personalized respiratory support for everyone.

MACAWI SERA

DEMCON | MACAWI RESPIRATORY SYSTEMS

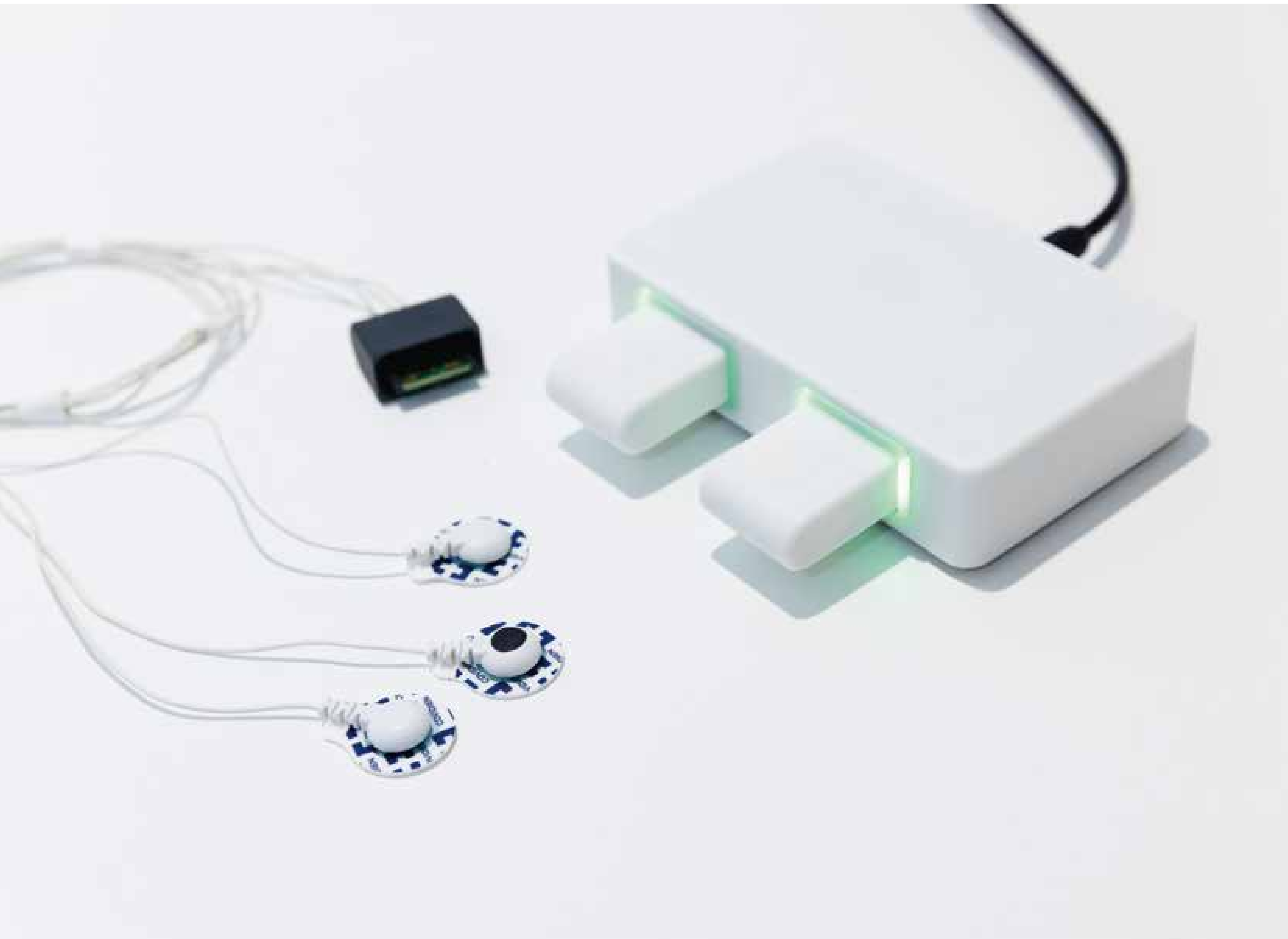
INTRODUCTION

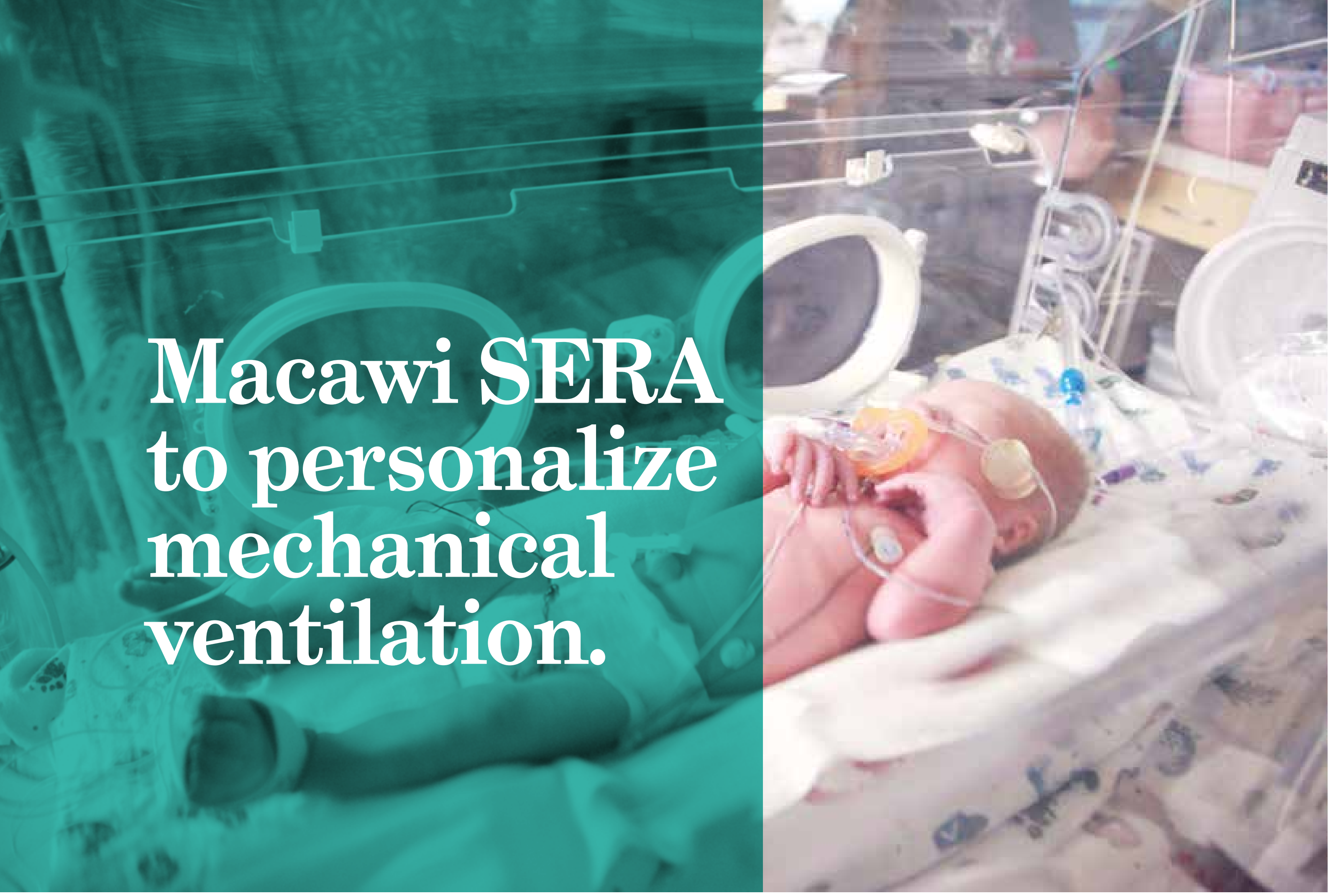
Imagine a world where personalized mechanical ventilation is available for everyone! A world where each ICU-patient is monitored and treated in line with its own personal needs - optimizing respiratory care to the best possible level. This situation has come a significant step closer to become reality with the introduction of the Macawi SERA – Surface Electromyography Respiratory Assist.

Mechanical ventilation (MV) is one of the most relevant life-saving therapies to support organ function in the intensive care unit (ICU). However, inappropriate MV settings are associated with e.g. lung injury (ventilator-induced lung injury, VILI). The desire for personalized care drives technological developments focusing on faster patient recovery and shorter hospital stay. And this is exactly what we want to achieve by offering Macawi SERA, our diaphragm monitoring device, to optimize respiratory care for everyone – from neonatal to adult patients.

From the idea of helping the most vulnerable and youngest amongst us because they still have a life to start and we want that start to be as best as possible, Macawi SERA's first focus is providing monitoring support in the neonatal market – followed by paediatric patients and adults in a later stage. Therefore, this whitepaper will focus on Macawi SERA and neonatal respiratory applications in a NICU environment.

TABLE OF CONTENTS





Macawi SERA to personalize mechanical ventilation.

Macawi SERA is based on electromyography (EMG) technology which is a technique to measure the electrical activity of muscles. The muscle fiber contractions are controlled by the respiratory control center in the human brain. By recording the electrical activity of the respiratory muscles (where the diaphragm is the main breathing muscle), mechanical ventilation and/or respiratory care in general can be personalized and optimized. Where other electromyography techniques are often based on invasive measurements, i.e. needle EMG or esophageal EMG, Macawi SERA offers a non-invasive interception of the electrical signal that is generated by the diaphragm. By placing three skin electrodes , the patient's own respiratory drive provides valuable information about the patient's needs, condition and next steps in treatment and eventually enable fully personalized and synchronized respiratory care.

For decades the surface electromyography (sEMG) technology was regarded as an interesting tool for research, though not useful outside the controlled research environment. This perception has clearly changed with the introduction of the NAVA (Neurally Adjusted Ventilatory Assist) ventilating technique, where a special esophageal 'Edi catheter' (Electrical activity of the diaphragm) measures the diaphragm activity to trigger the ventilator based on the patient's breathing effort. The NAVA technology has scientifically proven benefits for the patients[1]. However, it is an invasive technique requiring training to place the catheter and the use of costly consumables. Surface electromyography on the other hand, has gone through an interesting evolution during the past years and has been subject to numerous clinical (neonatal) trials[2] to gain insight into possible clinical applications, even beyond respiratory applications. Research[3] has shown a good correlation between sEMG and esophageal diaphragm electromyography which makes sEMG an interesting technique to take seriously in improving respiratory care.

DEMCON | MACAWI RESPIRATORY SYSTEMS

Macawi SERA performs continuous real-time measurement of respiratory muscle activity (diaphragm and/or intercostals), and it provides the following derived physiological parameters:

- o EMG waveform
- o ECG waveform
- o Heart rate
- o Heart Rate variability
- o Respiratory Rate
- o Breath-by-breath values associated with Work of Breathing (WOB) such as Area Under Curve (AUC), Tonic level and Phasic (peak) level
- o Technical indicators e.g. battery lifetime status, signal quality and lead connection.

The design of the Macawi SERA is built around a wireless measuring device with highly accurate amplifiers to pick up the very weak electrophysiological muscle signals[2]. The choice for wireless is mainly driven from the point of view of freedom of movement for the patient and nursing staff and the need to reduce disturbances and interference on the measured signals to a minimum. Additionally, wireless devices help to reduce the cable clutter around patients.

The main system elements of the Macawi SERA system are (see the foto below):

A – **BODY SENSOR:** Re-usable part that consists of a connector with three attached lead cables with connectors which can be snapped on standard disposable ECG (snap) electrodes[3]. The skin electrodes are placed on the chest and/or back of the patient to measure electrical activity of the respiratory muscles. It is connected to the MEASURING DEVICE with a dedicated connector.

B – **MEASURING DEVICE:** A small chargeable battery-operated device that amplifies signals from the BODY SENSOR, and sends them via a Bluetooth connection to the BASE STATION. The measuring device has an interface connector for various types of patient interfaces to allow for easy adaptation to different use cases.

C – **BASE STATION:** This unit receives raw signals from the wireless measuring device and performs advanced signal processing to derive various waveforms and measurement values. The BASE STATION also serves as a docking station to charge the battery of two MEASURING DEVICES and to establish a unique pairing link for the wireless connection. All processed data is transferred via a serial (wired) connection to a PC or other device/host for displaying on a graphical user interface (GUI) and/or logging the data.

---

1. Two electrodes left and right at the costo-abdominal margin of the nipple line and the third, i.e. the reference electrode, on the lower sternum.
2. The measured signals are in the µV-range.
3. For neonatal use a special patch electrode is in development to reduce the likelihood of unwanted pressure points

neonatal respiratory sEMG applications.

WOB is associated with the amount of energy required by the respiratory muscles to produce enough ventilation and respiration to meet the metabolic demand of the human body. WOB is affected by various factors and is highly patient- and situation depending. For example, during weaning the patient's WOB needs to increase to provide adequate respiration. In another situation the patient's WOB might need to decrease to save energy for physical recovery. Also, a sudden change in WOB might indicate underlying suffering or clinical deterioration.

To quantify the patient's WOB, breath-by-breath parameters like Area Under Curve, Tonic Level and Phasic (peak) Level can be derived from the EMG waveforms. As already explained, continuous monitoring of these trend values provides valuable information concerning the patient's status and changes in respiration. In addition, sEMG can proof useful to assess surfactant dosage response, patient ventilator asynchrony (PVA) and apnea detection and classification.

Big advantage is that sEMG monitoring allows assessment in all premature infants, contributes to patient comfort and, as already proven with the NAVA technology, will reduce hospital stay time and costs. Below a more detailed explanation of possible monitoring applications in the NICU field is provided.

Evaluate, reduce and eliminate PVA

PVA is associated with adverse effects [4] like patient discomfort, increased need for sedation, diaphragmatic injury and prolonged medical ventilation. Where proportional assist ventilation (PAV, NAVA) provide invasive monitoring methods to detect and reduce PVA, these methods do not cover all ventilation techniques. There is an urgent call for new synchronization techniques [5] addressing both inspiratory

DEMCON | MACAWI RESPIRATORY SYSTEMS

and expiratory asynchrony. Research [6] has shown that sEMG provides a useful signal for evaluating and monitoring patient–ventilator interaction. As Macawi SERA continuously monitors the diaphragm activity, this also provides the opportunity to trigger onset and offset of a mechanical inflation in response to a spontaneous breath.

Cardiorespiratory monitoring

Today, respiratory activity in preterm infants is mainly monitored by chest impedance (CI), which measures changes in electrical impedance caused by changes in lung aeration and chest wall movements via two transcutaneous ECG electrodes. CI in combination with ECG provides continuous monitoring of heart rate (HR) and respiratory rate (RR), and the latter is also used for detection of apnea of prematurity (AOP). However, CI has important limitations as it does not provide direct and quantitative information on breathing effort and often provides inaccurate data due to non-breathing related chest wall movements and cardiac interference. Investigations have proven [7,8] that cardiorespiratory monitoring using sEMG is possible and repeatable, making sEMG a promising technology.

Recognize and identify AOP

Apnea of prematurity (AOP) is caused by the immaturity of the respiratory system and the respiratory control centre in the brainstem of these preterm infants. These two different origins also result in different types of apnea: obstructive, central and mixed apnea. As the treatment of either obstructive (caused by upper airway collapse) and central apnea (caused by the absence of neural input to initiate inspiration) differs, monitoring the breathing of the infants and detecting these apnea periods is very important. Choosing the wrong treatment is not effective and wastes time. However, currently no easy to use and accurate measurement technique is available that can continuously monitor the occurrence of apnea periods and inform the clinician about the type of AOP. As sEMG measures the electrical activity and not airway flow or chest displacement, sEMG is considered to be more suitable to distinguish central from obstructive apnea[4]. A previous clinical study [9] revealed that transcutaneous electromyography of the diaphragm might be a candidate technique to cover this issue.

Monitor treatment effects

sEMG has also been used to assess the effect of other respiratory interventions on diaphragmatic activity [10,11] e.g. that an intravenous loading dose of caffeine citrate (a breathing stimulating drug often given to preterm infants) in ventilated infants resulted in an increased diaphragm activity. Also the effect of increased diaphragmatic activity when preterm infants are exposed to a higher level of inspired oxygen has been shown, using sEMG technology [12,13].

Weaning of respiratory support

Today there is no clinical consensus about a protocol for clinical decision taking concerning weaning of respiratory support, despite the availability of so-called weaning predictors intended to help clinicians to predict whether weaning attempts will be successful or not. Since for successful weaning an active diaphragm is needed, using sEMG to continuously monitor the patient's diaphragmatic activity can be of great added value to show the progression over time.

Next to the abovementioned monitoring applications, the integration of sEMG technology into mechanical ventilators enables a wide range of additional applications from proportional ventilation to closed loop triggering.

4. Recently Demcon Macawi has initiated a clinical investigation at the Emma Children's Hospital (Amsterdam UMC, Amsterdam, the Netherlands) to realize non-invasive apnea detection (and possible classification) by using Macawi SERA.


5
710
1:2
15
21
3000
40
0
5
710
15
1:2
21
0

FOLLOW UP

The Macawi SERA is designed to be an original equipment manufacturer (OEM) module and is intended to be integrated into a host system, i.e. a mechanical ventilator or patient monitor, to support various monitoring functions for diagnostic purposes in the area of respiratory care. Macawi SERA is developed according to the latest Medical Device Regulation (MDR) and comes with all required documentation and risks analysis information. Additionally, a GUI is available for research / demo purposes. Host Interface Documentation supports a smooth integration into a host system.

Are you interested to learn more about Macawi SERA and its capabilities and/or Macawi's other respiratory products, please visit our website https://macawi.demcon.com or contact Sytske Klomp, product manager sEMG technology, directly by sending an e-mail to sytske.klomp@demcon.com

Together let us improve respiratory care for everyone – starting today for the smallest ones!

REFERENCES

1. Piastra M, et al. Neurally adjusted ventilatory assist vs pressure support ventilation in infants recovering from severe acute respiratory distress syndrome; nested study. J Crit Care. 2014 Apr;29(2):312.e1-5

2. Scholten A.W.J, van Leuteren R.W., de Waal C.G., et al, "Diaphragmatic electromyography in infants: an overview of possible clinical applications', 2023.

3. Lin, L., Guan, L., Wu, W. & Chen, R. Correlation of Surface Respiratory Electromyography with Esophageal Diaphragm Electromyography. Respir Physiol Neurobiol 259, 45-52 (2019).

4. Scott K Epstein, "How often does patient-ventilator asynchrony occur and what are the consequences?", 2011

5. Cornelia G de Waal , Ruud W van Leuteren , Frans H de Jongh, Anton H van Kaam, Gerard J Hutten, "Patient-ventilator asynchrony in preterm infants on nasal intermittent positive pressure ventilation", 2018

6. Alette A. Koopman, Robert G. T. Blokpoel, Leo A. van Eykern, Frans H. C. de Jongh, Johannes G. M. Burgerhof and Martin C. J. Kneyber, "Transcutaneous electromyographic respiratory muscle recordings to quantify patient–ventilator interaction in mechanically ventilated children", 2018

7. van Leuteren, R. W. et al. Cardiorespiratory Monitoring in the Delivery Room Using Transcutaneous Electromyography. Arch Dis Child Fetal Neonatal Ed 106, 352-356 (2021).

8. Juliette V. Kraaijenga, "Transcutaneous Electromyography of the Diaphragm: A Cardio-Respiratory Monitor for Preterm Infants", 2015

9. Juliette V Kraaijenga, Gerard J Hutten, Cornelia G de Waal, Frans H de Jongh, Wes Onland, Anton H van Kaam, "Classifying Apnea of Prematurity by Transcutaneous Electromyography of the Diaphragm", 2017

10. Williams, E. E. et al. "Electrical Activity of the Diaphragm Following a Loading Dose of Caffeine Citrate in Ventilated Preterm Infants". Pediatr Res 87, 740-744 (2020).

11. Juliette V Kraaijenga , Gerard J Hutten , Frans H de Jongh , Anton H van Kaam, "The Effect of Caffeine on Diaphragmatic Activity and Tidal Volume in Preterm Infants", May 2015

12. J Dekker, SB Hooper, M Giera, EV McGillick, GJ Hutten, W Onland, AH van Kaam, AB te Pas, "High versus low initial oxygen to improve the breathing effort of preterm infants at birth: study protocol for a randomized controlled trial"; 2019

13. van Leuteren, R. W. et al. "The Effect of Initial Oxygen Exposure on Diaphragm Activity in Preterm Infants at Birth". Front Pediatr 9, 640491 (2021).

NOTES

Demcon macawi respiratory systems
Kanaaldijk 29
5683 CP Best
+31 (0)88 622 29 77
info@macawi.com
www.macawi.demcon.com