myoMOTION Research PRO & Clinical

Hardware User Manual

(Rev K)

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CE Marking and Notified Body:

Clearance to market this product (#810) in the European Community has been certified by Notified Body #2797, British Standards Institution (BSI). Clearance to market this product (#810) in the United Kingdom has been certified by Notified Body #0086, British Standards Institution (BSI).

CE 2797
UK CA 0086

1 General Warnings and Cautions

1.1 Risks and Benefits

There is no identified risk of physical harm or injury with use of the myoMOTION sensors and receiver. The benefit provided by use of the device is the provision of objective measures to assess the severity of pathological human movement conditions and gauge any subsequent improvement offered by therapy, training or design changes.

1.2 Safety Information Summary

Cautions

- Never use the myoMOTION System on a person with an implanted pacemaker
- Never operate the myoMOTION System within 1 meter of any critical medical device

Warnings

- Do not immerse the myoMOTION sensors in any water or liquid
- Do not drop the sensors or receiver
- Do not use in conditions where the temperature can exceed 55 °C (130 °F)
- Do not use the myoMOTION equipment on individuals undergoing MRI, Electro Surgery or Defibrillation
- The myoMOTION product produces results that are informative, not diagnostic. Qualified individuals must interpret the results
- Do not modify this equipment without authorization of the manufacturer.

Attention

- The operator must be familiar with typical characteristics of the signals acquired by the myoMOTION equipment and be able to detect anomalies that could interfere with proper interpretation.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Instructions for Use are to be provided in electronic form unless specifically requested. Should the user like to obtain a hard copy of these Instructions, please contact the manufacturer.
- Power Supply (PSU1) should be positioned in a manner that ensures accessibility.

Guidance on Conditions for Safe Use

- The myoMOTION sensors are suitable for use as medical devices. To ensure safe operation the following guidelines must be strictly followed.
- The myoMOTION receiver and computer must not be accessible (touchable) by the patient. Ensure the myoMOTION receiver and computer are positioned at least 6 feet (2 meters) away from the patient at all times.
- The myoMOTION receiver must only be connected to a certified commercial grade computer produced by a reputable manufacturer. This is necessary to ensure the computer is designed and built in accordance with established safety standards. To ensure safe operation the use of myoMOTION with custom built computers (those assembled from discrete sub-assemblies) must be avoided.
- The operator must never touch the patient and any other device (myoMOTION receiver, computer or myoMOTION Sensor charging station) at the same time.

2 Introduction

2.1 Brief Description:

Noraxon's myoMOTION System is a combination of hardware and software that enables the capture of human motion in three degrees of freedom (3 DOF). A compact Inertial Measurement Unit (IMU) placed on any segment of the body precisely tracks the 3D angular orientation of that body segment. By positioning individual IMU sensors on two contiguous body segments, the intervening joint range of motion (ROM) can be determined. This concept is easily expandable from a single joint of interest to a simultaneous 16 sensor full body measurement across all major joint articulations.

The myoMOTION sensors transmit the motion of the human body directly to the myoMOTION receiver to quantify the angular changes of the selected body segments. The captured data may then be analyzed using Noraxon MR3 software.

The main advantage of this technology is that it is easy and quick to use, fully portable, and can be used with independent external cameras. This unique concept gives the user flexibility to operate the myoMOTION system without limitations.

myoMOTION complies with all applicable safety and performance standards for electronic devices. Further, the myoMOTION System has been designed and tested to operate in a compatible manner with other devices in a medical care setting.

2.2 Intended Use

Noraxon's 3D myoMOTION system is intended to measure and quantify angular changes of selected body segments.

Intended Users
Researchers or individuals trained in physical medicine, physical therapy, human performance or ergonomics and who have gained familiarity with the myoMOTION System and its software.

Subject Populations – Medical
Individuals with neurological disorders, physical injuries, pre/post-surgical or post stroke conditions.

Subject Populations – Non-medical
Athletes, workers at their work site, subjects in new product trials.

Common Applications
Gait analysis; identification of inconsistencies and abnormalities; tracking over time the outcome of surgical, therapeutic or orthotic interventions; identification of ergonomic stress factors in the workplace or new product designs.

Suitable Environments
The myoMOTION System is suitable for use in hospitals, clinics, academic laboratories except near active HF SURGICAL EQUIPMENT or MRI IMAGING EQUIPMENT.

Expected (Essential) Performance
The myoMOTION System (Sensor and Receiver) synchronously acquires and displays motion signals from joint segments in real time.

Consideration should be given to common place wireless networks that may be present in the environment. Under the conditions of excessive wireless communications performance of the myoMOTION System may exhibit sluggish (non-real-time) behavior.

Risk-Benefit
There is no identified risk of physical harm or injury with use of the myoMOTION devices. The benefit provided by use of the device is the provision of objective measures to assess the severity of pathological human movement conditions and gauge any subsequent improvement offered by therapy, training or design changes.

Special Concerns
The myoMOTION devices operate by means of microwave radio frequency transmissions. Certain (older, vintage model) pacemaker devices may be susceptible to such microwave transmissions. Therefore, use of the device is contra-indicated in individuals who have implanted pacemakers.

2.3 Contraindications

Use of the myoMOTION analysis system is contra-indicated in individuals who have implanted pacemakers.

3 Definitions

3.1 Graphic Symbols and Meaning

The following international icons and symbols are found on the myoMOTION system enclosures and in this user manual. Their meaning is described below.

CE 2797	Approval to market this product (610, 616) in the European Community was certified by Notified Body #2797 BSI.
CE	Approval to market this product (680,684,613,610C) in the European Community was certified by Noraxon USA.
	The device generates radio frequency energy during operation.
⎓ 5V DC	A 5 Volt DC external power source is applied to this connection.
	Type B Applied Part: This symbol indicates that the sensor is a Type B applied part.
	Read material in the Instruction Manual wherever this symbol appears.
	Identifies the manufacturer of the device.
SN	Identifies the serial number of the device.
DOC	Additional information available in a separate document

3.2 Glossary of Terms

myoMOTION Receiver – A USB-connected Receiver which receives signals from one or more sensors.

myoMOTION Sensor -- A small individual IMU sensor and radio transmitter typically worn on the body used to measure and transmit motion related signals.

myoMOTION Serial Number – A unique four-character tag used to identify each myoMOTION Sensor. The members of any myoMOTION network are determined by their serial numbers.

RF – (Abbreviation for Radio Frequency) Wireless communication takes place on assigned radio frequencies or channels. For the myoMOTION System, RF transmissions occur at frequencies between 2.4 GHz and 2.5 GHz. Other wireless systems including WiFi and Bluetooth commonly operate at the same frequencies and can be a source of interference.

RF Network – RF transmissions for the myoMOTION System can be selected to occur on one of 8 different channels made up for 4 different radio frequencies each. The ability for a channel to operate over several different frequencies allows the myoMOTION System to reposition its radio operation if needed to avoid interference.

RF Traffic – The presence of radio activity present on a given frequency is similar to the number of cars on an expressway. Several users (wireless devices) may be communicating using the same frequencies. Best operation of the myoMOTION System occurs when the RF Traffic is low (no other users) on the selected RF Channel.

4 Product Information

4.1 Model Designation and Identification

The model 680 (Research PRO) and 684 (Clinical) versions of the myoMOTION System each consists of two primary components.

Research PRO System

1. Model 680 myoMOTION Research Receiver (1 to 4 per system)
2. Model 610 myoMOTION sensor (up to 9 per receiver (100 Hz))

Clinical System

1. Model 684 myMOTION Clinical Reciever, with docking station (1 per system)
2. Model 616 myoMOTION Sensor (up to 9 per system)

4.2 System Configurations

Research Model Configurations			Clinical Model Configurations	
Version	Consists of:		Version	Consists of:
680-3	680 Receiver (1),	610 Sensors (3)	684-1	684 Receiver (1), 616 Sensors (1)
680-5	680 Receiver (1),	610 Sensors (5)	684-2	684 Receiver (1), 616 Sensors (2)
680-7	680 Receiver (1),	610 Sensors (7)	684-3	684 Receiver (1), 616 Sensors (3)
680-9	680 Receiver (1),	610 Sensors (9)	684-4	684 Receiver (1), 616 Sensors (4)
680-13	680 Receiver (2),	610 Sensors (13)	684-5	684 Receiver (1), 616 Sensors (5)
680-16	680 Receiver (2),	610 Sensors (16)	684-7	684 Receiver (1), 616 Sensors (6)

4.2.1 myoMOTION Resarch Model Maximum Configurations

Max Number of MyoMotion Sensors per Receiver				
Number of Receivers	100 Hz	100 Hz + Acceleration	200 Hz	200 Hz + Acceleration
1	9	9	9	4
2	18	18	18	8
4	36	18	36	16

4.3 Software Requirements

The myoMOTION System requires software to perform its function and the equipment is offered in combination with the following computer program package:

- Model 405 – Noraxon myoRESEARCH® Software Platform with myoMOTION Software Module

5 Setting up the Hardware

5.1 System Unboxing

The myoMOTION System is packed within a reinforced padded box for storage and protection during transport. Upon arrival, carefully remove all contents and verify the following components are present.

Contents will depend on purchased package

Figure 1: myoMOTION Research Receiver (Part# 680)

Figure 2: myoMOTION Clinical Receiver (Part# 684)

Figure 3: myoMOTION Research Sensor (Part# 610)

Figure 4: MyoMOTION Clinical Sensor (Part# 616)

Figure 5: Sensor Charging Station (Part# 613)

Figure 6: Charging Station Power (Part# PSU1)

Figure 7: USB A to mini-B Cable (Part# CBL17)

Additional items that may be included with your myoMOTION System are:

- myoMOTION Strap System (Part# 874X or 610X)
- Double side tape samples (part #610C)
- Sensor Body Segment Label Set (part #610A)
- myoMOTION Hardware User Manual (part #680A) *This document*

Accessories

If additional accessories have been included, please see www.noraxon.com for more information.

Figure 8: myoMOTION Datalogger (Part# 682)

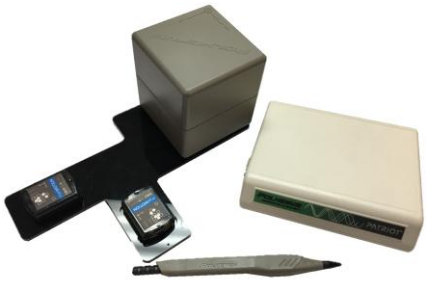
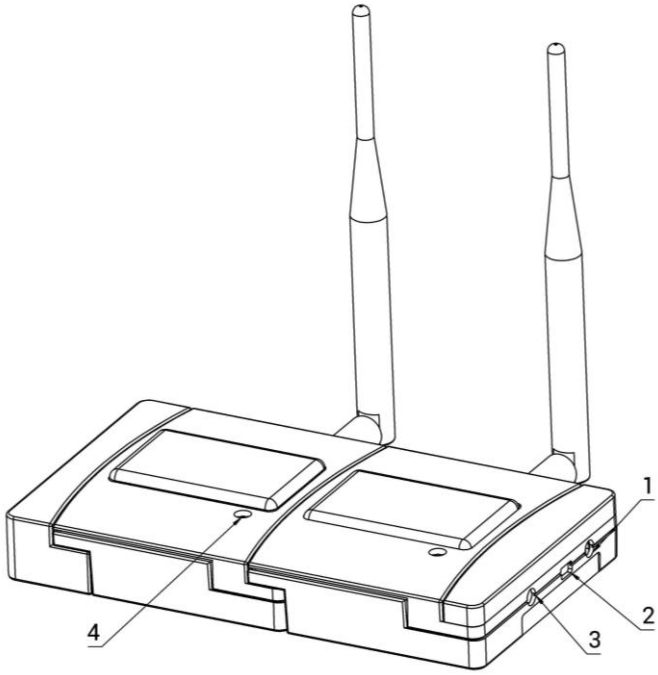


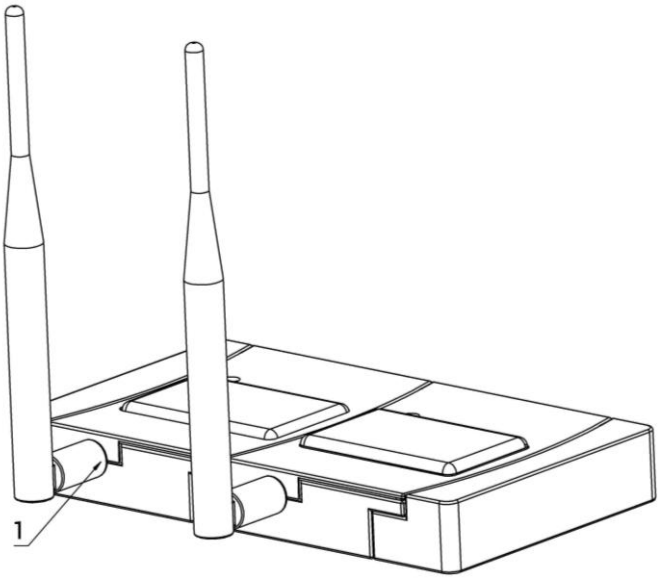
Figure 9: myoMOTION Calibration Adjustment Tool (Part# CAT01)

5.2 myoMOTION Research Receiver Overview



Front

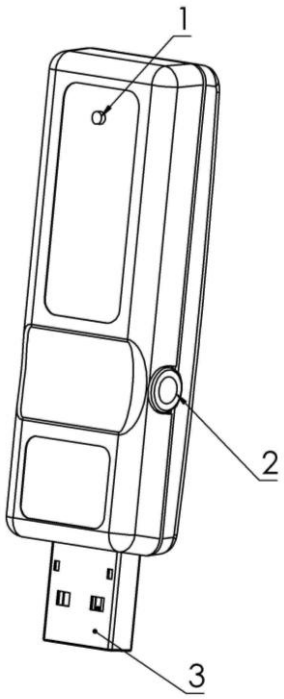
1. Sync Out – Provides a TTL output signal for synchronization to other devices.
2. USB Port – USB connection between the computer and receiver.
3. Sync In – TTL (on-off) compatible 3.5mm
4. Status LED – Indicates the status of the receiver



Back

1. Antenna – Screw on connector for attachment of external antenna.

5.3 myoMOTION Clinical Receiver Overview



1. Status LED – Indicates the status of the receiver
2. Sync In – TTL (on-off) compatible 3.5mm
3. USB plug – USB connection between the computer and receiver.

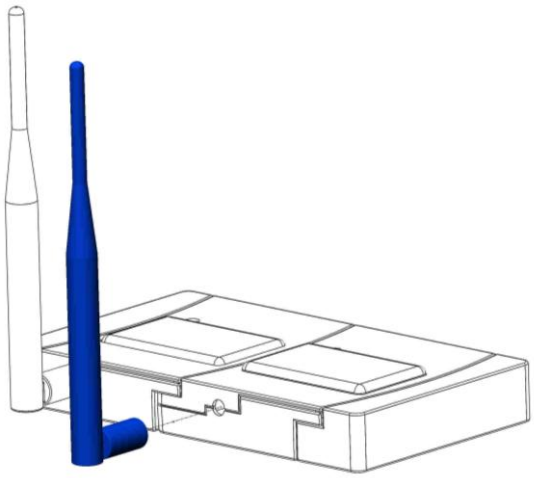
5.4 myoMOTION Sensor Overview

1. Status – Sensor operational indicator flashes green. Flash rate is faster when measuring, slower when idle.
2. Charge – Indicator illuminates steady amber while sensor is charging. When the battery is fully charged, the indication is off.
3. Axis Indicator – Indicates the orientation of the myoMOTION sensor.
4. Charger Contacts – Sensor battery is charges through these two points
5. Serial Number – Unique 4 character serial number which identifies each sensor.

5.5 Hardware Setup Instructions

Step 1 – Research Receiver

Screw on the antenna (ANT3) to the antenna connector located on the rear of the myoMOTION Receiver (680). If the antenna is already attached, check that it is securely tightened.



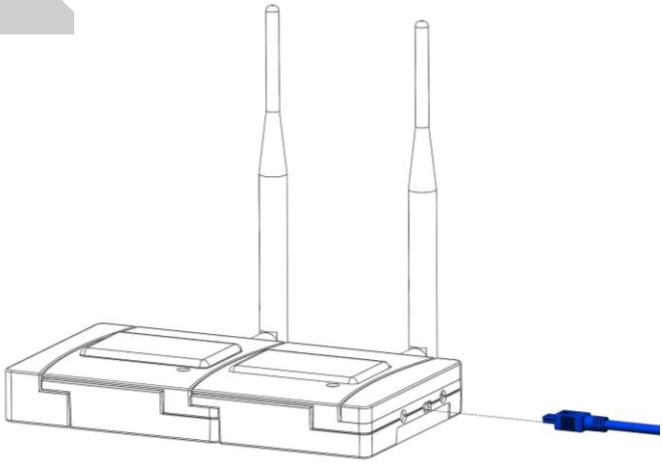
Step 1 – Clinical Receiver

Insert the receiver into an available USB port on your computer. (not pictured) Skip forward to Step 3.

Step 2

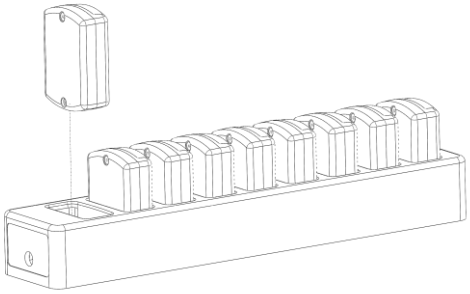
Insert the mating (smaller) end of the USB cable (CBL17) into the USB connector on the side of the receiver.

Insert the opposite end of the USB cable into an available USB port on the computer.



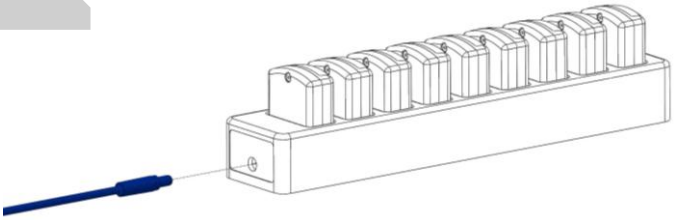
Step 3

Place Sensors in the Charging Station.



Step 4

To charge the sensors, insert the power supply (PSU1) barrel connector into the jack of the Sensor Charging Station (613).



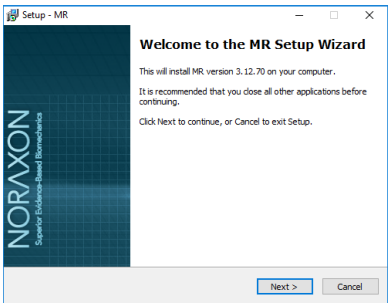
5.6 Installing the Companion Software - myoResearch™ 3

To utilize the full functionality of the myoMOTION system, and ensure the system has updated drivers, Noraxon's *myoResearch 3* needs to be installed on the computer.

No driver installation is needed. The myoMOTION receiver uses a G2 driver for communication over the USB port.

Companion Software Installation

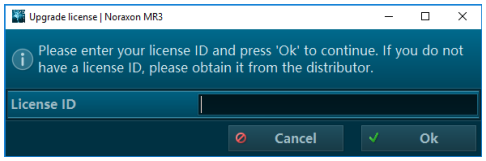
The myoMOTION System is compatible with Noraxon MR3 software.



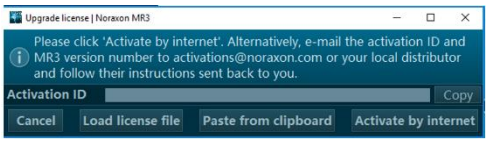
1. Insert the MR3 USB flash drive into the PC
2. A menu will automatically pop up
3. Click on the Noraxon installation file and follow the Wizard's instructions

Companion Software Activation

The installed companion software must be *activated* before unrestricted use is possible.



1. Open MR3
2. A dialog box will indicate how many more times MR3 can be opened
3. Click on "Activate"
4. Enter the License ID provided on your USB flash drive and press "OK"



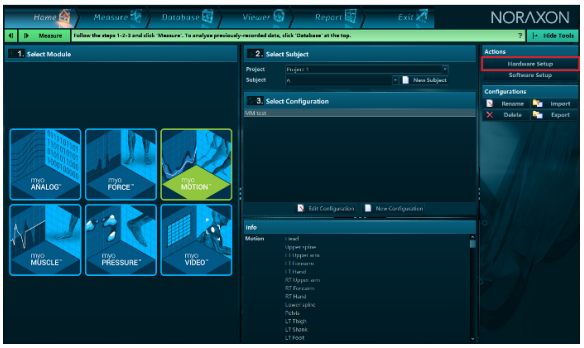
5. If you have an internet connection, click Activate by Internet for immediate activation
6. Alternatively, email the provided activation ID to activation@Noraxon.com Noraxon Support will email or respond by phone with the Activation Code. Enter the provided Activation Code to remove any restrictions on use.

5.7 Configuring the Hardware

Before the myoMOTION system can be used, the companion software must be configured to recognize the different components that make up the system. Follow the below instructions to update the receiver firmware, sensor firmware, and populate sensors to prepare for a data collection.

Step 1

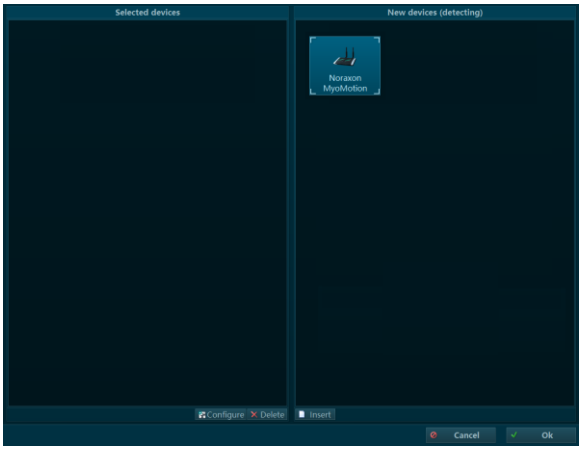
Open the MR3 program and click on the **Hardware Setup** button.



Step 2

Select the Noraxon myoMOTION icon and click on the **Insert** button OR drag the icon into **Selected Devices.**

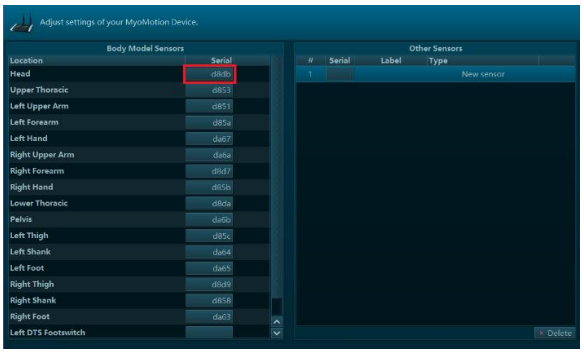
Make sure the Receiver is attached to the USB port of the computer.



Step 3

The myoMOTION Settings Dialog will appear as shown.

Start by inputting the serial numbers for the sensors you wish to use next to the body part where you will place the sensor.

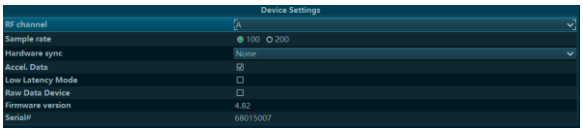


Step 4

Go to Device Settings.

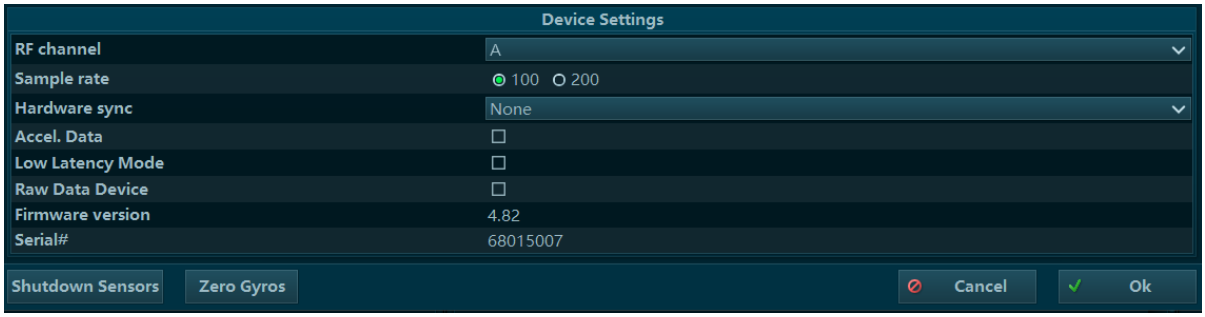
Select a RF Network from the RF Network list. In most cases the default "A" will work. However, if using multiple myoMOTION systems they must be placed on separate networks. Please refer to Section 9.4 and Appendix C for more detailed information on radio channel selection.

You may also choose to turn on Acceleration data and choose to use a Hardware sync here. If you are using a Noraxon MyoSync, check the Hardware Sync box.



5.8 Device Settings

In the Hardware Configuration, there are several receiver settings available under Device Settings.



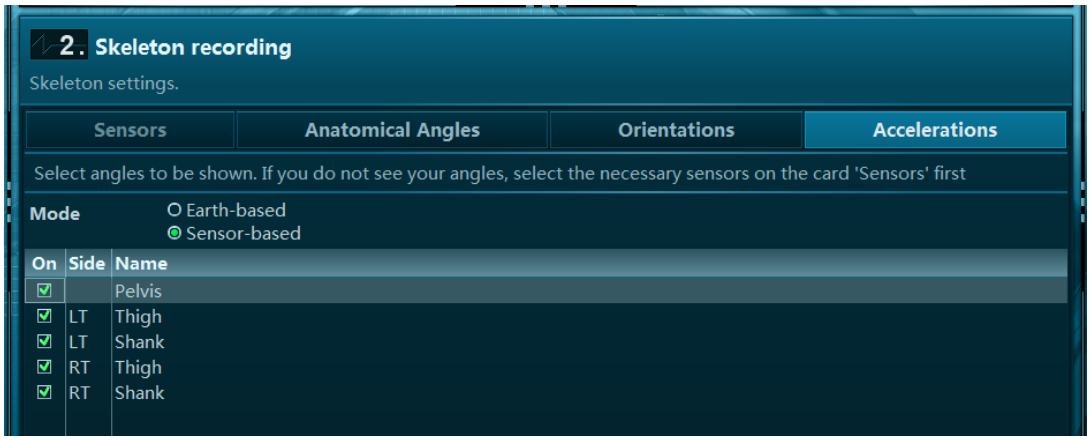
RF Channel: options A-H reflect the frequencies available for data transmission from the sensors to the receiver. If there is data loss, it may be due to interference on the RF channel and the channel should be changed. If there are other wireless devices included, take care to make sure all devices are on separate RF channels.

Sample Rate: the sample rate is a selectable setting of 100 or 200Hz.

Hardware Sync: The Clinical myoMOTION system can have None or Sync In (Noraxon MyoSync) while the Research system also has Sync Out setting. The sync signal is used (and required) to automatically synchronize all devices in the MR3 software for multi-device setup. See Section 7.1 for setup instructions for synchronization.

- None – no sync signal
- Sync In – receives a sync signal from another Noraxon Device
- Sync Out – creates a sync signal to send to another system(s)

Accel. Data: Acceleration data can be enabled or disabled for the sensors. If enabled, the user will need to select the sensors to be measured and select Earth or Sensor based acceleration data which can be done in the Configuration setup. A greater explanation of the various acceleration settings is provided in the MyoResearch Software User Manual.



Low Latency Mode: data is constantly being collected by the sensor and sent in packets to the receiver. Low latency mode reduces the sensor delay to approximately 50 milliseconds. This results in an almost immediate reaction seen in the avatar and no chance of delay.

Warning: This mode should only be selected when a fast reaction from the avatar is necessary. In low latency mode, because packets of data are being sent constantly, there is a greater chance for loss of data in poor wireless environments.

6 Basic Operation Instructions

6.1 Safety Information Summary

Strictly follow all safety practices given in Section 1 of this manual. The most critical safety practices are repeated here.

CAUTION

- Never use the Ultium System on a person with an implanted pacemaker
- Never operate the Ultium System within 1 meter of any critical medical device

6.2 Operating Environment

The software is structured into 3 levels or tiers:

1. Microsoft Windows Operating System
2. MR3 or MyoResearch 3 - A common multi-device service module running under Windows for management of various specific types of devices and their related software modules
3. MyoMotion - One of the software modules running under MR3 that is specific to IMU devices such as the Ultium Motion System

The Ultium Motion System acquires motion signals (position, velocity, and acceleration) from the patient via inertial sensors (the medical device) which wirelessly transmit the measured signals to any receiver that is part of the Ultium product family. In the case of the Ultium Receiver, the receiver is attached to a general-purpose computer via a USB connection which may include an optional (non-

medical) USB Hub. The computer is any standard (non-medical) Microsoft Windows based PC. The accompanying MR3-MyoMotion software combination records and displays the motion signals during a measurement session and provides analysis and reporting.

Required Computer Specifications

The following are the current specifications for computer systems needed to run the various software programs that are distributed by Noraxon. These specifications are subject to change without notice due to the volatility of the computer industry. It may be assumed that systems shipped by Noraxon will meet or exceed these specifications. Systems quoted with these specifications are good for three months after the date of the quotation.

Processor: Intel® Core™ I5 Processor or equivalent (I7 or better recommended)
Memory: 8 GB RAM (16 GB or higher recommended)
Hard Drive: HDD 500GB (1 TB or higher recommended)
Graphics board: Dedicated GPU[1] equivalent to NVidia 540M or Radeon HD 6620G or better[2]
OpenGL: Version 3.3 (4.3 or higher recommended)
Camera: Logitech C920 equivalent or better if the camera is to be used as a reference camera
USB: At least 3 available USB Ports[3] (Use of pressure plates or treadmills requires a USB 2.0 port.) Noraxon USB cables must be used[4].
O/S: MR3: Windows XP, 7, 8.1, or 10[5] (32/64 bit)

These computer specifications must be met for all customers who are purchasing MR3. The recommended specifications are required for multi-device systems due to the increased demand on the computer system. It is also recommended that an external hard drive be available for data backup.

Lastly, although your computer may have the hardware indicated above, it is highly recommended that you update your graphic board drivers using the manufacturer's website.

1. Integrated graphics controllers such as the Intel HD 4600 or better will work for single device systems; the HD 4000 and older are not supported.

2. Having a Passmark G3D Mark of at least 562, a score of 700 or better is recommended.

3. One port is needed for each Noraxon device to be connected. A Noraxon approved USB hub can be used to add ports. Note when combining myoVideo and myoPressure more than one USB controller may be required. myoVIDEO cameras are not recommended to be plugged into a USB hub.

4. Note the cable length limit is 5 meters for USB 2.0 and 3 meters for USB 3.0. Longer lengths can be accommodated using Noraxon provided active extension cables or USB hubs.

5. Note that not all features are supported with Windows 8; Windows 8.1 or greater is required. Windows XP only works with MR 3.6 or earlier.

6.3 Determining the Sensor Assignments

Before performing a recording, decide which body segments will be included in the recording. Sensor configuration best practices are listed below.

Note: A full-body recording does not need to be used every time. Additionally, if you have purchased a partial body set of sensors, you can re-assign sensors to be used for different body segments. See Section 5.7 to reassign sensors to different body segments.

Using object sensors

Any myoMOTION sensor may be used as an object sensor. There is no limit to the number of sensors that can be used as object sensors. These object sensors are assigned to the hardware configuration using the sensor's serial number. For more information on object sensors, refer to Section 7.3.

Sensor Configuration Best Practices

- For anatomical angles to be calculated, at least two sensors need to be located around a joint. For example, for the software to calculate elbow angles, the upper arm and lower arm sensors for the corresponding arm must be used in the configuration.
- Any sensor configuration is supported; even single sensor or two distant sensor measures (left and right foot only) are possible. But we recommend whenever possible to start with the Pelvic or Upper thoracic sensor and create uninterrupted sensor chains to distal segments.
- If the Pelvic or Upper thoracic sensors are available, any distal sensor can be mounted to any position of the selected segment. We recommend positions that best follow the bone movement and are not too much influenced by muscle belly movements. Whenever possible the sensors should have sticky skin contact and not move relative to the bone (s).
- If the Pelvic or Upper Thoracic sensors are not used, each sensor must be positioned in-line with the long axis of the bone segment.
- Please also note that the distance of a given sensor to the joint center does not influence the angular calculations in both of the above-mentioned modes. However, contralateral sensors should be placed at equal distance from the joint center.

6.4 Attaching the Sensors

Sensor Attachment

The sensors can be attached with special fixation straps. These straps are designed for clinical use and slow, not highly dynamic, movements. For sports activities or impact related movements, we recommend additional fixation of the sensors with the use of elastic self-adhesive tape.

- Pelvis and Lower Thoracic: elastic belt with torso adapter
- All extremities, including hand, and head: Elastic strap
- Foot: Shoe adapter
- Upper Thoracic: double sided tape with torso adapter

Sensor Placement

Sensor Placement Orientation:

- Sensors must be placed so the Noraxon logo is facing away from the subject.
- The positive x-coordinate on the sensor label should have a superior orientation (i.e. up to the sky/ceiling) for the trunk, head, and pelvis. The limb segments sensors should have the positive x-coordinate in line with a proximal orientation (i.e. towards the proximal joint along the long axis of the bone segment).

Exception: For the foot sensor, the X-coordinate points distally (to the toes).

Sensor Placement Assumptions for the myoMOTION System:

- Place sensors symmetrically between each sides of the body.
- Pay careful attention to attachment of the pelvic sensor. Any dislocation between the pelvic sensor and pelvic bone will influence the accuracy and validity of all angular calculations.

Sensor Placement Locations:

Head	Middle of the back of the head
Upper Thoracic	Below C7 in line with the spinal column, but high enough to not be affected by upper trapezius muscle movement
Lower Thoracic	In line with the spinal column at L1/T12. Strap belt will be positioned on lower ribs on the front side of the body.
Pelvic	Body area of sacrum
Upper Arm	Midway between the shoulder and elbow joints, lateral to the bone axis
Forearm	Posterior and distal, where there is a low amount of muscle tissue
Hand	Dorsal
Thigh	Frontal and distal half, where there is a lower amount of muscle displacement during motion
Shank	Front and slightly medial to be placed along the tibia
Foot	Upper foot, slightly below the ankle

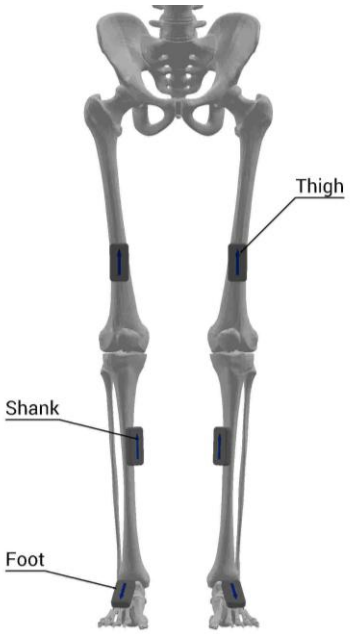


Figure 10: Lower body sensor placement

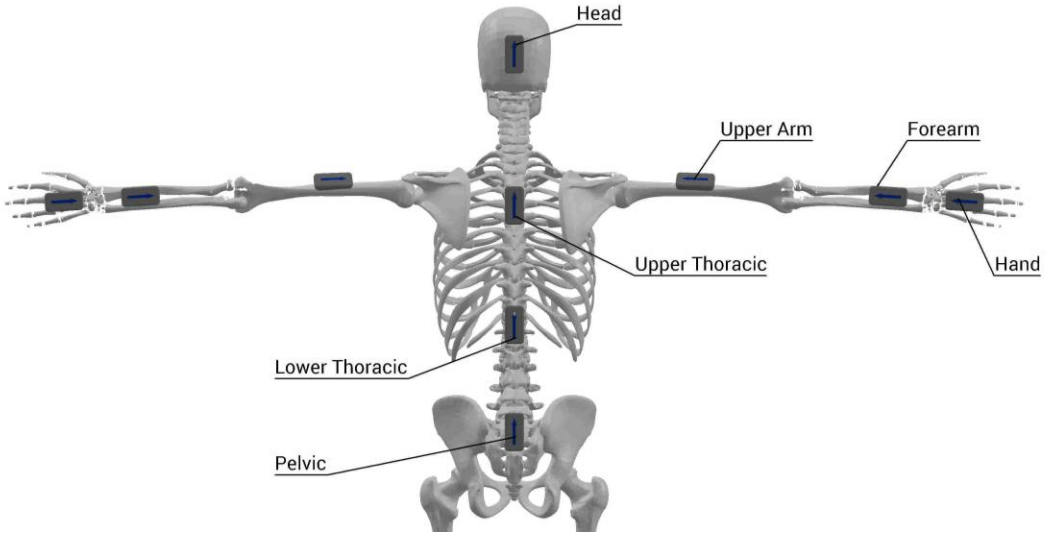


Figure 11: Upper body sensor placement

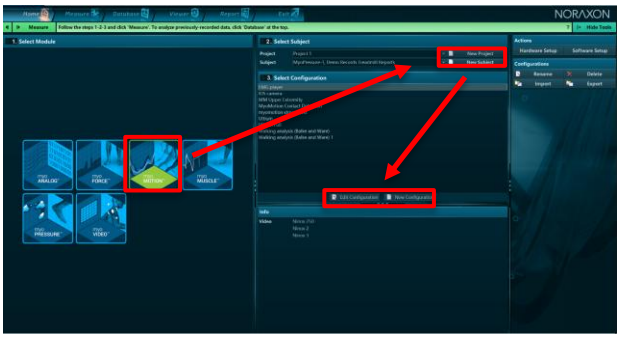
6.5 Creating a New Configuration

Step 1

Within the **Home** screen click the myoMOTION module icon.

Create a **New Subject.**

Note: Defining the height for the subject is important since the software uses subject height in its algorithm to compute bone lengths and create an accurate avatar while recording and later viewing a record

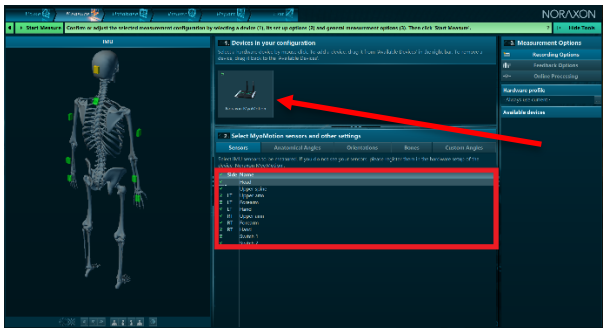


Select **New Configuration.**

Step 2

Insert the devices to be used for the measurement into the configuration by dragging a device in the list of **Available Devices** to the **Devices in your configuration window**.

Select the desired body segments to include in the measurement configuration. Deselect the body segments you do not wish to include in the measurement. The example image depicts what is seen for a full body MyoMotion set up.



Step 3

Select the desired measurement configuration options. Each are described below.

Configuration Options

Sensors: Select all the sensors you wish to use in the recording by checking the boxes,
Anatomical Angles: Select the angles you want to be shown in the recording.
Orientations: Check all orientations and make sure they are set to the desired orientation. Orientations should be adjusted to standard directions initially.
Acceleration: Check all the accelerations you wish to include in the recording. Accelerations will appear in this tab if you have **Accel. Data** turned on in the **Hardware Setup**. **Sensor-based** acceleration means that the acceleration data will be in reference to the sensor and the sensors directions. **Earth-based** acceleration data will be in reference to the earth reference frame.
Bones: The Bones tab shows the bone measurements for the myoMOTION avatar. These are calculated based on the height chosen for your subject. You can enter manually measured bone lengths here.

Custom Angles: You can input two sensors into the custom angles tab to create a custom angle based on the difference between two selected sensors. This is also where you can add a customs angle between object sensors.

6.6 Entering the Measurement Screen

Continue to the next step by selecting Measure.

A sensor activation dialogue will appear on the next window. After approximately 20 seconds, the time needed to activate the sensors, the full measurement screen will appear.

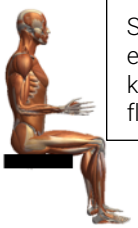
6.7 Calibrating the Sensors

Before a measurement can commence, the software model must be calibrated to the sensor placement.

The calibration procedure defines the 0° point or 90° point (dependent on calibration position) of the angular displacement that is measured by each myoMOTION sensor. Particular attention should be used to ensure the calibration position is as accurate as possible. For example, if in standing straight position and the knee joint is not brought to the neutral zero joint position; there will be an angle offset error in each angle measured during recording.

Standing straight:
All joints are in "neutral" zero position, palms aligned with the sagittal plane

Standing, arms flexed:
All joints in "neutral" zero position with elbow flexed to 90°



Sitting:

Seated with elbow, hip and knee are 90° flexed

Step 1

In the right-hand toolbar, select the desired calibration method.

Ensure sure the subject is in the calibration position and is prepared to hold the calibration position for 20 seconds during the calibration procedure.

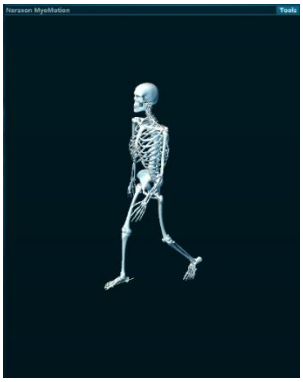
Step 2

Select **Calibration.** Monitor the subject to confirm the calibration position was held for 20 seconds after clicking **Calibration**.

Once a given sensor set is calibrated the calibration data can be used for repeated measure series (see option "**Use last calibration**" in right tool bar of myoMOTION measurement screen). Frequent re-calibration of sensors within test series is recommended.

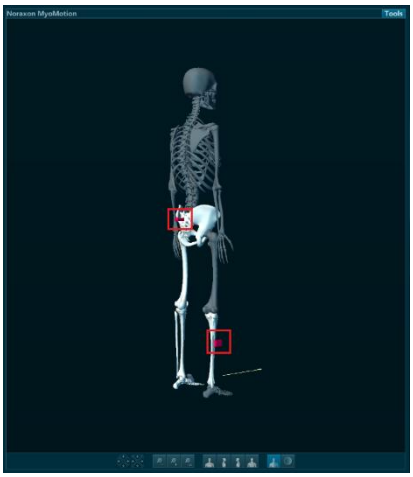
6.8 Checking Signal Quality

Check the signal quality by having the subject move around and confirming the joint angles, avatar display, and accelerations are appropriate for the subject's motion.



6.9 Correcting for Magnetic Interference

Magnetic interference is shown as a red sensor on the myoMOTION avatar. If you have already determined a clean calibration location and have training on proper calibration, you may use one of the correction modes to correct for magnetic interference.



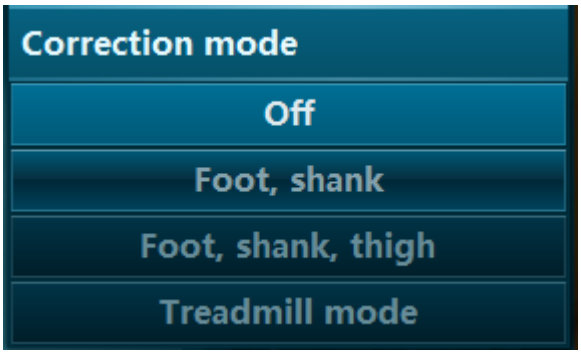
There are several correction mode options available to reduce magnetic interference in recordings.

Off – no correction applied to the myoMOTION model

Foot, shank – Magnetic correction applied to the foot to shank joint angle to correct for heavy magnetic interference

Foot, shank, thigh – Magnetic correction applied to the foot-shank-thigh joint angles to provide additional magnetic correction in the presence of heavy magnetic interference.

Treadmill mode – Magnetic correction applied to the entire model, correcting for magnetic interference (60 Hz) while performing gait analysis on the treadmill.

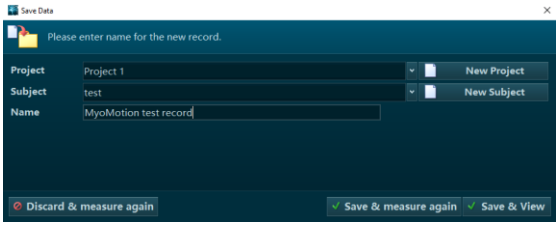


6.10 Recording a Signal as Desired

After performing your calibrations and selecting a correction mode (if desired), select Record.

Record your signal based on predetermined protocols. After performing desired movements in the record, click Stop and Save.

Chose Discard & measure again or Save after typing your chosen record name.



6.11 Shutting down after Use

At the end of the day:

1. Place all myoMOTION sensors inside the sensor changing station(s).
2. Apply AC wall power to the charging station.
3. Enter the Hardware Setup from the Home screen in MR3.
4. In the myoMOTION device settings, choose Shutdown Sensors in the bottom left corner. You will see the myoMOTION sensors' flashing lights go out, indicating that they are shut down.
5. Unplug the myoMOTION receiver's USB cable from the computer or turn off the computer.

6.12 Exceptional Functions/Situations (error messages)

Error Message	Meaning
The following sensors are not available: Please make sure they are not being charged and are within range.	One or more myoMOTION sensors failed to respond to a start measurement command. The specific sensor name will be displayed, e.g "Lower Thoracic". Check to see if any MyoMotion sensors are still in the charging station.
Magnetic Disturbance:	One or more myoMOTION sensors are experiencing a magnetic field that could cause distortion of data. The specific sensor name will be displayed, e.g. "Pelvis".
Low Batteries:	One or more myoMOTION sensors have a low battery and need to be returned to the charging station. The specific sensor name will be displayed, e.g. "Head".

The Receiver operates utilizing power provided through the USB connection to a computer. Certain power saving modes employed by modern computers may disable USB ports when a period of inactivity is detected. If a USB shutdown occurs the Receiver power indicator will be extinguished, and the system will fail to respond. It is recommended that the power settings on the computer be checked and if needed changed to allow continuous operation of all USB ports.

7 Additional myoMOTION System Use Situations

7.1 myoMOTION Receiver Synchronization

The myoMOTION System may be used with other devices. To synchronize the signal of the myoMOTION System with these other devices, it is necessary to set up both the software and

hardware correctly. The Receiver can accept a sync pulse via the Sync In port located on the back of the Receiver unit.

Sync In

The Sync In port allows a capture of a TTL (0-5V) sync signal. The standard source for this sync input is Noraxon's MyoSync device. The key purpose is to allow myoMOTION data to be synchronized with data from other devices.

MR3 Sync Setup

myoMOTION Receiver Sync is set up in the MR3 software, in Hardware Setup, under the Device Setting section. To enable Sync, simply check the Hardware Sync checkbox.

Once sync is selected, the sync channel in MR3 will be displayed as a Sync channel in the Measurement Configuration. Without sync, this channel appears as a Switch channel. By selecting the sync channel, a signal channel will appear in the record displaying when the sync pulse is generated. If not selected, synchronization will not occur.

7.2 myoMOTION Software Settings

myoMOTION Software settings are in a myoMOTION tab in the Software Setup in the Home screen. There are 3 different options: Magnetometer Control, Magnetometer Table, and Secondary Knee Angles.

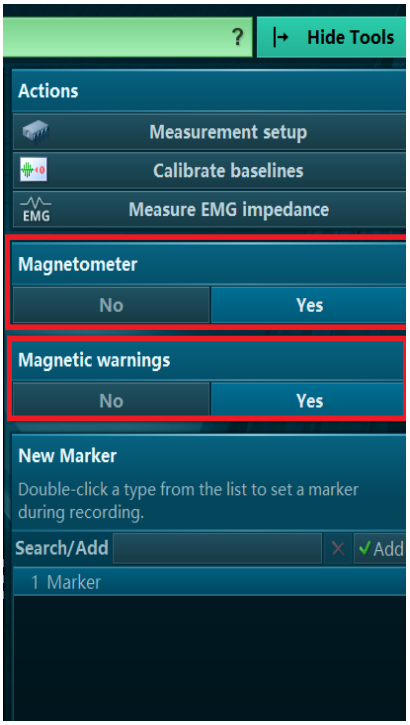
7.2.1 Magnetometer Control

Selecting this feature in the Software setup allows the user the option to turn off the magnetometer in the Measure screen after a calibration (the magnetometer is needed for a clean calibration) before taking a record. Only users with a high amount of magnetic interference that is making data unusable

should utilize this feature. Not using the magnetometers while recording data can cause drift over the course of the record, so using this feature only for short records is advisable.

After calibrating myoMOTION, on the right-hand side of the Measure window, you will see an option that says “Magnetometer” with a Yes/No option. Click No to disable the magnetometers. The option to disable magnetic warnings also present. Magnetic warnings is the indicator that shows you a red magnetic value in the magnetometer table if the magnetic interference is too high.

Magnetic warnings will not work if the magnetometer is set to “off” within Hardware settings.



7.2.2 Magnetometer Table

Selecting this feature in Software setup allows the user to turn off the magnetometer table seen in the Measure screen. The table can be disabled if the magnetometer table is not useful for the user’s application or they know that they have magnetically clean data.

7.2.3 Secondary Knee Angles

Turning on Secondary Knee Angles allows the angles LT/RT Knee Abduction, and LT/RT Knee Rotation Ext (external rotation) to show up in a lower body myoMOTION configuration. These angles are not already provided with other myoMOTION settings. These angle measurements add data that quantifies severity of valgus or varus knee flexion or external rotation at the knees during gait or a range of motion exercise.

7.3 Using Object Sensors

To utilize a sensor to record an object movement, the hardware configuration must be adjusted.

Step 1

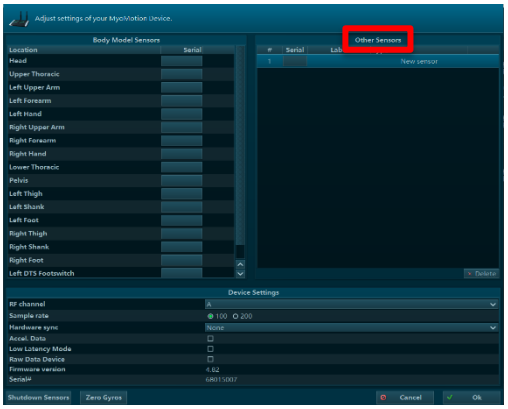
Select Hardware setup from the Home screen.

Double click on the myoMOTION icon to open the device settings.

Step 2

Assign the sensor(s) to be used as an object sensor under the Other sensor tab.

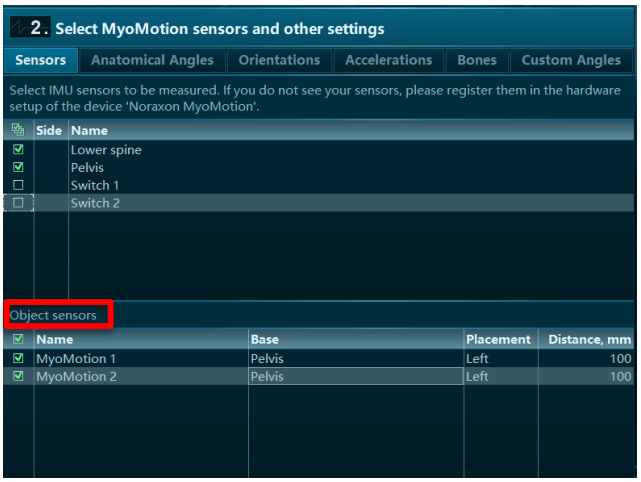
Select **Ok** to enter back to the Home screen.



Step 3

Select **Edit configuration.**

Once inserted into the hardware configuration, the object sensors will appear available in the software configuration under the sensors tab: object sensors.



Step 4

Under the Object sensors section there are 5 tabs. Adjust the information in each column as needed for the measurement.

On (checkbox) – enables the sensor to be displayed/measured
Name – the name of the object sensor, may be changed to anything you would like
Base – object sensors are anchored/linked to a body segment in the biomechanical model
The base sensor selected must be an enabled body segment in the measurement.
Placement - position of the object sensor in relation to the base sensor (left, right, front, back)
Distance (mm) – the distance between the object sensor and the base sensor, this will also change the distance between the object and skeletal avatar in the display.

Step 5

Once object sensors have been enabled, they will appear as cubes in the screen with the avatar. As the object moves, the illustrative cube will rotate in accordance with the object sensor's movements. The data for the curves will be displayed in the acceleration or orientation angles tabs.

At this point, the object sensors are ready for recording.

7.4 Enabling Contact Detection

The contact detection feature uses the gyroscope and accelerometer data from the sensors assigned to the feet to determine when the foot is in stance and swing phase via an on/off signal.

The foot sensors MUST be included in the Hardware Setup and turned on in the Measurement Configuration for the contact detection feature to work. You must also be sure that acceleration data is enabled in hardware setup and the foot acceleration channels are selected.

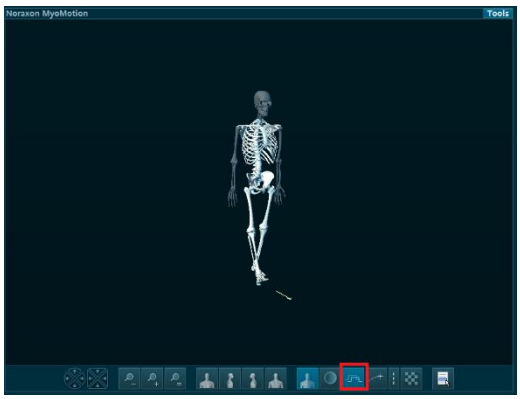
View the contact detection data within a record

Step 1

Open the recording of interest from the Database screen.

Step 2

Within the record Viewer screen, select the button that looks like two square waves at the bottom of the avatar window. This enables contact detection.



Step 3

After selecting the button, a tab will show up next to the rest of the signals called Contact. This contains the contact detection signals for the left and right feet.

Once the configuration is set up correctly, footsteps will be displayed as on/off signals with a value of 1000 or 0. A value of 1000 indicates stance phase while a value of 0 indicates swing phase.

Currently the contact detection feature should only be used for normal walking or jogging. The contact detection may not record activities such as running, walking upstairs, fast change of direction, or abnormal walking accurately due to the nature of the foot movement.

The contact detection feature allows users to visually see the steps of the subject and have the added benefit of allowing the user to utilize the MyoMotion Gait Foot Switch Report. The MyoMotion Gait Foot Switch Report is based on the stance and swing phases to determine spatial gait parameters and

display the averaged kinematic angle curves using the contact detection data to determine the time interval. Any additional information from the record, such as EMG signals, will be displayed in the same manner as the kinematic angles.

7.5 Anti-Wobble Mode

Anti-wobble mode can be used to smooth data susceptible to soft tissue artifact. Soft tissue artifact occurs when the sensor moves relative to the skin, which creates a “wobble” that is not indicative of normal human movement.

Step 1

Open the recording of interest from the Database screen.

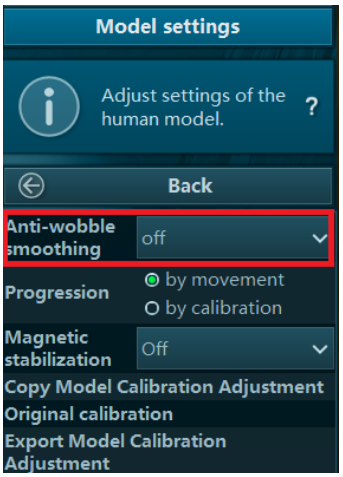
Step 2

Within the record Viewer screen, select the model settings button that looks like a note pad at the bottom of the avatar window. This opens the Model settings tool bar.

Step 3

Select the desired Anti-wobble smoothing option.

1. Light (BW 15 Hz on 300 ms residual)
2. Medium (BW 10 Hz on 300 ms residual)
3. Heavy (BW 5 Hz on 300 ms residual)



7.6 Lossless Data Recovery

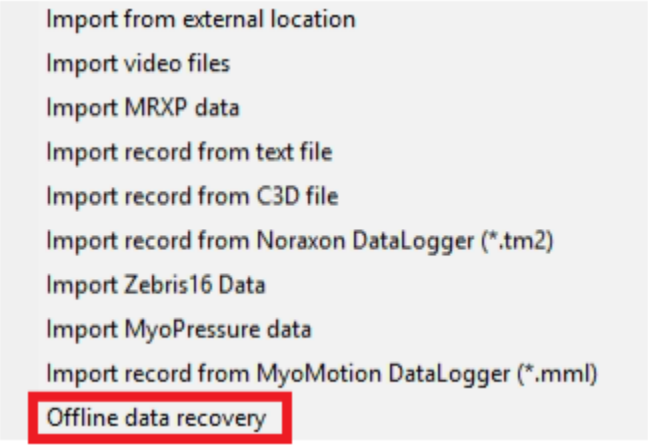
The MyoMotion System supports "lossless data recovery. The sensors continue to capture and store data (>8 hours of data) when communication with the receiver is temporarily lost. Once the record is completed, the data can be recovered in real-time or at a later time using the Import function.

7.6.1 Real-time (Online) Recovery

Immediately following the recording, MR3 will being recovering any data that may have been lost. It is recommended to instruct your subject to stay within, or return to, a 2-5 meter radius of the receiver during this recovery process. If the recovery is terminated (i.e. you select cancel during recovery), you may not be able to recover it if using MR 3.14 or earlier. The data can still be recovered later if you are using MR 3.16 or later.

7.6.2 Offline Data Recovery (Import function)

Data can be recovered at a later point in time via the 'import' function within the MR3 Database. When you are ready to recover data (offline) for one or multiple records, go to the Database tab within MR3. Then select 'import' from within the tools on the right side of the screen. The following options will be displayed:



- Selection of 'Offline data recovery' will then provide you with a list of all records that have lost data.
- Select each record you would like to recover at this time.
- The sensors must be on and blinking green and the receiver must be connected to the PC with USB when you recover data.
- Press OK to initiate recovery.

When recovering data offline, the data is retrieved from the sensors wirelessly one at a time. The length of time it takes to recover the lost data will depend on how many sensors were used in the measurement and how much data is missing.

Note: Offline data recovery is ONLY available with software versions MR 3.16 and newer. If you have MR 3.14 or earlier, only online data recovery is possible. If you wish to access offline data recovery and you have MR 3.14 or earlier, you must upgrade your software version.

8 Maintenance

Routine maintenance recommended for the myoMOTION system involves cleaning the bottom pads of the myoMOTION Sensor periodically and zeroing the gyros monthly. Because the myoMOTION sensor batteries are Li-Ion, the only battery maintenance required is recharging.

8.1 Consumable Items

Part No.	Image	Description
610C		Double sided tape for attaching myoMOTION sensors, 500 per package

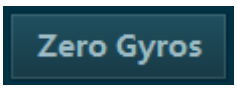
8.2 Replaceable Items

Part No.	Image	Description
BP9		Replacement battery for myoMOTION sensors*
610A		Sensor Body Segment Labels
610D		Torso mounting strap specifically for sensors in the Pelvis/Lower Thoracic
610E		Shoe clip for sensors
610S,M,L,X		Segment straps for holding sensors (small, medium, large, X-large)
610H,N,T		Hand straps for holding sensors (small, medium, large)

*The myoMOTION battery packs cannot be replaced by the user. Only qualified Noraxon technical personnel may perform maintenance.

8.3 Zero Gyros

Zeroing Gyros in the myoMOTION IMUs is generally recommended to keep the sensor data accurate. MR3 will alert you that you should zero gyros once a month. To do this, follow these steps:



1. Place sensors above the ground away from any magnetic interference. This means they must be away from any computers, treadmills, or other equipment.
2. Select Zero Gyros in the bottom left corner in Hardware Setup to zero gyros.

8.4 Charging the myoMOTION Sensors

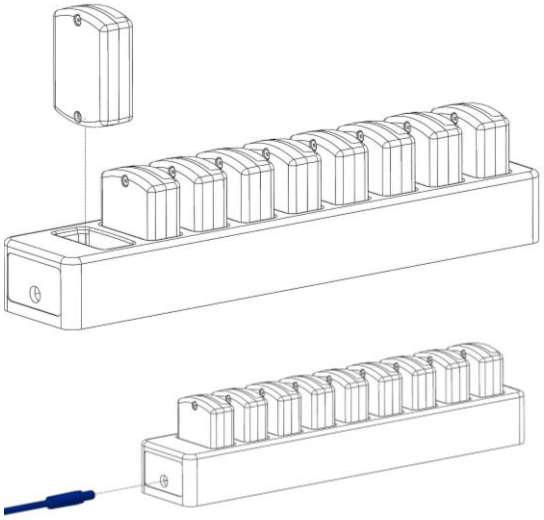
Safety precautions for charging the myoMOTION Sensors: No Precautions required.

The myoMOTION Sensors may be charged using the MyoMotion Sensor Charging Station.

Step 1

Insert the myoMOTION Sensor(s) into the myoMOTION Sensor Charging Station.

Verify that all the sensors are correctly inserted into the Charging Station.



Step 2

Insert the myoMOTION Sensor charger power source (Part #PSU1) into the charger jack on the myoMOTION Sensor Charging Station.

Step 3

Insert the myoMOTION Sensor Charger Power Source into a Power Strip (recommended) or into the wall outlet (mains).

The Charge LED on the myoMOTION sensor will show an orange light while charging. The LED will turn off when the charging cycle is complete

8.5 Storage and Protecting Between Use

For extended storage or when travelling:

- Put the myoMOTION sensors into shutdown mode *
- Place all sensors into the sensor charging station
- Position all components inside the system travelling case according to their prepared cavities
- Store sensors away from any magnetic material

If storing for more than 3 months, be sure to take sensors out and charge them completely once every 3 months before returning to normal storage.

* A special setting in the companion user software initiates sensor shutdown mode. To access the shutdown mode in MR3:

- Click on the Home button in the top navigation bar
- Select Hardware Setup in the upper right corner of the screen
- Double-click the Noraxon myoMOTION icon
- Select Shutdown Sensors at the bottom of the dialog box.

When the sensors are shutdown they will stop blinking completely. The sensors are reactivated by briefly charging them.

8.6 Cleaning the myoMOTION Sensors

Safety precautions for cleaning the myoMOTION Sensors:

WARNING

- Only use a damp cloth with mild soap and water or isopropyl alcohol to clean the bottom of the **myoMOTION** Sensors
- Do not immerse **myoMOTION** Sensors in any water or liquid.

For sanitary purposes, it is advisable to clean the bottom of the clean the bottom of the myoMOTION Sensors on a regular basis. The myoMOTION Sensors can be cleaned with a cloth slightly dampened with a solution of mild soap and water or disinfectant solution(i.e. isopropyl alcohol swabs or household disinfectant wipes).

The myoMOTION Sensors are not warranted against exposure to any of the conventional forms of sterilization(autoclave, heating, etc.). Users wishing to utilize this equipment in a sterile environment, such as an operating theater, should consult Noraxon for other options.

8.7 Companion Software Updates

- Perform a backup of the data folders to a separate drive as a precaution. this is done using the export “to external location” function on the database tab.
- Click on the Patch/Update link provided in the email or as given on the Noraxon website.
- Download the Patch/Update file.
- To install the Patch/Update, click “Run” on the dialog box. No password is required.

8.8 Device Software (firmware) updates

The internal program (firmware) inside the myoMOTION system can be updated with a special utility program available through a supplied link through the Noraxon website:

https://www.noraxon.com/support-learn/support-content/downloads/#firmware-downloads

The installed program will permit updates to both the myoMOTION Receiver and the myoMOTION Sensors.

Attention

All myoMOTION sensors should be fully charged before a firmware update is performed.

8.9 Battery Replacement

The Lithium Polymer battery used in the myoMOTION sensors is rated for a minimum of 300 charge-discharge cycles. Typical usage is 500 charge-discharge cycles. As the number of charge-discharge cycles increases the battery capacity slowly declines thereby reducing run time despite being fully charged.

Brand new batteries can operate for more than 8 hours when fully charged. If the run time of the sensors drops to 5-6 hours, battery replacement should be considered. The replacement batter is part #BP9.

The myoMOTION battery packs cannot be replaced by the user. Only qualified Noraxon technical personnel may perform maintenance.

9 Troubleshooting, Fault Diagnosis

9.1 Troubleshooting Chart

Symptom: Problem with the PC recognizing the myoMOTION System

Possible Reason	Remedial Action
USB cable is disconnected or loose	Check USB cable connection at both Receiver and computer

Symptom: Problems with myoMOTION Sensors communicating with the myoMOTION Receiver

Possible Reason	Remedial Action
Sensors were not assigned to Receiver	Assign sensors (see Section 5.7Error! Reference source not found.)
Receiver antenna is loose or not vertical	Hand tighten antenna and align vertically
Interference on wireless channel	Use another RF channel (see sections 5 and 9.4)
Too many sensors were assigned to receiver	Deselect some of the sensors to be measured, change sampling rate, and/or disable acceleration data

Symptom: Problems with individual myoMOTION Sensors

Possible Reason	Remedial Action
Sensor was not assigned to Receiver	Assign sensor (see Section 5.7)
Sensor battery is low (or sensor does not flash)	Retry after charging sensor for at least 15 minutes
Sensor shifts with very dynamic movements	Secure sensor with overlying elastic wrap

Symptom: Problems with intermittent myoMOTION Sensor signals

Possible Reason	Remedial Action
Sensor is too far from receiver	Move within 30m (90 ft) of the receiver
Sensor radio signal is partially blocked (absorbed) by the subject's body (especially at long distances)	Reposition sensor on subject to obtain a direct line-of-sight relationship between sensor and receiver
The skeleton avatar motion lags behind the subject's movements	A single sensor is blocked or faulty, check for sensor problems (possible sensor problems listed above) OR There is heavy wireless traffic and the RF channel should be changed.

9.2 Website Link to FAQ

Answers to frequent questions can be found at Noraxon's Frequently Asked Questions (FAQ) website page at this link:
https://www.noraxon.com/support-learn/technical-support/faqs/

Other educational material is available at this link:
https://www.noraxon.com/support-learn/technical-support/

9.3 Radio Considerations

The myoMOTION radio system operates in the 2400 MHz ISM (Industrial, Scientific and Medical) radio band reserved for use in most countries of the world. The radio transfers data digitally using a proprietary wireless sensor protocol. Other devices operating in this frequency band include computer networks, microwave ovens, cordless phone sets and other WiFi enabled devices.

Despite all this competing radio activity the myoMOTION System is able to discern its particular information from all the surrounding radio traffic. Reliable transmission depends on good signal quality. Signal quality will fall with extended distances between the myoMOTION Receiver and the myoMOTION Sensors. Obstructions (walls, metal structures, trees, etc.) between the myoMOTION Receiver and the myoMOTION Sensors will also lower the signal quality.

While the myoMOTION System is quite immune to interference, it does transmit a deliberate radio signal that could affect nearby sensitive equipment. Users should always be aware of this possibility. In a similar manner, although the energy level of the radio is considered harmless to human beings, it is still prudent to minimize exposure.

Finally, although available worldwide, each country places certain restrictions on the operation of radios in the 2400 MHz ISM band. These restrictions include allowable transmitter power levels and broadcast frequencies.

9.4 Setting the RF Network

The Sensor RF Channel is the frequency used for communication between the myoMOTION Receiver and the myoMOTION Sensors. Typically, the default option of RF Channel “A” (as set inside MR3), works well. However, sometimes there is a lot of WiFi traffic in the area that may affect the data transmission between the myoMOTION Receiver and the myoMOTION Sensors.

If there is too much traffic on the selected RF Channel, significant data loss may occur. To avoid data loss, changing the RF Channel to another frequency may solve the problem.

If the RF Channel needs to be changed, select a different letter in MR3 myoMOTION Settings and take another measurement to determine if the data loss problem is resolved.

If data loss is still a problem, please refer to Appendix A for instructions to select another RF Channel. Appendix C shows the actual frequency of each Sensor RF Channel. This information may be helpful in determining the best Sensor RF Channel.

10 Support, Service, and Repair

10.1 Submitting Technical Support Requests

A Support Request can be submitted using the online form available at this link:

https://www.noraxon.com/support-learn/support-request/

Provide all information requested by the form including a **detailed** description of the problem being experienced and your telephone number or e-mail address.

10.2 Returning Equipment

Be sure to obtain an RMA Number (return material authorization) before returning any equipment. Completing the online service request form will assign an RMA Number. Otherwise contact Noraxon USA.

https://www.noraxon.com/support-learn/rma-request/

Send the equipment **postage prepaid** and **insured** to the address below. Include the RMA Number on the shipment label. Mark the package "Goods to be repaired – Made in USA" to avoid unnecessary customs charges. (Beware listing a Customs or Insurance value of $5,000.00 USD or more will result in a delay at United States Customs.)

Noraxon USA
15770 N. Greenway-Hayden Loop
Suite 100
Scottsdale, AZ
85260, USA

If you are shipping from outside the USA please use UPS, FedEx, DHL, or EMS (US Postal Service) and **not a freight-forwarder.** Using a freight-forwarder incurs additional brokerage fees. If a package is shipped to Noraxon via a carrier other than the ones listed above, it may be refused.

11 Taking Product out of Operation

11.1 Disposal of Equipment and Batteries

The myoMOTION Sensors contain Li-Polymer batteries, which may be hazardous if disposed of incorrectly. Please check with the governing authorities in your location before disposing of the myoMOTION and its contents.

12 Technical Information

12.1 Theory of Operation

The myoMOTION wireless system is based on a pre-certified transceiver module: UGWG4USHN33 by Unigen. This radio module operates in the 2.4 GHz bands with an output power level of 1 mW and is based on a Wireless USB product by Cypress Semiconductor.

Part 610/616 myoMOTION Transmitter (myoMOTION Sensor)

Each myoMOTION transmitter module (part #610 and #616) incorporates one Unigen transceiver module together with an internal motherboard. The 610 and 616 are powered by one Lithium polymer battery (600maH). Each transmitter module is identified by a unique serial number.

The opposite end of the transmitter has two recessed contact pads for recharging its battery. To recharge the battery the #610/ 616 module is placed inside a charging station. The myoMOTION sensor cannot be applied to the subject and charged at the same time.

Part 613 myoMOTION Charging System

The charging station (part #613) is configured to hold up to nine (9) #613 myoMOTION Sensor modules. All battery-charging controls are inside the sensor modules. The charging station merely supplies a 5VDC source of power through a set of spring-loaded pins. The spring-loaded pins make contact with the recessed charging pads of the myoMOTION sensors. The 5VDC supply is a medical grade external power supply by Globtek (model GTM41060).

Part 680/684 myoMOTION Receiver

The myoMOTION receiver (part #680 and #684) consists of a main motherboard, a Unigen transceiver module. The model 680 receiver includes an optional Bluetooth module. The receiver has no applied parts.

The receiver interfaces to a PC via a USB port. The myoMOTION Receiver is also powered via the USB connection to the PC.

The Unigen transceiver in the #680 and #684 myoMOTION Receiver can communicate with up to nine (9) #610/616 myoMOTION Sensors.

12.2 Electro-Magnetic Compatibility Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The myoMOTION system is intended for use in electromagnetic environment specified below. The customer or the user of the myoMOTION system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The myoMOTION system must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The myoMOTION system is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity			
The myoMOTION system is intended for use in electromagnetic environment specified below. The customer or the user of the myoMOTION system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 64000-4-2	±6 kV contact ± 8 kV air	±6 kV contact ±6 kV air	Device user should avoid touching subject and sensor probes while a measurement is active.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines Not applicable	For battery charging mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	For battery charging mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) For 25 cycles <5 % U_T (>95 % dip in U_T) For 5 sec	Not applicable to operation Not applicable to operation Not applicable to operation Not applicable to operation	For battery charging mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The myoMOTION system is intended for use in electromagnetic environment specified below. The customer or the user of the myoMOTION system should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6
(Charging System)</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3Vrms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the myoMOTION system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>3V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such a base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the myoMOTION system is used exceeds the applicable RF compliance level above, the myoMOTION system should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the myoMOTION system

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the myoMOTION System			
The myoMOTION system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MyoMotion system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the myoMOTION system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

13 Appendices

13.1 Appendix A – Product Specifications

Expected Useful Lifetime

The myoMOTION sensors (#610/616) operate with a rechargeable Lithium Ion battery. The battery capacity will decline with ongoing use and may require replacement. There are 500+ discharge/charge cycles to preserve the device's rated 8 hours of operating time.

Dimensions and Weight

- myoMOTION Sensor Dimensions
  37.6 mm L x 52 mm W x 18.1 mm H
- myoMOTION Sensor Weight: Less than 34g.
- myoMOTION Research Receiver Dimensions
  100 mm L x 108 mm W x 25.4 mm H
- myoMOTION Receiver Weight: Less than 215g.
- myoMOTION Compact Receiver Dimensions (excluding docking station)
  78 mm L x 20 mm W x 4 mm H
- myoMOTION Compact Receiver Weight: Less than 17g

Performance Characteristics

Output & Transmission Frequency (Depending on country)

- Up to 2.5 mW (depending on country allowance)
- DSSS 2415-2472 MHz on (up to) 8 selectable radio channels
- Utilizing up to 4 different radio frequencies on each channel
- myoMOTION sensor transmission range: 30m (typical)
- Signal latency of 140 ms during data collection

myoMOTION Sensor Data Acquisition System

- X, Y, Z acceleration sampled at:
  - Low g accelerometer: 800 Hz
  - High g accelerometer: 400 Hz
- X, Y, Z angular velocity sampled at:
  - Low speed gyro: 800 Hz (available in the Research System only)
  - High speed gyro: 400 Hz
- X, Y, Z magnetic field sampled at 50 Hz
- Sampled sensor values algorithmically combined into 16-bit quaternion values
- Quaternion estimates generated at 100 Hz and 200 Hz (200 Hz only available in the Research System)
- Orientation data (joint angles) are available in both the Basic and Research systems, but only the research system has linear acceleration data available.

myoMOTION Sensors

- Fully wireless Inertial Measurement Sensor
- Accuracy +/- 1 degree in vertical plane, +/- 2 degrees in horizontal plane
- Battery life: > 8 hours, 3 hour charge time
- Sample rates: 100 Hz and 200 Hz
- 2.4 GHz unlicensed radio
- Sensor operation over 8 hours on a fully charged battery (recharge time 3 hours)

Energy Consumption, Condition of Use

- Receiver is powered by 5V USB host
- Sensor Charging Station is powered by PSU1

Environmental Conditions for Normal Operation

- Ambient Temperature: 0C to 38C
- Relative Humidity: 10% to 100%
- Atmospheric Pressure: 70kPa to 107 kPa

Environmental Conditions for Storage and Transport

- Ambient Temperature: -40C to +70C
- Relative Humidity: 10% to 100%
- Atmospheric Pressure: 50kPa to 106kPa

IP (Ingress Protection) Rating

The instrument is not protected against the ingress of water and carries no IPX rating (i.e. is ordinary equipment). The myoMOTION receiver and sensors are not waterproof. Care must be taken to avoid exposure to all liquids. Heavy perspiration may present problems if the myoMOTION sensors are secured to bare skin with in over wrap of tape or elastic. In such cases it is advisable to first add adsorptive material or cloth over the myoMOTION sensor before covering the sensor with tape or elastic bands.

13.2 Appendix B – Interference Between WiFi and myoMOTION Radio Frequency Channels

Because any neighboring WiFi radios and the myoMOTION System share the 2.4GHz frequency spectrum there is the possibility that the RF channels may overlap and interfere with each other resulting in lost data. To avoid interference, use the chart below to identify myoMOTION System RF and WiFi channels that do not interfere with each other. For example, myoMOTION System RF Channels starting with the letter "A" do not interfere with WiFi Channels 4-11. myoMOTION System RF Channel Set D does not interfere with WiFi channels 1-4 and 11.

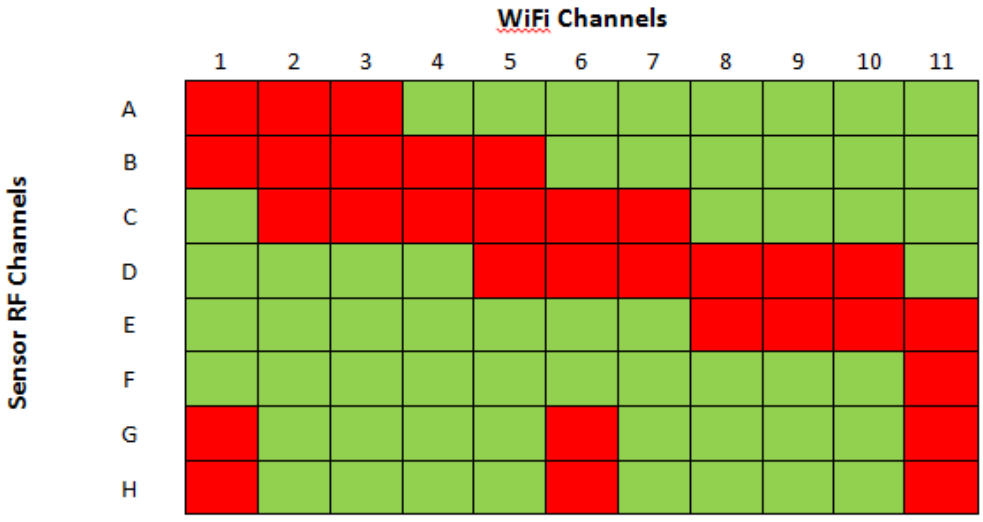
If you are aware of WiFi activity in the vicinity of the myoMOTION system, it is helpful to identify which combinations of the eleven WiFi channels are being used. Once this is determined, use the chart below to select a myoMOTION channel set (A-H) that avoids, as much as possible, WiFi channels that share the same radio frequencies.

Instructions to change the RF channel

Use a network sniffer program to determine which WiFi RF channels are being used in your area. InSSIDer" is a network sniffer with a graphical display that is available as a free download from the Noraxon website under "Drivers and Firmware":

http://www.noraxon.com/support-resources/

This network sniffer is compatible with Windows XP, Vista, 7, and 10 (32 and 64-bit). You can use most 802.11 a/b/g wireless adapters, e.g. PC internal WiFi, PCMCIA card Wireless network adapter and USB Wireless network adapter, to scan the networks in the area. Once the busy WiFi channels are identified, change the myoMOTION RF Channel to avoid those WiFi channels.



Note: G and H will not work if any of the channels above in red are being used.

13.3 Appendix C – Sensor RF Channel Frequencies

The myoMOTION Sensors operate on a RF channel. The RF Channels (A-H) are assigned to the RF frequencies according to the table below.

RF Channel	Frequency (GHz)
A	2.400-2.409
B	2.415-2.424
C	2.427-2.436
D	2.439-2.448
E	2.451-2.460
F	2.463-2.472
G	Various frequencies
H	Various frequencies

13.4 Appendix D – Radiation Exposure Information Regarding Use of myoMOTION Sensors

Each myoMOTION sensor contains a radio frequency transmitter. The radiated power emitted from each individual myoMOTION sensor is very low. To put this in perspective, at full power each myoMOTION sensor transmits at less than 0.1% of the power of a typical active cell phone. Radiation exposure from a single MyoMotion sensor is thus extremely low.

The myoMOTION sensors are designed to operate at two different power levels in order to keep the already very low levels of radiation exposure to an absolute minimum. The myoMOTION sensors activate their higher power level only during periods of actual data collection. During idle times (at setup and in between actual measurements) the myoMOTION sensors reduce their radiated power to an even lower level (less than 0.01% of the power of a typical active cell phone).

The effects of non-ionizing radiation on biological tissue are still being studied and published 'safe levels' of exposure are subject to review. Today, cell phone usage is widespread and declared 'safe,' although the long-term cumulative effect of cell phone usage has yet to be determined. In contrast, the myoMOTION sensors operate at power levels 1000 to 10,000 lower than typical cell phones while limiting exposure to a single episode over a brief time interval.

Because there can be multiple myoMOTION sensors applied in intimate contact with the body, their sum total collective radiation effect may be questioned. Based on comparative power levels, a full complement of 16 myoMOTION sensors emit a combined (distributed) radiation level still several orders of magnitude lower than that of a typical cell phone, which radiates all of its energy from one focal point (next to the person's head).

At present, Noraxon identifies no restrictions on use and placement of the myoMOTION sensors on any portion of the human body. The myoMOTION sensors operate at radio frequencies known to effect older style pacemakers. Because the effects are not known at this time, Noraxon advises against using the MyoMotion system on anyone with an implanted pacemaker.

In summary it is prudent to keep in mind that due to biological diversity, certain individuals may have higher sensitivity to radiated emissions. Although it has never been known to occur, the use of the myoMOTION system should be stopped if the person being monitored reports any unusual sensations.

FCC Statement

This device 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. Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device contains modules with FCC ID: R8KUGWG4USHN33A.

Industry Canada Statement

This product contains Unigen Wireless USB module Canadian Cert No IC: 5125A-UGWG4US