This document is intended to provide relevant safety and performance information to the user of the MultiSense® PRODUCT.

I. Abbreviations

- Arms: Average root mean square
- BPM: Beats Per Minute
- BrPM: Breaths Per Minute
- GDPR: General Data Protection Regulation
- HA: Hospital Administrator
- HR: Heart Rate
- IR: Infra-Red
- PM: Patient Manager
- PPG: Photoplethysmography
- PRM: Patient Relationship Manager
- RDS: Rhythm Diagnostic Systems
- RF: Radio Frequency
- RR: Respiratory rate
- SpO2: Peripheral oxygen saturation

II. General information

MultiSense® PRODUCT is a medical device that is used in the MultiSense® KIT for remote measurement of clinical data designed to facilitate patient monitoring and improve patient quality of life in non-critical care settings, at home or in a care center.

Trade name	MultiSense®
Medical device product category	Active device for remote monitoring
Model number or catalogue number	MultiSense® PRODUCT MS1.0
Basic UDI-DI (GMN)	3770026382MSPR4P
UDI-DI (GTIN)	3770026382066
Medical CE	*Ongoing*
Name, postal address & identification number of the notified body responsible for the conformity assessment	Eurofins Product Testing Italy S.r.l. Via Courgnè, 21 10156 - TORINO (TO) Italy NB n°0477

MultiSense® PRODUCT is a Class IIa medical device according to regulation (EU) 2017/745 of the European parliament and the council of 5 April 2017 on medical devices.

This documentation is available and can be provided in the languages accepted in the Member States where the device is sold.

The instructions for use are provided in a paper format with the MultiSense® PRODUCT.
The instructions for use are also available in an electronic format:

- For the patient: provided within the smartphone application of the MultiSense® PRODUCT
- For the professional user: provided within the smartphone application during the installation step of the MultiSense® PRODUCT and within the MultiSense® PRODUCT webportal.

III. Manufacturer Information

The MultiSense® PRODUCT is manufactured and marketed by RDS SAS.

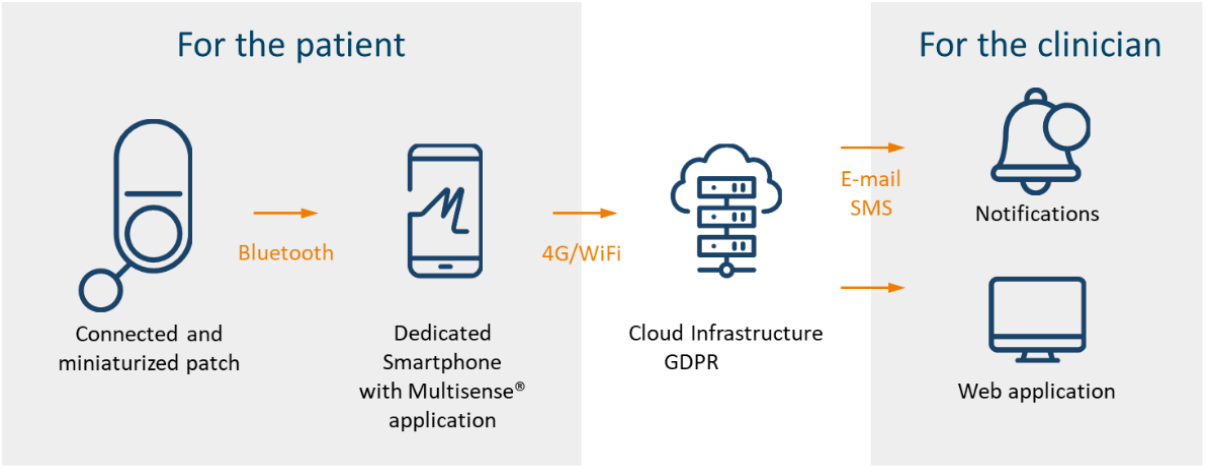
RDS SAS
℅ IHU, 1 Place de l'hôpital
67000 Strasbourg
FRANCE

Website: https://rdsdiag.com
SRN: FR-MF-000022301

Contact details:
Users of the MultiSense® PRODUCT can contact RDS via the HelpDesk (link provided on the product box and in the manuals supplied with the product).
RDS may also be contacted via the 'Contact Us' form on the homepage of the website.

IV. Product Description

1) Introduction



The MultiSense® PRODUCT is composed of the following key functional elements:

- Hardware part: An innovative multiparametric device in the form of a single miniaturized adhesive **patch with a pre-applied patient adhesive** that enables its placement on the upper body of a patient to collect physiological data continuously. The patch is worn by the patient for up to 5 days and holds 5 embedded sensors (PPG, ECG, skin temperature, accelerometer and piezoelectric) protected by a medical silicone cover. When installing the patch on a patient, an additional protective adhesive, the overlay, is placed on top of the patch.
- Software systems:
    - A MultiSense® PRODUCT **firmware** that collects the data from the patch.
    - A MultiSense® PRODUCT **smartphone app**, intended to be installed on a smartphone, which allows to receive by Low Emission Bluetooth the data collected by the patch and send it to a secured cloud using a wireless connection (cellular network or WiFi);
    - A **GDPR/HDS compliant cloud infrastructure** for data storage and analysis, running proprietary algorithms that derivate clinical parameters / vital signals (heart rate, spo2, respiratory rate, skin temperature, activity and posture) from the raw data collected by the patch, detect service interruption or degradation, and allows physicians to set thresholds on physiological values to receive SMS and/or email notifications (whenever notification feature is activated by the entity admin). ;
    - And a **secured web portal** for medical professionals that allows them live and retrospective inspection of patient's data.

The device is designed to provide healthcare professionals with valuable clinical-grade information relative to physiological trends. It is compatible with patient monitoring whether inside or outside the hospital, in non-critical care settings, and in patients who are not in immediate danger.

2) Intended Purpose

2.1 Intended use

MultiSense® PRODUCT is a medical device that is used in the MultiSense® KIT for remote measurement of clinical data designed to facilitate patient monitoring and improve patient quality of life in non-critical care settings, at home or in a care center.

2.2 Intended users

The MultiSense® PRODUCT is intended to be used by the following user profiles:

- Patient and patient's caregiver
- Patient Manager (PM)
- Hospital Administrator (HA)
- Patient Relationship Manager (PRM)

2.2.1 Identification & responsibilities of the Hospital Administrator (HA)

The HA is the first user to enter the MultiSense® PRODUCT Web portal after he receives an email for his initial account creation. **He is responsible for activating and configuring the MultiSense® PRODUCT account for his hospital's PMs**: creation of a password, implementation of the two-factor activation, and connection to the account.

It is the entire responsibility of the healthcare professionals to decide which hospital users shall have Hospital Administrator (HA) rights and which shall have Patient Manager (PM) rights.

2.2.2 Identification & responsibilities of the Patient Manager (PM)

The Patient Manager, a healthcare professional, is responsible for the patient monitoring set-up and follow-up.

He is responsible for the patient monitoring initiation, for the patch commissioning and application onto the patient, and for providing important instructions and information to the patient. MultiSense® PRODUCT is supplied within the MultiSense® KIT. Once the patch is attached to the patient, the PM must provide the MultiSense® KIT to the patient (box, compatible devices and accessories, compatible smartphone).

Once the patient is wearing the MultiSense® PRODUCT, he can be remotely monitored by one or multiple PMs. To do so, the PM connects to the RDS Web app using his credentials and the URL of the Web portal (provided in the account creation email). This URL must be kept. If necessary, the Hospital Administrator can re-send it.

2.2.3 Identification & responsibilities of the Patient Relationship Manager (PRM)

Once the PM has indicated that the patient is discharged, a Patient Relationship Manager (PRM, third-party provider) can consult the Web portal and see all the patients that were recently discharged.

The PRM must call the discharged patient on his cell phone to ensure that he has understood the instructions for use. At the end of the monitoring, the PRM guides the patient through the patch removal and return procedures.

2.2.4 Identification & responsibilities of the Patient

The patient is monitored with the MultiSense® PRODUCT. **He is responsible for the correct use of the MultiSense® PRODUCT and the compatible devices and accessories provided in the KIT.** He must follow the guidelines, warnings and cautions provided by the PM and indicated in the paper patient instructions.

At the end of the monitoring period, the patient is contacted by the PRM to guide him through the next steps. With the assistance of a caregiver, the patient is responsible for the patch removal and the return of the device and its compatible accessories. These instructions are also provided in the paper patient instructions.

To use the MultiSense® PRODUCT, users must be able to understand and follow the instructions provided with the PRODUCT, depending on their profile. The instructions provided in the manuals are sufficient to use the MultiSense® PRODUCT; no training is required.

2.3 Indication for use

The MultiSense® PRODUCT is indicated for the following uses:

- Patients who are not in immediate danger and who would benefit from clinical data monitoring
- Patients in non-critical care settings (e.g., in a low-acuity care unit, at home, or in a follow-up care unit)

The MultiSense® PRODUCT is a single use product for a single patient.
Note: *Re-use of the patch is considered abnormal use of the device. In addition to performance degradation and sensor malfunction due to lack of adhesion, such misuse will generate mechanical discomfort for the patient.*
In any case, the closure of a monitoring does not enable the reopening of a second monitoring without the device having been refurbished by RDS.
The safety and the performance of the fully refurbished product are validated and certified by the manufacturer. ***Do not use/reuse if the refurbishing was not made by the manufacturer.***

No cleaning or disinfection step is required for the patch prior to its use (ready to apply).
Before attaching the patch, the patient skin must be cleaned as per the instructions provided in the manual provided with the MultiSense® PRODUCT.

2.4 Intended patient population

Demographics	Adult over 18 years old
Specificity	No specific patient population
	Not socially isolated
	No known skin allergy
Medical conditions to be diagnosed	None (not a device intended for diagnostic)
Medical conditions to be monitored	Any medical condition that would require monitoring based on the clinical parameters captured by the solution. It is to note that the product is designed to monitor the patient's state of health at regular intervals, but not to detect sudden events.
Patient selection criteria	Any patient that complies with the inclusion checklist criteria presented on the overpackaging of the kit: - Patient is adult and not in immediate danger - No active implantable device (pacemaker, automatic defibrillator,…) - No known skin allergy to adhesive or silicone or skin disease - Application site is prone for setup: no tattoo, freckle, scar or irritated/infected skin - No elective surgery or imagery planned in the next 5 days

	- No risk of pressure sore at the point of patch placement - The patient lives in an area with either data connectivity or ability to set up a WI-FI connection at home on the first day (alone or with some help) - The patient is able to understand information, to comply with them and to use a smartphone - The patient owns his own smartphone in order to receive the technical notification sent to him by text message - Patient has a helper to provide support for the patch removal

2.5 Intended use environment

The MultiSense® PRODUCT is intended to be used in the following environments:

- Hospital (non-critical care settings/general wards/conventional units)
- Patient's home
- Patient's accommodation
- Long-term care facility
- Travels between the above-mentioned locations

***Note** – A wireless Internet access (Wi-Fi or mobile network) must be available in these locations*.

***Note** – Environment should enable proper reception of emails from the solution to the PM*

2.6 Essential performances

The two essential performances of the MultiSense® PRODUCT are the heart rate and the SpO2. Refer to "*Technical description*".

2.7 Contraindications

- Do not use the device with patients with a high risk of health deterioration or patients that are considered in immediate danger by the clinical team in charge of their follow-up.
- Do not use the device with patients in critical care settings.
- Do not use the device with patients with a known allergy to adhesives and/or silicon.
- Do not use the device in an MRI environment.
- Do not use the device with patients with an implantable device (pacemaker, automatic defibrillator…). Do not use the device with patients with localized infection, ulceration, or skin lesions at the patch location.
- Do not use the device on tattooed skin, or on moles or freckles.
- Do not use the device with neonatal or pediatric patients.
- Do not use the device with pregnant or breastfeeding women.

2.8 Side effects

- Skin reactions or injuries can occur at the patch location (irritation, redness, itching, maceration, allergic reaction).
- Pressure sore at the patch location.

2.9 Residual risks

The residual risks were assessed individually and globally in regard to the benefits. There are no unacceptable residual risks which would impact patients' safety. Overall residual risk is estimated as negligible.

3) Sensors & measurements

The MultiSense® PRODUCT patch includes five embedded sensors.
These sensors allow the MultiSense® PRODUCT to provide the healthcare professional with different measurements such as

- ECG trace[1]
- Heart rate
- Oxygen saturation
- Respiratory rate
- Skin temperature
- Activity level
- Posture

WARNING ABOUT THE PPG SENSOR
Use of controls, settings or procedures other than those specified in this manual might result in exposure to harmful radiations.
Do not directly look into the light emission opening of the PPG sensor.

***Note** – This device must be protected against unauthorized use.*

4) Compatible elements

Compatible elements must be used in combination with the MultiSense® PRODUCT to pursue its medical purpose. These elements are provided together with the MultiSense® PRODUCT, within the MultiSense® KIT.

4.1 Compatible Smartphone

MultiSense® PRODUCT smartphone application is installed on a dedicated smartphone acting as a gateway. Thus, the smartphone and its charger are needed to enable continuous transfer of data.

4.2 Compatible Battery

The battery is inserted into the battery lid, which is fixed into the battery compartment ("battery socket") of the patch, to provide sufficient energy to enable the proper functioning of the device.

4.3 Compatible ECG snap-on electrodes

[1] Not for clinical interpretation; for evaluation of data consistency only

One compatible electrode must be placed on the external ECG cable to allow the device to collect ECG data. Additional identical spare electrodes are made available for replacement during the monitoring period if necessary (at least 1 additional).

4.4 Abrasive tape, disinfectant wipe, cleaning wipe

Tape & wipes used for the preparation of the skin before patch installation.

4.5 Adhesive remover wipe

Wipes specifically designed to help the removal of strong adhesive from the skin

4.6 Return label & box

A label to return the product to RDS is placed in the MultiSense® KIT box. It will enable the patient to easily return the product to RDS wherever he is located.

5) Equipment necessary for operating the PRODUCT

5.1 For patch positioning

When positioning the patch on the patient, a **skin compatible marker** can optionally be used to mark the outline of the patch.

After taking note of this location and before cleaning the skin, a **shaver** (electric or manual) must be used, if necessary, to shave both patch and external electrode application areas.

5.2 For patient monitoring

The patient must have a **personal cell phone with text message capacities**, to receive notifications from the MultiSense® PRODUCT.

The PM must have access to a **computer with a Web browser meeting following minimum requirement**:

- Hardware:
  - minimum resolution for screen device: 1280x1024 pixels
  - minimum power for device: core i5 or equivalent
  - minimum memory for device: 4Go
  - minimum free space of hard disk: 500Mo

- Software: a recent compatible Internet browser installed: HTML5 / PWA compatible Internet browser with no incompatible extension or plugin installed (if an extension and/or plugin is installed, RDS cannot guarantee the proper operation of the Web portal)

- RDS recommendations:
  - chrome: Version >= 94.0.4606.81
  - Firefox: >= 93.0

6) Installation of the MultiSense® PRODUCT

A step-by-step tutorial for installing the MultiSense® PRODUCT is provided to the healthcare professional in the professional manual ("Global User Manual"), which is supplied with the device in paper format.

WARNING
Only healthcare professionals in charge of the patients can install the MultiSense® PRODUCT.

7) Replacement of elements

7.1 Replacement of the compatible ECG electrode by the PM

If the ECG electrode is coming off, it must be replaced with another compatible electrode:

1) Ensure the ECG electrode to be replaced is entirely removed from the snap button and placed in the appropriate bin
1) Remove any remaining adhesive from the skin, if applicable
2) Disinfect the skin with a compatible disinfectant wipe
3) Please note that skin abrasion should only be done if the electrode location differs from the initial one
4) Clean and dry the area
5) Fix the snap button onto a new compatible ECG electrode, then apply the electrode on the patient's skin; this electrode can remain in place during the monitoring period

A compatible electrode must be used: Do not use any other ECG electrode.

7.2 Replacement of the compatible ECG electrode by the patient (at home during the remote monitoring phase)

In case the ECG electrode must be replaced by the patient at home:

1) Ensure that the place where the ECG electrode was previously placed is identified
2) Ensure the ECG electrode to be replaced is entirely removed from the snap button and placed in the appropriate bin
3) Remove any remaining adhesive from the skin, if applicable
4) Clean the skin with soap and water, then dry the skin
5) Place the new ECG electrode on the snap button then on the skin at the same place it was previously; this electrode can stay in place during the monitoring period

A compatible electrode must be used: Do not use any other ECG electrode.

7.3 Replacement of the overlay by the PM

The patient is not allowed to replace the overlay. The overlay must only be replaced by the PM in case of difficulties during the patch installation.

In case of replacement, the new overlay must be positioned on the patch by centering its hole with the membrane on the battery lid. The overlay must not cover the battery lid membrane.

If this overlay has come off during patient monitoring (because it loosened up or has been removed), the patient must contact the clinical team that will fix a new overlay over the patch. In the meantime, the patch must be protected against moisture as much as possible, and the patient must refrain from taking a shower.

V. Warnings and cautions for the healthcare professional

Warning, Caution and Note in this document	
WARNING	A WARNING calls attention to a condition or possible situation that could cause injury to the user and/or patient.
CAUTION	A CAUTION highlights a condition or a potential situation resulting in degraded performance.
NOTE	A NOTE highlights an important piece of information.

1) Important warnings

IMPORTANT WARNINGS
Sometimes, the patient's physiological data may appear normal while the patient's state of health is not. Never overlook a patient who does not feel well based on your trust on "satisfactory" monitoring data. The patient's physiological data may falsely appear normal. As a consequence, normal monitoring data do not rule out an underlying clinical deterioration. A patient who reports something should always be investigated.
The MultiSense® PRODUCT is designed to allow the clinical team to monitor a patient's physiological parameters at regular intervals but is not an emergency management device. It is important to clarify with your patient that if he doesn't feel well or in the event of a sudden health event, he must contact the emergency services or the clinical team without delay to notify them.

2) Safety warnings and cautions

WARNINGS
The MultiSense® PRODUCT is not for patients in immediate danger; notifications are used to simplify patient care and they are not intended for the detection of rapid health deterioration.
Notifications are a support for patient management and should not preclude regular review of any patients. It is the responsibility of the clinical team to ensure patients are reviewed regularly.
The Mute mode must only be used under the conditions defined by the healthcare professionals.
The raw signals are only displayed for consistency check of the derived values: they must not be used for diagnostic purposes.
Do not use the MultiSense® PRODUCT during magnetic resonance imaging (MRI) or in an MRI environment or

in the presence of X-ray equipment.
Use of controls, settings or procedures other than those specified in the user manual might result in exposure to harmful radiations.
Do not directly look into the light emission opening of the PPG sensor.
The conductive parts of the external electrodes must not touch other conductive parts, including a ground connection.

CAUTIONS
Do not use the MultiSense® PRODUCT if it appears or is suspected to be damaged, or if its package is damaged.
Do not apply the MultiSense® PRODUCT patch and the compatible electrodes on damaged, wounded, or non-intact skin.
Do not use other sensors and/or other components than those defined to be compatible by RDS.
The Patient Manager should always check the raw data after assessing the patient's derived vitals and before making a decision regarding readmission.
Only healthcare professionals in charge of the patients can set up the MultiSense® PRODUCT.
The maximum use duration of the MultiSense® PRODUCT is five (5) days.
Do not keep a patch on a patient's skin after the end of a monitoring period.
If multiple patches are placed on multiple patients at the same time, check that the phone number matches the patient phone number.
If multiple patches are placed on multiple patients at the same time, ensure that the correct compatible smartphone is provided to the correct patient.
The conductive parts of sensors and connectors should not contact other conductive parts, including earth.
Applying the MultiSense® PRODUCT patch with excessive pressure for prolonged periods can induce pressure sore injuries.
Do not try to remove the adhesive, the electrode or the battery from the patch.

3) Warnings and cautions with regard to performances

WARNINGS
The patch adhesive is sensitive to environmental influences such as mechanical interactions, water/moisture, …

WARNINGS
The patch operation is subject to protection against humidity. Some situations are to be avoided (e.g.: improper protection of the patch during a shower with hot water, a situation with air humidity and water condensation like being outside during cold weather).
As the device is not compliant with IEC 60601-1 (clause 8.5.5), it is not defibrillation proof.
In case a defibrillation is necessary on a patient wearing the MultiSense® PRODUCT patch, the monitoring device must be removed before defibrillating.
Remove the device if it is placed in an area where defibrillation pads must be applied.
The MultiSense® PRODUCT patch is not compatible with surgery and high frequency electro-surgical equipment.
The device must be used immediately after opening the kit.

CAUTIONS
The MultiSense® PRODUCT is not compatible with implantable devices (pacemaker, automated defibrillator…).
While dressing and undressing the patient, take care of the MultiSense® PRODUCT patch and its distant ECG electrode. A detached or poorly attached electrode may result in reduced performance.
The SpO2 measurements precision is guaranteed only under low level activity during the monitoring period.
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the MultiSense® PRODUCT and the other devices should be closely monitored to check that they are properly operating.
Use of components other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity and consequently, cause a MultiSense® PRODUCT failure.
To minimize the risks of interference between the MultiSense® PRODUCT and other devices, it is recommended to avoid using it near other electrical equipment.
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12”) to any part of the MultiSense® PRODUCT. Otherwise, this could result in degradation of the device performances.
You must use a compatible battery: Do not use any other battery.

4) Warnings and cautions with regard to service and maintenance

WARNING
The device must only be used for the purpose stated in this document.

CAUTIONS
No modifications of the device and its accessories are allowed.
Do not adjust, repair, open, disassemble, or modify the MultiSense® PRODUCT patch or its accessories. It may lead to injuries to the users or equipment damages.
Do not throw the MultiSense® PRODUCT patch and its accessories away. Please follow the disposal and return procedure of the device.

5) Warnings and cautions with regard to the patient

WARNINGS
If the patient wants to remove the patch during the predefined monitoring period, he must call the clinical team before making any decision.
After removal of the patch, do not replace or reuse it on yourself or someone else.
Remove the patch according to the instructions in "*Removal and return of the MultiSense® PRODUCT patch*".
Do not cover the patch battery lid.
Keep the device away from direct sunlight exposure or heat sources.
Avoid the presence of lint or dust on the device, in particular close to the sensors or on the adhesive parts as it can affect the quality of the measure.
Do not excessively cover the device and keep it away from heat sources. It is recommended to wear loose and comfortable clothing while wearing the device.
The patch operation is subject to protection against humidity. Some situations are to be avoided (e.g.: improper protection of the patch during a shower with hot water, a situation with air humidity and water condensation like being outside during cold weather).
Keep the device away from electromagnetic sources (Wi-Fi router, 4G antenna).
Do not pull the electrode wire.
Do not tamper with the compatible smartphone and its accessories.
Do not use the device if tampered.

CAUTIONS
An Internet connection (via Wi-Fi or mobile network) must be available to enable the monitoring.
Whenever possible, use the Wi-Fi network, particularly at home. Do not change other connection settings (ensure that Internet access is always turned on).
Always verify the integrity of the compatible smartphone charger before plugging it to the smartphone or to the mains outlet.
Always verify the compatible charger is not wet before using it.
Do not remove the SIM card.
Do not alter the compatible dedicated smartphone settings beyond the instructions provided in the user manual.
The dedicated smartphone must be turned on and have a sufficient load for functioning at all times.
Keep the dedicated smartphone at close distance (within Bluetooth range, <10m).
Ensure that the dedicated smartphone is always with you, in order to avoid losing it or having it manipulated by a malicious person. In case the smartphone is lost or robbed, please contact your Patient Relationship Manager (PRM) or your Patient Manager (PM).
Avoid situations where the smartphone might lose the Internet connection (basement, cinema, etc.), within limits defined by your clinical team.
Avoid applying important temperature changes to the device during monitoring.
Avoid situations where your body temperature may artificially increase (excessive clothing, blankets or warm clothing).
Do not apply the MultiSense® PRODUCT patch on wounded/irritated skin.
Do not immerse the MultiSense® PRODUCT patch: Do not take a bath or go the swimming pool.
Do not immerse the patch or expose it to water sprays for an excessive amount of time.
Avoid lying down on the patch over a long period.
Do not engage in intense physical activity.
Keep the device out of reach of pets, pests or children.
If you feel uncomfortable or itchy, you may consider removing the MultiSense® PRODUCT patch. Please inform the clinical team in charge of your monitoring before removing the patch.
If the patch is not easily accessible to remove it, please ask a relative to help you remove the patch.
Use the adhesive remover wipe provided by the clinical team to slowly detach the adhesive from your skin, starting at the top of the patch.

CAUTIONS
If your skin is irritated, do not use adhesive remover wipes. Use soap and water instead.
Do not swallow the solvent of the adhesive remover wipe. In case of such an event, contact your clinical team immediately for medical advice.
Do not bend the MultiSense® PRODUCT patch while handling it.
Do not throw the patch into the bin.

6) Warnings and cautions with regard to safety

CAUTIONS
PASSWORD: you must use a personal password. A good password is at least 8 characters long and includes upper- and lower-case letters, numbers and special characters. Warning: You must remember your password without showing or sharing it. This password prevents unauthorized access to the Web portal and the patient's data. You must not share it (intentionally or unintentionally) to a third party.
MESSAGING: do not open suspicious messages or attachments and notify nearby IT upon receipt. Do not click on suspicious Web links or links that require a login and password.
SOFTWARE: do not download or install software that is not authorized by local IT.
MOBILITY: as you will receive 2FA codes by SMS do not leave your personal cell phone unattended. Outside your home, keep it with you.
INCIDENTS/ALERTS: Do not ignore incidents that occur to the device. Immediately contact your IT team in order to take the appropriate measures.
You must prevent any unauthorized access to patients' data: Do not share your password; Use a secured network; Follow the user manual's instructions and the instructions regarding cybersecurity.
You will receive a 2FA code by SMS every 15 days or when your password has been modified. You will have to use this code when logging onto the Web portal. This code allows you to fight against unauthorized access and enhances the security when accessing health data (please refer to "*Connecting to the Web portal*" for more information).
Do not open any emails from untrusted sources: always verify the integrity (domain name, spelling…) of the sender. RDS will never ask for your credentials (ID & password) in an email.
Do not give the benefit of the doubt to offers made by strangers.
Lock your laptop whenever you are away from your workstation.
Purchase and install an anti-virus software for the computer where the Web portal will be accessed.

CAUTIONS
RDS will never contact the user to ask for personal information including password and login details.
Users should maintain their computer operating system (OS) and Web browser up-to-date and should ideally perform automated security updates and use an anti-virus and anti-spyware tool (OS and Web browser).
Computers should have a firewall activated.
Always check that the Web site is secure. To do so, ensure that a lock symbol is displayed next to the URL. This symbol ensures that the communication with the Web site is encrypted.

For more information, visit the following link:
https://www.ssi.gouv.fr/uploads/2020/09/anssi-guide-attaques_par_rancongiciels_tous_concernes-v1.0.pdf (in French only).

7) Other cautions

CAUTIONS
The compatible smartphone should only be used by authorized personnel (the Patient Manager [PM] of the patient for whom the medical device is intended and the patient).
The environmental conditions defined for the storage and the transport must be respected, to avoid the degradation of the safety and performances of the device.
Protect the device against sudden temperature changes that could lead to condensation inside the device.
The user and the patient must report any serious incident that has occurred in relation to the MultiSense® PRODUCT directly to RDS (refer to the contact information in "*General information*" in the user manual) and the local legal authority.

VI. Warnings and cautions for the patient

This section provides the information and instructions to be delivered to the patient and that he must follow during the monitoring period. All these instructions are provided to maintain a safe and efficient use of the MultiSense® PRODUCT.

The PM must explain to the patient the reasons for the monitoring with the MultiSense® PRODUCT and the operating principle of the device.

The patient can report specific events that may have impacted long term performance of the device (examples: use of a defibrillator, use of an X-Ray machine, …). These events can be reported in the smartphone application or directly to the Patient Relationship Manager.

1) Precautions with regard to connectivity

- Always keep the dedicated smartphone turned on, charged and close to you, in the same room, and within 10 meters.

- Avoid situations where the dedicated smartphone might lose the Internet connection (basement, cinema, etc.), within limits defined by your clinical team. A connection (via Wi-Fi or mobile network) must be available to enable the data transfer from the smartphone application to the cloud.
- Always take the dedicated smartphone with you when traveling.
- Whenever possible, configure Wi-Fi access and in particular at home.
- Always keep your personal cell phone close to you in order to be able to receive text messages and technical notifications. Make sure you are always available to answer your personal cell phone should the clinical team try to contact you. Always follow the instructions provided in the text message sent by the clinical team.

***Note** – The PM must ensure that a correct primary cell phone number is recorded in the MultiSense® PRODUCT Web portal to be able to further contact the patient.*

2) Precautions with regard to water interference

- Do not shower in the six hours following the patch application.
- If the patch gets wet, dry it by dabbing with a dry towel. Do not rub. The patch may temporarily stop working after showers. It will restart automatically.
- To protect the patch, avoid immersing it while taking baths or swimming and avoid any other activity resulting in excessive sweating.
- Do not immerse the patch in water, do not expose it to water sprays for an excessive amount of time.
- Do not take long hot showers as the patch should rarely and barely be exposed to a direct stream of hot water. Short showers are allowed.

3) Precautions with regard to environmental interferences

- Remove the patch if you need to do an MRI, X-ray, CT or PET-scan
- The MultiSense® PRODUCT patch is **not** compatible with surgery and high frequency electro-surgical equipment
- Keep the device away from direct sunlight or it may affect the PPG sensor and temperature sensor
- Keep the MultiSense® PRODUCT patch away from heat sources and extreme temperatures
- During the monitoring period, avoid exposing the device to important temperature changes
- Do not excessively cover the MultiSense® PRODUCT patch or it may affect the temperature sensor
- Keep away from electromagnetic sources (Wi-Fi router, 4G antenna)
- Avoid situations where your body temperature may be artificially increased (excessive clothing, blankets or warm clothing)
- Do not engage in intense physical activities
- Avoid being outside during cold weather
- Keep out of reach of children,pets and pests.

4) Handling of the MultiSense® PRODUCT patch

- Do not bend the patch while handling it
- Do not pull the external electrode wire
- Do not cover the patch battery lid
- While changing clothes, be careful with the MultiSense® PRODUCT patch and the ECG electrode. A detached or poorly attached electrode may lead to degraded performances
- Avoid the prolonged application of pressure on the patch, such as sleeping on a hard surface

WARNING
Applying the MultiSense® PRODUCT patch with excessive pressure for prolonged periods can induce pressure sore injuries.

5) Discomfort and irritation

- If you feel uncomfortable, itchy or if you are encountering intense skin irritation, you may consider removing the MultiSense® PRODUCT patch. Always call the clinical team in charge of your monitoring before removing the patch. If the patch is not easily accessible, please ask a relative to help you remove the patch;
- If you experience severe irritation or if you feel unwell, talk to a nurse or your doctor so that they can inspect and remove the patch if necessary
- If you have any problem with the dedicated smartphone or the patch, talk to a nurse or to your doctor

WARNING
If your skin is irritated, do not use solvent wipe. Use soap and water instead.

6) Information on the compatible smartphone

- Please do not tamper with the compatible dedicated smartphone and its accessories
- Please always keep the dedicated smartphone charged and nearby at all times
- In the RDS MultiSense® PRODUCT smartphone application, two icons indicate the connection between the patch and the smartphone and between the smartphone and the Internet network, respectively. If one of these connections is interrupted, the icon turns red. It is essential that the left “Bluetooth” icon remains green (keeping the charged smartphone nearby). If it turns red, all you have to do is move closer to the smartphone for the Bluetooth connection to be restored.
- Do not charge the dedicated smartphone in the presence of moisture (when the charger is wet, close to a wet surface...).
- Make sure that you always have the dedicated smartphone with you, in order to avoid losing it or to prevent it from being manipulated by a malicious person. In case the dedicated smartphone is lost or robbed, please contact your Patient Relationship Manager or your Patient Manager.
- Do not remove the SIM card.

7) Discharge from hospital and patient location

The Patient Manager informs the patient to always contact the hospital in case of doubt, if he feels bad, uncomfortable or itchy. A phone number is indicated on the cover of the paper version of the patient manual. This phone number will enable the patient to contact the clinical team in charge of his monitoring in case of any problem.

The Patient Manager gives instructions on how to use the MultiSense® PRODUCT at home with the support of the paper patient instructions provided. In particular, the PM highlights the warnings and cautions related to the use of the MultiSense® PRODUCT at home.

The Patient Manager informs the patient that a Patient Relationship Manager will contact him as soon as he gets home and at the end of the monitoring.

If the patient has additional questions, the Patient Manager must answer them.

8) Removal and return of the MultiSense® PRODUCT patch

8.1 Removal of the patch

The patient will be told by the PRM when the monitoring is over and when to remove the patch. If the patient wants to remove the patch before the end of the predefined monitoring period, he must call the clinical team before making any decision. The removal procedure must be carried out with the help of a third person.

- The patch must be carefully removed so as to not damage the skin.
- Remove the patch according to the instructions provided in the instructions for use.
- After removal of the patch, do not replace or reuse it on yourself or someone else.
- Do not bend the device. If the adhesive remover wipe does not help to remove the MultiSense® PRODUCT patch, do not pull and bend the device, but rather push on the skin to slowly loosen the device.
- If your skin is irritated, do not use the solvent wipe. Use soap and water instead.
- Do not swallow the solvent of the compatible adhesive remover wipe. In case of such an event, contact your clinical team immediately for medical advice.
- Do not throw the patch into the bin.

8.2 Return procedure

The Patient Relationship Manager (PRM) will call the patient at the end of the monitoring to guide him through the return procedure. This procedure is also described in the instructions for use of the MultiSense® PRODUCT.

The MultiSense® PRODUCT patch must be returned to RDS SAS. The charger and the dedicated smartphone must also be returned to RDS together with the device.

- Do not keep or discard the patch.
- Do not try to remove the adhesive, the electrode cable or the battery from the device.

VII. Troubleshooting for professional users – Error messages

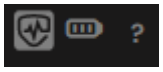
1) Web portal

If the platform is unavailable: try again after 5 minutes.

If the problem persists, contact your patient by phone at regular intervals to check on his status, or ask him to return to your service if necessary, and contact RDS Help Desk.

Troubleshooting event	What to do?
Anywhere on the Web portal	

Troubleshooting event	What to do?
Fatal error An unexpected bug or network infrastructure problem has occurred. The Web portal cannot work anymore and tries to restart (10 times) in order to solve the problem and allow users to continue working.	If the problem persists, it is a Web portal failure. You must: ● Manually restart the Web portal (F5) ● Contact RDS Help Desk if previous step was unsuccessful
Local device Internet disconnection When the Web portal detects an Internet disconnection, the following message is displayed: *"A problem was identified on webportal! Interruption in Internet Network connectivity prevents webportal to work! Please wait when trying to reconnect…"* When the connection is restored, the following message is displayed: *"The internet connection is back! Webportal will now restart in 3 seconds to reconnect you!"* If the connection is not restored after 10 attempts, the following window appears: *"A problem was identified on webportal ! Interruption in Internet Network connectivity prevent webportal to work !"*	The Web portal tries to reconnect in order to solve the problem. If the problem persists, it is a Web portal failure. You must: ● Check your Internet connection or configuration ● Contact your Internet provider ● Manually restart the Web portal (F5)
RDS infrastructure disconnection When the Web portal detects a disconnection to the cloud, the following message is displayed: *"A problem was identified on webportal! Cannot connect webportal anymore to RDS Cloud Service! Please wait when trying to reconnect…"* When the connection is restored, the following message is displayed: *"The RDS Cloud Service is back! Webportal will now restart in 3 seconds to reconnect you!"* If the connection is not restored after 10 attempts, the following message is displayed: "*A problem was identified on webportal ! Cannot connect webportal to RDS Cloud Service anymore !*"	The Web portal tries to reconnect in order to solve the problem. If the problem persists, it is a Web portal failure. You must: ● Manually restart the Web portal (F5) ● Contact RDS Help Desk
Login page	
Forgotten password	Patient Manager: Contact the Hospital Administrator or RDS Help Desk. Hospital Administrator: contact RDS Help Desk.
"Bad Email or Password" even if you use the correct password.	A wrong password has been entered too many times and the user account has been temporarily blocked. Please contact RDS Help Desk.
When a session timeout occurs, the Web portal disconnects the user and redirects him to the login page.	You can re-authenticate yourself to reconnect to the Web portal.

<table>
<tr><th>Troubleshooting event</th><th>What to do?</th></tr>
<tr><td>2FA code not received</td><td>Click “Did not receive my 2FA code” on the login page. Should you not be able to login, contact the Hospital Administrator or RDS Help Desk.</td></tr>
<tr><td colspan="2">Live viewer</td></tr>
<tr><td>The message “No enough calculated patient monitoring data” is displayed on the viewer.</td><td>If the problem persists, it is a Web portal failure. You must:
Go back to the dashboard
Manually restart the Web portal
Contact RDS Help Desk if previous steps were unsuccessful</td></tr>
<tr><td>Battery status problem
Patch battery status
<table><tr><td>  </td><td>No information received about the patch battery</td></tr><tr><td>  </td><td>Patch battery is too low to ensure correct operation of the patch</td></tr></table>
Smartphone
<table><tr><td>  </td><td>No information received about the smartphone battery</td></tr><tr><td>  </td><td>Smartphone battery is too low to ensure a correct behaviour</td></tr></table></td><td>When a battery status problem occurs on the smartphone or on the patch, the Web portal tries to warn users. If the problem persists:
If the patch battery is low and the monitoring period far from being completed, assess the need to contact your patient.
If the phone battery is low, the patient is automatically informed that he must charge the smartphone as soon as possible. If the situation persists during an extended period of time, assess the need to contact your patient.
If no information about the smartphone battery or the phone battery is displayed, contact RDS Help Desk.</td></tr>
<tr><td>Date/time of last update is not the current one</td><td>The dedicated smartphone does not currently have an Internet connection (data are buffered on the smartphone and will be processed on the server once received).</td></tr>
<tr><td>The ECG stops being displayed after some minutes</td><td>This is a known software bug. Refresh the page in order to restore the ECG display.</td></tr>
<tr><td>The heart rate is derived while the ECG is only noise</td><td>This is a known software bug. Development is currently ongoing not to display low confidence data for Heart Rate.</td></tr>
<tr><td colspan="2">Retro viewer</td></tr>
<tr><td>The message “Not enough calculated patient monitoring data” is displayed on the viewer.</td><td>If the problem persists, it is a Web portal failure. You must:
Go back to the dashboard
Manually restart the Web portal
Contact RDS Help Desk if previous steps were unsuccessful</td></tr>
<tr><td>Only raw data is displayed (ECG filtered, Raw PPG and Respiration amplitude), other graphs display “Data unavailable”</td><td>The raw data has been collected with a delay (due to an Internet connection failure). Therefore, only the raw data will be visible (ECG, PPG and</td></tr>
</table>

Troubleshooting event	What to do?
	respiratory rate) as long as the other data are not computed on the server.
Dashboard	
Patient monitoring data is no longer sent or is late (“*latency*” symbol)	If the problem persists, it is a Web portal failure. You must: ● If the monitoring period is far from being completed, contact your patient, verify that the patient strip and phone are ok ● if the monitoring is terminated, or if an early withdrawal has been performed by the patient, close the monitoring ● Contact RDS Help Desk
Modification of notification rules and notification rules templates	
Simultaneous modification of the notification rules by two users of the Web portal Once you click “*Save*” in the notification rules page, the following error message appears:  This means that there is a backup conflict: two users have clicked the “Save” button at the same time for the same “patient monitoring”. This generates a conflict in the corresponding rules.	Please check what has changed in the notification rules, and click “Save” again to apply your changes if necessary.

2) Application interface

In case of unsuccessful pairing between the patch and the dedicated smartphone, please use another MultiSense® PRODUCT.

Context	Title and type	Description	User actions
The PM has incorrectly completed the patient creation form	Error	● A gender must be selected ● 3 characters min. required ● Invalid numerical format ● Invalid date format ● Invalid height ● Invalid weight	Update the available fields.

Context	Title and type	Description	User actions
The PM tries to create a patient without an Internet connection	Network unavailable Error	The Internet connection is not currently available. If you can, please use a Wi-Fi network. OR The Internet connection is not currently available. Please check the configured Wi-Fi connection.	• Configure the Wi-Fi network • Try again • Cancel
The PM tries to create a patient but the API generates an error (a patient might have been created twice or a data format might no longer be accepted by the API or there is temporary outage of RDS servers).	An error occurred Error	An error occurred while trying to create the patient.	• Try again • Cancel
The API generates an unknown error or there is a temporary outage of the RDS servers when the PM tries to start the monitoring.	An error occurred! Error	The launch of the monitoring failed; you can contact RDS Help Desk.	• Try to launch the monitoring again • Contact the Help Desk
The PM has started creating a patient and tries to exit the creation view (which would result in the loss of the entered data)	Warning	You have started creating a patient. Are you sure you want to cancel and return to the Home page?	• Return to the Home page • Cancel
A warning is displayed in the patch application tutorial performed by the PM.	Warning! WARNING	• DO NOT apply the patch to the patient until the skin is completely dry. • DO NOT touch the adhesive layer! • The adhesive takes approximately 6 hours to fully adhere to the skin.	Close the warning and repeat the procedure, by strictly following the instructions.

3) Connectivity

If the Bluetooth or Internet connection is lost, please contact the patient. If the problem persists, contact RDS.

4) Loss of performances

In the event of loss (or degradation) of device performances, arrange for the patient's return to the hospital if you think that he should be monitored more closely.

5) Incorrect battery insertion

If you have attached the patch to the patient before inserting the battery, remove the MultiSense® PRODUCT patch and restart the procedure with another patch.

VIII. Technical description

1) Technical safety data

1.1 Electromagnetic compatibility (IEC 60601-1-2)

The MultiSense® PRODUCT has been tested and found compliant with the requirements of IEC 60601-1-2 4th edition for electromagnetic compatibility of medical devices in the home healthcare environment.

The MultiSense® PRODUCT operates in the 2400 - 2484 MHz frequency range using FSK modulation (reception and transmission). The maximum radiated output power with the internal antenna is +5.4 dBm.

1.1.1 Guidance and manufacturer's declaration

The MultiSense® PRODUCT is suitable for use in the following environment. The user must assure that it is used only in the electromagnetic environment as specified.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions - CISPR 11	Group 1	The MultiSense® PRODUCT uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions - CISPR 11	Class B	The MultiSense® PRODUCT is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current emissions - IEC 61000-3-2	N/A	N/A
Voltage changes, voltage fluctuations and flicker EMISSIONS - IEC 61000-3-3	N/A	N/A

Immunity tests	IEC 60601-1-2 Compliance	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD), IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors shall be wood, concrete, or ceramic tile. If floors are covered

Immunity tests	IEC 60601-1-2 Compliance	Compliance level	Electromagnetic environment - guidance
			with synthetic material, the relative humidity shall be at least 30 %
Radiated RF electromagnetic field, IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	10V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of MultiSense® PRODUCT, including cables.
IMMUNITY to proximity fields from RF wireless communications equipment, IEC 61000-4-3	Levels of table below	Levels of table below	
Conducted RF, IEC 61000-4-6	Not applicable	Not applicable	Not applicable
Electrostatic fast transient / burst, IEC 61000-4-4	Not applicable	Not applicable	Not applicable
Surge, IEC 61000-4-5	Not applicable	Not applicable	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m (50/60 Hz)	30 A/m (50/60 Hz)	Power frequency magnetic fields should be at levels characteristic of a location in a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply	Not applicable	Not applicable	Not applicable

1.1.2. Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Modulation	Immunity test level (V/m)
385	Pulse modulation 18 Hz	27
450	FM, ± 5 kHz deviation 1 kHz sine	28
710	Pulse modulation 217 Hz	9

Test Frequency (MHz)	Modulation	Immunity test level (V/m)
745		
780		
810	Pulse modulation 18 Hz	28
870		
930		
1720	Pulse modulation 217 Hz	28
1845		
1970		
2450	Pulse modulation 217 Hz	28
5240	Pulse modulation 217 Hz	9
5500		
5785		

WARNINGS
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12”) to any part of the MultiSense® PRODUCT. Otherwise, this could result in degradation of the device performances.
The MultiSense® PRODUCT is not compatible with specific investigations or treatments such as MRI, diagnostic ECGs.
Inform the patient to keep the smartphone at a minimum distance of 30cm from the patch placed on his back.

2) Performance Characteristics

2.1 Shelf life and expected service life

The MultiSense® PRODUCT is only provided within the MultiSense® KIT. The safety and performances of all the elements of the KIT (including the MultiSense® PRODUCT patch, the compatible devices and accessories) are guaranteed over the following periods :

Shelf life	**200 days**
Extended Service Life	**200 days (storage) + 5 days (use)**

2.2 Technical performances

Parameter	Range	Conditions	Temporal resolution	Accuracy	Unit
HR (Heart rate)	30-200	Under normal operating conditions and medium activity level	10 seconds	10% or ± 5 bpm (Whichever is greater)	bpm
RR (Respiratory Rate)	6-40	Under normal operating conditions and low activity level	30 seconds	<4 rpm	rpm
SpO2 (Arterial oxygen saturation)	70-100	Under normal operating conditions and low activity level	30 seconds	<3.5%	%
Skin temperature	20-45	Under normal operating conditions and medium activity level	5 minutes	1°C	°C
Posture & activity level	• Low = Still • Medium = Walking • High = Activity higher than walking slowly	N/A	N/A	N/A	N/A

***Note** – Because the pulse oximeter measurements are statistically distributed, only about two-thirds of the pulse oximeter measurements can be expected to fall within the Arms of the value measured by a co-oximeter.*

3) Environmental specifications – Storage conditions

3.1 Environmental operating conditions

Temperature	+5°C to +45°C
Relative humidity	15% to 95% (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa

The water resistance of the MultiSense® PRODUCT patch is class IP24: the device is protected against the penetration of solid objects >12.5 mm and against water splashes in accordance with IEC 60529.

3.2 Environmental storage and transport conditions

	Transport	Storage
Temperature	● - 10°C to + 5°C, and ● + 5°C to + 35°C at a relative humidity up to 90%, non-condensing. ● > 35°C to 60°C at a water vapor pressure up to 50 hPa after having been removed from its protective packaging and subsequently between uses.	10°C to 35°C
Relative humidity	Up to 90%, non-condensing	Up to 90%, non-condensing

The MultiSense® PRODUCT must not be exposed to direct sunlight, a heat source or moisture and must not be stored at low temperature.

4) Connectivity specifications

The MultiSense® PRODUCT is a connected solution. It is important that data upload correctly to RDS servers: make sure that you are not in a "white zone" where the mobile network is notoriously weak; we recommend having at least 1 bar of 4G network in the rooms where the device will be used.

For healthcare professionals

- Check that your hospital infrastructure offers an open Wi-Fi network to which the MultiSense® PRODUCT can connect without authentication.
    - In order for the data to flow effectively from your patients to our servers and back to your Web portal, we recommend the following minimal bandwidth configuration:
        - Upwards Connectivity (smartphone to server): bandwidth > 2Mbps per patient
        - Downwards connectivity > 1Mbps per patient
          You can use tools such as https://speedtest.net/ to check your environment compliance.
- Make sure that the majority of your patients live in areas where mobile connectivity is good. Otherwise, ensure these patients have access to Internet at home through Wi-Fi and know how to configure the Wi-Fi network on the MultiSense® PRODUCT smartphone application.

5) Security recommendations when using software

Please refer to good cybersecurity practices while using our product. You can refer to the "*Digital security warnings and cautions*". We advise you to regularly consult the latest good practices:

https://www.enisa.europa.eu/

IX. Regulatory Information

1) Regulatory Symbols

Please refer to the packaging or the labels of the device for the corresponding information.

Symbol	Description	Symbol	Description
	Manufacturer identification		Date of manufacture
	CE marking logo		Serial number
	Lot/batch number		Catalogue number
	Use by date		Medical device logo
IP24 	General warning sign – IP classification		Do not re-use/Single use
	The instruction manual/booklet must be read		Atmospheric pressure limitation
	Humidity limits		Temperature limits
	Keep dry		Keep away from sunlight
	Fragile, handle with care		Do not use if package is damaged
	Refurbished medical device		Not for general waste
	Consult Instruction For Use		Type-BF applied parts
	MR Unsafe		No alarm on SpO2
	Unique Device Identifier		

2) Standards compliance

The most relevant regulation and standards related to the product are cited in the table below:

European regulation	(EU) 2017/745 (EU) 2016/679 (EU) 2011/65/EU [RoHS 2] and (EU) 2015/863 [RoHS 3] or equivalent
General requirements	ISO 13485:2016 + A11:2021 ISO 14971:2019 IEC 62366-1:2015 (Amd2020) ISO 10993-1:2018 ISO 14155: 2020 ISO 15223-1:2021 ISO 20417:2021 IEC 62304: 2006 +AMD:2015 IEC 80001-1:2021
Safety conformity	IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 IEC 60601-1-6:2010 +AMD1:2013+AMD2:2020 IEC 60601-1-11:2015 + AMD1:2020 IEC 60601-2-57:2011 IEC 80601-2-61:2017
Electromagnetic compatibility (EMC) conformity	IEC 60601-1-2:2014 + AMD1:2020

Safety classification according to IEC 60601-1	
Protection against electric shock	Internally powered equipment
Applied parts	Type BF
Mode of operation	Continuous
Protection against harmful ingress of water or particulate matter	IP24 (According to IEC 60529)

X. Errors in this document

In case errors are detected in this document, please reach out to the manufacturer. Spotted errors will be corrected and this version of the document will be updated.

XI. Incident reporting

The patient must report any serious incident that occurred while telemonitoring with the MultiSense® PRODUCT to his clinical team who will pass on the information to the manufacturer. The patient can also report it to the local legal authority (in addition to his clinical team).

Once the patient has informed his clinical team of any serious incident, the clinical team has to contact RDS directly or can relate to its local vigilance contact who will take the lead to contact RDS. The clinical team can also additionally contact the local authority, regarding the seriousness of the incident.

A serious incident is defined as any incident that has directly or indirectly led, might have let or may lead to any of the following (as per Regulation 2017/745):

- The death of a patient, user or other person
- The temporary or permanent deterioration of a patient's, user's or other person's state of health
- A serious public health threat

XII. Version history

Version	Rationale	Date
1.0	Creation	26/10/2023