		N
	Controls are secured to prevent the movement relative to scale marking (safety related only)	Not applicable.	N
	Detachable indicating devices are prevented from incorrect connection without the use of a tool	Not applicable.	N
	c) Stops are provided on rotating controls:		N
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard	No rotating controls.	
	- to prevent damage to wiring		N
56.11	Cord-connected hand-held and foot-operated control devices		P

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17. g)		P
	b) Hand-held devices comply with the requirement and test of 21.5	No hazard	P
	Foot-operated control devices designed to support the weight of an adult human being		N
	c) Devices shall not change their setting when inadvertently placed	No hazard	N
	d) Foot-operated control devices are at least IPX1		N
	For surgical use, electrical switching parts are IPX8		N
	e) Adequate strain relief at the cord entry provided		N

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IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict

6.1	TABLE: marking durability	P
marking tested		Remarks
Product rating label		Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit at ambient temperature and then for 15 s with a cloth rag soaked with isopropyl alcohol. Markings remained clearly legible and edges did not curl

56.1	TABLE: lists of critical component parts				P
object/part No.	manufacturer/ trademark	type/model	technical data	standard	mark(s) of conformity[1])
Sensor Case, Cable Coat, Connector and Strain Relief	--	--	--	ISO 10993-1 ISO 10993-5 ISO 10993-10	By Testing Center of Radiological Medical Research Institute, Soochow University Report Number: SDFY-2005-2337-2, SDFY-2006-2031 and SDFY-2005-2337-1
Note: 1. An asterisk indicates a mark which assures the agreed level of surveillance.					

Attachment: Photo documentation

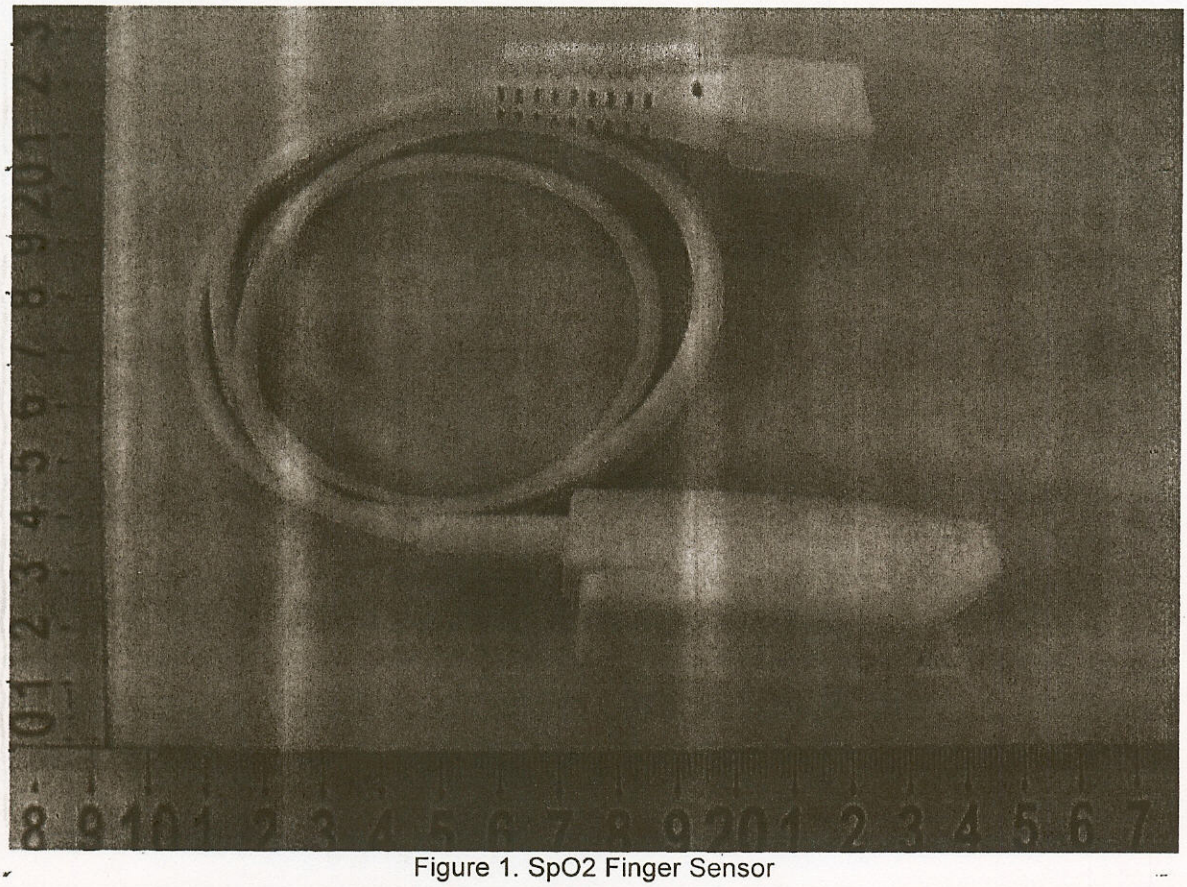

Figure 1. SpO2 Finger Sensor

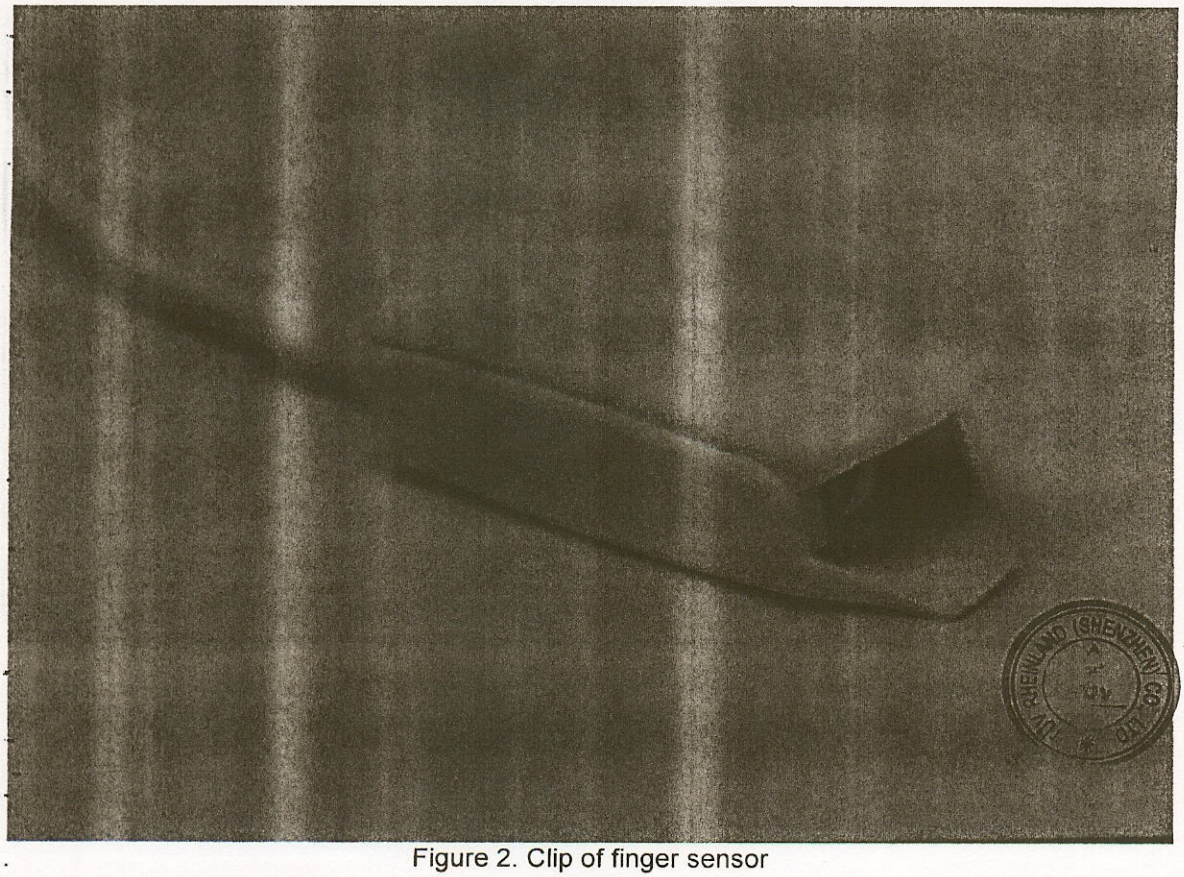

Figure 2. Clip of finger sensor

Attachment: Photo documentation

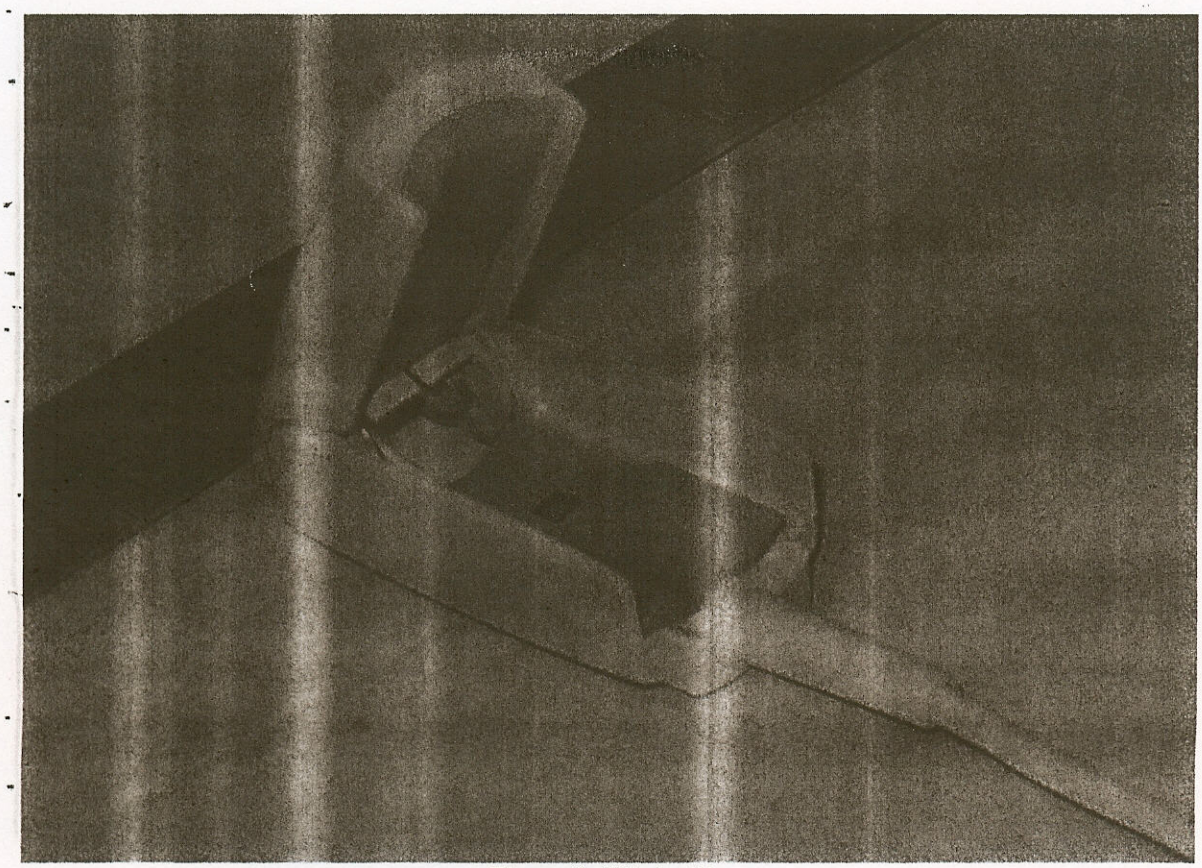

Figure 3. Clip inside

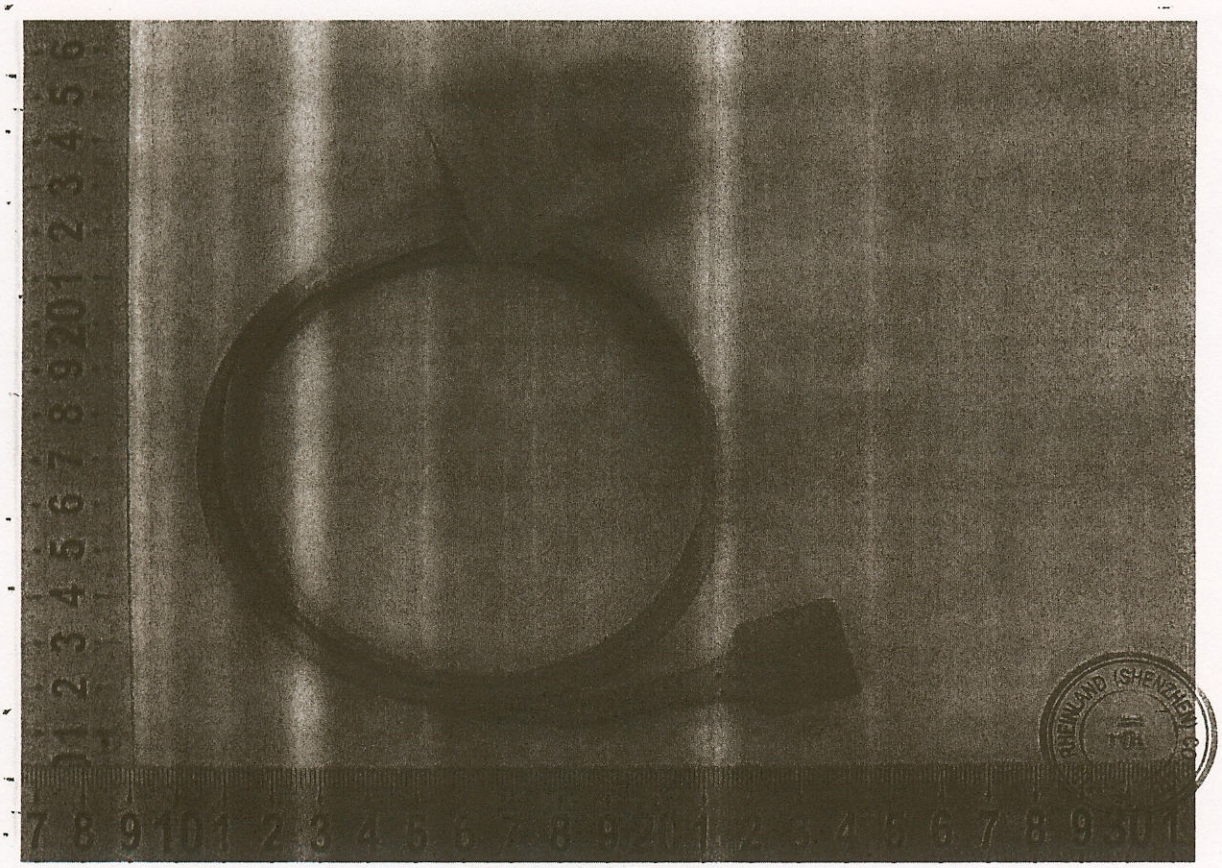

Figure 4. Soft Tip Sensor