

9.0 Components Description

The main components of the SENTIO MMG® System consist of the SENTIO MMG® Control Unit with pre-installed SENTIO MMG® Software and the SENTIO MMG® Sensor Harness.

The SENTIO MMG® Control Unit provides digital data processing and audio and visual notifications of mechanomyographic (MMG) activity. The SENTIO MMG® Control Unit provides high speed digital data acquisition and electrical current stimulation generation.

10.0 SENTIO MMG® System Quick Setup

10.1 Plugging in Control Unit

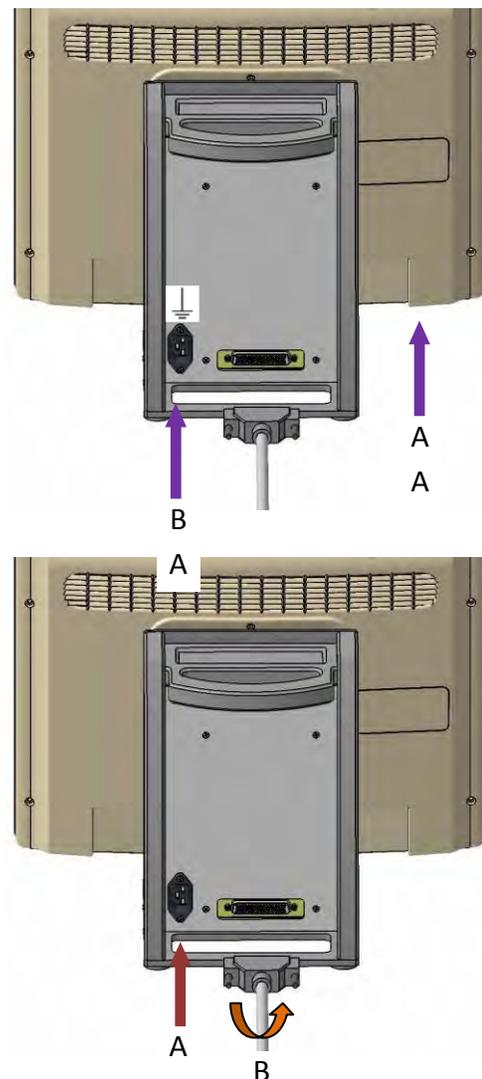
Plug the SENTIO MMG® Control Unit to the AC power supply as shown in (A). Using the provided “Y” power cable, one side of the “Y” is connected to the Power Supply; the other is used as a grounding cable (B) to the Earth Ground connection on the Control Unit:

Functional Earth 

Plug the AC power supply into a hospital grade outlet. Use only the provided Medical Grade AC Power Supply.

10.2 Attaching Sensor Harness

Connect the free end of the SENTIO MMG® Sensor Harness to the SENTIO MMG® Control Unit. The sensor harness is attached to the back of the control unit (A). Be sure to lock in the cable by securing the screws on both sides of the cable plug (B).

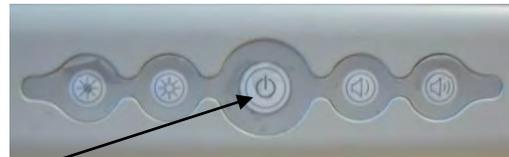


The SENTIO MMG® Harness Cable comes pre-attached to the SENTIO MMG® Harness Box. There is no need to disconnect the Cable from the Box. Together this unit is referred to as the SENTIO MMG® Sensor Harness.



10.3 Powering on Control Unit

Power the SENTIO MMG® Control Unit ON by switching the toggle button of the power supply to the on position and pressing the center button on the bottom front of the control unit as indicated below. The blue light will illuminate to indicate the system has turned on.



Press and HOLD 2 seconds for ON



10.4 Launching the Software

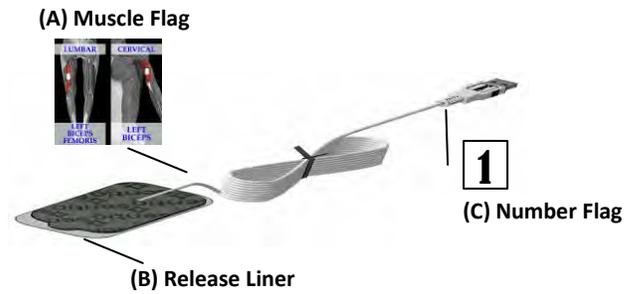
The SENTIO MMG® software application will launch automatically and bring you directly to the Start Menu. Press the green START button on the lower right hand corner to begin the set-up process.

Complete Software set-up instructions are located in Section 11.0



10.5 Connecting Sensors

The SENTIO MMG® Sensors are non-sterile single use (disposable) sensors. The Release Liner (B) covering the sensor must be removed prior to sensor placement. The sensor will not function properly unless the sensor is applied directly to the patient's skin.



Each sensor has a Muscle Flag (A) and a Number Flag (C). The Muscle Flag is labeled with both a lumbar muscle and cervical muscle placement choice. Place the sensor over the indicated muscle appropriate to the type of procedure.

The Sensor USB connector is plugged into the Sensor Harness box. Each USB connector has a Number Flag that corresponds to the number on the harness box, 1 is plugged into 1, 2 into 2, and so on until all sensors are plugged in. There may be empty harness connections depending on the type of procedure.



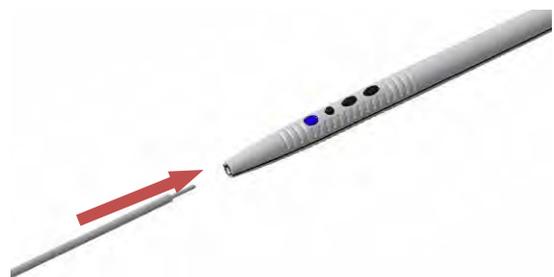
Sensor Number Flags can be referenced in Section 16.0.

10.6 SENTIO MMG® Navigational Stimulation Disposable Probe

10.6.1 Setting up the SENTIO MMG® Navigational Stimulation Disposable Probe

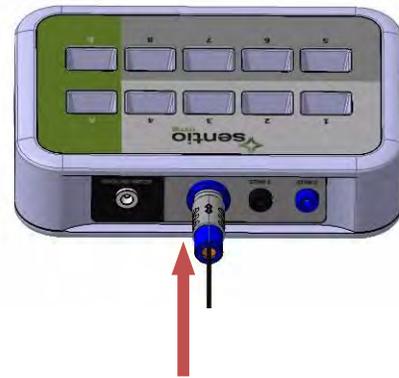
The SENTIO MMG® Navigational Stimulation disposable probe is a sterile item. Check all packaging for evidence of contamination or damage as well as the expiration date before opening the probe for transfer to the sterile field.

Note: If the packaging is damaged or there is concern of a breach of sterility, DO NOT USE - discard and replace.



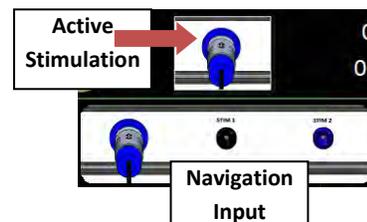
The SENTIO MMG® Single Use (Disposable) Probe Tip plugs into the Stimulator Probe Handle as shown to the right.

The blue end of the SENTIO MMG® Navigational Stimulation Disposable Probe will be handed off the sterile field and plugged into the indicated port on the sensor harness box. Be sure to leave enough length on the sterile field so that the surgeon can comfortably direct the probe during use.



10.6.2 Navigating with the SENTIO MMG® Navigational Stimulation Disposable Probe

The SENTIO MMG® Navigation Probe Handle features user controllable buttons. Navigation allows the user to turn stimulation on and off, as well as adjust the current up and down.

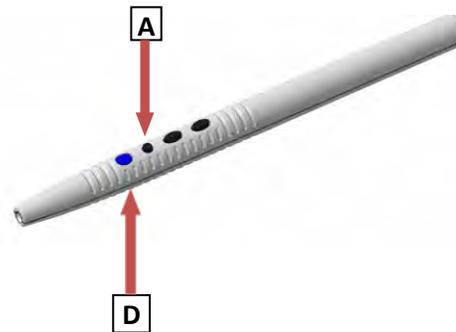


10.6.2.1 Navigation Function

These settings allow the user to turn the current ON and OFF as well as adjust current up and down.

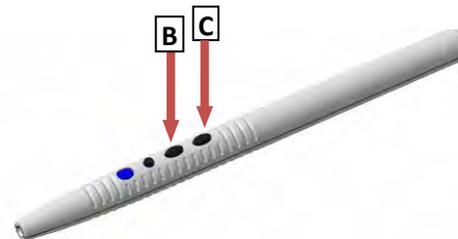
10.6.2.1a Power Button (A) & LED (D):

The user may turn the current “ON” or “OFF” by pressing the power (A) button. The LED (D) will illuminate blue when stimulation is turned ON and turns red when there is a Muscle Activity. For more information regarding the Muscle Activity alert please reference Section 12.0.



10.6.2.1b Changing Current (B) (C):

The current level can be easily adjusted by depressing the (B) or (C) button. Each click changes the current level by 1 mA.



10.7 SENTIO MMG® Stimulation Accessory

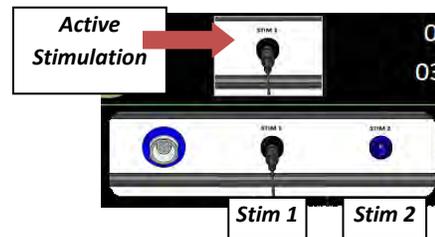
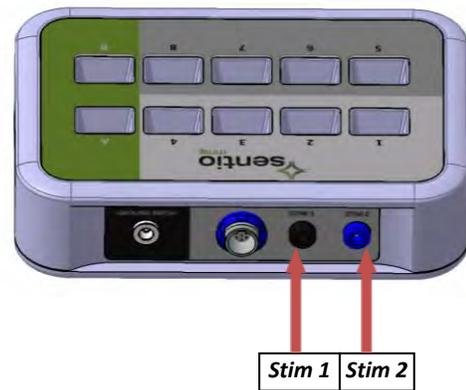
When using a SENTIO MMG® Stimulation Accessory the system can be navigated by touch screen.

NOTE: Only compatible Sentio MMG® stimulation accessories are recommended for use with the Sentio System.

10.7.1 Setting up the SENTIO MMG® Stimulation Accessories

The small end of the SENTIO MMG® Stimulation Disposable Probe will be handed off the field and plugged into the **Stim 1** or **Stim 2** port on the sensor harness box. Be sure to leave enough length on the sterile field so that the surgeon can comfortably direct the probe while in use.

The user must now make sure the **Active Stimulation** icon is set for the correct stimulating device. Touch the Active Stimulation icon on the upper right hand side of the screen. Select **Stim 1** or **Stim 2** to change the input to the desired stimulation accessory port. See Section 10.7.2.4 for details on changing input settings.



10.7.2 SENTIO MMG® Touch Screen Navigation

Touch screen navigation can be used at any time during the surgery by simply touching the screen over the desired control.



10.7.2.1 Turning Stimulation ON (A):

The user may turn the stimulation “ON” or “OFF” by tapping the center of the screen. When stimulation is off there will be a gray triangle. When the stimulation is on the triangle will turn yellow, green or red depending on the state of the stimulation as described in Section 12.6.

10.7.2.2 Changing Current (B):

The current level can be easily adjusted by touching the number bar on the bottom of the Procedure Monitor to the required current setting.

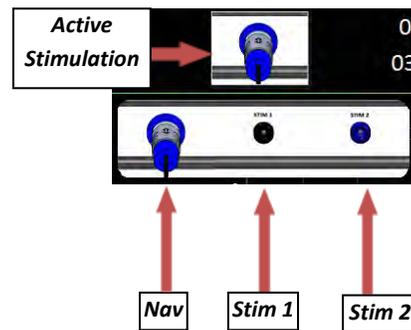
10.7.2.3 Menu Selection (C):

The Menu options can be reached by touching the green MENU button at the top left of the Procedure Monitor screen. Each MENU item is described in Section 13.0.

10.7.2.4 Changing Stimulation Input Setting (D):

The icon on the upper right hand of the screen indicates the channel on the harness that is currently active. The default stimulation is the “NAV” option. The NAV references the SENTIO MMG® Navigational Stimulation Disposable probe as referenced in 10.6.2. To change this setting touch the icon and select the appropriate channel: NAV, STIM 1, or STIM 2. The active channel will now appear in the icon window. Each time a surgeon wishes to use multiple stimulation devices, this icon must be used via touch screen to choose the correct stimulation device.

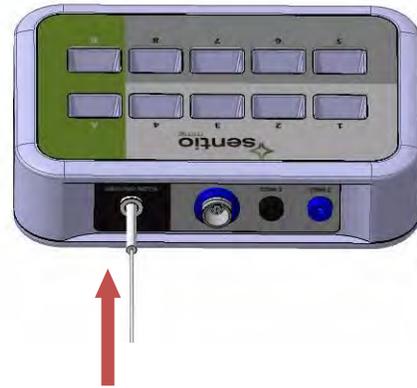
The stimulation settings directly relate to the harness box stimulation input names. The Ground is not a stimulation input and is described in Section 10.8.



10.8 SENTIO MMG® Ground Patch

The SENTIO MMG® Ground patch connects to the Ground port of the sensor harness. Place the small end of the ground patch into the **Ground Patch** port on the harness box. Additional Instructions of where the ground patch should be placed on the patient is indicated on the SENTIO MMG® software onscreen instructions as noted in Section 11.7.

NOTE: The Ground Patch must be plugged in prior to use of the SENTIO MMG® Navigation Probe and any SENTIO MMG® Stimulating Accessory. Current will not flow if the ground is not plugged in correctly.



 **WARNING**

Substituting for this power supply may compromise patient safety.

 **WARNING**

Use only approved hospital grade plugs and outlets for this system.

 **WARNING**

Do not exceed the power rating of the SENTIO MMG® System.

 **WARNING**

Do not use this system with Multiple Portable Socket-Outlets.

 **WARNING**

AC outlets should be periodically checked for improper grounding by qualified personnel.

 **WARNING**

To insure patient safety, do not connect this instrument to external line-operated equipment without insuring compatibility with IEC60601-1 specifications.

 **WARNING**

Do not touch non-medical equipment and patient simultaneously.

 **WARNING**

This instrument and accessory components are designed and manufactured with integral patient safety mechanisms. Under no circumstances should the operator modify or attach non approved peripheral equipment, electrode switching boxes, etc., to the instrument.

 **WARNING**

Check the polarity and function before inserting peripheral connectors. The Patient Interface Cable will mate easily with the SENTIO MMG® Control Unit and the SENTIO MMG® Patient Module if proper alignment is attained. Damage will occur if excessive insertion force is used.

 **CAUTION**

Do not modify, change, alter or delete the software in this equipment. Third party software may interfere with proper operation of this medical device. Do not install any off-the-shelf software without first consulting the factory. Installing unapproved software will void the warranty.