

Dräger

Instructions for Use **JM-105**



WARNING

To properly use this medical device,
read and comply with these instruc-
tions for use.

Jaundice Meter

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Definition of target groups

For this product, users, service personnel, and experts are defined as target groups.

These target groups must have received instruction in the use of the product and must have the necessary training and knowledge to use, install, reprocess, maintain, or repair the product.

The product must be used, installed, reprocessed, maintained, or repaired exclusively by defined target groups.

Users

Users are persons who use the product in accordance with its intended use.

Service personnel

Service personnel are persons who are responsible for the maintenance of the product.

Service personnel must be trained in the maintenance of medical devices and install, reprocess, and maintain the product.

Experts

Experts are persons who perform repair or complex maintenance work on the product.

Experts must have the necessary knowledge and experience with complex maintenance work on the product.

Screen reproductions

The reproductions of screen content in the instructions for use can differ from the content shown on the screen.

Typographical conventions

- 1 Consecutive numbers indicate steps of action, with the numbering restarting with "1" for each new sequence of actions.
 - Bullet points indicate individual actions or different options for action.
 - Dashes indicate the listing of data, options, or objects.
- (A) Letters in parentheses refer to elements in the related illustration.
- A Letters in illustrations denote elements referred to in the text.

Any text shown on the screen and any labeling on the device are printed in bold and italics, for example, **AVERAGE**, *Air*, or **5 MIN**.

The "greater than" symbol > indicates the navigation path in a dialog window, for example, **System setup** > **Ventilation** > **Basic settings**.

Trademarks

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Windows Vista®	Microsoft Corporation
Windows XP® operating system	Microsoft Corporation
Windows 7® operating system	Microsoft Corporation
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Safety information definitions

WARNING

A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property.

NOTE

A NOTE provides additional information intended to avoid inconvenience during operation.

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For your safety and that of your patients

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General safety information

The following WARNING and CAUTION statements apply to general operation of the medical device.

WARNING and CAUTION statements specific to subsystems or particular features of the medical device appear in the respective sections of these instructions for use or in the instructions for use of another product being used with this medical device.

Strictly follow these instructions for use

WARNING

Risk of incorrect operation and of incorrect use

Any use of the medical device requires full understanding and strict observation of all sections of these instructions for use. The medical device must only be used for the purpose specified under "Intended use" on page 8 and in conjunction with appropriate patient monitoring (see page 3).

Strictly observe all WARNING and CAUTION statements throughout these instructions for use and all statements on medical device labels. Failure to observe these safety information statements constitutes a use of the medical device that is inconsistent with its intended use.

Maintenance

WARNING

Risk of medical device failure and of patient injury

The medical device must be inspected and serviced regularly by service personnel. Repair and complex maintenance carried out on the medical device must be performed by experts.

If the above is not complied with, medical device failure and patient injury may occur. Observe chapter "Maintenance".

Dräger recommends that a service contract is obtained with DrägerService and that all repairs are performed by DrägerService. For maintenance Dräger recommends the use of authentic Dräger repair parts.

Connected devices

WARNING

Risk of electric shock and of device malfunction

Any connected devices or device combinations not complying with the requirements mentioned in these instructions for use can compromise the correct functioning of the medical device and lead to an electric shock. Before operating the medical device, strictly comply with the instructions for use of all connected devices or device combinations.

Not for use in areas of explosion hazard

WARNING

Risk of fire

The medical device is not approved for use in areas where combustible or explosive gas mixtures are likely to occur.

Safe connection with other electrical equipment

CAUTION

Risk of patient injury

Electrical connections to equipment not listed in these instructions for use or these assembly instructions must only be made when approved by each respective manufacturer.

Connection to other devices

Device combinations (Dräger devices + Dräger devices or Dräger devices + third-party devices) approved by Dräger (see instructions for use of individual devices) meet the requirements of the following standards:

- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

If a device combination is not approved by Dräger, proper operation of the devices can be compromised.

The operator must ensure that the device combination meets the applicable standards.

Strictly observe instructions for use and assembly instructions of all connected devices.

Patient safety

The design of the medical device, the accompanying documentation, and the labeling on the medical device are based on the assumption that the purchase and the use of the medical device are restricted to persons familiar with the most important inherent characteristics of the medical device.

Instructions and WARNING and CAUTION statements are therefore largely limited to the specifics of the Dräger medical device.

The instructions for use do not contain any information on the following points:

- Risks that are obvious to users
- Consequences of obvious improper use of the medical device
- Potentially negative effects on patients with different underlying diseases

Medical device modification or misuse can be dangerous.

Patient monitoring

CAUTION

Risk of patient injury

Do not make therapeutic decisions based solely on individual measured values and monitoring parameters.

The user of the medical device is responsible for choosing a suitable patient monitoring system that provides appropriate information on medical device performance and patient condition.

Patient safety can be achieved by a wide variety of means ranging from electronic surveillance of medical device performance and patient condition to direct observation of clinical signs.

The responsibility for selecting the best level of patient monitoring lies solely with the user of the medical device.

Information on electromagnetic compatibility

General information on electromagnetic compatibility (EMC) according to international EMC standard IEC 60601-1-2:

Medical electrical equipment is subject to special precautionary measures concerning electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC information provided on page 81.

Portable and mobile radio frequency communication equipment can affect medical electrical equipment.

Training

Training for users is available via the Dräger organization responsible (see www.draeger.com).

WARNING

Risk of device malfunction

Electromagnetic fields can compromise proper operation of the device. Electromagnetic fields are generated by, e.g., radio frequency communication equipment such as:

- Mobile phones
- Radio frequency electrosurgical equipment
- Defibrillators
- Shortwave therapy equipment

Storing the instructions for use

CAUTION

Risk of incorrect use

Instructions for use must be kept accessible to the user.

Product-specific precautions

Electrical precautions

WARNING

Risk of fire, electric shock, or equipment damage

Using a docking station or AC adapter other than JM-A33 provided with the device could damage the device.

Use only the docking station JM-A33 and the AC adapter JM-A32 with the device.

WARNING

Risk of fire, electric shock, or equipment damage

Connecting to a power source without a protective earth ground could damage the device.

Connect the device only to a power source with a protective earth ground.

WARNING

Risk of fire, electric shock, or equipment damage

Pulling the power cable by the cable could damage the cable and cause fire or electric shock.

Hold the AC power cable by the plug-end when disconnecting from a power source or the AC adapter.

WARNING

Risk of fire

Dust or water could collect at the plug of the power cable.

Disconnect the power cable when the device is not being used or charged for any length of time.

WARNING

Risk of electric shock

Touching the AC power cable with wet hands could cause electric shock.

Do not connect or disconnect the AC power cable with wet hands.

WARNING

Risk of electric shock or device malfunction

Penetrating metal objects may damage the device or docking station, causing malfunction of the device, which may endanger the patient.

Do not allow metal objects to penetrate into the device or docking station.

WARNING

Risk of fire

Operating the device and its accessories when they are damaged could cause a fire.

Do not operate the device or its accessories if any of them are damaged, or if there is smoke or an odd odor.

WARNING

Risk of patient injury

Strong ambient light, electromagnetic interference, and mobile telephone use can interfere with accurate measurement of data.

Do not use the device in strong ambient light, or near electronic devices or mobile telephones.

General precautions

WARNING

Risk of injury

Operating the device while the probe is directed at the eyes can cause eye damage.

Do not press the measuring probe when it is directed at the eyes.

CAUTION

Risk of equipment damage

The device or docking station could overturn or fall.

Do not place the device on an unstable or sloped surface.

CAUTION

Risk of equipment damage

Do not drop the device or place heavy objects on top of the device.

CAUTION

Risk of equipment damage

The device is not waterproof or liquid proof.

Do not expose the device to rain, water, blood, or other liquids.

CAUTION

Risk of equipment damage

Excessive vibration or impact could damage the device.

Handle the device gently, and avoid excessive impact or vibration.

CAUTION

Risk of equipment damage

Avoid vibration and physical shock during transportation.

NOTE

Thoroughly clean the device and accessories before storing.

NOTE

Ensure that the device is placed near the AC power source. Also ensure the AC power cable can be easily connected and disconnected.

NOTE

To prove measuring reliability of the device, compare TcB value (Transcutaneous Bilirubin) measured by the device and TsB value (Total Serum Bilirubin) measured from collected blood samples.

Storage and transportation precautions

CAUTION

Risk of equipment damage

Do not store the device in areas where direct sunlight, pressure, temperature, humidity, ventilation, dust, strong magnetic fields, or saline or sulphurous atmospheres affect the device.

Do not store the device where it is exposed to water.

Do not store the device in areas where chemicals are stored or where gas is emitted.

CAUTION

Risk of equipment damage

The device or docking station could overturn or fall.

Do not store the device on an unstable or sloped surface, or a surface subject to vibration or physical shock.

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Intended use

The Jaundice Meter is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit provides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.

The device is intended for use in hospitals or doctors offices under a physician's supervision, or at their direction. It helps clinicians to monitor newborn infants. The device is not intended as a stand-alone screening device for diagnosis of hyperbilirubinemia. It is used as a screening device with other clinical signs and laboratory measurements.

Indications/contraindications

Indications

The Jaundice Meter is indicated for use in neonatal patients born >24 weeks gestation who have not undergone transfusion or phototherapy treatment.

The device is indicated only for use before phototherapy treatment.

Contraindications

The device is not intended as a stand-alone screening device for diagnosis of hyperbilirubinemia. It is used as a screening device with other clinical signs and laboratory measurements.

The Jaundice Meter is not intended for home use.

Do not use this device on infants with pathologic jaundice. If there is a possibility that the infant is suffering from pathologic jaundice, as a result of an incompatible blood type or hemolytic jaundice, then total serum bilirubin should be measured.

Further information on application

Newborn infants whose Jaundice Meter test results are indicative of hyperbilirubinemia should be evaluated by their physicians for appropriate patient management. Specific neonatal patient bilirubin levels should be confirmed by other methods, such as serum bilirubin, before treatment determinations.

Limitations (Doctors Office Use)

Use only on infants up to 14 days of age.

For doctors office application, use only the sternum location when taking measurements.

Please be aware, performance in doctors offices may vary from performance in hospitals.

Measuring Point

Measurements must be taken only on the infant's sternum (at hospital sites or physicians' offices) or forehead (at hospital sites only) where a sufficient amount of blood is circulated. A possibility exists that the bilirubin in the subcutaneous tissue may measure low for areas with minimal blood flow or areas in which the subcutaneous tissue is subject to keratinization.

Although correlation with serum bilirubin was observed for both sternum and forehead measurements, the clinical studies performed with the Jaundice Meter JM-103 show consistently better results with measurements taken at the sternum versus the forehead. There is a possibility that this difference may be more pronounced for infants that have been exposed to sunlight, such as infants seen at doctors' offices. Only sternum measurements were evaluated during the studies conducted at doctors' offices; correlation of forehead measurements with serum bilirubin has not been evaluated, and the device is not intended for forehead measurements at doctors' offices.

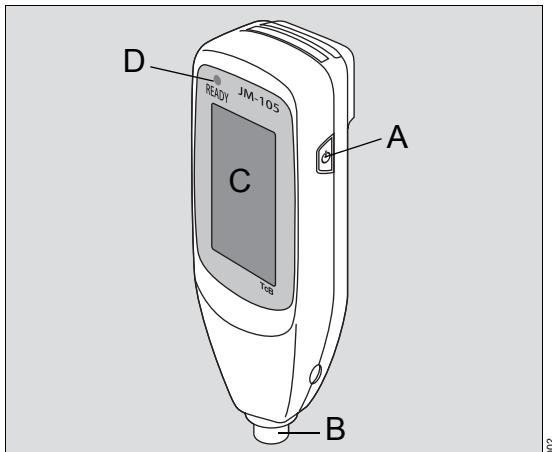
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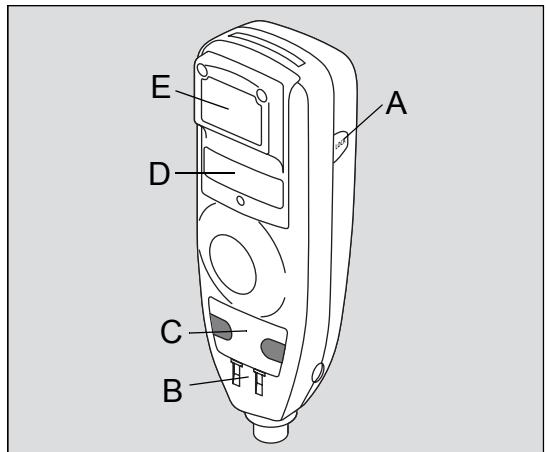
Device views

Jaundice meter JM-105 - Front

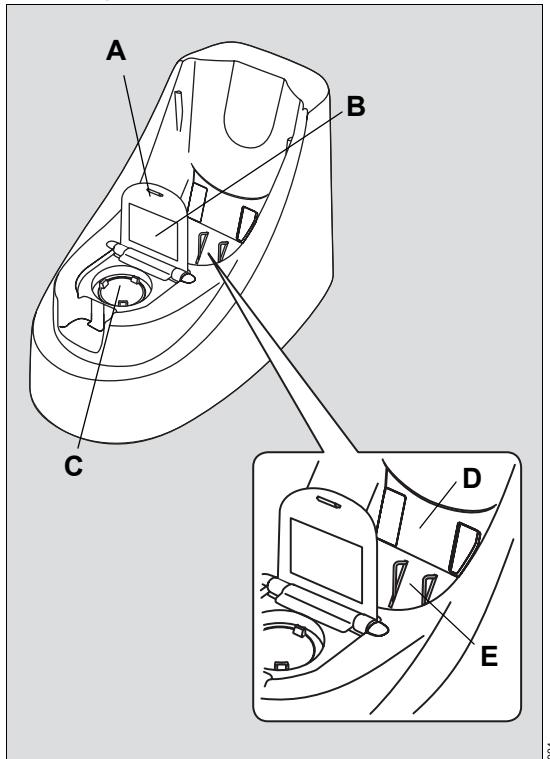
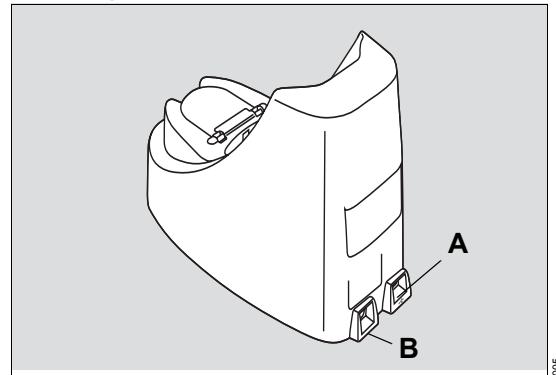


- A Power button
- B Measuring probe
- C Display/Touch panel
- D **READY** lamp

Jaundice meter JM-105 - Rear



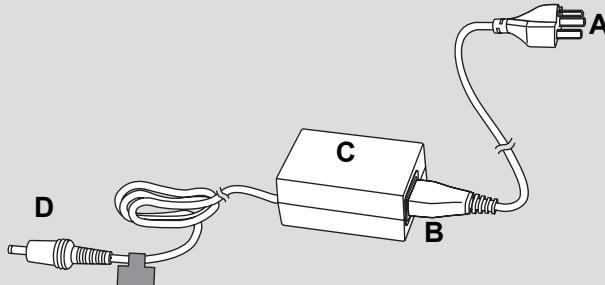
- A Screen **LOCK** button
- B Charging contact
- C Communication port
- D Battery cover
- E Barcode reader

Docking station JM-A33 - Front**Docking station JM-A33 - Rear**

- A USB connector
B DC jack

- A Checker cover
B Standard checker values
C Reading checker
D Communication window
E Charger jack

AC adapter JM-A32



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- A AC power cable plug
- B AC power cable
- C AC adapter
- D DC plug

External devices

Valid device combinations

The JM-105 can only be combined with the JM-A33 docking station and the JM-A32 AC adapter to measure bilirubin. It can also be connected to a computer to transmit data from the device to an electronic health records system.

Interfaces

The USB port provides a connection for transmitting data to electronic health records systems. It also provides an alternate method to charge the device.

Software

Device software

The JM-105 is a non-invasive transcutaneous bilirubinometer. It uses the digital data generated by converting the amount of light reflected from human tissue. The device displays the results on the LCD display. The software is installed in the device ROM. The device becomes operable when the batteries supply power and then the release signal is released.

Data transmission software

The data transmission software, SW JM-S1w, enables the JM-105 to transmit measurement data to a PC and send it to an electronic health record system (EHR). It also enables saving the data to a CSV file.

Abbreviations

Abbreviation Meaning

AC	Alternating current
AP	Applied part
CD	Compact Disc
CSA	Canadian Standards Association
DC	Direct current
DVD	Digital Video Disc
EHR	Electronic Health Record
EMC	Electromagnetic compatibility
ESD	Electrostatic discharge
GMDN	Global Medical Device Nomenclature
IEC	International Electrotechnical Commission
LCD	Liquid crystal display
PC	Personal computer
RH	Relative humidity
ROM	Read only memory
UMDNS	Universal Medical Device Nomenclature System
USB	Universal Serial Bus

Symbols

Symbols on device



Warning



Caution



Degree of protection against electric shock: Type BF



Refer to instructions for use



AC power



DC Power



Do not discard with regular waste



Date of manufacture



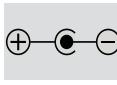
USB port



Standby or On/Off



Input



Circuit output terminal

Symbols on touch screen

Go BACK to previous screen



Rechargeable battery



Priority flag



EDIT the selected item



Lock



CLEAR the entry



Not used at this time, for future use



Proceed to the NEXT BABY



Menu

Nurse ID



Key



Baby ID



Scan



L Value (long)



Sent to chart



S Value (short)



Delete



Delta Value (difference between long value and short value)



Delete



CANCEL the entry or stop the task



Confirm the entry



Busy



Symbols on the PC



JM-S1w



JM-S1w error

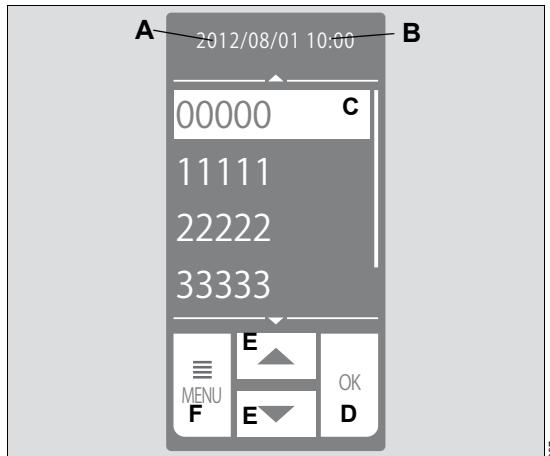
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Operating concept

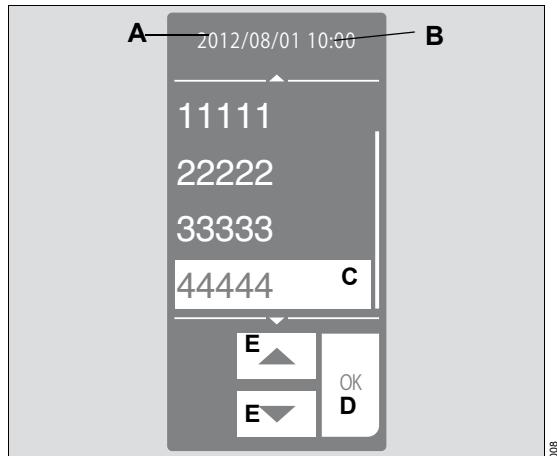
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Screen layout for device

Main screen



MENU screen

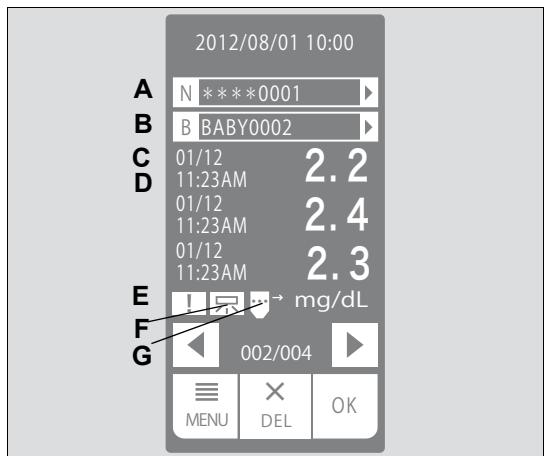
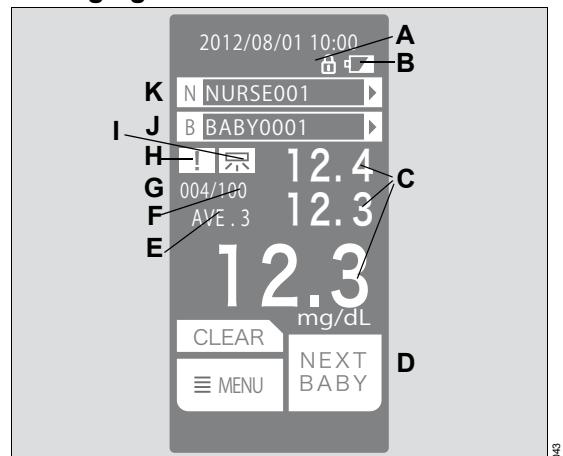


The main screen contains these fields:

A	Date
B	Time
C	Available selections <ul style="list-style-type: none">- MEASURE- CHECKER- HISTORY- CLR ALL
D	OK
E	Arrows
F	MENU

The **MENU** screen contains these buttons:

A	Date
B	Time
C	Available selections <ul style="list-style-type: none">- MEASURE- CHECKER- HISTORY- CLR ALL- CONFIG
D	OK
E	Arrows

Measured data screen**Averaging screen**

The Measured data screen contains these fields:

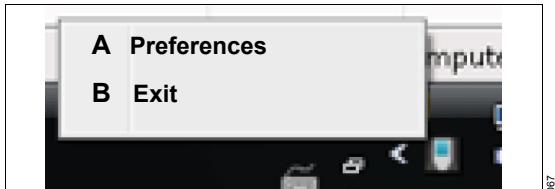
A	NURSE ID (nurse ID)
B	BABY ID (baby ID)
C	Date of measurement
D	Time of measurement
E	Priority flag
F	Not used at this time, for future use
G	Sent to electronic chart

The Averaging screen contains these fields:

A	Display lock
B	Battery indicator
C	Measurement result
D	Touch to proceed to next baby
E	Number of measurements for averaging
F	Data log capacity
G	Number of measurements stored in data log
H	Priority flag
I	Not used at this time, for future use
J	BABY ID (baby ID) (9 trailing characters if ID is 10 or more characters long.)
K	NURSE ID (nurse ID) (9 trailing characters if ID is 10 or more characters long.)

Screen layout for data transmission software

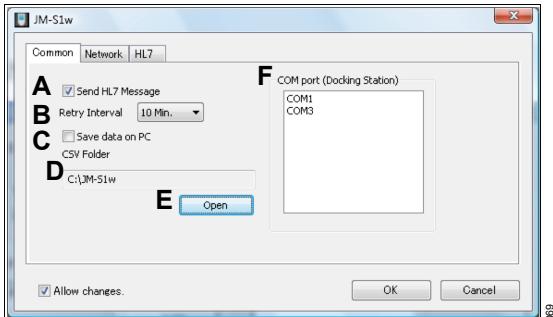
JM-S1w menu



The JM-S1w menu screen contains these selections:

- | | |
|----------|---|
| A | Preferences - Opens the JM-S1w dialog box where preferences are set. |
| B | EXIT |

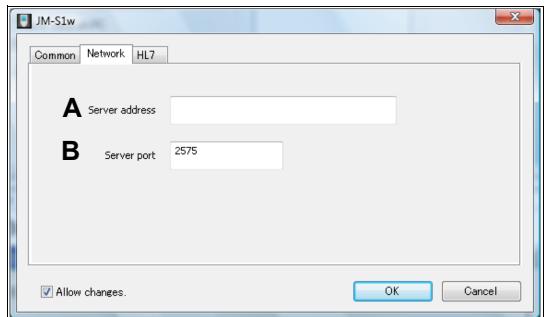
Common screen



The **Common** screen contains these fields:

- | | |
|----------|---|
| A | Send HL7 Message - Enables/disables communication with an electronic health records system. |
| B | Retry Interval - Sets the time to wait before resending data after an error occurs.
Available selections:
No retry
1 Min.
10 Min.
30 Min. |
| C | Save data on PC - Enables/disables saving data to CSV (comma-separated value) text files on the computer. |
| D | CSVFolder - Shows the selected folder in which to save the CSV file. |
| E | Open - Opens a window for selecting the CSV folder. |
| F | COM port (Docking Station) - Shows a list of available COM ports. |

Network screen



The **Network** screen contains these fields:

- | | |
|----------|--|
| A | Server address - Input the IPv4 address or alphanumeric host name of the electronic health records server.

Restrictions:
Proxy cannot be used.
A PC on the LAN should be set as the destination. |
| B | Server port - Input the communication destination port on the server. The default is the HL-7 default port (2575). |

HL-7 screen

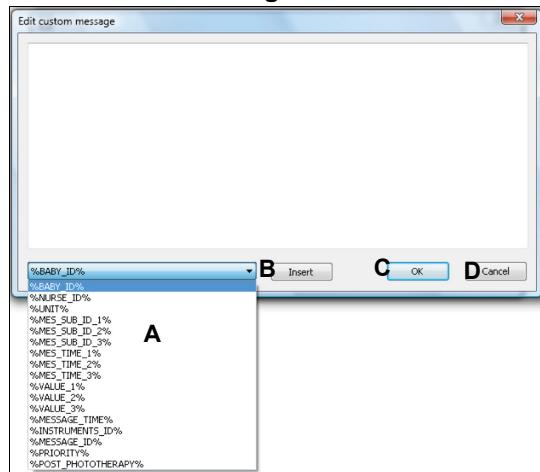


The **HL-7** screen contains these fields:

- | | |
|----------|--|
| A | HL7 Version - Select Ver. 2.3.1 or Ver. 2.5.1. |
| B | Message structure - JM-105 can take up to 3 measurements per baby ID. Select how JM-S1w handles such grouped measurements. |
| C | Send 1 message per measurement - JM-S1w creates 1 message for each measurement taken. If 3 measurements have been taken for a baby ID, then 3 messages are created. |
| D | Send 1 message per baby - JM-S1w creates 1 message for each baby ID. If 3 measurements were taken for a baby ID, then 1 message is created containing all 3 measurements. |
| E | Swap ORC - OBR field - When checked, switches the sending order of the ORC and OBR fields. |
| F | Swap AR - AE - When checked, switches AR and AE in sent and received messages. |
| G | Add 'OB' before message - When checked, adds OB to the beginning of sent messages. |

H	Use custom message - Enables the use of a custom message. When checked, the " Edit custom message " button is enabled.
I	When this button is checked, the settings for " HL7 Version " and " Swap ORC - OBR field " is ignored.
I	Edit custom message - When enabled, clicking this button opens the " Edit custom message " dialog.

Edit custom messagescreen



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The **Edit custom message** dialog box appears when the Edit custom message button on the HL7 screen is clicked. The **Edit custom message** screen contains these fields:

A	Pull-down menu - lists fields available for customizing.
B	Insert - Inserts the selected field at the end of the current message or wherever the cursor is placed.
C	OK - saves the custom message format and closes the dialog box.
D	CANCEL - cancels the transaction.

Assembly and preparation

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Charging the battery

Before using the instrument, charge and inspect the instrument.

When using the instrument for the first time, ensure that it is fully charged. To always maintain a full charge, place the instrument on the charger unit when it is not being used for measurements. When the battery charge is low, the Battery display blinks.

NOTE

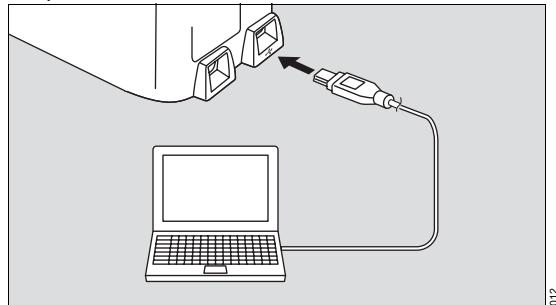
When the device is placed in the docking station, the power switches on and the **READY** lamp turns orange. When charging is completed, the **READY** lamp switches off.

The device charges in 2 hours. Two hundred fifty measurements can be performed with a fully charged new battery.

NOTE

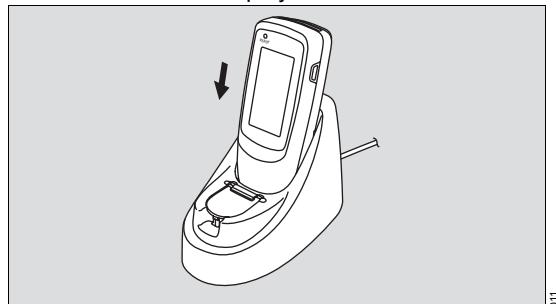
The power of the battery diminishes when the device is left uncharged for a long time. Ensure that the battery is charged before use.

- 1 Plug the USB cable into the DC jack of the docking station.
- 2 Plug the USB cable into a USB port on a computer.



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- 3 Place the device into the docking station. Ensure that the display faces forward.

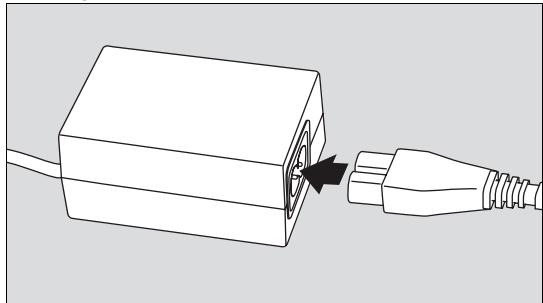


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Alternate charging method using AC adapter (optional)

The AC adapter can be used to charge the device instead of the USB cable.

- 1 Plug the power cable into the AC adapter.



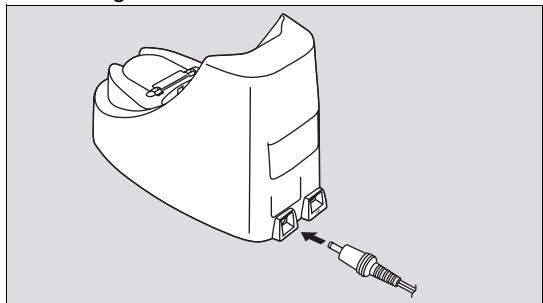
WARNING

Risk of fire, electric shock, or equipment damage.

Using a docking station or AC adapter other than the JM-A33 provided with the device could damage the device.

Use only the docking station JM-A33 and the AC adapter JM-A32 with the device.

- 2 Plug the AC adapter into the DC jack of the docking station.



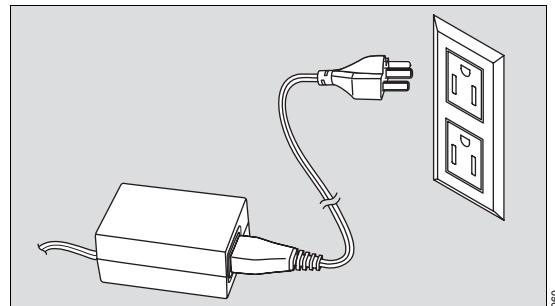
WARNING

Risk of fire, electric shock, or equipment damage.

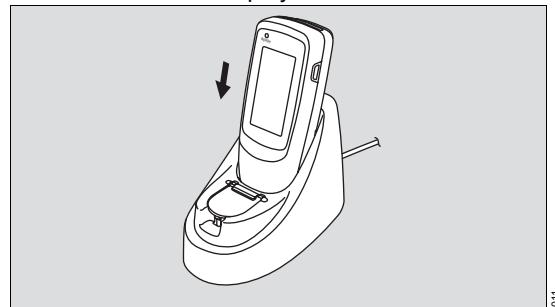
Connecting to a power source without a protective earth ground could damage the device.

Connect the device only to a power source with a protective earth ground.

- 3 Plug the power cable into an appropriate AC source.



- 4 Place the device into the docking station. Ensure that the display faces forward.



NOTE

When the device is placed in the docking station, the power switches on and the **READY** lamp turns orange. When charging is completed, the **READY** lamp switches off.

NOTE

When the docking station is plugged into both the AC adapter and the USB port, the device takes power from the AC adapter.

Unpacking the data transmission software

WARNING

Risk of fire, electric shock, or equipment damage.

Connecting to a power source without a protective earth ground could damage the device.

Connect the device only to a power source with a protective earth ground.

Software SW JM-S1w enables the PC to receive measurement data from a JM-105 and send it to an electronic health record system (EHR). It also enables saving the data to a file.

Please note that this manual assumes that the user is familiar with basic Windows operations.

Package contents

- Installation CD-ROM of data transmission software for jaundice meter, SW JM-S1w
- USB Cable
- Authorized Service Facility list

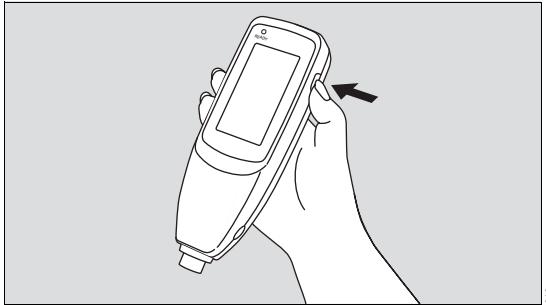
Getting started

Switch on and pre-set the device for the first time	32
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Switch on and pre-set the device for the first time

When switching on the device for the first time, you can select display language and date format, and set the date and time.

- 1 Press the **POWER** button and hold for 1 s. The language screen appears.



- 2 Select display language by touching the desired language or by using the **UP/DOWN** buttons.
Selected language is highlighted.

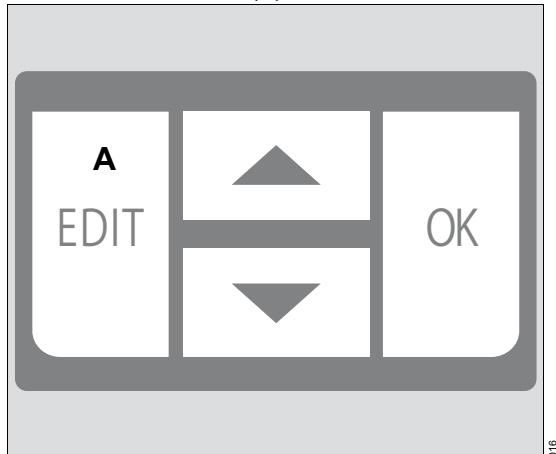


- 3 Touch **OK** to save selection.
- 4 Date format screen appears.

- 5 Select date format.



- 6 Touch **OK** to save selection.
- 7 Set date/time screen appears.
- 8 Set date and time by touching the item you want to change.
- 9 Touch **EDIT** button (A).



- 10 To change value, touch **UP/DOWN** arrows.

- 11 Touch **OK** to save selection.
- 12 Touch **OK** again when you complete changes.
OPENING and the software version appear on the display.

Pre-use checkout

NOTE

Do not touch the checker surface. If the checker surface is dirty, wipe with a soft cloth dampened with alcohol. To dry it, wipe with a soft cloth.

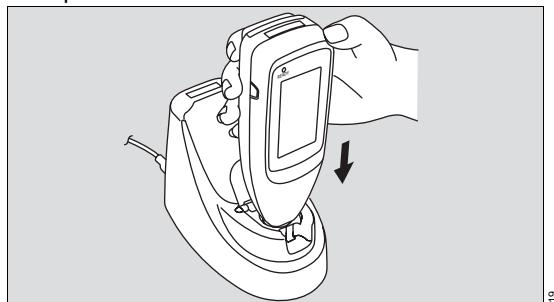
1 Switch on device.

2 Select **CHECKER**.

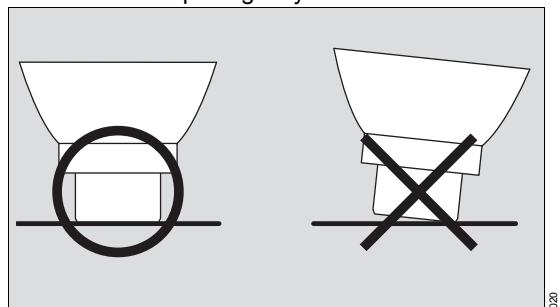


3 Touch **OK** to save selection.

4 Open checker cover.



- 5 Place the measuring probe perpendicular to the checker and push gently until a flash occurs.



NOTE

Do not take measurements with the device slanted on the checker.

6 Review check results.

- L value (measured value of long optical path)
- S value (measured value of short optical path)

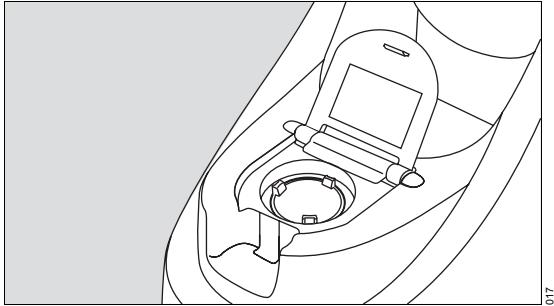
Delta value (difference between L and S values)

NOTE

If values are repeatedly out of range, contact DrägerService.

Getting started

- All values should fall within the ranges shown on the checker cover.



017

- If any value is out of range, clean the checker and probe. Repeat the measurement.



021

7 Close checker cover.

NOTE

If a device check has not been performed during the current day, the **MEASURE READING CHECKER** message appears for 3 s. when you switch on the device.

To clear the message, check the device.

NOTE

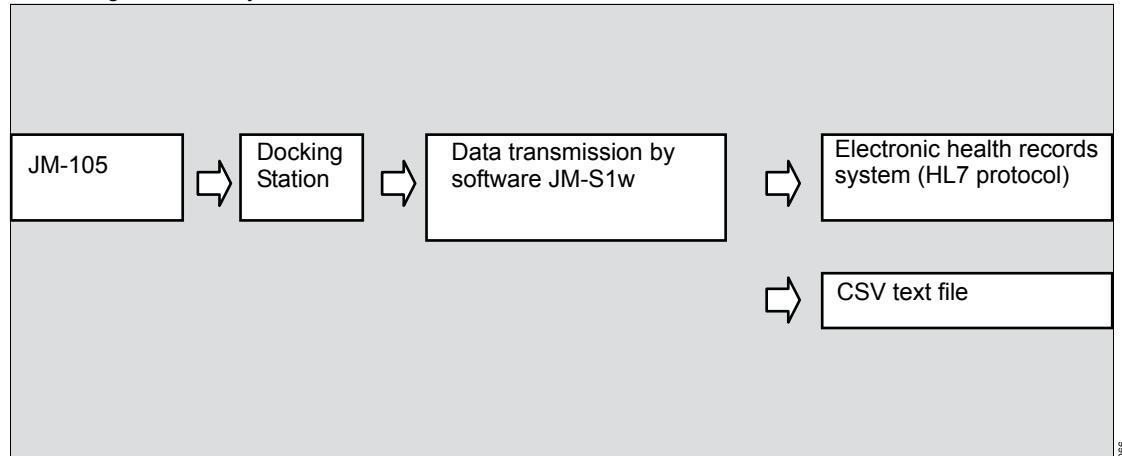
If 12 months or more have passed since the last device calibration, the **TIME FOR PERIODIC CALIB.** message appears for 3 s. when you switch on the device.

To clear the message, calibrate the device.

Data transmission software

After the user sets the JM-105 **MEMORY** to **LINK ON** and the device is set into the docking station, it sends data to the docking station. Through the USB port, the docking station then sends data to the data transmission software SW JM-S1w. The software sends data to an electronic health records system using the HL-7 Application Protocol for Electronic Data Exchange in Healthcare Environments using TCP/IP. Or it sends a CSV file to a folder on the PC as identified during set-up.

Block diagram of the system



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Notes on Use

- No operating system is included with this software.
- Operating system must be installed on the PC before this software can be installed.
- When inserting the CD-ROM into the CD-ROM drive, note the correct orientation of the disc and insert it gently.
- Keep the CD-ROM clean and free from scratches. If the recorded surface becomes dirty or the label surface is scratched, a read error may result.

- Avoid exposing the CD-ROM to rapid temperature changes and condensation.
- Avoid leaving the CD-ROM in locations where it is exposed to high temperatures from direct sunlight or heaters.
- Do not drop the CD-ROM or subject it to strong impact.
- Keep the CD-ROM away from water, alcohol, paint thinners, and other such substances.
- Remove the CD-ROM from the DVD-ROM drive while the computer is turned on.

System requirements

Operating Systems	Windows XP Professional SP3 Windows XP Professional x64 Edition Windows Vista Business SP1 32-bit Windows Vista Business 64-bit Windows 7 Professional 32-bit Windows 7 Professional 64-bit
Screen resolution	640 X 480 or higher
CPU	Pentium III 600 MHz or higher
Memory	128 MB or more (256 MB or more recommended)
Hard disk	At least 350 MB of available disk space (Of this disk space, at least 300 MB must be on the system drive.)
Other	CD-ROM drive (for installation)
USB port	For connecting docking station
Languages (CE1)	English, French, German, Italian, Spanish
Languages (CE2)	English, Dutch, Portuguese, Russian, Swedish
Languages (CE3)	English, Croatian, Polish, Serbian, Turkish

Preparations

Software license compliance

The license agreement terms of the data transmission software for Jaundice Meter, SW JM-S1w are provided in the Software License Agreement dialog box displayed on-screen during installation. This software can be installed only if you agree to all the terms of the agreement.

Installing the USB driver for the docking station

Before using the software, it is necessary to connect the docking station to the computer.

When the docking station is connected to a computer for the first time, installation of the USB driver is required.

- 1 Ensure **MEMORY** is set to **LINK ON**.
- 2 Plug the USB cable, TA-15, into the docking station and the USB port of the computer.
- 3 The Found New Hardware Wizard starts on the PC, prompting for installation of the driver for the Jaundice Meter. Accept the software license agreement.
- 4 Check that *Install the software automatically (Recommended)* is selected, and click *Next >*.
- 5 If a warning message stating that the software has not passed the Windows logo test appears, click *Continue* or *OK*. Then continue the installation of the USB driver.
- 6 When the dialog with the message that driver installation has been completed, click *Close* to close the dialog.

Checking the COM port

To check the COM port that has been assigned to the docking station, follow the procedure.

- 1 Open **Control Panel**.
- 2 Double-click **System**.
- 3 Select the **Hardware** tab, and click **Device Manager**.
- 4 Click the + next to **Ports (COM & LPT)**. The list of connected devices appears.
- 5 **Jaundice meter** appears in the list, followed by the assigned COM port in parentheses.

If **Jaundice meter** is not shown in the list under Ports (COM & LPT), then the driver has not been installed correctly. If **Jaundice meter** is shown somewhere else on the list, select it and uninstall the driver. Then unplug the docking station from the computer and plug it back into the computer and reinstall the driver.

Verifying software load

- 1 Restart PC.
- 2 Once JM-S1w has been installed on a PC, JM-S1w starts when Windows starts. The JM-S1w runs in the background. A symbol  appears in the task tray when JM-S1w is in progress.

NOTE

While JM-S1w is in progress, the computer is prevented from automatically entering Sleep mode. If the computer is set to Sleep mode manually, communication errors may occur when Sleep mode is canceled.

- 3 If JM-S1w does not start automatically, it can be started by clicking **Start > All Programs > Draeger > JM-S1w**.

Exiting JM-S1w software

- 1 Right-click on the task tray symbol  for JM-S1w.

- 2 Select **Exit**. JM-S1w shuts down.

When Windows is restarted, JM-S1w also restarts.

Notes on CD-ROM Storage

- After using the CD-ROM, return it to its case and store in a safe place.
- Do not leave the DVD-ROM in locations that are exposed to high temperatures from direct sunlight or heaters.
- Do not store the CD-ROM in areas of high humidity.

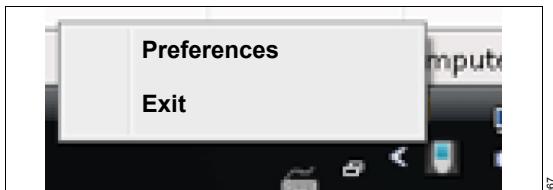
Setting preferences

- 1 Access the JM-S1w menu by clicking or right-clicking on the JM-S1w symbol on the task tray.

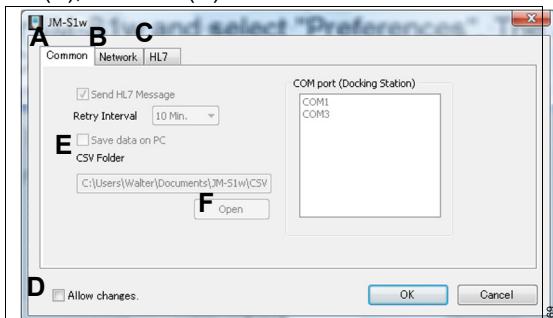


This action opens the JM-S1w menu.

- 1 Select **Preferences**.



- 2 A dialog box opens that shows tabs for each of 3 setting categories: **Common** (A), **Network** (B), and **HL7** (C). The **Common** tab is in front.



- 3 Check the box (D) to allow changes to settings.
4 Determine if you want to save to CSV text file or to EHR.
5 If CSV text file is preferred, change **Common** settings, by checking the **Save data on PC** box (E).
6 Click on the **OPEN** button (F) to select CSV file storage location.
7 If EHR is preferred, select the **Network** tab (B).
8 Change **Network** settings to input the server address and the server port.

- 9 Select the **HL7** tab.



- 10 Change **HL7** settings: **HL7 version** (A) and **Message structure** options (B), (C), (D), (E), (F) and (G).

- 11 Click the **Edit custom message** button (H), if desired.
12 Edit messages as desired (I).
13 Click **OK** to save.

Operation

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Ensuring correct measurement

WARNING

Risk of injury.

This device emits intense light.

**Never allow device to emit light into the eyes.
Always take measurements from either the
sternum or the forehead.**

NOTE

Clean measuring probe with alcohol before use.

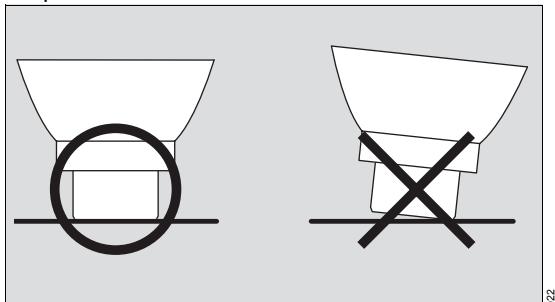
NOTE

Incorrect position of measuring probe can result in erroneous measurements. Ensure that measuring probe is perpendicular to measuring point.

NOTE

Ensure that patient is calm before taking measurements. Movement can interfere with correct probe placement.

- 1 Place measuring probe perpendicular to measuring point.
- 2 Push down gently. Do not lean the measuring probe.



022

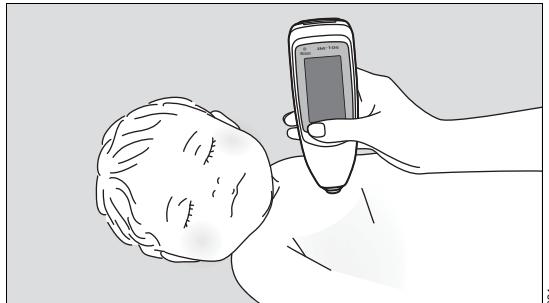
- 3 Configure the device to the desired number of measurements (refer to Choosing settings for measurement on page 41). Dräger recommends that the device is set to average 2 times to 5 times. This setting minimizes measurement errors due to leaning measuring probe.



- Before beginning measurements, ensure that all phototherapy lights are shut off.

Measuring point

Measurements must be taken only on the sternum (at hospital sites or physicians offices) or forehead (at hospital sites only) where enough blood is circulated.



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Choosing settings for measurement

This device performs single measurements and average measurements. Single measurements take the results from each measurement as the measured value. Average measurements take the average results from 2 to 5 individual measurements as the measured value.

The device also allows the user to select whether to store the measurements. Set-up of the device depends on the measuring point and conditions.

Setting the number of average measurements

- 1 Touch **MENU** button, if needed.
- 2 Using **UP/DOWN** arrows, scroll through the list until **CONFIG** appears.

3 Select **CONFIG**.



4 SETTING screen appears.

5 Select **AVERAGE**.



6 Touch **OK** to save selection.

7 Select the number of measurements.

- **SINGLE**: Shows the result from one measurement.
- **2TIMES** to **5TIMES**: Shows the average of the results from 2 measurements to 5 measurements. **AVE** indicates that multiple measurements were selected.



8 Touch **OK** to save selection.

Selecting whether to store measurements

1 Touch the **MENU** button, if needed.

2 Select **CONFIG**.



3 Touch **OK** to save selection.

4 **SETTING** screen appears.

5 Select **MEMORY**. Previous selection is highlighted (**OFF**, **MEM ONLY**, or **LINK ON**).



6 Select desired option

- **OFF:** No measured data is stored in data log.
- **MEM ONLY:** Measured data is stored in data log.
- **LINK ON:** Measured data is stored in data log and sent to PC.



Measuring

Removing from docking station

- 1 Remove device from docking station.
- 2 Clean measuring probe.
- 3 Switch on device.

NOTE

If not operated for 1 min or longer, touch screen goes blank. If needed, touch the display to activate it.

- 4 Touch **MENU** button, if needed.
- 5 Select **MEASURE**.



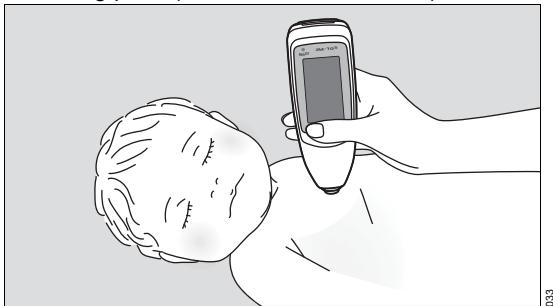
NOTE

After a few s. the **READY** lamp turns green. This action indicates that the device is ready.

Measuring bilirubin (not storing measurements in data log)

- Ensure that **MEMORY** is set to **OFF** (refer to Selecting whether to store measurements on page 42).

- 1 Ensure that the **READY** lamp is on.
- 2 Place measuring probe perpendicular to measuring point (on forehead or sternum).



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- 3 Push gently until it flashes.
 - If **AVERAGE** is not selected, display shows the measured data.
 - If **AVERAGE** is selected, display shows remaining number of measurements needed for averaging.

- 4 If averaging, wait for green **READY** lamp and repeat measurement for the number of times selected (**2TIMES** or **5TIMES**). Display shows the average calculated from the multiple measurements.



5 Read measurements.

- Display shows up to 3 measured values.
- If a measured value blinks, it is outside measurement accuracy range.
- If **-0-** blinks in a measured value field, the measured value is outside the display range (>20.0 mg/dL/>340 mmol/L).
- To take another measurement, touch **CLEAR** button (A) and repeat step 2 through step 6.

NOTE

Touching **CLEAR** once deletes the last measured value. Touching and holding **CLEAR** deletes all displayed measured values.

Measuring bilirubin (storing measurements in data log)

- Ensure that **MEMORY** is set to **MEM ONLY** or **LINK ON** (refer to Selecting whether to store measurements on page 42).
- Maximum 15 characters

Entering **NURSE ID** (nurse ID) and **BABY ID** (baby ID) using barcode reader

- 1 Touch **SCAN** button. Barcode reader emits light.



- 2 Scan **NURSE ID** (nurse ID) (optional).
 3 Scan **BABY ID** (baby ID).
 4 Ensure that the **READY** lamp is on. Go to Performing measurements on page 47.

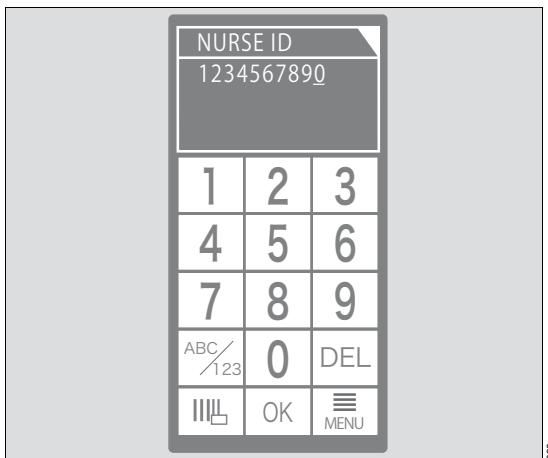
Entering **NURSE ID** (nurse ID) and **BABY ID** (baby ID) using touch screen

- 1 To select letter/number input mode, touch **KEY** button .

NOTE

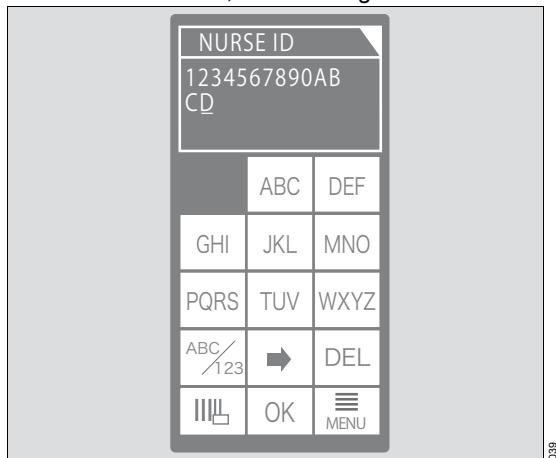
Touching the **BARCODE** button switches you back to barcode input mode.

- 2 To switch between alphabet mode and numeric mode, touch **ABC/123** button .
- 3 When in numeric mode, touch the number desired.



038

- When in alphabet mode, touch the appropriate button for the desired letter. To move to the next letter, touch the right arrow button .



039

- Example of alphabet mode:
To enter BR, touch **ABC** button twice.
Touch the right arrow button.
Touch the **PQRS** button 3 times.
- 4 Touch **OK** to save the ID entered. Device returns to measurement screen.
- 5 Ensure that the **READY** lamp is on.

Performing measurements

- 6 Place measuring probe perpendicular to measuring point (on forehead or sternum).



- 7 Push gently until it flashes.

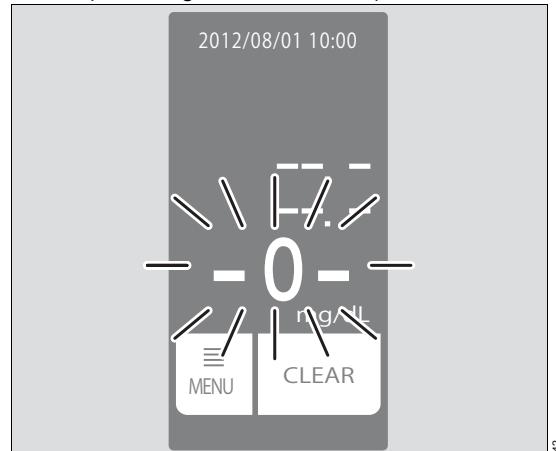
- If **AVERAGE** is not selected, display shows the measured data.
 - If **AVERAGE** is selected, display shows remaining number of measurements needed for averaging.
- 8 If averaging, wait for green **READY** lamp and repeat measurement for the number of times selected (**2TIMES** or **5TIMES**). Display shows the average calculated from the multiple measurements.



- 9 Read measured data.

- Display shows up to 3 measured values.
- If a measured value blinks, it is outside measurement accuracy range.

- If **-0-** blinks in a measured value field, the measured value is outside the display range (>20.0 mg/dL/>340 mmol/L).



- To attach a priority flag, touch ! button (indicates high bilirubin level in the patient).
- To proceed to the next patient, touch **NEXT BABY** button (A) and repeat steps 6 through 9.

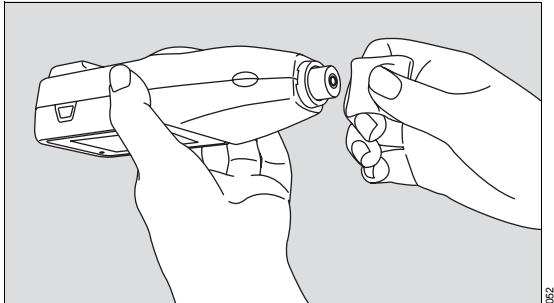
NOTE

When the number of measurements stored in the data log reaches 100, measuring is disabled.

Refer to Storing the device on page 48.

Storing the device

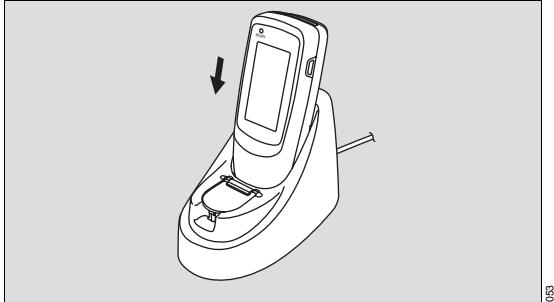
1 Clean the measuring probe.



3 Leave the device in the docking station when not in use.

- While the device is in the docking station, power remains on. After 1 min, the screen goes blank. The power remains on.
- If the device is left out of the docking station for 1 min, the screen goes blank. After 9 mins, the power switches off.

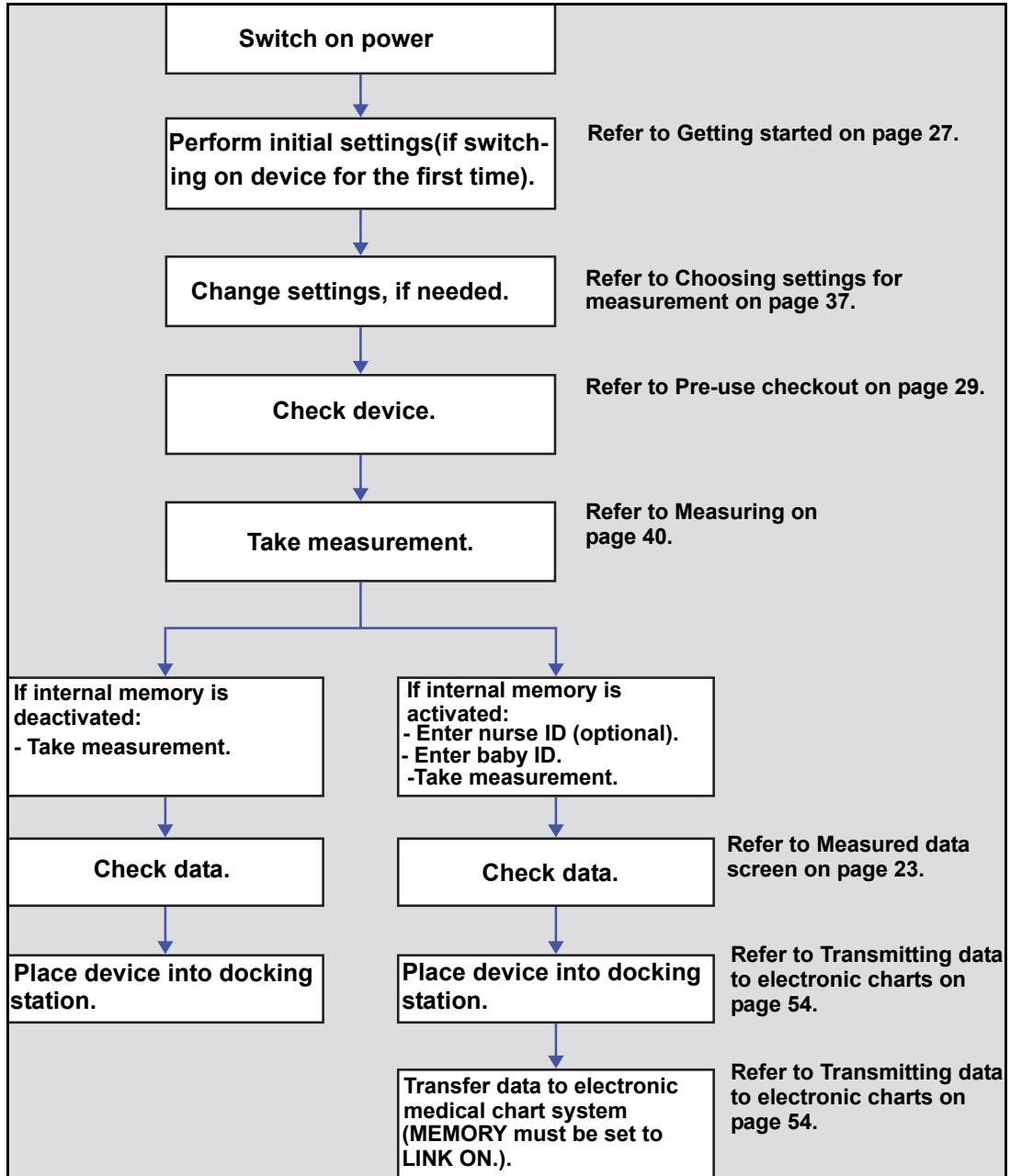
2 Place the device in the docking station.



Switching off the device

To switch off power when the device is not in the docking station, press the power button and hold it down for 1 s.

Quick guide for measuring



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Trends and Data

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Viewing measurements stored in the data log

1 Touch **MENU** button, if needed.

2 Touch **HISTORY**.

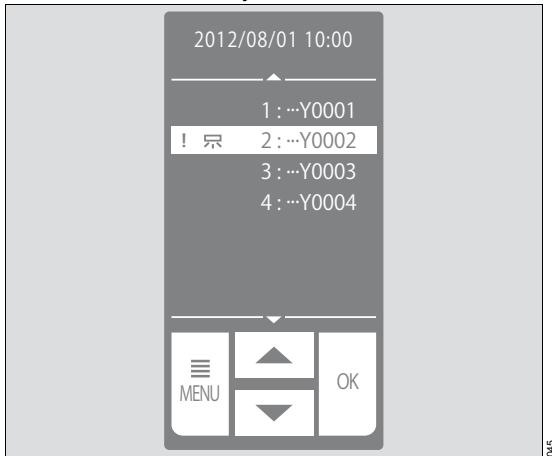


5 Touch **OK** to save selection. Display shows detailed measured data.



3 Touch **OK** to save selection. Display shows list of baby IDs (5 trailing characters if ID is 6 or more characters long), measurement numbers, and flags.

4 Select desired baby ID.



Deleting individual measurements in the data log

1 Touch **MENU** button, if needed.

2 Touch **HISTORY**.

3 Select the desired baby ID.



4 Select the desired measurement.



5 Touch **DELETE** (A).

6 Touch **OK** to save selection.

Deleting all measurements in the data log

1 Touch **MENU** button, if needed.

2 Touch **CLR ALL**.



3 Touch **CLEAR** on the confirm screen.

4 Touch **OK** to save selection. All measurements in the data log are deleted.

Transmitting data to electronic charts

If **Send HL7 Message** is enabled in the **Common** tab of the **JM-S1w** dialog box, measurements from JM-105 are automatically sent to the electronic health records system. If **Send HL7 Message** is not enabled, then measurements from the JM-105 are sent to a CSV log file on the PC.

- 1 Ensure that **MEMORY** is set to **LINK ON**.
- 2 Connect docking station to PC.
- 3 Open SW JM-S1w on the PC.

NOTE

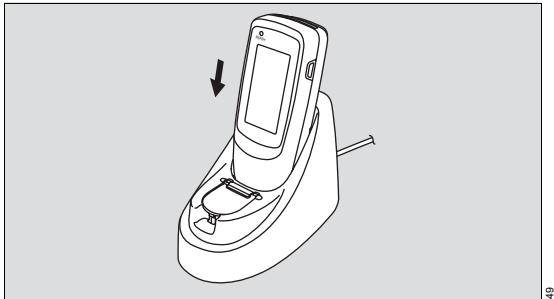
Ensure the Common screen shows (Docking Station) above the list of COM ports and that there is at least 1 COM port in the list.

- 4 Make appropriate settings for HL7 or CSV files.

NOTE

Ensure the COM port is selected before placing the JM-105 into the docking station.

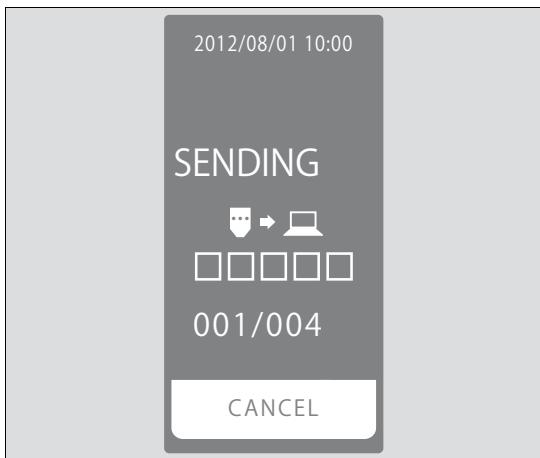
- 5 Place the device in the docking station that is connected to the PC.



- 6 Display shows **CONFIRM** screen.



- 7 Touch **OK** to transmit data. Display shows **SENDING** screen.



Display shows the number of data transferred and the number of data in memory to be transferred. It also shows the progress of the transfer of all data in memory.

NOTE

Touching **CANCEL** during data transmission stops data transmission. The data already transmitted is considered transmitted.

Data transmission errors

If data transmission could not be completed, for example, if the wrong COM port was selected, data transfer times out on the JM-105. JM-105 display shows **SEND FAILED** and a balloon with the error message appears above the JM-S1w tray symbol on the PC.

When an error message appears on the JM-105, press **OK** to continue. When the balloon with the error message appears on the PC, close it.

If data transmission to the electronic health records system fails, JM-S1w saves the data in a file. It later attempts to resend the data after the period specified by the Retry Interval setting. If **No retry** is set, no attempt to resend is performed. Resend attempts are performed at the specified interval until success is achieved or until **Send HL7 Message** is disabled.

Log file

If the server address and server port are set correctly, the results of sending measurements to the HL-7 system is saved in a log file. The log file is at:

Windows Vista, Windows 7:

C:\Users\()\AppData\Local\ Draeger
JM-S1w

Windows XP:

C:\Documents and Settings\()\Local Settings\Application Data\ Draeger \JM-S1w

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Configuration

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Changing settings on the JM-105

- 1 Switch on device.
- 2 Touch **MENU** button, if needed.
- 3 To select **CONFIG**, touch **CONFIG** button or press **UP/DOWN** buttons.
- 6 Touch item you want to change.
- 7 To change value, touch **UP/DOWN** buttons.
- 8 Touch **OK** to save selection.



- 4 Touch **OK** to save selection.
- 5 Settings screen appears.



- 9 Touch **OK** again when you have finished changing settings.

System and default settings for the JM-105

Setting	Description	Options	Description
UNIT	Select unit for measuring and viewing data log.	mg/dL μmol/L	Default
AVERAGE	Select number of measurements for averaging.	SINGLE 2TIMES 3TIMES 4TIMES 5TIMES	Default

Setting	Description	Options	Description
MEMORY	Select whether to store data in device or transfer to PC.	OFF	Default No data stored in data log.
		MEM ONLY	Data stored in data log.
		LINK ON	Data stored in data log. Data transmitted to PC (USB cable and communication software required).
NURSE ID	Select whether to enter nurse ID.	NONE	No nurse ID entered.
		BAR-CODE¹⁾	Default ¹⁾ Enter nurse ID using barcode reader.
		TOUCH	Enter nurse ID using touch screen.
BABY ID	Select how to enter baby ID.	BARCODE	Default ¹⁾ ¹⁾ Enter baby ID using barcode reader.
		TOUCH	Enter baby ID using touch screen.
		OFF	No beep sound.
BUZZER	Select whether to activate beeper.	ON	Default Beep sound.
		ALERT ON	Beep sounds for alerts only.
SET TIME	Set date and time.		Must be set or selected when device is switched on for the first time.
DATE FMT²⁾	Select date format.	M/D/Y	
		D/M/Y	
		Y/M/D	
TIME FMT	Select format of time stamp for measured data in data log. (Time in upper right of touch screen is always 24-hour format.)	12 HOUR	
		24 HOUR	Default
		ENGLISH	Default
LANGUAGE²⁾	Select display language. for CE1	GERMAN	

Setting	Description	Options	Description
		SPANISH	
		FRENCH	
		ITALIAN	
LANGUAGE²⁾	Select display language. for CE2	ENGLISH	Default
		DUTCH	
		SWEDISH	
		RUSSIAN	
		PORTU-GUESE	
LANGUAGE²⁾	Select display language. for CE3	ENGLISH	Default
		POLISH	
		TURKISH	
		CROATIAN	
		SERBIAN	
CONTRAST	Select contrast of touch screen.	1	Darkest
		2	
		3	Default
		4	
		5	Lightest
TOUCHSCR	Adjust touch screen. Touch the center of X.		
COM T.O.	Select the time after which data transmission is canceled.	1 MIN	Default
		5 MIN	
S/W VER.	Shows software version.		
INITIAL	Initialize device. (Allows you to select display language, date format and to set date and time.)		

- 1) Only applies to devices with barcode feature.
 2) Must be set or selected when device is switched on for the first time.

Problem solving

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Fault – Cause – Remedy

The table shows possible causes for a fault and corresponding remedies. Causes and remedies must be worked through in the order listed until the fault has been resolved.

Error messages

Fault	Cause	Remedy
ERROR01	Measured value is abnormal. For averages, the difference between measurements is excessively large.	Repeat the measurement.
ERROR03	RAM error. Abnormalities or corrupted data in RAM.	Switch off the device and remove it from service.
ERROR03 ERROR04 ERROR06	Averaging failure	Switch OFF power. Wait 10 s. Switch ON power.
	Hardware failure	If the failure continues, switch off the device and remove it from service. Switch OFF power. Wait 10 s. Switch ON power.
		If the failure continues, switch off the device and remove it from service.
ERROR04	Memory error. Abnormalities or corrupted data in EEPROM.	Switch off the device and remove it from service.
ERROR05	Insufficient charge, circuit error	Charge the device. If the failure continues, switch off the device and remove it from service.
ERROR06	Calibration data error. Calibration data in the EEPROM is corrupted.	Switch off the device and remove it from service.
ERROR07	Communication error between PC and electronic clinical record system	Review setup of PC and repeat data transmission.

Battery indications

Fault	Cause	Remedy
Battery indicator is on.	Battery power is low.	Charge battery.
Backlight of touch screen illuminates for 5 s and then a shutdown occurs.	Battery power is depleted.	Charge battery. Switch OFF power. Wait 10 s. Switch ON power. If the failure continues, switch off the device and remove it from service.
Battery power depletes quickly.	Touch screen is used frequently. Battery often recharged before power was fully discharged.	Establish measurement procedures that reduce activation of the backlight of the touch screen. Backlight of touch screen consumes a lot of power. Allow battery to discharge completely and then recharge. Repeat this procedure a few times. Switch OFF power. Wait 10 s. Switch ON power. If the failure continues, switch off the device and remove it from service.
READY lamp blinks red during charging	Battery is overdischarged when placed on the docking station. Battery temperature too high.	Wait for a few minutes. The battery charge increases to 1.2 V or higher. The red READY lamp illuminates continuously. Allow battery to cool. Charging starts automatically when battery has cooled. If the failure continues, switch off the device and remove it from service.

Other problems

Fault	Cause	Remedy
Blank screen	Power switched OFF. Battery power depleted. Device has not been used for 1 min or more after power was switched ON.	Switch ON power. Charge battery. Touch any part of the touch screen. Switch OFF power. Wait 10 s. Switch ON power. If the failure continues, switch off the device and remove it from service.
Slow response of touch screen	Touch on touch screen is too light.	Increase pressure of touch on touch screen. Switch OFF power. Wait 10 s. Switch ON power. If the failure continues, switch off the device and remove it from service.
Charger lamp does not illuminate even when device is placed on the docking station	Docking station not connected to AC adapter or not connected correctly. AC adapter not connected to AC power or not correctly connected to AC power. USB cable not connected to the docking station or not correctly connected to the docking station. USB cable not connected to the PC or not correctly connected to the PC. Device is not seated correctly in the docking station.	Correctly connect docking station to AC adapter. Correctly connect AC adapter to AC power. Correctly connect USB cable to docking station. Correctly connect USB cable to PC. Reseat the device in the docking station. Switch OFF power. Wait 10 s. Switch ON power.

Fault	Cause	Remedy
		If the failure continues, switch off the device and remove it from service.
Not possible to take measurements	Battery power is depleted.	Charge battery.
	Touch screen is locked.	To unlock the touch screen, press the display lock button.
	Touch screen is frozen or has failed.	Press the On/Off switch and the display lock button simultaneously and HOLD for 5 s. Power switches OFF. Then, switch ON power.
		Switch OFF power. Wait 10 s. Switch ON power.
		If the failure continues, switch off the device and remove it from service.

JM-S1w errors

When an error occurs, a balloon with an error message appears above the JM-S1w tray symbol. The symbol changes to include a red line through it. If a send error occurs and the JM-S1w error symbol appears, check the JM-S1w settings, exit from the software, and restart the software.

Error symbol: 

Fault	Cause	Remedy
Could not save/delete cache/CSV file. Check hard disk, cache folder ¹⁾ , or CSV folder.	JM-S1w failed to save or delete cache file for sending/re-sending. Hard disk could be full or cache folder set to "read-only."	Check hard disk, cache folder1, or CSV folder. Clear space on hard disk or reset cache folder to read/write.
Server could not receive data. Check server setting or message setting.	Settings for message or server are wrong and HL-7 server could not receive the data. The data are not stored on the server, and JM-S1w does not retry sending the data since the server does not accept the messages.	Correct the server setting or message setting.

Fault	Cause	Remedy
Server response may be wrong. Check Server setting.	The format is wrong for the message received. Server may or may not have accepted the message, but JM-S1w cannot know the result and does not resend the data	Correct the server settings.
Cannot connect to server. Check network setting or server setting.	JM-S1w cannot connect to the HL-7 server via the network: -Wrong server address or port -Connection is physically down. The data is resent.	Correct network setting or server setting.
Some data were not received. JM-S1w retries with the same settings.	Server could not accept the message because server was processing. Server may accept the message later, so JM-S1w retries automatically.	Wait a little while and try again.
Could not save Log data. Check HDD space.	JM-S1w could not save log data. HDD is full or cache folder is set to "Read-only". The Log files could not be created, but connections are OK and data transfer to the HL-7 server was successful.	Reset cache folder ¹ or clear space on HDD.

- 1) Cache folder: On Windows Vista, Windows 7 - C:\Users\(\user name)\AppData\Local\ Draeger \JM-S1w\cache. On Windows XP - C:\Documents and Settings\(\user name)\Local Settings\Application Data\ Draeger \JM-S1w\cache

Cleaning and disinfection

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Safety information

Disassembly

WARNING

Risk of serious injury or equipment damage.

Disassembling or modifying the device or accessories could cause electric shock or fire.

Do not disassemble or modify the device or accessories.

Preclean

WARNING

Risk of serious injury or equipment damage.

Cleaning device while it is connected to power could cause electric shock or fire.

Disconnect all parts and accessories from AC outlet.

- 1 Switch off power.
- 2 Disconnect AC adapter from AC outlet.
- 3 Disconnect DC plug from device.

Reprocessing procedures

Classification of medical devices

For reprocessing, medical devices and their components are divided by type of application and the resulting risk:

- Non-critical medical devices: Surfaces accessible to users and patients, e.g., device surfaces, cables
- Semicritical medical devices: parts conducting breathing gases, e.g., breathing hoses, masks

For reprocessing, the JM-105 is classified as a non-critical medical device.

Testing of procedures and agents

Cleaning and disinfection of medical devices has been tested with the following procedures and agents. At the time of testing, the following procedures and agents showed good material compatibility and effectiveness:

Non-critical medical devices

Manual disinfection and simultaneous cleaning:

- Rubbing alcohol

Do not use these disinfectants:

- Benzene
- Solvents
- Thinners

Non-critical medical devices

Manual disinfection and simultaneous cleaning

Perform manual disinfection with alcohol.

Strictly observe the manufacturer instructions for using disinfectants. The composition of disinfectants may change.

CAUTION

Risk of equipment damage.

Benzene, solvents, and thinners may dissolve the case of the JM-105.

Do not use benzene, solvents, or thinners.

- 5 Wipe with a dry cloth.

Visual inspection

Check all items for damage and external signs of wear, such as cracking, embrittlement, or pronounced hardening, and residual dirt.

CAUTION

Risk due to faulty accessories

Even reusable accessories have a limited service life. External signs of wear can occur, e.g., cracks, deformations, discolorations, or peeling.

If there are external signs of wear, exchange affected accessories.

Procedure:

CAUTION

Risk of equipment damage.

Touching connector terminals could break terminal pins.

Do not touch connector terminals during cleaning and disinfection.

- 1 Remove dirt immediately with a wipe soaked in rubbing alcohol.

WARNING

Risk of electric shock or device malfunction

Penetrating liquid may damage the device or docking station, causing malfunction of the device, which may endanger the patient.

Only scrub-and-wipe-disinfect device surfaces and cables and make sure that no liquids penetrate into the device or docking station.

- 2 Perform surface disinfection (scrub-and-wipe disinfection).
- 3 Disinfect measuring probe with a wipe soaked in alcohol.
- 4 After the contact time has elapsed, remove disinfectant residues.

Reprocessing list

Applicable to non-infectious patients.

The reprocessing list contains approximate values only. The instructions of the hospital infection control officer responsible have priority.

Items which can be reprocessed	Recommended reprocessing intervals	Precleaning	Machine cleaning and disinfection	Manual		Sterilization
				Cleaning	Disinfection	
Jaundice meter	Before use and between patients	Yes	No	Yes	Yes	No
Docking station	Before use and between patients	Yes	No	Yes	Yes	No
AC adapter	Before use	Yes	No	Yes	No	No

Before reuse on patients

Clean measuring probe with alcohol before use.
Wipe dry with a dry cloth.

Maintenance

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Overview

This chapter describes the maintenance measures required to maintain the proper functioning of the medical device. Maintenance measures must be performed by the personnel responsible.

WARNING

Risk of infection

Users and service personnel can become infected with pathogenic germs.

Disinfect and clean device or device parts before any maintenance measures and also before returning the medical device for repair.

WARNING

Risk of electric shock

Current-carrying components are located under the cover.

- **Do not remove the cover.**
- **Maintenance measures must be performed by the personnel responsible. Dräger recommends DrägerService to perform these measures.**

Definition of maintenance concepts

Concept	Definition
Maintenance	All measures (inspection, preventive maintenance, repair) intended to maintain and restore the functional condition of a medical device
Inspection	Measures intended to determine and assess the actual state of a medical device
Preventive maintenance	Recurrent specified measures intended to maintain the functional condition of a medical device
Repair	Measures intended to restore the functional condition of a medical device after a device malfunction

Inspection

Perform inspections at regular intervals and observe the following specifications.

Checks	Interval	Personnel responsible
Inspection and safety checks	Every 1 year	Service personnel

Safety checks

Safety checks are no substitute for preventive maintenance measures (including preventive replacement of wear parts) as identified by the manufacturer.

WARNING

Risk of medical device failure

If safety checks are not performed regularly, the proper operation of the medical device can be compromised.

Perform safety checks at the indicated intervals.

1 Check accompanying documents:

- Instructions for use are available

2 Perform a functional test of the following features according to the instructions for use:

- Light measurement
- Internal battery

3 Check that the device combination is in good condition:

- All labels are complete and legible
- There is no visible damage to device or power cables

4 Using the instructions for use, check that all components and accessories required to use the product are available.

5 Check the electrical safety according to IEC 62353.

Preventive maintenance

WARNING

Risk of faulty components

Device failure is possible due to wear or material fatigue of the components.

To maintain the proper operation of all components, this device must undergo inspection and preventive maintenance at specified intervals.

WARNING

Risk of electric shock

Before performing any maintenance work, disconnect all electrical connectors from power supply.

The table shows the preventive maintenance intervals:

Component	Interval	Task	Personnel responsible
Internal battery	Every 2 years	Exchange	Service personnel

Calibration

Dräger recommends that calibration is performed by DrägerService every 12 months. Return the device to DrägerService for calibration.

The initial calibration is valid for one year from the date of manufacture. Subsequent calibrations are valid for one year from the date of the prior calibration.

Performing service

Removing battery

- 1** Remove battery cover (refer to Jaundice meter JM-105 - Rear on page 12).
- 2** Replace battery.
- 3** Charge battery for 2 hours.
- 4** Perform operational checkout.

Repair

Dräger recommends that all repairs are performed by DrägerService and that only authentic Dräger repair parts are used.

WARNING

Risk of injury or equipment damage.

This device has a built-in battery.

Ensure only properly trained personnel open device or attempt to replace battery.

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Disposing of the medical device

At the end of its service life:

- Have the medical device appropriately disposed of in accordance with applicable laws and regulations.

For countries subject to the EU Directive

2002/96/EC

This device is subject to EU Directive 2002/96/EC (WEEE). In order to comply with its registration according to this directive, this device may not be disposed of at municipal collection points for waste electrical and electronic equipment. Dräger has authorized a company to collect and dispose of this device. To initiate collection or for further information, visit Dräger on the Internet at www.draeger.com. Use the Search function with the keyword "WEEE" to find the relevant information. If access to Dräger website is not possible, contact the local Dräger organization.

Disposing of batteries

WARNING

Risk of explosion and of chemical burns

Improper handling of batteries can result in explosions and chemical burns.

Do not throw batteries into fire. Do not force batteries open.

Observe the applicable laws and regulations for battery disposal.

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Specifications

Device classification

Protection class per IEC 60601-1 (Jaundice Meter) Internally powered ME equipment, Type BF, continuous operation, not AP

Protection class per IEC 60601-1 (AC adapter) Class I ME equipment, externally powered, Type BF, continuous operation, not AP

Ingress of liquids and particulate matter (IEC60601-1) IPX0

Classification in accordance with EU Directive 93/42/EEC Appendix IX IIa

UMDNS code/GMDN code 16-166/35475

Electrical specifications

Battery Internal NiMH

Number of measurements (when fully charged) 250

AC adapter

Input 100 V~ to 240 V~, 50/60 Hz, 11 VA to 18 VA

Output 9 VDC, 500 mA

Light source Pulse xenon arc lamp

Light source life 150,000 measurements

Sensors Silicon photodiodes

Physical specifications

Width 56 mm

Depth 45 mm

Height 168 mm

Weight 203 g ± 10%

Expected service life 5 years

Performance specifications

Measurement range 0.0 mg/dL to 20.0 mg/dL (0 µmol/L to 340 µmol/L)

Accuracy (σ) ± 1.5 mg/dL or ± 25.5 µmol/L (>35 weeks gestation)

Clinical Data Standard Error of Estimate (SEE)

± 1.6mg/dL or ± 27.4 µmol/L (24 to 24 weeks gestation)

Data Transmission

USB port HL-7 or CSV

Ambient conditions

During operation

Temperature	10 °C to 40 °C (50 °F to 104 °F)
Air pressure	700 hPa to 1060 hPa
Altitude range	-400 m to 3000 m
Relative humidity	30 % to 95 % (without condensation)

During storage and transport

Temperature	-10 °C to 50 °C (14 °F to 140 °F)
Air pressure	700 hPa to 1060 hPa
Altitude range	-400 m to 3000 m
Relative humidity	30 % to 95 % (without condensation)

Standards compliance

RoHS 2 Directive 2011 / 65/ EU: 2011

DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)

IEC60601-1: 2005; EN 60601-1:2006

Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance

IEC60601-1-2: 2007; EN 60601-1-2:2007

Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC60601-1-6: 2007

Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

ISO14971: 2007

Medical devices - Application of risk management to medical devices

EMC Declaration

General information

The EMC compliance of the product has been evaluated with the external cables, transducers, and accessories specified in the list of accessories.

Other accessories which do not affect

EMC compliance may be used if no other reasons forbid their use (see other sections of the instructions for use). The use of noncompliant accessories can result in increased emissions or decreased immunity of the medical device.

The medical device must only be used adjacent to or stacked with other devices if this configuration is approved by Dräger. If adjacent or stacked use of non-approved configurations is inevitable, verify normal operation of the medical device in the configuration in which it will be used. In any case, strictly observe the instructions for use of the other devices.

Detailed radio frequency characteristics

Communication devices in accordance with IEEE 802.11b:

- 2412 to 2472 MHz
- DSSS (direct-sequence spread spectrum) limited to 100 mW
- Applicable to access points and client adapters

Communication devices in accordance with IEEE 802.15.1:

- 2400 to 2485 MHz
- FHSS (frequency-hopping spread spectrum) limited to 2.5 mW

See the instructions for use of the wireless devices for further details.

Electromagnetic emissions

When using wireless networking, be aware that the system operates at 2.4 GHz range. Other equipment, even if compliant with CISPR emission requirements, can interfere with reception of wireless data. When selecting wireless systems (wireless communication media, pager systems, etc.) for use in installations where wireless networking is used, care must always be used to ensure that operating frequencies are compatible. For example, selecting wireless communication media that operate at 2.4 GHz will likely cause difficulty with the networking components. Low-level signals such as ECG signals are particular susceptible to interference from electromagnetic energy. Even if the equipment meets the test requirements described below, smooth operation cannot be guaranteed – the ‘quieter’ the electrical environment the better. In general, increasing the distance between electrical devices decreases the likelihood of interference.

Electromagnetic environment

The medical device is intended for use in an electromagnetic environment as specified below. The user must ensure that the medical device is used in such an environment.

Emissions	Compliance according to	Electromagnetic environment
Radio frequency emissions (CISPR 11)	Group 1	The medical device uses radio frequency energy only for its internal function. Therefore, its radio frequency emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	The medical device is suitable for use in all establishments, including domestic establishments and those directly connected (without transformer) to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations/flicker emissions (IEC 61000-3-3)	Complies	

Electromagnetic immunity

The medical device is intended for use in an electromagnetic environment as specified below. The user must ensure that the medical device is used in such an environment.

Immunity against	IEC 60601-1-2 Test level	Compliance level (medical device)	Electromagnetic environment
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ±6 kV	±6 kV	Floors should be wood, concrete, or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	Air discharge: ±8 kV	±8 kV	
Electrical fast transients/bursts (IEC 61000-4-4)	Power supply lines: ±2 kV	±2 kV	Mains voltage quality should be that of a typical commercial or hospital environment.
Surge on AC mains lines/surges (IEC 61000-4-5)	Differential mode: ±1 kV	±1 kV	Mains voltage quality should be that of a typical commercial or hospital environment.
Power frequency magnetic field (50/60 Hz) (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	Dip >95 %, 0.5 periods	Dip >95 %, 0.5 periods	Mains voltage quality should be that of a typical commercial or hospital environment. If the user of the medical device requires continued operation during mains power supply interruptions, it is recommended that the medical device is powered from an uninterruptible power supply or a battery.
	Dip 60 %, 5 periods	Dip 60 %, 5 periods	
	Dip 30 %, 25 periods	Dip 30 %, 25 periods	
	Dip >95 %, 5 seconds	Dip >95 %, 5 seconds	

Immunity against	IEC 60601-1-2 Test level	Compliance level (medical device)	Electromagnetic environment
Radiated radio frequency (IEC 61000-4-3)	80 MHz to 2.5 GHz: 3 V/m	3 V/m	Recommended minimum distance to portable and mobile radio frequency transmitters with transmission power PEIRP to the medical device including its lines: $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz ¹) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Conducted radio frequency (IEC 61000-4-6)	150 kHz to 80 MHz: 3 Vrms ²)	3 Vrms	
NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.		NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.	

- 1) For PEIRP, insert the highest possible "equivalent isotropic radiated power" of the adjacent radio frequency transmitter. In the vicinity of equipment marked with the symbol (●), interference can occur. Field strengths from fixed, portable, or mobile radio frequency transmitters at the location of the medical device should be less than 3 V/m in the frequency range from 150 kHz to 2.5 GHz and less than 1 V/m above 2.5 GHz.
- 2) ISM bands in this frequency range are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; 40.66 MHz to 40.70 MHz.

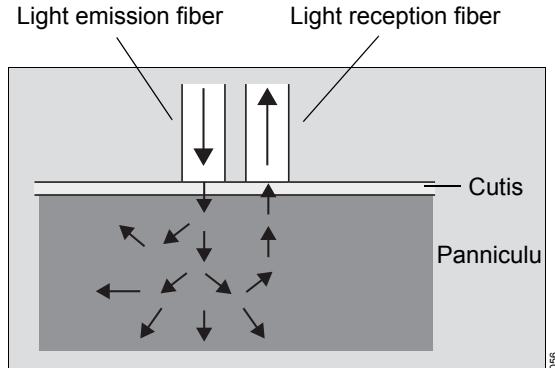
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Measuring principle

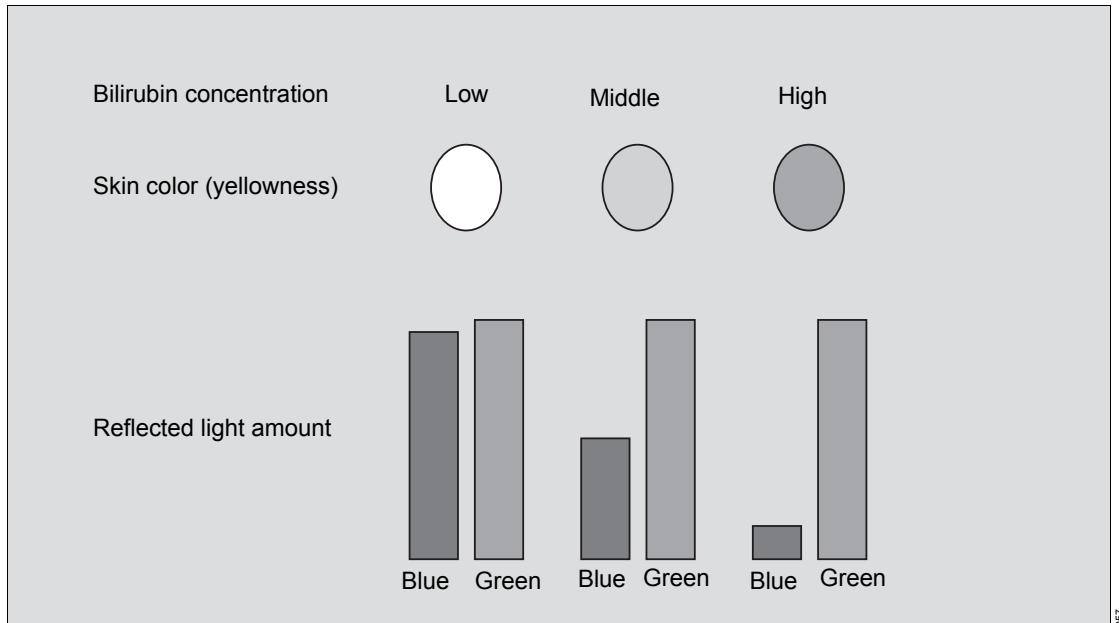
The transcutaneous bilirubin, an indicator of jaundice in infants, absorbs blue and green light. The Jaundice Meter determines the yellowness of the subcutaneous tissue by measuring the difference in the optical densities for light in the blue (450 nm) and green (550 nm) wavelength regions. The measuring probe has 2 optical paths. When the measuring probe is pressed against the sternum or forehead of the infant, the built-in xenon lamp flashes. The light from the xenon lamp passes through the glass fiber and illuminates the skin. The light scatters and is absorbed in the skin and subcutaneous tissue repeatedly, and then finally returns to the sensor side of the glass fiber



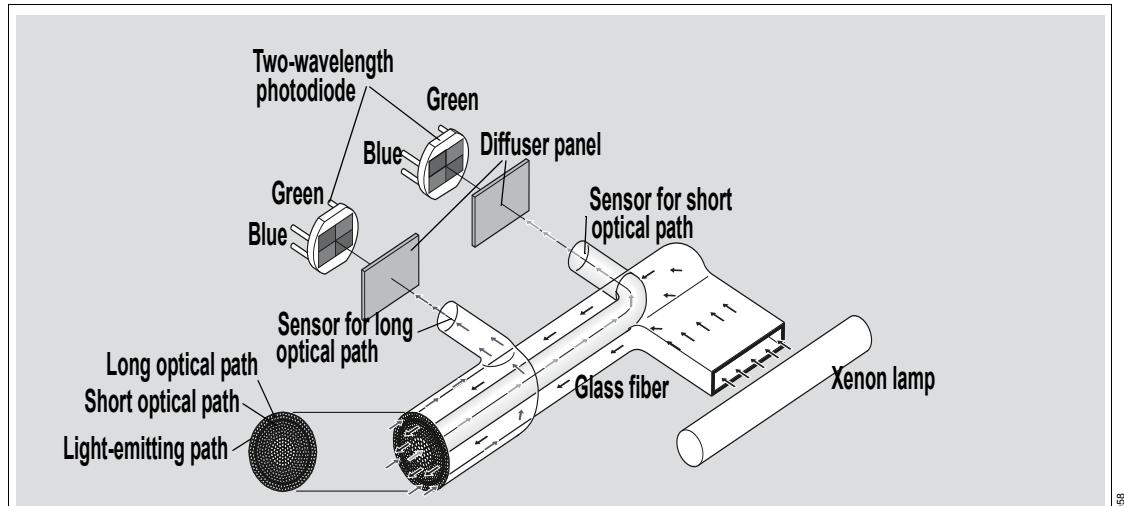
Conceptual drawing of measurement

The denser the transcutaneous bilirubin, the weaker the reflected blue light. The reflected green light remains unchanged regardless of the density of the bilirubin.

Because the optical density difference shows a linear correlation with the total serum bilirubin concentration, it is converted to the estimated bilirubin concentration. It is indicated digitally.

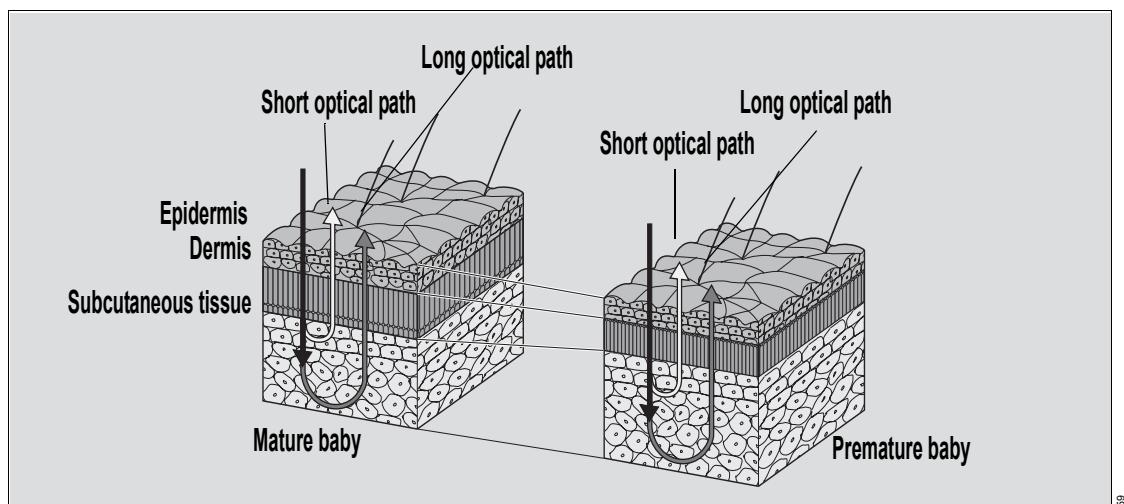


The measuring probe has 2 optical paths. This method allows measurement of yellowness of skin and subcutaneous tissue without influence of melanin pigment and skin maturity.



Of the light that returns to the fiber, the part scattered from shallow subcutaneous tissue passes through the inner core (short optical path) of the fiber. The part scattered from deep subcutaneous

tissue passes through the outer core (long optical path) of the fiber. Then both reach the corresponding photodiode.



By calculating the difference in the optical densities, the parts that are common to the epidermis and dermis are deducted. As a result, the difference

in the optical densities between the 2 wavelength regions can be obtained for the subcutaneous tissue only.

Test results

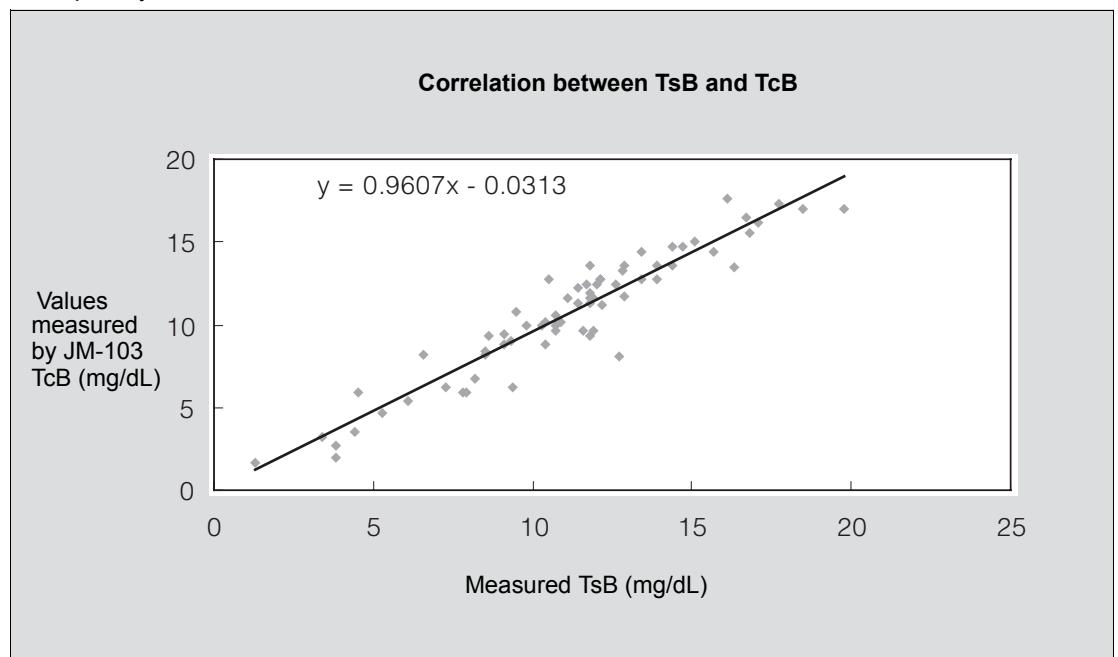
The JM-105 is equivalent to JM-103 in measurement accuracy. To verify serviceability of the JM-103, the correlation between TcB measured with the device and TsB measured from collected blood samples was determined at 3 hospital facilities.

The standard deviation (σ) from the regression line obtained was ± 1.24 .

NOTE

The standard deviation (σ) being ± 1.24 means that approximately 68% of the data taken from measurements performed on a living body is within this range.

Data quantity n=69



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List of accessories

Standard accessories	
Dräger Jaundice Meter JM-105	MU20105
Docking station with built-in checker, JM-A33, en	MU24489
Docking station with built-in checker, CE, JM-A33, en	MU24488
Docking station with built-in checker, CE, JM-A33, de	MU24751
Docking station with built-in checker, CE, JM-A33, fr	MU24753
Docking station with built-in checker, CE, JM-A33, es	MU24752
Docking station with built-in checker, CE, JM-A33, it	MU24756
Docking station with built-in checker, CE, JM-A33, nl	MU24757
Docking station with built-in checker, CE, JM-A33, sv	MU24765
Docking station with built-in checker, CE, JM-A33, ru	MU24762
Docking station with built-in checker, CE, JM-A33, pt	MU24760
Docking station with built-in checker, CE, JM-A33, pl	MU24759
Docking station with built-in checker, CE, JM-A33, tr	MU24766
Docking station with built-in checker, CE, JM-A33, hr	MU24754
Docking station with built-in checker, CE, JM-A33, sr	MU24764
USB cable T-A15 for data transmission software	MU24774
Data transmission software, CD-ROM/USB, SW JM-S1w	MU24775
Optional accessories	
AC adapter, JM-A32	MU19791
AC adapter, JM-A32 CE	MU19792

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These Instructions for Use only apply to

JM-105

with the Serial No.:

If no Serial No. has been filled in by Dräger,
these Instructions for Use are provided for general
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