

NIPE Monitor VI

PRODUCT BROCHURE



The **FIRST** comfort **ASSESSMENT** monitoring system for **NEONATES**.

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 reactions 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.

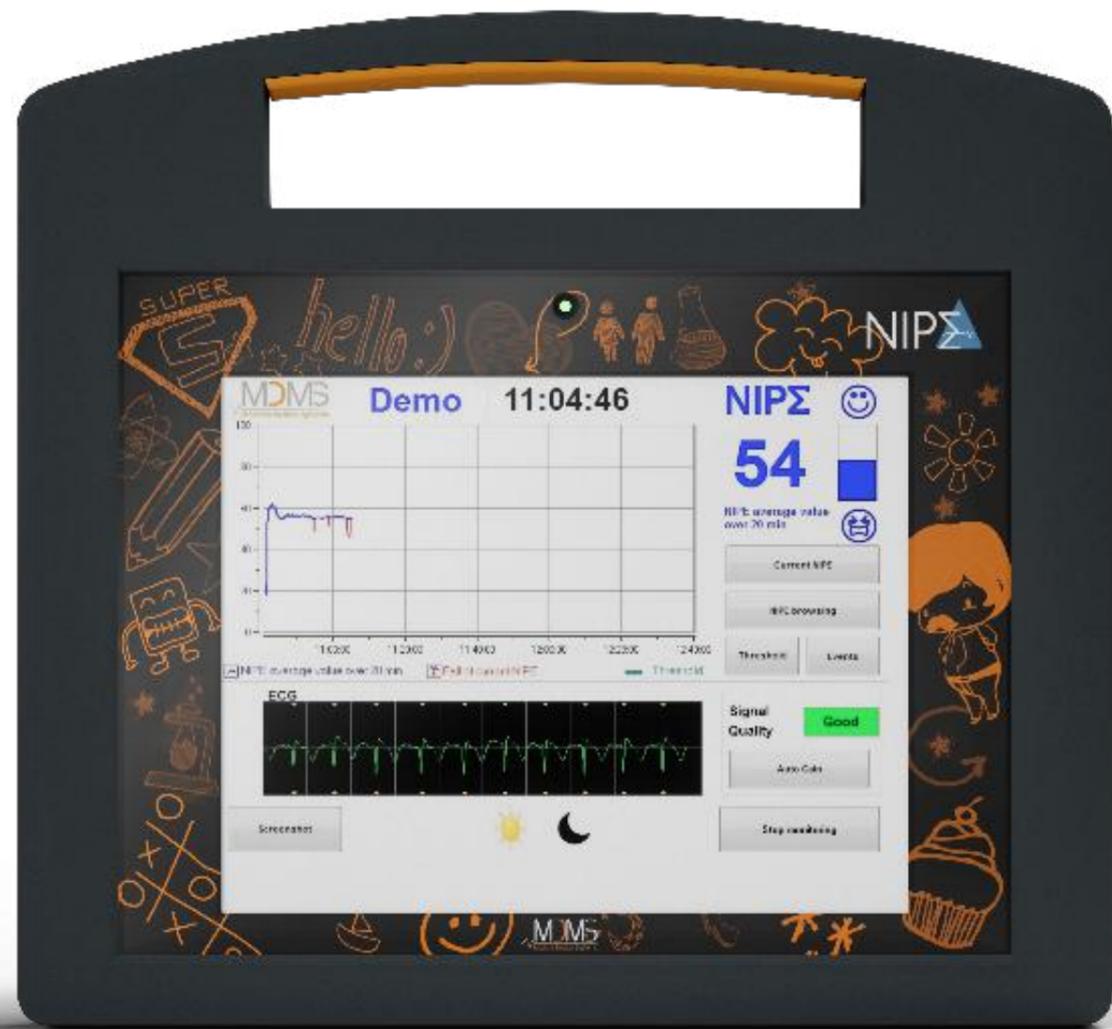
The EPIPAIN (EPIdeology of Procedural Pain In Neonates) study* showed that painful procedures are particularly common in young hospitalised children. Carbajal R, et al, reported that results from 430 infants showed that an average of 16 invasive procedures per day were performed on very sick neonates, of which over 60% were determined as painful. The study also showed that the vast majority of these procedures are typically carried out without any specific analgesia.

The NIPE technology provides an objective way to assess discomfort for newborn infants, allowing healthcare professionals to deliver individualised care.

* Carbajal R, et al, JAMA 2008.



NIPE MONITOR



Solving the PROBLEM of BEHAVIORAL rating SCALES.

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, as reported by Arias & Ginsberg*. 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.

The NIPE Monitor V1 provides an index based on an electrophysiological signal and it evaluates continuously. This ensures a consistent and objective rating of patient comfort, available at all times and with minimal demand on nursing time.

* Arias MC, Guinsburg R. Clinics. 2012



Importance of the PARASYMPATHETIC tone for newborns.

The NIPE technology enables an objective and continuous assessment of the parasympathetic component of the autonomic nervous system in babies and young infants. The unique technology has efficacy proven to work with extremely premature babies from around 26 weeks gestation through to infants up to two years of age and is based on the electrocardiogram taken from the patient monitor in use. The level of parasympathetic tone is correlated to the infant's discomfort or wellbeing, giving an objective measure.

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*.

In premature infants there are two possible explanations for the functional deficit of their autonomic nervous system. One is a deficiency in maternal neurotropic factors not compensated by nutrition. The other is stress induced by hospitalisation, which includes factors such as invasive and often painful procedures or other stimuli.

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, with an increased risk of developing cardiovascular and metabolic diseases such as hypertension, diabetes, and obesity**. They may also have cognitive influences that could lead to later depressive or addictive behaviour.

*Patural H, et al, Early Hum Dev. 2008.
** Heindel Jj, et al, Endocrinology. 2015.



WHY?

Continuous and non-invasive measurement

No additional sensors required and real-time analysis.

Easy to interpret

A simple digital scale - the higher the index, the more comfortable the patient.

Evaluation of comfort and discomfort with NIPE

Monitoring with NIPE may allow nursing staff to observe the impact of environmental conditions such as noise, light, positioning, choice of face-mask, etc... and optimize for the individual patient. The NIPE Monitor VI demonstrate impact of professional practices on newborn comfort state (Rakza T, *et al*, Clin J Pain. 2018).

Allow a non-personal and objective monitoring of the parasympathetic tone

The treatment before and during a potentially painful or stressful procedure in the NICU, including medication, can be adapted by monitoring the NIPE index.

The system can also be used to adapt analgesia protocols to the individual patient's needs intraoperatively, to avoid the risk of over or under dosage and associated side effects. (Faye PM, *et al*, Clin J Pain 2010. – De Jonckheere J, *et al*, Conf Proc IEEE Eng Med Biol Soc. 2011. – Rakza T, *et al*, Clin J Pain. 2018. - Butruille L, *et al*, Infant Behav Dev. 2017.)

A tool to improve all aspects of infant wellbeing

The positive influences generated by developmental care activities such as parental contact, cocooning, human voice, kangaroo care, etc. (Alexandre C, Arch Pediatr. 2013 - Butruille L, Infant Behav Dev. 2017).





How to interpret the two indexes?

The average NIPE

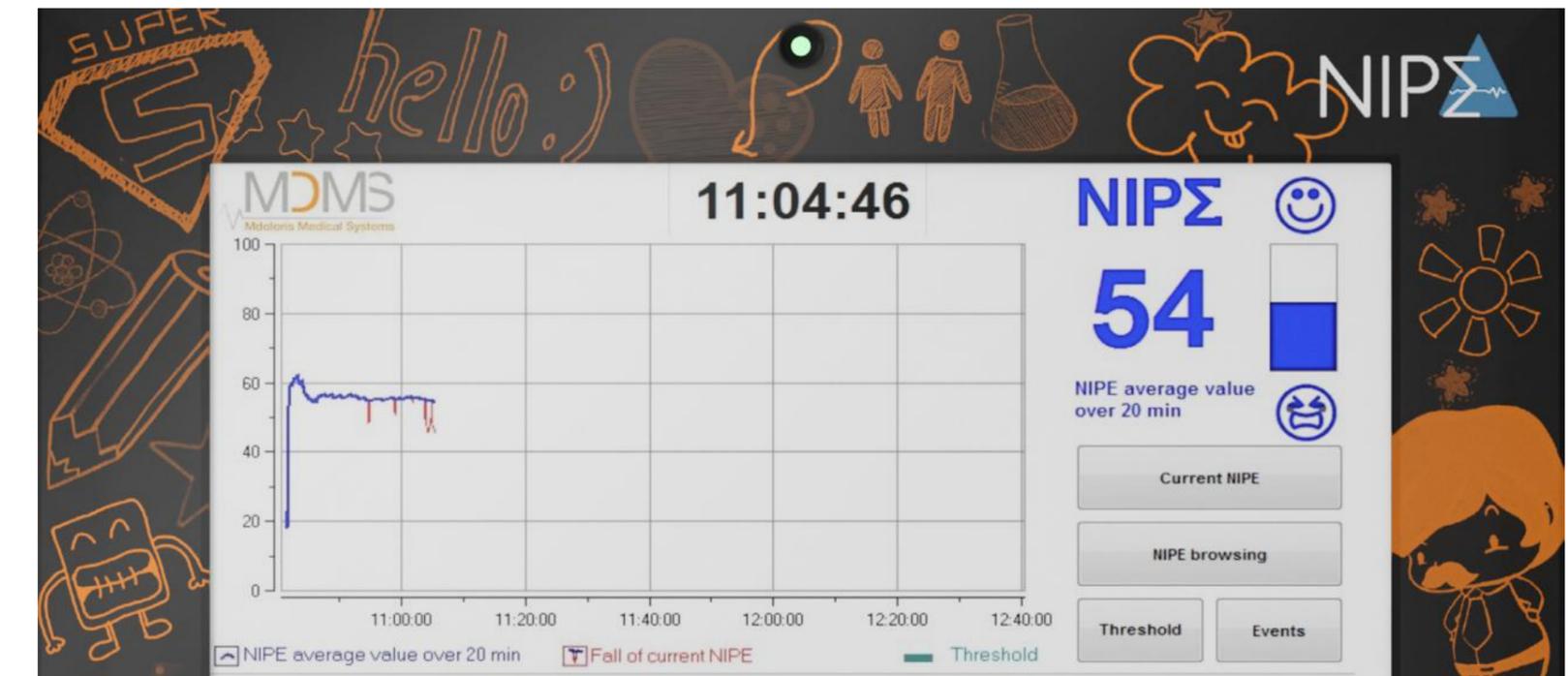
The averaged index, NIPE, is displayed in blue at the right top of the screen with corresponding blue trend curve plotted graphically. This index correlates to the overall wellbeing and chronic or prolonged pain of the infant.

The goal is to maintain the NIPE value above 50; research and experience indicates that below this threshold the patient can be considered to be uncomfortable or in pain. Treatment protocols and environmental factors should be adapted to ensure the trend curve is maintained or returned above the target level.

The instantaneous NIPE

The instantaneous NIPE (NIPEi), is represented by the red spikes on the trend display. This is used to assess acute pain during a potentially painful or stressful procedure. The user can select display of the instantaneous digital reading instead of the averaged value at top right of the screen if required. This index will highlight pain induced by procedures and allow the clinical team to adapt care accordingly.

The interpretation remains the same as with the NIPE; if the index falls below 50 then staff can immediately conclude that the current situation is painful or stressful for the patient.



Publications

Rakza T, Butruille L, Thirel ML, Houfflin-Debarge V, Logier R, Storme L, De Jonckheere J. **Short-term Impact of Assisted Deliveries: Evaluation Based on Behavioral Pain Scoring and Heart Rate Variability.** Clin J Pain. 2018 Nov 10.

Heindel JJ, Balbus JI, Birnbaum LI, Brune-Drisse MN, Grandjean PI, Gray KI, Landrigan PJ, Sly PD, Suk WI, Cory Slechta DI, Thompson CI, Hanson MI. **Developmental Origins of Health and Disease: Integrating Environmental Influences.** Endocrinology. 2015 Oct;156(10):3416-21.

Carbajal R, Rousset A, Danan C, Coquery S, Nolent P, Ducrocq S, Saizou C, Lapillonne A, Granier M, Durand P, Lenclen R, Coursol A, Hubert P, de Saint Blanquat L, Boëlle PY, Annequin D, Cimerman P, Anand KJ, Bréart G. **Epidemiology and treatment of painful procedures in neonates in intensive care units.** JAMA. 2008 Jul 2;300(1):60-70.

Arias MC, Guinsburg R. **Differences between uni- and multidimensional scales for assessing pain in term newborn infants at the bedside.** Clinics (Sao Paulo). 2012 Oct;67(10):1165-70.

Faye PM, De Jonckheere J, Logier R, Kuissi E, Jeanne M, Rakza T, Storme L. **Newborn infant pain assessment using heart rate variability analysis.** Clin J Pain. 2010 Nov-Dec;26(9):777-82.

Butruille L, De Jonckheere J, Jeanne M, Logier R, Storme L. **Un nouvel outil pour évaluer le confort des nouveau-nés: le moniteur NIPE, Oxymag.** 2015 Jan-Fev :18-20.

De Jonckheere J, Rakza T, Logier R, Jeanne M, Jounwaz R, Storme L. **Heart rate variability analysis for newborn infants prolonged pain assessment.** Conf Proc IEEE Eng Med Biol Soc. 2011; 2011:7747-50.

Alexandre C, De Jonckheere J, Rakza T, Mur S, Carette D, Logier R, Jeanne M, Storme L. **Impact of cocooning and maternal voice on the autonomic nervous system activity in the premature newborn infant.** Arch Pediatr. 2013 Sep;20(9):963-8.

Hugues Patural, Vincent Pichot, Fethi Jaziri, Georges Teyssier, Jean-Michel Gaspoz, Frédéric Roche, Jean-Claude Barthelemy. **Autonomic cardiac control of very preterm newborns: A prolonged dysfunction.** Early Hum Dev. 2008 Oct;84(10):681-7.



NIPE Monitor VI

Technical Specifications

General

Parameter	Specification
Power Requirements	100-250 VAC through AC power adapter
Mains Frequency	50Hz
AC Power consumption	49W
DC Input	12V+/- 5% 60W

Output

Parameter	Specification
Export Protocol	UART interface
Data Export	USB interface

Environment

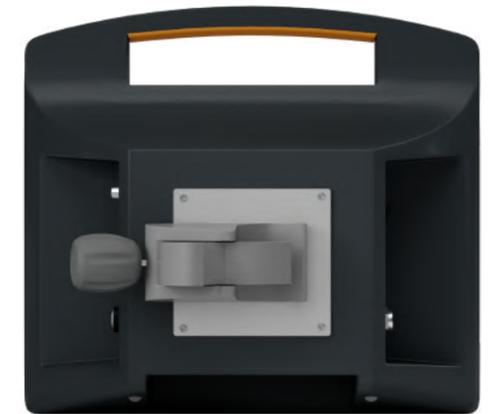
Parameter	Specification
Cooling Method	Convection. Fan less
Temperature Operating Storage	5°C to 35°C -20°C to 60°C
Relative Humidity Operating Storage	> 15% and < 95% non-condensing > 15% and < 95% non-condensing
Altitude Operating Storage	480 hPa to 1066 hPa 480 hPa to 1066 hPa
Dimensions Monitor (with collet fixture)	27(width) x 24,7(height) x 14,5(depth)cm
Weight Monitor (with collet fixture)	1,83kg

Connectors

Parameter	Specification
AC Input (monitor)	Jack DC 3-pin power connector
Export (monitor)	Sub-D9 connector to export data in real time
Data Export (Monitor)	USB connector to export data and snapshot to USB stick
Multi parametric link	6 pin circular connector (to multiparametric scope)

Screen

Parameter	Specification
Type	Color Liquid Crystal
Size	200 mm (8 inches)
Resolution	800 x 600 pixels
Active Viewing Area	173 x 130 mm
Pixel pitch	0.216 x 0.217 mm





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