SafeOp™
NEURAL INFORMATIX SYSTEM

OPERATOR MANUAL

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Table of Contents

About the SafeOp System

Intended Use:

The SafeOp^{TM} System is intended for use by trained healthcare professionals as a diagnostic device that provides intraoperative neuromonitoring during various surgical procedures.

Indications for Use

The SafeOp System is intended for use in monitoring neurological status by recording somatosensory evoked potentials (SSEP), electromyography (EMG), or assessing the neuromuscular junction (NMJ). Neuromonitoring procedures include intracranial, extracranial, intratemporal, extratemporal, neck dissections, upper and lower extremities, spinal degenerative treatments, pedicle screw fixation, intervertebral fusion cages, rhizotomy, orthopedic surgery, open/percutaneous, lumbar, thoracic, and cervical surgical procedures.

Magnetic Resonance (MR) Environment

The SafeOp System is considered "MR Unsafe." "MR Unsafe" items pose unacceptable risks to patient, medical staff, or other persons within the MR environment. Keep the system away from magnetic resonance imaging (MRI) equipment.

System Overview

The SafeOp System consists of the SafeOp System Head Unit with power supply and IV pole mount, a tablet computer (the Alpha Informatix or AIX tablet) with docking station and power supply and a data transfer USB cable. Associated disposable equipment consists of an electrode harness, surface or subdermal needle electrodes, and stimulating probe or clip contained in various kits. Each of these components is described below.

SafeOp System Head Unit

The SafeOp System Head Unit contains a complete data acquisition system that has built-in amplifiers, analog to digital converters, and digital signal processors.

SafeOp Head Unit Features

- Eight differential analog input channels
- One isolated electrical stimulator with five switchable output ports
- Full bandwidth acquisition (20 kHz sampling)
- OR (operating room) ready
- Ultra-low-noise amplifiers
- Connects through USB or encrypted wireless communication to tablet
- Mounts on an OR bed rail, Jackson Frame, or IV pole with adapter
- Small and light enough to be carried into the OR

- Used for recording somatosensory evoked potentials (SSEP), neuromuscular junction testing (NMJ) and electromyography (EMG)
- Built-in cautery detection suspends waveform averaging in the presence of high frequency interference

Alpha InformatiX Tablet

The tablet touchscreen computer provided with the SafeOp System is the Panasonic FZ-A2 and runs on the Android operating system. The application is preloaded onto the tablet. The application serves as the user interface for the SafeOp System Head Unit to input patient and procedure information, adjust stimulus and acquisition parameters, control stimulus delivery, display acquired data, and deliver messages and alerts to the clinician. It includes:

- An algorithm that detects changes in evoked response amplitude and latency and alerts user to check waveform view for artifact or potential true data change; and
- An algorithm which detects a muscular response from stimulating a supplying nerve or nerve element and displays the stimulation threshold in mA required to produce a detectable response.

Communication between the AIX tablet and SafeOp System Head Unit is via encrypted Wi-Fi® wireless or USB connection.

Monitoring Modalities

Three recording types or 'monitoring modalities' are supported by the SafeOp System. These are somatosensory evoked potentials (SSEP), electromyography (EMG) and neuromuscular junction testing (NMJ).

SafeOp System Electrodes

The SafeOp System Surface Electrodes are solid gel electrodes designed to minimize the amount of skin preparation required. The electrodes are single-use, disposable, and biocompatible for use on intact skin. These electrodes are used for both acquisition and stimulation, including somatosensory evoked potentials and electromyography. Please see the electrode setup guide for placement instructions and the electrode package for specific storage instructions and expiration date.

The SafeOp System Needle Electrodes are paired standard 13 mm 27-gauge subdermal electrodes that may be used in place of surface electrodes for recording electromyography signals and for electrical stimulation. The electrodes are single-use, disposable, and biocompatible for subdermal placement. Please see the electrode package label for specific storage instructions and expiration date.

Please see the "Electrode Placement" section of this manual for instructions on how to apply the electrodes.

There are various stimulation and recording setups for the SafeOp System depending on the goal of the monitoring being performed. If it is not possible or necessary to place all the electrodes, then any can be

omitted so long as a ground is attached to the patient. Which electrodes and channels are in use are automatically detected by the SafeOp System at the beginning of the procedure.

Electrode Cables

The SafeOp System is supplied with two (2) configurations of three (3) compatible patient cables. Two (2) patient cables attach to non-cranial electrode locations for EMG or EMG and SSEP monitoring. One (1) patient cable is used for cranial electrodes with SSEP monitoring. These cables connect the SafeOp System Head Unit to the patient. This cable arrangement allows convenient placement on either side of the patient with minimal need to cross cables over the patient from side to side. What is recorded from each acquisition port can vary between a central or peripheral SSEP signal, NMJ signal, or an EMG signal.

The SafeOp Head Unit cable stimulation and acquisition ports are color-coded for correct connection to the SafeOp System Head Unit:

- SSEP & NMJ Stimulation – Blue
- SSEP Stimulation – Yellow
- EMG Acquisition & Ground – Red
- SSEP Acquisition – White
- EMG Stim 1 & 2 ports - green

The stimulator cable connectors are also uniquely physically keyed to facilitate connection to the correct SafeOp System Head Unit stimulator output and to limit connection of an acquisition cable to a stimulator output.

Labeled and color-coded tabs on each cable correspond to the locations for appropriate electrode connections displayed on the AIX Tablet.

A probe and/or clip lead also connects to the top side of the Head Unit utilizing a color-coded and physically keyed connector. The electrical current return for the probe and/or clip attaches to an adjacent green color-coded 1.5 mm touch proof port on the Head Unit, and is part of both non-cranial patient cables.

Warnings and Cautions

- A warning advises against actions or situations that might result in personal injury or death.
- A caution advises against actions of situations that might damage equipment or invalidate data.

General Warnings

This user manual should be read and understood fully prior to commencing use of the SafeOp System.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth. The SafeOp System Head Unit is a Class 1 device. The mode of operation is Continuous Operation. For protection against electric shock the Head Unit requires a properly grounded electrical outlet. The internal isolation transformer must not be bypassed under any circumstances.

The SafeOp System Head Unit is type BF because it has medium or long-term contact with the patient. The SafeOp System Head Unit is isolated from other parts of the equipment to such a degree that no current greater than a set level flows if an unintended voltage is connected to the patient. This set level of current is the maximum patient leakage current allowable in a single fault condition. All the patient connections of the SafeOp System are electrically isolated. However, these connections are not intended for direct cardiac contact.

Hazardous voltages are exposed when the lid of the SafeOp System Head Unit is removed.

Electrical Shock Hazard. Do not connect electrode inputs to earth ground. The SafeOp System Head Unit contains warning symbols to remind you that the connections are intended for isolated patient connections only. Avoid accidental contact between connected but unused applied parts and other conductive parts including those connected to protective earth. Do not place containers of liquid or metal objects on top of the tablet cradle. Inadvertent spills may lead to electric shock.

All wires to/from the patient must **NOT** contact any of the conductive parts of the device, including earth.

When using electrocautery on a patient who is also being monitored with the SafeOp System, be sure to follow the electrocautery manufacturer's instructions for proper placement and connection of the electrocautery return electrode to avoid burns at any of the SafeOp System electrode sites.

⚠️ Evoked potential waveforms measured by the SafeOp System may be susceptible to external sources of electromagnetic radiation, such as CT scanners, diathermy or RFID devices. Disconnect the SafeOp System prior to any patient CT scanning or connection to a diathermy machine. Use care when operating the SafeOp System in the presence of RFID or other electromagnetic security systems. Please note that some RF emitters, such as RFID emitters, which may adversely impact the performance of the device, may not be visible to the SafeOp System user.

⚠️ The device is not protected against defibrillation. All wires to/from the device should be removed before using a defibrillator.

⚠️ The electrical stimulus and electromagnetic radiation emitted by the SafeOp System are not expected to cause any interference with other implanted or body worn powered medical devices. However, use care when treating patients with such devices, and stop using the system if there are any signs of interference.

⚠️ The SafeOp System is **NOT** AP or APG rated. Therefore, it should not be used in the presence of flammable anesthetics.

⚠️ The SafeOp System Head Unit shall be used **ONLY** with SafeOp surface electrodes or recommended off-the-shelf electrodes. SafeOp surface electrodes and internal settings prevent the current density from exceeding 2 mA $_{rms}$/cm^2. Calculated stimulation settings for off-the-shelf electrodes are provided in the System Hardware section.

⚠️ The use of cables other than those specified in this manual, or otherwise qualified by the manufacturer for use with this equipment, may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2 regarding electromagnetic compatibility.

⚠️ Operation of the SafeOp System in close proximity to electrocardiogram (ECG) or pulse oximetry devices could disrupt the signals measured by these devices and may result in an inaccurate reading including erroneous indication of tachycardia.

⚠️ Do not position the SafeOp System device where it is difficult to operate the power on/off switch on the Head Unit.

Electrode Warnings

⚠️ Only use the SafeOp System electrodes provided with the SafeOp System. Use of other electrodes has not been qualified with the SafeOp System Head Unit and may adversely affect the safety and effectiveness of electrical stimulation and recording.

⚠️ Attach the cables to the electrodes with care to prevent the stimulating cable being attached to the acquisition electrodes.

⚠️ Do not place the stimulation electrodes such that the stimulation current will be trans-thoracic (crossing the area of the chest and thorax.)

⚠️ Do not place stimulation electrodes over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

⚠️ Do not place stimulation electrodes on the patient's chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.

⚠️ Do not place stimulation electrodes over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).

⚠️ Do not place stimulation electrodes over, or in proximity to, cancerous lesions.

⚠️ Carefully place the electrodes to avoid interference with conductive intravenous (IV) needles. Contact between the stimulation electrodes and IV needles could result in an unintended level of electrical stimulation and patient injury.

General Cautions

⚠️ The SafeOp System acts as an adjunct to clinical judgment and training. Clinical judgment and training should always be utilized when interpreting the physiological signals recorded by the SafeOp System.

⚠️ While the SafeOp System is designed to record evoked potentials under typical operating room conditions, the robustness of evoked potentials may be reduced by certain inhaled or high-dose injectable anesthetic agents, particularly if the doses used are increased quickly. This may lead to a reduction in waveform amplitude that is unrelated to neuronal dysfunction.

⚠️ Assessment of neuromuscular function using the SafeOp System is likely to be affected by concurrent use of paralytic agents. Do not use the SafeOp System for free run muscle recordings in conjunction with paralytic agents.

⚠️ Do not remove the AIX tablet from the room where the SafeOp System Head Unit is in use. This avoids improper pairing of the tablet and Head Unit and minimizes potential disruptions in wireless data transfer between the Head Unit and tablet.

⚠ Use the USB connection instead of wireless if wireless quality of service (QoS) is insufficient for sustained data transfer. Wireless communication and wired communication may be disrupted due to inadequate bandwidth or nearby causes of interference such as multiple busy Wi-Fi® or Bluetooth networks, electrostatic discharge or ESD (e.g., due to rubbing with woven fabrics), or RF emitting devices (e.g., cell phones, microwave ovens, MRI, or electrocautery).

⚠ It is the responsibility of the institution where the SafeOp System unit is installed to ensure that the requirements of IEC 60601-1 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* are fulfilled in the particular installation.

⚠ Do not turn on the system until all cable connections have been made and their integrity checked.

⚠ The SafeOp System Head Unit can only be powered up by the SafeOp Head Unit power supply (PN AIX1191A).

⚠ The isolated switch mode power supply is intended for connection only to a 110V, 120V, 220V or 240V external (wall) outlet.

⚠ The USB connector on the SafeOp System Head Unit is intended only for connection to the tablet provided with the SafeOp System.

⚠ Do not turn on the power to the SafeOp System Head Unit immediately after bringing it in from a cold environment to one at room temperature. Allow the unit to assume the ambient environmental temperature (i.e., one-hour warm-up).

⚠ The SafeOp System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration which it will be used.

⚠ When data acquisition first begins, or upon restart if the data transmission signal is lost, there may be up to a 30 second delay in waveform display.

⚠ Operation in close proximity (for example 1 m) to shortwave or microwave therapy equipment may produce instability in the SafeOp System electrical stimulator output.

⚠ As with any monitoring device that records minute physiological signals, the SafeOp System is subject to artifacts and poor signal quality due to poor skin contact, motion, improper stimulator or sensor placement, and excessive or sustained electrical interference. Interpretation of the signals must also take into account any known neurological disorders.

⚠ Possible interference with the SafeOp System waveforms may occur in certain situations, for example, poor grounding in circuitry and/or operation in close proximity to other instrumentation such as an MRI (See Declaration of Electromagnetic Immunity for more information).

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SafeOp System, including cables specified in this manual. Otherwise, degradation of the performance of this equipment could result.

⚠ In noisy environments the SafeOp System may be unable to identify amplitude reductions accurately.

⚠ The SafeOp System Head Unit may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.

⚠ The SafeOp System Head Unit carries ordinary classification for the level of protection against ingress of liquids (IPXO). It is not drip or splash proof. The power supply is protected against dripping water when the device is rotated 15 degrees in any direction from vertical for at least 10 minutes (IP22).

⚠ Be sure to clean the SafeOp System components in accordance with the cleaning instructions provided in this manual. It is recommended that the Head Unit be disinfected between patients with 70% isopropyl alcohol. Turn off all system power and disconnect the power cord from the system and the wall before attempting to clean the unit.

⚠ Inspect all cables and connections (especially the power cord) often for signs of fraying or other damage. Do not operate the SafeOp System if you suspect damage to any cables or the power cord.

⚠ Preventive maintenance is recommended every six months as described in the Preventive Maintenance section of this manual.

⚠ Do not leave any cables attached to the SafeOp System Head Unit when transporting the unit. This may cause connections to become loose or malfunction during operation of the unit.

⚠ Use tape to prevent cable ends from falling away from the vicinity of the patient.

⚠ The AIX tablet connected to the SafeOp System Head Unit can overheat if it is operating while insulated with blankets. Keep this device open to the air to prevent overheating.

⚠ The AIX Tablet is intended to only run the SafeOp System applications. Do not install any other applications other than those approved by Alphatec Spine, Inc.

⚠️ When the SafeOp System comes to the end of its operating life, it should be returned to Alphatec and be disposed of in accordance with local waste disposal regulations.

⚠️ Do not place the SafeOp System Head Unit, AIX Tablet or AIX Tablet Cradle on unstable surfaces. The product may fall or drop resulting in an injury.

⚠️ Do not utilize the SafeOp System in excessively hot, cold, or humid conditions for which it is not rated.

⚠️ Do not place SafeOp System power or other cables in areas where they may cause tripping and injury.

⚠️ Installing or inserting a USB device other than the provided SafeOp cable to the Head Unit or AIX Tablet ports may lead to interrupted function of the device and should be avoided.

⚠️ Use of electrocautery during neuromuscular junction testing or electromyographic thresholding should be avoided as excessive noise may interfere with signal acquisition or analysis.

⚠️ Use of AIX Tablet Bluetooth communication during operation may lead to unexpected communication behavior.

Electrode Cautions

⚠️ The long-term effects of cutaneous electrodes for electrical stimulation and/or recording are unknown.

⚠️ Since the effects of stimulation of the brain are unknown, stimulation electrodes should not be placed on opposite sides of the patient's head.

⚠️ Keep electrodes out of the reach of children.

⚠️ Use caution if electrodes are applied over areas of skin that lack normal sensation.

⚠️ Carefully place the electrodes to avoid interference with conductive IV needles or metallic objects. Contact between the stimulation electrodes and IV needles could result in unintended level of electrical stimulation and patient injury.

⚠️ Replace self-adhesive electrodes if they no longer stick firmly to skin.

⚠️ Stimulation with excessive current densities may be a hazard to the patient.

⚠️ If replacing surface electrodes on a patient due to poor contact or incorrect positioning, carefully remove the remaining gel from the patient prior to applying the new electrodes.

Adverse Reactions

The patient may experience skin irritation beneath the surface electrodes applied to skin. The adhesive may irritate the skin when removed from the skin. It is a strong adhesive and should be removed from the skin with care.

Needle electrodes may cause bruising or bleeding in patients using blood thinners or who have blood dyscrasias. Do not move or wiggle electrodes excessively after placement.

Statements of Conformity

The SafeOp System conforms with the following regulations and standards. The SafeOp System has no essential performance as defined by IEC60601-1.

SafeOp System Medical Device Standards Conformity

- AAMI ES60601-1 2005 (R2012) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Incorporating Amendment 1:2012; Amendment 2:2010

- CAN/CSA C22.2 No.60601-1:14 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Third edition

- CAN/CSA C22.2 No 60601-2-40: 2017 /IEC 60601-2-40:2016 Medical electrical equipment – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment – Edition 2.0

- CAN/CSA C22.2 No 60601-1-6:11 / IEC 60601-1-6, 3_{rd} Edition, 2010, Collateral standard usability. [lus AMD.1 2015. In conjunction with IEC 62366, 1_{st} edition, 2007, Medical devices – Application of usability engineering to medical devices, plus AMD.1 2014

- IEC 60601-1 Edition 3.1, 2012: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Incorporating Amendment 1

- IEC 60601-1-2 4_{th} Edition: Medical Electrical Equipment Part 1: General requirements for safety 2. Collateral standard: electromagnetic compatibility.

Federal Communications Commission (FCC) Conformity

The SafeOp System Wi-Fi® communication complies with 47 CFR 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.

NOTE: "Harmful interference" is defined by the FCC as follows:

Any emission, radiation, or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

FC
Assembled from tested components
Complete system not tested

Explanation of Labeling Symbols

Several symbols appear on the various components or labels of the SafeOp System.
Please consult the table below for their meanings and significance.

Symbol	Description	Symbol	Description
⚠	ATTENTION: Consult accompanying documents	🚫MR	'MR Unsafe' items pose unacceptable risks to patient, medical staff, or other persons within the MR environment
👤	Type BF equipment	📖	Refer to instruction manual booklet
~	Alternating current	🚫	Do not use if package damaged
===	Direct current	**Rx only**	Prescription only
I	Power on	LATEX	Not made with natural rubber
O	Power off	🌡	Temperature limitation
♲	Carefully dispose of this product	(((•)))	Non-ionizing radiation
USB	USB 2.0 supported	STERILIZE 2	Do not re-sterilize
IPx4	Protection against spraying water		
🏭	Manufactured by		
📖	Consult accompanying documents		
REF	Part number		
LOT	Lot number		
SN	Serial number		
②	Do not reuse		
STERILE EO	Contents pre-sterilized with ethylene oxide		
⚡	Static sensitive		
⧗	Use by date		

SafeOp System Suggested Workflow
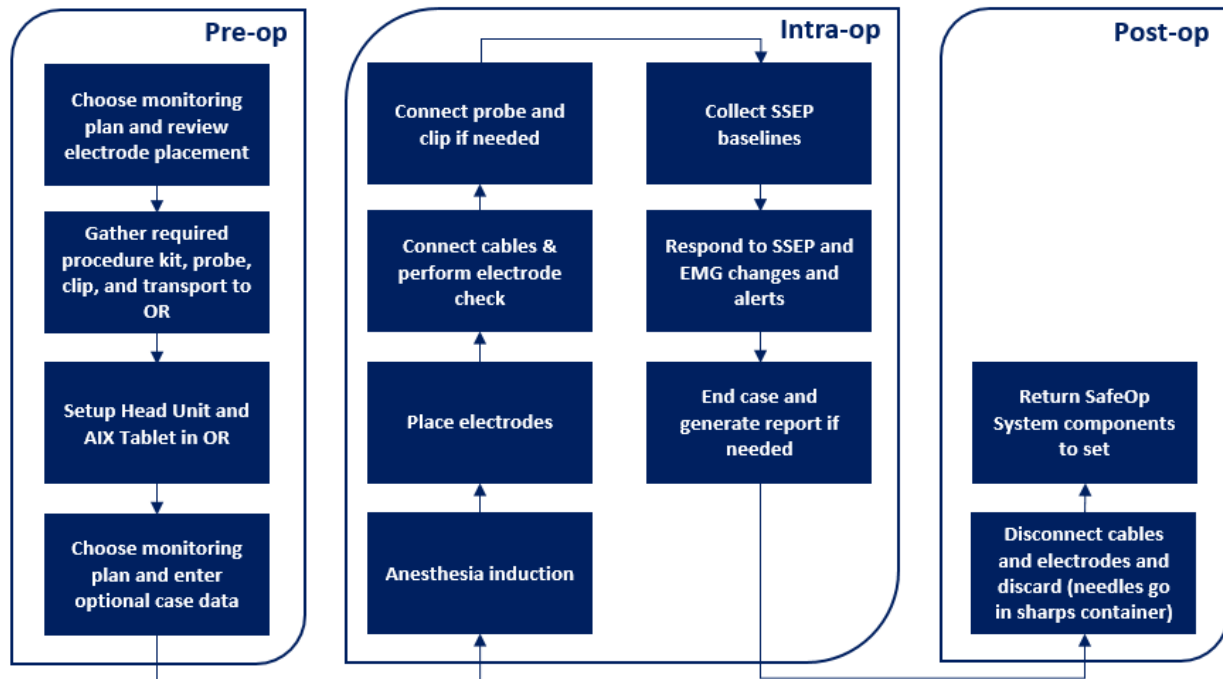
Figure 1 SafeOp System Workflow

The SafeOp System is designed for simplicity of monitoring. Because, however, there are multiple stimulator and acquisition channels, modalities, and possible target structures to be monitored, several possible monitoring arrangements are possible. The particular arrangement for channel, modalities and structures monitored in any one case is defined by the 'monitoring plan'.

Monitoring Plans

The SafeOp System allows recording from up to 8 channels. Which channels record which type of recording (also known as modalities) is determined by the user's choice of 'monitoring plan' located in the SafeOp application in the 'Case Data' screen which is shown immediately after the application loads or a new case is started. Once a monitoring plan is chosen for a case it cannot be altered until the end of the case. To use a different monitoring plan a new case must be initiated by choosing 'End the current case' in the left dropdown menu.

The SafeOp System provides five (5) monitoring plans for simplicity in application (See Figure 2 - Monitoring Plans).

The monitoring plan may be chosen, and all electrodes may be applied in the operating room, however time can be saved by applying any *surface* electrodes in pre-op. This also allows the surface electrodes to adapt to the skin creating better connections and cleaner monitoring signals. Needle electrodes

should be applied only after induction of anesthesia to avoid unnecessary discomfort. For detailed
information about placing the electrodes refer to 'Applying the electrodes' on page 25.

Channel Markings

Each channel is color coded and comes with a detailed placement reference printed near the electrode
connection. The electrode connection ports are also color coded to provide a reference to the
anatomical area they are to be applied. The table below highlights the color rubric.

Channel	Patient Cable Type	Lead Color	Electrode Connection Color	Anatomical Location
EMG 1 (Right)	Shielded Twisted	Red – Stipe	White	Right Side
EMG 2 (Right)	Shielded Twisted	Green – Stripe	White	Right Side
EMG 3 (Right	Shielded Twisted	Blue – Stripe	White	Right Side
EMG 1 (Left)	Shielded Twisted	Red	Blue	Left Side
EMG 2 (Left)	Shielded Twisted	Green	Blue	Left Side
EMG 3 (Left)	Shielded Twisted	Blue	Blue	Left Side
SSEP Record 1	Shielded Twisted	Orange	Red	Cranial
SSEP Record 2	Shielded Twisted	Gray	Red	Cranial
Ground	Shielded Twisted	Black	Gray	Left/Right
tEMG	Twisted Pair	Bright Green – Gray	Gray	Left/Right
TO4	Twisted Pair	Yellow – Gray	Gray	Left/Right
SSEP Stim 1 (Right)	Twisted Pair	Pink – White	White	Right Side
SSEP Stim 2 (Right)	Twisted Pair	Brown – White	White	Right Side
SSEP Stim 1 (Left)	Twisted Pair	Pink – Blue	Blue	Left Side
SSEP Stim 2 (Left)	Twisted Pair	Brown – Blue	Blue	Left Side

First Button Element	Second Button Element	Might be used with	Stimulating Point (Function)	Recording Location (Function)
Cervical	**EMG**	Anterior or posterior cervical spinal surgery such as ACDF, PCF	Ulnar groove (TO4)	Bilateral deltoid (EMG), bilateral medial biceps (EMG), bilateral BR-FCU (EMG/TO4)
	EMG & SSEP: Standard		Ulnar groove (TO4), bilateral ulnar (SSEP), bilateral tibial (SSEP)	Bilateral deltoid (EMG), bilateral medial biceps (EMG), bilateral BR-FCU (EMG/TO4), mastoid (SSEP), transcortical (SSEP)
Lumbar	**EMG**	Lumbar disc and fixation surgery	Peroneal (TO4)	Bilateral quadriceps (EMG), bilateral biceps femoris (EMG), bilateral tibialis anterior (EMG/TO4)
	EMG & SSEP: LIF/PTP		Peroneal (TO4), bilateral saphenous (SSEP), bilateral tibial (SSEP)	Bilateral quadriceps (EMG), bilateral biceps femoris (EMG), bilateral tibialis anterior (EMG/TO4), cortical (SSEP), transcortical (SSEP)
	EMG & SSEP: Standard		Peroneal (TO4), bilateral ulnar (SSEP), bilateral tibial (SSEP)	Bilateral quadriceps (EMG), bilateral biceps femoris (EMG), bilateral tibialis anterior (EMG/TO4), cortical (SSEP), transcortical (SSEP)

Figure 2 - Monitoring Plans

Operating Room Device Setup

The SafeOp System (Head Unit, disposable cables, AIX Tablet, AIX Tablet Cradle and power supply) may be setup in the operating room prior to the patient entering.

Head Unit Placement and Setup

The SafeOp System Head Unit is typically mounted on the operating room table distal to the patient on the opposite side of the surgeon. The device is oriented such that the power cord is pointed towards the ground. The SafeOp System Head Unit can be mounted on an OR bed rail or a Jackson frame. Alternatively, the SafeOp System Head Unit may be mounted to an IV pole adjacent to the table utilizing the Pole Clamp (PN 100625).

Care should be taken not to place excessive strain on the cables due to the position of the Head Unit in relation to the patient.

Connecting the Power Supply

The power cord from the Head Unit Power Supply (PN AIX1191A) inserts directly into the 'Power In' receptacle on the bottom side of the Head Unit. Confirm that the power switch is toggled to the off position before connecting to power.

Figure 3: USB and power ports on Head Unit

Figure 4: Connection and power up of Head Unit

Head Unit Power Up

Toggle the Head Unit on by pressing the "On" side of the rocker power switch. If the box is connected to power the 'Power On' light should turn green. It takes 10-12 seconds for the internal system to load and for the Head Unit to be ready for connection to the tablet.

AIX™ Tablet Placement and Setup

The AIX Tablet (PN 200507-SS & AIX11801) may be placed away from the operating room table in a convenient location for easy access and viewing. Power is supplied via the power input beneath an access door in the right upper corner, or to the AIX Tablet Docking Station (PN 200519-SS). The AIX Tablet must be seated securely in the AIX Tablet Docking Station for the battery to charge.

Do not place containers of liquid or metal objects on top of the AIX Tablet Docking Station or place the AIX Tablet Docking Station on an unstable surface or exposed to a high temperature or high moisture environment.

AIX Tablet Power Up

Press the AIX Tablet power button located on the right lower front surface of the AIX Tablet until the 'Android' logo appears (see Figure 6: AIX Tablet). Once the AIX Tablet has booted, swipe upwards on the screen to reach the desktop. To start the SafeOp System application, tap the square blue and green SafeOp application icon located at the bottom of the screen (see Figure 7: AIX Tablet Desktop). If there is delay and the AIX Tablet screen turns off before starting the application, press the power button again to wake the AIX Tablet.

AIX Tablet Communications with Head Unit

Communication between the SafeOp System Head Unit and AIX Tablet can be either via a USB connection or using Wi-Fi® wireless signal. Wireless communication is automatically initiated if no USB cable is connected. Status of the communication is shown by an icon in the left upper area of the screen.

Data Communication

Wireless communication and wired communication may be disrupted due to inadequate bandwidth or nearby causes of interference such as multiple busy Wi-Fi® or Bluetooth networks, electrostatic discharge or ESD (e.g., due to rubbing with woven fabrics), or RF emitting devices (e.g., cell phones, microwave ovens, MRI, or electrocautery). Additionally, communication can be disrupted due to transient coupling from adjacent high-power main cables, therefore it is advisable to keep the SafeOp System main cables separated from other main cables. The system will attempt to reconnect or may require a manual restart.

The Quality of Service (QoS) for wireless communication is assessed by the SafeOp System in real-time. If the Wi-Fi® connection is unreliable, the SafeOp System Tablet software will display a message on the Tablet screen and will attempt to re-establish Wi-Fi® connection. The connection state is identified on the screen as connection via USB (USB icon with checkmark), Wi-Fi® (Wi-Fi® connection icon with checkmark) or indicates if the Head Unit is disconnected (Head Unit icon with red line through it). If there is no connection the following message will also appear on the screen:

"Waiting for Head Unit"

Wi-Fi® Data Communication

Do not connect to any outside Wi-Fi® network with the AIX Tablet. This may lead to unexpected connectivity issues with the Head Unit. If the AIX Tablet has been connected to an external Wi-Fi® network, go to settings and 'forget' the network.

Wi-Fi® Security

The Wi-Fi® protocol uses encryption for all transmissions except during the startup discovery time. The SafeOp System Head Unit and Tablet are "paired" at the factory prior to shipping. Once paired, the Head Unit and Tablet will "discover" each other upon startup, and the Head Unit will switch to Serial Port Protocol (SPP). It is not possible for another wireless device to "discover" the Head Unit once it is in SPP. The SafeOp System Head Unit takes up to 6 seconds to begin communicating with the Tablet via Wi-Fi® after power on and opening the SafeOp System application.

Pairing the SafeOp System Head Unit to the AIX Tablet

For proper operation, check to make sure that the serial numbers on the SafeOp System Head Unit and AIX Tablet App startup screen match and be careful to keep the 'paired' SafeOp System Head Unit and Tablet together. The SafeOp System Head Unit and Tablet are programmatically uniquely joined at the factory prior to shipping.

Each AIX Tablet is set to uniquely connect only to a single specified Head Unit. If more than one SafeOp System is within the same environment it will not connect to the other Head Unit.

At first startup the tablet may take some time (10-12 seconds) to find its Head Unit, particularly if there are multiple Wi-Fi or Bluetooth devices nearby.

USB Data Communication

The mini-USB connector can be employed at the user's discretion or when the Wi-Fi® connection cannot be reliably established.

In case of continual communication disruptions, use the USB connection instead of Wi-Fi between the SafeOp System Head Unit and Tablet. To use the USB connection, connect the USB cable from the AIX Tablet to the Head Unit. USB data connection should start immediately. This will be indicated by a USB icon with a check mark appearing in the left upper areas of the screen. If it does not start, then close and restart the SafeOp System software.

Connecting Cables to the SafeOp System Head Unit

Once the SafeOp System Head Unit is mounted on the OR table, the color coded cables can be plugged into the SafeOp System Head Unit.

The cable connectors and probe port are color-coded to facilitate correct placement. Each stimulating cable and the acquisition cables also have differing sets of ridges that slide into associated grooves on the receptacles, enabling the correct cable in the correct receptacle and the proper alignment of the cable pins. To insert a cable connector *gently* place the cable in the correct receptacle, rotate until the ridges engage and then push in until it clicks into place. The arrows should align with the side of the case with the logo on it.

If a probe is to be used *both* the probe and the return should be connected. The probe connects to the green port in the same way that the other color-coded adapters connect. The probe current return connects to the touchproof green connector.

Choosing Electrodes and Electrode Setup

Please note: The SafeOp System shall be used only with SafeOp electrodes. Use of improper electrodes may result in malfunction or injury.

Overview of Electrode Placement

The most common placements are summarized below.

Electrode Placement for SSEP Recordings

A surface or subdermal needle electrode may be placed on the saphenous nerve, tibial nerve, or ulnar nerve. A subdermal needle or corkscrew electrode made be placed on the cortical and trans-cortical recording sites.

Depending on the monitoring plan, the electrode placement for SSEP recordings are as followed:

- Saphenous Nerve – Find the tibial plateau by palpating up the medial edge of the tibia. Place the white electrode on the medial tibial edge in the angled groove of the plateau. Place the blue electrode three inches distal along the tibial edge.
- Tibial Nerve – Place the white electrode on the inside of the patient's ankle between the medial malleolus and the Achilles tendon. Pace the blue electrode distal by no less than one inch apart.
- Ulnar Nerve – Place the blue electrode one inch cranial of the patient's wrist crease and one inch medial (towards the pinky finger) from the flexor carpi ulnaris tendon. Place the white electrode one inch cranial to the blue electrode.
- Cortical – Find the mid-point of the patient's head (midline from right tragus to left tragus & crossline from inion to nasion). Place the blue lead two inches posterior to this mid-point. Place the white lead at the midline of the patient's hairline.
- Trans-Cortical – Referencing the blue cortical lead, place the white trans-cortical lead 2 inches to the patient's right (where the lines from the ipsilateral eye and ear cross) and the blue trans-cortical lead two inches to the patient's left.
- Mastoid - Place the blue lead on the mastoid process which is the bony prominence directly behind the ear. Place the white lead on the hair line of the forehead.

Electrode Placement for Neuromuscular Junction, or Train of Four (TO4) recordings

The SafeOp System is designed to record Train of Four tests from ulnar groove and peroneal nerve stimulation.

Depending on the monitoring plan, the electrode placement for TO4 recordings are as followed:

- Peroneal Nerve – Place the blue electrode just posterior to the fibular head. Place the white just medial to the lateral flexor tendon of the popliteal fossa.
- Ulnar Groove – Place the blue electrode one inch cranial of the patient's wrist crease and one inch medial (towards the pinky finger) from the flexor carpi ulnaris tendon. Place the white electrode one inch cranial to the blue electrode.

Electrode Placement for EMG Recordings

The SafeOp System may monitor up to 6 channels of active (muscle to tendon) or active-reference (muscle to muscle) EMG using either surface electrodes or subdermal needle EMG electrodes. Needle electrodes have a short wire lead allowing a greater distance between active and reference sensors and thus more flexibility in performing active-reference recordings.

Depending on the monitoring plan, the electrode placement for EMG recordings are as followed:

- Quadriceps – Place the blue lead over Vastus Medialis palpated from the proximal patella and located superior and medical. Place the white lead on the Rectus Femoris located on the middle third of the femur.
- Biceps Femoris - Place blue electrode half the distance from the distal aspect of the pelvis and the popliteal fossa. Place the white electrode lateral and superior 3 inches.
- Tibialis Anterior – Place the blue electrode lateral to the tibial crest at midline of the tibia. Place the white lead 3 inches cranial still in the belly of the muscle.
- Deltoid – Place the white lead into the medial deltoid with the blue lead over the posterior deltoid
- Medial Biceps – Place the white lead at the midpoint between the shoulder and the elbow joint with the blue lead toward the elbow at least 1 inch apart.
- BR-FCU – Place the blue lead midway between the wrist and elbow on the radial side of the forearm. Place the white lead midway between the wrist and elbow on the ulnar side of the forearm
- Upper Back (tEMG) – Place the stim return electrode as close to the surgical site as possible while avoiding fluids and sterile draping. Keep the electrode superior to the site of surgery.
- Acromion (Ground) – Place the electrode over the extrusion at the end of the collar bone.
- Hip (Ground) – Place the electrode on the patient's hip.

Applying the Electrodes

Confirm that the appropriate types of electrodes (subdermal needle or surface) and configurations of electrodes for the planned monitoring are available prior to beginning. Also confirm the AIX Tablet is fully charged and the SafeOp System Head Unit is plugged in and turned on. See the section below on "The AIX Tablet" for information about charging the AIX Tablet battery.

Please note: the SafeOp System Head Unit requires up to 6 seconds after being turned on before it can connect to the AIX Tablet if not using a direct wired connection.

1. The SafeOp System may be used to monitor SSEPs from stimulation of a combination of one or more lower and upper limb nerves according to clinical need. The SafeOp System may also be used to monitor more than one nerve per limb.

2. Surface electrodes may be applied prior to entering the operating room and optimally should be acclimatized to the patient for ten (10) minutes prior to use to improve contact (strongly recommended). Subdermal needle electrodes are typically applied after anesthesia induction has occurred.

3. In all cases, remove the backing or needle coverings from the electrodes prior to placing on the patient.

4. Inspect the patient's skin prior to electrode application to assess that the skin is healthy, intact, clean, and dry.

5. The solid gel electrodes are designed to require minimal skin preparation. However, Alphatec recommends preparing the skin with "NuPrep"[1] skin prep gel and wiping any residual gel from the skin before applying the electrodes for optimal recordings. Do not apply over an ionic skin prep such as a polyvinylpyrrolidone mixture.

6. In all cases of using surface electrodes it is important to firmly attach the electrode to the patient using the adhesive on the conductive portion of the electrode. Provide a firm distributed pressure with the palm of the hand or press over the perimeter of the electrode to promote adhesion.

7. Subdermal needle electrodes should be inserted after cleansing the skin with a non-ionic disinfectant such as isopropyl alcohol. Do not insert electrodes through a wound or infected site. Acutely angle the needle so that it passes downward at 3-5 degrees and is fully inserted to the hub. Do not insert the proximal insulated lead wire.

8. Anchor all electrodes with medical tape.

9. For all electrodes a '2x2' swab may be placed under the cable connector if it appears that cushioning is needed. Adhesive tape can be placed over the connector or cables to provide strain relief.

Do's and Don'ts for Surface Electrode Application

Following these simple suggestions greatly improves the chances of achieving good recordings using the SafeOp System device surface electrodes.

DO:

- Prepare the skin prior to electrode placement.
- Place the electrodes in the appropriate places and tape them to prevent inadvertent removal.
- Wait 10 minutes before running baselines to allow electrodes to optimize (improves connection 3-4-fold).
- Tape a strain release loop in place.

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[1] NuPrep is a registered trade mark of Weaver and Company

DON'T:

- Re-orient electrodes in a non-recommended direction.
- Remove and reposition the electrode.
- Reposition an electrode without replacing the electrode.
- Replace an electrode without wiping the skin dry in between to remove excess gel.
- Slide the electrode along the skin.
- Excessively bend or twist the connecting tails of the electrodes.

Do's and Don'ts for Subdermal Electrode Application
DO:

- Wear gloves for protection from bloodborne diseases during application.
- Report any inadvertent needle sticks using hospital or facility protocols.
- Insert the needle electrode on a shallow trajectory so that it remains subdermal.
- Insert the needle to its hub.
- Remove needles carefully and dispose in an appropriate biohazard container.
- Tape the needle lead to provide strain relief.

DON'T:

- Insert a needle through a wound or infected area.

System Operation

The AIX Tablet

The AIX Tablet is pre-loaded with the SafeOp System software. The user should not load other software applications on the AIX Tablet because this may affect the SafeOp System operations.

The AIX Tablet battery should be fully charged prior to each case (at least 8 hours or more) using the provided charging cable with or without the AIX Tablet Docking Station provided with the AIX Tablet. Be aware that it takes longer to charge the battery when the Tablet is in use. The AIX Tablet battery can be charged by placing it in the provided power docking station or plugging the charging cable directly into an outlet. Only use the charging unit that is supplied with your device; using other types of chargers may cause damage to the equipment. It is recommended that the AIX Tablet be connected to a power source whenever it is stationary to prevent discharge.

Please note that the AIX Tablet battery is expected to last up to 5 hours while running the SafeOp System application after being fully charged (at least 8 hours). However, battery life is dependent on a number of factors including use conditions and battery age. Be sure to monitor the battery charge during a case by sliding down the top portion of the screen. The battery icon will display the percent battery charge remaining. Switch to the wall or AIX Tablet Docking Station charger if the battery charge falls below 20% during a case.

To power on your AIX Tablet, press and hold down the power button for about 4 seconds or until the 'Android' symbol appears. When the AIX Tablet is powered on, you can press the power button to put it into or out of sleep mode. To power off the AIX Tablet, press and hold the power button for 4 seconds. When prompted, tap 'Power Off' on the screen to shut down.

Please note that the AIX Tablet has a touch screen panel that is operated by using a stylus or touch gestures. The diagram below details the location of the inputs and control buttons.

It is recommended that the audio button on the AIX Tablet always be left at a comfortable volume to enable that the user is able to hear any alerts. The display will also flash when an alert is generated. There are a number of features of the AIX Tablet that are not used when operating the SafeOp System which include the built-in front camera, the audio jack, and the microphone.
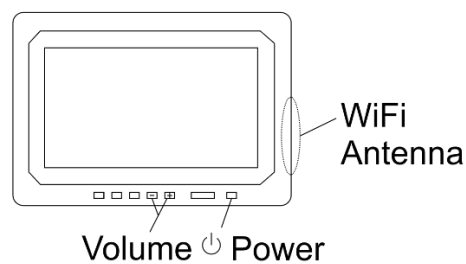

Figure 6: AIX Tablet

AIX Tablet GUI and Operation

1. Turn on the AIX Tablet and a screen should appear as displayed in Figure 7. The SafeOp System manual may also be displayed on the desktop as a PDF icon.
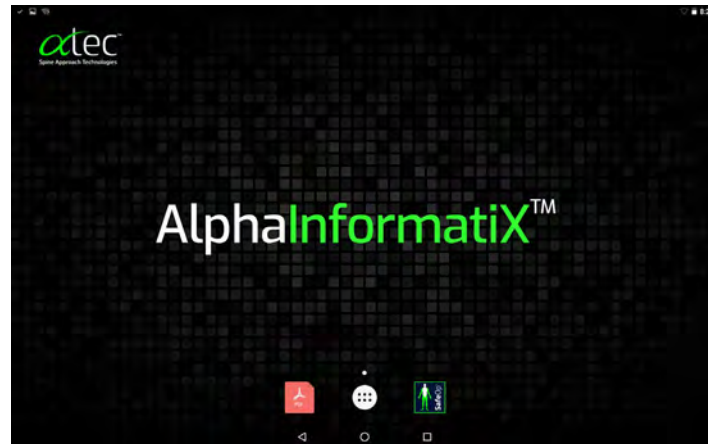
Figure 7: AIX Tablet Desktop

2. To safeguard patient data confidentiality the AIX Tablet may be encrypted. If the AIX Tablet is encrypted a message will appear asking the user to "Type password to decrypt storage".

3. If needed swipe the padlock button to the side or upwards to access the desktop.

4. The AIX Tablet can be connected to the SafeOp System Head Unit using either Wi-Fi® (wireless) or USB communication. Per the factory setting the AIX Tablet will attempt to connect via Wi-Fi® first. Please note that to connect by Wi-Fi® the AIX Tablet must first be paired with the SafeOp System Head Unit. See "Pairing the SafeOp System Head Unit with the AIX Tablet." Make sure that the AIX Tablet is paired with the correct Head Unit by checking the serial number displayed upon opening the SafeOp System app with the serial number on the Head Unit label. If the Wi-Fi® connection is unsuccessful or USB communication is the desired method, attach the USB cable from the AIX Tablet to the SafeOp System Head Unit. USB connection may be used without pairing.

5. Start the SafeOp application by tapping the SafeOp logo on the AIX Tablet desktop:

6. The first screen to appear will indicate the serial number and host software version while doing internal checks.

Figure 8: Application Start Screen

7. The next screen will show the "Monitoring Plan" entry. The screen consists of 2 tabs: Monitoring Plan and Case Data. If no patient identifiers are entered in the Case Date tab prior to proceeding, the system will automatically enter the case name as the current date and time. The messaging bar at the top of the screen will display the state of the Wi-Fi® connection with the Head Unit, the detection of electrocautery, battery level, and the time on the left. The Settings button, Comment button, Alert Sound button and Screenshot buttons are displayed on the right. The triple layer (hamburger) icon to the left provides access to all other non-tabbed screens in any particular view.
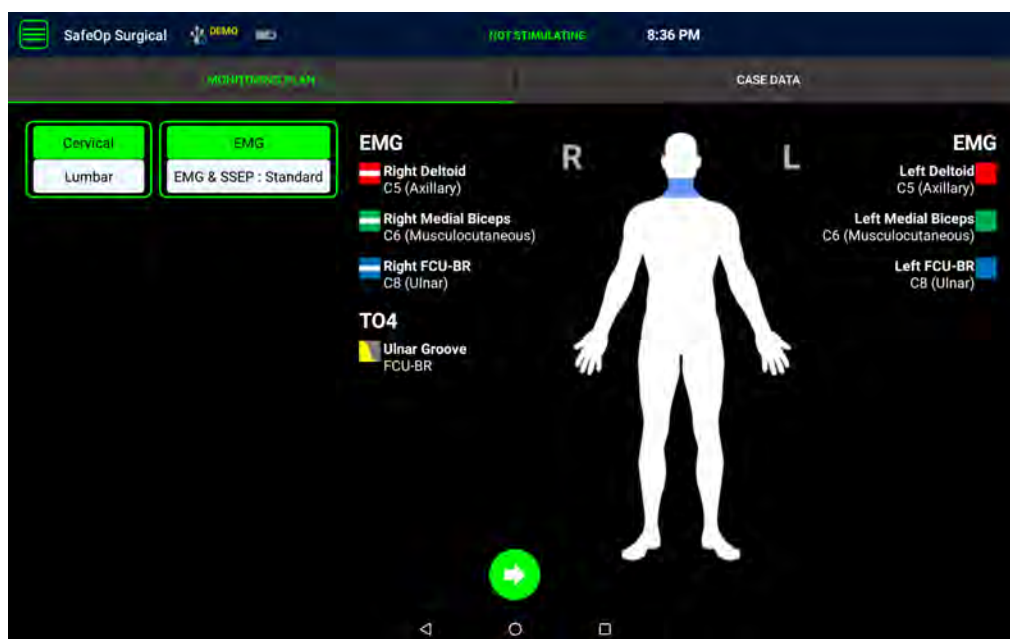

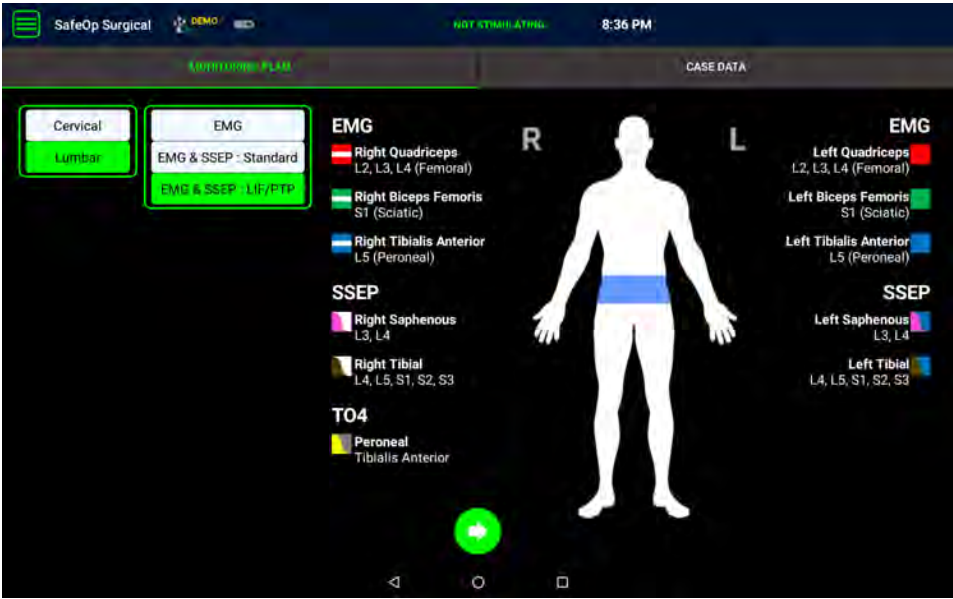Figure 9: Monitoring Plan and Case Data Screen

Figure 10: Monitoring Plan displayed after choosing from each of the two left side columns

8. To choose what is going to be monitored select a 'Monitoring Plan' by choosing one button from each of the options in the two columns to the left. The components of the chosen plan are displayed on the right along with a pictogram.

9. Once you have chosen your monitoring plan and entered data (if any) in the Case Data area, tap the pulsating green 'Proceed' button that appears in the lower middle of the screen to move to the Sensor Check screen.

10. At this point the impedances of all the possible acquisition electrodes in the chosen monitoring plan are checked. The electrodes on the touchscreen image will be grey if the impedance check has not been completed. The electrodes on this screen will appear green when the impedance is acceptable (≤ 15 kΩ, see Figure 11) and red when unacceptable (> 15 kΩ). In the case of unacceptable impedance, check to make sure the electrode and cable connections are secure and apply or reapply a new electrode to clean dry intact skin if necessary. The impedance check will automatically cycle through the electrodes it expects to be present according to which monitoring plan was chosen and display any updated data. Touching and holding for two (2) seconds on a recording electrode presents the user with the ability to mute a channel. This effectively turns the channel off and is primarily used as a troubleshooting tool. If some electrodes that are present in the monitoring plan have unacceptable impedances, the application will enable you to proceed without resolving them. Once the system has completed the impedance check of the acquisition electrodes, it will automatically proceed to check the connection of the stimulating electrodes, which is then automatically updated every 5 seconds.
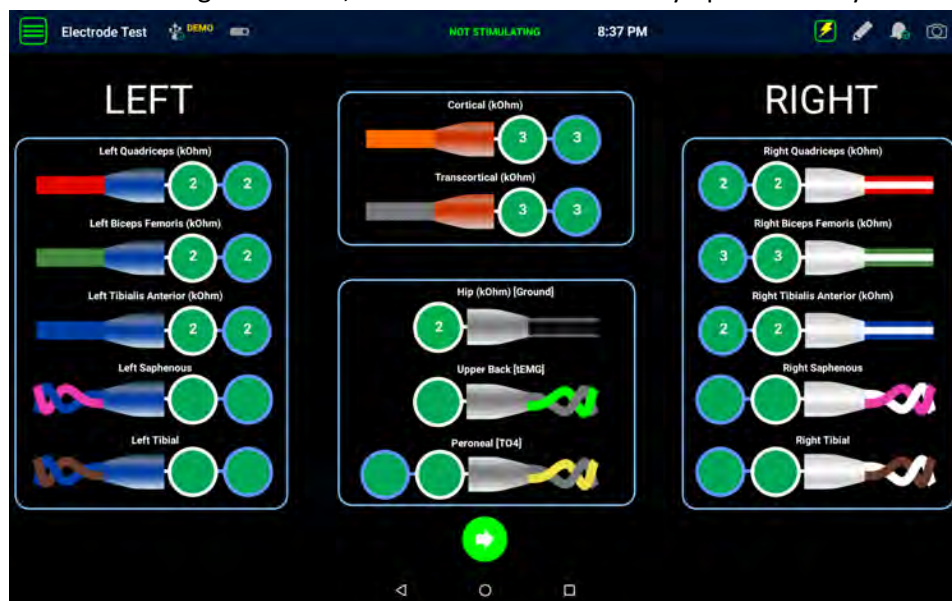

Figure 11: Electrode Check Screen

11. Once the stimulating electrodes have been checked their status will be displayed as green for passed testing and red for failed testing. Testing of the stimulating electrodes is for contact status only and does not exclude a poorly placed or high impedance electrode. If any of the stimulating electrodes do not pass the impedance test for a site, that site will not be stimulated / monitored until the electrode connection is repaired and are acceptable before proceeding.

It is important that all electrodes, both acquisition and stimulating, pass the electrode check test. Please note that once the sensor ACQ check has started it takes approximately 10-15 seconds to complete the first cycle of checking the impedance of all the acquisition electrodes. The sensor check continues to cycle until the user chooses another action. The stimulating electrodes will be automatically tested for connection every 5 seconds.

12. Electrode checks can be repeated at any time during a case when stimulation is not occurring. If during subsequent sensor checks electrodes are found to develop unacceptably high impedance, then the user is alerted, and those electrodes will not be used or monitored until the electrode is replaced or repositioned and an acceptable electrode check is again run.

Short Latency Somatosensory Evoked Potential (SSEP) Testing

After electrode setup, placement and connection to the patient, SSEPs may be monitored. If SSEPs are in the chosen monitoring plan, tapping the Proceed button on the Electrode Check screen will automatically default to an SSEP screen. Alternatively, the screens can be accessed from the Main Menu icon in the upper left.

Four tabs are available: Pictogram, SSEP Full Screen, SSEP Waterfall, SSEP Trends.

Two additional tabs will be available if the chosen monitoring plan also includes EMG: EMG Full Screen, and SSEP EMG (see EMG section on page 39).

The pictogram tab shows a simplified view of any changes in waveforms from baseline by changing the color of the limb being stimulated for the recording. If more than one nerve is being stimulated in the same limb, any change will turn the limb color.

The SSEP Full Screen tab shows recordings from each of the possible four stimulation sites in a quadrangle. The baseline and ongoing moving average waveforms are shown.

The SSEP Waterfall shows a waterfall view of the last 60 minutes of the SSEP recordings in two columns. Which waveforms are displayed is determined by which radio buttons are activated at the bottom of the screen.

The SSEP Trends tab shows the calculated amplitude and latency of any of the recorded waveforms according to which radio buttons are activated at the bottom of the tab. The Numeric History always shows one of 15 minutes, 30 minutes, 60 minutes or whole case data according to which radio button is activated at the bottom of the screen.

To begin recording, tap the 'SSEP Not Stimulating, Press to Start' button at the top of the screen while on any SSEP tab. When the stimulator is being triggered there will be a 'Stimulating' label at the top of the screen that will flash yellow.

To adjust the stimulator output current and duration level, select the 'Settings' icon while any of the SSEP tabs are active. The user can manually adjust the stimulator current and duration by either typing in a value, by pressing the "-1" or "+1" or "-10" or "+10" selections to adjust the current or choosing the duration from the drop-down menu. Press "Save" and these settings remain saved for that patient. Upon starting a new patient, the program will revert back to the default settings. To save the new settings and set them as the new default press "Save and set as default". To restore factory default settings press "Restore Factory Default Settings."

In neurophysiology, latency measurements are often done using onset latency or peak latency. The purpose of this is to measure absolute conduction velocities. The SafeOp System is not intended to measure conduction velocities. In the SafeOp System, the latency measures may be done using the first peak of the waveform, depending upon the waveform being measured.

Figure 12: SSEP FULL Screen

Figure 13: SSEP WATERFALL Screen

Figure 14: SSEP TRENDS Screen

To stop the stimulator and/or pause the averaging, press the SSEP Stimulating, Press to Stop button in the top middle of the screen. Stimulation will also stop if the 'End the current case' button on the drop down menu is pressed or if the user switches to a different modality using the drop-down menu.

The SSEP Pictogram tab will show the four limbs of the patient. The limbs are initially grey and will turn to green once the baseline has been established. The LAT and AMP for each limb are the latency and amplitude measurements taken at the transcortical recording from upper limbs and cortical recordings from lower limbs. The possible colors are: grey (not measured because of inadequate stimulation and/or undetectable potentials or not in the chosen monitoring plan), green (adequate responses), yellow (significant changes in latency or amplitude from baseline). A yellow limb indicates that the SafeOp System has detected a 50% or greater decrease in response waveform amplitude and/or a 10% or greater increase in response waveform latency as compared to baseline, changes that may signal physiological change in neural function such as nerve injury or dysfunction.[2] Please note that when the limb color changes from green to yellow it is recommended that the user review the waveforms to determine whether this is due to signal artifact or a clinical change and take appropriate action.

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[2] Nuwer M, Dawson E, Carlson L, et al. Somatosensory evoked potential spinal cord monitoring reduces neurologic deficits after scoliosis surgery: Results of a large multicenter survey. *Electroencephalogr and Clin Neurophysiol* 1995;96:6-11.
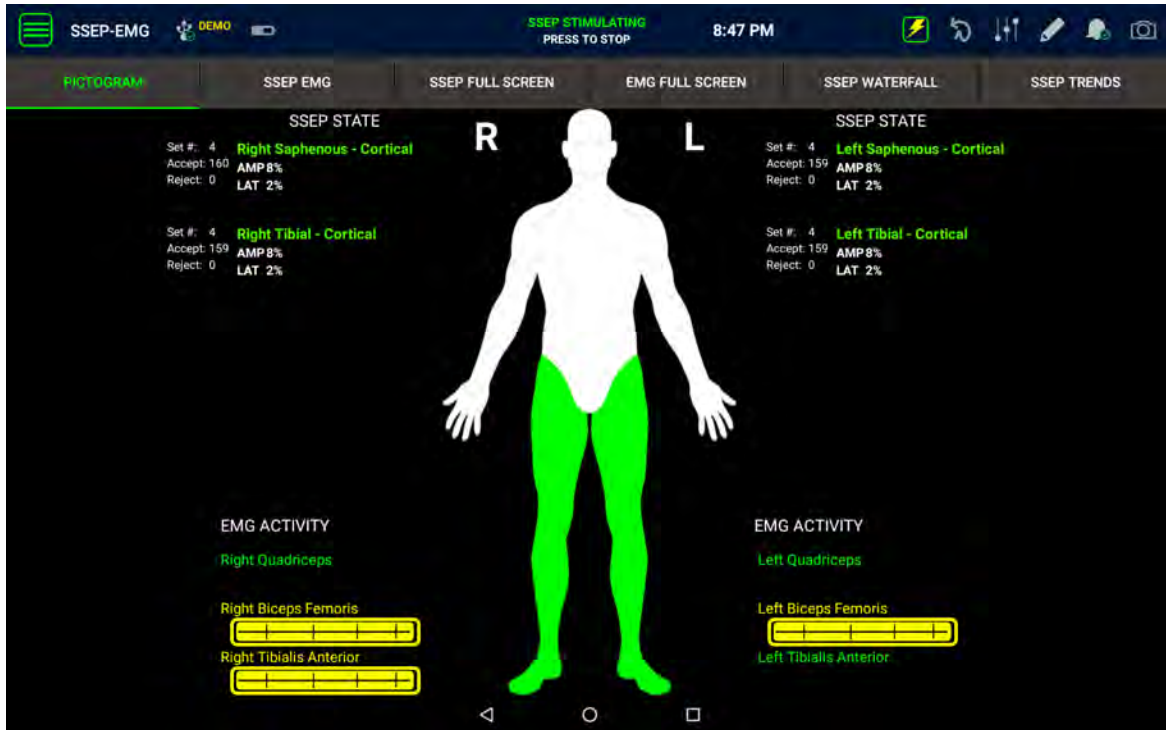
Figure 15: Pictogram Figure Screen

When the system first establishes a baseline, the user is encouraged to review the waveforms to ascertain that the algorithm has properly identified that the waveform is present and has accurately marked the onsets and peaks. If the algorithm does not believe that there is a waveform present it will highlight the trace in grey.

If you disagree with the identification of the waveforms or the marking of the peaks the user has the option of overriding the algorithm. To do this, tap anywhere on the waveform set in question on the Waveforms tab. A waveform icon will appear in the lower right corner of the window. Tap on the icon to activate it and change the onset or peak location. Then tap anywhere on the waveform to move the nearest cursor to the tap point. Repeat until satisfied with the cursor placement. If the SafeOp System finds a monitorable waveform within the new cursor area it will color the tracing. If it does not, the tracing will be grey.
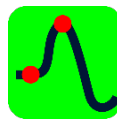

Figure 16: Icon for changing cursor locations

Neuromuscular Junction Testing

To start a neuromuscular junction test, also known as a "Train of Four" (TO4) test, press the Menu icon on the upper left side of the screen and choose TO4 Test.

To adjust the stimulator output current and duration level, select the 'Settings' icon while any of the TO4 Tabs are active. The user can manually adjust the stimulator current and duration by pressing the -1 or +1 or -10 or +10 selections to adjust the current or choosing the duration from the drop-down menu. Press Save and these settings remain saved for that patient. Upon starting a new patient, the program will revert back to the default settings. To save the new settings and set them as the new default press Save and set as default. To restore factory default settings press Restore Factory Default Settings.

Train of Four

In this test, the nerve indicated in the monitoring plan is stimulated and the associated muscle (tibialis anterior or BR-FCU) is the acquisition site for this test.

The application will automatically stimulate the nerve four times with a frequency of 2 Hz and will display the motor action potentials on the screen (see Figure 17).

The number of responses above an amplitude of 0.5 mV and the average ratio of the peak-to-peak amplitude and negative peak amplitudes of the fourth response (if present) to the first response is calculated and displayed on the screen.

The history of up to the last 4 TO4 measurements taken can be seen on the TO4 History Tab as columnar or bar graphs with the most recent on the left (see Figure 18).

Figure 17: Train of Four showing waveforms

Figure 18: TOF History Screen

Electromyography (EMG) Testing

There are two types of EMG tests: Spontaneous EMG and Triggered EMG.

Triggered EMG utilizes a separate stimulator output that is automatically chosen when the tEMG screen is active. This stimulator outputs to two green coded outputs on the top side of the SafeOp System Head Unit and returns current to the adjacent 'Stim Return' input. The sterile SafeOp Stimulating Probe and sterile SafeOp Stimulating Clip may be attached for output and either the surface electrodes or subdermal needle electrodes may be used for current return.

Free Run or Spontaneous EMG

The Free Run EMG test displays information on the 'SSEP EMG' and the 'EMG FULL SCREEN' tabs.

Figure 19: EMG Full Screen

Triggered EMG

To navigate to the EMG Thresholding screen use the menu button and select tEMG. Alternately, pressing the lightning button ⚡ at the top of the screen will bring the user to the tEMG screen. If there is active SSEP stimulation when this button is pressed the system will pause SSEP stim and take the user to the tEMG screen.

Alternately, EMG Thresholding can be initiated from the sterile field by pressing the stimulation button on a compatible stimulating accessory such as the SafeOp Stimulating Clip (PN AIX1310-S) or the SafeOp Stimulating Ball-Tip Probe (PN AIX1320-S). When this button is pressed, the application will automatically navigate to the EMG Thresholding screen and begin stimulation.

The stimulator can only be active when the 'EMG Thresholding' screen is active. If the stimulator is activated when any other screen is active, the view automatically switches to the 'tEMG' screen to allow for visualization of the responses. The interrogation range may be adjusted using the dropdown beneath

the 'Press to Start' buttons. The default interrogation range is 0-20 mA. Other selectable ranges include 0-6 mA, 0-12 mA, 0-30 mA, and 0-40 mA.

The stimulator is activated by tapping one of the two 'Not Stimulating' buttons at the top of the screen, and halted by tapping a button when it shows 'Stimulating' in the same location. When the stimulator is on, it sweeps through the interrogation range repeatedly from lowest to highest stimulus intensity. Any muscle responses from stimulation are identified in the tEMG window by turning the recorded waveform yellow. The response with the lowest stimulation threshold, that is the response first identified as the stimulation intensity increases from 1 mA, displays the lowest intensity resulting in a response and is confirmed with a subsequent stimulation. If the second response is not deemed to be sufficiently equivalent (confirmed) to first, then two dashes '- -' are displayed, and the sweep repeats from the beginning. If no response is found within the sweep range the screen will show the symbol '>' followed by the maximum value of the sweep range, and the sweep will repeat from the beginning. The lowest response threshold and threshold muscle are updated with each sweep of the stimulator. This method for reporting stimulated EMG results is called the Validated Response Threshold (VRT).
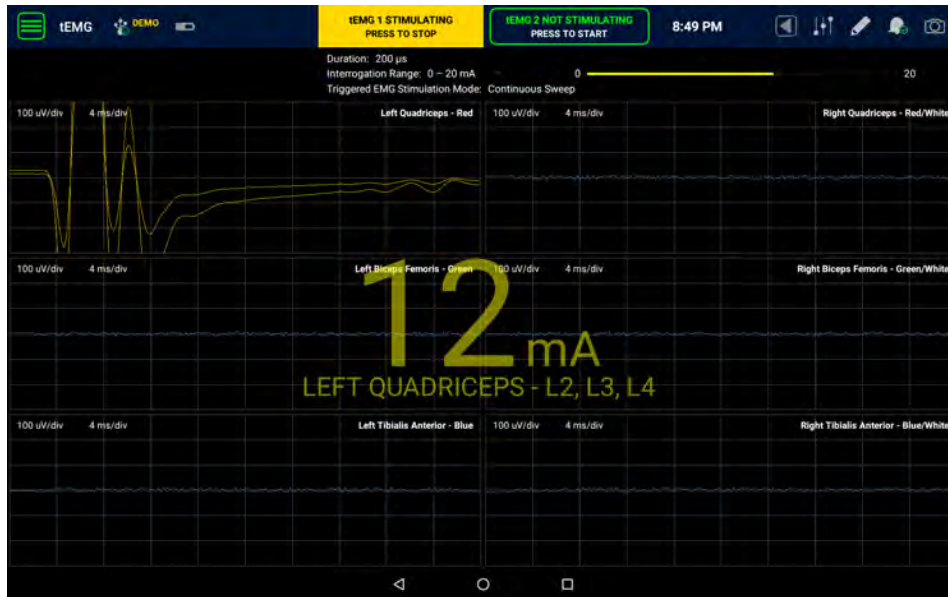

Figure 20: Triggered EMG Screen

Figure 21: EMG Settings Popup

Software Details

Baseline Calculation

When SSEP is first started the application tries to create a baseline waveform upon which all future responses are compared. The baseline is the average of a serious of stimuli taken before the initial incision. Once the baseline has been established the SSEP Waveform screen will turn the waveforms blue, indicating that this trace is now the baseline upon which all subsequent traces will be compared. The SSEP Figure screen will indicate that a baseline has been set by turning the figure's limbs from grey to green. All subsequent averaged responses are compared to this baseline to see if the latency or amplitude of the response has changed since the baseline was acquired. Please note that to optimize the latency and amplitude measurements, the baseline is processed to remove any background noise. Lack of noise in the baseline waveform may look like an artifact to the user but is a result of this processing. If the system does not detect a monitorable response a baseline will not be established and the limbs will remain grey indicating that there are not reliable waveforms to monitor. If ongoing waveforms continue to be consistent with the baseline waveform the figure limbs will remain green and subsequent waveforms will be drawn in green.

If there has been a change in the status of the patient or the recording paradigm has been changed (e.g. stimulus level increased or electrodes changed) such that the original baseline no longer applies, then the user can update the baseline by pressing the 'Reset Baselines' icon and selecting the desired baseline(s) from the pop-up window to be reset.

Events

To enter an event (such as "cautery started") during SafeOp System operation, press the 'Event' icon that appears as a pencil at the top right of the screen. Select the appropriate event from the dropdown or scroll down to reveal the text box and enter a new event using the AIX Tablet touchscreen keypad which will pop up. New events can be entered at any time and are saved in a time-stamped fashion and are reproduced in a report if one is produced using the report generator.

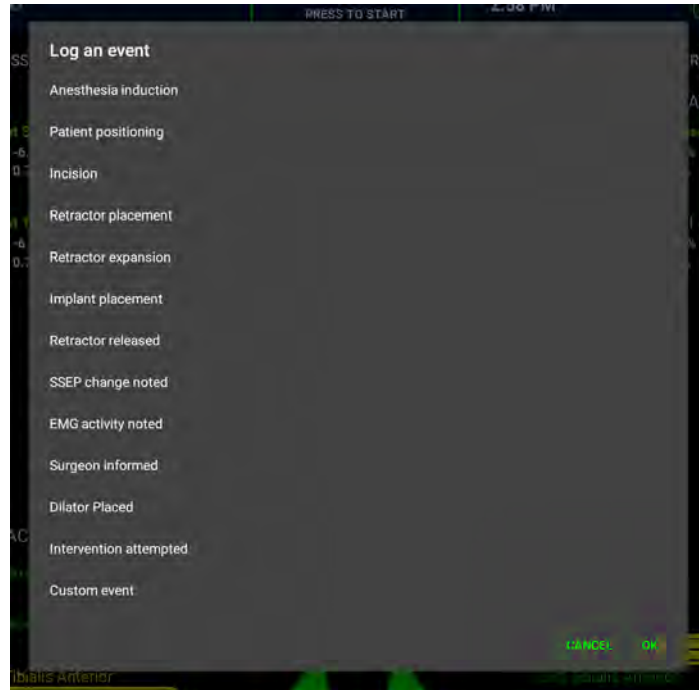Figure 22: Event Menu

Menu

Access to all the various monitoring modalities, settings, and system information is through the Main Menu. The Main Menu is made available by tapping the three horizontal bar icon in the upper left of the screen (see Figure 23: Main Menu). The Main Menu will only show those monitoring methods or modalities that are active in the monitoring plan.
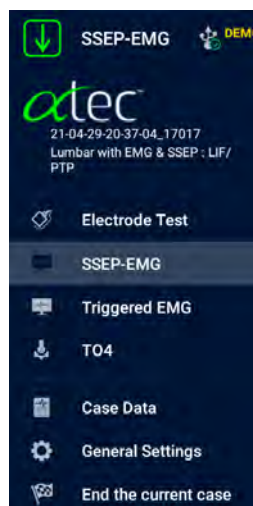

Figure 23: Main Menu

Case Data

This button takes the user back to the first Monitoring Plan and Case Data tabs that were presented at the beginning of the case. Details of the ongoing monitoring plan are presented but cannot be changed. Case Data may be revised if needed. SSEP stimulation continues during those operations unless the stimulating button is pressed to pause it.

To return to another screen (e.g., SSEP-EMG) choose it from the hamburger icon drop down menu.

General Settings

The General Settings screen provides the options to edit the type of SSEP data logging (single sweep or averaged epochs), change the SSEP alerting sensitivity, change the percentage of waveforms resulting in an alert, alter the triggered EMG sound produced for thresholding (tonal sound or read numeric) and alter the degree of EMG data logging. It is recommended that none of the default settings be changed by anyone other than an experienced user.

The About menu at the bottom of the General Settings screen allows the user to see the versions of software for both the AIX Tablet and for the SafeOp System Head Unit.

Ending a Case

To end a case and start a new case, choose the checkered flag icon from the drop-down menu.

Note: Patient information, if entered, will remain present if a case is restarted, even if the AIX Tablet or device has been turned off in between. To prevent inadvertent display of patient data from the last case always choose to end the last case before turning off the unit.

Alerts

Please note that the pictogram interface is in the anatomical position with right side on left screen and left side on right screen while the Waveforms screen is arranged opposite to this. A multiplicity of alerts suggests that there is excessive noise that is not being adequately filtered or a malfunctioning system. Generalized changes in all limbs suggest a systemic cause such as hypotension or cooling of the patient and is likely not a positioning effect. If cooling has occurred such that all amplitudes are reduced and to avoid false positive alerts the baseline can be reset. Finally, if an alert does not make clinical sense, check the waveforms to confirm that the algorithm has been collecting and analyzing waveforms correctly.

The Over Voltage Alert

The stimulator in the SafeOp System Head Unit is a constant current stimulator. As an example, if the SafeOp System Head Unit is asked to deliver 10 mA, and the impedance is 5 kΩ, the stimulator circuit will adjust the voltage to 50 volts so that 10 mA is delivered to that stimulator location. If the stimulator circuit impedance is 10 kΩ then the SafeOp System Head Unit will raise the voltage to 100 volts to achieve the desired 10 mA of current. If the stimulator electrodes have too high of impedance or have fallen off the patient, then the SafeOp System Head Unit will reach its maximum output voltage and will generate a message on the stimulating button to tell the user that something is wrong with the stimulating electrode. The alert identifies the channel involved.

Message Alerts

The SafeOp System may deliver popup messages to the user to aid in assessing the device status or in troubleshooting. The messages displayed may include the following:

Alert Message	Circumstance
Waiting for Head Unit	The AIX Tablet has not yet connected to the SafeOp Head Unit via either Wi-Fi or USB. If this status persists see 'troubleshooting.'
Fault	A fault alert will be generated if the system determines there may be an error in the stimulator control, even if caused by benign external stray electrical noise. In those instances, the system will halt. The user should contact technical support.

Figure 24: Alert Messages with Descriptions

Pictogram Status Change Alerts

A graphical alert occurs when there is a recognizable change in amplitude or latency unhampered by significant noise that repeats consecutively at least once. The alert is also indicated in the waveforms by a change of waveform color to yellow. An audible alert also sounds (see Figure 15: Pictogram Figure Screen).

Spontaneous EMG activity is indicated by a change in color of the muscle name and production of a yellow EMG activity badge below it.

Other Icons

Icon	Type	Function
📷	Action	Takes a screenshot of current screen and saves it to the case folder. Provides a feedback notification when complete.
💾	Information	Indicates that the AIX Tablet memory is 70% full and needs to be managed.
↩	Action	Resets baselines to most recent viable SSEP waveforms if present.
🔔 🔕	Action	Allows user to turn on and off sound alarms and indicates if sound alerting for any modality is turned on or off. Yellow indicates some sound alerting is on while some is off.
▭	Information	Spontaneous EMG activity has been detected for the associated muscle. Review the waveforms.
📶 🔗 🚫	Information	Indicates state of connection to Head Unit: Connected by Wi-Fi, Conncted by USB, Not connected.
⬆ ⬇	Information	Indicates a short-term trend in amplidude of SSEP waveforms: amplitude trending higher, amplitude trending lower.
✏	Action	Opens drop-down list allowing the user to enter a time-stamped pre-defined or custom comment for the report.
⫬	Action	Opens the contexual Settings page for the currently viewed monitoring modalities.
⚡ ◀	Action	Navigates to EMG Thresholdiong screen and pauses SSEP stimulation if occuring. Navigates back to prior screen.
☰	Action	Opens main navigation menu for access to individual monitoring modality displays, Case Date, Electrode Test, General Settings, and to end the case.
✒	Information	Indicates that electrocautery has been detected and signal acquisition transiently haulted.

Turning On and Off Sound Alerts

Sound alerts for individual monitoring modalities may be turned on or off by tapping on the sound bell icon and choosing one or more of 'SSEP', 'EMG', 'EMG Thresholding' or 'Global' functions. Choosing 'Global' turns off all sound alerts. Tapping it again returns to any level of sound alert that was previously present.

If some but not all of the sound alerts are turned off, a bell icon with a half yellow circle appears in the status bar.

SafeOp System Troubleshooting Guide

Setup

PROBLEM	Possible Cause	Solution
Tablet will not turn on	Not pressing power button long enough	Press the power button on the bottom right of the Tablet for at least 6 seconds or until the Android logo appears.
	Tablet is discharged	Make sure Tablet or Docking Station is plugged into power outlet and the Tablet is properly seated in the Docking Station. Wait for a few minutes and then try to power it on. Keep Tablet attached to Docking Station or directly to the power supply until it is fully charged. The Tablet must seat securely in the charger to get full charge. Keep 'Adaptive Brightness' active on the tablet (Settings>Display) to reduce battery drainage.
	Tablet is broken	Replace Tablet. Contact SafeOp support.
	Tablet is asleep	Push power button to wake.
Tablet touchscreen is unresponsive	Power cable overlying screen	Remove any overlying power cables from the screen.
	Screen is broken	Test the screen responsiveness outside the SafeOp application and after Tablet restart. If all screen touch function is unresponsive the screen may be broken. Return the tablet for service.
Surface electrodes will not stick or will not stick well	Cream on patient skin	Clean patient skin with mildly abrasive skin cleaner (e.g., NuPREP), *wipe off cleaner* (non-alcohol-based cleaners do not evaporate) and apply new electrode to <u>dry clean skin.</u>

	Patient is excessively sweaty or drooling on electrode	Remove electrode, wipe skin dry and reapply or place new electrode.
Surface Electrodes detach or peel away	Too much tension on electrode wire	Relieve tension on electrode wire. Replace electrode if necessary. Tape electrode tail and tape a loop of wire as strain relief.
	Electrode dislodged by tight wrappings or manipulations	If accessible remove electrode, wipe area dry and replace.
Cables will not insert	Wrong cable for port	Cables are color-coded at their insertion point with the Head Unit. Match cable color to Head Unit receptacle / port color.
	Cable is not aligned with Head Unit receptacle	The cable inserts have ridges that align to grooves on the insertion point to the Head Unit. Place the cable connector into the Head Unit receptacle and gently rotate the cable until you feel the ridges fit into the grooves. Then gently insert until you feel a click. The arrows on the cable connector should point toward the side of the SafeOp System with the logo.
	Cable is broken or bent and will not insert	Replace cable.

Connecting Tablet to Head Unit

PROBLEM	Possible Cause	Solution
Waiting for Head Unit	Head Unit not powered up or turned on	Check that power cord is plugged in and attached to Head Unit. Check that power switch is turned on and green LED power indicator is lit.
	Wireless pairing lost – pairing message request displayed	Confirm that Wi-Fi is enabled on the tablet and Head Unit is powered on. Use the supplied SafeOp Data Cable if the issue persists.
	Wireless turned off on tablet	Go to device apps interface, choose 'Settings', tap the button on the right beside Wi-Fi® to 'ON'.
	Wi-Fi® has been previously connected to a network with internet service	Go to the Tablet Wi-Fi® settings and 'forget' any outside networks.
	Too far from Head Unit	Move to within 10 feet of Head Unit without intervening obstacles.
	Tablet is in 'Airplane' mode	Go to the tablet settings and turn off 'Airplane' mode.
	Wi-Fi® functionality is broken	Connect using provided USB to go connection cable. Contact SafeOp support.
	Excessive electromagnetic noise interferes with communication	Separate the SafeOp System Head Unit and Tablet from other equipment or use USB connection.
	Wi-Fi® connection interrupted and fails to reconnect automatically	Reset Head Unit by momentarily turning the Head Unit power off, then on again to re-establish Wi-Fi® connection.

Entering Patient Demographic Data

PROBLEM	Possible Cause	Solution
Data does not appear to save	By design	Data is automatically saved upon proceeding to another screen.

| I don't want to enter patient data | By design | Patient data does not have to be entered to use the SafeOp System. Simply tap 'Proceed' to go the electrode check. |
| Keyboard is in the way of the buttons | By design | Press the down button at the bottom of the keyboard to move it off the screen. |

Running Acq and Stim Checks

PROBLEM	Possible Cause	Solution
Acquisition or stimulation electrode fails with surface electrodes	Poor adhesion	Remove old electrode and WIPE CLEAN AND DRY. Replace electrode. Tape tail.
	Electrode failure	Check electrode connection to both the patient and the harness, and replace if necessary.
	Electrode has been saturated with cleaning solution (e.g., Proviodine)	When placing electrodes in an area that might be subject to liquid exposure cover it with an adhesive membrane such as Tagaderm or consider a different location if possible.

Collecting SSEP Waveforms

PROBLEM	Possible Cause	Solution
SSEP waveforms are absent greyed out) after baseline collection	Poor STIM (stimulator) electrode placement	Check STIM (stimulator) electrodes are properly placed in accordance with diagrams.
	Poor ACQ (acquisition) electrode placement	Check that ACQ (acquisition) electrodes are properly placed in accordance with diagrams.
	Patient pathology such as diabetic neuropathy	The SafeOp System is performing correctly. If peripheral nerve injury is present there may be insufficient nerve activity to be monitored.

	Stimulator setting is too low	Check stimulator settings (tap the settings icon on the action bar at the top left of the screen) and increase stimulation duration or intensity if necessary. Choose 'Save' to save for this monitoring case only and 'Save and Set as Default' to use on this and future monitoring cases. Choose 'Reset Baseline' upon exiting.
	SafeOp System has not identified a monitorable waveform even though it is present	The SafeOp System tries to identify any monitorable waveform. If the waveform is outside the expected range of occurrence it may not be identified. To mark the waveform correctly, go to the Waveform screen, tap to display the pointer finger and tap the pointer finger to make it active. Next tap the waveform at the points where the cursors should appear. Tap the pointer finger icon again to deactivate it.
	Excessive rejection of waveforms is present	Check electrode causing rejection and replace if necessary. If all electrodes are rejecting check and replace ground electrode if necessary.
Stimulator won't go above 70 milliAmps	The 'auto stim control' is on	Go to Menu>Settings and turn off the auto-stim control.
Collecting waveforms is taking a long time	Excessive waveform rejections due to noise	Re-run ACQ check and STIM check. Replace or fix electrodes if needed.
	Collection is paused	Collection will pause if user switches to TO4 or tEMG screens or taps the pause button. Tap Stimulation button at the top of the SSEP screen.

The SafeOp System appears to be monitoring the incorrect peak	The SafeOp System has calculated the wrong peak because it is not a typical waveform	To change the peak that the SafeOp System is monitoring go to the waveform window. Tap the window, then tap over the pointer finger that appears. You may now adjust the cursor by tapping over the area on the waveform you feel the cursor should be at. Tapping the pointer finger again will remove it from the screen.

Collecting TO4 Waveforms

PROBLEM	Possible Cause	Solution
No waveforms appear	TO4 ACQ electrode is improperly placed	Check location of recording electrode. Remove, wipe dry and replace if necessary.
	Patient is paralyzed	Taking a baseline TO4 test prior to administering paralytics is often useful.
	ACQ cables are not plugged in or connected to the electrode.	Check cable and cable connections. Connect if necessary.
	TO4 stimulator is set too low.	Click on 'Stimulator Settings' in the TO4 screen and adjust stimulator settings.
	Patient has severe neuropathy	TO4 testing may not be available. As an alternative, the Anesthesiologist can perform an alternative twitch test.

Collecting EMG Waveforms

PROBLEM	Possible Cause	Solution
Visual alert but audible alarm does not sound	Volume is turned down	Toggle the volume up using the '+' button at the bottom of the tablet face.
	Audible alert is turned off	Toggle the audible alert on by pressing the bell icon until no bar overlays it.

Alert occurs repeatedly despite no surgical activity	Device may be alerting to extraneous noise	Run electrode check. Replace or repair electrode(s) if necessary.
	New electrically noisy device placed or started nearby	Reposition new device or SafeOp System cables/electrodes away from each other.
No Free Run waveforms appear	EMG is not chosen in the monitoring plan	Change monitoring plans.
	EMG electrodes are not placed or not connected	Place and connect electrodes.
	Wi-Fi® connection has failed	See Connecting Tablet to Head Unit above.
No triggered response is seen	Stimulator electrode failure	Replace or repair electrode making sure the electrode is placed on clean dry skin.
	EMG is not chosen in the monitoring plan	Change monitoring plans and restart case.
	EMG electrodes are not placed or not connected	Place and connect electrodes.
	Wi-Fi® connection has failed	See Connecting Tablet to Head Unit above.
	Responses are not present within the chosen sweep range	A response may not be present within the range chosen or the effective range of the stimulator. You may adjust sweep ranges in settings.

Dealing with Alerts

PROBLEM	Possible Cause	Solution
Low/No Audio	Volume is turned down	Press the '+' button on the Tablet to increase volume.
	Audible alert is turned off	Confirm audio is enabled on the SafeOp application.

Alert occurs or remains despite repositioning or intervention	Repositioning may not have adequately relieved the problem to restored normal nerve function which can take up to 20-30 minutes	If position is the suspected issue, wait 10-15 minutes. Try repositioning again if able.
	Stimulating or acquisition electrodes may be coming detached	Run ACQ and STIM check. Replace or repair electrode(s) if necessary.
	Patient has cooled excessively	Check patient temperature. Increase stimulation intensity slightly.
	Baseline waveform is too small to reliably monitor	The SafeOp System tries to identify any monitorable waveform. If the waveform is too small, it may be subject to variation due to noise. This may cause a false alert.
	Excessive noise is present	The SafeOp System uses ultra-high fidelity amplifiers and digital filters, however occasionally excessive noise may contaminate the signals and cause a false alert, particularly if any of the electrodes fail. View the waveform screen. If there is a large amount of noise in the waveforms run an ACQ and STIM check. Replace any high impedance or failed electrodes on dry clean skin if necessary.
Over Voltage Alert (in red)	Stimulator electrode failure	Replace or repair electrode making sure the electrode is placed on clean dry skin.
	Electrode or cable is not attached or has become detached	Pause stimulation if needed. Check cable and electrode attachments and repair if necessary. Run STIM check to verify that the stimulators are adequately attached. Restart stimulation.
Check probe message	Stim Return electrode not placed	Confirm that tEMG electrode is in contact with the patient and connected to the Head Unit.

	Stimulating accessory not in contact with patient	Confirm that the Clip or Probe is connected to the Head Unit and is in contact with the patient.

Artifact

PROBLEM	Possible Cause	Solution
SSEP stimulus artifact on Electrocardiogram (ECG)	SafeOp System SSEP stimulator may be overlapping ECG cables or close to ECG electrodes	Move cables away or turn on pacemaker filter on ECG monitor.
SSEP stimulus movement artifact on pulse oximetry	Pulse oximetry is placed on finger or toe moving due to SSEP stimulus	Move pulse oximetry to non-moving extremity or earlobe.

PROBLEM	Possible Cause	Solution
Error Code ##	The system determined there may be an error in the stimulator control, even if caused by benign external stray electrical noise	Press "OK" to clear message. If issue persists, turn the Head Unit off and back on. Close the SafeOp app by pressing the Square button and swiping left on the SafeOp app's window. Reopen the SafeOp app and select "Resume Case."

SafeOp System Operator Manual

The Operator Manual for the SafeOp System is available electronically on the Tablet and is accessed from the desktop.

Guide to the buttons on the SafeOp System Tablet:

Icon	Name	Meaning
or	Back	Goes back, closes the application and dismisses the on-screen keyboard
or	Home	Goes to the home screen

Icon	Name	Meaning
⬜ or ◻	Recent	Displays recently opened apps
⌄	Hide	Dismisses the on-screen keyboard
⋮	Menu	Displays the menu for the app. This icon is often found on the top right of the screen.
⇅	Settings	Adjusts the settings in the app or on the tablet.

Tapping the round 'Home' button while the SafeOp System application (app) is running takes the user to the Android home page. The application continues to run in the background, but only audible alarms will be available. To access the SafeOp System application again, tap the 'Recent' square button. An icon of the running SafeOp System app will be shown and the program can be accessed by tapping on it.

Tapping the triangular 'Back' button while the SafeOp System application is running brings up a dialog box telling the user to tap again if they are sure that they want to exit. Tapping again will exit the SafeOp System application. Not tapping will return to it automatically after a few seconds.

Maintenance and Security

Safeguarding Patient Identifying Data on the SafeOp System

The SafeOp System provides recordings of somatosensory evoked potentials, electromyography, and neuromuscular junction tests. It has been designed for ease of use and is meant to be operated by facility personnel. The only portion of the SafeOp System which stores any data is the AIX Tablet.

All patient identifying data is stored in an encrypted format. Responsibility for maintenance of the security of any sensitive data entered into the AIX Tablet either in the application or otherwise lies solely with the user.

SafeOp System devices are supplied in an initiated state with the most current software and settings required for stable operation. The initiated state is sanitized of any sensitive or encrypted information which is considered the default factory setting. You may restore the system to the default factory settings at any time which will remove any files or saved settings that are on the device (see "factory data reset below").

Protected Health Information (PHI)

The SafeOp System ***does not require that the operator enter any PHI in order to function properly*** and does not recommend it unless required by hospital protocols. The application does allow the operator to enter additional notes.

Each case is stored in its own folder under EpadFiles.

Each case folder is named by date and time of the recordings.

The additional notes, if created, and case data reside only on the Tablet and only in the case folder in an encrypted file. If a report has been generated using the SafeOp System report generator, then this information is copied to the password protected file(s) 'report.pdf' located within the associated case folder. In the event that PHI was typed into the additional notes section, and a report was created, the PHI would reside in the resultant .pdf file report which is not encrypted but password-protected.

The user may encrypt the Tablet. To accomplish this, follow the instructions below in 'Encrypting Your Device'. Alternatively, the user may limit access to the device using a passcode.

Encrypting Your Device (This procedure may change with updates of the Android operating system. Refer to the Google Android support website for the most up to date procedure):

1. Plug your device into the charger and allow it to fully charge.

2. Schedule an hour or more for the encryption process. If you interrupt the process, you will lose some or all of your data.

3. Set a lock screen PIN, pattern, or password.

- Open the Settings menu on your SafeOp System Tablet

- Under 'Personal,' touch 'Security.'

- Under 'Screen security,' touch 'Screen lock.'

- Choose 'Pattern,' 'PIN,' or 'Password' as your screen lock.

- You'll be prompted to add additional data protection to your device by requiring this PIN, pattern, or password when your device starts up.

Note: A Wi-Fi®-paired device such as the SafeOp System Head Unit won't function when your Tablet initially starts up. You will need to enter your PIN, pattern, or password in order to start Android and initiate the connection.

4. Set your PIN, pattern, or password and touch 'Continue.'

5. Power off the Tablet.

6. Power on the Tablet and enter your Pattern, PIN, or Password.

7. Tap 'Menu.'

8. Select 'Settings.'

9. Choose 'Security.'

10. Tap 'Encrypt tablet' and then 'Encrypt Tablet' again on the following screen.

Note: If the Tablet is not fully charged and plugged in, the process will not start.

11. You will be asked to enter your PIN to continue.

12. Hit 'Encrypt Tablet' again.

PHI and waveform data can be erased at any time from the AIX Tablet through the SafeOp System report generator interface or by using a file browsing utility. While these utilities allow some security during daily use, they may not fully remove PHI but only the pointers to it. Specialized software may allow access.

If PHI has been entered into the AIX Tablet and if the AIX Tablet is being returned to Alphatec for service or other reason Alphatec recommends that the Tablet be sanitized according to NIST 800-88r1 standards. To accomplish this on the AIX Tablet follow the instructions in the section 'Sanitization of AIX Tablet Device' below.

Sanitization of AIX Tablet Device (using Android 5.1 or later)

Sanitization of the AIX Tablet may be accomplished by performing an 'Erase data' function using the Settings menu.

Erasing your data may take some time, so make sure that you plug your device in to a power source before you start.

- o   Open your device's Settings menu.

- o   Under 'Personal,' touch 'Backup & Reset.' You may need to enter your pattern, PIN, or password.

- o   Under 'Personal Data,' touch 'Factory Data Reset' > 'Reset Tablet.'

- o   If you have a screen lock, you'll need to enter your pattern, PIN, or password.

- o   When prompted, touch 'Erase Everything' to erase all data from your device's internal storage. This may take some time.

- o   When your device has finished erasing, select the option to reboot your device.

- o   Manually navigate to the SD card and confirm that the 'EpadFiles' folder has been erased.

Exporting Data from AIX Tablet

The SafeOp System does allow exportation of waveform data with or without PHI over direct USB connection in native data format. The responsibility for the security of any data exported form the SafeOp System lies with the user. If the operator chooses to connect the SafeOp System to a network SafeOp recommends the following:

- o   Only connect to a trusted Wi-Fi® network.

- o   Install a reputable antivirus software.

- o   Disconnect from the Wi-Fi® network after each data export or support activity.

The SafeOp System does not need to be connected to a Wi-Fi® network at your facility to function properly. It should NOT be used for connecting to the internet unless this is required for remote support or troubleshooting activities supplied by the manufacturer.

Cleaning and Disinfection

The SafeOp System Head Unit can be wiped clean with a soft, damp cloth using nonconductive distilled water and/or electrically nonconductive inert surfactants. It is important to dry off the units quickly. Avoid letting liquid seep into any of the internal electronics of the system. Do not use any abrasive cleaner on the system. The SafeOp System Head Unit cannot be adequately disinfected if it becomes contaminated with blood or other body fluids. Dispose of or return a contaminated SafeOp System Head Unit to the manufacturer following hospital protocol approved procedures.

The SafeOp System electrodes, cables, probe and clip are for single patient use only and should be disposed of after use following hospital protocol.

Routine System Operation Check

In a solid-state system, with no moving parts, there is no need for mechanical routine maintenance. However, Alphatec recommends that each unit be returned to the manufacturer on a yearly basis for routine review, or as any time if there is physical damage, the appearance of system dysfunction or when recommended by technical support.

General Preventative Maintenance and Memory Management

To keep the SafeOp System in good working condition, follow a regular schedule of preventative maintenance as recommended below. Regular preventative maintenance does not involve access to the interior of the SafeOp System Head Unit and components. For service problems that require corrective maintenance and/or internal component service, contact Alphatec Customer Service.

Regularly inspect and clean all system components by wiping with a clean, damp, lint-free cloth (see Maintenance Warnings below), including:

- Connectors on the SafeOp System Head Unit
- Head Unit Power supply
- AIX Tablet

Note: Taking basic care of the system and avoiding extreme physical abuse helps prolong the lifespan of system components.

The AIX Tablet may gradually fill its own memory with study information. When the memory is 70% full, a floppy disc icon will appear in the status bar . Study files should be removed at that time. The user may also check that the file system still has room left by checking memory usage under settings in the Android operating system.

SafeOp System Tablet Battery

The Tablet battery should be replaced when it no longer holds a charge for at least 2 hours without needing to be plugged in. Note that a case can still be run even under these circumstances with the Tablet plugged into the charger or power connected cradle. Do not attempt to change the battery. Please contact your Alphatec sales representative for instructions on returning the Tablet for battery replacement.

Maintenance Warnings

⚠ Disconnect the SafeOp System Head Unit from the power supply before wiping. Disconnect all cables. Use a lint- free cloth. Do NOT use cleaners on any system component.

⚠️ Be careful not to allow any fluid to seep into the internal electronic components of the Head Unit or cables.

Leakage Current Measurement

To measure the leakage current from the SafeOp System Head Unit it is important to measure both chassis leakage and patient leakage.

Using a leakage meter, plug the SafeOp System Head Unit into the meter and confirm that the chassis leakage is less than the local requirement (see Figure 25).

To measure the patient leakage, it is necessary to use adapters into the cable ends to provide a connection to the patient cable. Please contact Alphatec Spine, Inc. to obtain adapters (p/n 100078).

Current in µA

APPLIED PART TYPE	NORMAL CONDITION	SINGLE FAULT CONDITION
BF	100	500
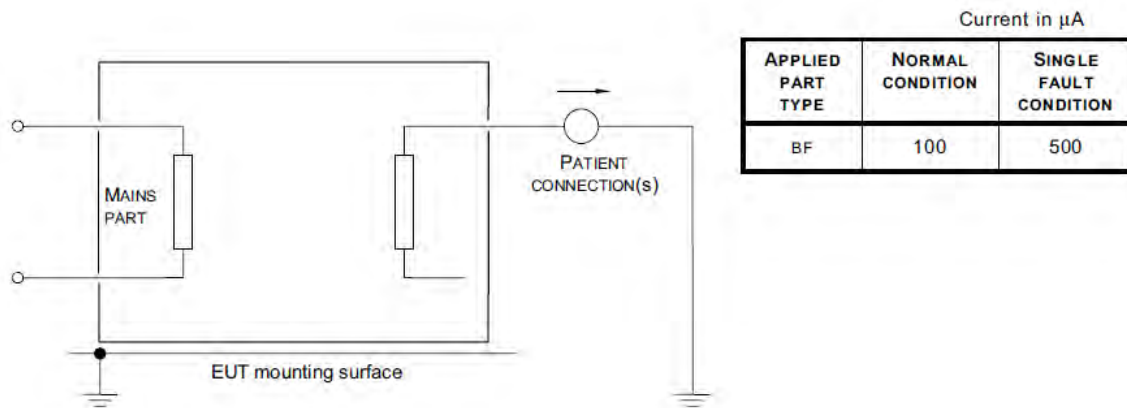
Figure 25: Patient Leakage Current IEC60601-1 method and limits

Returning SafeOp Systems or Parts

Do not discard or dispose of any SafeOp System components, either malfunctioning or functioning into regular waste. Return all items to Alphatec Spine, Inc. or its designated agent for proper disposal.

To return an item contact Alphatec Spine, Inc. use one of these means:

In North America

Alphatec Spine, Inc. Customer Service:
Tel: 1-800-922-1356

Please include details of the items the user wishes to return, the reason for the return (s), whether the item(s) appears to be malfunctioning and whether the return is associated with a complaint. Upon

replying, customer service will supply the user with an RMA number and appropriate postage if necessary.

SafeOp System Possible Software Stimulation and Display Settings

EMG

Free Run

Time Base: 1 s/div

Display Gain: 10-2,000 µV/div (100 µV/div default)

Stimulated (Triggered) EMG

Display Gain: 20-5,000 µV/div (100 µV/div default)

Stimulator Frequency: 5 to 20 Hz

Stimulator Pulse Duration: 200 microseconds

Stimulator Interrogations Ranges:

0-6 mA, 0-12 mA, 0-20 mA, 0-30 mA, 0-40 mA

Sweep Behavior: Continuous repeated sweeps or sweep once to threshold

SSEP

Stimulator Frequency: Fixed

Stimulator Pulse Duration: 100, 200 or 300 (default) microseconds

Stimulator Pulse Current: 0-100 mA (default 30 mA upper & 50 mA lower extremities)

Display Gain: 0.25 to 8.0 µV/div (default 1 µV/div)

NMJ

Stimulator Frequency: Fixed per test

Stimulator Pulse Duration: 100, 200 (default) or 300 microseconds

Stimulator Pulse Current: 0-70 mA

Display Gain: 100-10,000 µV/div (default 2,000 µV/div)

SafeOp System Hardware Specifications

SafeOp System Head Unit and Power Supply

General Specifications

Classification: Class I

Type: Type BF applied part

Protection against Ingress of Water: IP22 (Power Supply Only)

Power Supply: 100 to 240 VAC, 50-60 Hz (input); 12 VDC, 2.5A (output)

SafeOp System Head Unit Power Input: 12 VDC 2.5A

Mode of Operation: Continuous

Power Consumption: < 24 W

Operating Environmental Limits:

Temperature: 50°F (10°C) to 104°F (40°C) (max 95°F (35°C) for power supply)

Relative Humidity: 30%–75%

Altitude: Up to 2000 meters above sea level

Atmospheric pressure: 700 hPa to 1,060 hPa

Transport and Storage:

Temperature: -40°F (-40°C) to 158°F (70°C)

Humidity Range: 10–100%, including condensation

Atmospheric Pressure: 942 hPa to 1,060 hPa

Dimensions: Head Unit: 12"W x 8"H x 2"D

Weight: < 2 lbs

Patient Environment: All parts of the SafeOp System can enter the patient environment.

Protection against Flammable Anesthetics: Not suitable to be used in the presence of flammable anesthetics.

Minimal Stimulator Load: The SafeOp System stimulator channels are expected to be used in stimulating tissue with a minimal load of 1000 Ohms.

System Architecture: 8 independent 16 bit analog-to-digital converters with 20,000 Hz sampling per channel

SSEP Waveform Acquisition

Time Base: 2 ms/division to 10 ms/division

Sensitivity: 0.5 µV/division to 20 µV/division

Acquisition: Can record up to 8 EP recordings simultaneously. All recordings are differential.

Rejection: Independent rejection for each channel plus cautery detection ground lead

Impedance Measurement: +/- 30% when values displayed

Amplifiers

Number of Channels: 8 differential in software and hardware

Sensitivity: 0.5 µV/division to 20 µV/division

Input Impedance: > 50 MΩ (at DC)

CMRR: >93 dB

SSEP Acquisition Channels:

LFF: 10 Hz

HFF: 2.7 kHz

EMG Acquisition Channels:

LFF: 30 Hz

HFF: 2.7 kHz
Notch Filter: 50 or 60 Hz (unused)
Noise Level: < 20nV/√Hz

Stimulator
Number of Outputs: 4 for SSEP, 1 for triggered EMG
Intensity: 0–100 mA for SSEP; 0–40 mA for triggered EMG
Duration: 0.1, 0.2 or 0.3 milliseconds for SSEP; 0.05, 0.10 or 0.20 milliseconds for triggered EMG
Pulse Repetition Frequency: from 0.1 Hz to 50 Hz
The pulse repetition frequencies are not user adjustable through the user interface.
Accuracy: 30%
Maximum Voltage: 380 VDC
Load Impedance Range: 1000 Ω to 3600 Ω

The stimulator is designed to provide constant current for the specified duration. The maximum voltage between the stimulator anode and cathode is 380 V; if the load impedance exceeds the maximum range the stimulator may not be able to deliver the set current intensity. There is no significant DC component of the stimulator other than the stimulator pulse itself.

AIX Tablet

Operating System:
- 200507-SS – Android 6.01 powered tablet with software encryption for enterprise-grade security and management.
- AIX11801 – Android 9.0 powered tablet with software encryption for enterprise-grade security and management.

Power Supply: Input voltage: 16V with AC adapter

Wireless Communication (Head Unit)

Incorporated Wireless Technology: Wi-Fi®
Wireless Protocol: IEEE 802.11a/b/g/n
IEEE 802.11d/e/i/h/r/w
Frequency Band: 2.4 GHz: 1-13
5 GHz: 36-165 (U-NII Band 1, 2, 2e, 3)
Maximum Range: 30 feet to Head Unit (10 feet recommended to avoid degraded signal)
Max Power Output: 18 dBm EIRP (63 mW)
Maximum Throughput: IEEE 802.11a/g: 54 Mbit/s
IEEE 802.11b: 11 Mbit/s
IEEE 802.11n: 130 Mbit/s (MIMO),
65 Mbit/s (SISO)
Intrusion Prevention: Encrypted, passcode protected
Certifications and Approvals:
Type Approvals: Europe (ETSI R&TTE); US (FCC/CFR 47 part 15 unlicensed modular transmitter approval); Canada (IC RSS); Japan (MIC); Taiwan (NCC); China (SRRC); South Korea (KCC); Australia (ACMA); New Zealand; Brazil (Anatel); South Africa (ICASA)
Safety and Health: EN 62479, EN 60950-1, IEC 60950-1

Medical Electrical Equipment: EN 60601-1-2
Explosive Atmospheres: ATEX and IECEx

SafeOp System Surface Electrodes

Type: Solid gel, surface electrodes with Nicomatic 3-pin connection.
Nonsterile, single patient use
Use by date on package label
LOT on package label
Dispose in accordance with hospital protocol
Transport and Storage Temperature: Rhythmlink® Sticky Pad™ surface electrode is provided non-sterile and must be stored at room temperature (10°C to 40°C or 50°F to 104°F) in a clean, dry location. This product should NOT be sterilized.

SafeOp System Subdermal Needle Electrodes

Type: Paired 13 mm 27 Gauge surgical steel subdermal electrodes with Nicomatic 3-pin connection.
Sterile, single patient use
Use by date on package label
LOT on package label
Dispose in accordance with hospital protocol
Transport and Storage Temperature: Rhythmlink® needle electrodes may be stored at ambient temperatures in a clean, dry location. All sterile accessories are intended for single use only. This product should NOT be re-sterilized.

SafeOp System Stimulating Probe

Type: Disposable monopolar 2.3 mm ball tip Probe with 6 pin circular push-pull locking connection.
Sterile, single patient use
Use by date on package label
LOT on package label
Dispose in accordance with hospital protocol
Transport and Storage Temperature: SafeOp Stimulating Probes may be stored at ambient temperatures in a clean, dry location. All sterile accessories are intended for single use only. This product should NOT be re-sterilized.

SafeOp System Stimulating Clip

Type: Disposable monopolar Stimulating Clip with 6 pin circular push-pull locking connection.
Sterile, single patient use
Use by date on package label
LOT on package label
Dispose in accordance with hospital protocol
Transport and Storage Temperature: SafeOp Stimulating Clips may be stored at ambient temperatures in a clean, dry location. All sterile accessories are intended for single use only. This product should NOT be re-sterilized.

SafeOp System Component List

Part No.	Description
AIX11901	SafeOp 1.5 Head Unit
AIX1191A	SafeOp Head Unit Power Supply
AIX11910	SafeOp Head Unit Power Type I
100747	SafeOp Data Cable
200507-SS Or AIX11801	AIX Tablet
200509-SS	AIX Tablet Power Supply
AIX11802	AIX Tablet Power Supply Type I
200519-SS	AIX Tablet Docking Station
100625	Pole Clamp

Compatible Accessories List

Part No.	Description
AIX1310-S	SafeOp Stimulating Clip, Sterile
AIX1320-S	SafeOp Stimulating Probe, Sterile
AIX12010	SafeOp EMG Needle Electrode Kit
AIX12015	SafeOp EMG Surface Electrode Kit
AIX12020	SafeOp EMG & SSEP Needle Electrode Kit
AIX12025	SafeOp EMG & SSEP Surface Electrode Kit

Declaration of Electromagnetic Immunity

The SafeOp System is intended for use in the electromagnetic environment specified below. The customer or the user of the SafeOp 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 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 20% (the cited levels are adequate for relative humidity greater than 5%).

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ± 1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short and interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 VAC	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles No anomalies 95 % dip meets requirements	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or battery.
Power frequency (50 & 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The SafeOp System is intended for use in the electromagnetic environment specified below. The customer or the user of the SafeOp System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating equipment or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The SafeOp System is intended for use in the electromagnetic environment specified below. The customer of the user of the SafeOp System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic environment guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz Recommended separation distance (d): $d = 1.2 \sqrt{P}$	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SafeOp System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz Recommended separation distance (d): 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$	3 V/m	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 base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SafeOp System is used exceeds the applicable RF compliance level above, the SafeOp System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SafeOp System. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

⚠️ **WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SafeOp System, including cables specified in this manual. Otherwise, degradation of the performance of this equipment could result.**

Recommended separation distances between portable and mobile RF communications equipment and the SafeOp System			
The SafeOp System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SafeOp System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SafeOp System as recommended below, according to the maximum output power of the communications equipment, except as noted in the warning above. Should you experience interference either with the SafeOp System operation from other RF emitters or by the SafeOp System to other devices, increase the separation distance until the interference is resolved or switch from Bluetooth to USB operation of the SafeOp System.			
Rated maximum power of transmitter (W)	**Separation distance according to frequency of the transmitter (meters)**		
	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
0.10	0.38	0.38	0.73
1.00	1.2	1.2	2.3
10.0	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.			

Frequencies of portable and mobile transmitters for which the recommended separation distance is 30 cm (12 inches)

Band (MHz)	Service
380 –390	TETRA 400
430 – 470	GMRS 460, FRS 460
704 – 787	LTE Band 13, 17
800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5
1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS
2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7
5,100 – 5,800	WLAN 802.11 a/n

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