nemo
HEALTHCARE

Technical Brochure

# NemoRemote

## *INTRODUCTION AND SYSTEM IDENTIFICATION*

NemoRemote (NRM) system is a non-invasive and wireless medical device that accurately monitors fetal and maternal heart rate and uterine activity. NemoRemote components, accessories and compatible devices can be identified in the table below.

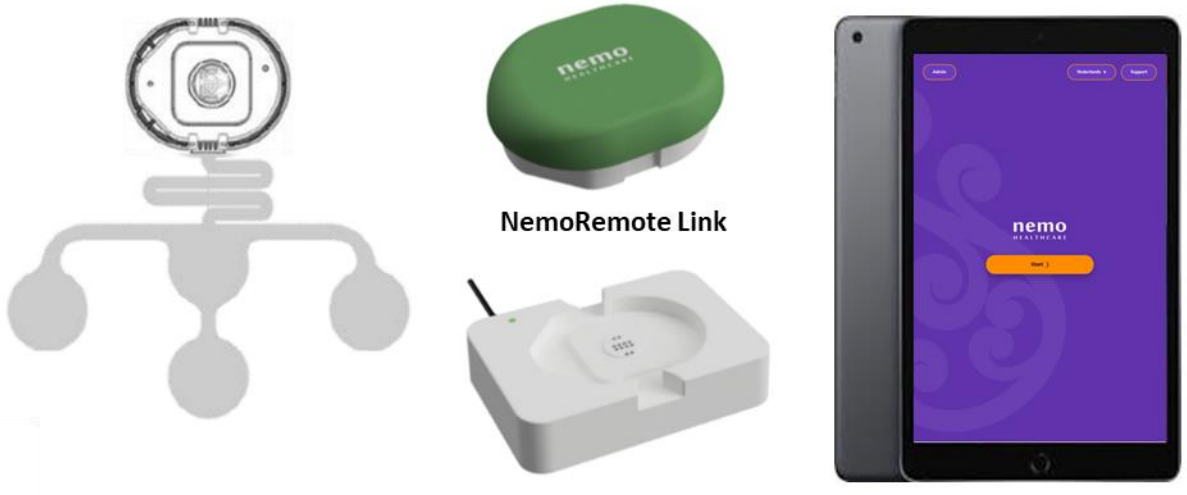
| | | |
|---|---|---|
| **Product name (REF code)** | **NemoRemote** | (NRM01) |

| | | |
|---|---|---|
| **Components (REF code)** | NemoRemote Link | (NRMLNK01) |
| | NemoRemote Link Charger | (NRMLCH01) |
| | NemoRemote App | (NRMAPP01) |
| **NRM accessory (REF code)** | Nemo Patch box 20 items | (ATLPAT01020) |
| **Compatible devices (model number)** | Apple iPad Air (2020) | (A2072) |
| | Apple iPad Air (2022) | (A2589) |

## *OPERATION*

*NemoRemote Link* – a wearable electronic measurement unit, and *Nemo Patch* – a passive self-adhesive electrode sensor, 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. The NRM Link is battery operated and is charged by docking it to *NemoRemote Link Charger.*

*NemoRemote App* utilizes advanced signal processing software, installed on a tablet, 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 NRM Link and the tablet via a wireless connection which utilizes low-power 2.4GHz ISM frequency band. The app also serves as the primary user interface.



## *INTENDED USE*

NemoRemote is an electrophysiological measurement device that non-invasively measures fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR) from the fetal and maternal electrocardiography (ECG) and uterine electromyography (EMG) signals as acquired from abdominal surface electrodes.

NemoRemote communicates 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 patients in a home setting (prescribed by their healthcare professional) and for use in non-acute care settings in a midwifery practice or hospital by healthcare professionals.

## *CLINICAL BENEFITS*

### Direct benefits

There are no benefits directly from the system itself.

### Indirect benefits

- In comparison to current remote monitoring devices (based on Doppler ultrasound) NemoRemote can also be used from 21 to 32 weeks of gestation.
- In comparison to fetal monitoring in the hospital NemoRemote provides the possibility to be monitored at home.
- In comparison to current non-invasive fetal monitoring techniques (Doppler ultrasound + tocodynamometer) NemoRemote has a non-inferior performance and decreased maternal discomfort.

## *CONTRAINDICATIONS*

The system is not intended for:

- Use in gestation period < 21 completed weeks
- Use in multiple pregnancies
- Use on patients with dermatologic diseases in which abdominal skin is involved
- Use on patients connected to external or implanted stimulators
- Use during defibrillation, electrosurgery or magnetic resonance imaging (MRI)
- Use in x-ray departments

## *SAFETY*

*NRM Link*, *NRM Link Charger* and *NRM App* are parts of NemoRemote (NRM). NemoRemote is classified as class IIb, following Rules 10 and 11 of Chapter III of Annex VIII as well as implementation rules 3.3 and 3.5 of the Medical Device Regulation EU Regulation 2017/745.

NemoRemote complies with the following standards:

- EN 15223-1:2016
- EN ISO 20417:2021
- EN ISO 14971:2019
- IEC 60601-1:2005+AMD1:2012+AMD2:2020

- IEC 60601-1-2:2014+ AMD1:2020
- EN 60601-1-6: 2010+A1:2015
- IEC 60601-1-11:2015/AMD1:2020
- EN 62304:2006+A1:2015
- IEC 82304-1:2016
- EN 62366-1:2015+A1:2020
- Regulation (EU) No 207/2012

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

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 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.
- The system is not designed for
    - use during defibrillation, electrosurgery or magnetic resonance imaging (MRI)
    - 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 based on the CTG registration, other observation and monitoring methods must be used.
- In some cases, the use of the Patch, in combination with skin prep, may result in skin irritation. Try to reduce the duration of use and the skin prep as far as possible if the skin is irritated.
- To prevent reduced performance, replace a Patch when its adhesive properties have reduced or the electrode gel has come partially loose.
- To prevent cross-contamination, never reuse a Patch on another patient.
- To prevent the risk of skin irritation, ensure that no cleaning or disinfection agent residues remain on the system.
- 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, interchange 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 over a certain period of time, 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.
- The measurement of abdominal fetal ECG, as performed by the system, is based on extremely small signals. For optimum measurement of these signals, the Link contains sensitive components that are subject to technological limitations. To prevent incorrect measurements through external electromagnetic interference, it is recommended to avoid using equipment that emits electromagnetic radiation in the vicinity of these measurements.
- The system shall only be used if the tablet is configured by mobile device management to ensure data privacy and guarantee the performance of the system.

## *PHYSICAL SPECIFICATIONS*

| **NemoRemote Link** | | |
|---|---|---|
| Battery | Type | Nickel-Metal Hydride |
| | Charging time | 2 hours |
| | Maximum time on battery power | 24 hours |
| Protection against electric shock | BF | |
| Electrical class | Class II (internal battery) | |
| Dimensions and weight | Dimensions l x b x h | 88 x 68 x 24 mm |
| | Weight | 96 g |
| Ingress protection | IP45 | |
| | Protected against solid foreign objects of 1mm diameters and greater. Protected against water jets | |
| Service life | 5 years | |

| **NemoRemote Link Charger** | | |
|---|---|---|
| Electrical class | Class II | |
| Dimensions and weight | Dimensions l x b x h | 120 x 85 x 30 mm |
| | Weight | 551 g |

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|---|---|---|
| Power supply unit | Product name | Mean Well GSM06E05-P1J |
| | Power input | 100-240 VAC<br>50/60 Hz<br>0.18-0.09 A |
| | Power output | 5V DC<br>1.2 A (6 A max) |
| | Directive compliance | 93/42/EEC |
| Service life | 5 years | |

| **NemoRemote App** | | |
|---|---|---|
| Compatible device | Name | Apple iPad Air (2020) |
| | Model number | A2072 |
| | Operating system | iPadOS 14 |
| | Directives compliance | 2014/53/EU<br>2011/65/EU<br>2009/125/EC ] |
| Compatible device | Name | Apple iPad Air (2022) |
| | Model number | A2589 |
| | Operating system | iPadOS 14 |
| | Directives compliance | 2014/53/EU<br>2011/65/EU<br>2009/125/EC |

NemoRemote accessories

| **Nemo Patch** | | |
|---|---|---|
| Dimensions and weight | Dimensions w x h x l | 12.2 x 10.1 x 1.0 in<br>(310 x 256 x 25 mm) |
| | Weight (exclusive packaging) | 1.3 oz (36 g) |
| Properties | Non-sterile | |
| | Bio-compatible (ISO 10993-1) | |
| Shelf life | 2 years | |

Supported central monitoring systems

| | | |
|---|---|---|
| Supported CMS | Server name | Medexa Milou |
| | Versions | 4.1 and higher[1] |

[1] For questions about compatibility with Medexa Milou server versions 3.1 please contact your distributor.

## *ENVIRONMENTAL SPECIFICATIONS*

If the system is stored and used outside the specified temperature and humidity range, the specified performances may not be achieved.

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|---|---|
| During use | • a temperature range of + 5 °C to + 40 °C;<br>• a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa; and<br>• an atmospheric pressure range of 700 hPa to 1060 hPa |
| During storage and transport | • 20 °C to + 5 °C, and<br>• + 5 °C to + 35 °C at a relative humidity up to 90 %, non-condensing;<br>• > 35 °C to 70 °C at a water vapor pressure up to 50 hPa |

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