Nemo Fetal Monitoring System

Technical Brochure

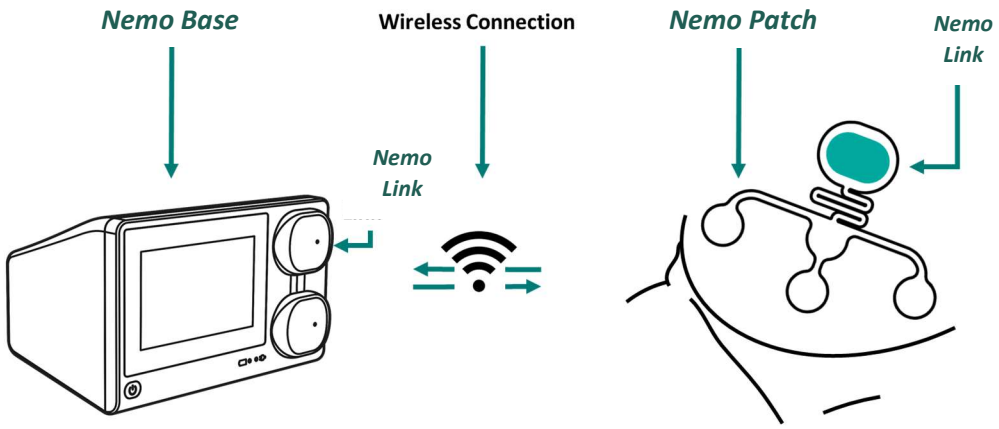
Introduction and System Identification

Nemo Fetal Monitoring System (NFMS) is an non-invasive and wireless device that accurately monitors fetal and maternal heart rate and uterine activity. NFMS components and accessories can be identified in the table below.

Product name	**Nemo Fetal Monitoring System**	
Components (REF code)	Nemo Base	(ATLBAS01)
	Nemo Link	(ATLLNK01)
Accessory (REF code)	Patch box 20 items	(ATLPAT01020)
	Nemo Patch	(ATLPAT01)

Operation

Nemo Patch – a passive self-adhesive electrode sensor, and *Nemo Link* – a wearable electronic measurement unit, are used for recording of electrophysiological signals from the maternal abdominal surface. These recordings contain a mixture of signals including maternal electrocardiogram (ECG), fetal ECG, electrohysterogram (EHG), and various noise sources. *Nemo Base* – a central processing and control unit, utilizes advanced signal processing techniques to suppress noise sources and separate maternal ECG, fetal ECG, and EHG. The first two signals are used to calculate maternal heartrate and fetal heartrate, respectively. The latter is used to calculate a measure for uterine activity. Recorded data is transferred between Nemo Link and Nemo Base via a wireless connection which utilizes low-power 2.4GHz ISM frequency band.



INTENDED USE

The system is an electrophysiological measurement medical device that non-invasively measures fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR) from the fetal/maternal ECG and uterine electromyography (EMG) signals as acquired from abdominal surface electrodes. The system connects to existing monitoring systems and is indicated for use on women with a gestational age ≥ 21 completed weeks, with singleton pregnancies. The product is intended for use by healthcare professionals in a clinical setting.

CLINICAL BENEFITS

Direct benefits

There are no benefits directly from system itself.

Indirect benefits

In comparison to current invasive fetal monitoring techniques (fetal scalp electrode, intrauterine pressure catheter) by the absence of risks due to the technique (fetal skin damage, trauma to placenta, umbilical cord and/or uterus) and a decreased maternal and the absence of fetal discomfort. In comparison to current non-invasive fetal monitoring techniques (Doppler ultrasound, tocodynamometer) by a non-inferior performance and by a decreased maternal discomfort. In comparison to wired diagnostics, the system is wireless and therefore permits mobility of the patient, which is positively correlated to progress of first stage of labour.

CONTRAINDICATIONS

The system is not intended for:

- Use in gestation period < 21 completed weeks
- Use during defibrillation, electrosurgery or magnetic resonance imaging (MRI)
- Use on patients connected to external or implanted stimulators

SAFETY

Nemo Base and Nemo Link are parts of NFMS, classified together as single Class IIb device according to rule 10 of Chapter III of Annex VIII of the Medical Device Regulation EU 2017/745.

Nemo Patch is an accessory of NFMS, classified as Class I device according to rule 1 of Annex VIII of the Medical Device Regulation EU Regulation 2017/745.

The Nemo Base and Nemo Link comply with the following standards:

- EN 15223-1:2016
- EN 1041:2008 + A1:2013
- EN ISO 14971:2012
- EN 60601-1:2006 + A1:2013
- EN 60601-1-2:2015
- EN 62304:2006+A1:2015
- EN 62366-1:2015
- EN 60601-1-8:2007/AC:2010
- EN ISO 10993-1:2009/AC:2010

The Nemo Patch complies with the following standards:

- EN 15223-1:2016
- EN 1041:2008 + A1:2013
- EN ISO 14971:2012
- EN 62366-1:2015
- EN ISO 10993-1:2018

CLINICAL WARNINGS

- The safety and effectiveness of the system for monitoring uterine activity, fetal and maternal heart rate have NOT been established for the following patient populations:
    - Gestational age < 21 completed weeks
    - Multiple gestations
- The system is not intended and designed for
    - use during defibrillation, electro-surgery or MRI
    - use on patients connected to electrical stimulators, or with cardiac pacemakers
    - use in x-ray departments.
      Remove the Patch prior to performing any of the above scenarios, otherwise harm to the patient or damage to equipment may occur.
- From 27 to 36 weeks gestational age, the chance of fetal heart rate signal loss is higher due to the presence of vernix caseosa, which can reduce transmission of electrical signals. In case clinical decision-making cannot be properly substantiated, other observation and monitoring methods must be used.
- Due to the computational complexity of the used algorithms, the fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR) are presented with a small, but noticeable delay. This delay is approximately 6 seconds, when compared to simultaneously applied invasive fetal monitoring methods.
- The system detects repeating characteristics of the fetal and maternal ECG signal to calculate the fetal and maternal heart rate. If either the pregnant woman or her fetus has a highly irregular ECG, the heart rate may not be calculated correctly and the system may temporarily provide incorrect output. In case clinical decision-making cannot be sufficiently substantiated, other observation and monitoring methods must be used.
- In rare cases, the amplitude of the fetal ECG signal that is measured on the maternal abdomen is in the same order of magnitude as the amplitude of the maternal ECG that is being measured. In these circumstances, mix-up of fetal and maternal heart rate may occur. The system will then temporarily display fetal heart rate values as maternal heart rate and maternal heart rate values as fetal heart rate. In case clinical decision-making cannot be sufficiently substantiated, other observation and monitoring methods must be used.
- The system is developed to detect fetal heart rate from extremely small fetal ECG signals in electrical measurements that may contain significant amounts of noise. The system evaluates the quality of the fetal ECG component in the measured signals. When the fetal ECG quality is too low to reliably detect the fetal heart rate, the fetal heart rate output is suppressed. In case clinical decision-making cannot be sufficiently substantiated, other observation and monitoring methods must be used.
- To prevent incorrect output, the system continuously evaluates the quality of the fetal heart rate output. If the fetal heart rate output repeatedly has not passed this quality check, the

fetal heart rate output is suppressed. In case clinical decision-making cannot be sufficiently substantiated, other observation and monitoring methods must be used.

- The system detects uterine activity based on electrohysterography (electrical activity of the uterine muscle). In limited cases, the registration may show deviations from the baseline that are not related to actual contractions, when compared to an intra-uterine pressure catheter. In case clinical decision-making cannot be sufficiently substantiated, other observation and monitoring methods must be used.
- The system only provides qualitative information about uterine activity and no information about pressure.
- To assess the CTG, the system must always be connected to the hospital's central information and monitoring system and the CTG display originating from the central information and monitoring system should be used. The screen of the Base only displays instantaneous values of uterine activity and fetal and maternal heart rate, and is therefore not suitable for assessment of the CTG. Assessments made using only the screen of the Base can result in unnecessary interventions or in not implementing necessary interventions.
- The system is not a replacement for observation and evaluation of the patient and fetus at set times by a qualified healthcare provider, who makes diagnoses and takes decisions regarding treatment and interventions. For accurate care of the patient and fetus, clinical assessment of the CTG should be combined with knowledge of patient anamnesis and risk factors.
- Never use Links from one Base on more than one patient at a time. Also do not exchange Links from different Base systems between patients. This can result in exchange of CTG registrations and assessment of patients.

PHYSICAL SPECIFICATIONS

Nemo Base		
Power	Supply voltage	100 – 240 VAC
	Frequency range of supply voltage	50 / 60 Hz
	Energy consumption	100 VA (maximal)
	AC socket	Earthed
Electrical class	Class I (internal power supply)	
Battery	Technology	Lithium-ion
	Charging duration	3 hours*
	Maximum duration on battery power	2.3 hours*
Dimensions and weight	Dimensions w x h x l	11.8 x 7.2 x 7.6 in (300 x 183 x 193 mm)
	Weight	7.4 lbs (3.4 kg) (excluding 2 Links and power cord)

** Value can vary after a period of time and is subject to the environmental conditions in which the system is used and stored.*

Nemo Link		
Battery	Type	Nickel Metal hydride
	Charging duration	2 hours*
	Maximum duration on battery power	24 hours*
Dimensions and weight	Dimensions w x h x l	3.5 x 0.9 x 2.7 in (88 x 24 x 68 mm)
	Weight	3.2 oz (92 g)
Ingress protection	IP45	

** Value can vary after a period of time and is subject to the environmental conditions in which the system is used and stored.*

Nemo Patch		
Dimensions and weight	Dimensions w x h x l	12.2 x 10.1 x 1.0 in (310 x 256 x 25 mm)
	Weight (exclusive packaging)	1.3 oz (36 g)
Properties	Non-sterile	
	Bio-compatible (ISO 10993-1)	
	Single patient multi use	

ENVIRONMENTAL SPECIFICATIONS

Temperature	During use	+10 to +30 °C (+50 to + 86 °F)
	During storage	Base, Link: -20 to +35 °C (-4 to 95 °F) Patch: +10 to +30 °C (+50 to +86 °F)
Humidity	10 – 90%	
Air pressure	Base, Link: 70.0 – 101 kPa Patch: Not applicable	

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