Pain Monitor for Neonates and Infants

A breakthrough in neonatal developmental care.
**Clinical Considerations**

It is estimated that a human being can feel pain starting from the 24th week of intrauterine life; there is a correlation between the age of the newborn baby and their reaction to pain. The younger the infant, the more significant the reaction is in response to a painful stimulus. Similarly with repetition of painful procedures, the intensity of the response will be proportional to the number of stimulations. In general fear, anxiety or depression can increase perception of pain in adults; similarly these factors influence the neonate, who cannot understand what is happening.

Behavioural rating scales are not always easy to use and all can be time-consuming. Those used for prolonged pain assessment, such as the Neonatal Pain Assessment Tool (PAT), have to be repeated, typically at hourly intervals. Even tools used only for checks during procedures become significant with the typical number of interventions each patient requires in a single day. The demand on nursing time to carry out pain assessments is therefore almost impossible in today’s busy neonatal unit and paediatric care environments.

Whichever of the numerous pain evaluation protocols are used, the subjectivity of the assessment adds possible uncertainty. The clinician must be able to assess what they see and disregard subjective impressions; pain scores can often vary for the same patient, as individual nurses may perceive responses differently. This inevitably makes it difficult to achieve consistency and accuracy of assessment.

It is particularly important to evaluate the activity of the parasympathetic nervous system of pre-term babies as it is now well documented that whatever the degree of prematurity there is a large deficit in autonomic regulation capacity compared to that of full-term babies. Parasympathetic tone correlates to discomfort or wellbeing, giving an objective measure of pain.

Numerous developmental care studies have shown that premature infants are particularly sensitive to stress. Situations that cause pain or discomfort can impact the neurodevelopment of the baby and can have long-term health consequences.

**Developmental Care**

Monitoring allows nursing staff to observe the impact of environmental conditions such as noise, light, positioning, choice of face-mask, etc, and optimise for the individual patient. The positive influences generated by developmental care activities such as parental contact, cocooning, kangaroo care, etc, can be quantified, reinforcing the benefits and encouraging family centred care.

The NIPE index assists clinical staff in adapting post-operative and other analgesia protocols to the individual patient. Similarly the treatment before and during a potentially painful or stressful procedure in the NICU can be adapted by monitoring the NIPE index, as can analgesia at these times or during surgery.
Objective Pain Assessment

The NIPE monitor provides an index based on an electrophysiological signal and it evaluates continuously, without the need for any extra sensors. This ensures a consistent and objective rating of acute pain and/or patient comfort, available at all times and with minimal demand on nursing time.

The system allows both continuous and instantaneous assessment of the parasympathetic component of the autonomic nervous system in babies and young infants. The NIPE technology has proven efficacy in premature babies from around 26 weeks’ gestation through to infants up to two years of age, using the ECG signal from the patient monitor in use.

Correlation of acute or chronic pain

The NIPE monitor displays a trend curve which correlates to both chronic and acute pain levels. The overall trend shows the averaged (NIPEm) index and gives an assessment of long term pain or comfort, whilst red spikes indicate acute episodes, typically from procedures or surgical stimuli.

A highly visible digital display indicates current NIPE index, with the user able to toggle between averaged or instantaneous (NIPEi) value to quantify chronic and acute pain status. Substantial research has quantified the NIPE index thresholds that correlate to significant pain, or conversely to a patient who is comfortable.

Features & Benefits

Patient Centred Care

- Enhances developmental care practice
- Treatments can be adapted for individual infant
- Pain management protocols can be adapted for the infant
- Removes subjective interpretation of behavioral rating scales
- Effectively proven from 26 weeks’ gestation up to age of 2 years

Simple, Effective, Time-Saving

- Easy to use device
- Simple interpretation of readings
- No additional sensors required
- Continuous assessment of long term pain or comfort
- Instantaneous assessment quantifying chronic and acute pain
Specifications:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Input (Adapter)</td>
<td>100 - 250Vac, 50Hz</td>
</tr>
<tr>
<td>Power Consumption</td>
<td>49W</td>
</tr>
<tr>
<td>Power Input (Monitor)</td>
<td>12Vdc ±5%, 40W</td>
</tr>
<tr>
<td>Display</td>
<td>Colour LCD, with backlight</td>
</tr>
<tr>
<td>Size</td>
<td>27.0 x 24.7 x 14.5 cm (W x H x D)</td>
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<tr>
<td>Weight</td>
<td>1.85kg</td>
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<tr>
<td>Operating Temperature</td>
<td>+5°C to +35°C</td>
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<tr>
<td>Storage Temperature</td>
<td>-20°C to +60°C</td>
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<tr>
<td>Compliance</td>
<td>EN 60601-1, EN 60601-1-2, MDD 93/42/EEC</td>
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Notes:
These specifications may change without notice due to continuous product improvement.
This product is manufactured and marketed by Mdoloris Medical Systems.

References:

5. Kuissi et al. Effect of the positioning on the HRV in premature newborns. JFRN, 2009