myon

SIMPLY WIRELESS

Transmitter, Receiver, Charging Cradle

Model: myon m320

USER MANUAL

History of changes

Version	Author	Date	Comments
1.0	myon AG	06.10.2011	Initial release.
1.1	myon AG	18.01.2012	Minor changes.
1.2	myon AG	21.03.2012	Minor addendum.
1.3	myon AG	07.05.2012	Minor addendum and changes.
1.4	myon AG	14.06.2012	Enhanced usage guidance.
1.5	myon AG	23.08.2012	Minor addendum and some smaller changes.
1.6	myon AG	03.01.2013	Address changes and minor corrections.
1.7	myon AG	28.04.2014	Added device verification procedures; added mains plug instructions; updated FCC information; technical data addendums; corrections.

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1 Important information

1.1 Introduction

In this manual you will find important information, needed for the commissioning and operation of the device.

Always adhere to the safety instructions in the manual of your computer or other systems involved and the ones in this handbook! If you experience any problems, please contact your local sales agency or the respective manufacturer.

1.2 Conventions used in this text

Throughout this manual the following conventions are used.

	Indicates important information that may damage your health, the functioning of the device or the safety of your data if not adhered to.
	Indicates additional information and tips.

1.3 Important information

	Please follow these safety instructions to ensure your safety and the optimal functioning of the device.

The product may be used only as intended (see Section 2.1) and in compliance with the instructions in this user manual, by appropriately trained and qualified personnel. Assembly, modifications, maintenance and repairs have to be carried out by the manufacturer or personnel authorized by the manufacturer.

	Repair attempts by the user are not permitted and will result in a loss of warranty as well as in a loss of conformity with regulatory requirements voiding the user's authority to operate the device.

The product can only be used in combination with accessories, that are specified in the user manual or by the manufacturer by other means. Other combinations, accessories and consumable parts may only be used if they are specifically designed for the intended application and do not affect performance, and safety requirements.

The device contains Lithium-Polymer batteries. Do not damage, crush, burn, freeze or otherwise mishandle the device. Recharge only with the power supply and charging cradle supplied with your myon m320 system.

1.4 Power supply safety

- Disconnect the system from the mains when not in use. You can disconnect the receiver and the charging cradle by pulling the power plug from the mains power outlet.
- The power cord in devices with mains plugs is used for separation from the mains. The power outlet must be located in the vicinity of the device and must be easily accessible.
- The power supplies must be used with a suitable power outlet. If you are not sure if the outlet is suitable, please contact the local power company.
- Make sure that your power supply is equipped with the correct country specific mains adaptor and that the adapter is correctly and firmly installed.
- The device is not suitable for use outdoors.
- The device is not suitable for unattended continuous operation.

1.5 Cleaning and care

- Unplug the power cord from the outlet before cleaning a device.
- The devices can be cleaned with a slightly water and/or alcohol moistened, soft, lint-free cloth. Do not use harsh cleaners, aerosol cleaners or glass cleaners.
- Objects or liquids must not get into the interior of the device.
- Check the device after each cleaning to its functions and to possible damage occurred. If you notice any damage, do not make any repair attempts, but contact your sales agency or the manufacturer.

	To maintain functionality of the myon system all electrical contacts should always be kept clean. In particular, adhesive tape or similar substances must not be attached to the charging contacts of the transmitter or the charging cradle slots' contacts. Please note that myon offers special fastening straps (P/N PA0003 ... PA0009) for the purpose of affixing the transmitter securely to the body.

1.6 Maintenance

No user serviceable parts inside. Do not open or remove the protective housing yourself as you might expose yourself to dangerous voltages and other risks. In case of abuse or accident (such as dropping the unit or improper use) please contact your local sales agency or the manufacturer for maintenance. Store all devices in a secure and dry place when not in use.

2 Preface

2.1 Intended use

The myon320 system is designed to capture and wirelessly transmit EMG sensor signals recorded from human muscles. The myon320 can not be used for the electrical stimulation of muscles.

All product models and types of the product may only be used externally and non-invasively by professional users (e.g. healthcare professionals, doctors, researchers, etc.). Only the components (sensors, power supply, etc.) supplied by the manufacturer are to be used. Additional sensors or spare parts are available upon request from the manufacturer.

2.1.1 Transmitters

The transmitters are intended to record a signal from a pair of electrodes. The recorded signal is immediately digitized and transmitted to the receiver.

The electrode sensor cables are made from material allowing the implementation of thin leads with a very high grade of flexibility to reduce cable and movement artefacts.

However, please keep in mind, that the sensor cables have a limited capability of dealing with mechanical stress. You therefore must avoid any tractive and/or shearing forces and/or torsion to be applied onto the sensor cables.

2.1.2 Receivers

The receivers are intended to receive the sensor data from the transmitter and to output the received data via an analogue output interface for further use with 3rd party hardware systems and/or software.

2.1.3 Charging Cradles

The charging cradle is used to re-charge the transmitter batteries. It is also intended as a place in which to safely store the transmitters when they are not in use.

2.2 Contraindications

Do not use the device on patients with implanted electronic devices of any kind (e.g. cardiac pace makers). The device must not be used in critical care settings / applications or on irritated skin or open wounds.

If the device is used on a patient also connected to high-frequency surgical equipment, such usage may result in burns at the site of the EMG sensor.

The medical practitioner and/or user always has to decide on the basis of the general condition of the patient or subject whether or not the intended application is reasonable. Further information is

accessible in current scientific literature.

The device is not intended for use in an operating theatre, anesthetic gas or oxygen-rich environments. Not for use where there is a risk of compromising the essential performance of medical electrical equipment. Not suitable for use in high magnetic flux, ionizing radiation, sterile, or life- or safety-critical environments. The device is not suitable for unattended continuous operation.

2.3 Possible combinations

In addition to these instructions, the instructions of those products used in combination (e.g. analog-to-digital converters, video motion capture systems, EMG electrodes) must also be observed.

Potential electromagnetic or other interference that occurs between the product and other products may lead to disturbances or malfunctions.

3 System overview

The systems is comprised of three main components: Transmitter, charging cradle and receiver.

Image 1: Transmitter

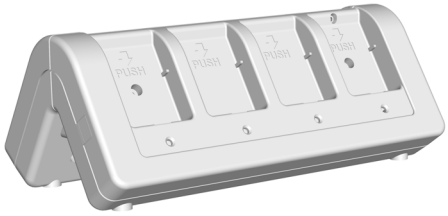


Image 2: Charging cradle

Image 3: Receiver

3.1 Power supplies

Receiver and charging cradle each require a different specific medical grade external power supply to operate.

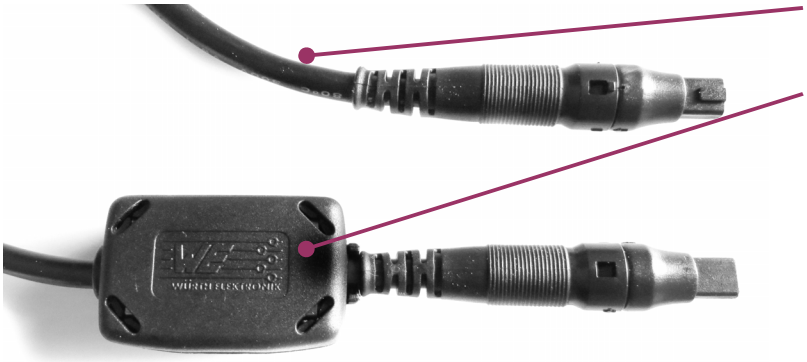
- Mains power supply
- Country specific mains plug
- Device's power supply plug with mechanical reverse voltage protection

Image 4: Power supply

3.1.1 Power supply leads with and without ferrite

Please note that although both types of power supplies are basically identical, for regulatory purposes, m320 charging cradles require the use of a power supply with a ferrite additionally attached to its lead (see Image 5).

In contrast, m320 receivers may be powered by a standard power supply without ferrite.



- Without ferrite: for use with receiver (PA0014)
- With ferrite: for use with charging cradle (PA0016)

Image 5: Power supply lead with and without ferrite

3.1.2 Country specific mains plug

The primary plug is interchangeable. This allows a world wide use. The procedure of changing the plug is shown in Image 6.

Image 6: Assembly of primary plug (Image courtesy of FRIWO Gerätebau GmbH, Germany)

⚠	Power supplies other than those shipped with the myon320 system must not be used.

3.2 Transmitter

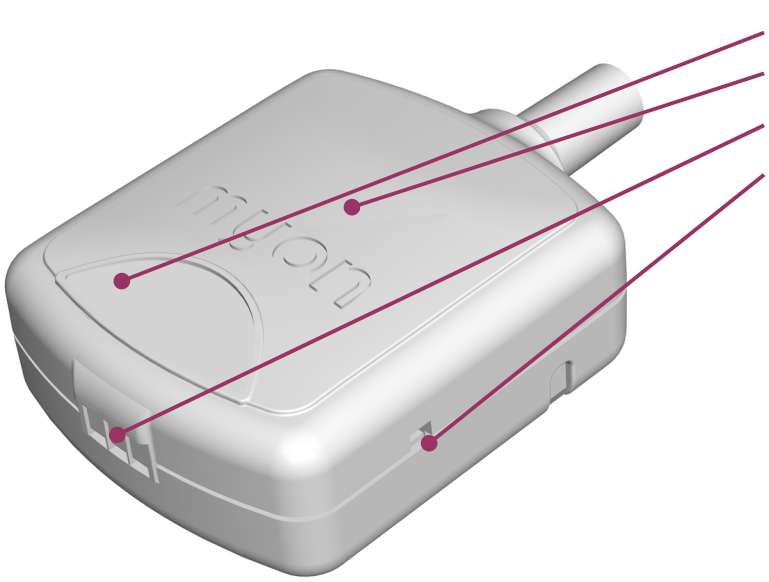


Image 7: Transmitter

3.2.1 Reset switch

In case the transmitter doesn't start transmitting or should stop operation, first check that the transmitter is fully charged. Re-insert the transmitter into a charging slot for a few seconds and try again.

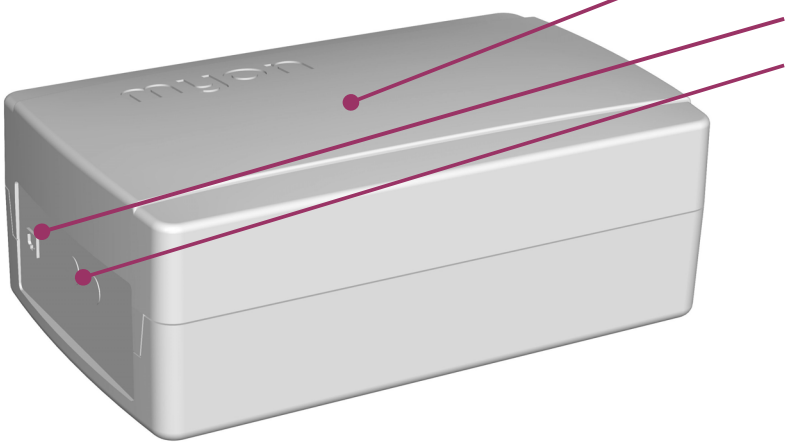
If this doesn't help, resetting of the device may be required.

⚠	A reset must not be carried out without prior advice by the myon support team.

To perform a hard-reset carefully insert the tip of a ball pen into the opening on the side of the transmitter housing and gently press and hold down the reset micro switch for about 5 seconds. The transmitter should restart itself and begin operation immediately. Please make sure that the transmitter has enough battery capacity left to start operation.

ℹ	It may take up to 1 minute for the transmitter to restart after a reset.

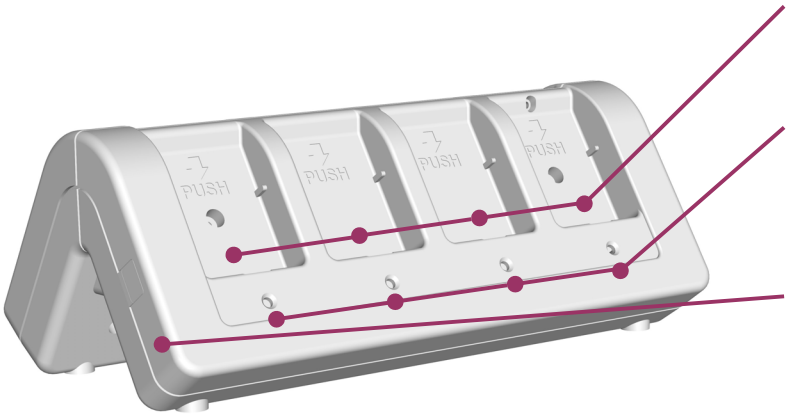
3.3 Receiver



- LED function indicators (inside of housing)
- External power supply
- DSub25 analog output

Image 8: Receiver

3.4 Charging cradle



- 4 charging slots (4 more are on the other side of the device)
- 4 LED function indicators (4 more are on the other side of the device)
- External power supply

Image 9: Charging cradle

4 LED function indicators

4.1 Transmitter

The transmitter indicates its state as described below:

- When removing the transmitter from the charging cradle, the blue transmitter LED located inside the housing will flash for about 2 minutes to signal the proper operation of the transmitter.
- After about 2 minutes the transmitter LED is switched off.
  Thus, during a measurement, there is no LED indication of transmitter operation. This is to prevent the distraction of patients by simultaneous flashing of a relatively large number of transmitter LEDs.
- If during a measurement the remaining capacity of the built-in battery reaches a low value, the transmitter's LED will begin to flash again. In this state further operation of the transmitter is possible for a maximum of about 30 minutes before the transmitter will be switched off automatically. The flashing frequency will be noticeably higher and it is advisable to put the transmitter back into the charging cradle to reload its batteries.

4.2 Receiver

- Within the receiver's enclosure there is one blue LED for each transmitted channel.
- As soon as a wireless connection between a transmitter and the receiver has been established successfully, the respective receiver LED will start flashing.

4.3 Charging cradle

Each charging slot of the charging cradle features a single indicator LED located beneath the slot. The indicator LED indicates three states:

- Battery is re-charging:
  In this state, the charging slot indicator LED will blink at a low frequency, indicating that re-charging of the transmitter's build-in battery is in progress. Please note, that the re-charging process - and therefore blinking of the indicator LED - might take place from time to time even if the transmitter has not been used and stayed in its slot in the charging cradle.

Please check each time you insert a transmitter into a charging slot that the respective charging slot LED starts blinking to make sure the re-charging process started successfully.

- Battery fully charged:
  After the transmitter's battery has been fully re-charged, the charging slot indicator LED is illuminated constantly.
- Empty charging slot / transmitter not properly inserted:
  If a charging slot is empty, the respective charging slot indicator LED will not light up. The

same happens if a transmitter has been inserted incorrectly into a charging slot and thus the electrical contact between transmitter and charging cradle cannot be established.

5 Operation

5.1 Parts included in shipment

The myon system is shipped in a durable carrying case. Depending on your individual system configuration, you may find a varying number of parts and accessories as part of your shipment in the carrying case:

- The number of transmitters you ordered, including the EMG sensor cable.
- A sufficient number of single-use electrodes will be included in the shipment to allow you to conduct at least one measurement with all transmitters at the same time .
- A receiver, including power supply and an analog connector cable (for the analog output version of the receiver).
- As many charging cradles as required to charge all ordered transmitters at the same time. The appropriate number of power supplies is also included.
- This printed manual.
- The carrying case.

5.2 Unpacking and transport

The system is shipped in a durable carrying case that prevents the system from being damaged. It is therefore recommended to use the provided carrying case to store the system if you plan not to use the system for a longer period of time or if you would like to take the system with you on a journey, e.g. by plane.

Also the carrying case shall always be used in case the device needs to be shipped, e.g. for repairs.

- Carrying handle
- Fasteners (press dimple to open)

Image 10: Carrying case

5.3 Device installation

⚠	The installation of the system must be done by adequately qualified personnel.

- Place the receiver and the charging cradle on a flat surface.
- Plug the power connector for the receiver into the power socket on the receiver.
  Do the same for the charging cradle. Do not plug in the mains connector, yet.
- Next, you will have to connect the socket for analog output signals to your specific recording system (e.g. a Vicon Motion Capture System or a National Instruments ADC):

⚠	For the preparation of this interface specific technical knowledge may be required. If you do not have the necessary skills, please consider consulting an expert.
ℹ	For this connection a specifically designed adapter cable may be required.
ℹ	The analog ouput is designed to be acquired with “single ended” inputs of an analog-to-digital converter only. No “differential” input configuration must be used.

  - Dismantle each individual cable of the supplied DSub cable that you intend to connect to your individual analog capture unit. Do not dismantle any cable that will not be connected. If cables have already been dismantled that will not be connected, re-

insulate them with electrical tape.

- Connect each individual cable of the supplied DSub cable to the relevant screw terminal for the analog capture unit you wish to use. See Section 9.2.3 for pin assignment details.
- Make sure that electric ground is correctly and firmly connected.
- Make sure you chose the correct assignment of the individual pins (see Section 9.2 for details).
- Connect the 25-pin DSub cable plug to the analog output connector of the receiver.

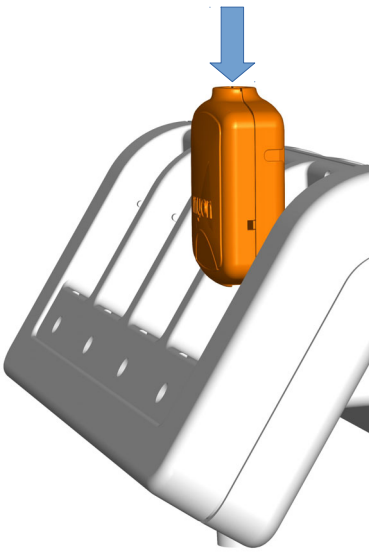
- Plug the external power supplies of receiver and charging cradle into a mains power outlet. You will see several blue LEDs light up inside the receiver. Blue LEDs of the charging cradle will light up if transmitters are inserted (see Section 5.4).
- You may now also turn on your specific recording system (e.g. Vicon) as well as all other interacting systems (e.g. force plates, etc.).

5.4 Charging of transmitters

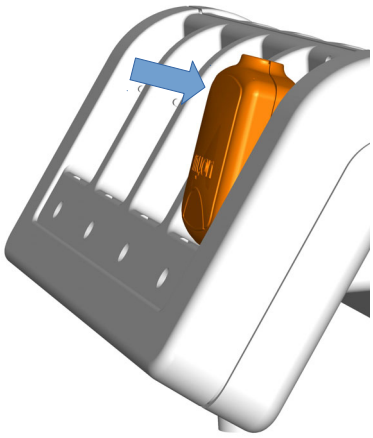
- Make sure that the charging cradle is connected to its external power supply.
- If not done already carefully place each transmitter in a charging slot: Insert it by vertically pushing the transmitter into the charging slot. Then let the transmitter snap into place by pushing the top of the transmitter as shown in the three images below.

⚠	Make sure that no double sided tape or similar adhesive material still remains on the transmitter's rear side from the last measurement. This could make it difficult to remove the transmitter from the charging cradle after charging.

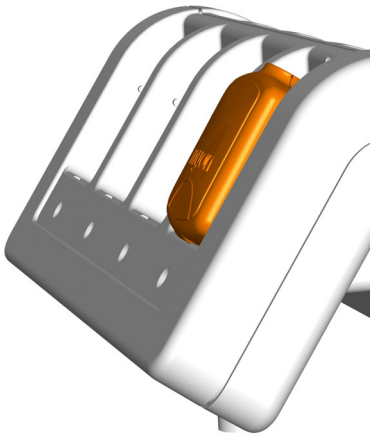
- When charging, the charging slot indicator LED will start to flash. This indicates that re-charging of the transmitter's battery is in progress. After the battery has been recharged, the charging slot indicator LED is lit constantly. See Section 4.3 for details.



Charging transmitters: Step 1



Charging transmitters: Step 2



Charging transmitters: Step 3

- Depending on the charge condition of the battery, the re-charging process can take between 30 and 90 minutes. When the battery is charged for the first time, the charging process may take longer.

You cannot overcharge the battery.
You can top up the battery by charging it before it is fully exhausted.

Further increasing battery life

All transmitting modules are equipped with newest generation LiPo batteries that do not suffer the problem of “memory effect” common to older batteries. These batteries can be recharged any time regardless of their current charge condition without reducing the performance of the battery.

In addition, in certain situations, the battery life can be increased further by observing the following instructions:

- When the system is not in use for a short time, the batteries should be charged. The transmitter modules may be plugged into the charging cradle all the time when the system is not in use.
- When the system is not in use for an elongated period of time, the whole system - including receiver and charging cradle - has to be disconnected from the mains.

5.5 Conduction of measurements

It is recommended that you verify the correct function of your equipment prior to important measurements or if you have any doubts concerning the integrity of your system. See Section 7 for details.

5.5.1 Establishing a wireless connection

- Make sure that the receiver is connected to its external power supply. You will see blue LEDs inside the unit.
- Take the transmitters you need from the charging cradle.
- The transmitters' LEDs will start flashing. This indicates that the transmitter is transmitting data.

The transmitter indicates its state by its indicator LED
as described in Section 4.1.

- An LED in the receiver will start flashing. There is one LED per transmitter. When the LED is flashing, the data from the transmitter is received.

5.5.2 Capturing and transmission of sensor signals

- With the steps described in Section 5.5.1 the wireless connection is established and the device is ready to start measuring.

- A minimum sampling rate of 2.000 Hz is highly recommended for each analog output channel.

5.5.3 Transmitters with EMG sensor cable

The following single-use electrodes are recommended for use with m320 transmitters:

- Ambu Blue Sensor N, Item No.: N-00-S/25.
  Specially developed for children for short- to mediumterm application.
- Ambu Neuroline 720, Item No.: 720-00-S/25.
  Strong yet skin-friendly adhesive for mid- to long-term application.

Both manufactured by Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup, Denmark. www.ambu.com.

- Prepare the muscle areas to be measured. Please see clinical guidelines for measuring surface EMG.
- Attach a pair of electrodes to each muscle. Please consult clinical guidelines to find the best place and on how to affix the transmitter securely to the body. A good place to start may be the European SENIAM project (Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles) at www.seniam.org.
- Affix the transmitters securely to the body near to each pair of electrodes. Consider using myon's special re-usable fastening straps (P/N PA0003 ... PA0009) for quick and easy re-adjusting of the transmitters position.

Make sure that you do not touch any accessible contacts of connectors and patient simultaneously.

- Connect a pair of electrodes to the sensor cable. The connectors on the cable will snap onto the electrode.
- Take a look at the software used with the system for data acquisition to check the signal. The software will show the signal in real time. Make sure the signal quality is good before you conduct your experiments.

5.6 Recommendations for optimal signal transmission and radio coverage

Because of the physical nature of wireless transmission, radio signals sent by the transmitter are not guaranteed to reach the receiver. The maximum legal limit on the transmission power means that the maximum theoretical transmission distance is up to 200 metres. In practice, indoor environments tend to limit the distance to 20-30 metres. Walls, floors and furniture limit the transmission range depending on what type of material they contain. Concrete walls, for example, are not easily penetrated, and such walls will limit the range.

Low signal strength at the receiver can be caused by poor positioning of the receiver as well as interference from other sources of radio waves such as wireless LAN, mobile or cordless phones or an active microwave oven. Please read the next sections carefully and follow the recommendations to achieve optimum range of the system.

5.6.1 Receiver

- An elevated position may be advantageous.
- The receiver should be positioned with a free line of sight to the measurement area.
- As far as possible, try to position the receiver centrally in the measurement volume.
- As far as possible, avoid using other signal emitting devices such as wireless LAN routers, wireless phones and microwave ovens in the measurement volume.
- Depending on the room's geometry, small changes in the receiver's position may have a large impact on the transmission range; if the range is insufficient, try to reposition the receiver.

5.6.2 Transmitter

- Optimum placement of the transmitter improves the range; the transmitter is designed so that the signal is focussed towards its top hemisphere (the one with the brand name “myon” on it).
- As a rule of thumb, the transmitters should be positioned as much lateral on the body as possible and ideally within a line of sight with the receiver.

6 Turning off the device

Always turn off the device after concluding your measurements.

Leaving the device running continuously may negatively influence its expected lifetime as well as stability and has a negative impact on the environment.

6.1 Transmitters

Transmitters that are inserted into a charging cradle slot will stop transmitting and switch themselves off. They will remain switched off even if the charging cradle is disconnected from its external power source. However, note that the transmitter's battery will slowly discharge when the charging cradle is disconnected from mains power. In case of doubt, make sure that you reconnect the charging cradle to the mains prior to an important measurement session.

If a transmitter is not placed into a charging cradle slot, it will keep transmitting until its battery capacity is exhausted and then switch itself off.

6.2 Receiver

To turn off the receiver, please disconnect the receiver's external power supply from the mains. You may also want to disconnect the cables between the receiver and other interacting devices (e.g. video based motion capture systems) if you intend not to use the receiver for an elongated period of time.

6.3 Charging cradle

To turn off the charging cradle, disconnect the charging cradle's external power supply from the mains.

7 Checks

Please perform the following checks before each use of the device.

- Check the system for potential damage and completeness. If you notice any damage, do not use the device and contact your local sales agency or the manufacturer.
- Check all connecting cables and accessories for damage. If you notice any damage, do not use the device and contact your local sales agency or the manufacturer.
- Avoid excessive bending and stretching when positioning the cables, and make sure that the cables never pose a tripping hazard.
- Check that all connectors fit properly, including the country specific mains plug (see Section 3.1.2).
- Check that all connection contacts are clean.
- Check that the labels are complete and legible.

7.1 Verification procedure for the correct functioning of the equipment

The scope of this section is to make sure your system has been correctly installed and that it is functioning as intended. Please perform the steps below in the given order prior to a measurement or if you have any doubts as to the integrity of your system's performance.

If at any time your system should not pass any of the tests described below, please first re-check your sytem's configuration and wiring again, as well as Section 8, before contacting the support team.

If after re-checking, your systems does not pass certain tests, please take note of those codes (e.g. BF001) mentioned before each step and pass them on to the support team together with a brief description of what you observed.

7.1.1 Visual check of basic functions

- Preparation
  - BF001: Ensure that the system is configured and connected according to this manual.
  - BF002: Make sure that only the components that were supplied by myon as part of your shipment are used, such as the D-sub cable, power supplies, etc.
  - BF003: If your system is already connected to the mains, separate all system components from the mains.
  - BF004: Make sure that all of your AC adapters are equipped with the correct country specific plug (see Section 3.1.2 for details).

- Conduction
  - BF005: Connect all components to the mains with the supplied AC adapters and switch on all components.
  - BF006: Insert all transmitters into the respective charging slots of the charging cradle(s).
- Check
  - Charging cradle(s)
    - BF007: For proper operation, the LEDs of all charging slots into which a transmitter is inserted, must either be blinking or glowing constantly.
  - Transmitters
    - For proper operation, all of the following conditions must be met:
      - BF008: If a transmitter is placed into a charging slot of a charging cradle, the transmitter's LED must not blink or glow.
      - BF009: If a charged transmitter is taken out of its charging slot in a charging cradle, the transmitter's LED has to start blinking for about 2 minutes. If the transmitter is inserted back into a charging slot again, the transmitter's LED has to stop blinking.
  - Receiver
    - For proper operation, all of the following conditions must be met:
      - BF010: If all of the transmitters are placed into charging slots of a charging cradle, all LEDs on the inside of the receiver have to glow constantly but none of them must blink.
      - BF012: If one transmitter is taken out of its charging slot in a charging cradle, the LED of the associated receiver channel on the inside of the receiver must begin to blink. When the transmitter is inserted back into its charging slot in a charging cradle, the corresponding LED on the inside of the receiver has to stop blinking and must glow constantly.

7.1.2 Check of installation and wiring

- Preparation
  - IW001: If your system is already connected to the mains, separate all system components for at least 10 seconds from the mains. Then reconnect all components to mains.
  - IW002: Completely set up your system according to this manual. Connect all components to the mains and switch on all components.
  - IW003: Place all transmitters into a charging slot of a charging cradle. The LED of each charging slot into which a transmitter has been inserted must be either glowing or blinking. The transmitter's LED must not blink.
  - IW004: Connect the analog output port of the receiver with the supplied myon D-sub cable to a suitable analog-to-digital converter (see Section 5.3 for details).
- Conduction
  - IW005: Make sure that the analog output signals of the receiver are to be recorded in the analog-to-digital converter's “single ended” mode (see Section 5.3 for details) with an appropriate software and a sampling rate of at least 2000 Hz per channel.
  - IW006: Record all analog output channels of the receiver for a short period of time, e.g.

10 seconds.

- Check
  - IW007: For all available analog output channels of the receiver the recorded signal must be a sinus signal with an amplitude of -2.5 to +2.5 V. There must be no relevant offset from 0 V.

7.1.3 Check of transmitter's sensor cable integrity

- Preparation
  - CI001: Please follow the preparation instructions of previous Section 7.1.2.
  - CI002: Make sure that the analog output signals of the receiver are to be visualised in the analog-to-digital converter's “single ended” mode (see Section 5.3 for details) with an appropriate software at a sampling rate of at least 2000 Hz per channel.
- Conduction
  - CI003: Press the ends of the transmitter's sensor cable firmly together at their metal surfaces with your fingertips and hold them together; alternatively, the metal surfaces may also be held together with a suitable clamp.
  - CI004: Briefly hold the transmitter and sensor cable steady at first, then move the sensor cable back and forth in all directions.
- Check
  - For each transmitter, the output signal of the respective analog output channel must meet all of the following conditions:
    - CI005: The output signal throughout the test must always show a value of 0V, regardless of whether the sensor cable is at rest or in motion (a slight amount of noise in the output signal however, is normal).
    - CI006: No relevant positive or negative offset from 0 V must occur.

8 Solving problems

To verify the correct function of your equipment please also refer to Section 7.

No.	Symptom	Solution
1	The transmitter LED does not flash after you remove the transmitter from the charging cradle	• Check that the transmitter is charged and that the charging cradle is switched on / connect to the mains. • Re-insert the transmitter into a charging slot for a few seconds and try again. • See Section 3.2.1 in case a reset of the device may be required.
2	The receiver LED does not start flashing when the transmitter LED starts flashing	• Check that the receiver is connected to its external power supply. • Move the transmitter closer to the receiver. • Move the receiver away from other radio transmitting devices. For example: laptops, mobile phones, WLAN routers etc. • Reset the receiver by pulling out the power adapter. Plug in the power adapter again after a few seconds.
3	You do not see a signal in your data acquisition software.	• Check that the transmitter is charged. • Make sure that the EMG electrodes are correctly connected to the transmitter's sensor cable. • Make sure that the EMG electrodes are attached to the muscle. • Check that the analog-to-digital device is correctly connected to your computer. • Check that all the wires from the receiver's analog output are connected correctly. • Check that pin 25 from the receiver's analog output is connected to ground. • Reduce the distance between transmitters and receivers.
5	There are strong noise / hum artefacts on EMG channels	• Check that all interacting systems (PCs, notebooks, etc.) are firmly connected to ground. • Make sure that you are using fresh electrodes from a recently opened package and that the expiry date has not been exceeded.

9 Technical description

9.1 Technical data

		Receiver	Transmitter[1]	Charging cradle
Manufacturer		myon AG, Sonnenrain 75, 6103 Schwarzenberg, Switzerland		
Model series		m320RX	m320TXA	m320CC
P/N		PR0006	PT0001	PA0001
Operating voltage		110-240 V / 50-60 Hz. External medical grade power supply (P/N PA0014) with exchangeable country specific mains plug.	Built-in battery	110-240 V / 50-60 Hz. External medical grade power supply (P/N PA0016) with exchangeable country specific mains plug.
Power consumption		5W / 1A / 5V DC	0,75W / 0,15A / 5V DC	6W / 1,2A / 5V DC
Properties	Weight	430 g	23 g[2]	319 g
	Housing color	blue		
	Dimensions	203 x 123 x 77 mm	36 x 45 x 16 mm[1]	215 x 115 x 80 mm
	Inputs / outputs	Power supply socket, 25 Pin DSub socket	Charging contacts, EMG electrode sockets	Charging contacts, power supply socket
	Sampling rate	n/a	4000 Hz	n/a
	Resolution	14 bit	12 bit	n/a
		System ENOB: 11,4 bit (typical)		
	Bandwidth	5...500 Hz (3dB, typical)		n/a
	Filter characteristics	4th order		n/a
	Input range[3]	n/a	±5,0mV (g=500) ±2,5mV[4] (g=1000) ±1,25mV (g=2000) ±0,625mV (g=4000)	n/a

1 Excluding EMG sensor cable and sensor, if not specified otherwise.
2 Including EMG sensor cable.
3 Selectable by "Model specific options sheet" at the time of ordering.
4 Default.

	Input impedance	n/a	2 MΩ[5]	n/a
	CMRR	Cannot be determined: Two-wire measurement without ground reference using floating ground.[6]		n/a
	SNR	Approximately 42 dB		n/a
	Output range	±2,5V	n/a	n/a
	Range	n/a	up to 30 m	n/a
	Transmission frequency	2,4 GHz, ISM band		n/a
	Transmission protocol	proprietary		n/a
	Battery life	N/A	up to 10 hours	n/a
	Battery re-charging time	N/A	30-90 min	
	Latency	16 ms, constant		n/a
	Inter channel offset	≤ 2 samples		n/a
	Included accessories	Ext. power supply (P/N PA0014), DSub25 connector cable (with flying wires, P/N PA0010)	n/a	Ext. power supply (P/N PA0016).
Environment	Operation	+10...+40°C ; 20...80% humidity		
	Storage	-20...+60°C ; 10...90% humidity		
Regulatory information		See section 10 for details. European Union: ED1999/5/EC (R&TTE), ED1993/42/EC (Medical Devices). United States of America: Part 15 of the FCC Rules		

9.2 Description of interfaces

The interface layout may differ if myon systems have been specifically adapted to your individual requirements. Individual systems will include a pin assignment sheet showing the mapping of the individual output pins. Contact your local sales agency if you need further assistance.

9.2.1 Models with analog EMG output for up to 16 channels

The analog output is provided via a female DSUB25 socket located in the receiver. For numbering of

5 Two-wire measurement without ground reference using floating ground to minimize set up time for the user (> 100 MΩ if transmitter utilized a separate 3rd electrode for ground reference).

6 A Common mode can only occur with definition of a capacitive ground-coupling, which varies strongly under field conditions.

the individual pins, please refer to the following figures.

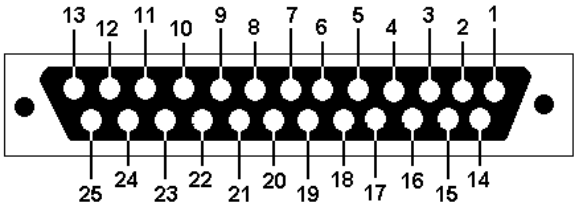


Image 11: Female DSub25 socket. View from outside into the socket.

Pin no.	Signal
1...16	Transmitter signal 1...16
17...24	NC
25	GND

9.2.2 Models with analog EMG output for more than 16 channels

The analog output of output channels 17 to 32 is provided in quite the same way as described in Section 9.2.1. The only difference is that the pin numbers 1...16 reflect the signals of transmitters 17...32, instead of transmitters 1...16.

9.2.3 Pin assignment of DSub25 connector

The pin assignment of the male DSub25 connector is shown in the following figure.

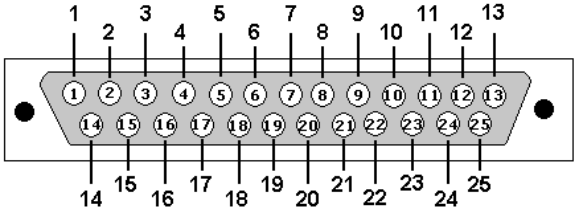


Image 12: Male DSub25 connector. View from outside into connector.

For all myon m320 systems that have been shipped later than 1st May 2012[7], the following colour code for the single wires of the respective DSub cable applies.

Pin no.	Wire color	Assignment
1	white	Channel 1
2	brown	Channel 2
3	green	Channel 3
4	yellow	Channel 4
5	gray	Channel 5
6	pink	Channel 6
7	blue	Channel 7
8	red	Channel 8
9	black	Channel 9

Pin no.	Wire color	Assignment
10	purple	Channel 10
11	white-green	Channel 11
12	gray-pink	Channel 12
13	red-blue	Channel 13
14	white-gray	Channel 14
15	yellow-brown	Channel 15
16	brown-green	Channel 16
17 - 24	-	unused
25	white-yellow	Signal GND
	gray-brown	Shield

7 Receiver S/N: RX00509 and higher.

9.3 Technical support

In the following paragraphs more in depth information about the myon m320 system and how it works in detail is provided. The information provided however, is neither complete nor is it mandatory to operate the system as intended.

Please contact your local sales representative for further technical support.

9.3.1 How your EMG signals should look like

This is an example of an EMG signal recorded from the small superficial m. extensor carpi ulnaris of the lower arm. Signals from other sensors (e.g. accelerometers) may look different.

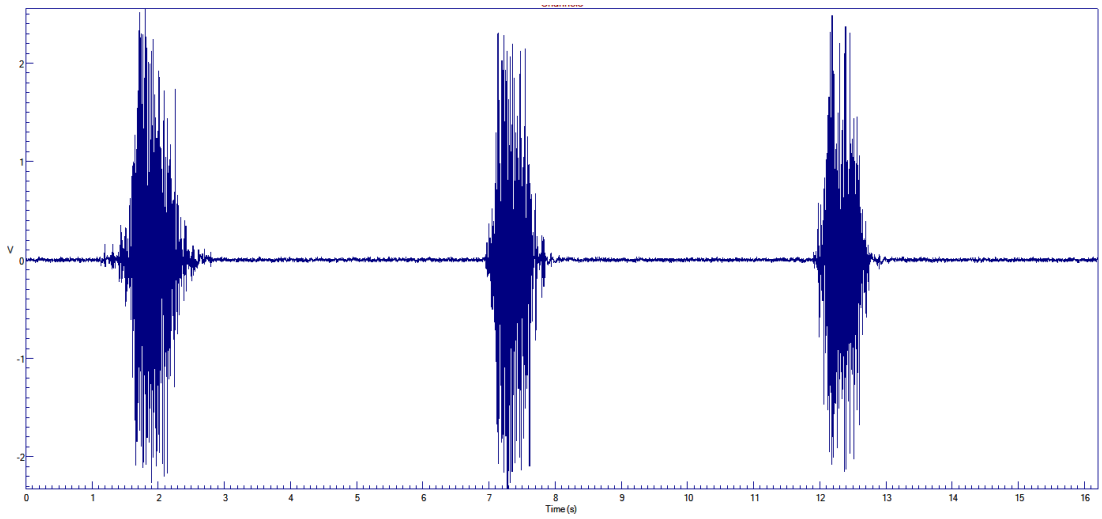


Image 13: Proper EMG signal recording

9.3.2 Visualization of transmission errors

The visualization of transmission errors is done in two different ways:

- If the wireless connection between a transmitter and the receiver is broken only shortly for less than one second, the receiver will output a zero amplitude signal on the affected channel.
  In most cases only one or two frames of transmission may be lost, resulting in a signal drop to zero for 5 or 10 ms. The example in Image 14 below shows a longer drop in transmission for about 150 ms.

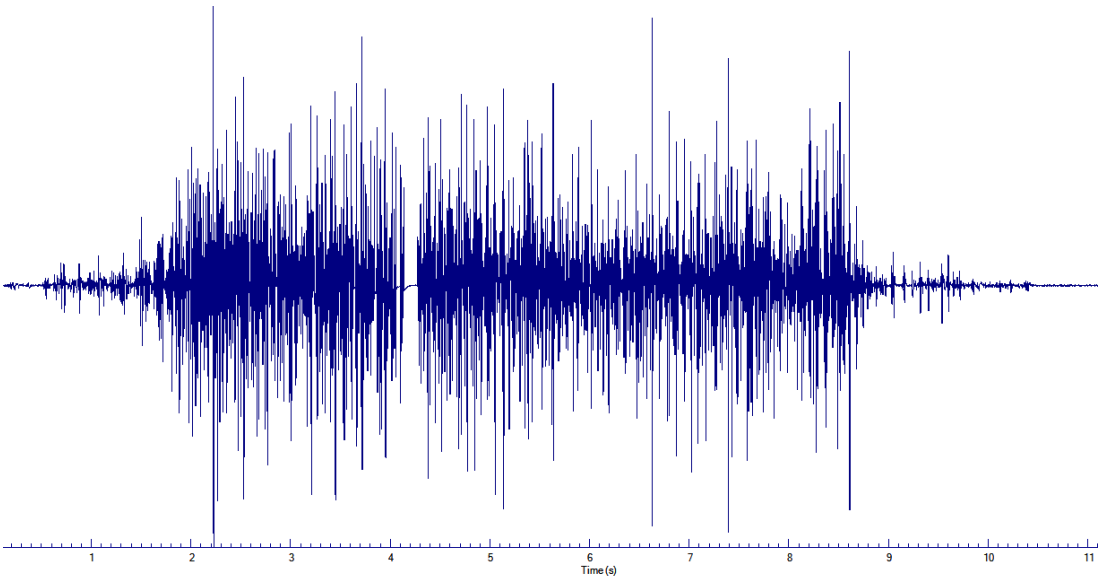


Image 14: Visualization of two short transmission errors of less than one second each in succession

- If the wireless connection between a transmitter and the receiver is broken for more than one second (e.g. because of a transmitter switching itself off due to battery drainage or because the distance between the transmitting module and receiving unit is exceeded), the receiving unit will output a clearly distinguishable sine signal with maximum output amplitude (±2,5V) on the affected channel.

10 Regulatory Information

10.1 Name and address of the manufacturer

myon AG
Sonnenrain 75
6103 Schwarzenberg
Switzerland

10.2 Identification of the devices covered

10.2.1 Trade or proprietary names

myon m320 system consisting of

- transmitter unit (Model m320TXA)
- charging cradle unit (Model m320CC)
- receiver unit (Model m320RX)

10.3 International Electrotechnical Commission (IEC)

	Type BF device, according to IEC 60601-1
	Class II equipment, according to IEC 60601-1

10.4 For customers within the European Economic Area

For additional information a regulatory fact sheet for the myon m320 device is available from the manufacturer upon request.

10.4.1 Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)

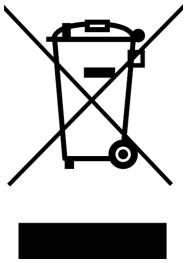
myon m320 hardware is fully RoHS-compliant. The European Union Directive 2002/95/EC provides that new electrical and electronic equipment put on the market for the first time from 1 July 2006 shall not contain more than permitted levels of lead, cadmium, mercury, hexavalent chromium,

polybrominated biphenyls (PBB), or polybrominated diphenyl ethers (PBDE).

10.4.2 Registration, Evaluation, Authorisation and restriction of CHemicals (REACH)

myon m320 hardware is fully REACH-compliant. European Union Directive 1907/2006/EC (REACH) requires companies which manufacture and import chemicals to evaluate the risks to human health and the environment resulting from the use of those chemicals and to take the necessary steps to manage any identified risk.

10.4.3 Waste Electrical and Electronic Equipment (WEEE)



WEEE-Reg.-No.
DE 73916203

The use of the symbol indicates that this product may not be treated as household waste. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

Please contact myon AG or your local sales agency for information about myon's acceptance of returned goods at product's end-of-life.

10.4.4 Declaration of Conformity

CE

Declaration of conformity

myon AG, Sonnenrain 75, 6103 Schwarzenberg, Switzerland declares under our sole responsibility that the devices, listed hereafter;

- myon m320 system consisting of
  - myon m320 transmitters (Model m320TXA, Type PT0001)
  - myon m320 receiver (Model m320RX, Type PR0006)
  - myon m320 charging cradle (Model m320CC, Type PA0001)

are in conformity with

- the Council Directive 93/42/EEC for medical devices (MDD), and
- the essential requirements and other relevant requirements of Council Directive 1999/5/EC on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (R&TTE).

3rd January 2013
Schwarzenberg, Switzerland

Dr.-Ing. Lars Meinecke
Director of Regulatory Compliance

Not for use in an operating theatre, anesthetic gas or oxygen-rich environments. Not for use where there is a risk of compromising the essential performance of medical electrical equipment. Not suitable for use in high magnetic flux, ionizing radiation, sterile, or life- or safety-critical environments. The device is not suitable for unattended continuous operation. This declaration does not apply to custom made systems. Further details regarding the declaration of conformity is available upon request from myon AG, Switzerland.

10.4.5 Medical Device Adverse Event Reporting

Should an adverse incident occur, the appropriate form is to be completed and forwarded within one working day to myon AG at the following address:

myon AG
Sonnenrain 75
6103 Schwarzenberg
Switzerland

email: info@myon.ch

10.5 For customers within the United States of America

10.5.1 Federal Communications Commission (FCC)

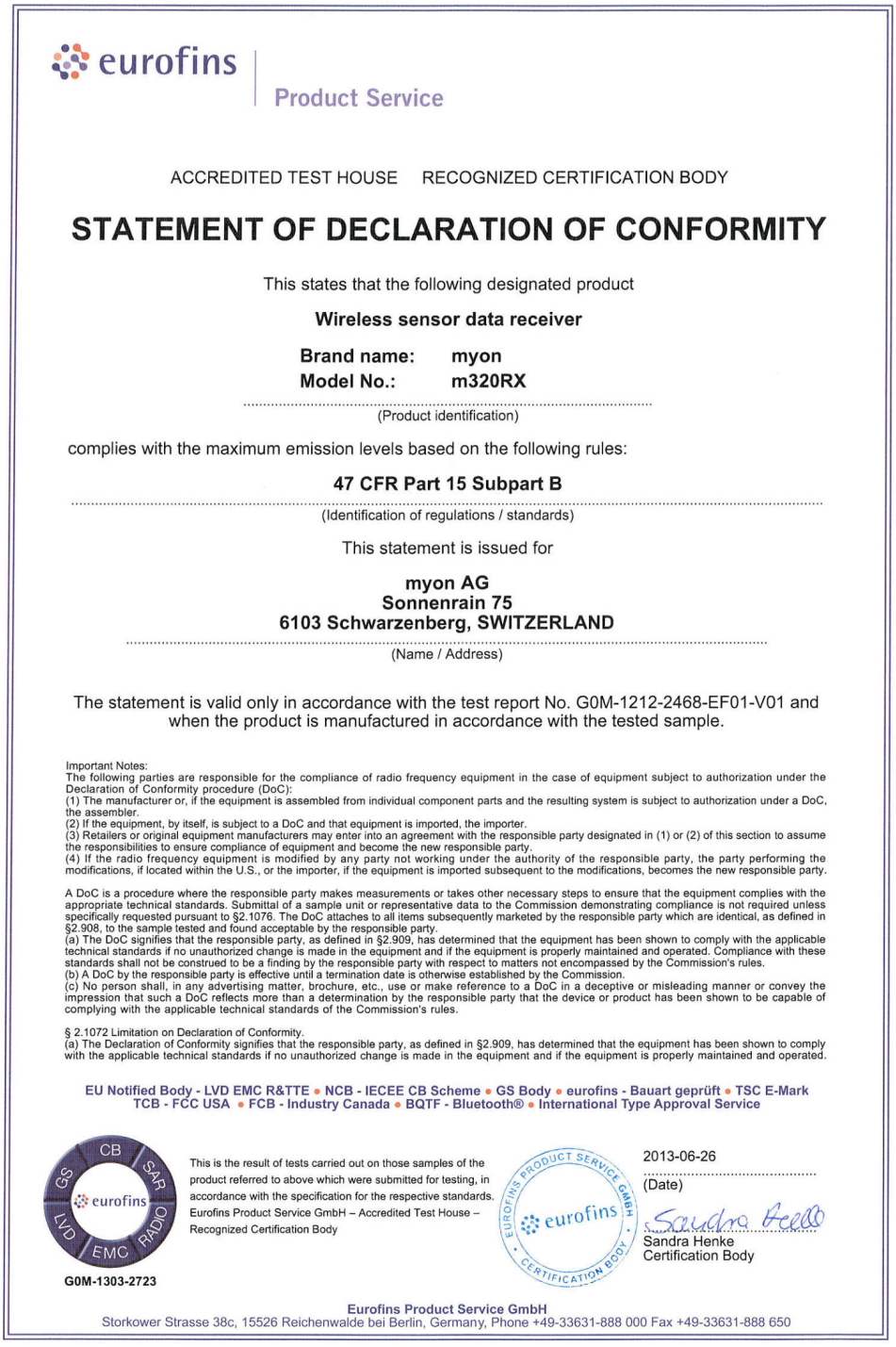
This device (FCC ID: SZSM320-1) complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by this company could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

10.5.2 Statement of Declaration of Conformity



eurofins | Product Service

ACCREDITED TEST HOUSE RECOGNIZED CERTIFICATION BODY

STATEMENT OF DECLARATION OF CONFORMITY

This states that the following designated product

Wireless sensor data receiver

Brand name: **myon**
Model No.: **m320RX**

(Product identification)

complies with the maximum emission levels based on the following rules:

47 CFR Part 15 Subpart B

(Identification of regulations / standards)

This statement is issued for

myon AG
Sonnenrain 75
6103 Schwarzenberg, SWITZERLAND

(Name / Address)

The statement is valid only in accordance with the test report No. G0M-1212-2468-EF01-V01 and when the product is manufactured in accordance with the tested sample.

Important Notes:
The following parties are responsible for the compliance of radio frequency equipment in the case of equipment subject to authorization under the Declaration of Conformity procedure (DoC):
(1) The manufacturer or, if the equipment is assembled from individual component parts and the resulting system is subject to authorization under a DoC, the assembler.
(2) If the equipment, by itself, is subject to a DoC and that equipment is imported, the importer.
(3) Retailers or original equipment manufacturers may enter into an agreement with the responsible party designated in (1) or (2) of this section to assume the responsibilities to ensure compliance of equipment and become the new responsible party.
(4) If the radio frequency equipment is modified by any party not working under the authority of the responsible party, the party performing the modifications, if located within the U.S., or the importer, if the equipment is imported subsequent to the modifications, becomes the new responsible party.

A DoC is a procedure where the responsible party makes measurements or takes other necessary steps to ensure that the equipment complies with the appropriate technical standards. Submittal of a sample unit or representative data to the Commission demonstrating compliance is not required unless specifically requested pursuant to §2.1076. The DoC attaches to all items subsequently marketed by the responsible party which are identical, as defined in §2.908, to the sample tested and found acceptable by the responsible party.
(a) The DoC signifies that the responsible party, as defined in §2.909, has determined that the equipment has been shown to comply with the applicable technical standards if no unauthorized change is made in the equipment and if the equipment is properly maintained and operated. Compliance with these standards shall not be construed to be a finding by the responsible party with respect to matters not encompassed by the Commission's rules.
(b) A DoC by the responsible party is effective until a termination date is otherwise established by the Commission.
(c) No person shall, in any advertising matter, brochure, etc., use or make reference to a DoC in a deceptive or misleading manner or convey the impression that such a DoC reflects more than a determination by the responsible party that the device or product has been shown to be capable of complying with the applicable technical standards of the Commission's rules.

§ 2.1072 Limitation on Declaration of Conformity.
(a) The Declaration of Conformity signifies that the responsible party, as defined in §2.909, has determined that the equipment has been shown to comply with the applicable technical standards if no unauthorized change is made in the equipment and if the equipment is properly maintained and operated.

EU Notified Body - LVD EMC R&TTE • NCB - IECEE CB Scheme • GS Body • eurofins - Bauart geprüft • TSC E-Mark
TCB - FCC USA • FCB - Industry Canada • BQTF - Bluetooth® • International Type Approval Service

CB SAR RADIO EMC LVD GS eurofins

G0M-1303-2723

This is the result of tests carried out on those samples of the product referred to above which were submitted for testing, in accordance with the specification for the respective standards.
Eurofins Product Service GmbH – Accredited Test House – Recognized Certification Body

EUROFINS PRODUCT SERVICE GMBH eurofins CERTIFICATION BODY

2013-06-26
(Date)

Sandra Henke
Certification Body

Eurofins Product Service GmbH
Storkower Strasse 38c, 15526 Reichenwalde bei Berlin, Germany, Phone +49-33631-888 000 Fax +49-33631-888 650

F31_V01

10.6 For customers within all other countries

Please contact myon AG for information.

11 Safety and usage guidance

We have made every effort to ensure that we have provided you with a safe and robust product. For your safety and to ensure that your myon m320 continues to meet your expectations and requirements, take note of the following guidance:

- Always adhere to the information comprised in this user manual.
- Warranty is void if any part of the system is disassembled.
- The device is not suitable for unattended continuous operation.
- Prevent the system being exposed to long periods in direct sunlight, such as car interiors or hot surfaces, such as radiators.
- Use the system indoors, only. Do not use the system in wet or damp conditions.
- Insert only supplied cables into the system's interface ports.
- Do not spill food or liquids onto the system (including the transmitters).
- Do not insert any objects into any openings of the system, with the exception of the reset switch of the transmitter only after being instructed by myon support to do so.
- When transmitters are not in use, place them in the charging cradle.
- Do not wear the transmitters when they are being charged.
- Use only the supplied power adapter. Other adapters may be dangerous for your health and/or they may damage the device.
- Use only the supplied cables.
- Do not touch the connectors as these are delicate and may be damaged.
- In the unlikely event that the device should become unusually warm during use, remove it from contact with the body and any clothing. If charging, immediately disconnect the product from the adapter.