

Dräger Jaundice Meter JM-105

Sample Usage Protocol Template

Purpose

This Sample Usage Protocol is provided as a template for creating a facility or department-specific protocol for using the Dräger Jaundice Meter JM-105.

Description and Intended Use

The Dräger Jaundice Meter JM-105 is intended for use as a screening device for jaundice in the newborn. The Jaundice Meter JM-105 provides a transcutaneous measurement of bilirubin in mg/dL or $\mu\text{mol/L}$, identifying neonates who require a serum bilirubin measurement.*¹

- For the intended use please refer to the instructions for use

Screening for Hyperbilirubinemia

When combined with a systematic assessment of the risk factors for hyperbilirubinemia, the Dräger Jaundice Meter JM-105 can identify neonates who are at increased risk for more severe hyperbilirubinemia in the first week of life, and who might require closer monitoring.

Two protocols are suggested for using the Dräger Jaundice Meter JM-105 as a screening device for hyperbilirubinemia. One is based on risk factors, the other is universal screening.

1. Risk Factors

Neonates with the following risk factors should be screened for hyperbilirubinemia with the Jaundice Meter JM-105*³:

- Jaundice within 1st 24 hours (also send TSB to laboratory)
- Blood group incompatibility/+DAT (also send TSB to laboratory)
- Visible jaundice after 24 hours of age
- ≤ 38 weeks gestation
- Bruising/vacuum extraction/cephalhematoma
- Breastfeeding
- Inadequate feeding/excessive weight loss
- Sibling with jaundice
- East Asian race
- Ethnic group at risk for G6PD deficiency (African-American male, Greek/Mediterranean, Italian, Middle Eastern)

When risk factors are used, the neonate with risk factors should be screened with the Dräger Jaundice Meter JM-105 prior to discharge, or earlier if jaundice is noted.

2. Universal Screening

Screen all neonates with the Jaundice Meter JM-105 prior to discharge.

Note: neonates with jaundice in the first 24 hours of life should be screened immediately and also have a serum bilirubin sent to the laboratory.

Testing Procedure

Prepare the Jaundice Meter JM 105 for Use – Perform the Daily Operational Checkout Procedure

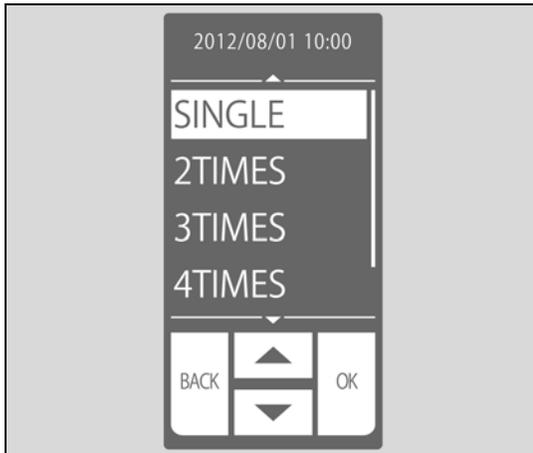
1. Remove the Jaundice Meter JM-105 from the docking station.
2. Press the power switch on.
3. Select CHECKER and touch OK to save selection.
4. Open the checker lid on the charging unit.
5. When the green READY light illuminates, place the tip of the Jaundice Meter perpendicular on the reading checker circle. Press down until you hear a click.
6. The display screen shows the "L" (long), "S" (short), and Delta values. The meter must read within the reference values posted under the checker lid. If so, the unit is ready to use. If not, clean the tip and repeat. If values are still out of range, do not use the unit (contact the Dräger service department).

Configure the Jaundice Meter JM-105

1. Press the power switch on.
2. If you want to change your file storage option, configure the device as desired by selecting CONFIG > MEMORY > OK > your desired setting (OFF, MEM ONLY, or LINK ON) > OK. If not, go to step 4.



3. Press the MENU button to exit the CONFIG screen.
4. Determine whether or not you want to average your measurements and how many measurements you want to take. Configure the device as desired by selecting CONFIG > AVERAGE > OK > your desired setting (SINGLE through 5TIMES) > OK.



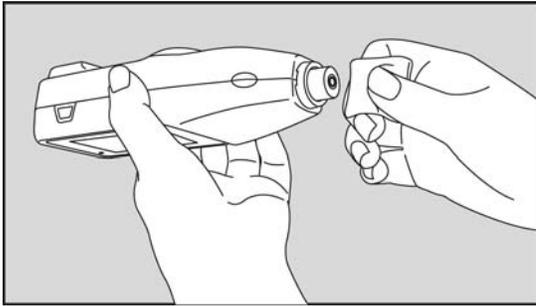
- Determine the current setting for measurements that are out of range. Select CONFIG > UNIT. One of the screens below will appear. The default for devices with SW 1.20 or higher is HI: >20 or HI: >340, depending on the unit configured. For devices with SW 1.10 or lower, the default is not editable and will only be a blinking zero.



NOTE: To change this setting to blinking zero (HI: -0-), refer to the instructions for use. It must be changed using the data transmission software, SW JM-S1w. Requires JM-S1w version 1.40 or higher.

Take a Transcutaneous Bilirubin (TcB) Measurement

1. Clean the tip of the probe with an alcohol swab.



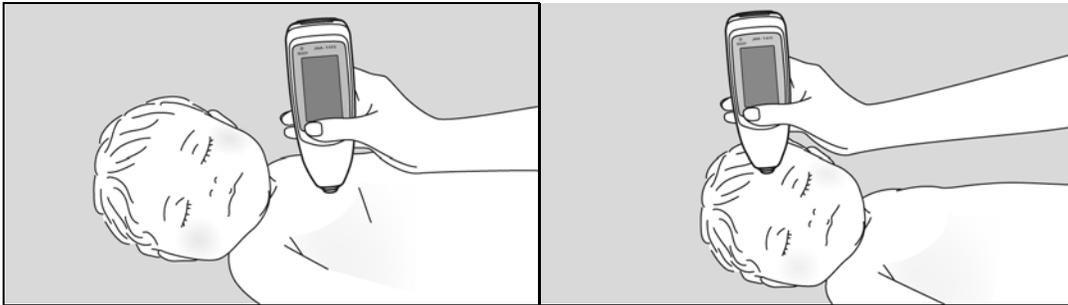
2. Press the power switch on.
3. Select MENU, select MEASURE, and press OK. The letters AVE with the number of measurements selected will appear in the display.



4. Select measurement site:

Hospital Nursery/Postpartum/Family Birth Center – the neonate’s mid-sternum is preferred but the forehead can be used.

Physician’s Office/Clinic/Outpatient Setting/Emergency Room – use *only* the neonate’s mid-sternum. Rationale: these neonates have been discharged from the hospital and their faces have been exposed to more ambient sunlight.



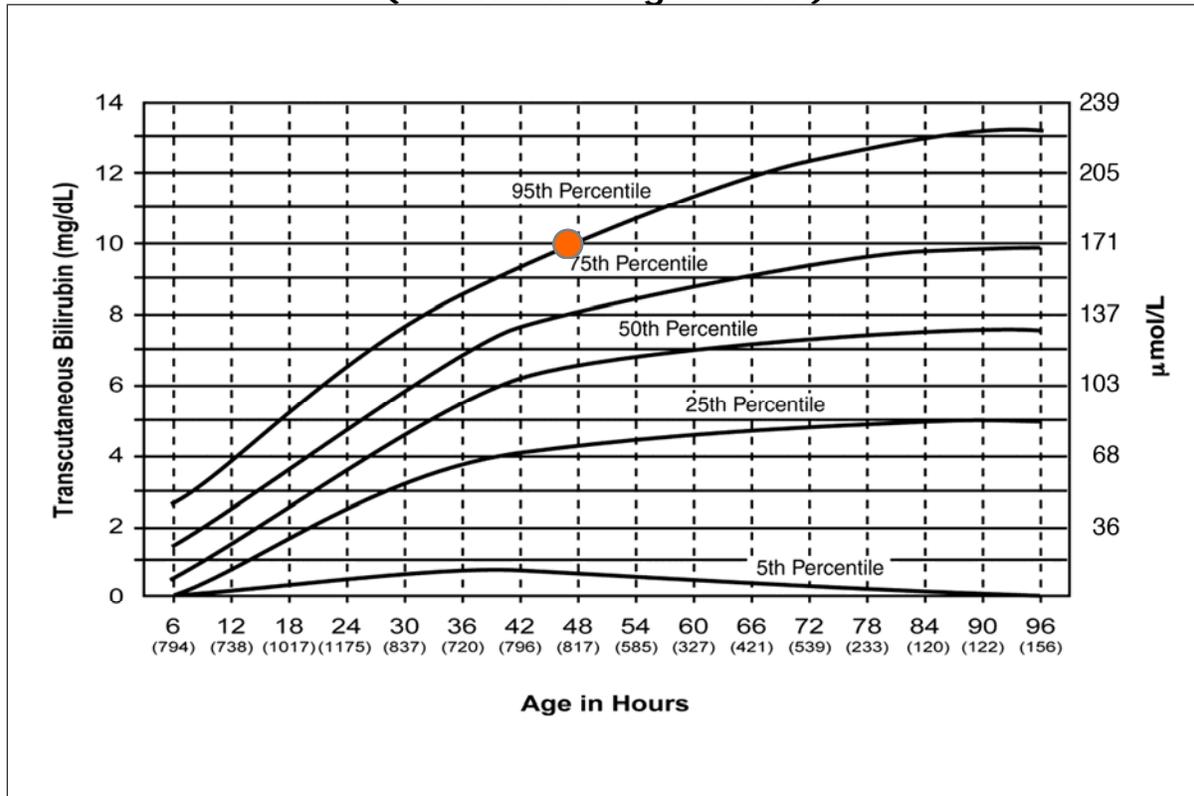
5. Place the Jaundice Meter JM-105 probe tip flat against the baby’s skin, **not at an angle**, and press lightly until you hear a click. Lift the Jaundice Meter JM-105 from the skin between measurements and pause until the green READY light illuminates again. Repeat the testing procedure until the required number of measurements has been taken.
6. If the measured value is out of the measuring range (0 to 20 mg/dL or 0 to 340 μ mol/L), a blinking value appears. The blinking value depends on the preference set, -0-, >20, or >340.



NOTE 1: Blinking >20 and >340 are only available on devices with SW 1.20 or higher.

NOTE 2: To check this setting, refer to **Configure the Jaundice Meter JM-105, step 5**.

**Plot the Result on the Transcutaneous Bilirubin Nomogram
(Neonates Up to 96 Hours of Age Only) *4
(≥35 weeks of gestation)**



On the horizontal axis, find the baby’s age in hours. Follow this line up along the vertical axis to the point where it meets the transcutaneous bilirubin meter reading you just obtained. Make a small circle where these two values intersect. You can now see into which percentile range the baby’s TcB value falls.

In the example above, the baby’s TcB is 10 mg/dL at 50 hours of age. This places the baby just at the edge of the 95th percentile. [A TSB should be obtained on this baby.]

Consult your department policy or routine orders regarding when to send a total serum bilirubin to the laboratory, and/or report these TcB results to the baby’s physician.

Subsequent TcB measurements should also be plotted on the graph to allow detection of an unusual trend such as a rapidly rising TcB.

Staff Competency Validation

All clinical personnel responsible for performing Jaundice Meter JM-105 testing must be properly trained prior to using the device in a clinical setting. Training will be completed as follows:

1. Staff responsible for using the Jaundice Meter JM-105 will receive a demonstration of the JM-105 by an experienced Jaundice Meter JM-105 operator OR will view the Jaundice Meter JM-105 training video. Learners are also responsible for reading the information provided in the Operating Instructions Manual.
2. Learners will perform a return demonstration on three infants in the presence of an experienced Jaundice Meter JM-105 operator and complete the attached Skills Checklist.
3. Successful completion of training will be documented in the employee's education record.

New or Serviced Device Validation

It is recommended that users validate the Jaundice Meter JM-105 in their individual patient populations prior to putting it into clinical use. You can do this by taking transcutaneous bilirubin readings with the Jaundice Meter on infants who are already scheduled to have blood drawn for serum bilirubin analysis by the lab. The time gap between the transcutaneous bilirubin readings and the blood sample should not be greater than one hour. Record the reading along with the serum bilirubin results from the lab on a data collection sheet like the one attached to this document. When you have recorded enough simultaneous jaundice meter readings and serum bilirubin, you can use this information to develop a protocol for use of the jaundice meter in your facility.

References

1. Dräger Jaundice Meter Model JM-105 Instructions for Use.
2. E T Schmidt, C A Wheeler, G L Jackson and W D Engle, Evaluation of transcutaneous bilirubinometry in preterm neonates, *Journal of Perinatology* 29 : 564-569 March 2009.
3. Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation. *Pediatrics* Vol. 114 No. 1 July 2004
4. Maisels MJ, Kring E. Transcutaneous bilirubin levels in the first 96 hours in a normal newborn population of ≥ 35 weeks' gestation. *Pediatrics*. 106;117(4):1169-117.

Dräger Jaundice Meter JM-105 Data Collection Sheet

Please write your Jaundice Meter SN #: _____
 Site for all Jaundice Meter measurements: _____

- Patient # - Hours of Age & - Race or Skin Color	JM-105 reading TcB	Time / Date JM-105 Reading taken*	Serum Bilirubin analysis Result TSB	Time/ Date blood sample drawn*	Staff Initials and Comments:
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*The time gap between the Jaundice Meter JM-105 readings and the blood sample should **not** be greater than one hour.