


Technical Documentation IPM

JM-105 Jaundice Meter



Warning


All servicing and/or test procedures on the device require detailed knowledge of this documentation. Use of the device requires detailed knowledge and observance of the relevant Instructions for Use.



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Function descriptions

This chapter contains descriptions of the device's technical functions.

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1 Jaundice Meter JM-105 with Docking Station JM-A33

1.1 Introduction

This chapter describes the design and the functional principle of the Jaundice Meter JM-105 and its Docking Station JM-A33.

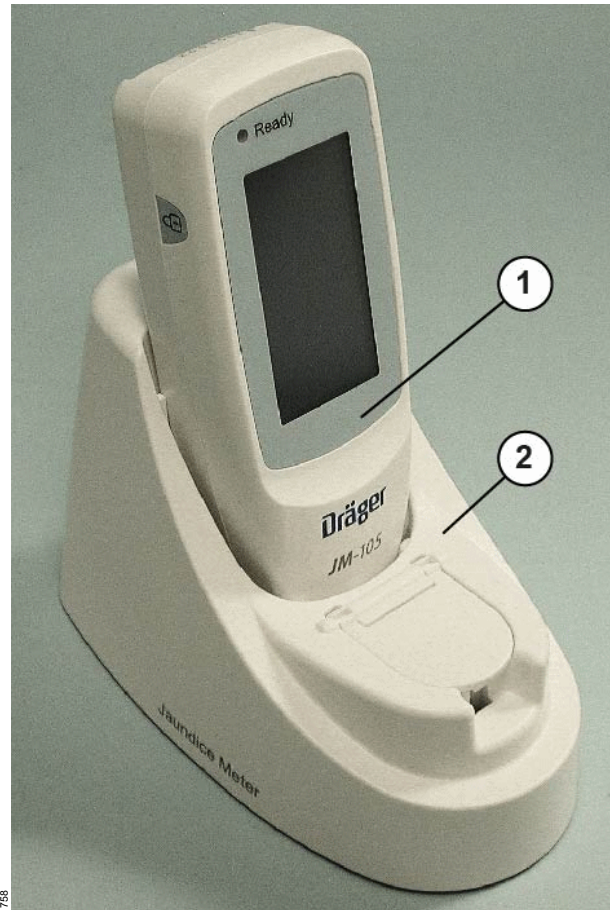


Fig. 1 Jaundice Meter JM-105 and Docking Station JM-A33

1.2 Design

The Jaundice Meter JM-105 contain the following components:

- Touch panel with LCD Module
- Bar code reader module (optional)
- Main PCB with Controller CPU
- Power PCB
- Xenon lamp with Sensor PCB

The Docking Station JM-A33 contain the following components:

- IR PCB

– Main PCB

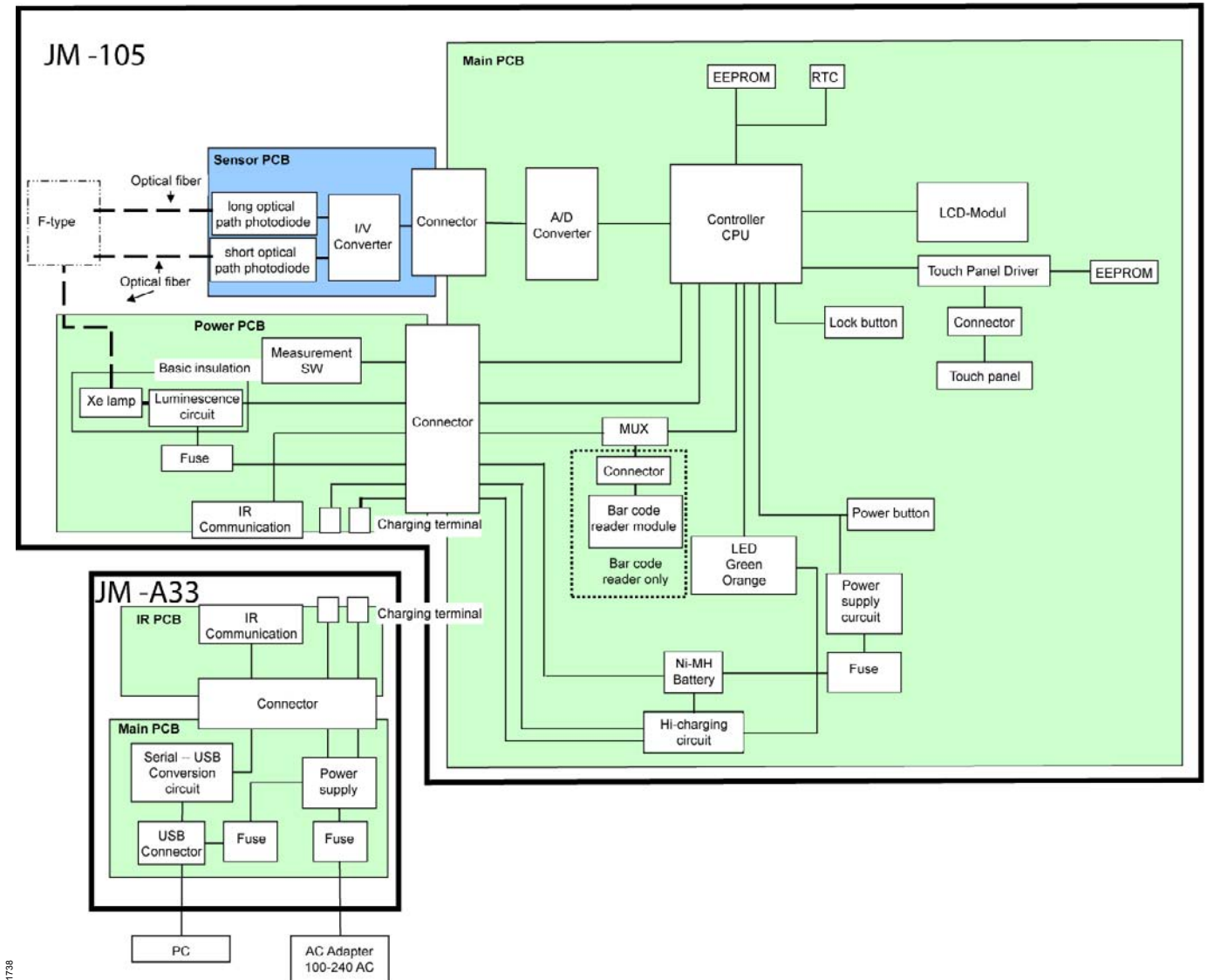


Fig. 2 Block diagram

1.3 Functional principle

The transcutaneous bilirubin, an indicator of jaundice in infants, well absorbs blue light but little absorbs green light. Jaundice Meter JM-105 determines the yellowness of the transcutaneous bilirubin by measuring the difference in optical densities for light in the blue and green wavelength regions. When the measuring probe is pressed against the forehead or sternum of the infant, the built-in xenon lamp flashes, and the blue light (450 nm) and green light (550 nm) from the xenon lamp are guided to the skin surface through the light emission glass fiber and illuminates the skin. These lights are then scattered and absorbed in the skin repeatedly, and finally returns to the light reception glass fiber (Fig. 3). The denser the transcutaneous bilirubin is, the weaker the reflected blue light is. On the other hand, the reflected green light stays unchanged, no matter how dense the bilirubin is (Fig. 4). Since the optical density difference shows a linear correlation with serum bilirubin concentration, it is converted to serum bilirubin concentration and indicated digitally.

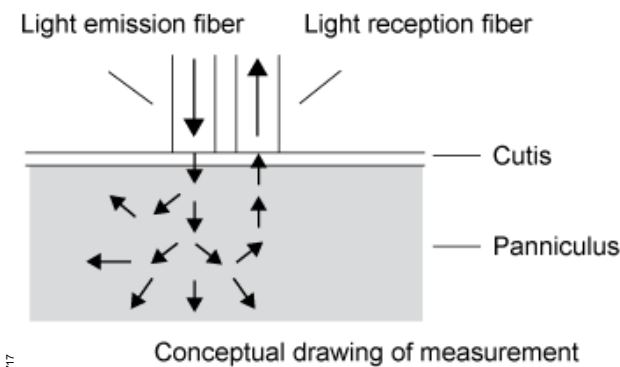


Fig. 3 Reception glass fiber

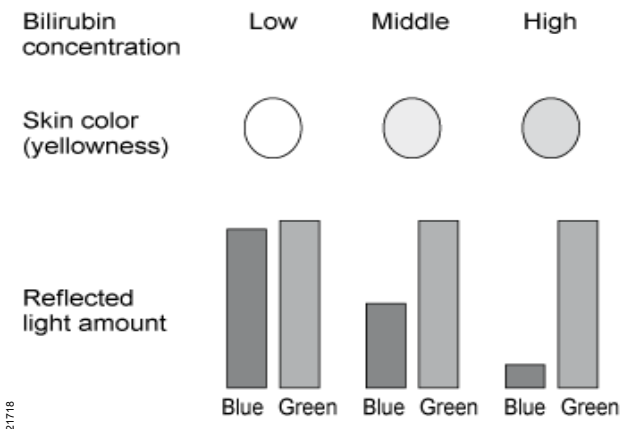


Fig. 4 Bilirubin concentration

The measuring probe has two optical paths (Fig. 5). The use of this method allows measurement of yellowness of the skin and subcutaneous of a newborn infant with the influences of melanin pigment and skin maturity kept at a minimum, which was impossible with conventional methods.

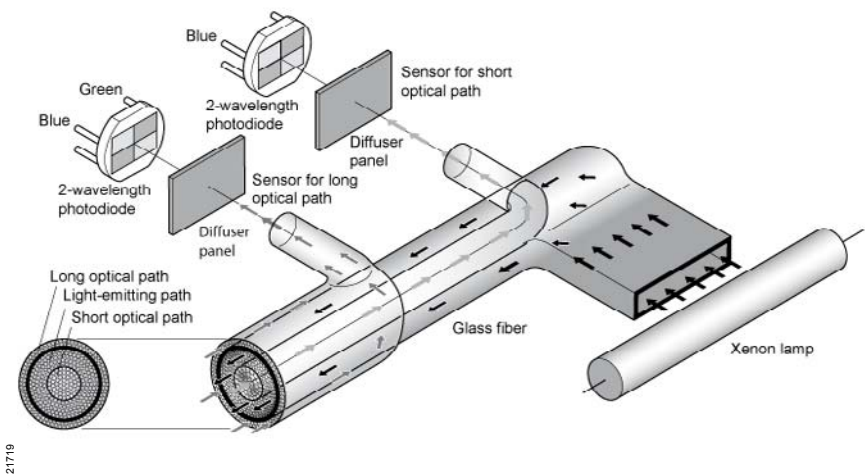


Fig. 5 Functional principle

Of the light that returns to the fiber, the part scattered from shallow areas of the subcutaneous tissue passes through the inner core (short optical path) of the fiber while the part scattered from deep areas of the subcutaneous tissue passes through the outer core (long optical path), and then they reach their corresponding photodiode.

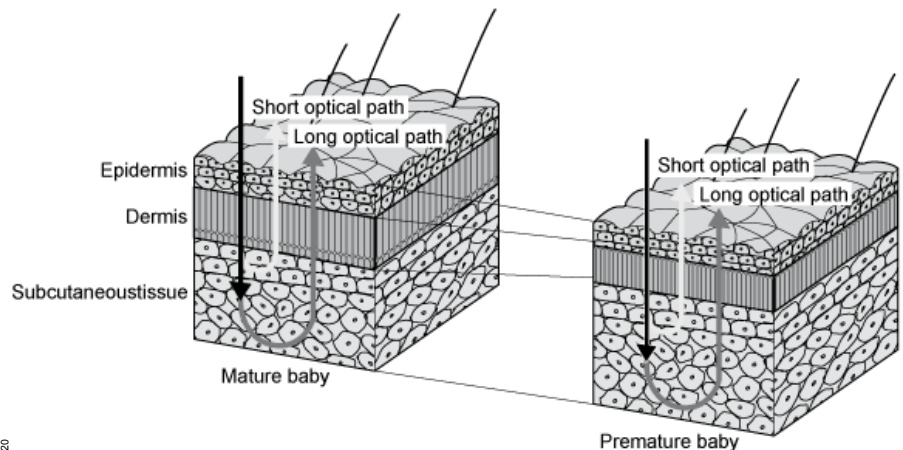



Fig. 6 Functional principle

By calculating the difference in optical densities, the parts that are common to the epidermis and dermis will be deducted, and as a result the difference in optical densities between the two wavelength regions can be obtained for the subcutaneous tissue only.

1.4 Connections and interfaces

The Docking Station JM-A33 includes a USB Connector for a PC and a DC jack for an AC Adapter (see Instructions for use).



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Maintenance

This chapter describes the measures required to maintain the specified condition of the device.

1	Disassembling and Reassembling the battery for JM105	12
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1 Disassembling and Reassembling the battery for JM105

1.1 Introduction

This chapter describes the step by step disassembling and reassembling of the battery of the Jaundice Meter JM105.

1.2 View



Fig. 7 Jaundice Meter JM105

1.3 Removing the Battery

1. Remove the three screws (Fig. 8/1) on the back of the main body.

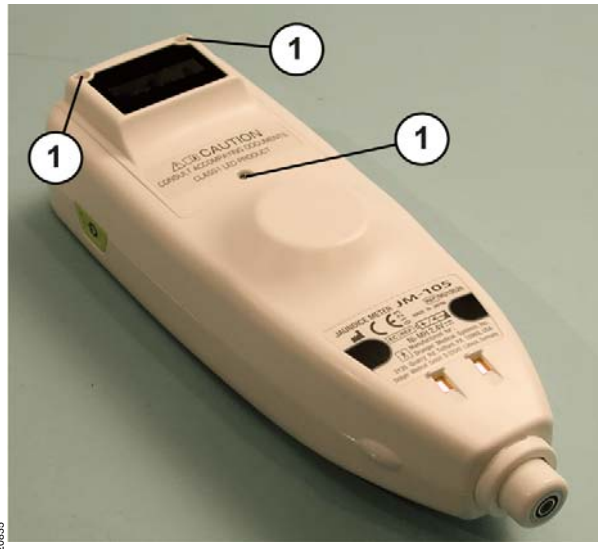


Fig. 8 Main body

2. Open the bar code reader cover (Fig. 9/1).
3. Lift the connector lever (Fig. 9/6) and remove the flexible cable (Fig. 9/3) from the connector (Fig. 9/2) of the bar-code reader (for product with bar-code reader), and then remove the bar-code reader cover (Fig. 9/1).

4. Remove the battery harness (Fig. 9/4) from the connector on the Main PCB, and then remove the battery (Fig. 9/5).

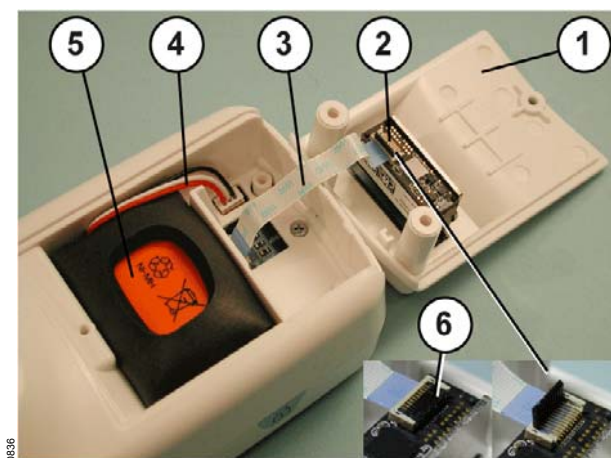


Fig. 9 Battery

1.4 Reassembling the battery

1. Reassemble the battery using the reverse method of its disassembly:
2. Inserting the battery (Fig. 10/1) and mounting the Barcode reader cover, making sure that the blue face (Fig. 10/3) of the flat cable and the black cable (Fig. 10/2) is positioned correctly.

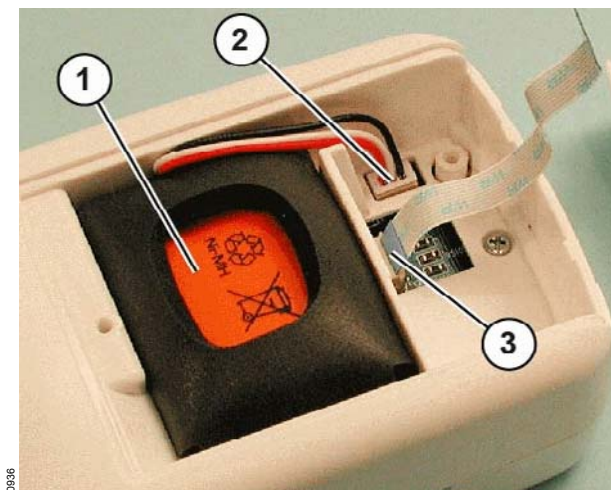


Fig. 10 Change battery



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Annex

Parts catalog

This chapter contains a list of the device's orderable parts.

Test Instructions

This chapter contains the measures required to determine the actual condition of the device.

Parts catalog

JM105-Jaundice Meter

Revision: 00

2013-12-06

6016.196

Parts catalog

Concerned products



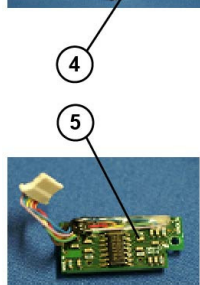
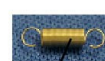
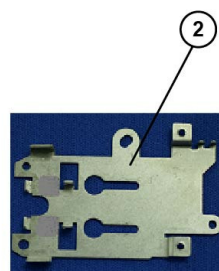
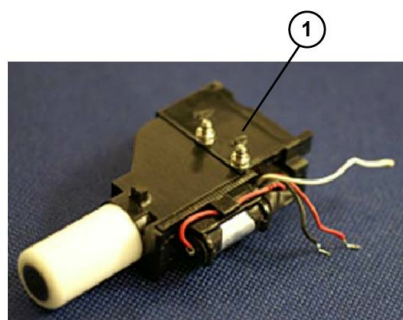
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Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	MU24768	DRAEGER JAUNDICE METER,JM-105,CE	1.000	St	
2	MU24769	DRAEGER,JAUNDICE METER,JM-105,CE2	1.000	St	
3	MU24770	DRAEGER,JAUNDICE METER,JM-105,CE3	1.000	St	
4	MU24771	DRAEGER JAUNDICE,SCAN,JM-105,CE	1.000	St	
5	MU24772	DRAEGER JAUNDICE,SCAN,JM-105,CE2	1.000	St	
6	MU24773	DRAEGER JAUNDICE,SCAN,JM-105,CE3	1.000	St	
7	MU24801	DRAEGER JAUNDICE METER,JM-105,MET	1.000	St	
8	MU24802	DRAEGER JAUNDICE,SCAN,JM-105,MET	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog

Xenon Block



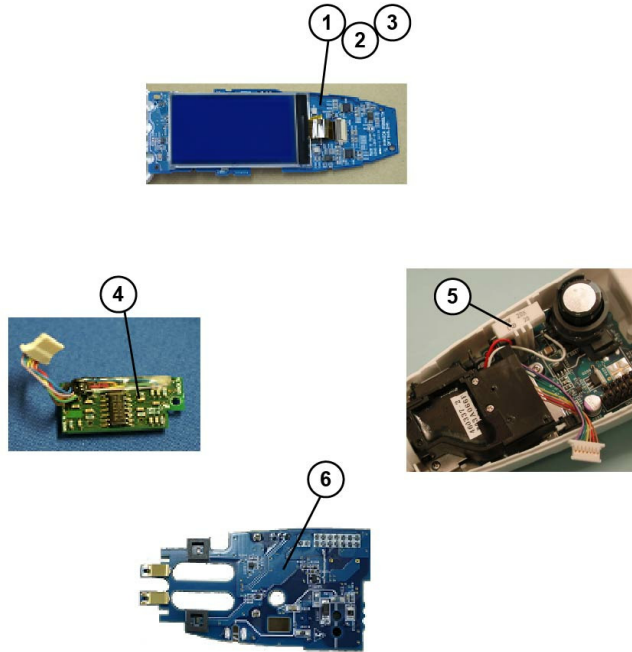
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Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	MU24870	XENON LIGHT UNIT,JM-105	1.000	St	
2	MU24871	FRAME FOR XENON LIGHT UNIT	1.000	St	
3	MU24872	SPRING FOR XENON LIGHT UNIT	1.000	St	
4	MU24873	XENON LIGHT,JM-105	1.000	St	
5	MU00791	SENSOR SET 1712-0651-05	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog

PCBs



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Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	MU24865	MAIN PCB,JM-105,CE1	1.000	St	English, german, espanol, francaise, italiano
2	MU24866	MAIN PCB,JM-105,CE2	1.000	St	English, netherland, svenska, pyc.(russian),portug.
3	MU24867	MAIN PCB,JM-105,CE3	1.000	St	English, polski, türkce., hrvatski, srpski
4	MU00791	SENSOR SET 1712-0651-05	1.000	St	
5	MU24869	POWER RESISTOR,JM-10X	1.000	St	
6	MU24868	POWER SUPPLY PCB,JM-105	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog
Housing / touch panel



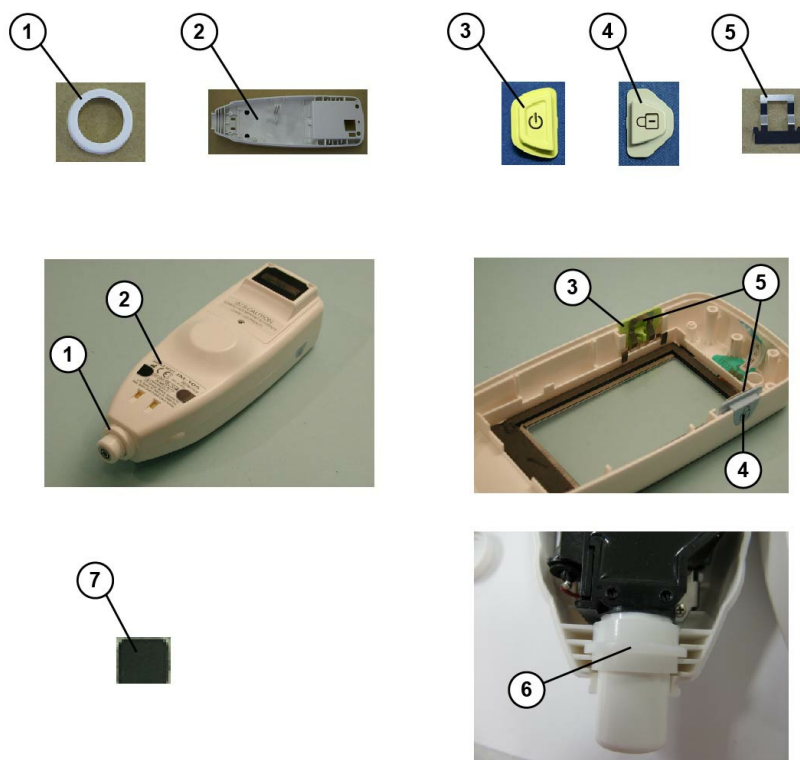
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Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	MU25317	FRONT HOUSING&TOUCH PANEL SET	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog

Housing



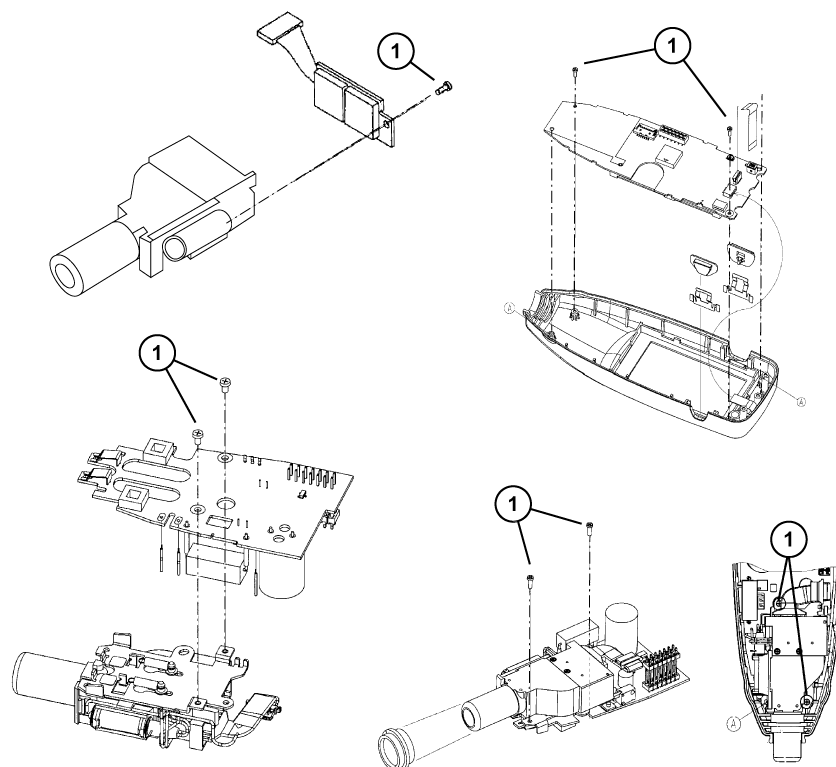
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Item No.	Order No.	Description	Qty.	Qty.unit	Remark
0		Screws set	1.000	St	
1	MU19686	CAP D 1712-1706	1.000	St	
2	MU24851	REAR HOUSING,JM-105	1.000	St	
3	MU24853	POWER BUTTON,JM-105	1.000	St	
4	MU24854	LOCK BUTTON,JM-105	1.000	St	
5	MU24855	SPRING FOR BUTTON,JM-105	1.000	St	
6	MU24857	GUIDING RING	1.000	St	
7	MU24856	INSULATING SHEET	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog

Screws set



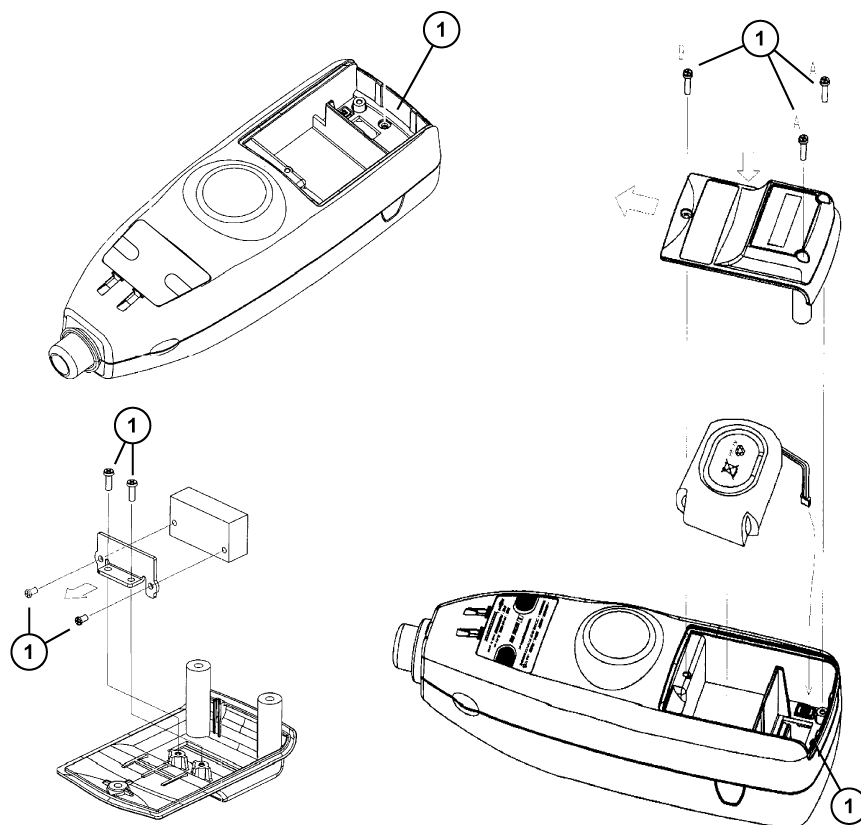
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Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	MU24860	SET OF SCREWS JM105 BASIC UNIT	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog

Screws set

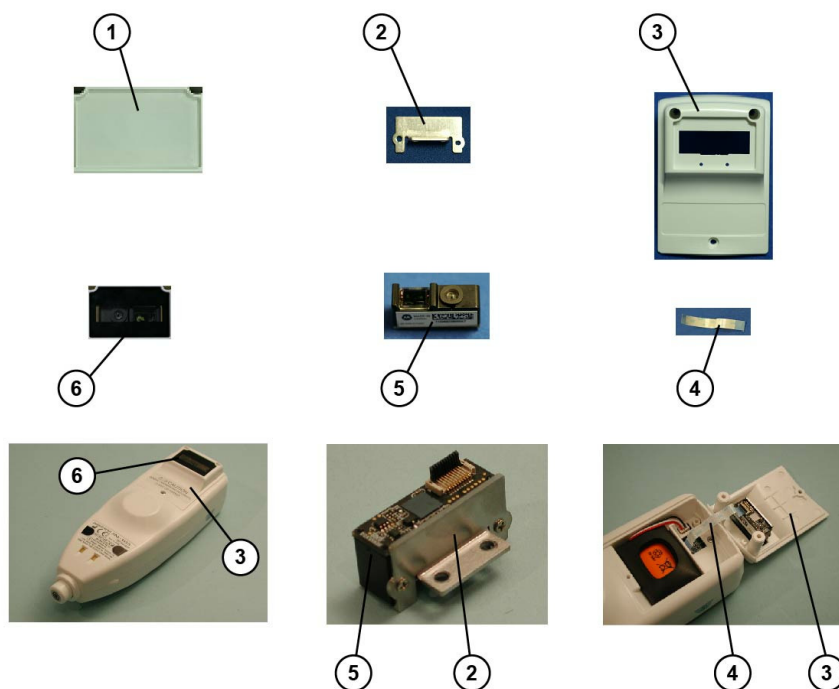


Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	MU24860	SET OF SCREWS JM105 BASIC UNIT	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog

Barcode reader



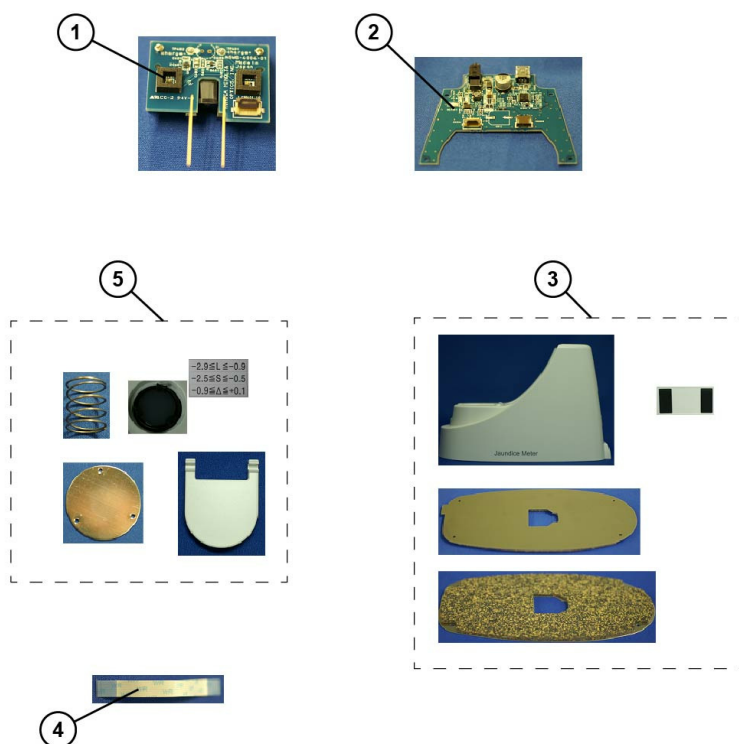
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Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	MU24858	BARCODE READER BLIND CAP	1.000	St	
2	MU24863	FIXATION ANGLE BARCODE READER	1.000	St	
3	MU25358	BANC,BATTERY COVER,JM-105	1.000	St	order togehter with MU24858 or MU24861
4	MU24845	RIBBON CABLE,JM-105	1.000	St	
5	MU24864	BARCODE READER,JM-105	1.000	St	
6	MU24861	BARCODE READER WINDOW,JM-105	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog

Docking station and AC adapter



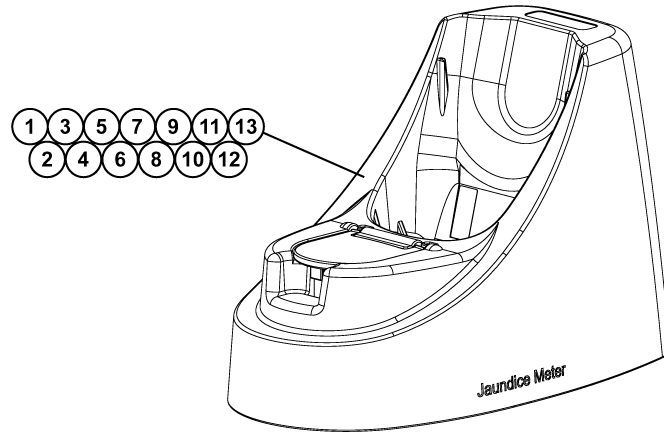
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Item No.	Order No.	Description	Qty.	Qty.unit	Remark
0	MU24774	USB CABLE,JM-105,T-A15	1.000	St	
0	MU19792	AC ADAPTER,240V,EU 1712-743	1.000	St	
0	MU19791	AC ADAPTER,120V,US 1712-742	1.000	St	
0		Docking station	1.000	St	
0	MU24850	SET OF SCREWS DOCKING STATION	1.000	St	
1	MU24844	IR PCB DOCKING STATION,JM-105	1.000	St	
2	MU24843	DOCKING STATION MAIN PCB,JM105	1.000	St	
3	MU24848	DOCKING STATION HOUSING PARTS	1.000	St	
4	MU24845	RIBBON CABLE,JM-105	1.000	St	
5	MU24846	DOCKING STATION CHECKER SET	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog

Docking station

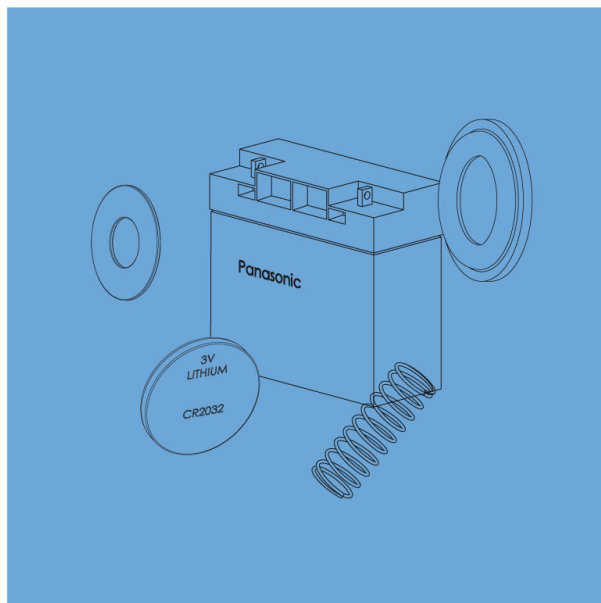


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Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	MU24755	DOCKING STATION,JM-105,CE,HU	1.000	St	
2	MU24756	DOCKING STATION,JM-105,CE,IT	1.000	St	
3	MU24757	DOCKING STATION,JM-105,CE,NL	1.000	St	
4	MU24758	DOCKING STATION,JM-105,CE,NO	1.000	St	
5	MU24759	DOCKING STATION,JM-105,CE,PL	1.000	St	
6	MU24760	DOCKING STATION,JM-105,CE,PT	1.000	St	
7	MU24761	DOCKING STATION,JM-105,CE,RO	1.000	St	
8	MU24762	DOCKING STATION,JM-105,CE,RU	1.000	St	
9	MU24763	DOCKING STATION,JM-105,CE,SK	1.000	St	
10	MU24764	DOCKING STATION,JM-105,CE,SR	1.000	St	
11	MU24765	DOCKING STATION,JM-105,CE,SV	1.000	St	
12	MU24766	DOCKING STATION,JM-105,CE,TR	1.000	St	
13	MU24767	DOCKING STATION,JM-105,MET,FR-CA	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

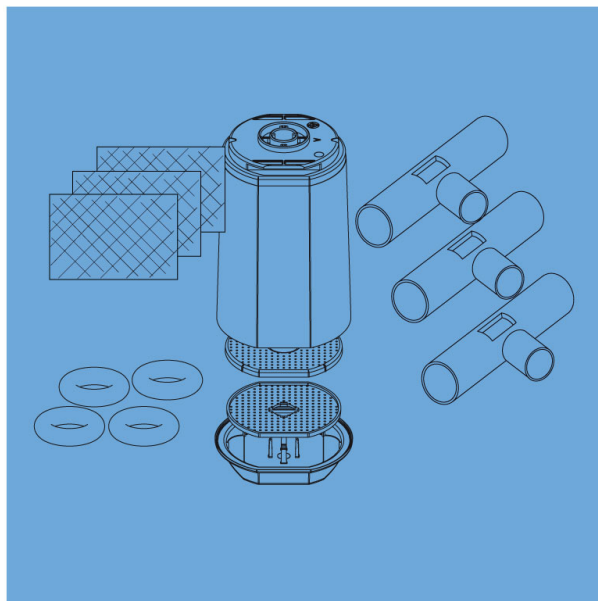
Parts catalog
Maintenance parts/service kits



Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	MU24842	BATTERY,JM-105	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Parts catalog
Accessories/Consumables



Item No.	Order No.	Description	Qty.	Qty.unit	Remark
0	MU24775	JM-105,PC DATA TRANSFER SW,CD	1.000	St	
0	MU24776	DRÄGER,JM-105 TRAIN VIDEO,EN	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Test Instructions / Service Card IPM JM-105 Jaundice Meter

NOTE

- Prior to using these test instructions, check that they are the latest revision (compare revision with current service documentation).
- All results and inputs must be documented in the "Test Report" or "Result Sheet", as applicable.



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1 Device Configuration

This chapter is used to record the device configuration.

1.1 Device Configuration

The basic device configuration includes the following items:

- JM-105 Jaundice Meter
- Charger unit with integrated checker
- Option AC adapter
- Option Power supply cord

1.1.1 Serial numbers

- | | | |
|--------|---|------------|
| Action | • Read the serial number on the JM-105 Jaundice Meter. | |
| Input | Enter the serial number of the JM-105 Jaundice Meter . The serial number is located on top above the battery cover/barcode reader cover of the Jaundice Meter. | [_____txt] |
| Action | • Read the serial number of charger unit. The serial number is located on top of the charger unit. | |
| Input | Enter the serial number of the Charger unit with integrated checker . | [_____txt] |
| Action | • Read the serial number of the AC adapter. The serial number is located on the name plate attached to the back of the AC adapter. | |
| Input | Enter the serial number on the name plate at the bottom right corner attached to the back of the AC adapter . | [_____txt] |

1.1.2 Software version

NOTE

Read out the software version using the test equipment.

- | | | |
|--------|--|--|
| Action | • Switch the JM-105 Jaundice Meter on. | |
| | • Read out the software version from the bootscreen. | |
| Test | The device completes its self-test. No error messages appear on the display after completion of the self-test. | |

NOTE

If the JM-105 Jaundice Meter fails the self-test, an error message will appear on the display.

- | | | |
|-------|-------------------------------------|------------|
| Input | Enter the Software version . | [_____txt] |
|-------|-------------------------------------|------------|

2 Maintenance Parts

This chapter contains interval-related maintenance parts, measures, and tests that can only be performed on an open device.

2.1 Maintenance parts, 2-yearly

2.1.1 Replace the battery

Amount	Designation	Number	Location/Remark
1	Battery JM-105	MU24842	JM-105 Jaundice Meter inside.

Input

Next replacement: [_____] dat]

3 Electrical Safety

This chapter contains tests that need to be performed in order to verify that the medical electrical system is operational.

3.1 Electrical safety according to IEC 62353

NOTE

Perform the electrical safety tests only on AC adapters that have a 3-pole AC cable connector.

NOTE

The medical product to be tested conforms to the requirements of protection class I, type BF.

3.1.1 Visual check

- Action
- Check the following items for contamination or damage:
 - Docking station (JM-A33 model)
 - Option AC adapter (JM-A32 model)
 - Option AC power cable

Test The items mentioned above are neither contaminated nor damaged.

Result

[_____] OK]

3.1.2 Protective earth conductor resistance (power supply cord of the AC adapter)

Action • Prepare the test set-up.

CAUTION

For the protective earth conductor resistance the tester applies voltage to the tip of the test probe. Since the tip of the test probe is too big for the protective earth conductor contact of the power supply cord to be tested, the test must be carried out with an appropriate aid, e.g. a 2-mm Allen key. Do not touch the tip of the test probe or the aid during the measurement!

- Insert an appropriate aid, e.g. a 2-mm Allen key, into the protective earth conductor contact of the power supply cord's socket, and, at the same time, hold the tip of the test probe against the Allen key while moving the power supply cord section by section.

Test The value of the protective earth conductor resistance must not exceed **0.1** ohms.

Result Protective earth conductor resistance

[_____ Ohm]

3.1.3 Equipment leakage current

NOTE

- The equipment leakage current can be tested by the differential measurement method or the direct measurement method.
- In direct measurement, set up the device under test with insulation and scan all accessible conductive components using the probe (the protective earth is internally interrupted in the tester).

Prerequisites The tester is switched on.

Test set-up

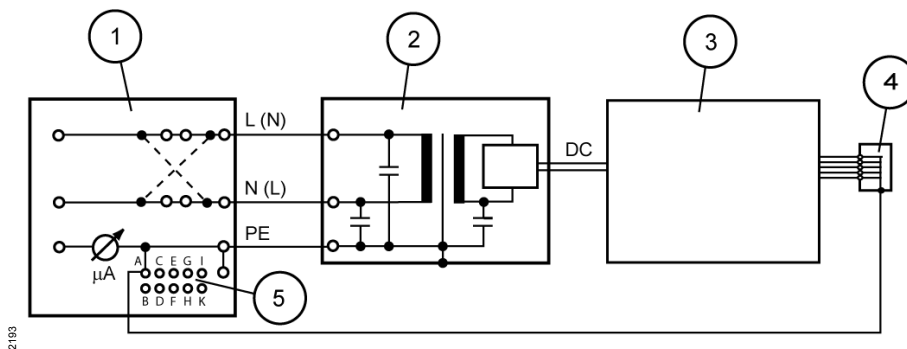


Fig. 1 Equipment leakage current

Item	Designation
1	Tester
2	Mains adapter
3	Monitor
4	(Applied part) Device-specific test adapter for tester
5	Configurable ports for applied part
L	Conductor

Item	Designation
N	Neutral conductor
PE	Protective earth
DC	Direct voltage

- Action
- Prepare the test setup.
 - (Applied part) Connect the device-specific test adapter on one end to the device under test and on the other end to the tester's configurable port "A" for applied parts (paying attention to the configuration!).
 - Follow the instructions on the tester.

NOTE

For symmetrical mains plugs that have no preferential position in the socket-outlet, perform the test twice! Perform the second test with the plug rotated 180° in the socket. In many test devices the mains plug rotation is simulated by means of a built-in selector switch. Document the higher measured value.

NOTE

Always enter the reference value (initial value measured) in the "Test Report" or "Result Sheet" document.

NOTE

If the measured values are between 90% and 100% of the permissible limit value, the reference value and the previously measured values of the recurrent test should be applied to assess electrical safety!

Test The reference value must not exceed **500** μA .

Result **Reference value**

[] μA

Test The recurrent test value must not exceed **500** μA .

Result **Recurrent test**

[] μA

3.2 Electrical safety according to IEC 60601-1

NOTE

Perform the electrical safety tests only on AC adapters that have a 3-pole AC cable connector.

NOTE

The medical product to be tested conforms to the requirements of protection class I, type BF.

3.2.1 Visual check

- Action
- Check the following items for contamination or damage:
 - Docking station (JM-A33 model)
 - Option AC adapter (JM-A32 model)
 - Option AC power cable
- Test
- The items mentioned above are neither contaminated nor damaged.
- Result

[_____] OK]

3.2.2 Protective earth conductor resistance (power supply cord of the AC adapter)

- Action
- Prepare the test set-up.

CAUTION

For the protective earth conductor resistance the tester applies voltage to the tip of the test probe. Since the tip of the test probe is too big for the protective earth conductor contact of the power supply cord to be tested, the test must be carried out with an appropriate aid, e.g. a 2-mm Allen key. Do not touch the tip of the test probe or the aid during the measurement!

- Insert an appropriate aid, e.g. a 2-mm Allen key, into the protective earth conductor contact of the power supply cord's socket, and, at the same time, hold the tip of the test probe against the Allen key while moving the power supply cord section by section.

- Test
- The value of the protective earth conductor resistance must not exceed **0.1** ohms.
- Result
- Protective earth conductor resistance

[_____] Ohm]

3.2.3 Earth leakage current

Test set-up

NOTE

To avoid false measurements, install the device under test insulated.

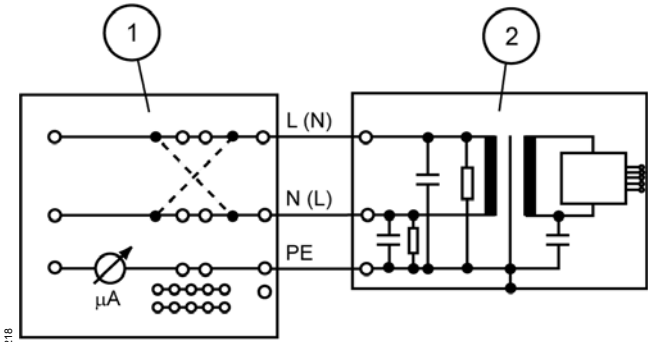


Fig. 2 Earth leakage current

Item	Designation
1	Tester

Item	Designation
2	Device under test
L	Conductor
N	Neutral conductor
PE	Protective earth

- Action
- Prepare the test setup.
 - Follow the instructions on the tester.

IEC60601

Test Normal condition (N.C.): The value must not exceed **500** μA .

Result **Normal condition (N.C.)**

[] μA

Test Single fault condition (S.F.C.): The value must not exceed **1000** μA .

Result **Single fault condition (S.F.C.)**

[] μA

- Action
- Plug the power supply connector (inverted, if possible) into the test socket of the test device (In many test devices the power supply connector inversion can be simulated by means of a built-in selector switch)

Test Normal condition (N.C.): The value must not exceed **500** μA .

Result **Normal condition (N.C.)**

[] μA

Test Single fault condition (S.F.C.): The value must not exceed **1000** μA .

Result **Single fault condition (S.F.C.)**

[] μA

UL2601

Test Normal condition (N.C.): The value must not exceed **300** μA .

Result **Normal condition (N.C.)**

[] μA

Test Single fault condition (S.F.C.): The value must not exceed **1000** μA .

Result **Single fault condition (S.F.C.)**

[] μA

NOTE

In order to avoid incorrect measurement, set up the device under test so that it is insulated.

NOTE

For symmetrical mains plugs that have no preferential position in the socket-outlet, the device leakage current test must be performed twice! The second test shall be performed with the plug reversed 180° in the socket. In many test devices the mains plug rotation is simulated by means of a built-in selector switch. The higher measured value shall be documented.

Action	<ul style="list-style-type: none"> Plug the power supply connector (inverted, if possible) into the test socket of the test device (In many test devices the power supply connector inversion can be simulated by means of a built-in selector switch)
Test	Normal condition (N.C.): The value must not exceed 300 μA .
Result	Normal condition (N.C.) [_____ μA]
Test	Single fault condition (S.F.C.): The value must not exceed 1000 μA .
Result	Single fault condition (S.F.C.) [_____ μA]

4 Function and Condition Test

This chapter contains tests that need to be performed in order to verify that the function and condition of the device and the accessories used meet the specifications according to the Instructions for Use.

4.1 Condition tests

4.1.1 General condition

Device and accessories

Action	<ul style="list-style-type: none"> Check the following devices/assemblies and the accessories as well as their connections, cables, and switches: <ul style="list-style-type: none"> JM-105 Jaundice Meter including measuring probe Charger unit with integrated checker and measuring probe AC adapter
--------	---

CAUTION

Incorrect measurements due to dirty or damaged measuring probe surfaces! The measuring probes of the JM-105 Jaundice Meter and of the charger unit with integrated checker must not be dirty or damaged!

Test	The above mentioned devices/parts and accessories as well as their connections, cables and switches are not contaminated or damaged. The device parts and accessories are complete as specified in the Instructions for Use manual. The surfaces of the JM-105 Jaundice Meter and of the charger unit with integrated checker are not dirty or damaged!
Result	[_____ OK]

4.1.2 Accompanying documents

Instructions for Use

Action	<ul style="list-style-type: none"> Check that the Instructions for Use are available.
Test	Instructions for Use/Operating Instructions manual is available (according to user).
Result	[_____ OK]

Medical product logbook (Germany only)

- Action • Check that the medical product logbook is available.
- Test The medical product logbook is available (according to user).
- Result

[_____]OK]

4.1.3 Labels (labeling)

JM-105 Jaundice Meter

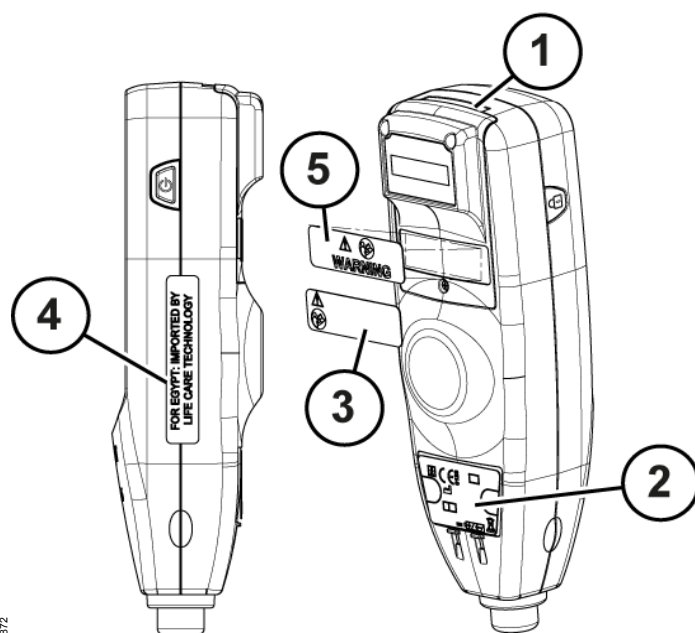


Fig. 3 Labels JM-105 Jaundice Meter

- Action • Check that the labels (labeling) are present on the JM-105 Jaundice Meter and that they are complete and legible.
- Serial number (Fig. 3/1).
 - Name plate with WEEE icon (Fig. 3/2).
 - Warning/Caution (Fig. 3/3).
 - Label for Egypt only (Fig. 3/4).
 - Warning/Caution (Fig. 3/5).
- Result The above mentioned labels (labeling) are present on the JM-105 Jaundice Meter are complete and legible.

[_____]OK]

Docking station with integrated checker

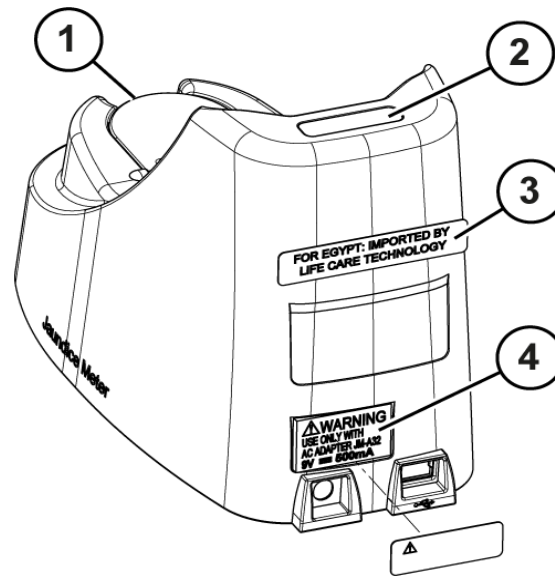


Fig. 4 Labels docking station

Test Check that the following labels (labeling) are available on the docking station with integrated checker and that it is complete and legible.

- Label below the checker cover with checker values (Fig. 4/1).
- Serial number (Fig. 4/2).
- Label for Egypt only (Fig. 4/3).
- Warning/Caution (Fig. 4/4).

Result The above mentioned label (labeling) is available on the charger unit with integrated checker and is complete and legible.

[_____] **OK**

AC adapter

Test Check that the following label (labeling) is available on the AC adapter and that it is complete and legible.

- "Name plate" label (the "name plate" label is attached to the bottom of the AC adapter.)

Result The above mentioned label (labeling) is available on the AC adapter and is complete and legible.

[_____] **OK**

4.2 Function tests

4.2.1 Charging function

- Action**
- Plug the connector of the AC adapter into the socket of the docking station.
 - Connect the AC plug of the AC adapter to the AC socket-outlet.
 - Place the JM-105 Jaundice Meter into the docking station.

Function tests

Test	The red LED of the charger unit comes on.	
Action	<ul style="list-style-type: none"> • Disconnect the AC adapter from the socket of the docking station. • Connect the USB cable to the docking station and to the service PC. 	
Test	The red LED of the charger unit comes on.	
Result		[_____]OK]
Action	<ul style="list-style-type: none"> • Remove the JM-105 Jaundice Meter from the docking station. 	

4.2.2 Measurement

Action	<ul style="list-style-type: none"> • Switch on the JM-105 Jaundice Meter. • Select "CHECKER". • Touch "OK" to save selection. • Open the checker cover on the docking station. • Place the measuring probe perpendicular to the checker and push gently until a flash occurs. 	
Test	All values should fall within the ranges shown on the checker cover.	
Action	<ul style="list-style-type: none"> • Close the checker cover. • Touch "MENU" button. • Select "MEASURE". • Touch "OK" to save selection. • Touch the barcode reader button. • Scan the following barcode by selecting "SCAN". 	

**Fig. 5** Barcode

Test	The measured value "ABCDEFGHIJKLMNO" is displayed.	
Result		[_____]OK]

4.2.3 Check date and time

Action	<ul style="list-style-type: none"> • Check the date and time displayed and, if necessary, adjust them as described in the Instructions for use. 	
Result	Date and time are correct.	[_____]OK]

4.2.4 Final actions

Prerequisites	<p>The test instructions have been performed as specified.</p> <p>All tests performed were passed successfully.</p>	
Action	<ul style="list-style-type: none"> • Place the ready-for-use JM-105 Jaundice Meter at the user's disposal. 	
Result		[_____]OK]

4.3 Final procedures

- Prerequisites
- The test instructions have been performed as specified.
 - All tests performed were passed successfully.

4.3.1 Test label and device handover

- Action
- Attach a test label to the device.
 - Supply the user/owner with a fully functioning device.


Result [_____ OK]

5 Test Equipment

This chapter lists the service equipment required to perform the tests specified in these test instructions.

5.1 Test equipment

5.1.1 Test equipment subject to mandatory calibration

Designation	Part number	
Measuring equipment for electrical safety	7910594 or equivalent	

Result **Valid calibrated test equipment used.** [_____ OK]

Result Sheet Test Instructions / Service Card IPM JM-105 Jaundice Meter

Order number: -

Location:

Department:

Maintenance interval:

--	--	--	--	--	--

Serial no. (basic unit):

Cust. invent. no.:

Other / Delivery date:

Key

- ✓ / OK = OK
- + = Spare part used
- ! = Error / Report
- / = Accessory not available
- = Not applicable

Applies to Test Instructions / Service Card IPM Revision 1.n

OK	Result
1 Device Configuration	
1.1 Device Configuration	
1.1.1 Serial numbers	
<input type="checkbox"/> 1.1.1.1 JM-105 Jaundice Meter	txt
<input type="checkbox"/> 1.1.1.2 Charger unit with integrated checker	txt
<input type="checkbox"/> 1.1.1.3 AC adapter	txt
<input type="checkbox"/> 1.1.2 Software version	txt
2 Maintenance Parts	
2.1 Maintenance parts, 2-yearly	
<input type="checkbox"/> 2.1.1 Replace the battery	dat
3 Electrical Safety	
3.1 Electrical safety according to IEC 62353	
<input type="checkbox"/> 3.1.1 Visual check	OK
<input type="checkbox"/> 3.1.2 Protective earth conductor resistance (power supply cord of the AC adapter) (Max=0.1)	Ohm
3.1.3 Equipment leakage current	
<input type="checkbox"/> 3.1.3.1 Reference value (Max=500)	µA
<input type="checkbox"/> 3.1.3.2 Recurrent test (Max=500)	µA
3.2 Electrical safety according to IEC 60601-1	
<input type="checkbox"/> 3.2.1 Visual check	OK
<input type="checkbox"/> 3.2.2 Protective earth conductor resistance (power supply cord of the AC adapter) (Max=0.1)	Ohm
3.2.3 Earth leakage current	
<input type="checkbox"/> 3.2.3.1 Normal condition (N.C.) (Max=500)	µA
<input type="checkbox"/> 3.2.3.2 Single fault condition (S.F.C.) (Max=1000)	µA
<input type="checkbox"/> 3.2.3.3 Normal condition (N.C.) (Max=500)	µA
<input type="checkbox"/> 3.2.3.4 Single fault condition (S.F.C.) (Max=1000)	µA
<input type="checkbox"/> 3.2.3.5 Normal condition (N.C.) (Max=300)	µA
<input type="checkbox"/> 3.2.3.6 Single fault condition (S.F.C.) (Max=1000)	µA
<input type="checkbox"/> 3.2.3.7 Normal condition (N.C.) (Max=300)	µA
<input type="checkbox"/> 3.2.3.8 Single fault condition (S.F.C.) (Max=1000)	µA
4 Function and Condition Test	
4.1 Condition tests	
<input type="checkbox"/> 4.1.1 General condition	OK
<input type="checkbox"/> 4.1.2 Accompanying documents	OK
4.1.3 Labels (labeling)	
<input type="checkbox"/> 4.1.3.1 JM-105 Jaundice Meter	OK
<input type="checkbox"/> 4.1.3.2 Docking station with integrated checker	OK
<input type="checkbox"/> 4.1.3.3 AC adapter	OK
4.2 Function tests	
<input type="checkbox"/> 4.2.1 Charging function	OK
<input type="checkbox"/> 4.2.2 Measurement	OK
<input type="checkbox"/> 4.2.3 Check date and time	OK
<input type="checkbox"/> 4.2.4 Final actions	OK
4.3 Final procedures	

OK	Result
<input type="checkbox"/> 4.3.1 Test label and device handover	OK
5 Test Equipment	
5.1 Test equipment	
5.1.1 Test equipment subject to mandatory calibration	
<input type="checkbox"/> 5.1.1.1 Valid calibrated test equipment used.	OK

Report:

Test has been performed according to the test instructions.

Name: : _____

Date/Signature:..... : _____

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Directive 93/42/EEC
concerning Medical Devices

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