

EFFECTIVE USE OF THE KONICA MINOLTA / DRAEGER MEDICAL AIR-SHIELDS® JM-103 JAUNDICE METER

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INTRODUCTION

The Air-Shields® JM-103 Jaundice Meter is an instantaneous and non-invasive device that can assist in the management of neonatal jaundice. Used in conjunction with other clinical signs and laboratory measurements this information can assist in making clinical decisions regarding the need for additional serum bilirubin measurements.

The Air-Shields® JM-103 Jaundice Meter has been designed as a screening tool to estimate the relative amount of bilirubin present in the infant's blood by utilizing transcutaneous measuring technology. It has not been designed to replace serum bilirubin analysis.

It should be noted that transcutaneous measurement of bilirubin in newborns has been an accepted screening tool since the early 1980's¹. The Air-Shields® JM-103 represents an advance in this technology in that the device reports the bilirubin level in the common units of measurement (mg/dl or $\mu\text{mol/L}$). These are the same units of measure reported by the clinical laboratory. Previous transcutaneous devices merely reported a "reference" number that had to be correlated to the laboratory results through a time consuming process of data collection and creation of a calibration curve.

There can be interlaboratory variability of bilirubin measurements² therefore the blood serum analysis performed in the clinical laboratory may not exactly match the results determined with the Air-Shields® JM-103. In clinical studies³ it was found that the RMSE (Root Mean Square Error) of the collected samples was ± 1.5 mg/dl (± 25.5 $\mu\text{mol/L}$). Some users may find a greater variability. Accuracy of the device is relative to the method or instrument it is compared against.

The Air-Shields® JM-103 can be used as a screening tool that provides an immediate assessment of the patients' condition and eliminates unnecessary and painful heel-sticks.

PRODUCT "VALIDATION"

Most users choose to "validate" the product prior to putting it into clinical use. They do this by taking Air-Shields® JM-103 readings on those patients who are already scheduled to have blood drawn for serum bilirubin analysis. The Air-Shields® JM-103 readings are recorded and compared to the subsequent laboratory results. When a suitable number of data points have been obtained the user generally finds one of three types of results:

a. The Air-Shields® JM-103 results and laboratory serum bilirubin results are virtually identical.

In this situation the user will begin to use the JM-103 and consider the meter's output a direct correlation to the laboratory.

b. The JM-103 results are lower to a consistent degree than the laboratory serum bilirubin results or the results are higher to a consistent degree than the laboratory serum bilirubin results.

This situation indicates that there is consistent variability between the JM-103 and the laboratory instrumentation. In this case the user should determine the relative difference and adjust their protocol accordingly. For example, if the NICU protocol considers a bilirubin measurement of 14 mg/dl (239 $\mu\text{mol/L}$) to be "critical" and the JM-103 is consistently showing results of about 3 mg/dl lower than the lab, the user could choose to consider any JM-103 reading of 11 mg/dl (188 $\mu\text{mol/L}$) or higher to meet their definition of "critical". A blood sample would then be obtained to verify the result and the appropriate clinical action taken. If the JM-103 is providing higher readings than the laboratory, the same logic can be applied.

c. The JM-103 results are sometimes higher, lower or equal to the serum bilirubin results

This situation indicates either a problem with the way the meter

is being used (i.e. poor technique) or a problem with the meter itself. Refer to the "troubleshooting" section of this document for information on how to assess this situation.

CHECKING THE UNIT

As with any piece of equipment it is advisable to periodically check the calibration of the unit. The JM-103 is supplied with a "reading checker" built into the charger base. Per the JM-103 user manual it is advisable to perform a calibration check once per day. The procedure for this is clearly outlined in the manual. In addition to the calibration check, there is value to periodically comparing the JM-103 results to serum bilirubin analysis. One user reported that they compared their older JM-102 Jaundice Meter every 3 months against 5 to 10 serum bilirubin determinations to confirm that readings were consistent with previous measurements⁴.

TROUBLESHOOTING

If the user finds that readings from the JM-103 are falling into situation "c" described in section 2 above, the list of questions outlined in Table 1 should be reviewed. If answers to any of these questions are "no", then the user should make the appropriate correction to their technique and try the product again.

It should be noted that the JM-103 can be set to take multiple readings and provide a result that is the average of these readings. This "averaging" method may help reduce any user error. The JM-103 can be set to take up to 5 readings and automatically average the results. If difficulty is experienced in obtaining consistent results, the user should try this method. The JM-103 user manual provides instructions on how to set the product to take average readings.

Clinical data collected³ indicates a slightly better correlation to the serum analysis when the sternum is used as the site for taking the JM-103 reading rather than the forehead. Users should consider this fact when evaluating their results.

Table 1: Troubleshooting the JM-103

Question	Rationale	Suggestion
Were the patients of a gestational age greater than 35 weeks?	The JM-103 has only been validated for use on patients with a gestational age of greater than 35 weeks. Babies younger than this may have skin that is not developed sufficiently to obtain accurate readings	Use only on patients with a gestational age greater than 35 weeks.
Is there assurance that patients had not undergone Phototherapy treatment prior to the JM103 measurement?	The JM-103 is only useful on patients that have not yet received phototherapy. The concentration of bilirubin in the skin will be lower relative to the blood concentration after phototherapy.	Use only on patients that are pre-phototherapy.
Is the measuring probe being held perpendicular to the skin surface when the reading is taken?	If the probe is not held properly against the skin, an inaccurate reading will result.	Review the operator manual and use proper measuring techniques.
Was the JM-103 reading taken at the same time the blood was drawn for the serum bilirubin analysis?	A time lapse from when the reading is taken and the blood collected (or vice a versa) could provide a difference between the JM-103 reading and the serum bilirubin level reported.	Take the JM-103 reading at the same time the blood sample is collected.
Was the blood sample analyzed within a reasonable amount of time after collection?	The longer it takes to analyze a blood specimen the greater the possibility that degradation of the sample can occur thus providing inaccurate results.	Assure that blood specimens are analyzed within an acceptable amount of time following collection.
Was the JM-103 checked against the "reading checker" to assure that the meter is properly calibrated?	If the JM-103 is not within the parameters stated on the reading checker, the unit will not provide correct results.	Check the JM-103 daily against the reading checker as outlined in the user manual.

MANAGEMENT OF HYPERBILIRUBINEMIA

Clinicians frequently seek advice on how to manage and evaluate hyperbilirubinemia in the newborn. The American Academy of Pediatrics has issued a Practice Guideline on this subject entitled, *Management of Hyperbilirubinemia in the Healthy Term Newborn*⁵. This document can be viewed on the AAP website at <http://www.aap.org/policy/hyperb.htm>.

REFERENCES

- 1 Maisels MJ, et al; Transcutaneous bilirubin measurements in full-term infants, *Pediatrics*, 1982 Sep
- 2 Vreman HJ, Verter J, Oh W, Interlaboratory variability of bilirubin measurements. *Clin Chem*. 1996; 42:869-873
- 3 Konica Minolta / Dräger Medical Air-Shields® JM-103 User Manual USR070RA, 2003 May; A1- A16
- 4 Maisels MJ, Kring E Transcutaneous bilirubinometry decreases the need for serum bilirubin measurements and saves money. *Pediatrics*. 1997; 99:599-601
- 5 Provisional Committee for Quality Improvement and Subcommittee on Hyperbilirubinemia. Practice Parameter: Management of Hyperbilirubinemia in the Healthy Term Newborn. *Pediatrics* 1994;84(4):558-565.