

# SafeOp™

NEURAL INFORMATIX SYSTEM



## MONITORING GUIDE

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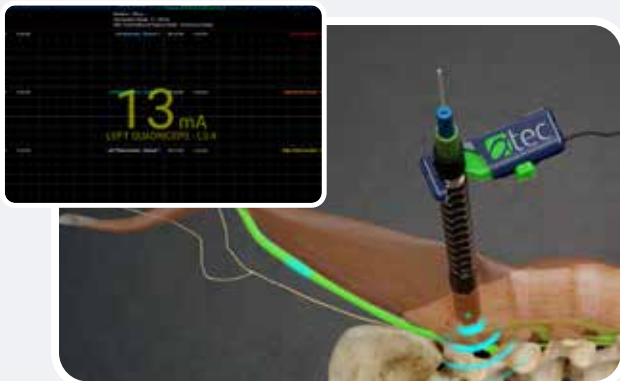


## SAFEOP NEURAL INFORMATIX SYSTEM

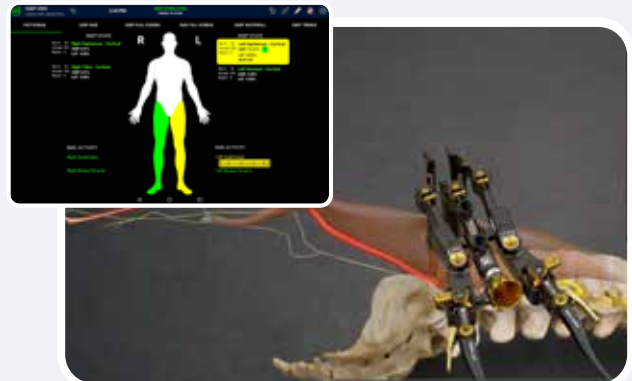
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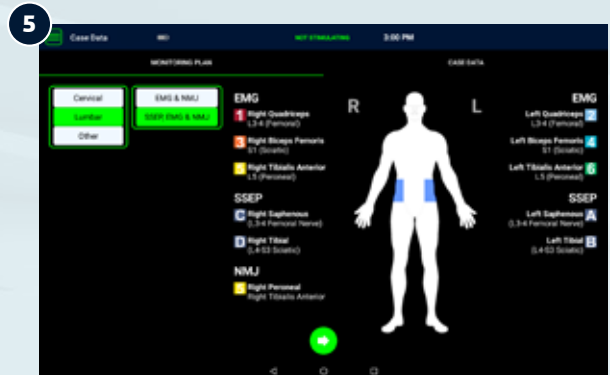
### NERVE IDENTIFICATION WITH AUTOMATED TRIGGERED EMG



### CONTINUOUS NERVE HEALTH INFORMATION WITH ADVANCED SSEP MONITORING

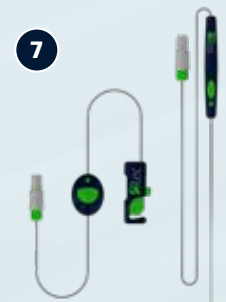
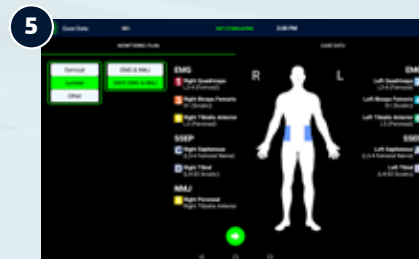
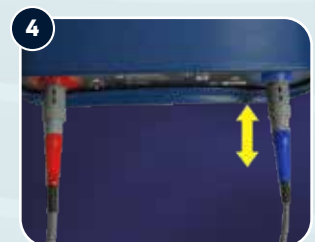
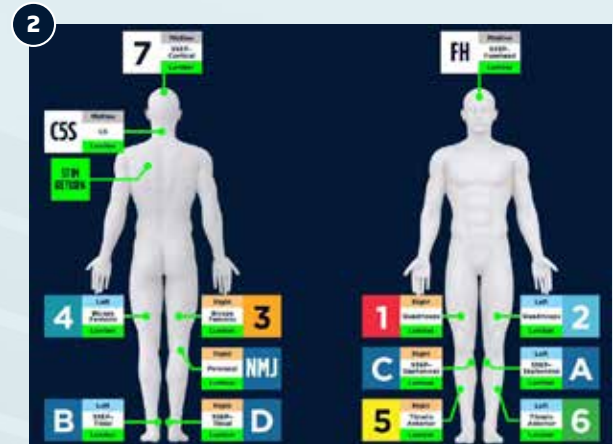


- 1 Before the patient has entered the operating room (OR), bring in the equipment from the **SafeOp Capital Equipment Set** and desired **Electrode Procedure Kit** to begin system setup.
- 2 Position the **Head Unit** on the bed rail where it will not be obtrusive to the procedure. If the bed rail is not available, use the provided **Pole Clamp** to attach the **Head Unit** to an IV pole near the head of the bed. Connect the **Head Unit Power Supply** to the **Head Unit** and to a grounded power outlet. Press the power switch on the **Head Unit** to “On” and the **Power On** light will turn green.
- 3 Identify a location to place the **Tablet Docking Station** in the OR. Connect the **Tablet Power Supply** to the **Tablet Docking Station** and to an available power outlet.
- 4 Power on the **AIX Tablet** by holding the **Power Button** for 5 seconds. Once powered on, select the **SafeOp** icon near the bottom of the display.
- 5 When the **SafeOp** application opens, the **AIX Tablet** will automatically connect to the **Head Unit** via point-to-point wireless connection.



# ELECTRODE PLACEMENT

- 1 Open the **Electrode Procedure Kit** and retrieve the cables and electrodes. Prepare the cables by connecting electrodes into the end of each lead to be used.
- 2 Once the patient is intubated, electrodes should be placed onto the patient by a licensed patient caregiver at the locations provided in the **Quickstart Guide** included in every **Electrode Procedure Kit**. The desired placement of each lead is further detailed on labels near the terminal end of each cable lead.
- 3 Once an electrode has been placed on the patient, secure its placement with the provided surgical tape. After electrode placement, it is helpful to wind the spare cables and place over and around the patient's hands/feet to assist with cable management during the patient positioning process.
- 4 Once the patient is positioned, route the cables to the **Head Unit's** location and plug the cables into the **Head Unit**. Do not force the cables into the connectors; they should seat easily when correctly oriented. Place the **Stim Return** electrode at this time per the **Quickstart Guide**.
- 5 Select the appropriate **Monitoring Plan** on the **SafeOp** application, determined by the type of procedure and monitoring modalities requested. Press the green button at the center bottom of the screen to bring up the **Electrode Test** screen.
- 6 On the **Electrode Test** screen, the indicators should change from gray to green or red. Red indicates an improperly placed electrode with high impedance that should be replaced. Once all electrodes show as green, select the green arrow in the bottom center of the screen. If at any point in the procedure an electrode is suspected of coming loose, the electrode test can be re-run by selecting **Electrode Test** from the **Menu** icon located in the top left corner of the application.
- 7 If the case requires the use of **EMG Thresholding**, provide the staff with the **SafeOp Clip** and/or **Probe** and connect them to the **Head Unit**.



**1** If using the **SSEP** modality, the first screen after the electrode check screen will be the **Pictogram** tab within the **SSEP-EMG** section. Begin **SSEP** stimulation to collect baseline readings as soon as the patient is positioned and the surgeon allows, by selecting the **Press to Start** stimulation button on the top center of the screen.

**2** Once an **SSEP** baseline has been established, the limbs being monitored will turn from gray to green. Cursors and baselines may also be manually set on the **SSEP-EMG** screen using buttons presented when tapping the waveform for the desired **SSEP** site. **Free Run EMG** notifications are shown on the **Pictogram** screen beneath the **EMG Activity** headings on the lower half of the screen. **SSEP** information is shown to the left and right of the pictogram.

- > SSEP amplitude and latency metrics are shown as percentage change relative to baseline by default. Tap on these numbers to toggle to/from absolute values.
- > If a positive or negative trend in SSEP amplitude is observed, a trend indicator will appear, indicating the direction of the trend.

**3** > If an SSEP response has degraded and an alerting state is entered, the associated limb and SSEP data will turn **yellow**. These will turn back to **green** when the alerting state has been exited.

**4** If at any point during the case new baselines need to be established, select the **Reset Baselines** button in the upper right corner.

To see **Free Run EMG** and **SSEP** data in different views, select the appropriate tabs across the top of the page.

### SSEP-EMG:

- > Shows only SSEP and Free Run EMG waveforms

### SSEP Waterfall:

- > Shows waterfall charts of SSEP waveforms

### SSEP Full Screen:

- > Shows SSEP waveforms

### SSEP Trends:

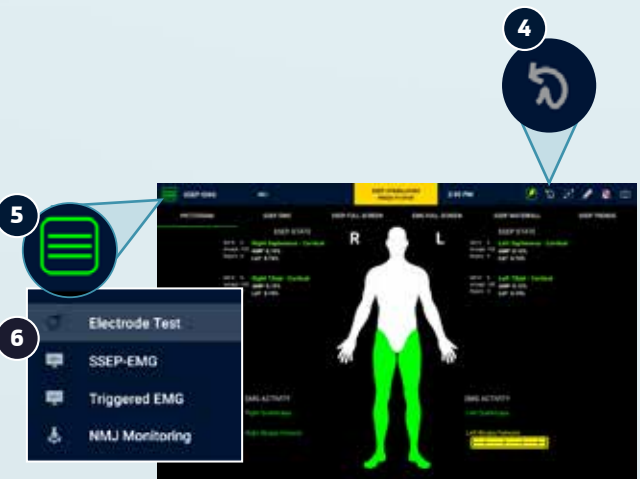
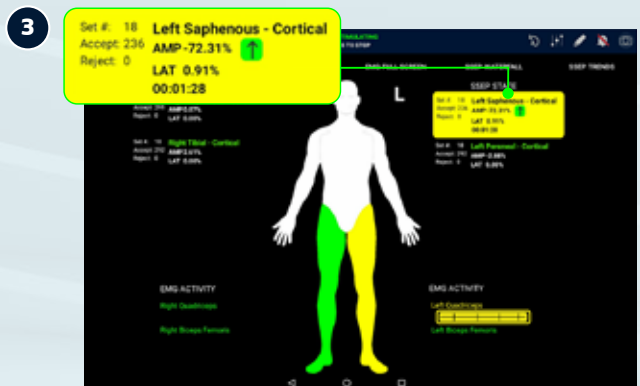
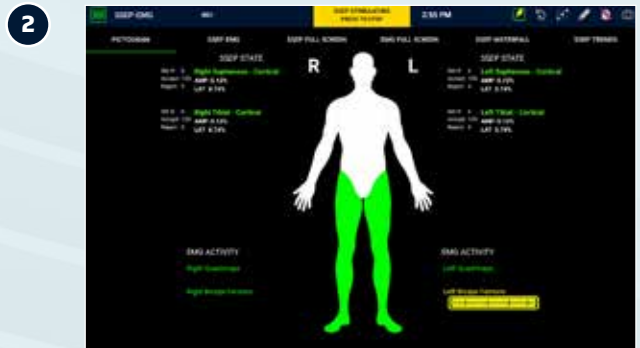
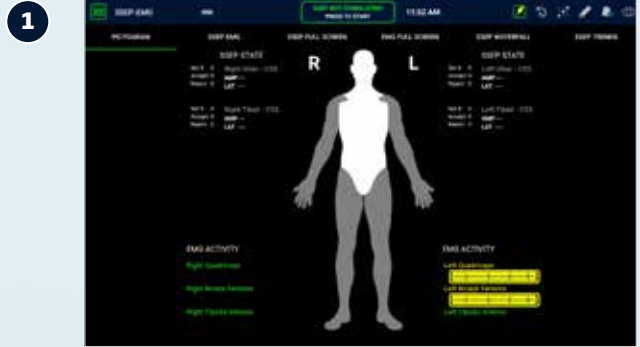
- > Shows the amplitude and latency trends throughout the procedure

### EMG Full Screen:

- > Shows only Free Run EMG waveforms

**5** To change between modalities during a procedure, use the **Menu** icon in the top left corner and select the modality desired from the menu that will appear on the left side of the screen.

**6** Before using the **EMG Thresholding** modality, it is recommended to first perform an **NMJ Train of Four** test. To do this, navigate to the **NMJ** page via the **Menu** icon.



**7** Upon selection of the **NMJ** modality, the default **NMJ** tab is titled **Train of Four**. To start the test, select the **Press to Start** button in the top center of the page.

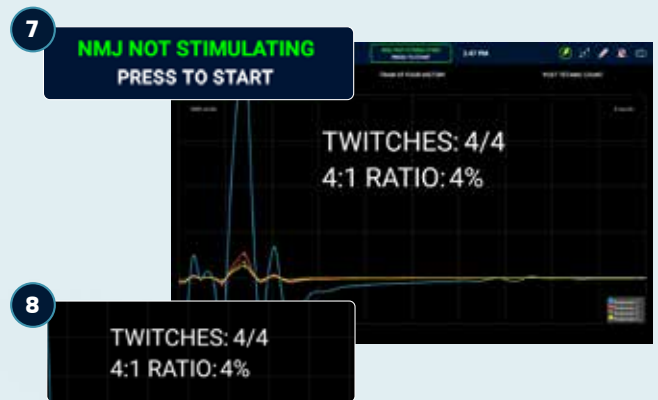
**8** The test will report the quantity of responses (up to 4) and provide a percentage stating the size of the amplitude of the fourth response compared to the first. This value is used to determine the level of paralytic in the patient and determines if **EMG Thresholding** can be performed without interference from non-metabolized paralytic.

*\*Refer to anesthesia guide for further information.*

**9** When the use of **EMG Thresholding** is required, navigate to the **EMG Thresholding** tab via the **Lightning Bolt** shortcut button on the upper right of the screen or via the **Menu** icon in the top left corner.

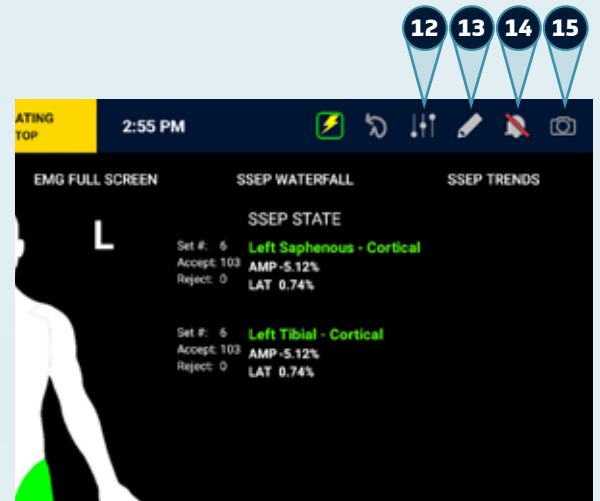
**10** Once the **Clip** or **Probe** is in position (e.g., attached to a screwdriver, dilator, or near a test site), and the surgeon is ready for stimulation to begin, press the associated **Start Stimulation** button in the top center of the tablet UI. Alternatively, the surgeon may at any time directly begin stimulation from the **Clip** or **Probe** by pressing the green button on the instrument which will automatically navigate to the **EMG Thresholding** screen and begin stimulation.

**11** Stimulation will begin a continuous sweep until the button is pressed again or significant time passes with the stimulating device (e.g., Clipped Screwdriver, Clipped Dilator, Probe) out of contact with the patient's anatomy. **EMG Thresholding** responses will be displayed on the screen and verbalized by the application. To navigate back to **SSEP/EMG** screens, use the **Menu** icon or the **Back Arrow** in the upper right of the **EMG Thresholding** screen.



- 12** Across all three modalities (**SSEP-EMG, EMG Thresholding, and NMJ**) the user has the ability to modify certain parameters of the tests, including the amount of current delivered and the scale of the waveform graphs, among others. To modify these settings, select the **Settings** button in the top right corner of the application.
- 13** Throughout the procedure the user can add time-stamped case notes that will be added to the case report. To access these notes, select the **Notes** button in the top right corner of the screen and select the appropriate note from the list available, or enter a free-form comment and select **OK**.
- 14** To turn audible alerts on and off for specific modalities, select the **Alert** button on the top right corner of the page. In addition, the + and – buttons on the **AIX Tablet** control the global volume levels.
- 15** Select the **Screenshot** button in the top right corner of the display to take a screenshot of the display at any point throughout the case.
- 16** Upon completion of the case, navigate to the **Menu** icon and select **End the current case**.

A notification will pop up asking if a case report is required. Select the appropriate answer. The application will then return to the **Monitoring Plan** selection page allowing you to begin a new case if desired.
- 17** Confirm the removal of all electrodes from the patient and dispose of all non-capital equipment into the appropriate disposal containers.
- 18** Return all capital equipment to the **SafeOp Capital Equipment Set** and coordinate shipment back to **ATEC**.



## ORDERING INFORMATION & CUSTOMER SUPPORT

### ORDERING INFORMATION

- Contact customer service via phone or email to order SafeOp.
- Cleared for use in the United States-K182542

### CUSTOMER SUPPORT CONTACT INFO

P: +1-800-922-1356 [Toll-free]

P: +1-760-431-9286

F: +1-800-431-9722

E: [customerservice@atecspine.com](mailto:customerservice@atecspine.com)

### SAFEOP TECHNICAL SUPPORT

P: +1-844-SAFEOP1 (1-844-723-3671)



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AlphaInformatix™

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