Instructions for Use

JM-105

WARNING
To properly use this medical device, read and comply with these instructions for use.

Jaundice Meter
Software 1.20

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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.

> The greater-than symbol indicates the navigation path in a dialog window.

Bold, italicized text indicates labels on the device and texts that are displayed on the screen.

Illustrations

Illustrations of products and screen content in this document may differ from the actual products depending on configuration and design.

Use of terms

Dräger uses the term "accessories" not only for accessories in the sense of IEC 60601-1, but also for consumables, removable parts, and attached parts.

Trademarks

Trademarks owned by third-party manufacturers

Trademark	Trademark owner
Actichlor	Ecolab USA
Oxycide	Ecolab USA
Adobe Reader	Adobe Corporation
Klorsept 17	Medentech
Peridox RTU	Bio Med Protect
Windows	Microsoft Corporation
Windows Vista	
Pentium	Intel Corporation
Dismozon pur	BODE Chemie

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.

Contents

For your safety and that of your patients

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 12 and in conjunction with appropriate patient monitoring (see page 4).

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 specialized service personnel.

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

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.

Service

WARNING

Risk if service is not performed regularly

If service is not performed regularly, malfunctions may occur, which can result in personal injury and property damage.

Perform the service in accordance with the chapter "Service".

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

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

WARNING

Risk of patient injury

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

WARNING

Risk of patient injury

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 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.

Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to special precautionary measures concerning electromagnetic compatibility. During installation and before initial operation, follow the information in section: "EMC declaration" (page 99).

This device can be affected by other electrical devices.

WARNING

Risk due to electrostatic discharge

Malfunctions that endanger the patient may occur if no protective measures against electrostatic discharge are employed in the following situations:

- **When touching the pins of connectors that carry the ESD warning symbol.**
- **When establishing connections with these connectors.**

To prevent malfunctions, observe the following measures and train the relevant personnel:

- **Observe the ESD protective measures. Such measures may include wearing antistatic clothing and shoes, touching a potential equalization pin before and while making the connection, or using electrically insulating and antistatic gloves.**
- **Observe the requirements for the electromagnetic environment. Observe the following section: "EMC declaration" (page 99).**

WARNING

Risk due to electromagnetic disturbance

Wireless communication devices (e.g., cellular phones) and medical electrical equipment (e.g., defibrillators, electrosurgical devices) emit electromagnetic radiation. When such devices are operated too close to this device or its cables, the functional integrity of this device may be compromised by electromagnetic disturbances. As a result, the patient could be put at risk.

Maintain a distance of at least 0.3 m (1.0 ft) between this device and wireless communication devices, to ensure that the essential performance of this device is fulfilled.

Maintain an adequate distance between this device and other medical electrical equipment.

Storing the instructions for use

CAUTION

Risk of incorrect use

Instructions for use must be kept accessible to the user.

Training

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

Service

WARNING

Risk if service is not performed regularly

If service is not performed regularly, malfunctions may occur, which can result in personal injury and property damage.

Perform the service in accordance with the chapter "Service".

Target groups

Duties of the operating organization

The tasks described in this document specify the requirements that have to be met by each respective target group.

The operating organization of this product must ensure the following:

– The target group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience).

– The target group has been trained to perform the task.

– The target group has read and understood the chapters required to perform the task.

Description of target groups

The target groups may only perform the following tasks if they meet the corresponding requirements.

User

Task	Requirement
Use of the product in accordance with the intended use	Specialist medical knowledge in neonatology
Use of the product in accordance with the intended use	Specialist medical knowledge in the use of the product

Reprocessing personnel

Task	Requirement
Reprocessing	Specialist knowledge in the reprocessing of medical devices

Service personnel

Task	Requirement
Installation	Specialist knowledge in electrical engineering and mechanics Experience in the servicing of medical devices
Basic service work (inspection, maintenance according to the "Maintenance" chapter)	

Dräger recommends arranging a service contract with DrägerService.

Product-specific precautions

Electrical precautions

WARNING

Risk of fire, electric shock, or equipment damage

Using a docking station or AC adapter other than the one 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 malfuntion 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 due to modifications

Modifications to the product may lead to malfunctions and unforeseen risks. This may result in injury to the patient or the user or in property damage.

Do not modify this product.

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.

WARNING

Risk of patient injury

Pathologic or other skin conditions that may affect light scattering or absorption could result in incorrect TcB measurements.

Do not conduct measurements in patients with early jaundice and pathologic jaundice.

Do not conduct measurements when skin conditions may violate the assumption made concerning light scattering and light absorption.

Use device only on healthy skin of the patient. Do not conduct measurements on birthmarks and hairy areas. Avoid areas of thickness that in the opinion of the physician would preclude or interfere with the use of the TcB meter.

WARNING

Risk of delayed therapy

Using the device without checking the accuracy of the measurements could cause incorrect measurements.

To check the measurement reliability of the system, compare the transcutaneous bilirubin value (TcB) determined by the device and the total serum bilirubin (TSB) determined on the basis of blood samples. Follow your hospital guideline to determine the frequency of checks (e.g. after repair or calibration of JM-105 or TSB lab equipment, or following a change to clinical processes.

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.

NOTE

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

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.

CAUTION

Risk of equipment damage

Avoid vibration and physical shock during transportation.

NOTE

Thoroughly clean the device and accessories before storing.

Restrictions for use

CAUTION

Device for use in health care facilities only and exclusively by persons with specific training and experience in its use.

Accessories

WARNING

Risk due to incompatible accessories

The use of incompatible accessories may adversely affect the functional integrity of the product. Personal injury and property damage may occur as a consequence.

Use only compatible accessories. The accessories that are compatible with this product are listed in the list of accessories supplied with the product.

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Application

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 a screening device for the detection of neonatal hyperbilirubinemia in the early stages. The measurement data provided by the device should be used in conjunction with other clinical symptoms and laboratory measurements for diagnosis and therapy decisions.

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.

The Jaundice Meter is not intended for home use.

The JM-105 is a prescription medical device.

The JM-105 may only be used at the sternum measurement site for Physician's office applications.

Indications/contraindications

Indications

The Jaundice Meter is indicated for use in neonatal patients born ≥24 weeks gestation who have not undergone exchange transfusion. The device is indicated for use before, during, and after phototherapy treatment.

Contraindications/limitations

The Jaundice Meter is not intended as a diagnostic device. It is a screening device for the detection of neonatal hyperbilirubinemia in the early stage that shall be used in conjunction with other clinical symptoms and laboratory measurements for diagnosis and therapy decisions.

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.

Do not use this device on patients with hydrops fetalis major, congenital malformations, diseases or skin conditions or thickness that in the opinion of the physician would preclude or interfere with the use of the TcB meter (e.g. skin infections, purpura, etc.)

Limitations (During phototherapy)

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

Limitations (Doctors Office Use)

Use only on infants up to 14 days of age.

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

Measuring Point

Typically clinicians measure the TCB on either the sternum, or the forehead or both. Some studies reported the sternum to be more accurate than the forehead in term and near term infants [17, 18]. Some studies show the forehead had a stronger correlation with TSB that the sternum. In other studies looking at the agreement between TCB and TSB measurements, the site of TCB measurement has not been indicated [19, 20].

Therefore, measuring site (forehead or sternum) shall be at the clinician's discretion in a hospital setting (avoid birthmarks and hairy areas). However, only sternum measurements are recommended at the doctor's office, as there is a possibility that the difference may be more pronounced for infants that have been exposed to sunlight.

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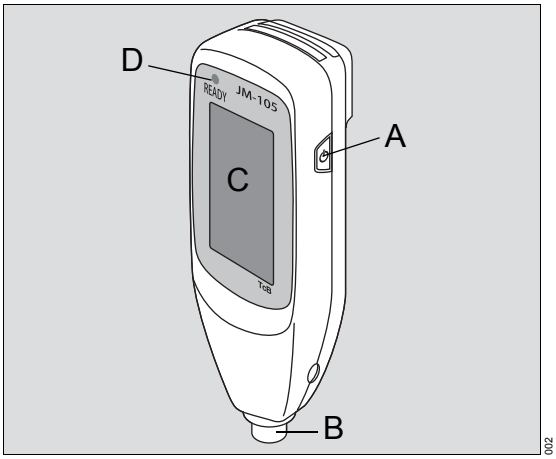
Overview

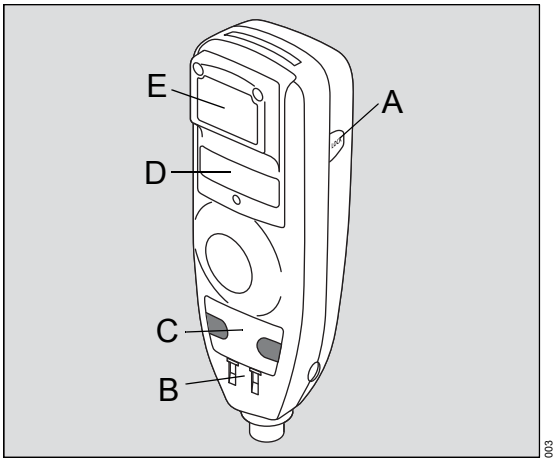
Device views

Jaundice meter JM-105 - Front



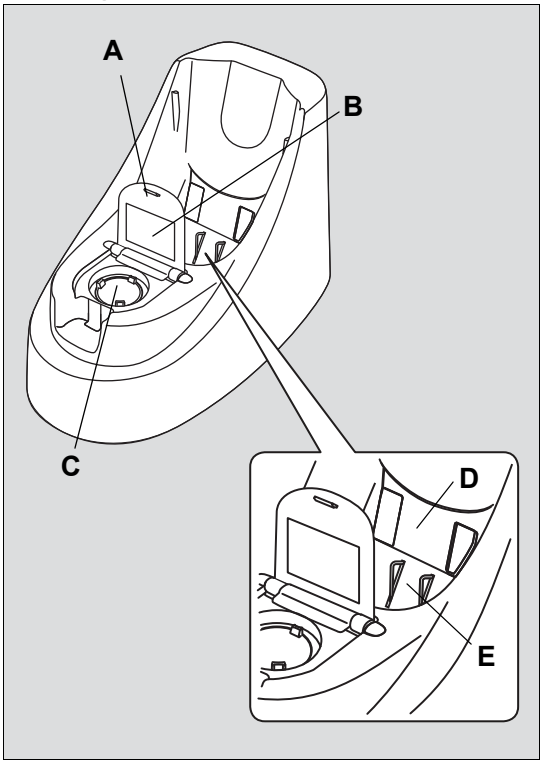
A Power button
B Measuring probe
C Display/Touch panel
D ***READY*** lamp

Jaundice meter JM-105 - Rear



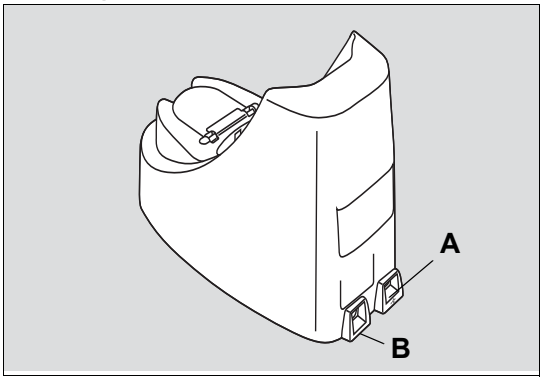
A Screen ***LOCK*** button
B Charging contact
C Communication port
D Battery cover
E Barcode reader

Docking station JM-A33 - Front



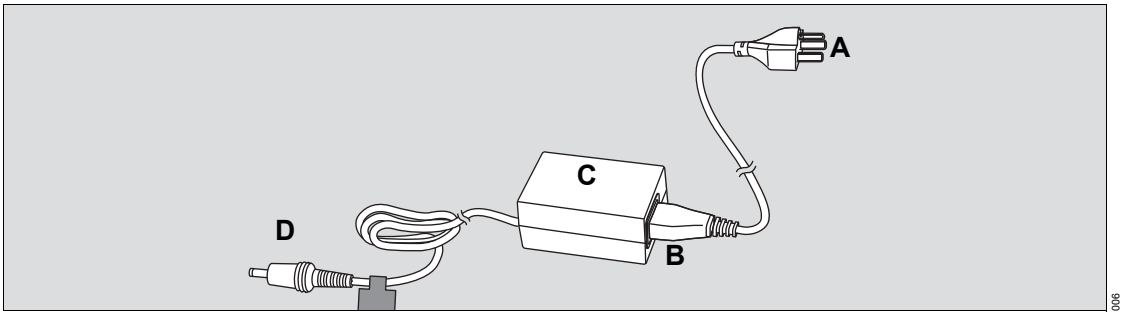
A Checker cover
B Standard checker values
C Reading checker
D Communication window
E Charger jack

Docking station JM-A33 - Rear



A USB connector
B DC jack

AC adapter JM-A32



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

The following symbols appear on labels on the JM-105 jaundice meter, on the screen, and in these instructions for use. These standards apply as noted in the table.

Symbols on device

Warning

Caution

Degree of protection against electric shock: Type BF

Refer to instructions for use

AC power

DC Power

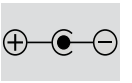
Do not discard with regular waste

Date of manufacture

USB port

Standby or On/Off

Input



Circuit output terminal

Symbols on touch screen

Rechargeable battery

Priority flag - to show baby has high bilirubin level and may need further evaluation.

Lock

Phototherapy flag - to show baby has been treated with phototherapy

Menu

Key

Scan

Sent to chart

Delete

Delete

Go BACK to previous screen

EDIT the selected item

CLEAR the entry

Proceed to the NEXT BABY

Nurse ID

Baby ID

L Value (long)

S Value (short)

Delta Value (difference between long value and short value)

CANCEL the entry or stop the task

Confirm the entry

Busy

Symbols on the PC

JM-S1w

JM-S1w error

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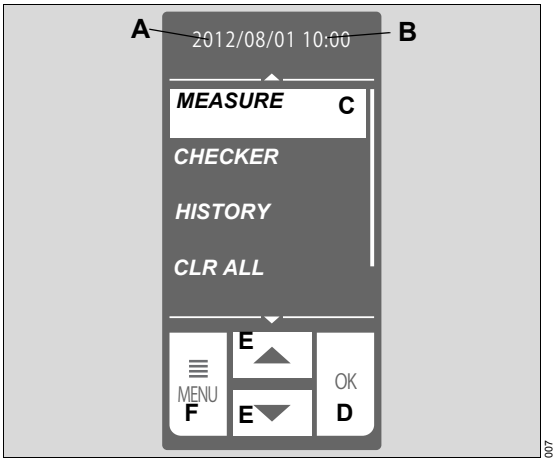
Operating concept

Screen layout for device

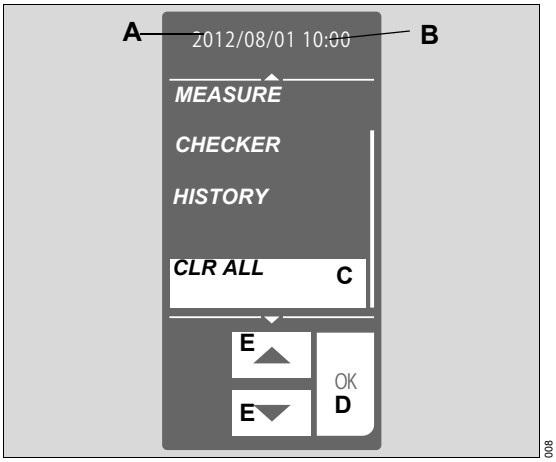
Main screen



The main screen contains these fields.

A	Date
B	Time
C	Available selections – ***MEASURE*** – ***CHECKER*** – ***HISTORY*** – ***CLR ALL***
D	***OK***
E	Arrows
F	***MENU***

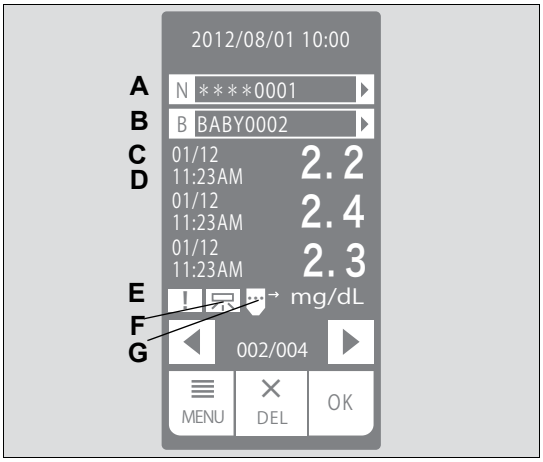
MENU screen



The ***MENU*** screen contains these buttons.

A	Date
B	Time
C	Available selections – ***MEASURE*** – ***CHECKER*** – ***HISTORY*** – ***CLR ALL*** – ***CONFIG***
D	***OK***
E	Arrows

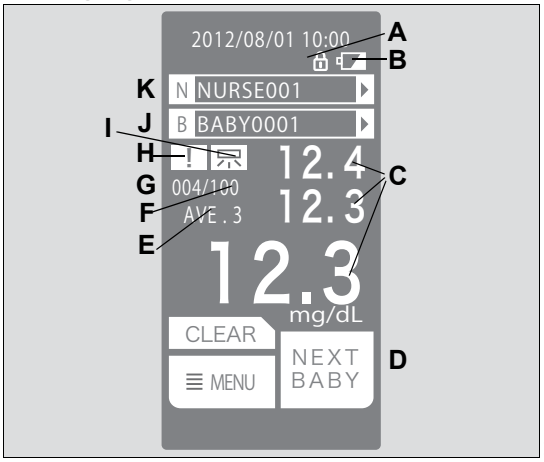
Measured data screen



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/ F	Dots .... - Indicates no flags are set. Push button to begin setting Priority or Phototherapy flags.
E	Priority flag - Push button to show baby has high bilirubin level and may need further evaluation.
F	Phototherapy flag - Push button to set flag to show baby has been treated with phototherapy.
G	Sent to electronic chart

Averaging screen

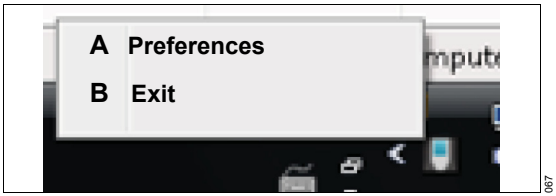


The Averaging screen contains these fields.

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/ I	Dots .... - Indicates no flags are set. Push button to begin setting Priority or Phototherapy flags.
H	Priority flag - Push button to show baby has high bilirubin level and may need further evaluation.
I	Phototherapy flag - Push button to set flag to show baby has been treated with phototherapy.
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

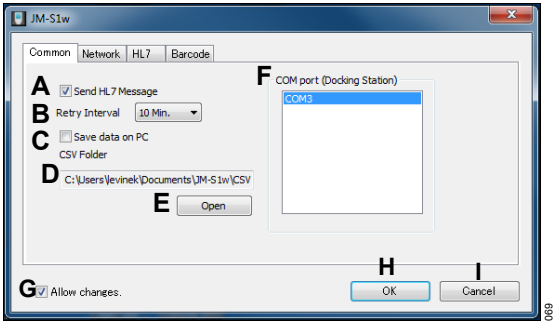
JM-S1w menu



The JM-S1w menu screen contains these selections.

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

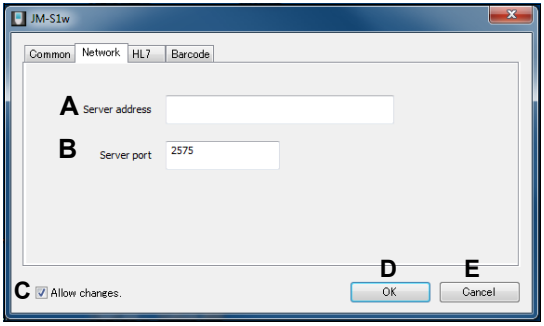
Common screen



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	***CSV Folder*** - 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.
G	***Allow changes.*** - Check if you want to change preferences on any of the preferences screens.
H	***OK*** - Saves the selections and closes the dialog.
I	***CANCEL*** - Cancels the transaction.

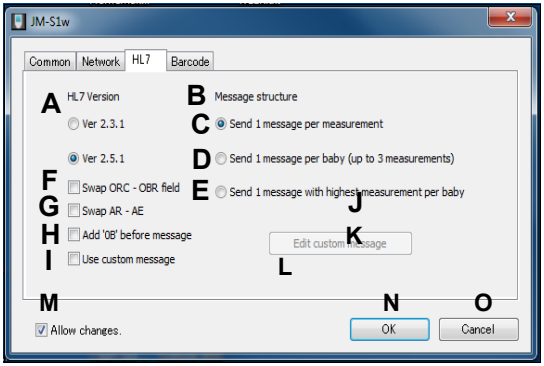
Network screen



The ***Network*** screen contains these fields.

A	***Server address*** - Enter 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*** - Enter the communication destination port on the server. The default is the HL-7 default port (2575).
C	***Allow changes.*** - Check if you want to change preferences on any of the preferences screens.
D	***OK*** - Saves the selections and closes the dialog.
E	***CANCEL*** - Cancels the transaction.

HL-7 screen

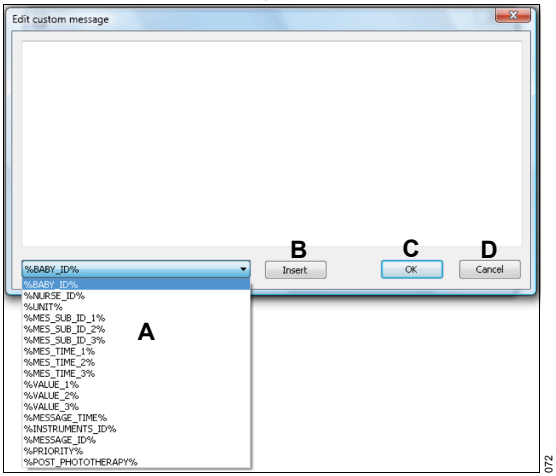


The ***HL-7*** screen contains these fields.

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 were taken for a baby ID, then 3 messages are created.
D	***Send 1 message per baby (up to 3 measurements)*** - 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. A maximum of 3 measurements per baby is allowed.
E	***Send 1 message with highest measurement per baby*** - JM-S1w creates 1 message containing only the highest measurement taken for each baby ID (maximum of 3 measurements per baby ID). If the highest value occurs for more than 1 measurement, the message contains the first highest measurement recorded.
F	***Swap ORC - OBR field*** - When checked, switches the sending order of the ORC and OBR fields.

G	***Swap AR - AE*** - When checked, switches AR and AE in sent and received messages.
H	***Add '0B' before message*** - When checked, adds OB to the beginning of sent messages.
I	***Use custom message*** - Enables the use of a custom message. When checked, the "***Edit custom message***" button is enabled. When this button is checked, the settings for "***HL7 version***" and " ***Swap ORC - OBR field***" is ignored.
J	***Edit custom message*** - When enabled, clicking this button opens the "***Edit custom message***" dialog.
K	***Transmission log*** - Opens the transmission log dialog. NOTE: This field only applicable for JM-S1w version 1.40 or higher.
L	***Sending facility*** - User can edit this field as needed. NOTE: This field only applicable for JM-S1w version 1.40 or higher.
M	***Allow changes.*** - Check the radio button if you want to change preferences on any of the preferences screens.
N	***OK*** - Saves the selections and closes the dialog.
O	***CANCEL*** - Cancels the transaction.

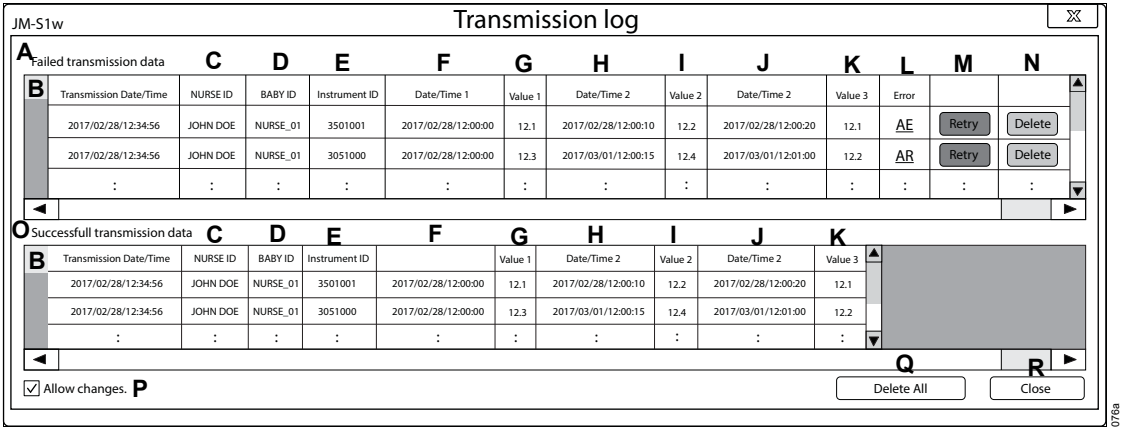
Edit custom message screen



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

A	Pick list - 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.
D	***CANCEL*** - Cancels the transaction.

Transmission log screen

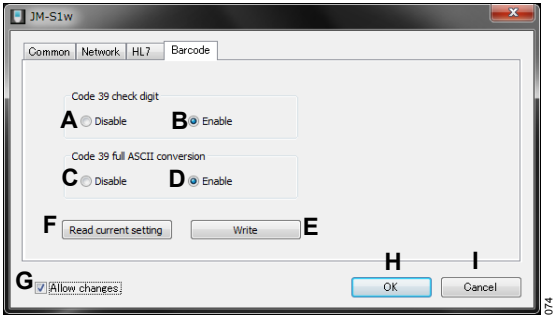


The ***Transmission log*** dialog appears when the ***Transmission log*** button on the HL7 screen is clicked. The ***Transmission log*** screen contains these fields.

A	***Failed transmission data*** - Lists all transmissions that failed or had errors.
B	***Transmission Date/Time*** - Shows the date and time of the transmission.
C	***Nurse ID*** - (Editable)
D	***Baby ID*** - (Editable)
E	***Instrument ID*** (instrument ID) -
F	***Date/Time1*** - Shows the date and time of the first averaged measurement.
G	***Value1*** - Shows the value of the first averaged measurement.
H	***Date/Time2*** - Shows the date and time of the second averaged measurement.
I	***Value2*** - Shows the value of the second averaged measurement.
J	***Date/Time3*** - Shows the date and time of the third averaged measurement.
K	***Value3*** - Shows the value of the third averaged measurement.

L	***Error*** - Shows the type of error. When you click on the error, a pop-up message appears with details of the error.
M	***Retry*** - Attempts the transmission again. NOTE: This field may be hidden if contents of other fields are long.
N	***Delete*** - Deletes the failed transmission. NOTE: This field may be hidden if contents of other fields are long.
O	***Successful transmission data*** - Lists all successful transmissions.
P	***Allow changes.*** - Check if you want to edit fields or delete/retry transmissions.
Q	***Delete All*** - Deletes all transmissions.
R	***Close*** - Closes the dialog.

Barcode reader screen



The ***Barcode*** reader screen contains these fields.

NOTE

The ***Barcode*** reader screen is only applicable to JM-S1w version 1.30 or higher and requires device firmware 1.10 or higher.

A	***Code 39 check digit Disable*** - disables the check digit.
B	***Code 39 check digit Enable*** - enables the check digit.
C	***Code 39 full ASCII conversion Disable*** - disables the ASCII conversion.
D	***Code 39 full ASCII conversion Enable*** - enables the ASCII conversion.
E	***Write*** - applies the selection of enable or disable.
F	***Read current setting*** - shows current barcode settings.
G	***Allow changes.*** - Check if you want to change preferences on any of the preferences screens.
H	***OK*** - Closes the dialog.
I	***CANCEL*** - Closes the dialog.

Assembly and preparation

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

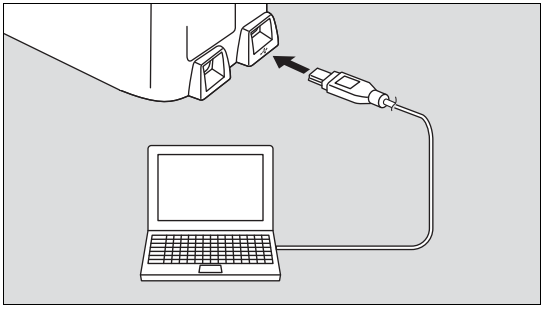
The power of the battery diminishes when the device is left uncharged for a long time. Ensure that the battery is charged before use.

1 Before charging the JM-105 using a USB connector, ensure the USB port meets these minimum specifications:

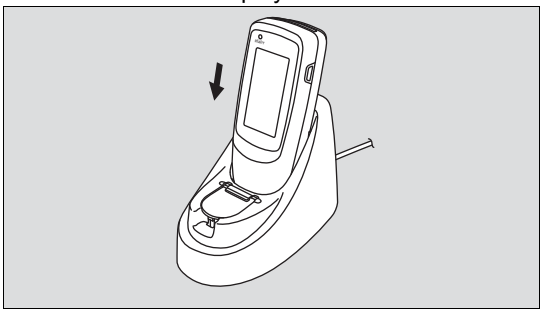
- USB connection must be USB 2.0 or later
- USB connection must supply 5V, 500mA or more of power to the JM-105
- USB connection must have passed electrical safety certifications for CE and UL

2 Plug the USB cable into the USB connector of the docking station.

3 Plug the USB cable into a USB port on a computer.



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.

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

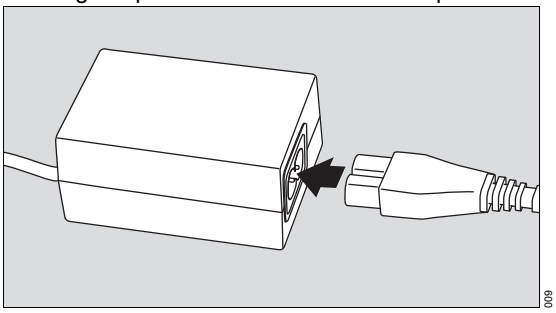
NOTE

Do not connect the JM-105 to bus-powered or self-powered USB hubs that are connected to a PC USB port. They do not provide sufficient power to charge the JM-105. The JM-105 may not charge fully or may not charge at all.

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.



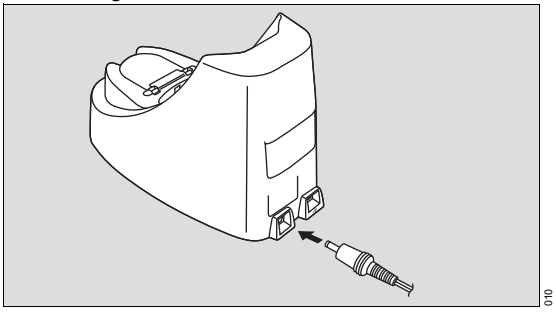
WARNING

Risk of fire, electric shock, or equipment damage.

Using a docking station or AC adapter other than the one 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.



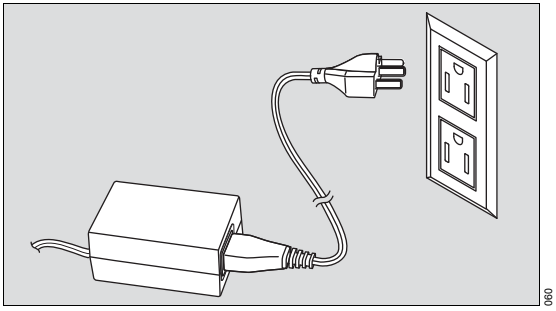
WARNING

Risk due to incorrect mains voltage or missing protective ground

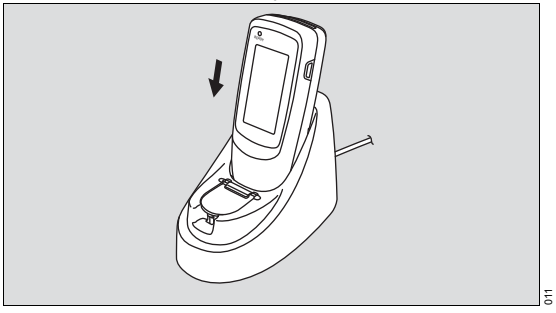
If the device is connected to a power socket with incorrect mains voltage or a power socket without a protective ground, an electric shock may occur.

Connect the device only to power sockets with correct mains voltage and a protective 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.

The JM-105 device is accompanied by data transmission software. 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

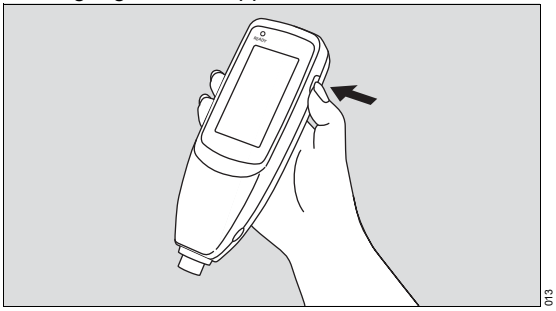
- Installation CD-ROM of data transmission software for jaundice meter, SW JM-S1w
- USB Cable

Getting started

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.

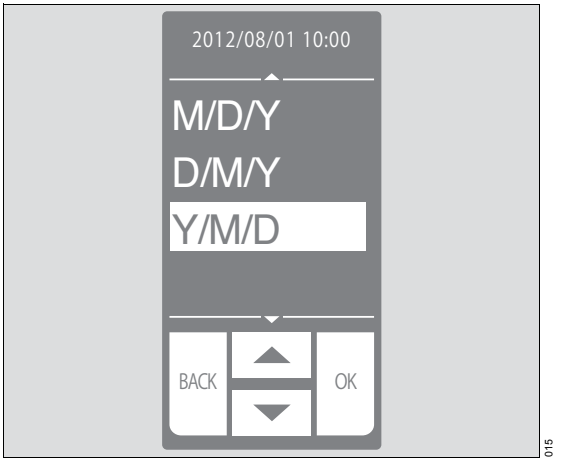


2 Select display language by touching the desired language or by using the UP/DOWN arrows. Selected language is highlighted.

3 Touch ***OK*** to save selection.

4 Date format screen appears.

5 Select date format.

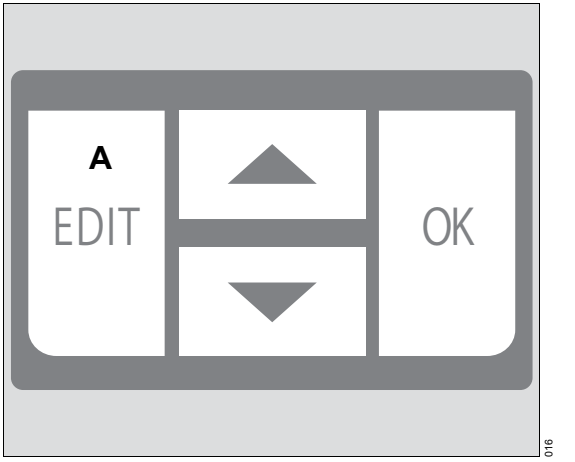


6 Touch ***OK*** to save selection.

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.

Configuring Code 39 barcode format

1 If using Code 39 barcode format, set preferences in the data transmission software (refer to Setting preferences - Barcode on page 50.)

NOTE
Requires device firmware version 1.10 or higher.

Checking Out of range message format

1 To check the current format, Touch ***MENU*** button, if needed.

2 Touch the ***CONFIG*** button or press UP/DOWN arrows.

3 Touch the ***UNITS*** button. The device shows the current setting as either ***HI:>20 or HI:>340***.

Pre-use checkout

WARNING

Risk of delayed therapy

Using the device without checking the accuracy of the measurements could cause incorrect measurements.

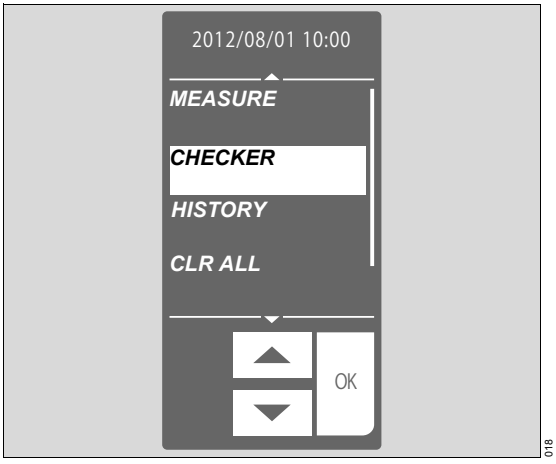
To check the measurement reliability of the system, compare the transcutaneous bilirubin value (TcB) determined by the device and the total serum bilirubin (TSB) determined on the basis of blood samples. Follow your hospital guideline to determine the frequency of checks (e.g. after repair or calibration of JM-105 or TSB lab equipment, or following a change to clinical processes.

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.

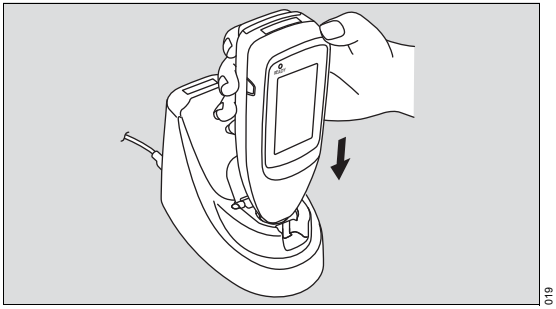
1 Switch on device.

2 Select ***CHECKER***.

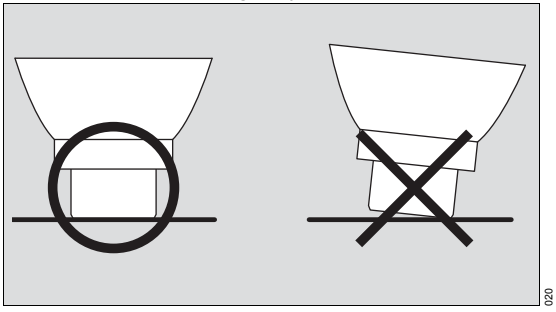


3 Touch ***OK*** to save selection.

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.

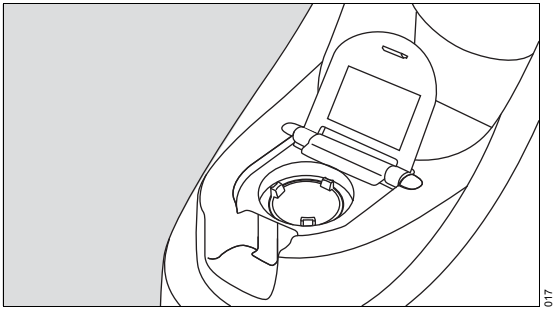
6 Review check results.

- L value (measured value of long optical path)
- S value (measured value of short optical path)
-  Delta value (difference between L and S values)

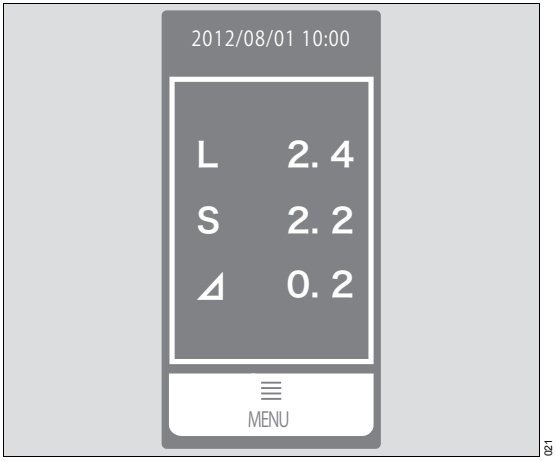
NOTE

If values are repeatedly out of range, contact DrägerService.

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



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



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.

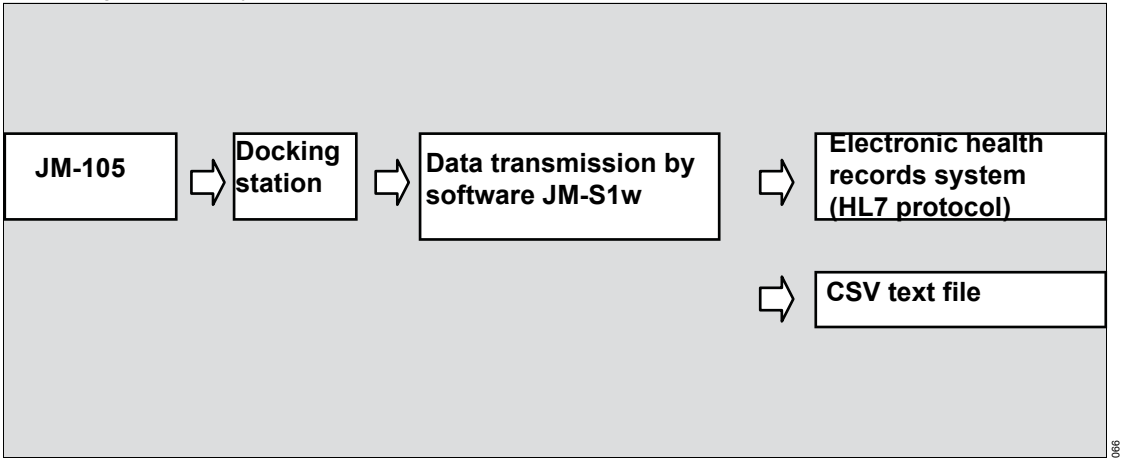
NOTE

Product labels shall be inspected for legibility before use.

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



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.
- Use only Data Transmission SW 1.50 or higher.

System requirements

Operating Systems	Windows 7 Professional SP1 32-bit Windows 7 Professional SP1 64-bit Windows 8.1 Professional 32-bit Windows 8.1 Professional 64-bit Windows 10 Professional 64-bit (Creators update)
Screen resolution	1024 X 768 or higher
CPU	Pentium III 1.6 GHz or higher
Memory	1 GB or more
Hard disk	At least 3.5 GB 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
Languages (CE4)	English, Czech, Hungarian, Norwegian, Slovakian
Languages (CE5)	English, Danish, Finnish, Greek, Romanian

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.

Introduction

Three setup files are needed to set up the JM-S1w (version 1.50) software. These three files must be installed in the following order:

1 setup1.exe: Microsoft Visual C++ 2015 Redistributable Package Installer

2 setup2.exe: Microsoft .NET Framework 4.6.2 Installer

3 setup3.exe: JM-S1w Installer

NOTE
Use only Data Transmission SW 1.50 or higher.

NOTE
If a previous software version of JM-S1w is installed, do not uninstall it. Installing JM-S1w (version 1.50) will automatically uninstall the previous version of software and inherit the previous settings.

NOTE
For JM-S1w (version 1.30) or older, settings were allocated to each Windows login user. JM-S1w (version 1.50) has only one set of settings for all users.

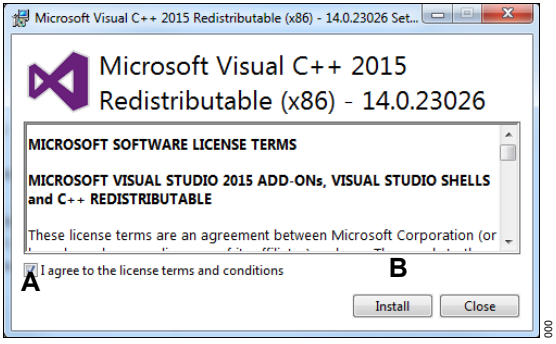
NOTE
If CSV file storage was used with the old software, it might be necessary to manually adjust the location to an appropriate directory. The default location is: C:\users\public\documents\jm-s1w\CSV.

Installation of Microsoft Visual C++ 2015 Redistributable Package

NOTE
When the Microsoft Visual C++ 2015 Redistributable package has already been installed on your PC, you should move to the next step (Installation of Microsoft .NET Framework 4.6.2).

NOTE
In case the login user who executes JM-S1w installer does not have administrative right of windows, the "User Account Control" dialog will appear.

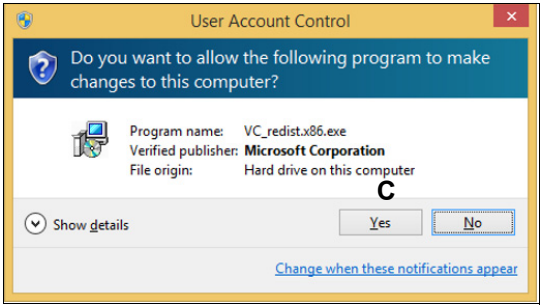
1 Run the setup1.exe.



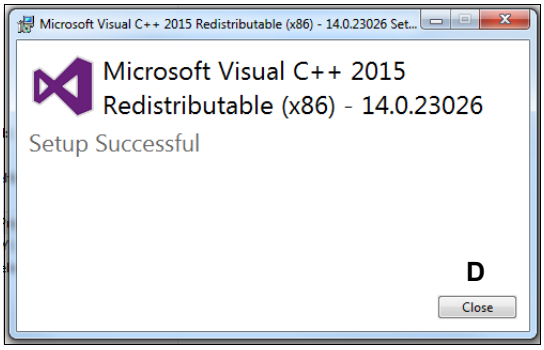
2 Check the ***I agree to the license terms and conditions*** check box (A).

3 Click the ***Install*** button (B).

4 Click the ***Yes*** button (C).



5 Click the ***Close*** button (D).



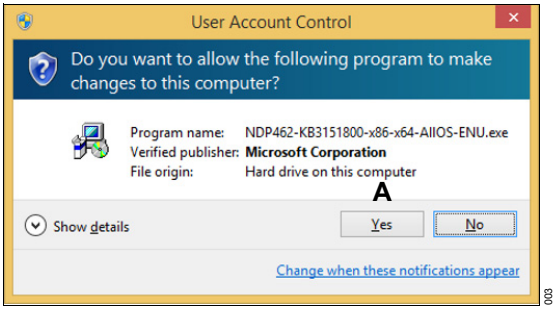
Installation of Microsoft .NET Framework 4.6.2

NOTE

When the later version of .NET Framework has already been installed on your PC, you should move to the next step (Installation of JM-S1w).

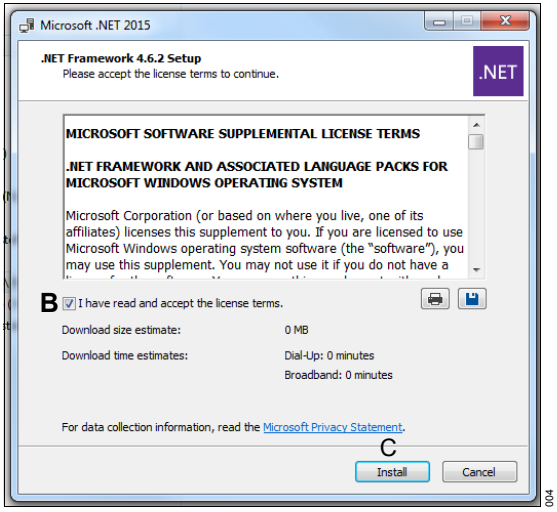
1 Run the setup2.exe.

2 Click the ***Yes*** button (A).

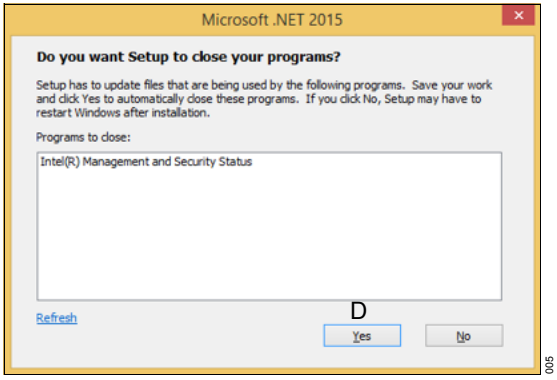


3 Check the ***I have read and accept the license terms.*** check box (B).

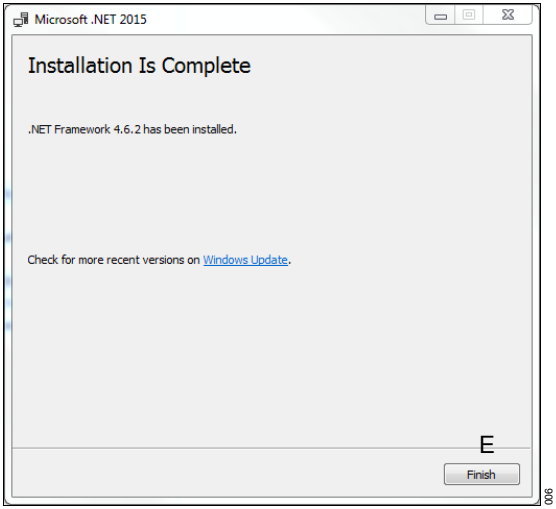
4 Click the ***Install*** button (C).



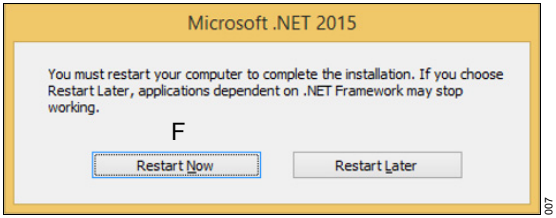
5 If the dialog below appears, click the ***Yes*** button (D).



6 Click the ***Finish*** button (E).



7 Click the ***Restart Now*** button (F) to restart the PC.

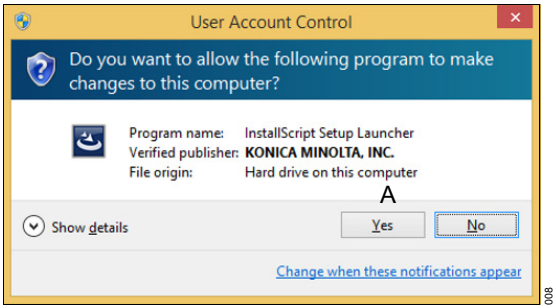


Installation of JM-S1w

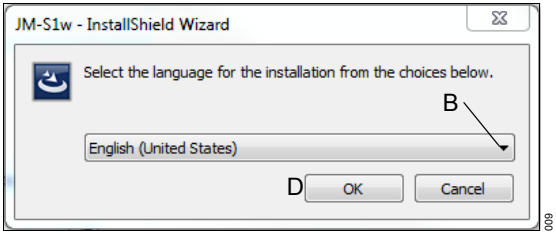
NOTE
Use only Data Transmission SW 1.50 or higher.

1 Run the setup3.exe.

2 Click the ***Yes*** button (A).

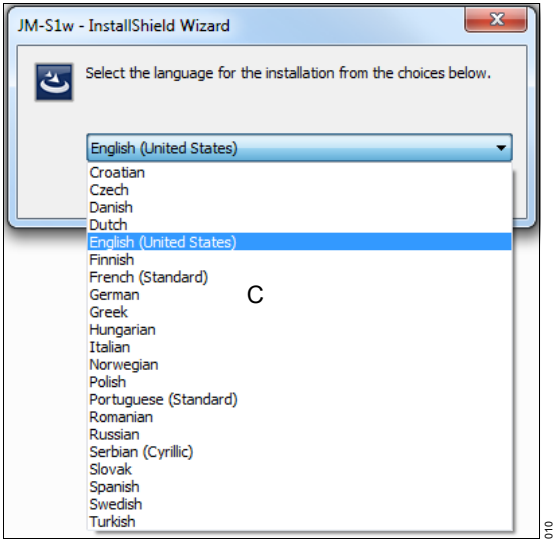


3 Open the drop-down list (B).

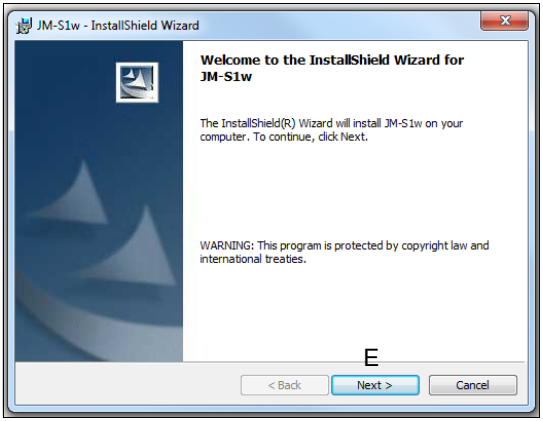


4 Select the language that you want to install (C).

5 Click the ***OK*** button (D).

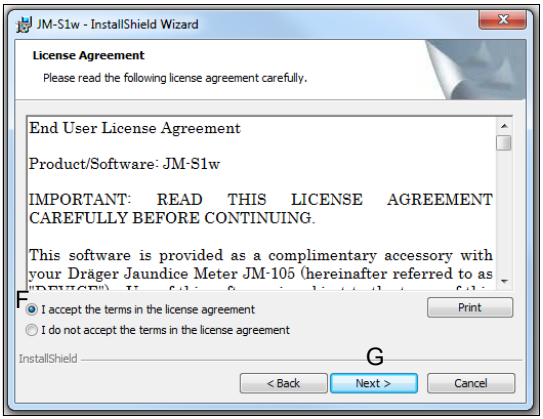


6 Click the ***Next*** button (E).



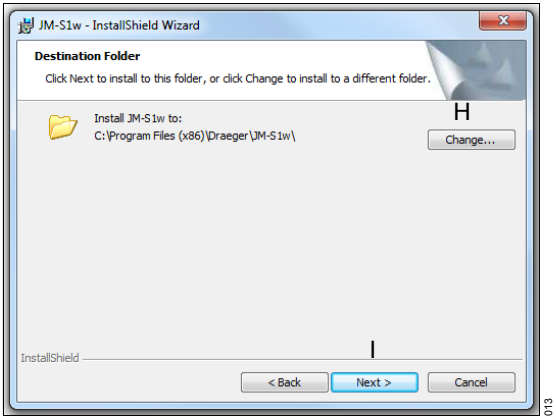
7 Select the ***I accept the terms in the license agreement*** button (F).

8 Click the ***Next*** button (G).

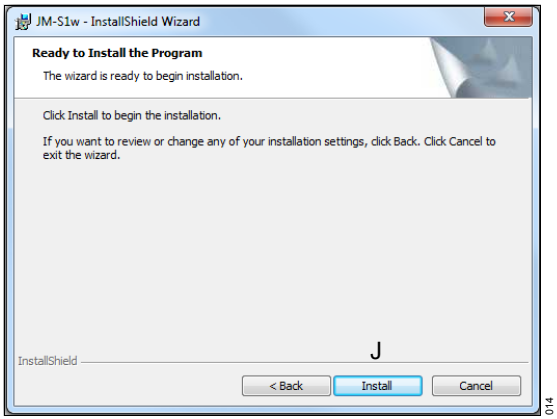


9 To install the software in another location, click the ***Change***... button (H).

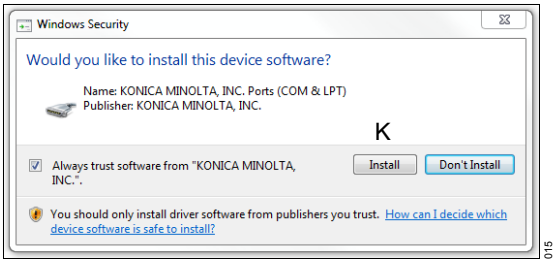
10 Click the ***Next*** button (I).



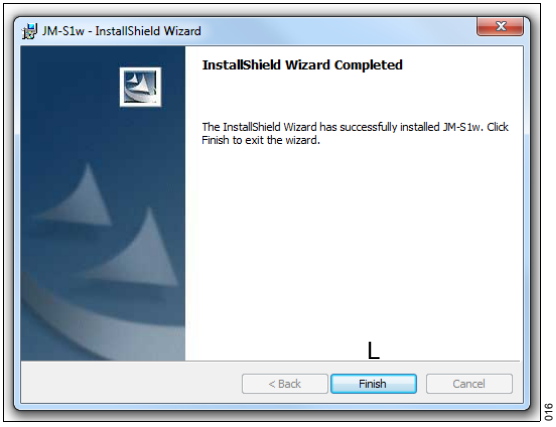
11 Click the ***Install*** button (J).



12 Click the ***Install*** button (K) to install the USB driver.



13 Click the ***Finish*** button (L).



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 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 CD-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

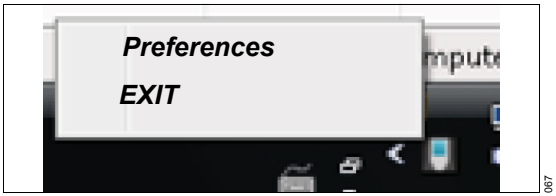
1 Access the JM-S1w menu by clicking or right-clicking on the JM-S1w symbol on the task tray. 

This action opens the JM-S1w menu.

NOTE

All users can change preferences. However, preferences apply to all users. Users cannot set individual preferences.

1 Select ***Preferences***.



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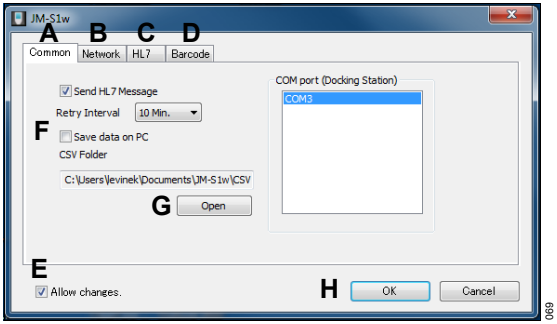
Setting preferences - Common

1 A dialog box opens that shows tabs for each of 4 setting categories: ***Common*** (A), ***Network*** (B), ***HL7*** (C), and ***Barcode*** (D). The ***Common*** tab is in front.



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2 Check the box (E) to allow changes to settings.

3 Determine if you want to save to CSV text file or to EHR.

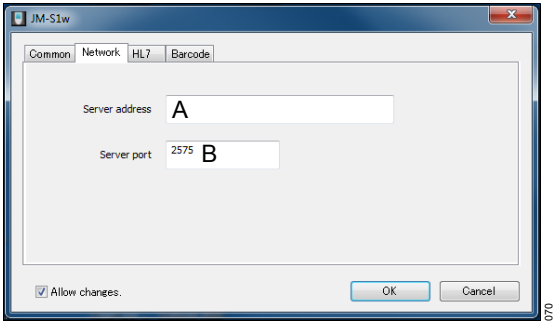
4 If CSV text file is preferred, change ***Common*** settings, by checking the ***Save data on PC*** box (F).

5 Click on the ***OPEN*** button (G) to select CSV file storage location.

6 Click ***OK*** (H) to save settings.

Setting preferences - Network

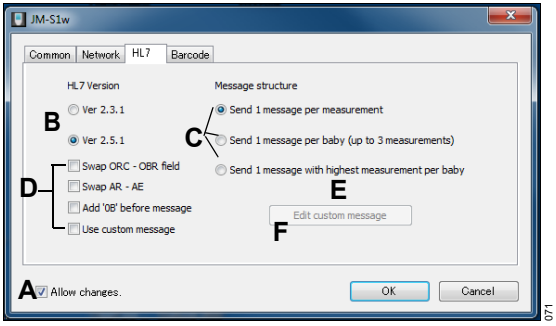
1 If EHR is preferred, select the ***Network*** tab.



2 Change ***Network*** settings to input the server address (A) and the server port (B).

Setting preferences - HL7

1 Select the ***HL7*** tab.



2 To allow changes to settings, check the radio button (A) to allow changes to settings.

3 Change ***HL7*** settings: ***HL7 version*** (B) and ***Message structure*** options (C) and (D).

4 Click the ***Edit custom message*** button (E), if desired.

5 Edit messages as desired.

6 Edit the ***Sending facility*** field (F), if desired.

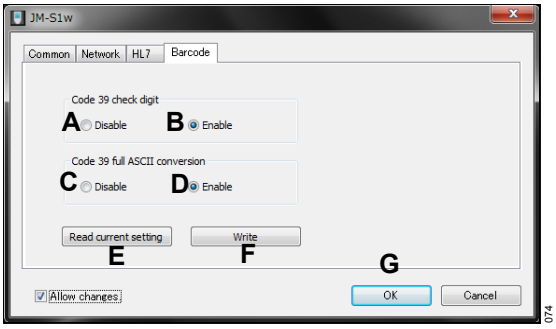
7 Click ***OK*** to save.

Setting preferences - Barcode

NOTE

This function is only available using JM-S1w version 1.30 or higher and device firmware 1.10 or higher.

1 If Code 39 barcode is preferred, select the ***Barcode*** tab.



2 Check the appropriate radio button to disable (A) or enable (B) the Code 39 check digit.

3 Check the appropriate radio button to disable (C) or enable (D) full ASCII.

4 Press the ***Write*** button (F) to apply the setting.

5 Click ***OK*** (G) to save.

NOTE

To see the current settings, click on the ***Read current setting*** button (E).

Operation

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.

WARNING

Risk of patient injury

Pathologic or other skin conditions that may affect light scattering or absorption could result in incorrect TcB measurements.

Do not conduct measurements in patients with early jaundice and pathologic jaundice.

Do not conduct measurements when skin conditions may violate the assumption made concerning light scattering and light absorption.

Use device only on healthy skin of the patient. Do not conduct measurements on birthmarks and hairy areas. Avoid areas of thickness that in the opinion of the physician would preclude or interfere with the use of the TcB meter.

NOTE

Clean measuring probe 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.

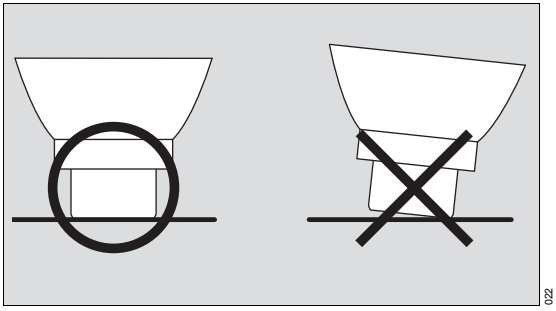
NOTE

There is a minor risk of administering phototherapy when not clinically indicated.

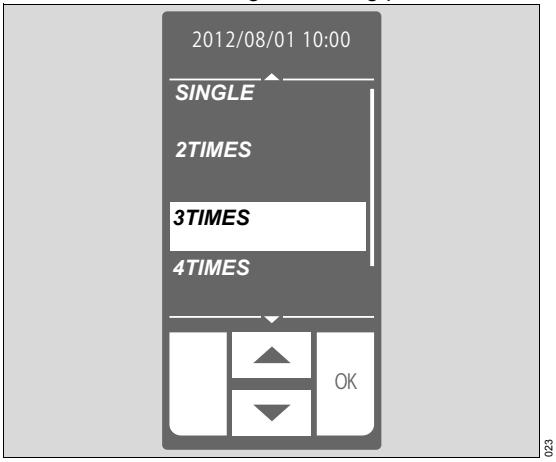
1 Before beginning measurements, ensure that all phototherapy lights are shut off.

2 Place measuring probe perpendicular to measuring point.

3 Push down gently. Do not lean the measuring probe.



4 Configure the device to the desired number of measurements (refer to Choosing settings for measurement on page 53). Dräger recommends that the device is set to average 2 times to 5 times. This setting minimizes measurement errors due to leaning measuring probe.



Measuring point

WARNING

Risk of patient injury

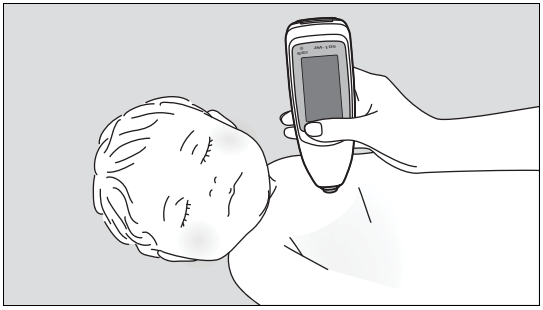
Pathologic or other skin conditions that may affect light scattering or absorption could result in incorrect TcB measurements.

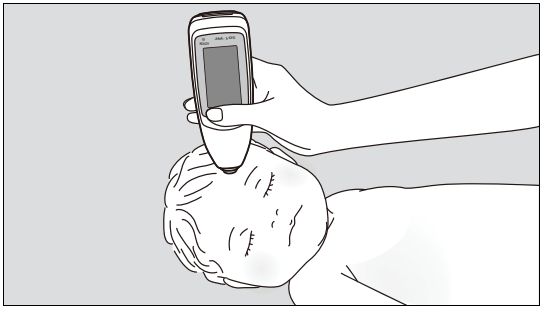
Do not conduct measurements in patients with early jaundice and pathologic jaundice.

Do not conduct measurements when skin conditions may violate the assumption made concerning light scattering and light absorption.

Use device only on healthy skin of the patient. Do not conduct measurements on birthmarks and hairy areas. Avoid areas of thickness that in the opinion of the physician would preclude or interfere with the use of the TcB meter.

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.





Choosing settings for measurement

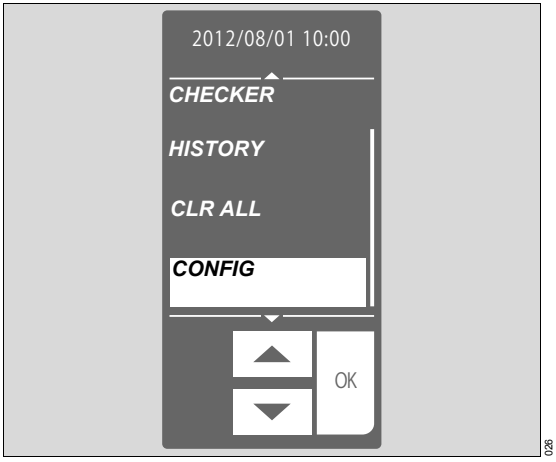
This device performs single measurements and average measurements. Single measurements take the results from each measurement as the measured value. Average measurements take the average results from 2 to 5 individual measurements as the measured value.

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

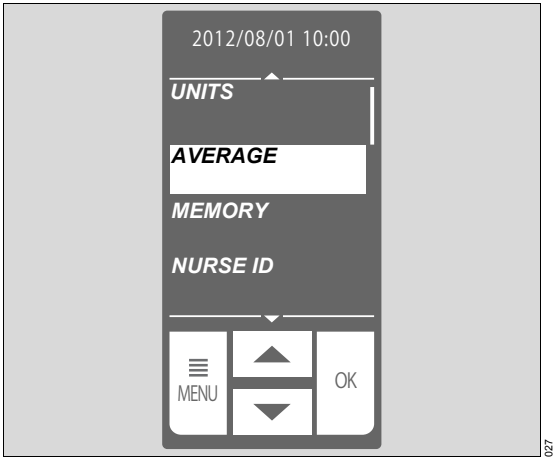
1. Touch ***MENU*** button, if needed.
2. Using UP/DOWN arrows, scroll through the list until ***CONFIG*** appears.

3 Select ***CONFIG***.



4 SETTING screen appears.

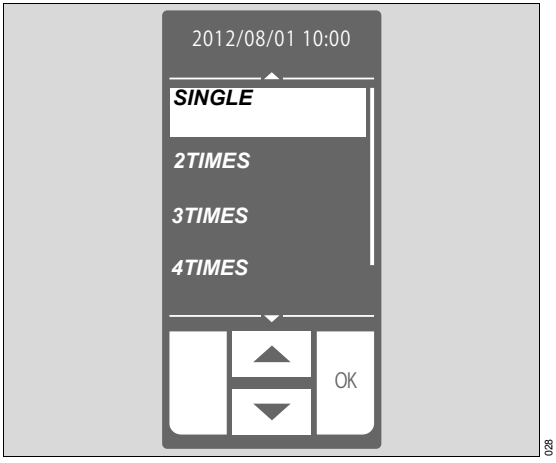
5 Select ***AVERAGE***.



6 Touch ***OK*** to save selection.

7 Select the number of measurements.

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

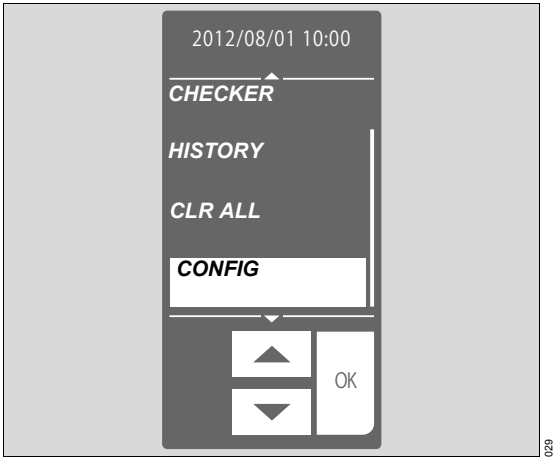


8 Touch ***OK*** to save selection.

Selecting whether to store measurements

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

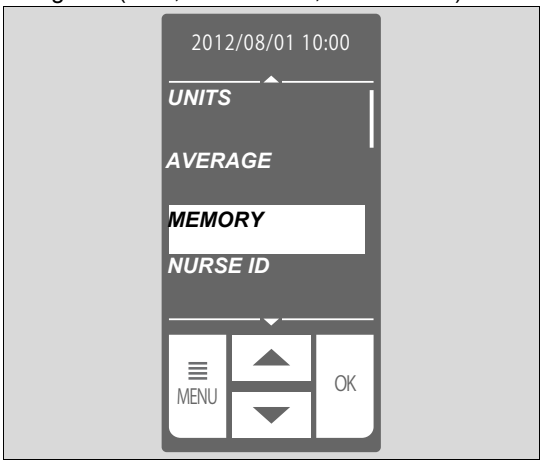
2 Select ***CONFIG***.



3 Touch ***OK*** to save selection.

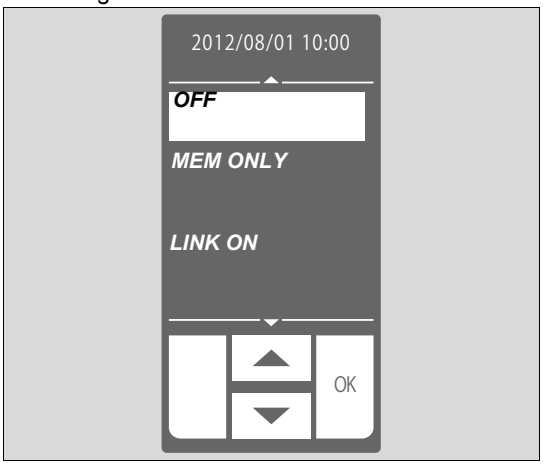
4 SETTING screen appears.

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

WARNING

Risk due to incorrect reading

Screening measurements must be compared to measurements from collected blood samples.

– Compare TcB value (Transcutaneous Bilirubin) measured by the device and TSB value (Total Serum Bilirubin) measured from collected blood samples.

NOTE

For quality control purposes, periodically compare the JM-105 to serum bilirubin results. This checks that the instrument maintains consistent performance over time and that the operators are using the instrument properly.

Removing from docking station

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

2 Remove device from docking station.

3 Clean measuring probe.

4 Switch on device.

NOTE

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

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

6 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)

WARNING

Risk of patient injury

Pathologic or other skin conditions that may affect light scattering or absorption could result in incorrect TcB measurements.

Do not conduct measurements in patients with early jaundice and pathologic jaundice.

Do not conduct measurements when skin conditions may violate the assumption made concerning light scattering and light absorption.

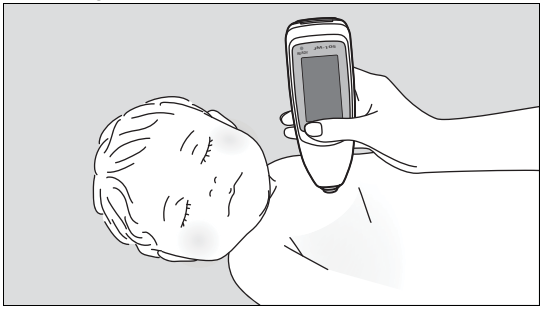
Use device only on healthy skin of the patient. Do not conduct measurements on birthmarks and hairy areas. Avoid areas of thickness that in the opinion of the physician would preclude or interfere with the use of the TcB meter.

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

2 Ensure that ***MEMORY*** is set to ***OFF*** (refer to Selecting whether to store measurements on page 54).

3 Ensure that the ***READY*** lamp is on.

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



5 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.

6 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.

7 Read measurements.

- Display shows up to 3 measured values.
- If >20 or >340 blinks in a measured value field, the measured value is outside the measurement range (>20.0 mg/dL/>340 μmol/L).
- To take another measurement, touch ***CLEAR*** button (A) and repeat step 2 through step 6.

NOTE

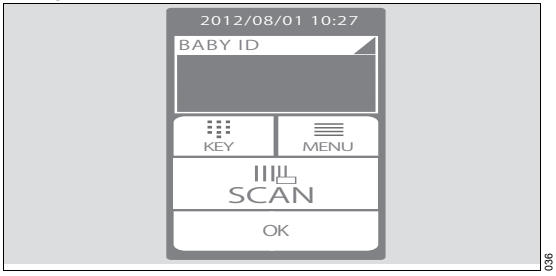
Touching ***CLEAR*** once deletes the last measured value. Touching and holding ***CLEAR*** deletes all displayed measured values.

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 54).
- 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), and touch ***OK***.

3 Scan ***BABY ID*** (baby ID), and touch ***OK***.

4 Ensure that the ***READY*** lamp is on. Go to Performing measurements on page 59.

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

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

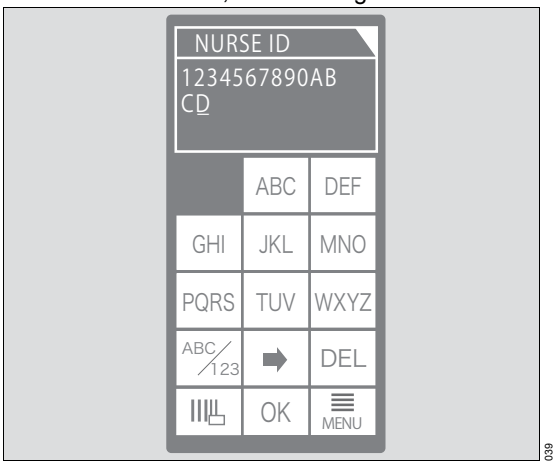
NOTE
Touching the ***BARCODE*** button switches you back to barcode input mode.

2 To switch between alphabet mode and numeric mode, touch ***ABC/123*** 

button.

3 When in numeric mode, touch the number desired.

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



- 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

WARNING
Risk of patient injury

Pathologic or other skin conditions that may affect light scattering or absorption could result in incorrect TcB measurements.

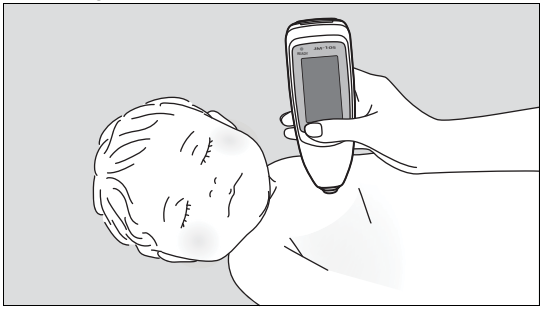
Do not conduct measurements in patients with early jaundice and pathologic jaundice.

Do not conduct measurements when skin conditions may violate the assumption made concerning light scattering and light absorption.

Use device only on healthy skin of the patient. Do not conduct measurements on birthmarks and hairy areas. Avoid areas of thickness that in the opinion of the physician would preclude or interfere with the use of the TcB meter.

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

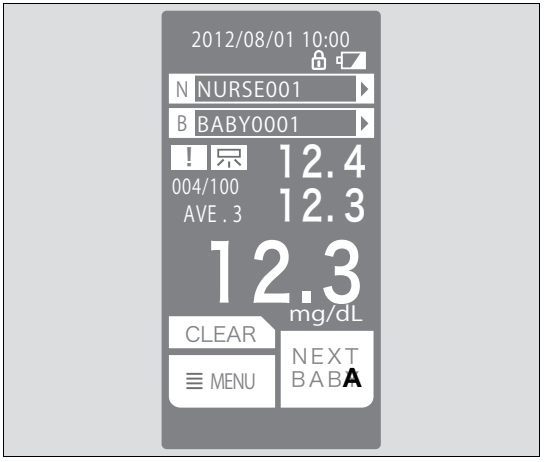
2 Place measuring probe perpendicular to measuring point (on forehead or sternum).


040

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.

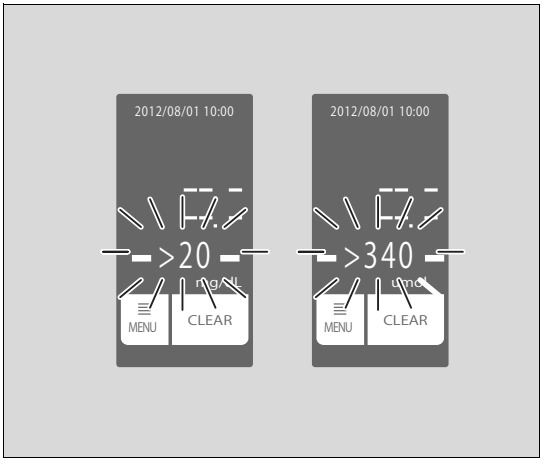
4 If averaging, wait for green ***READY*** lamp and repeat measurement for the number of times selected (***2TIMES*** or ***5TIMES***). Display shows the average calculated from the multiple measurements.



041

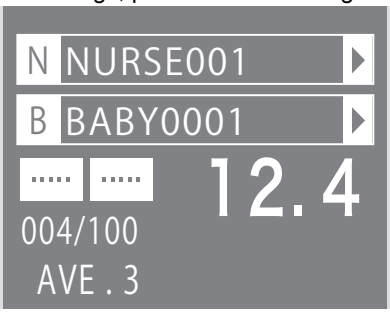
5 Read measured data.

- Display shows up to 3 measured values.
- If ***>20*** *or* ***>340*** blinks in a measured value field, the measured value is outside the measurement range (>20.0 mg/dL/>340 µmol/L).



042a

6 To attach flags, perform the following:



- To attach a priority flag, touch the dots button (the priority flag appears which indicates high bilirubin level in the patient).
- To attach a phototherapy flag, touch the button again (the phototherapy flag appears which indicates that patient has been treated with phototherapy).
- To attach both flags, touch the button again (both flags appear).
- To remove flags, touch the button again (both flag disappear and the dots return .

WARNING

Risk of delayed phototherapy

Set flags must be considered when intepreting test measurements. Otherwise there is an increased risk of incorrect therapy.

– Follow hospital procedures on the assessment of phototherapy needed or of any further evaluation needed.

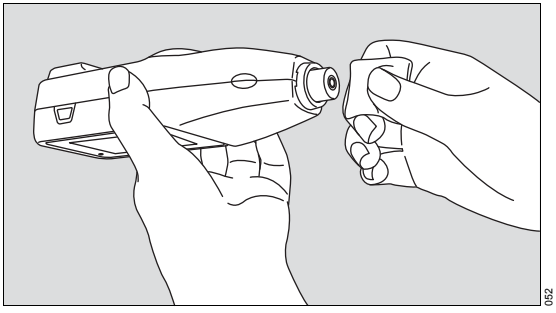
7 To proceed to the next patient, touch ***NEXT BABY*** button (A), enter ***NURSE ID*** (optional) and ***BABY ID***, and repeat steps 6 through 9.

NOTE

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

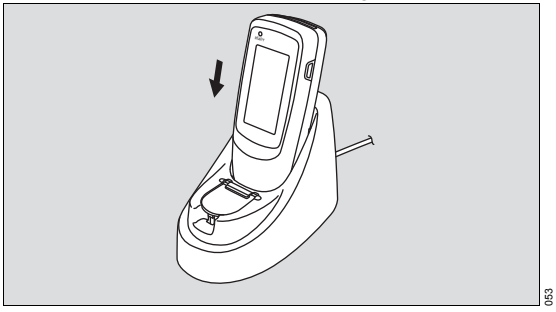
Storing the device

1 Clean the measuring probe with a wipe soaked in alcohol.



- While the device is in the docking station, power remains on. After 1 min, the screen goes blank. The power remains on.

2 Place the device in the docking station.



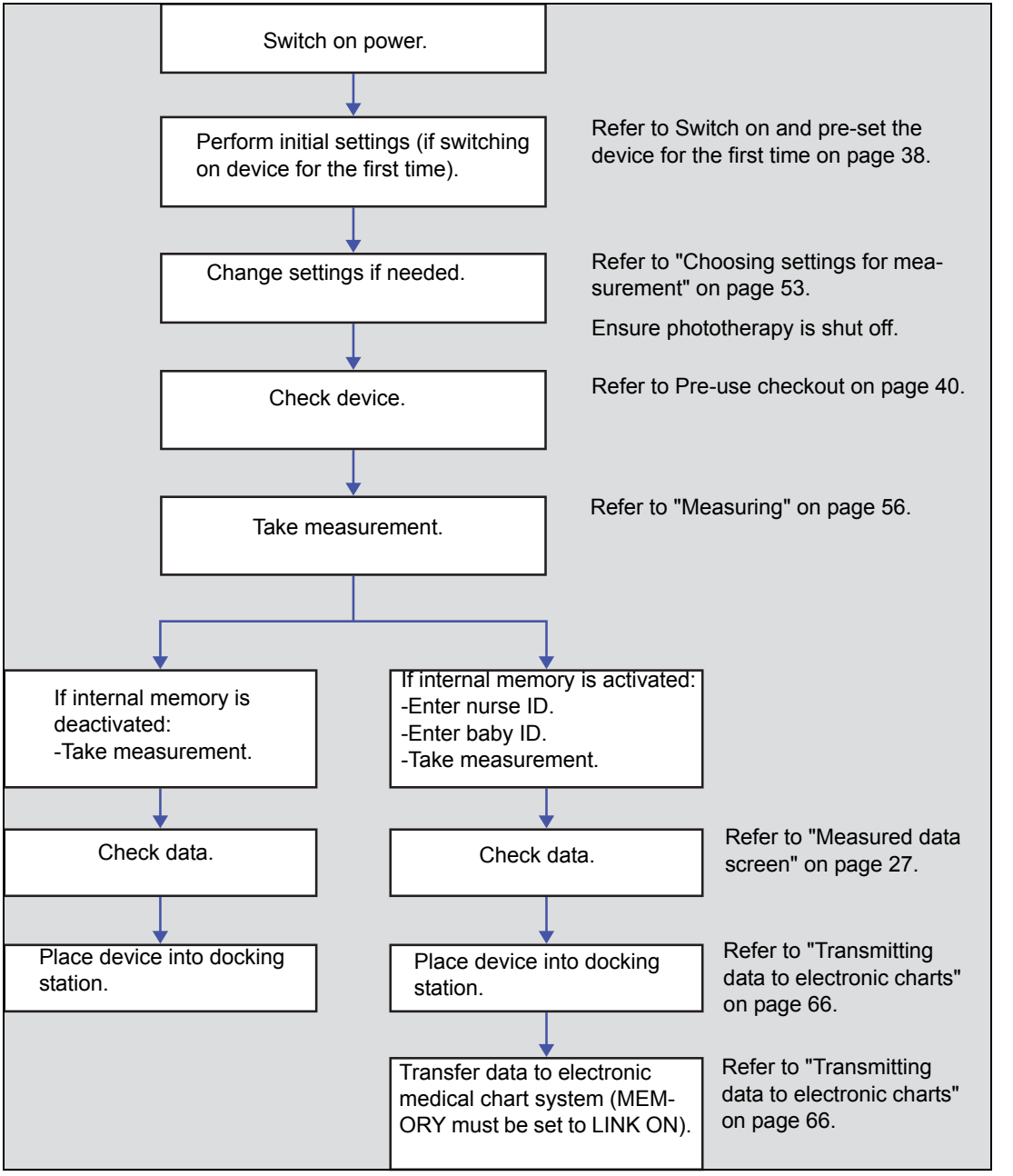
3 Leave the device in the docking station when not in use.

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

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.

Measuring quick guide

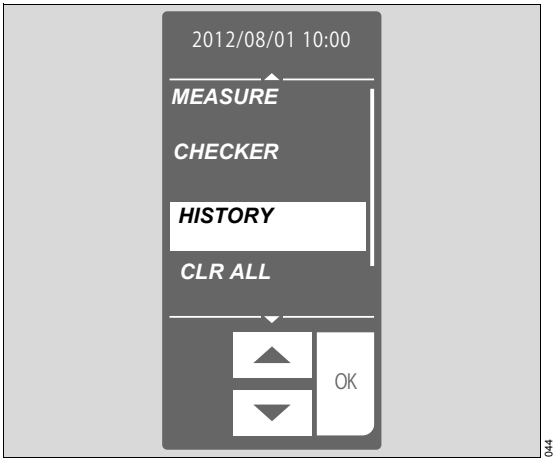


Trends and Data

Viewing measurements stored in the data log

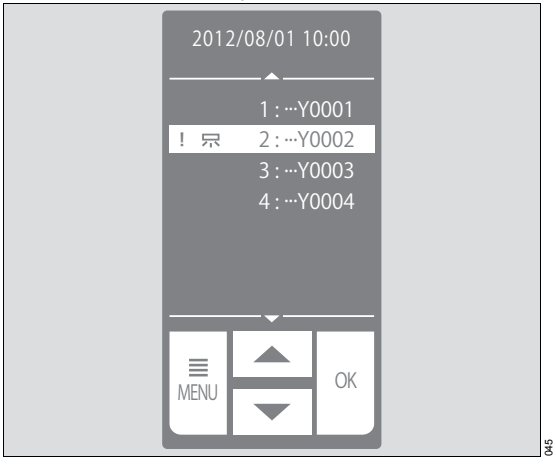
1 Touch ***MENU*** button, if needed.

2 Touch ***HISTORY***.

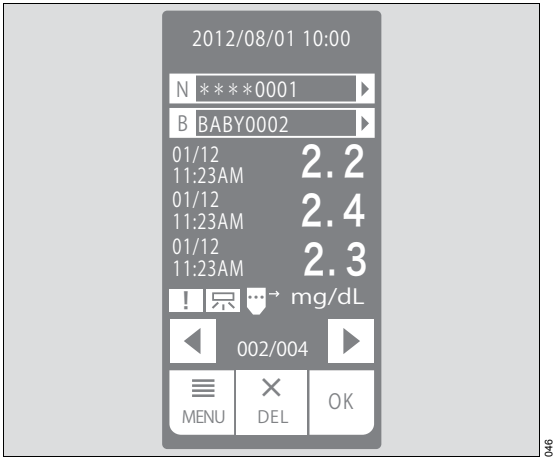


3 Touch ***OK*** to save selection. Display shows list of baby IDs (5 trailing characters if ID is 6 or more characters long), measurement numbers, and flags.

4 Select desired baby ID.



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



WARNING

Risk due to incorrect reading

Screening measurements must be compared to measurements from collected blood samples.

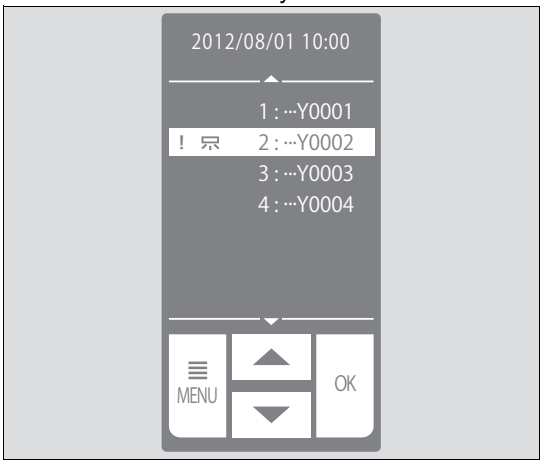
- **Compare TcB value (Transcutaneous Bilirubin) measured by the device and TSB value (Total Serum Bilirubin) measured from collected blood samples.**

Deleting individual measurements in the data log

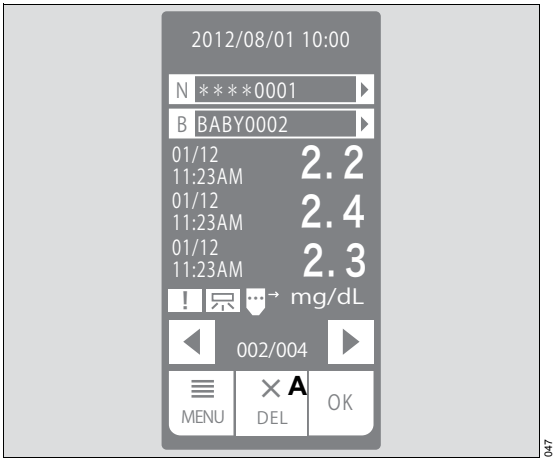
1 Touch ***MENU*** button, if needed.

2 Touch ***HISTORY***.

3 Select the desired baby ID.



4 Select the desired measurement.



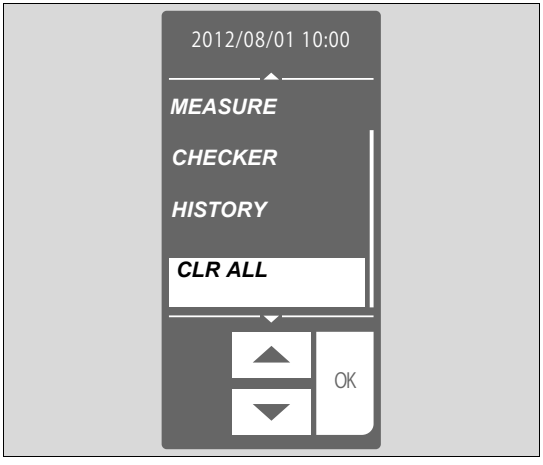
5 Touch ***DELETE*** (A).

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, measurements from JM-105 are automatically sent to the electronic health records system. If ***Save data on PC*** in the ***Common*** tab is enabled, then measurements from the JM-105 are sent to a CSV log file on the PC. Refer to Setting preferences - Common on page 49 to confirm settings.

1 On the jaundice meter, navigate to the settings menu: ***MENU>CONFIG***.

2 Select ***MEMORY*** from the menu items.

3 Select ***LINK ON*** from the menu items.

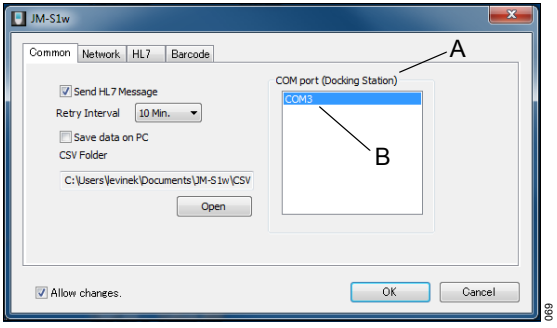
4 Connect the docking station to the PC.

5 Open the SW JM-S1w on the PC.

NOTE

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

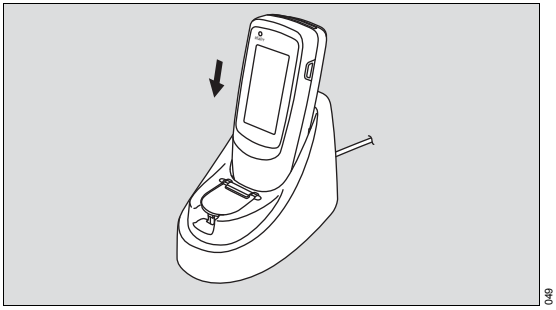
6 Confirm COM port (B) on ***Common*** screen.



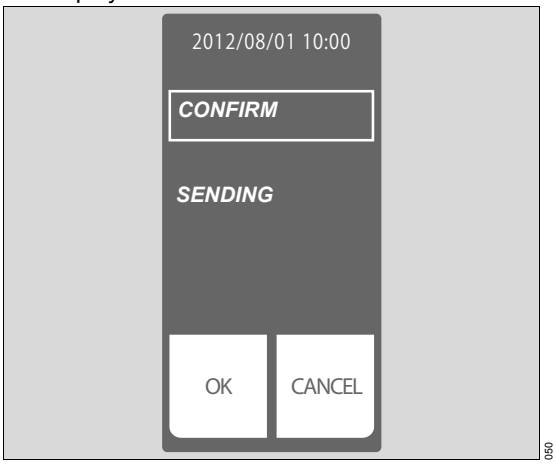
NOTE

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

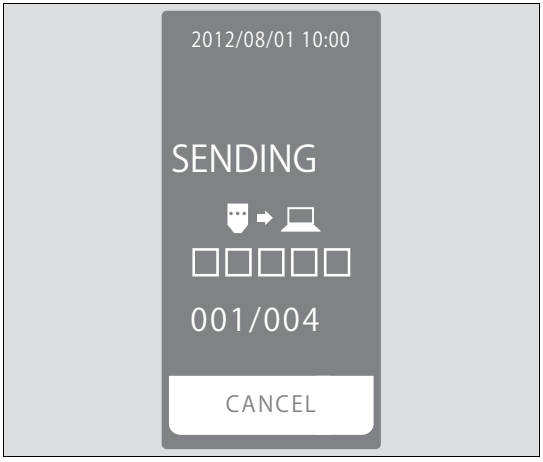
7 Place the device in the docking station that is connected to the PC.



8 Display shows the ***CONFIRM*** screen.



9 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 or no 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.

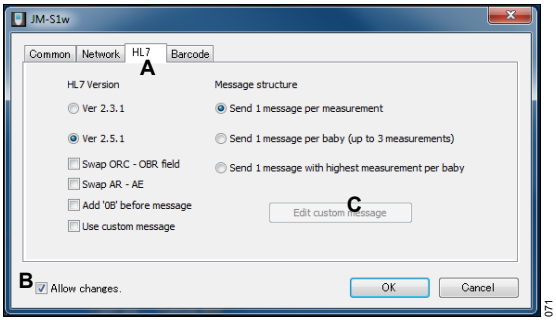
Transmission log

If ***Send HL7 Message*** is enabled in the ***Common*** tab of the JM-S1w dialog, the results of sending measurements to the HL-7 system are saved in the transmission log.

Refer to Viewing the transmission log from the JM-S1w software on page 68.

Viewing the transmission log from the JM-S1w software

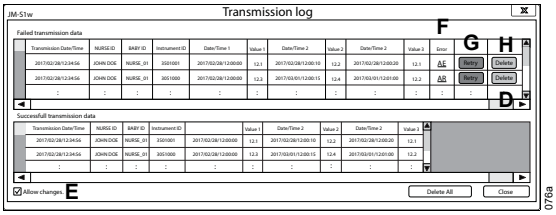
1 Select the ***HL-7*** tab (A).



2 Edit the Sending facility (B), if desired.

3 Select the ***Transmission log*** button (C).

4 The ***Transmission log*** dialog opens.



5 Use the scroll bars (D) to navigate through the data (left and right/ up and down).

6 Check the ***Allow changes.*** radio button (E) to allow editing of the transmission log.

7 To view error details, click on the ***AE/AR/CN/UN*** link (F).

8 To resend a failed transmission, click on the ***Retry*** button (G).

NOTE

The Retry and the Delete buttons may be hidden to the right if data in other fields is long. Use the scroll bars to find these buttons.

9 To delete a failed transmission, click on the ***Delete*** button (H).

10 Sort data as desired by date or by name by clicking the arrow (I) in the column header (ascending or descending order). Data can be sorted by fields: ***Transmission Date/Time***, ***Nurse ID***, ***Baby ID***, ***Date/Time1.***

NOTE

The default sort order shows the newest transmission on top.

11 Edit data as desired in fields: ***Nurse ID, Baby ID***.

NOTE

The transmission log can hold 500 entries. When the log reaches 500 entries, new entries push out the oldest entries in the log.

12 To clear all data from the transmission log, click on the ***Delete All*** button (J).

13 A confirmation message appears, ***Are you sure you want to delete all items?.***

14 Select yes or no.

15 To close the window, click on the ***Close*** button (K).

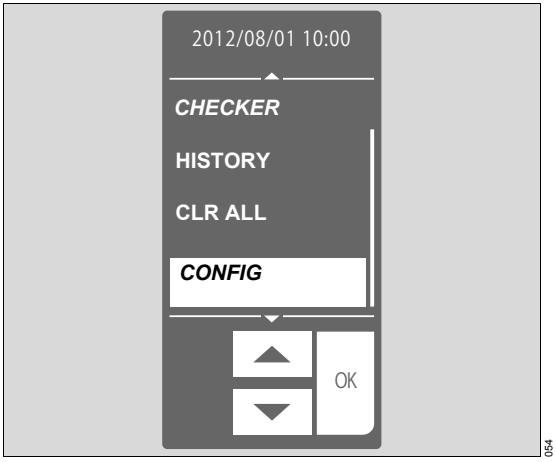
Configuration

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 arrows.



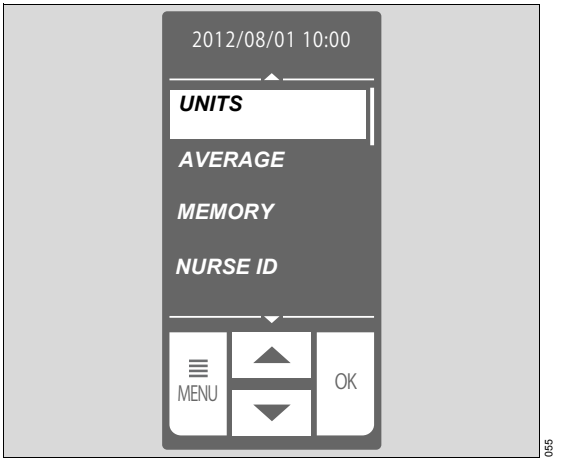
4 Touch ***OK*** to save selection.

5 Settings screen appears.

6 Touch item you want to change.

7 To change value, touch UP/DOWN buttons.

8 Touch ***OK*** to save selection.



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

System and default settings for the JM-105

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

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.
		BARCODE[1)]	Default[1)] Enter nurse ID using bar-code reader.
		TOUCH	Enter nurse ID using touch screen.
BABY ID	Select how to enter baby ID.	***BARCODE***[1)]	Default[1)] Enter baby ID using barcode reader.
		TOUCH	Enter baby ID using touch screen.
BUZZER	Select whether to activate beeper.	***OFF***	No beep sound.
		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 FMT[2)]	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

Setting	Description	Options	Description
LANGUAGE[2)] for CE1	Select display language.	***ENGLISH***	Default
		DEUTSCH	
		ESPAÑOL	
		FRANÇAIS	
		ITALIANO	
LANGUAGE[2)] for CE2	Select display language.	***ENGLISH***	Default
		NEDERL.	
		SVENSKA	
		PYC.	
		PORTUG.	
LANGUAGE[2)] for CE3	Select display language.	***ENGLISH***	Default
		POLSKI	
		TÜRKÇE	
		HRVATSKI	
		SRPSK	
LANGUAGE[2)] for CE4	Select display language.	***ENGLISH***	Default
		ČEŠTINA	
		MAGYAR	
		NORSK	
		SLOVENSK	
LANGUAGE[2)] for CE5	Select display language.	***ENGLISH***	Default
		SUOMI	
		DANSK	
		ΕΛΛΗΝΙΚΑ	
		ROMÂNĂ	
CONTRAST	Select contrast of touch screen.	1	Darkest
		2	
		3	Default
		4	
		5	Lightest

Setting	Description	Options	Description
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.)		
Data transmission software			
Code 39 check digit[1)]	Select whether or not the barcode contains a check digit.	***Disable***	
		Enable	Default
Code 39 full ASCII conversion[1)]	Select whether or not to enable full ASCII. This page intentionally left blank.	***Disable***	
		Enable	Default
Sending facility[3)] for ***HL-7***	Displays the facility sending the data during data transmission. This field is editable by the user.	***Nursery***	Default

1) Only applies to devices with firmware 1.10 or higher and barcode feature using JM-S1w version 1.30 or higher.
2) Must be set or selected when device is switched on for the first time.
3) Requires JM-S1w version 1.40 or higher.

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Problem solving

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.
		If the failure continues, switch off the device and remove it from service.
	Hardware failure	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.
JIG MODE Ver. 1.x	Battery exhausted.	Charge device for 32 hours.
		If failure continues, replace battery

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.	Establish measurement procedures that reduce activation of the backlight of the touch screen. Backlight of touch screen consumes a lot of power.
	Battery often recharged before power was fully discharged.	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.	Wait for a few minutes. The battery charge increases to 1.2 V or higher. The red ***READY*** lamp illuminates continuously.
	Battery temperature too high.	Allow battery to cool. Charging starts automatically when battery has cooled.
		If the failure continues, switch off the device and remove it from service.
	No battery connected to the JM-105.	Connect battery.

Other problems

Fault	Cause	Remedy
Blank screen	Power switched OFF.	Switch ON power.
	Battery power depleted.	Charge battery.
	Device has not been used for 1 min or more after power was switched ON.	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.	Correctly connect docking station to AC adapter.
	AC adapter not connected to AC power or not correctly connected to AC power.	Correctly connect AC adapter to AC power.
	USB cable not connected to the docking station or not correctly connected to the docking station.	Correctly connect USB cable to docking station.
	USB cable not connected to the PC or not correctly connected to the PC.	Correctly connect USB cable to PC.
	Device is not seated correctly in the docking station.	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 a data transfer 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 data transfer 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
Couldn't save Log data. Check HDD space.	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 folder[1)], or CSV folder. Clear space on hard disk or reset cache folder to read/write.
Server couldn't 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's 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 will retry 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.
Couldn't 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.
When performing barcode settings, select only one COM port (Docking Station).	This message appears on the JM-S1w ***Barcode*** screen when more than one port was selected on the ***Common*** JM-S1w screen.	Select only one COM port on the ***Common*** JM-S1w screen.
COMx Failure (where x is the number of the communication port)	An attempt was made to read current barcode 39 data, but there is no JM-105 connected or the connected JM-105 does not support the barcode 39 format.	Connect a JM-105 that supports the barcode 39 format, and attempt the reading again.

1) Cache folder: On Windows Vista, Windows 7, Windows 8, Windows 10 C:\ProgramData\Draeger\JM-S1w\

Reprocessing

Safety information

WARNING

Risk due to inappropriately reprocessed products

Reusable products must be reprocessed, otherwise there is an increased risk of infection.

- **Follow the infection prevention policies and reprocessing regulations of the health-care facility.**
- **Follow the national infection prevention policies and reprocessing regulations.**
- **Use validated procedures for reprocessing.**
- **Reprocess reusable products after every use.**

Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices.

CAUTION

Risk due to faulty products

Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.

Check the products for signs of wear and replace them if necessary.

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.

Information on reprocessing

Follow the national infection prevention policies and reprocessing regulations.

Follow the infection prevention policies and reprocessing regulations of the health-care facility (e.g., concerning the reprocessing cycles).

Classifications for reprocessing

Classification of medical devices

The classification depends on the intended use of the medical device. The risk of infection transmission through the application of the product to the patient without proper reprocessing is the basis of the Spaulding classification.

Classification	Explanation
Non-critical	Components that come only into contact with skin that is intact
Semi-critical	Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin
Critical	Components that penetrate skin or mucous membranes or come into contact with blood

Classification of device-specific components

The following classification is a recommendation from Dräger.

Non-critical

- Device components
  - JM-105 main device
- Chargers
  - JM-A33 docking station

Before reprocessing

Observe before 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.

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 the device.

2 Disconnect all power plugs.

Device-specific components

The device-specific components must be removed from the device and, if necessary, disassembled.

Removing the [AC adapter]

1 Disconnect AC adapter from AC outlet.

2 Disconnect DC plug from device.

Disassembling the [docking station]

1 Remove the jaundice meter from the docking station.

Visual inspection

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

Validated reprocessing procedures

Overview of the reprocessing procedures of the components

Components	Surface disinfection with cleaning	Manual cleaning followed by disinfection by immersion	Machine cleaning with thermal disinfection	Steam sterilization	Description of the procedure
JM-105 main device	Yes	No	No	No	See page 85

Surface disinfection with cleaning

Components:
– Device components
  – JM-105 main device

Surface disinfectant	Manufacturer	Concentration	Contact time
Dismozon pur	Bode	1.6 %	15 min

Prerequisites:
– The surface disinfectant has been prepared in accordance with the manufacturer's instructions.
– The manufacturer's instructions, e.g., regarding shelf life or application conditions, are observed.
– An uncontaminated, lint-free cloth soaked in surface disinfectant is used for the cleaning surface disinfection.

WARNING
Risk due to penetrating liquid

Penetrating liquid may cause the following:
– Damage to the device
– Electric shock
– Device malfunctions

Ensure that no liquid penetrates the device.

WARNING
Risk of cross contamination

Reusable products must be reprocessed, otherwise there is an increased risk of infection.
– Disinfect the measuring probe before and after every use on a patient.

Cleaning

1 Wipe off obvious soiling with a disposable cloth soaked in surface disinfectant. Dispose of the cloth.

2 Wipe all surfaces. After that, there must no longer be any soiling visible.

Surface disinfection

3 Wipe cleaned surfaces again to visibly wet all surfaces to be disinfected with surface disinfectant.

4 Wait for the surface disinfectant contact time.

5 At the end of the contact time, moisten a new uncontaminated and lint-free cloth with water (at least drinking water quality).

6 Wipe all surfaces until no remains of the surface disinfectant, such as foam residues or streaks, are visible.

7 Wait until the surfaces are dry.

8 Check the surfaces for visible damage and, if necessary, replace the product.

Supplementary information

9 Wipe clean the measuring probe with alcohol before and after taking a measurement on the next patient. Wipe dry with a dry cloth.

Storage and transport

After reprocessing, there are no special requirements for storage and transport of the product. However, the following must be observed:
– Store dry and free of dust
– Avoid recontamination and damage during transport

All further information on storage and transport included in the accompanying documents must be observed.

Other agents and reprocessing procedures

Disinfectants

WARNING

Risk of equipment damage.

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

Do not use benzene, solvents, or thinners.

Use disinfectants that are nationally approved and are suitable for the particular reprocessing procedure.

Surface disinfectants

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:
- Bactericidal
- Yeasticidal
- Virucidal or virucidal against enveloped viruses

Follow the manufacturer's instructions for surface disinfectants.

The following surface disinfectants were compatible with the material at the time of testing:

Class of active ingredient	Surface disinfectant	Manufacturer	Listing
Chlorine-releasing agents	Klorsept 17	Medentech	EPA[1)]
	Actichlor plus	Ecolab USA	EPA
Oxygen-releasing agents	Dismozon pur	BODE Chemie	CE
	Oxycide	Ecolab USA	EPA
	Periodox RTU	Bio Med Protect	CE
Alcohol	Alcohol, ethanol, 70%	Various	All

1) United States Environmental Protection Agency

Dräger states that oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate that the product is not functioning correctly.

Other surface disinfectants are used at one's own risk.

Reprocessing procedures

Surface disinfection with cleaning

Components:
– Chargers
  – JM-A33 docking station

Cleaning

1 For docking station, remove dust and dirt from the surface and from the bottom.

2 Wipe off obvious soiling with a disposable cloth soaked in surface disinfectant. Dispose of the cloth.

3 Wipe all surfaces. After that, there must no longer be any soiling visible.

After reprocessing

Assembling and fitting device-specific components

Prerequisites:
– All components have been reprocessed and are dry.

Assembling the JM-105

1 Prepare the device so that it is ready for use, see chapter Assembly and preparation.

Preparation before next use of device

Checking the operational readiness

Prerequisites:
– The device has been assembled and prepared so that it is ready for operation.

Procedure:

- Check the operational readiness, see chapter "Getting started“.
- Clean measuring probe with alcohol before taking a measurement on the next patient. Wipe dry with a dry cloth.

Service

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 due to inappropriately reprocessed products

The product may be contaminated with infectious agents.

Before service is performed and before the product is sent back for repair, reprocess the product in accordance with the chapter "Reprocessing".

WARNING

Risk when the housing is being opened

Under the housing, there are live electrical components, which may cause an electric shock.

- **The housing may only be opened by those target groups that are assigned to that particular measure.**

WARNING

Risk if service is not performed properly

Personal injury and property damage may occur if service is not performed properly.

Service must be performed by those target groups that are assigned to the particular measure.

WARNING

Risk if maintenance is not performed properly

If the device is connected to the power supply or the gas supply during maintenance, there is a risk of personal injury and property damage.

Before performing maintenance, disconnect all electrical connections from the power supply and all gas connections from the gas supply.

Definition of service terminology

Concept	Definition
Service	All measures (inspection, maintenance, repair) intended to maintain or restore the functional integrity of a product
Inspection	Measures intended to determine and assess the current state of a product
Maintenance	Regular specified measures intended to maintain the functional integrity of a product
Repair	Measures intended to restore the functional integrity of a product after a failure

Inspection

Checks	Interval	Personnel responsible
Inspection	Every 1 year	Service personnel

Performing the inspection

1 Check that the respective instructions for use are present.

2 Perform a functional test of the following functions according to the instructions for use:
- Light measurement
- Internal battery

3 Check that the product is in good condition:
- All labels are complete and legible
- There is no visible damage

4 Observe the instructions for use and check that all components and accessories needed to use the product are present.

5 Check the electrical safety in accordance with the IEC 62353 standard.

Maintenance

WARNING
Risk if service is not performed regularly

Wear and material fatigue of the components may lead to device failure and malfunctions.

Perform service at the specified intervals.

WARNING
Risk of electric shock

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

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 16).

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.

WARNING
Risk if the battery is not replaced properly

If the battery is not replaced properly, short circuits and high temperatures leading to explosion or fire may occur.

The battery must be replaced by the assigned target groups.

Disposal

Disposal of the product

- At the end of its useful life, dispose of the product in accordance with the applicable legal provisions.

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.

Technical data

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)	up to 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 (2.2 ")
Depth	45 mm (1.8 ")
Height	168 mm (6.6 ")
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)
	± 1.6 mg/dL or ± 27.4 μmol/L (≥24 weeks gestation)
Accuracy (σ) after phototherapy	± 2.3 mg/dL or ± 39.00 μmol/L (≥24 weeks gestation)
	± 2.2 mg/dL or ± 38.00 μmol/L (>35 weeks)
Clinical Data Standard Error of Estimate (SEE)	The standard deviation shown above is based on the average of the clinical data available. On average, 66% of results fall within this range, and the remainder fall outside this range. This value can be affected by variables such as age, skin color, and performance of the device in the hands of the user. Refer to Appendixes A for a detailed description of results by gestational age, measurement location, and patient demographics. The SEE shown in the table are based on the clinical data available and can be affected by variables such as infant developmental age, ethnicity, etc. Therefore, we recommend that the JM-105 be used in conjunction with other clinical signs and laboratory measurements. "Specific Bilirubin Measurement" should be confirmed by other methods such as laboratory blood serum analysis.

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.

Data Transmission

USB port	HL-7 or CSV

Barcode formats supported

Code 39

EAN/JAN

Code 128

ANSI/HIBC

Ambient conditions

During operation

Temperature	10 °C to 40 °C (50 °F to 104 °F)

NOTE: The maximum temperature of the measuring probe is less than 30 °C (86 °F) at ambient temperature 25 °C (77 °F).

NOTE: The maximum temperature of the measuring probe is less than 45 °C (113 °F) at ambient temperature 40 °C (104 °F).

Atmospheric pressure	700 hPa to 1060 hPa (-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 122 °F)
Relative humidity	30 % to 95 % (without condensation)
Atmospheric pressure	700 hPa to 1060 hPa

EMC declaration

General information

This device was tested for electromagnetic compatibility using accessories from the list of accessories. Other accessories may only be used if they do not compromise the electromagnetic compatibility. The use of non-compliant accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

This device may be used in the direct vicinity of other devices only if Dräger has approved this device arrangement. If no approval has been given by Dräger, it must be ensured that this device functions correctly in the desired arrangement before use. The instructions for use for the other devices must be followed.

Electromagnetic environment

This device may only be used in environments specified in section "Indications/contraindications" on page 12.

Emissions	**Compliance**
Radiated emissions	Class B, group 1 (30 MHz to 1 GHz)
Conducted emissions	Class B, group 1 (150 kHz to 30 MHz)

NOTE
The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

Immunity against	Test level and required electromagnetic environment
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ±8 kV
	Air discharge: ±15 kV
Fast transient electrical disturbances (bursts) (IEC 61000-4-4)	Power cable: ±2 kV
	Longer signal input lines/output lines: ±1 kV
Impulse voltages (surges) (IEC 61000-4-5)	Voltage, external conductor – external conductor: ±1 kV
	Voltage, external conductor – protective ground conductor: ±2 kV
Magnetic fields at mains frequency (IEC 61000-4-8)	50 Hz: 30 A/m
Voltage dips and short interruptions in the supply voltage (IEC 61000-4-11)	Voltage dips of 30 % to 100 %, 8.3 ms to 5 s, different phase angles
Radiated high-frequency disturbances (IEC 61000-4-3)	80 MHz to 2.7 GHz: 3 V/m
Conducted high-frequency disturbances (IEC 61000-4-6)	150 kHz to 80 MHz: 3 V, ISM bands: 6 V
Electromagnetic fields in the vicinity of wireless communication devices	Various frequencies from 385 MHz to 5785 MHz: 9 V/m to 28 V/m

Recommended separation distances from wireless communication devices

To ensure that the functional integrity of this device is maintained, there must be a separation distance of at least 1.0 m (3.3 ft) between this device and wireless communication devices.

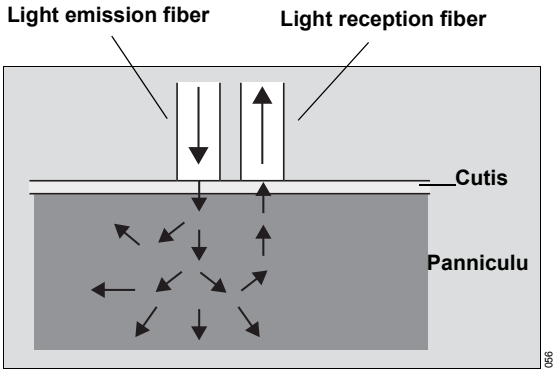
Principles of operation

Measuring principle

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.

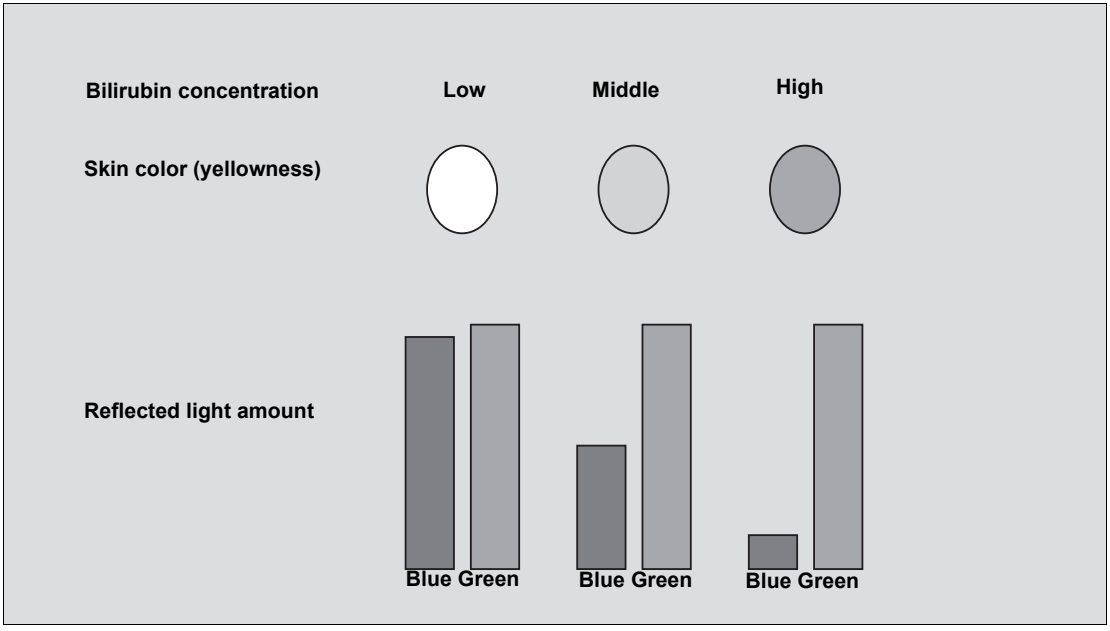
The transcutaneous bilirubin, an indicator of jaundice in infants, absorbs blue and green light. The Jaundice Meter determines the yellowness of the subcutaneous tissue by measuring the difference in the optical densities for light in the blue (450 nm) and green (550 nm) wavelength regions. The measuring 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
.



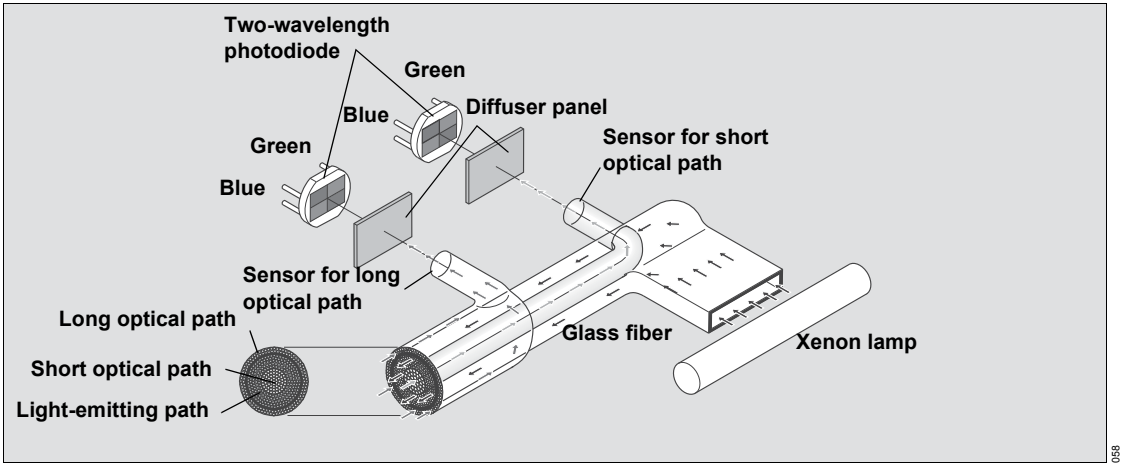
Conceptual drawing of measurement

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

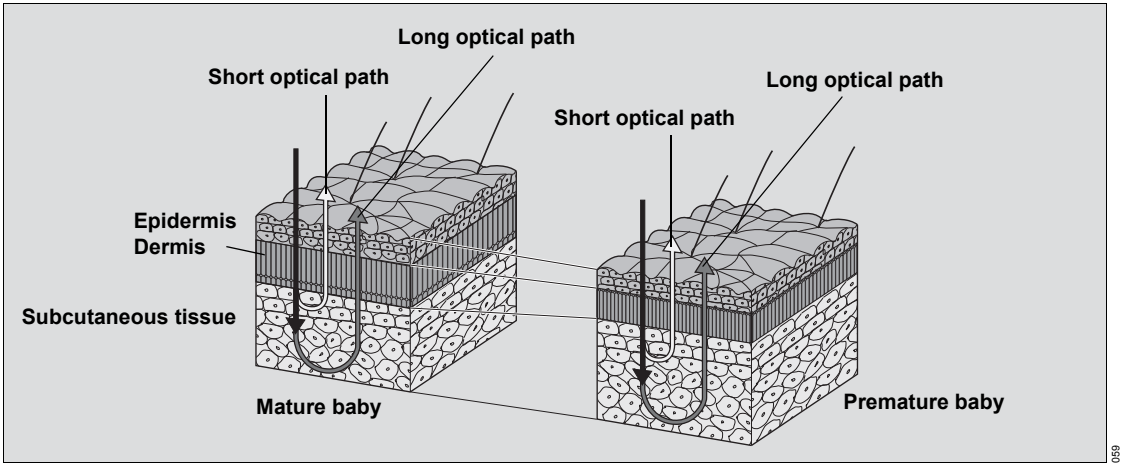
Because the optical density difference shows a linear correlation with the total serum bilirubin concentration, it is converted to the estimated bilirubin concentration. It is indicated digitally.



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.

List of accessories

Standard accessories	
Dräger Jaundice Meter JM-105	MU20105
Docking station with built-in checker, CE, JM-A33, en	MU24805
Docking station with built-in checker, CE, JM-A33, bg	MU24807
Docking station with built-in checker, CE, JM-A33, cs	MU24749
Docking station with built-in checker, CE, JM-A33, da	MU24750
Docking station with built-in checker, CE, JM-A33, de	MU24751
Docking station with built-in checker, CE, JM-A33, es	MU24752
Docking station with built-in checker, CE, JM-A33, fr	MU24753
Docking station with built-in checker, CE, JM-A33, hr	MU24754
Docking station with built-in checker, CE, JM-A33, hu	MU24755
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, no	MU24758
Docking station with built-in checker, CE, JM-A33, pl	MU24759
Docking station with built-in checker, CE, JM-A33, pt	MU24760
Docking station with built-in checker, CE, JM-A33, ro	MU24761
Docking station with built-in checker, CE, JM-A33, ru	MU24762
Docking station with built-in checker, CE, JM-A33, sk	MU24763
Docking station with built-in checker, CE, JM-A33, sr	MU24764
Docking station with built-in checker, CE, JM-A33, sv	MU24765
Docking station with built-in checker, CE, JM-A33, tr	MU24766
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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Appendix A Clinical performance summary

Investigating The Agreement Between Transcutaneous Bilirubin Measurements Using the JM-105 and Total Serum Bilirubin Measurements By Site, Before, During and After Phototherapy in an ethnically diverse population of infants ≥ 24 weeks gestation

Site information

The study was conducted at three academic tertiary hospitals, in the neonatal intensive care units of St. Michael's Hospital, Sinai Health Systems, and McMaster Children's Hospital. All three study sites are located in Ontario, Canada, in two large urban centres (Toronto and Hamilton).

JM-105

Jaundice Meter JM-105, cleared in the United States under K133175, 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.

Currently, the JM-105 is allowed to be used for neonates ≥24 weeks of gestation before undergoing phototherapy or exchange transfusion. In the US, the intended use is restricted to ≥35 weeks of gestation before undergoing phototherapy or exchange transfusion. As such this study evaluates the use of the JM-105 in; 1) term and late preterm neonates > 35 weeks gestation prior to, during and after phototherapy by site (forehead and sternum), 2) in preterm infants between 24-35 weeks gestation prior to, during and after phototherapy by site (forehead and sternum). To ensure generalizability across race and ethnicity, a diverse population was recruited into this study.

Methods

Design

A multi-site prospective trial of neonates born ≥24 weeks gestation was conducted to assess how the agreement between TCB and TSB differs according to the site (forehead vs sternum), treatment (with and without phototherapy) and reported ethnicity of preterm infants.

Population and Settings

Neonates born ≥24 weeks gestation from St. Michael's Hospital, (Toronto, ON) Sinai Health Systems (Toronto, ON) and Hamilton Health Sciences Centre (Hamilton, ON) were included in the study between September 2016- June 2018. As part of routine care all neonates had at least one serum bilirubin (TSB) but typically multiple serum bilirubins measured throughout their stay in the NICU and Post-Partum.

Exclusion criteria

Neonates were excluded from the study if they had one of the following conditions; hydrops fetalis major, congenital malformations, diseases or skin conditions or thickness that in the opinion of the physician would preclude or interfere with the use of the TCB meter (e.g. skin infections, purpura, etc).

Procedures

Upon obtaining informed consent, the JM-105, was used to measure TCB within 15 minutes of every TSB measurement taken in each participating infant. Furthermore, TCB measurements were taken on the forehead and sternum, to determine if its agreement varies by sampling site, when compared to TSB levels. Three separate measurements on the forehead and sternum were taken on each neonate at each routine TSB measurement. This was done for a 10 day period prior to during, and after phototherapy.

Controls

Each subject was their own control group. Each participant received standard of care (total serum bilirubin test) and the intervention (transcutaneous bilirubin measurement with JM-105) within 15 minutes apart. A separate control and intervention group was not possible because it is not ethical to deny participants the standard of care (total serum bilirubin test).

Blinding

All efforts were made to ensure physicians responsible for the clinical care of enrolled neonates were blinded from the transcutaneous bilirubin measurements to reduce bias in the number and frequency of serum bilirubin obtained for each neonate.

Data sources

Paired measurements of 3 TCB measurements on the forehead and sternum with TSB were collected. Hours of age the test was completed and initiation of phototherapy was collected to determine if the measurement was before, during or after phototherapy.

In addition, for all neonates enrolled in the study, demographic and clinical information was collected. This includes infant and maternal demographics, family history illnesses related to hyperbilirubinemia, neonate's medical information (clinical features, laboratory data, treatment and outcome at discharge) via chart extraction.

Outcomes

The primary outcome of the study was to assess how the agreement between TCB and TSB differs according to the site (forehead vs sternum), treatment (with and without) and ethnicity in infants ≥24 weeks gestation.

Analysis

Each infant received three individual measurements using the JM-105 per site per routine bilirubin test. The mean measurement per site per test was calculated according to the JM-105 algorithm manually. The analysis was based on these manually calculated TCB means by site per bilirubin test. The mean of TCB measurements per h To determine the agreement between TCB and TSB levels Bland-Altman plots were developed, and Bland-Altman analyses were run therein. Analyses were conducted over all for all preterm infants, and then further stratified by gestational age groups at 24-28 weeks, 29-32 weeks, 33-35 weeks and >35 weeks. Bland-Altman plots were also developed for a) TCB site measurement (i.e forehead and sternum), b) whether the TCB was obtained pre- or post-phototherapy, and c) by the infant's race/ethnicity. In addition, Pearson correlation coefficients were calculated between all values done on the meter and serum, prior to and after phototherapy.

Sample Size Calculation

Effect size calculations were based on a previous study reporting a mean TSB of 145.8 µmol/L and standard deviation of the average difference between TSB and TCB measurements of 30.0 µmol/L, with negligible variation by gestation length and ethnic group (28).

With the proposed sample sizes, it will be possible to detect a minimum difference between TSB and TCB measurements of 4.2 µmol/L (2.9% difference) for the whole sample (N=400) and a minimum difference of 8.5 µmol/L (5.8% difference)

within strata of GA (N=100), with a statistical significance of 5% and 80% power, 2-sided. Bland Altman plots will be used to determine agreement between the measurements and to identify possible outliers.

Results

Patients

Four hundred sixty four infants between 24-44 weeks were enrolled in the study from three neonatal centres between September 2016- June 2018. All neonates received at least one TCB measurement with the JM-105 on the forehead and sternum at the time of a routine TSB measurement. A total of 1163 TCB measurements were taken from the forehead and sternum. 332 were done prior to the initiation of phototherapy and 831 were done after. Of the 464 infants mean gestational age was 32 weeks and ranged between 24-44 weeks. Table 1 summarizes the demographic characteristics of the study population. Additional information on demographic characteristics of patients can be obtained upon request.

In preterm infants between 24-35 weeks a total of 881 TCB measurements were taken from the forehead and sternum. 186 were done prior to the initiation of phototherapy and 694 were done after. The mean TSB measurement was 124 μmol/L ± 42.17and the median was 121 μmol/Lwith an interquartile range of 30 μmol/L-260 μmol/L. Of the 304 preterm infants the mean gestational age was 30 weeks and ranged between 24-35 weeks gestation. Table 1 on page 112 summarizes the demographic characteristics of the study population.

Agreement Between TSB and TCB

Bland Altman plots were adapted to consider multiple measurements per infant. Traditionally bland altman plots include one measurement per infant, however in this study each infant contributed more than one measurement and a different number of measurements. To account for the repeated measurements per infant an adapted bland-altman plot was constructed using Zou et al 2013's adapted method [28]. The adjusted model calculates the mean difference, mean and variance between TCB and TSB of each infant. Then the mean of the mean differences are calculating taking into account subject variability both between and within. Then the limits of agreement are calculated the traditional way[28]. The Bland-Altman plot describes the agreement of the JM-105 by comparing the difference between TCB and TSB against the average of TCB and TSB by prematurity group, site, and prior to or during/after the initiation of phototherapy. The 95% levels of agreement are calculated using 2 standard deviations.

24-28 weeks

A total of 244 TCB measurements were obtained on the forehead and sternum in infants between 24-28 weeks. Sixteen were done prior to the initiation of phototherapy and 228 were done after the initiation of phototherapy. Mean TCB on the forehead and sternum prior to the initiation of phototherapy was 84.3 μmol/L (44.3-153.3 μmol/L) and 72.9 μmol/L (21.5-151.5 μmol/L) respectively. During and after the initiation of phototherapy the mean TCB was 79.7 μmol/L on the forehead (19.50-182 μmol/L) and 73.1 μmol/Lon the sternum (19.5-173 μmol/L).

29-32 weeks

A total of 398 TCB measurements were obtained on the forehead and sternum in infants between 29-32 weeks. Seventy were done prior to the initiation of phototherapy and 328 were done after/during the initiation of phototherapy. Mean TCB on the forehead and sternum prior to the initiation of phototherapy was 121.6 μmol/L (55.6-228.6 μmol/L) and 107.6 μmol/L (47.1-222.3 μmol/L) respectively. During and after the initiation of phototherapy the mean TCB was 112.7 μmol/L on the forehead (24.5-229.6) and 107.6 μmol/L on the sternum (20.5-256.1 μmol/L).

33-35 weeks

A total of 245 TCB measurements were obtained on the forehead and sternum in infants between 33-35 weeks. Ninety-nine were done prior to the initiation of phototherapy and 146 were done after/during the initiation of phototherapy. Mean TCB on the forehead and sternum prior to the initiation of phototherapy was 154.5 (17.6-272.1 μmol/L) and 150 μmol/L (20.6-247.5 μmol/L) respectively. During and after the initiation of phototherapy the mean TCB was 148.6 μmol/L on the forehead (48.8-268.6) and 143.1μmol/L on the sternum (43.00-267.50 μmol/L).

>35 weeks

A total of 276 TCB measurements were obtained on the forehead and sternum in infants >35 weeks gestation. One hundred and forty seven were done prior to the initiation of phototherapy and 129 were done after/during the initiation of phototherapy. Mean TCB on the forehead and sternum prior to the initiation of phototherapy was 140.1 (7.50-348 μmol/L) and 136.5 μmol/L (7.50-351.3 μmol/L) respectively. During and after the initiation of phototherapy the mean TCBwas 210.1 μmol/L on the forehead (51.6-348) and 190.2 μmol/L on the sternum (46-351.3 μmol/L).

Correlation between TSB and TCB

Pearson's correlation is described by gestational age, site of measurement and ethnicity. Precision between TCB and TSB does not appear to change substantially by gestational age, site, and initiation of treatment or ethnicity. The Pearson's correlation prior to phototherapy ranged between 0.481-0.886 and 0.397-0.796 after the initiation of phototherapy.

Tables

Table 1 – Demographic characteristics of study population

Demographic	
Gender	
Female	46 %
Male	54 %
Gestational age, weeks (mean ± SD) (μmol/L)	33.5 ± 4.6
Birth weight (g)	2155 ± 1001.7
Delivery type	
Cesarean section	48.9 %
Vaginal	41.4 %
Unknown (information not accessible)	9.7 %
TSB Phototherapy range and initiation of treatment	
TSB phototherapy range (mean ± SD range) (μmol/L)	137 ± 56.79 (21 to 409)
Hours of age phototherapy initiation (mean, ± SD) (h)	39.02 ± 31.08 (2 to 263)

Summary

To date this is the largest study comparing transcutaneous bilirubin measurements to total serum bilirubin measurements in preterm infants ≥24 weeks gestation. As per our sample size calculation of a minimum of 400 neonates ≥24 weeks gestation to ensure sufficient power to compare transcutaneous and total serum bilirubin measurements, a sample size of 464 neonates with 1163 TCB measurements meets the statistical requirement of a sufficient sample size for this study. This study also includes a very diverse and expanded demographic background including a wide range of ethnicities and races. To ensure optimal measurement points this study used different measurement sites including the forehead and sternum to determine the optimal use of the JM-105. Finally, to ensure generalizability this study was conducted at three large neonatal centres.

References

1 Sgro M, et al. Severe Neonatal Hyperbilirubinemia Decreased after the 2007 Canadian Guidelines. *J Pediatr.* 2016;171:43-47.

2 Chawla D, et al. Accuracy of transcutaneous bilirubin measurement in preterm low-birthweight neonates. *J Pediatr.* 2014;173(2):173-179.

3 Myers MG, McMahon BJ, Koontz FP. Neonatal calcaneous osteomyelitis related to contaminated mineral oil. *J. Clin Microbiol.* 1977;6(5):543-544.

4 Meites S. Skin-puncture and blood-collecting technique for infants: update and problems. *Clin Chem.* 1988;34(9):1890-1894.

5 Afanetti M, et al. Transcutaneous bilirubinometry is not influenced by term or skin color in neonates. *Early Hum Dev.* 2014;90(8):417-420.

6 Leite M, et al. Comparison of transcutaneous and plasma bilirubin measurement. *TJ Pediatr (Rio J).* 2007;83(3):283-286.

7 Wainer S, et al. Impact of a transcutaneous bilirubinometry program on resource utilization and severe hyperbilirubinemia. *IPediatricss.* 2012;129(1):77-86.

8 Campbell DM, et al. Transcutaneous bilirubin measurement at the time of hospital discharge in a multiethnic newborn population. *Paediatr Child Health.* 2011;16(3):141-145.

9 Bhutani VK, Wong RJ. Bilirubin neurotoxicity in preterm infants: risk and prevention. *J Clin Neonatol.* 2013;2(2):61-69.

10 Fine KL, et al. Defining the limitations of transcutaneous bilirubin measurement in late preterm newborns. *J Perinatol.* 2017;37(6):658-661.

11 N D. Clinical Summary Report for the Use on Preterm Infants. 2013.

12 Ebbesen F, Brodersen R. Comparison between two preparations of human serum albumin in treatment of neanatal hyperbilirubinaemia. *Acta Pædiatrica.* 1982;71(1):85-90.

13 Jangaard K, Curtis H, Goldbloom R. Estimation of bilirubin using BiliChektrade mark, a transcutaneous bilirubin measurement device: Effects of gestational age and use of phototherapy. *Paediatr Child Health.* 2006;11(2):79-83.

14 Schmidt ET, et al. Evaluation of transcutaneous bilirubinometry in preterm neonates. *J Perinatol.* 2009;29(8):564-569.

15 Rubio A, et al. Diagnosis Accuracy of Transcutaneous Bilirubinometry in Very Preterm Newborns. *Neonatology.* 2017;111(1):1-7.

16 Sajjadian N, et al. Transcutaneous bilirubin measurement in preterm neonates. *Acta Med Iran.* 2012;50(11):765-770.

17 Conceicao CM, et al. Influence of assessment site in measuring transcutaneous bilirubin. *Einstein (Sao Paulo).* 2014;12(1):11-15.

18 Kurokawa D, et al. Screening for Hyperbilirubinemia in Japanese Very Low Birthweight Infants Using Transcutaneous Bilirubinometry. *J Pediatr.* 2016;168:77-81 e1.

19 Kitsommart R, et al. Accuracy of transcutaneous bilirubin measured by the BiliCare device in late preterm and term neonates. *J Matern Fetal Neonatal Med.* 2016;29(22):3641-3645.

20 Nagasaka M, et al. Transcutaneous bilirubin monitoring predicts unexplained late-onset hemolysis in a very low birthweight infant. *BMC Res Notes.* 2016;9:153.

21 Juster-Reicher A, et al. Correlation of transcutaneous bilirubinometry (TcB) and total serum bilirubin (TSB) levels after phototherapy. *J Matern Fetal Neonatal Med.* 2014:1-3.

22 Casnocha Lucanova L, et al. Accuracy of transcutaneous bilirubin measurement in newborns after phototherapy. *J Perinatol.* 2016;36(10):858-861.

23 Nagar G, et al. Reliability of transcutaneous bilirubin devices in preterm infants: a systematic review. *Pediatrics.* 2013;132(5):871-881.

24 Quist FK, et al. Clinical utility of transcutaneous bilirubinometer (TcB) in very low birth weight (VLBW) infants. *J Perinat Med.* 2016;44(8):933-939.

25 Jnah A, Newberry DM, Eisenbeisz E. Comparison of Transcutaneous and Serum Bilirubin Measurements in Neonates 30 to 34 Weeks' Gestation Before, During, and After Phototherapy. *Adv Neonatal Care.* 2018;18(2):144-153.

26 Raimondi F, et al. Measuring transcutaneous bilirubin: a comparative analysis of three devices on a multiracial population. *BMC Pediatr.* 2012;12:70.

27 Taylor JA, et al. Discrepancies between transcutaneous and serum bilirubin measurements. *Paediatrics.* 2015;135(2):224-231.

28 Zou GY. Confidence interval estimation for the Bland-Altman limits of agreement with multiple observations per individual. *Stat Methods Med Res.* 2013;22(6):630-642.

29 Sgro, M, Shah, V, Twiss, J. Investigating The Agreement Between Transcutaneous Bilirubin Measurements Using the JM-105 and Total Serum Bilirubin Measurements By Site, Before, During and After Phototherapy in an ethnically diverse population of infants ≥ 24 weeks gestation. *Clinical study.* 2019.

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