ultium® EMG

Hardware User Manual

(Rev T)

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

Warnings

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

Attention

- The operator must be familiar with typical characteristics of the signals acquired by the Ultium EMG 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.
- 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 Ultium EMG sensors are suitable for use as medical devices. To ensure safe operation the following guidelines must be strictly followed.
- The Ultium Receiver, Ultium Sensor Charger, and computer must not be accessible (touchable) by the patient. Ensure the Ultium Receiver, Ultium Sensor Charger, and computer are always positioned at least 6 feet (2 meters) away from the patient.
- The Ultium Receiver must only be connected to a certified ITE/medical grade computer or devices (If ITE certified computer is used, then basic safety at a system level shall be verified).
- To ensure safe operation, the use of Ultium EMG with custom built computers (those assembled from discrete subassemblies) must be avoided.
- The operator must never touch the patient and any other device (Ultium Receiver, computer, or Ultium Sensor Charger) at the same time.

2 Introduction

2.1 Brief Description

The Ultium System for EMG and other biomechanical sensors wirelessly transmits data from the electrode or sensor site to a desktop receiver.

This wireless transmission concept greatly simplifies the collection of EMG measurements by eliminating cable connections between the EMG electrodes and EMG amplifier. The small, lightweight EMG sensors are also beneficial for small subjects like children and small animals.

This unique concept gives the user the flexibility to operate the Ultium System without the traditional laboratory-based measurement limitations. The Ultium System is designed to operate any configuration between 1 and 16 sensors. Multiple Ultium Systems can be used simultaneously to increase the configuration to 32 sensors.

The default system is equipped with EMG sensors but can be upgraded with other biomechanical sensors, e.g., goniometers, inclinometers, and foot switches. The EMG sensors can also be activated to measure IMU data or a combination of EMG with acceleration data. A synchronization capability can be used to accurately synchronize the Ultium System to other biomechanical devices.

2.2 Device Safety Categories

The Ultium System incorporates the following ratings:

Class II (double insulation) for electrical safety with internal battery power during operation
CISPR 11 Class A radio frequency compatibility (ref. Section 17 for details)

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

2.3 Intended Use

Noraxon's Ultium EMG sensor is intended to measure and quantify muscle biopotential signals separately or in combination with other kinematic or kinetic signals. These inter-related measurements can provide data to assist in understanding movement abnormalities. The system is designed as a measuring tool for clinical, investigational and research applications. Additionally, this device is compliant to the international standard for diagnostic EMG (IEC 60601-2-40).

Intended Users
Researchers or individuals trained in physical medicine, physical therapy, human performance or ergonomics and who have gained familiarity with the Ultium 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 Ultium System is suitable for use in hospitals, clinics, academic laboratories except near active HF SURGICAL EQUIPMENT or MRI IMAGING EQUIPMENT.

Expected (Essential) Performance
The Ultium System (EMG sensor and Receiver) synchronously acquires and displays muscle activity signals from multiple muscle sites 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 Ultium System may exhibit sluggish (non-real-time) behavior.

Risk-Benefit
There is no identified risk of physical harm or injury with use of the Ultium product. 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 Ultium EMG system operates 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.

2.4 Contraindications

Use of the Ultium EMG 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 Ultium enclosures and in this user manual. Their meaning is described below.

Approval to market this product (#870/876) in the European Community was certified by Notified Body #2797 BSI.

The device generates radio frequency energy during operation.

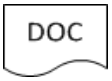
A 5 Volt DC external power source is applied to this connection.

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.

Identifies the serial number of the device.



Additional information available in a separate document

Standby- Power on/off sensors

3.2 Glossary of Terms

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

Ultium EMG Sensor -- A small individual radio transmitter typically worn on the body used to measure and transmit bio-potential signals (such as EMG) or motion related signals (such as position or acceleration). The Ultium System can accommodate up to 16 body worn EMG Sensors in one network.

Ultium EMG *SmartLead* – An accessory sensor that can be connected to an EMG sensor to provide other biomechanical signals. Examples include force, acceleration, etc.

Ultium EMG Serial Number – A unique five-character tag used to identify each EMG Sensor. The members of any Ultium network are determined by their serial numbers. Smart Lead Types are grouped into a predefined range of serial numbers. Thus, by serial number the Ultium system can automatically determine the type of signal parameter being transmitted from any Sensor in the network.

Multi-Channel Sensor – Certain Sensor Types provide more than one signal. Thus, a Multi-Channel Sensor behaves like two or three standard Sensors. An example is a 3-D Accelerometer that provides acceleration data for the x, y and z directions.

Probe – A generic term for any EMG Sensor.

RF – (Abbreviation for Radio Frequency) Wireless communication takes place on assigned radio frequencies or channels. For the Ultium 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 frequency and can be a source of interference.

RF Network – RF transmissions for the Ultium System can be selected to occur on one of 4 different networks. All networks use frequency hopping to avoid interference.

RF Traffic – The presence of radioactivity present on a given frequency similar to the number of cars on an expressway. Several users (wireless devices) may be communicating using the same frequencies. Best operation of the Ultium System occurs when the RF Traffic is low.

4 Product Information

4.1 Model Designation

The basic Ultium System consists of three primary components:

- Model 880 Ultium Receiver (1 per system)
- Model 810 EMG Sensor (up to 16 per system)
- Model 873 Ultium Sensor Charger (up to 2 per system)

4.2 Product Versions and Configurations

The model 880 Ultium Receiver can accommodate up to 16 Ultium EMG Sensors. The standard model 810 Sensor contains a 3-axis inertial measurement unit and can be combined with any of the following SmartLead types:

Model 802 Ultium Footswitch
Model 808 Ultium 2D Flexible Axis Goniometer
Model 811 Ultium 3-channel Analog Input Sensor
Model 817 Ultium 3D Accelerometer
Model 820 Ultium 500-lbf Force Sensor
Model 821 Ultium 100-lbf Force Sensor
Model 824 Ultium Local Pressure Sensor
Model 826 Ultium Insole
Model 842 Ultium EMG Lead
Model 852 Ultium BioMonitor (ECG and Respiration)

For additional equipment details refer to Section 14 and Appendix E of this User Manual.

4.3 Software Requirements

The Ultium System requires software to perform its function, the equipment is offered in combination with the following computer program packages:

Noraxon myoRESEARCH® (MR3.12 or newer) Software Platform and myoMUSCLE™ Software Module

5 Setting up the Hardware

5.1 System Unboxing

The Ultium 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.

Figure 1 – Ultium Receiver (#880)

Figure 2 – Ultium Sensor Charger (#873)

Figure 3 – EMG Sensor (#810)

Figure 4 – Ultium EMG Smart Lead (#842)

Figure 5 – Ultium Sensor Charger Power Source (#PSU1)

Figure 6 – A to B USB Cable (#CBL2)

Figure 7 – Ultium Charger to Receiver Cable (#CBL34)

Your system may differ depending on the number of sensors included with your shipment, quantities of EMG sensors, EMG SmartLeads, Sensor Chargers, and Charger to Receiver Cables.

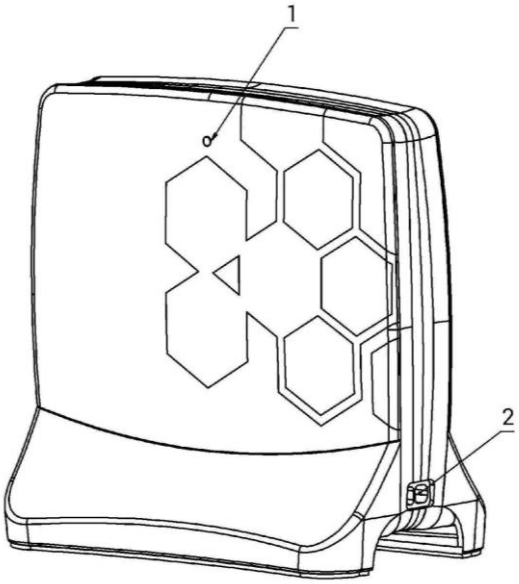
Additional items that may be included with your Ultium System include:

- Double side tape samples (#810C)
- Sample electrodes (typically dual electrodes (#272 or #272CASE)
- Ultium User Manual (#P-8808)

Accessories

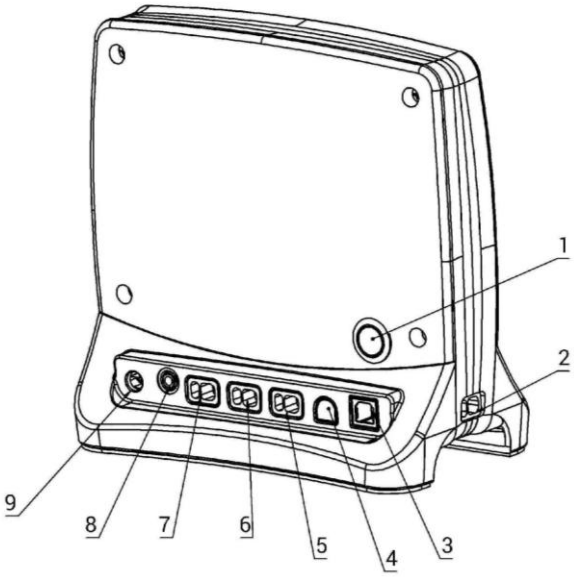
If additional accessories have been included, please see Section 14, Appendix E of this User Manual, or the www.noraxon.com for more information.

5.2 Ultium Receiver Overview



Receiver (Front)

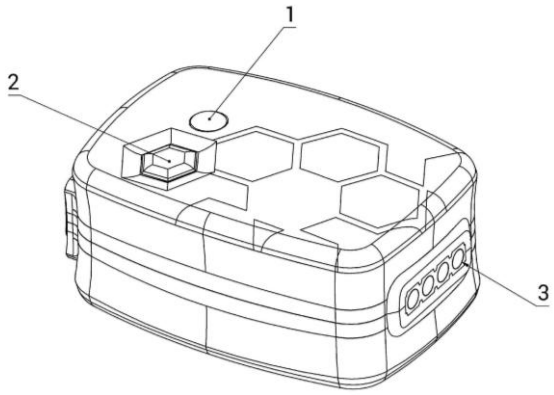
1. Status LED – Indicates the status of the Receiver.
2. Charging Dock Port – Connects the Sensor Charger to the Receiver for communication.



Receiver (Back)

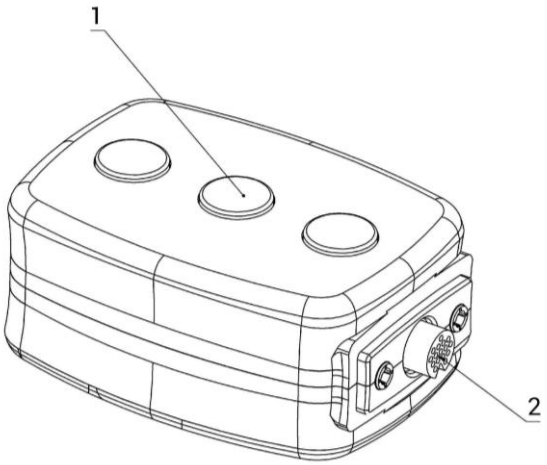
1. Sensor Power Button – Push to toggle power on sensors inserted into connected chargers.
2. Docking Ports - Allows sensor chargers to be connected for power and data communication to sensors.
3. USB Port – USB connection between the computer and receiver.
4. Lockstep – Reserved for future use.
5. AUX1, AUX2, AUX3 – Connect auxiliary accessories (Analog Output). NOTE: AUX3 is disabled.
8. Sync – TTL (on-off) compatible 3.5 mm stereo jack connection to other devices.
9. Charger Power – Apply 5V (PSU1) to power up to 2 Ultium Sensor Chargers.

5.3 Ultium EMG Sensor Overview



EMG Sensor (Front & Top)

1. Status LED – Sensor operational indicator flashes green when measuring. Solid Yellow when charging.
2. Power Button – Power the sensor On/Off. Hold for 3+ seconds for a hard reset.
3. Charger Contacts – Sensor battery is charged and sensor data is exchanged through these points.



EMG Sensor (Back & Bottom)

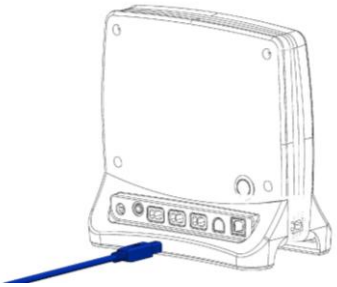
1. Reference Electrode– Third electrode that provides a ground reference for the differential signals collected by the EMG leads attached to the surface electrode.
2. Smart Lead Connector – Connector for smart leads to change function of EMG sensor.

5.4 Hardware Setup Instructions

Step 1

Insert the USB-B (smaller) end of the USB cable (#CBL2) into the USB connector on the rear of the Ultium Receiver (#880).

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

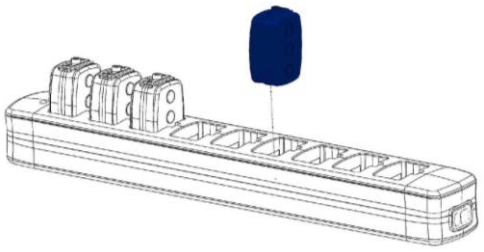


Step 2

Insert one EMG Smart Lead (#842) into each EMG probe (#810).

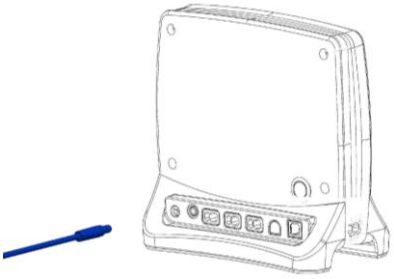
Step 3

Insert the EMG probes into the Sensor Charger (#873).



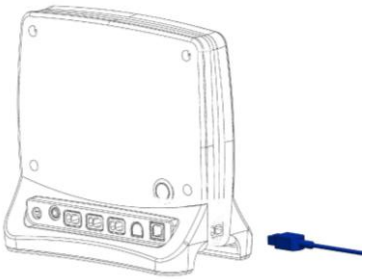
Step 4

Insert the power supply (#PSU1) barrel connector into the jack of the Ultium Receiver.



Step 5

Connect the Receiver to the Sensor Charger (#873). This will charge the sensors.



5.5 Installing the companion Software – myoRESEARCH™

To utilize the full functionality of the Ultium Motion System, and ensure the system has updated drivers, Noraxon's *myoRESEARCH*® needs to be installed on the computer.

Note: The Ultium Receiver requires the Noraxon USB device driver which is pre-installed by the MR software installation. It is also available in the Downloads Section of the Noraxon website.

Companion Software Installation

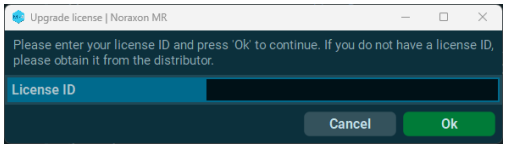
Within the Ultium Motion System shipment, there is a USB flash drive containing the latest *myoRESEARCH* software.

1. Insert the myoRESEARCH USB flash drive into the PC
2. Open the installer application (e.g., noraxon.mr.4.0.0) and follow the instructions
3. After installation, an icon will be created on the desktop

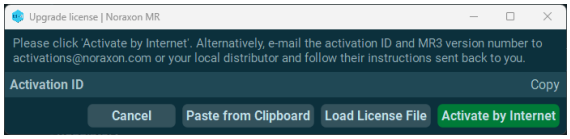
Companion Software Activation

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

1. Open myoRESEARCH (MR)
2. A dialog box will indicate how many more times MR can be opened in trial mode
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.
    a. Alternatively, email the provided activation ID to activation@Noraxon.com
    b. Noraxon Support will email or respond by phone with the Activation Code.
    c. Enter the provided Activation Code to remove any restrictions on use.

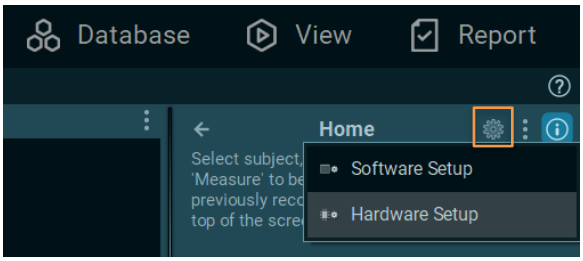


5.6 Configuring the Hardware

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

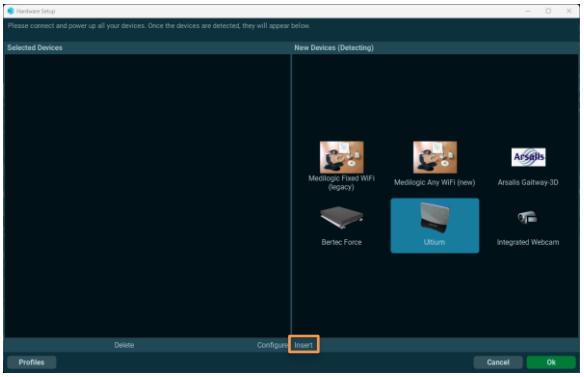
Step 1

Open the MR software, click on the settings icon ( ) in the upper right-hand corner, then click Hardware Setup.



Step 2

After connecting the Ultium Receiver to a USB port on the computer, select the Ultium Receiver icon in the New Devices area, and click Insert.



Step 3

The Ultium hardware setup window will appear as shown.

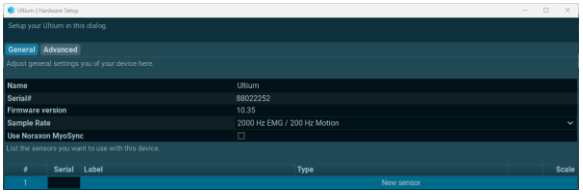
Within the “General” tab, select the desired settings for the system, i.e., name, sample rate, cutoff filters.

Note: If available, firmware updates for the Receiver and Sensors will be indicated here.

When using the myoSYNC, click the Use Noraxon myoSYNC checkbox.

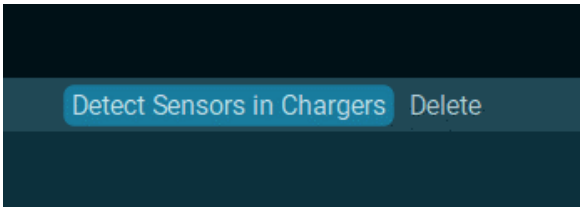
Additional settings are available within the “Advanced” tab.

Note: If multiple Ultium systems are in use, separate RF networks assignments are required for each Receiver.



Step 4

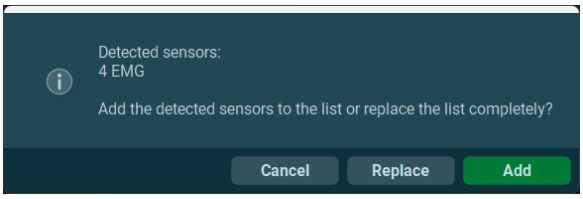
Make sure the EMG or SmartLead Sensors are placed in the Charger(s) and the Charger(s) are connected to the Ultium Receiver, then click Detect Sensors in Chargers to load all sensor serial numbers into the MR software.



Note: The first serial number in the list is associated with the Sensor closest to the front of the Charger (i.e., toward the Charger LEDs).

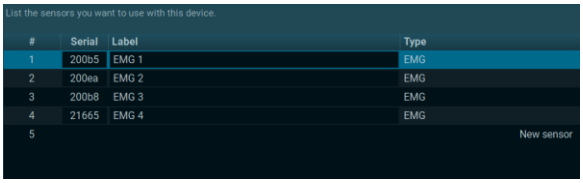
Step 5

After detection is complete, click Replace to replace all existing sensor serial numbers associated with this device or Add to append additional sensor serial numbers to an already existing list.



Step 6

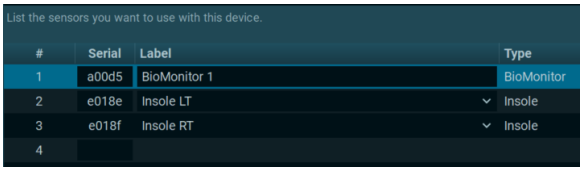
Click Ok to save the hardware settings and close the setup window.



5.7 Configuration using Ultium SmartLeads

If you are only using surface EMG leads, continue to Section 6.5: Recording a Measurement.

Connect the SmartLead to the Ultium sensor. The Ultium sensor LED will flash purple when a SmartLead is connected, and orange when the SmartLead is disconnected.



Click *Detect Sensors in Charger* and the SmartLead will be listed with the SmartLead serial number, not the Ultium sensor serial number.

Note: If the software does not recognize the SmartLead, the sensors may require a firmware update.

Click OK to save the hardware settings.

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. MR or myoRESEARCH - A common multi-device service module running under Windows for management of various specific types of devices and their related software modules
3. myoMUSCLE - One of the software modules running under MR that is specific to EMG devices such as the Ultium System

The Ultium EMG System (a member of the Ultium Wireless EMG Family product line) acquires EMG signals from the patient via EMG sensors (the medical device) which wirelessly transmit the measured signals to any receiver that is part of the Ultium EMG 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 MR-myoMUSCLE software combination records and displays the EMG signals during a measurement session and provides analysis and reporting.

Required Computer Specifications

Certain minimum specifications for computer systems are 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. The latest minimum computer specification requirements can be found on our website: Noraxon.com.

These computer specifications must be met for all customers who are purchasing MR. 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.

6.3 Ensure the Ultium Sensor is in Measurement Mode

Check the Sensor Status LED

The sensor's STATUS indicator provides a means of communicating its operational state. In the idle state, the STATUS indicator will flash blue. When the sensor is actively measuring, the STATUS indicator will flash green.

If the STATUS indicator is not flashing at all, the EMG Sensor may be powered off or may have a depleted sensor battery.

6.4 Attach the EMG Sensor with EMG Smart Lead Sensor to a Patient or Subject

CAUTION

DO NOT depend on the wire connection to the disposable electrodes as a means to secure the EMG sensor, using double sided tape to secure the sensor to the skin is recommended to ensure reliable sensor attachment.

For proper operation the EMG Sensor must be applied to the measurement site so that the center reference electrode pad on the bottom side is in direct contact with bare skin. The skin area in contact with the reference pad generally does not require any special preparation prior to applying the sensor. (Some skin preparation for the reference pad site may be beneficial if the EMG signal exhibits a wandering baseline. See Appendix A)

The EMG Sensors can be secured in place using Noraxon supplied double-sided adhesive tape and/or elastic straps. Straps are recommended if dynamic movements are expected.

The EMG Sensor allows for interchangeable terminal lead wires for attachment to disposable electrodes. The two lead wires are offset with one longer than the other by an amount equal to the standard 2 cm spacing for surface EMG electrodes. The 2-pin lead wire connector can be inserted either way into the EMG Sensor to facilitate attachment to the surface electrodes.

Noraxon also offers EMG Smart Leads with longer lead wires for special needs.

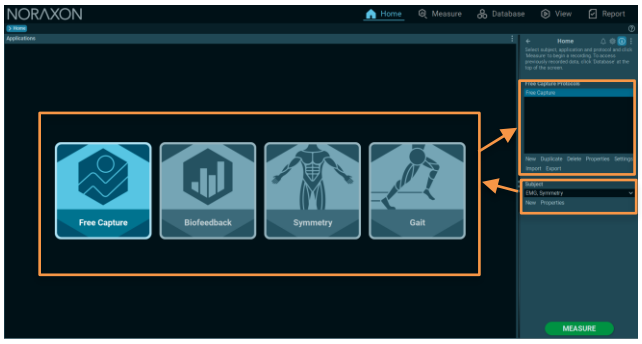
6.5 Recording a Measurement

Step 1

On the Home screen, select or create a subject.

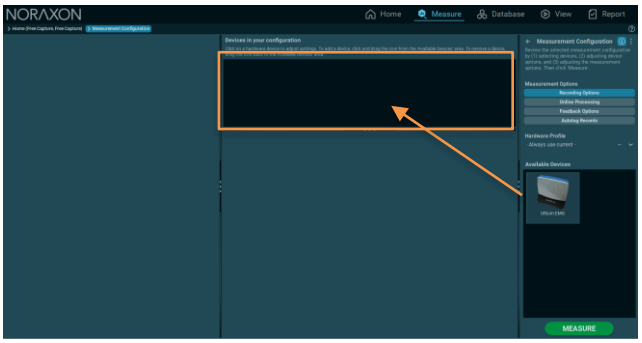
Select an application, then select or create a new protocol.

Click MEASURE to proceed.



Step 2

Insert the Ultium EMG device into the configuration by dragging it from the **Available Devices** list to the **Devices in Your Configuration** area.

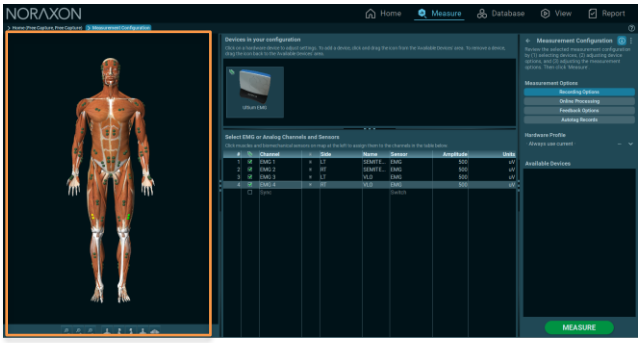


Step 3

Select the channels to include in the measurement by clicking the checkmark.

While a channel is selected, assign a label by selecting the corresponding muscle on the **Muscle Map** or entering the name manually.

Click **MEASURE** to proceed.



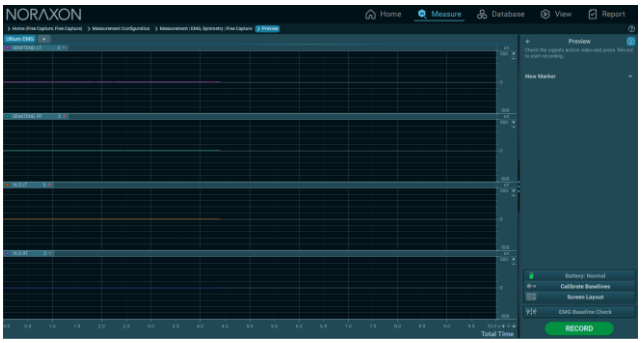
Step 4

Click **ACTIVATE** to begin the measurement.

Note: Additional operations, like measuring EMG impedance or creating an MVC, should be selected before clicking **ACTIVATE**.

Step 5

Confirm signal quality and click **RECORD** to begin your recording data.

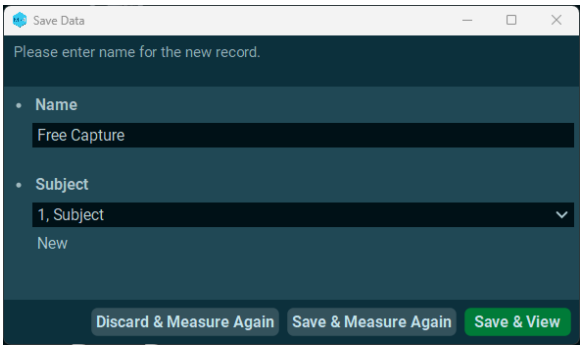


Step 5

Click STOP to end the recording, then enter a name for the new record.

Click Save & View to view and begin processing the record.

Click Discard & Measure Again or Save & Measure Again to return to the measurement screen.



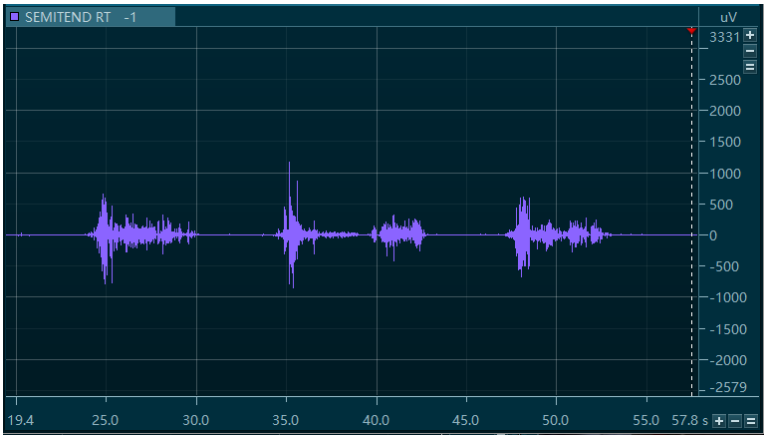
Exceptional Functions/Situations (Error Messages)

Error Message	Could not start all sensors or "XXXXX" not found.
Meaning	One or more EMG sensors failed to respond to a start measurement command. Check to see if any selected EMG sensors are powered off. This can also happen if the subject is more than 40m away from the Ultium Receiver.

Note: 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.

6.6 Check for Normal Signal Display with Interface to a PC

When used with the companion software the Ultium System displays and records raw (or processed) EMG waveforms will appear; similar to the waveform displayed below.



Consult the myoRESEARCH Software User Manual for additional instructions and descriptions for recording, playback, and processing of the data acquired by the Ultium system.

6.7 Check Signal Quality

Electromyography recordings are depending on many best practice standards to ensure ideal signal quality. Within the Noraxon myoRESEARCH platform, standard procedures and best practice functionality has been built to assist the practitioner with identifying their current signal quality. With the Ultium system, a live signal status monitor provides real-time information for practitioners to understand the current recording conditions.

EMG Signal Status Monitor

The Status Monitor appears at the top right-hand corner of the measurement screen to show relevant EMG baselines before recording. RMS voltage will appear in uV to ensure the signal is at a low resting amplitude before recording. Impedance will appear in kohms to check for high levels of impedance that may interfere with signal quality.

EMG Signal Status Monitor On/Off

Select EMG Baseline Check to show or hide the EMG Status Monitor within the measurement screen.

Red/Green Indicator

The circular red/green indicator will show if there are issues with the signal that will interfere with the quality of the recording. You can hover over it with the mouse for a full explanation of possible issues.

Green Indicator

The indicator will remain green when the impedance, RMS voltage, and frequency are sufficient to produce a clean signal.

Red Indicator

The indicator will turn red if:

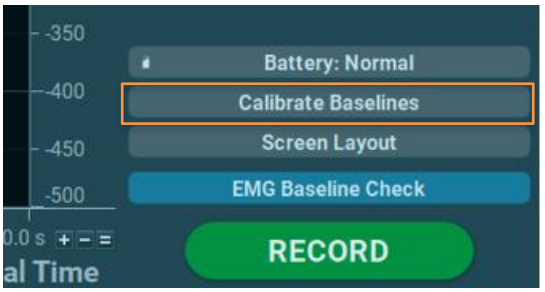
1. The impedance is > 100 kΩ
2. The RMS value is > 5uV and the median frequency of the signal is 50 Hz or 60 Hz (+/- 3 Hz). This is because these are the frequencies of mains AC power which can interfere with the EMG signal.

Related Software Measurement Tools

Within the Noraxon myoRESEARCH software is a suite of tools that can be used during EMG measurements. Below is a list of the most used features for electromyographic recordings. Additional information around more advanced features can be found on www.noraxon.com

Baseline Calibration

Data collected during the first second of a measurement is used to correct for any offset present in the signal. During the first second of each measurement, ensure that the subject is not performing highly dynamic movements to capture a clean signal recording.



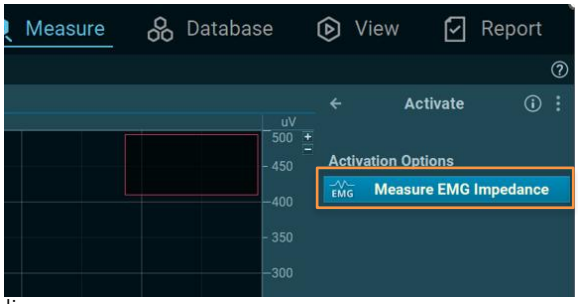
To perform this step manually, select Calibrate Baselines.

Choose EMG Baseline Check to show the baseline RMS voltage in the Status Monitor.

CAUTION

This tool will adjust baselines for all EMG and analog channels simultaneously.

Impedance Check



In versions of MR4 and MR 3.16 and newer:
To check the impedance of the signal coming through the sensor before measuring, select Measure EMG Impedance under "Activation Options" after entering the Measure window.

In versions of MR 3.14 and older:
Measure EMG Impedance is instead offered on the right-hand toolbar under "Actions" before recording.

Note: "Always Measure EMG Impedance" can be checked from the Ultium Hardware Setup, which will measure impedance after activation of the system when entering a measurement.

A low impedance (below 10 kΩ) is usually desired to obtain a cleaner signal. A high impedance may suggest that skin prep and electrode placement may not be sufficient to produce clean signal. For more details about EMG impedance and skin preparation, reference the ABC of EMG.

6.8 Record Signal as Desired

After checking the status monitor and impedance of your signals, you are ready to record a measurement. Select Record at the top left of the screen and begin your protocol. After completing your record, select Stop. Save the record as the name of your configuration, or type in a new name. After this, save your record by choosing Save & Measure, Save & View or Discard & measure again.

6.9 Shutdown after Use

At the end of the day:

1. Place all EMG sensors inside the sensor charger(s) and attach the chargers to the sides of the Ultium receiver.
2. Push the Sensor Power button on the Receiver to power all sensors off.

6.10 Storage and Protecting Between Use

For extended storage or when travelling:

3. Place all sensors into the sensor charger(s) and power them off.
4. Position all components inside the system travelling case according to their prepared cavities.
5. Every 3 months fully charge the sensors once and then normal storage without connection to power may resume.

Note: It is necessary to charge the sensors once every 3 months. The Litium Ion batteries will expand if left discharged for too long.

7 Additional Ultium EMG Settings and Features

7.1 Ultium Receiver Synchronization

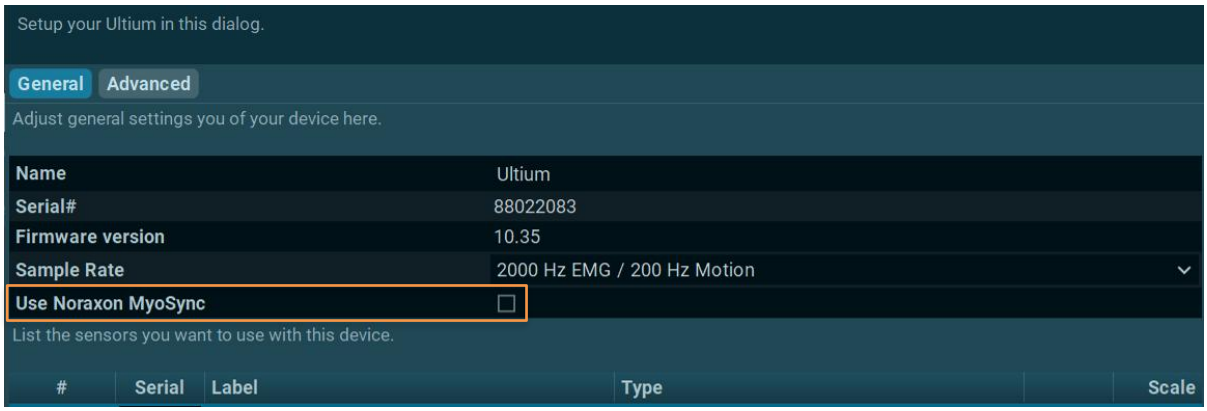
The Ultium System may be used with other devices. In order to synchronize the signal of the Ultium System with these other devices, it is necessary to set up both the software and hardware correctly. The Receiver can accept a sync pulse via the Sync In port located on the back of the Receiver unit.

Sync In

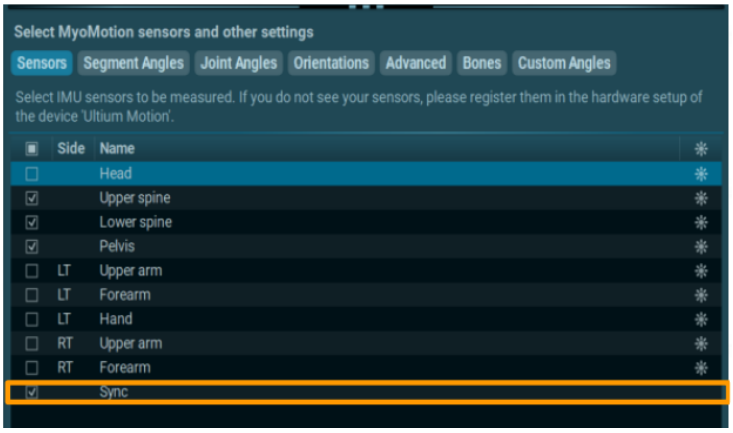
The Sync In port allows a capture of a TTL (0-5V) sync signal. The key purpose is to allow Ultium data to be synchronized with data from other devices.

MR Sync Setup

Ultium Receiver Sync is set up in the MR software, in Hardware Setup, which is found under the General tab. To enable Sync, simply check the Use Noraxon MyoSync checkbox.



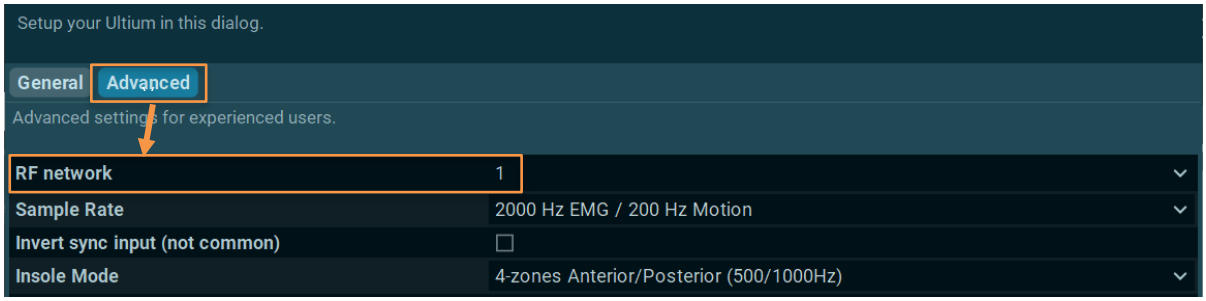
When Use Noraxon MyoSYNC is enabled in Hardware Setup, the digital channel will be labeled Sync. If MyoSYNC is not enabled, the channel will be labeled Switch and can be used as a generic digital input.



7.2 32-Channel Operation

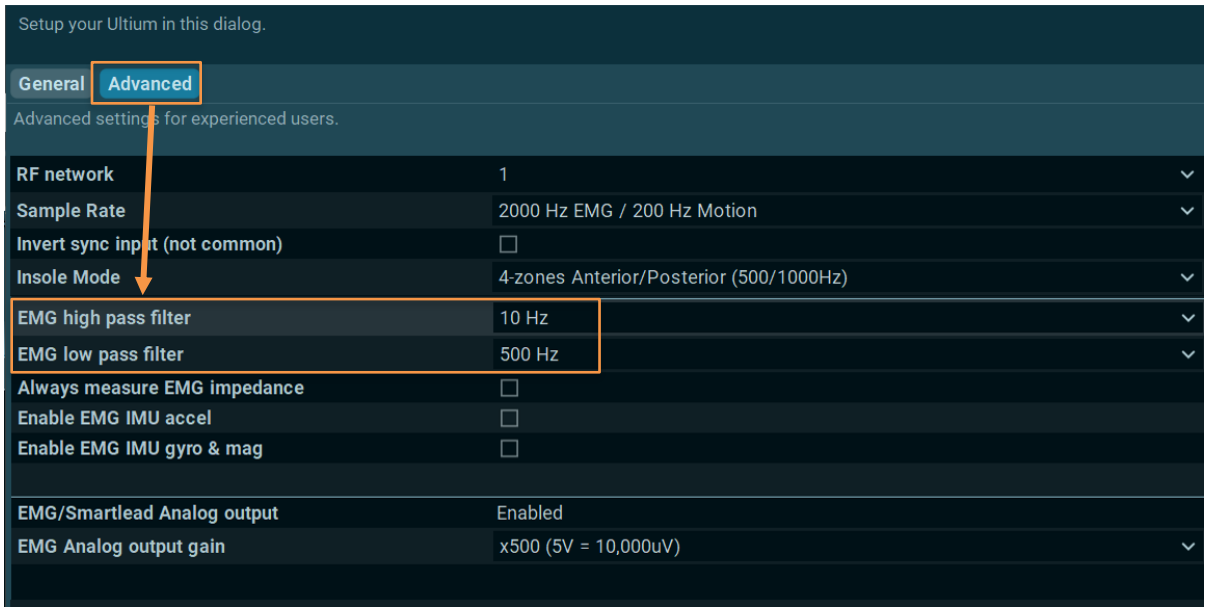
Ultium supports measuring up to 32 channels via 2 separate 16 channel systems. Insert both systems into the Hardware Setup, making sure to set each receiver to a different RF Network number. Use of the Noraxon MyoSYNC device is also recommended to synchronize the data streams of the 2 devices.

The RF Network number can be changed in the Advanced tab in the Ultium Hardware Setup.



7.3 Digital Filters

The Ultium EMG sensors have digital filters selectable from the Hardware setup for the Ultium device in the Advanced tab.



High Pass Filter

The high pass filters are implemented as IIR digital filters modelled as a 6th order Bessel filter with a cutoff of 5, 10, or 20 Hz.

Low Pass Filter

The low pass filters are modeled as 128th order FIR filters that do not follow a named filter convention. Due to the architecture of the A/D in the Ultium EMG sensor, the output has a sinc filter applied. This creates a passband within the desired passband range. To make the passband flat, we apply an inverse

sinc filter which is the mirror of the original sinc filter applied with a low pass cutoff. The net effect is that the measured EMG has a very flat passband and steep low pass cutoff due to the 128th order filter.

The low pass filter cutoffs are selectable between 500 Hz, 1000 Hz, and 2000 Hz at a 4000 Hz sample rate. Only the 500 Hz filter is available at a 2000 Hz sample rate.

No Filter Options

It is possible to remove filters from the EMG signal entirely if the "No filter" option is selected for the low pass or high pass filter. This is not recommended except for with specific applications.

Note: The application of a high pass filter is considered a basic requirement for measuring EMG and is standard across all EMG measurement systems. If the high pass filter is removed entirely, the EMG waveform will drift around the baseline. This drift is related to the behavior of the electrodes. There is a small DC voltage created by the two electrodes in contact with the body typically on the order of mV. This voltage changes over time and appears as a drift in the baseline of the EMG waveform.

7.4 Lossless Data Recovery

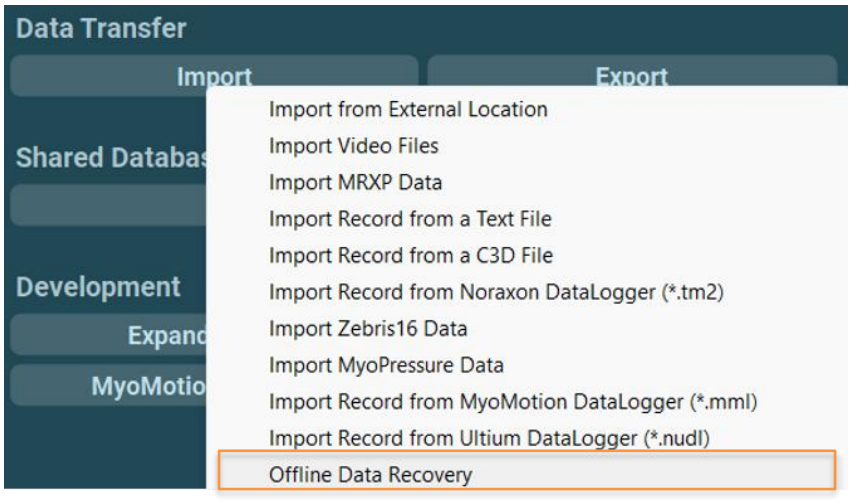
The Ultium System supports "lossless" data recovery. The sensors continue to capture and store data (>8 hours of data) when communication is temporarily lost with the receiver. Once the record is completed, the data can be recovered in real-time or at a later time using the Import function in the Database.

Real-time (Online) Recovery

Immediately following the record, MR will begin 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 recovery is terminated (i.e. you select "Cancel Recovery"), any data lost in real time can still be recovered later via offline data recovery.

Offline Data Recovery (Import Function)

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



6. Selection of 'Offline data recovery' will then provide you with a list of all records that have lost data.
7. Select each record that you would like to recover at this time.
8. Place all the sensors (#810) in the sensor charger (#873), connect the charger to the receiver (#880), and then plug the receiver into the PC as demonstrated in steps 1,3, and 5 of section 5.4 of this manual.
9. Press OK to initiate recovery.

Offline data recovery will occur approximately 20 times faster than online recovery.

7.5 Ultium Internal Inertial Measurement Unit (IMU)

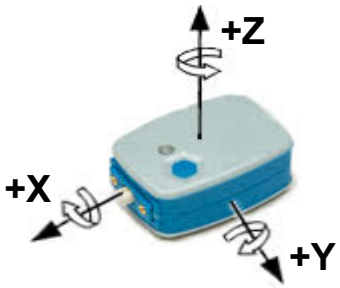
The Ultium sensor contains an IMU that allows for the measurement and transmission of angular velocity, acceleration, and magnetic field amplitude.

IMU Hardware Specifications

The table below displays range and sensitivity specifications for the IMU data.

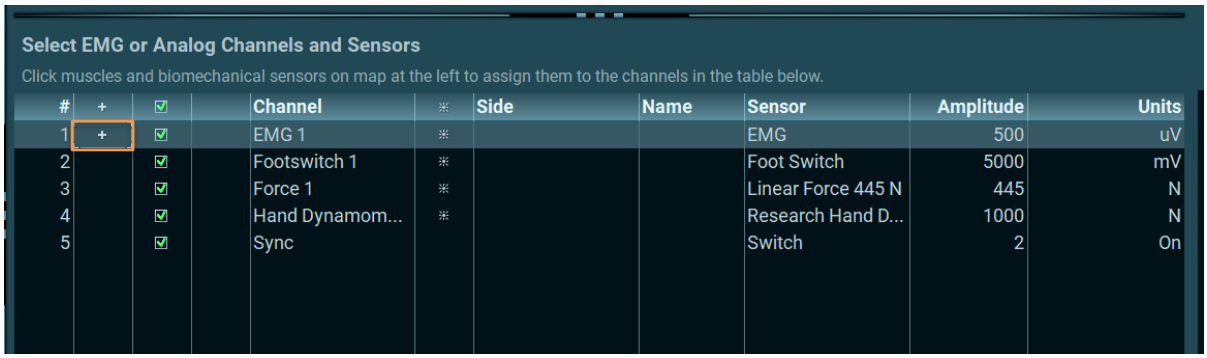
	Range	Sensitivity
Gyroscope	±2000 degrees/second	16.4 LSB/(degrees/second)
Accelerometer	±16 g	2048 LSB/g
Magnetometer	±4800 µT	0.6 µT/LSB

The IMU is placed within the Ultium sensor so that its 3-axis are oriented as displayed in the image below.

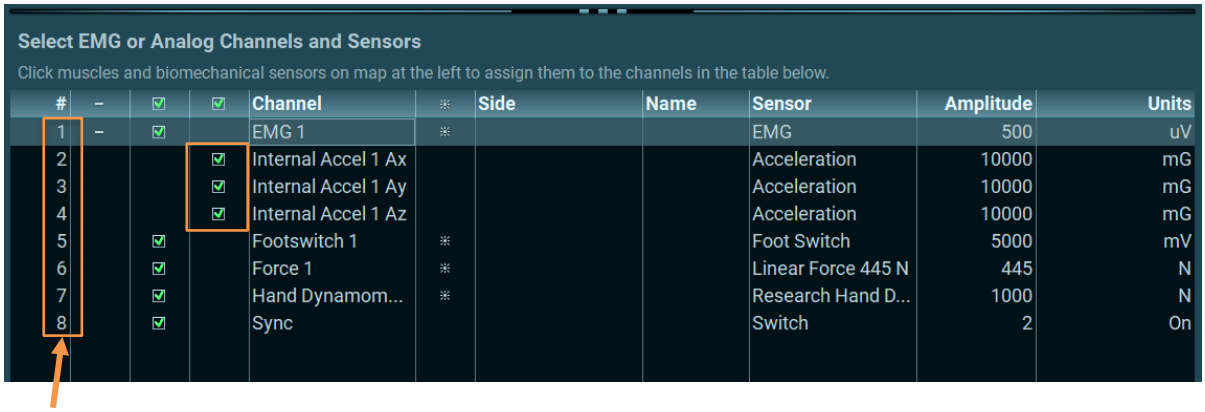


Enabling the Internal Accelerometer

To activate the accelerometer data channels for a recording select the **+** next to the name of the sensor within the Hardware setup screen found on the Home tab. This feature is available for sensors with no SmartLeads attached.



Acceleration channels will then be available under the sensor name.



Note: The order of analog outputs changes when the Internal Accelerometer is enabled. Instead of using outputs 1 and 2 for EMG 1 and EMG 2, acceleration channels use outputs 2-4 and 6-8. This can be changed, and any channel can be unused by simply unchecking the box next to it.

Sampling Rate Adjustments

Due to an increased amount of data being wirelessly transmitted when measuring IMU data alongside EMG data, sampling rates are modified dependent on the selected configuration.

	EMG Frequency Hardware Set-Up		
	EMG set at 2000 Hz (EMG selected)	EMG set at 2000 Hz (EMG not selected)	EMG set at 4000 Hz
Acceleration Only (Ax,Ay,Az)	500 Hz	500 Hz	Not Possible
Full IMU (Ax,Ay,Az, Gx,Gy,Gz ,Mx,My,Mz)	200 Hz	400 Hz	Not Possible

Example: Consider a situation in which full IMU is enabled, and EMG is set to 2000 Hz in the hardware set-up. If both the EMG and the IMU channels are selected in the measurement configuration, then the EMG will collect at 2000 Hz while the IMU channels collect at 200 Hz. However, if EMG is deselected from the configuration, the IMU channels will collect at 400 Hz.

All Analog Output Modules (#881) will be disabled if IMU channels are enabled (except for the Accelerometer channels.)

7.6 Signal Processing for Amplitude Normalization

The companion software program, MR, supports real-time and post-processing amplitude normalization of the EMG signal. To view the instructions and options for completing this process in MR, refer to the supplemental MR training material at www.noraxon.com.

8 Maintenance

8.1 Consumable Items

The consumable items listed here for use with your Ultium system are designed for one-time use. It is suggested to regularly restock your supply to have available product when needed.

Part No.	Image	Description
271S/271SCASE		Dual solid gel EMG electrodes (30 per pouch or 210 per box)
874E		Double-sided tape for Ultium EMG and Motion sensors (500 pieces per pack)

8.2 Maintenance by Users

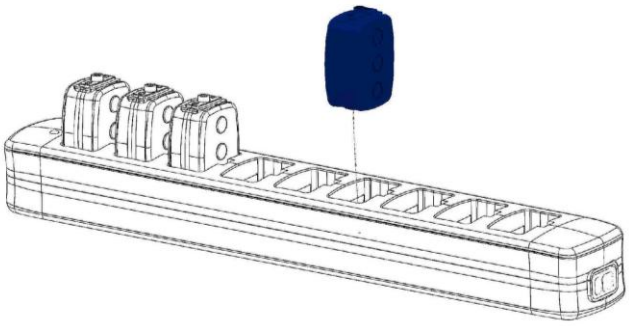
Routine maintenance recommended for the Ultium system is cleaning the bottom pads of the EMG Sensor periodically (see below for information on how to clean the bottom pads). Because the EMG sensor batteries are Li-Ion, the only battery maintenance required is recharging.

Charging the EMG Sensors

Safety precautions for charging the EMG Sensors: No Precautions required. The Ultium EMG Sensors are charged using the Ultium Sensor Charger.

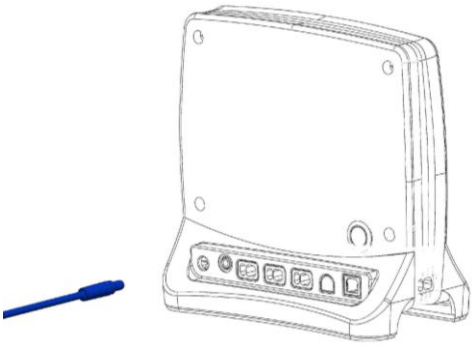
Step 1

Verify that all the sensors are correctly inserted into the Ultium Sensor Charger (#873).



Step 2

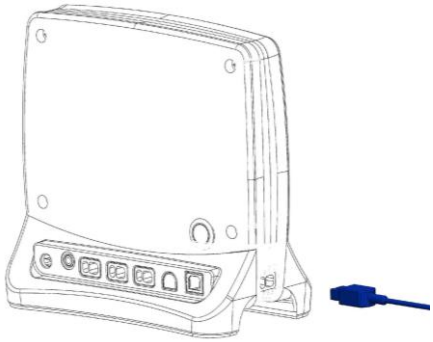
Insert power supply (PSU1) barrel connector into the jack of the Ultium Receiver. Insert the EMG Sensor Charger Power Source into a power strip (recommended) or into the wall outlet (mains).



Step 3

Connect the Receiver to the Sensor Charger (#873). This will charge the sensors.

- Verify that the "charge" indicator on all sensors glows amber (yellow).
- Charge for approximately 3 hours or until each sensor "charge" indicator turns off.



Cleaning The EMG Sensors

Safety precautions for cleaning the EMG Sensors:

For sanitary purposes, it is advisable to clean the back of the Ultium EMG sensors on a regular basis. Ultium EMG sensors can be cleaned with a cloth slightly dampened with a solution of mild soap and water. Use of even mild disinfectant solutions (i.e., isopropyl alcohol swabs or household disinfectant wipes) is not recommended as they can degrade polypropylene plastics in the sensor housing over time.

The EMG 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.

CAUTION

- Only use a damp cloth with mild soap and to clean the bottom of the EMG Sensors
- DO NOT immerse EMG Sensors in any water or liquid.

Storing the EMG Sensors

It is recommended to store the sensors inside the sensor charger. While in use, we recommend plugging this station into power to maintain charge during storage. During periods of time in which you do not plan on using the sensors, you can leave the sensor charger unplugged from power for a maximum of 3 months.

Note: The batteries will undergo expansion if left uncharged for too long. It is necessary to fully charge the sensors at least every 3 months during long-term storage without connection to power.

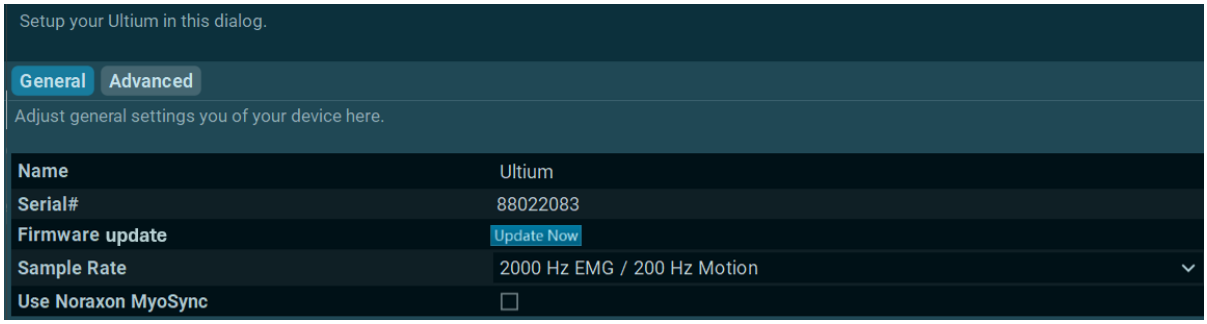
8.3 Companion Software Updates

1. Perform a backup of the data folders to a separate drive as a precaution.
2. Click on the Patch/Update link provided in the email or as given on the Noraxon website.
3. Download the Patch/Update file.
4. To install the Patch/Update, click "Run" on the dialog box. No password is required.

8.4 Device Software (firmware) updates

The internal program (firmware) inside the various Ultium devices can be updated via MR. The user will be notified if an update is required with a message that appears before measurement if a sensor firmware update is required.

Note: There are TWO updates required. The first "Update Now" button updates the Ultium receiver firmware. After the Ultium receiver firmware is updated, a second button will appear – "Update Sensors." Both updates should be performed to update the receiver firmware and the sensor firmware.



CAUTION

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

8.5 Battery Replacement

Battery Life Expectations

The Lithium Polymer battery used in the EMG 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 up to 8 hours when fully charged. If the run time of the sensors drops to 5-6 hours, battery replacement should be considered.

Battery Replacement Procedures

The EMG sensor battery packs may not be replaced by the user. Only qualified Noraxon technical personnel may perform maintenance.

Your Ultium EMG purchase comes with free battery replacement for the lifetime of the sensor*. To initiate a Battery Replacement Form, visit the Support section at Noraxon.com.

Note: The Ultium EMG sensor lifetime is up to 10 years from the date of shipment.

9 Troubleshooting, Fault Diagnosis

9.1 Troubleshooting Chart

Symptom: Problem with the PC recognizing the Ultium System

Possible Reason	Remedial Action
USB cable is disconnected or loose	Check USB cable connection at both Receiver and computer
USB Driver is not installed	Check the Device Manager for USB driver errors and update the driver if needed

Symptom: Problems with EMG Sensors communicating with the Ultium Receiver

Possible Reason	Remedial Action
Sensors were not assigned to Receiver	Assign sensors (see Section 0)
RF traffic is blocking data transmission	Change the RF channel in hardware setup
1+ sensor(s) are not turned on	Make sure sensor is charged and on

Symptom: Problems with individual EMG Sensors

Possible Reason	Remedial Action
Sensor was not assigned to Receiver	Assign sensor (see Section 0)
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 EMG Sensor signals

Possible Reason	Remedial Action
Electrode lead set is loose or disconnected	Check lead set connections at both the sensor and electrodes
Sensor reference pad is dirty or not in contact with bare skin	Clean reference pad if needed. Wipe and slightly abrade underlying skin if very dry
Sensor is too far from Receiver	Move to within 40m of Receiver
Sensor radio signal is partially blocked (absorbed) by subject's body (esp. at long distances)	Reposition sensor on subject to obtain a direct line-of-sight relationship between sensor and Receiver

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 Ultium 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 Ultium System can discern its information from all the surrounding radio traffic. Reliable transmission depends on good signal quality. Signal quality will fall with extended distances between the Ultium Receiver and the EMG Sensors. Obstructions (walls, metal structures, trees, etc.) between the Ultium Receiver and the EMG Sensors will also lower the signal quality.

The EMG sensors contain FLASH memory which backs up all measured data during a recording. The companion software can query the FLASH memory to recover data that was lost to interference.

While the Ultium 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 Ultium radio system utilizes a proprietary frequency hopping protocol for sensor communication. Three RF Network addresses may be optionally selected to allow co-location of multiple Ultium systems. All 3 networks hop on the same frequencies, but the hopping order is unique to each network, allowing them to co-exist without interfering with each other.

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 EMG 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 Ultium Receiver and its contents.

12 Technical Information

12.1 Theory of Operation

The Ultium wireless system is based on a pre-certified transceiver module. This radio module operates in the 2.4 GHz bands with an output power level of < 100 mW and is based on a proprietary frequency hopping protocol.

Model 810 Ultium EMG Sensor

Each Ultium EMG transmitter module (#810) incorporates one transceiver module together with an analog front end and supporting circuitry. The #810 EMG Sensor is powered by one 150mAh battery; each is identified by a unique serial number.

The #810 EMG Sensor has 5 patient contact points (applied parts). Two points are standard snap receptacles for attachment to disposable EKG style electrodes. The snap wires are removable. An additional 3 patient contact points are metal disks on the bottom of the #810 EMG Sensor enclosure. The disks are intended to be in contact with bare skin. Double-sided tape secures the sensor to the patient.

The opposite end of the #810 EMG Sensor has 4 contact pads for recharging its battery and communication. To recharge the battery, the #810 EMG Sensor is placed inside a charging station. The device cannot be applied to the patient/subject and charged at the same time.

Model 873 Ultium Sensor Charger

The Ultium Sensor Charger (#873) is configured to hold up to nine #810 EMG Sensors, #870 Motion Sensors, or any combination therein. All battery-charging controls are inside the sensor modules. The sensor charger merely supplies a 5VDC source of power through a set of spring-loaded pins. The spring-loaded pins contact the charging pads of the #810 EMG Sensor. The 5VDC supply is a medical grade external power supply by Globtek (model GTM41060)

Model 880 Ultium Receiver

The Ultium Receiver (#880) consists of a main motherboard and a radio transceiver module. The Ultium Receiver has no applied parts.

The Ultium Receiver interfaces to a PC and is powered via a USB port.

The transceiver in the #880 Ultium Receiver can communicate with up to sixteen (16) #810 EMG Sensors.

12.2 Electro-Magnetic Compatibility Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The Ultium System is intended for use in electromagnetic environment specified below. The customer or the user of the Ultium System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The Ultium 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 Ultium 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.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Ultium System is intended for use in electromagnetic environment specified below. The customer or the user of the Ultium 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	±8 kV contact ± 15 kV air	±8 kV contact ±15 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 cycles 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 secs	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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Ultium System is intended for use in electromagnetic environment specified below. The customer or the user of the Ultium System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 (Charging System)	3 Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Ultium System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d = 1.2\sqrt{P}$ 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 meters (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: 
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.			
[a] Field strengths from fixed transmitters, such as a base station 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 Ultium System is used exceeds the applicable RF compliance level above, the Ultium System should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the Ultium System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Ultium System			
The Ultium System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ultium System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ultium 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

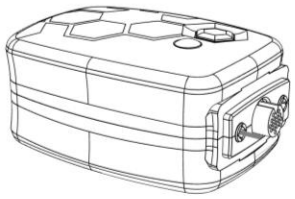
13.1 Appendix A – Product Specifications

Expected Useful Lifetime

Both the Ultium Receiver (#880) and EMG Sensors (#810) have a usable life of seven years.

The EMG sensors operate with a rechargeable Lithium-Ion battery. The battery capacity will decline with ongoing use and require replacement after 300+ discharge/charge cycles to preserve the device's rated 8 hours of operating time.

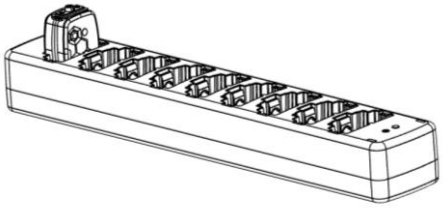
Dimensions and Mass



Ultium EMG Sensor

Dimensions
37 mm L x 24.5 mm W x 16.5 mm H

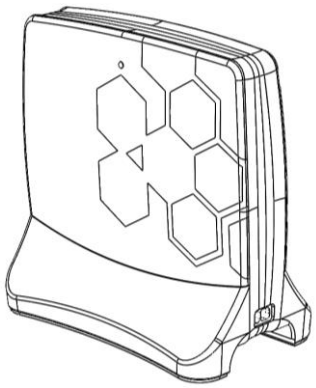
Mass
14 g



Ultium Sensor Charger

Dimensions
258 mm L x 44.5 mm W x 32 mm H

Mass
152 g



Ultium Receiver

Dimensions
174 mm L x 92 mm W x 169 mm H

Mass
590 g

Performance Characteristics

Output & Transmission Frequency (Depending on country)

- Up to 100 mW (depending on country allowance)
- GFSK 2402-2480 MHz, frequency hopping
- Utilizing up to 79 hopping channels
- Channel-to-channel hopping frequency 50Hz (20 msec)
- EMG sensor transmission range: 40m (typical)

EMG Sensor Data Acquisition System

- 16-bit resolution
- Selectable Sample Rate: 2000Hz or 4000Hz

EMG Specifications

- No notch (50/60 Hz) filters are used
- Selectable high-pass cutoff: 5Hz, 10Hz or 20Hz
- Selectable low-pass cutoff: 500Hz, 1000Hz or 1500Hz
- Internal 24-bit sampling
- Baseline noise < 1 uV RMS
- Input impedance > 100 MOhm
- CMR > 100 dB
- Input range: +/- 24,000 uV
- Adaptive Resolution:
  - < +/- 5,000uV: 0.3uV
  - > +/- 5,000uV: 1.16uV
- Measurement Functional Accuracy: +/-1% F.S.
- Analog Output scale factor: 24,000uV / 5V or 4,800uV / 1 V
- Sensor operation up to 8 hours on a fully charged battery (recharge time 3 hours)
- Pinch-style terminal electrode connections

Energy Consumption, Condition of Use

5. EMG Sensor Charger is powered by 5VDC at 3.0A using a 100-240 VAC 50-60 Hz external supply

Environmental Conditions for Normal Operation

6. Ambient Temperature: 0C to 38C
7. Relative Humidity: <95%RH
8. Atmospheric Pressure: 70kPa to 107 kPa

Environmental Conditions for Storage and Transport

9. Ambient Temperature: -40C to +70C
10. Relative Humidity: 95%RH
11. Atmospheric Pressure: 70kPa to 107kPa

13.2 Appendix B – Use of Disposable Electrodes

While the Ultium EMG sensors can operate with reusable electrodes, it is typically used with disposable surface electrodes. Any good quality silver/silver chloride electrode is acceptable. Noraxon provides several types of quality disposable electrodes for a wide variety of Surface EMG applications. Other electrodes may be used, but it is recommended that any electrodes used with the Ultium EMG sensors satisfy the requirements for standard ANSI/AAMI EC12-1991 Disposable ECG electrodes.

CAUTION

1. Because disposable electrodes have a shelf life, it is important not to use expired parts.
2. Bulk disposable electrodes come packaged in a sealed container or bag.
3. The expiration date can be found printed on the package container.
4. After the sealed bulk container is opened, the remaining electrodes should be used before their gel begins to dry out.
5. Always keep the remaining electrodes in their bulk package until they are used.
6. If the electrode package does not seal itself, closing the package with tape or using a zippered plastic bag is recommended.
7. Do not store the electrode package in the direct sun, as this will accelerate drying.
8. Avoid using electrodes that are randomly found lying outside of their bulk packaging as their expiration date is uncertain and their gel has been exposed to accelerated drying.

Be aware that when disposable electrodes are removed, some individuals may notice a faint red skin discoloration over the site previously occupied by the electrode. This skin discoloration is typically benign and temporary and may be due to a mild allergic reaction to the adhesive or simply be a slight abrasion caused by peeling away the tape. It will usually disappear within 24 hours.

Noraxon discourages any attempt to reuse a disposable electrode, even if it is simply pulled off to slightly reposition the electrode's muscle placement. Some of the electrode gel may remain on the original site and the EMG signal may be affected. Also, sometimes the electrode adhesive may not adhere to the skin as well when it is reapplied. Noraxon strongly recommends against the use of dried out electrodes that are re-wetted with electrode gel.

Electrode Application Guidelines and Facts

- If the subject has a fair amount of hair at the electrode application site, the hair should be clipped. Shaving is not necessary and may irritate the skin.
- The electrode application site should be clean and dry. The preferred method of cleaning is with soap and water plus drying the skin with a dry cloth. Dry skin contributes to good electrode adhesion and good trace quality.
- Cleaning with isopropyl alcohol should be limited to situations where electrode adhesion is an issue (diaphoresis, excessively oily or lotion covered skin), since it may dehydrate the skin thereby causing skin impedance to increase. If alcohol is used, allow it to dry prior to electrode application.
- Noraxon recommends attaching the lead wire to the electrode prior to placing the electrode on the skin. This will eliminate the potential for discomfort if snap lead wires are pressed onto the electrode after the electrode has been applied. It will also prevent the electrode gel from seeping out. Additionally, this method will prevent unattached leads from coming into accidental contact with other conductive objects.

- Electrode application sites may need to be abraded to lower the skin impedance. Fine sandpaper or electrode prep gel, e.g., NuPrep, can be used to abrade the skin.
- Electrodes are the weak link in the EMG measurement chain. Lack of proper attention to electrode quality or site preparation is by far the most common cause of inferior recordings.
- It may take up to 5 minutes for disposable electrodes to fully stabilize electrically once applied to the skin. If extremely critical or precise measurements are intended, the electrodes should be applied several minutes in advance of the recording.

13.3 Appendix C – Radiation Exposure Information Regarding Use of EMG Sensors

Each EMG sensor contains a radio frequency transmitter. The radiated power emitted from each individual EMG sensor is very low. To put this in perspective, at full power each EMG sensor transmits at less than 0.8% of the power of a typical active cell phone. Radiation exposure from a single EMG sensor is thus extremely low.

The EMG sensors are designed to operate at two different power levels to keep the already very low levels of radiation exposure to an absolute minimum. The EMG sensors activate their higher power level only during periods of actual data collection. During idle times (at setup and in between actual measurements) the EMG 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 EMG sensors operate at power levels 125 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 EMG sensors applied in intimate contact with the body, their total collective radiation effect may be questioned. Based on comparative power levels, a full complement of 16 EMG sensors emits a combined (distributed) radiation level still an order of magnitude lower than that of a typical cell phone, which radiates all its energy from one focal point (next to the person's head).

At present, Noraxon identifies no restrictions on use and placement of the EMG sensors on any portion of the human body. The EMG 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 EMG 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 EMG system should be stopped if the person being monitored reports any unusual sensations.

13.4 Appendix D – Radio Regulatory Statements

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: IWC-800.

Industry Canada Statement

This product contains a radio module with Canadian Cert No IC: 9113A-800

13.5 Appendix E – Ultium SmartLead Specifications

Model 802 Footswitch

Input Channels: 4 (4-zone FSR)
Sample Rate: 2000/4000Hz
FSR Response Time: ~2ms
Output Signal Range: 0 to +5V

Digital/Analog output voltages:
Heel: 0.266V
M5: 0.533V
M1; 1.066V
Toe: 2.133V

Model 808 2D Goniometer

Measurement Axes: 2 (X/Y)
Sample Rate: 500/1000Hz
Nominal Input Range: +/- 150 degrees
Resolution: 0.006 degrees
Analog Output scale factor: 25mV/degree
Accuracy: +/- 2 degrees
X-Y crosstalk: ≤ +/- 5% for deflections under 60 deg

Model 811 Analog Input

Input Channels: 3
Sample Rate: 500/1000Hz
Input Range: +/-5V or +/-20V (correct input range is marked on blue connector)
Resolution: 0.61mV
Accuracy: +/- 2% full scale
Noise: < 2mV RMS
Analog Output scale factor: 250 mV/V

Model 817 Accelerometer

Input Channels: 3 (X/Y/Z)
Sample Rate: 500/1000Hz
Input Range: +/-400g
Resolution: 0.000976g (-16g to +16g)
0.0234g (-400g to -16g, +16g to +400g)
Typical Noise: 0.029g RMS
Bandwidth: 0-250Hz (sample rate = 500Hz)
0-500Hz (sample rate = 1000Hz)
Analog Output scale factor: 12.5 mV/g

Model 820 500-lbf Force Sensor

Input Channels: 1
Sample Rate: 2000/4000Hz
Input Range: +/- 500 lbf (+/- 2224 N)
Resolution: 0.016 lbf
Analog Output scale factor: 9.524 mV/lbf

Model 821100-lbf Force Sensor

Input Channels: 1
Sample Rate: 2000/4000Hz
Input Range: +/- 100 lbf (+/- 445 N)
Resolution: 0.016 lbf
Analog Output scale factor: 9.524 mV/lbf

Model 824 Local Pressure Sensor

Input Channels: 1
Sample Rate: 2000/4000Hz
3 Flexiforce sensor options
Input Range: 0-1 lbf (0-4.5 N), 0-25 lbf (0-111 N), 0-100 lbf (0-445 N)
Resolution: 0.00009 lbf (0-1 lbf), 0.009 lbf (0-25 lbf), 0.00425 lbf (0-100 lbf)
Analog Output scale factor: 5V = F.S.
Linearity (Error): <± 5%
Repeatability: <± 2.5% of full scale with “conditioned” sensors
Hysteresis: < 4.5% of full scale

Model 826 Insole

Input channels: 4 or 8 (4- or 8-zone resistive pressure)
Sample Rate: 250/500/1000 Hz
Dependent upon the number of zones selected and sensor sample rate
Sensor response time: ~2-3ms
Max Pressure: 7 bar (101.5 psi)

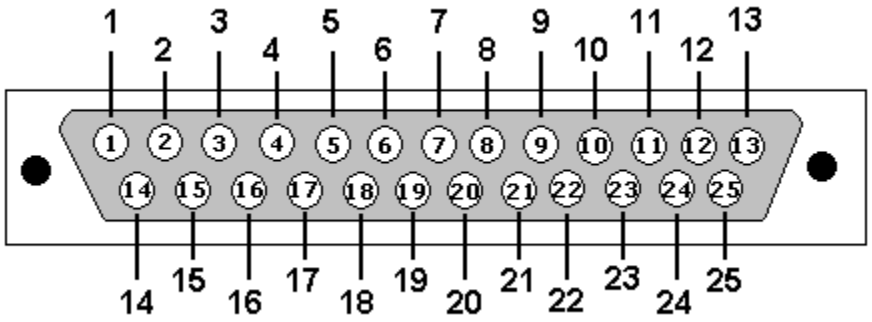
Model 852 Biomonitor (ECG and Respiration)

Input channels: 2 (ECG and respiration waveforms)
Sample Rate: 500/1000Hz
Input Range: +/- 24,000 uV
Analog Output scale factor: 0.208mV/uV

13.6 Appendix F – Ultium Analog Output Module (Model 881)

The Ultium Analog Output Box can be used to transmit data collected from the Ultium System to a 3rd party software/program in real-time. This device can be used to connect the Ultium receiver (via one of three auxiliary ports on the back of the receiver) to a 3rd party Data Acquisition Unit (DAQ) via a 25 Pin Male to Female Cable (#291D).

You can transmit up to 16 channels with one Ultium system (and up to 32 channels with 2 Ultium systems). Refer to the bottom of the Ultium Analog Output Box for pin assignment. The numbers given to the channels in the configuration (see MR configuration under Section 6) correspond to the order in which data is sent through the Analog Output Box. The pin numbers of the DB-25 connector are shown below.



Pins 17-20 are common or ground. Pins 21-25 are not connected to anything. Also, a picture of the pinout is printed on the Ultium Analog Output device itself.

The Analog Outputs have a fixed latency of 300 +/- 1 ms. It is possible to send EMG and accelerometer data through the analog outputs, but gyroscope or magnetometer data are not compatible with this function. If you enable IMU mode, you will disable the ability to output analog data.

13.7 Appendix G – Ultium LED Status Guide

Both the Ultium sensor and receiver have an LED located on the front face which displays the status of the sensor. Please reference the following list for information on what each LED status means.

Sensor

Color	Status Description
Continuous flashing dark blue	Sensor is on but not measuring data
Continuous flashing green	Sensor is on and actively measuring data in MR
Continuous flashing light blue	Sensor is on and actively measuring data via Bluetooth OR attempting to recover lost packets during *Online Data Recovery*
Single red flash	Flashes when the Sensor is turned off
Single green flash	Flashes when the Sensor is turned on
Flashes violet 3 times	Smart lead recognized by the Sensor
Flashes orange 3 times	Smart lead removed from the Sensor
Solid orange	Receiver did not recognize the Smart Lead (a software/firmware update may be required)
Solid amber	Indicates charging. If the Amber LED turns off while the sensor is still plugged into the charging station, this means that the sensor is fully charged.
Flash white 8 times	Sensor is found by "Find My Sensor" feature in the measurement configuration and can collect data
Flash red 8 times	Sensor is found by "Find My Sensor" feature in measurement configuration but cannot collect data of the chosen data type. If the "Find My Sensor" star is pressed for an EMG with a Smart Lead inserted but was not configured to collect data from a Smart Lead Ex: EMG serial number was either entered manually in Hardware Setup or Smart Lead was placed on a different EMG sensor after Hardware Setup.
Flash green then immediately to red and powers off	When turning on, this means that the sensor charge level is too low.
Continuously flashing green and red	Sensor firmware cannot be found. Please contact Noraxon Support (support@noraxon.com)

Receiver

Color	Status Description
Continuous flashing dark blue	Receiver is powered/on
Continuous flashing violet	Receiver is powered/on in Portable Lab mode
Flashing light blue	A firmware update may not have completed. Remove the USB cable and plug it in again. Wait 60 seconds for the light to change to dark blue. If the light does not change to flashing dark blue after 3 repeated tries, please contact Noraxon Support (support@noraxon.com).
Solid or flashing red	Another Ultium Receiver may be using the same RF Network