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The Preemie-Test for the assessment of the newborn skin maturity

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ABSTRACT

The authors describe the skin reflection measurement, obtained using a handheld optoelectronic device, to estimate gestational age of a newborn. The prototype unit of measurement and process of gestational age estimation were patented under number BR1020170235688 (CTIT-PN862) PCT/IB2017/056786 (WO2018083602).

The Preemie-Test device was developed to detect the preterm newborns by analyzing the photobiological properties of the newborn's skin. This noninvasive and non-ionizing technology features a probe containing light emitters and receivers that is brought in contact with the newborn's foot and, using mathematical algorithms, provides an estimated dating within seconds

The device provides automatic data acquisition with minimum operator influence and stores values in an electronic database. No values will be displayed on the device screen, thereby blinding the users to the results obtained at the time of acquisition.

GUIDELINES

The present protocol intended the standardization of the Preemie-Test assessment during clinical trials related with this medical device. Includes newborn care, equipment cleaning procedures, and the skin assessment.

MATERIALS

NAME

CATALOG #

VENDOR

70% isopropyl alcohol

SAFETY WARNINGS

- Ask permission for the health professional responsible for the childcare, and check if the health conditions of the newborn are stable enough to perform the assessment.
- Hand hygiene according to international recommendations, according to WHO Guideline: https://www.who.int/gpsc/5may/hh_guide.pdf
- Use 70% alcohol swab on the whole sensor of the equipment and the most touching parts.
- Wear gloves if necessary for newborn security, according to the NICU recommendations.
- Never use the incubator as an auxiliary table during the Preemie-Test assessment.

BEFORE STARTING

Check the Preemie-Test device equipment for dirt. If present, clean it using a lightly moistened pad with water and liquid soap without soaking to avoid damaging the equipment. Then remove the soap using another cloth slightly moistened with water and dry with a clean and dry cloth.

Make sure that the equipment is fully charged.

1 **The foot of the newborn examination:**

Expose the newborn's foot gently. Do not raise the lower limb to perform the exam.

Do not handle the newborn. Instead, examine the child where he is being cared for: inside the incubator, warm crib or mother's lap.

2 **Determining the position of the skin assessment:**

The Premie-Test should be performed on the skin of the posterior portion of the sole of the foot (Figure 1). Imagine two diagonal lines running through the child's sole region and choose the central area where these lines meet.

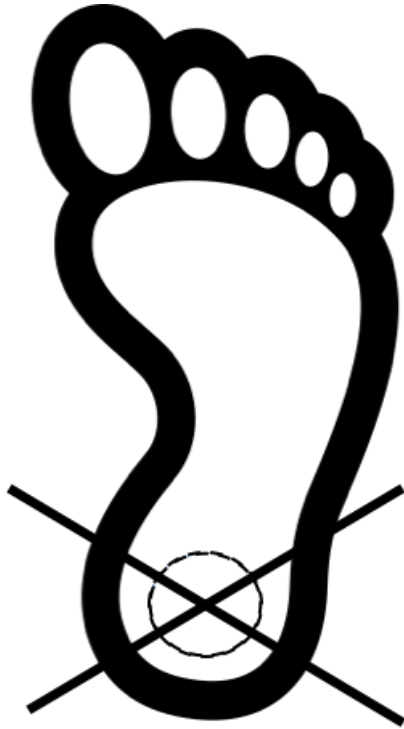


Figure 1 - Standard position to touch the newborn's skin with the sensor of the device

3 Position of the sensor during the assessment:

Touch the skin with the sensor should perpendicularly (90 degrees - Figure 2)



Figure 2 - Axis of the sensor when touching the skin

4 Performing the test:

Follow the instructions according to the messages that will appear on the Premie-Test display.

Repeat the assessment three times in the same site of the skin foot.



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