SafeOp 2: Neural Informatix System™
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The SafeOp 2: Neural Informatix 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 2: Neural Informatix 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.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS
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.

WARNINGS/CAUTIONS:
A warning advises against actions or situations that might result in personal injury or death.
A caution advises against actions or 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.

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 the user 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 docking station. 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 System electrodes.

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.

Do not remove the SafeOp tablet from the room where the SafeOp Head Unit is in use. This assures proper connection of the tablet and Head Unit and minimizes potential disruptions in wireless data transfer between the Head Unit and tablet.

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.

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).

The SafeOp system operates within a relative humidity range of 20-75%.

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.

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.

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).

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

⚠ Preventive maintenance is recommended every twelve months as described in the 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 Docking Station 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.

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

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

Electrode Cautions

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

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.

REPROCESSING OF REUSABLE INSTRUMENTS

The SafeOp System Head Unit is to be cleaned with 70% isopropyl alcohol (IPA). 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. If any SafeOp System component becomes contaminated with blood or other bodily fluids, return the system 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.

LABELING

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
	Warning		'MR Unsafe' items pose unacceptable risks to patient, medical staff, or other persons within the MR environment
	Type BF equipment		Caution
	Alternating current		Refer to instruction manual booklet
	Direct current		Do not use if package damaged
	Carefully dispose of this product	**Rx only**	Prescription only
	USB 2.0 supported		Not made with natural rubber
IPx4	Protection against spraying water		Temperature limitation
	Manufactured by		Non-ionizing radiation
	Consult accompanying documents		Do not re-sterilize

	Do not reuse	REF	Part number
STERILE EO	Contents pre-sterilized with ethylene oxide	LOT	Lot number
	Static sensitive	SN	Serial number
	The alarm symbol indicates that at least one priority alarm is active		Use by date
	ESU detection		The audio silence symbol indicates that the audio has been disabled
	Pause/stop a test or monitoring modality involving stimulation		Initiate a test or monitoring modality involving stimulation
	USB connected		Wi-Fi connected
	tEMG saturation		No Head Unit connection

ALARMS

Clinician Alarm Monitoring

Alphatec Spine recommends that the clinician's position should be at a distance no greater than 1 meter to monitor visual alarm signals and no more than four meters to monitor alarm condition and priority, and in proximity of the device so that any auditory alarm can be heard. Auditory alarm signal sound pressure levels that are less than ambient levels can impede the recognition of an alarm condition.

Alarm Settings

The audio volume can be adjusted from the settings tray from a range of 60%-100% (increments of 20%) of maximum volume with the option to mute the audio as well. A red bell with an 'X' ( ) will appear in the top right corner of the screen next to the volume icon when audio is muted. Alarm settings will be restored automatically if Tablet power (including battery) is interrupted for ≤ 30 seconds. The Tablet has an uninterruptable power supply (UPS) to retain the current state; however, it is not recommended to remove the battery – the system should be returned to Alphatec Spine for any servicing.

WARNING: Muting audio can render the audio ALARM SYSTEM useless as no audio alerts will be heard from the system.

Definitions

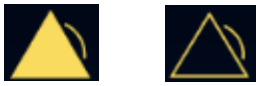
Alarms are indicated by a combination of audible tones, color coded notifications, and flashing elements on the AIX Tablet user interface. Alarms notify the clinician of a potential or an actual hazardous condition.

Definitions of Alarms

High Priority	A high-priority alarm is initiated by any alarm condition requiring immediate user response.
Medium Priority	A medium-priority alarm is initiated by any alarm condition requiring prompt user response.
Low Priority	A low-priority alarm is initiated by any condition requiring user awareness.
Informational Signal	A signal that provides information which may, or may not, require action to be taken by the clinician.

NOTE:
All alarms in the SafeOp System are either medium priority alarms or informational signals.

SafeOp System Priority Alarm Visual Elements

Medium Priority	In the event of a medium priority alert a yellow flashing alarm indicator will be visible on the top left area of the user interface. The display frame for the SSEP site associated with the alarm state will turn yellow as well.  This symbol will alternate every 1 second alternating between “on” and “off”.  The frame will remain yellow until the Amplitude and Latency measurements are in non-alert state values (see SSEP alerting section). Note: The pause button blinks at the same rate of the SSEP alert when stimulation is on.

SafeOp System Monitoring Alarms and Visual Characteristics
All alarms in the SafeOp System are either medium priority alarms or informational signals as defined per IEC 60601-1-8.

Condition	Alarm Type	Visual Indicator
SSEP significant change (see SSEP Alerting section)	Medium Priority	Flashing Medium priority icon (0.5 Hz, 51% duty cycle) location highlighted in yellow
sEMG activity (see Free-run EMG section)	Informational Signal	Location highlighted in yellow (steady on)

SafeOp System Monitoring Alarms and Audio Characteristics
All alarms in the SafeOp System are either medium priority alarms or informational signals as defined per IEC 60601-1-8.

Condition	Audible Indicator	SPL (Sound Pressure Level)	Fundamental Frequency	# of Harmonic Components in Range
SSEP significant change (see SSEP Alerting section)	Repeating sequence of 3 beeps followed by an approximate 20 second pause for a monitoring alarm	100% volume: Max 78 dB 80% volume: Max 75 dB 60% volume: Max 71 dB	495 Hz (for all volume levels)	Greater than 4 (for all volume levels)
sEMG activity (see Free-run EMG section)	Audio characteristics for sEMG information signals were validated under simulated clinical use conditions per IEC 60601-1-8 Clause 6.3.3.1.			

Alarm Logging
The alarm system provides logging for troubleshooting. These logs are only accessible by ATEC personnel. The log is not maintained when the head unit and tablet are powered down. A tablet shutdown or head unit shutdown will be logged by the system. If a total loss of power greater than 30 seconds occurs, the system will log a head unit disconnect followed by a tablet shutdown. Logging for a case will stop if the tablet reaches storage capacity.

ALARM CRITERIA
SSEP: Once a baseline has been established the SafeOp system will continuously monitor for SSEP signal changes as long as SSEP data is being collected. A significant SSEP signal change is defined by an amplitude reduction of 50% from baseline and/or an increase in the latency of a response from baseline of 10%. An ’SSEP Alert’ indicator will appear on the screen in the upper left corner of the screen flashing. This alert will stay active as long as the alert state is still active and SSEP data is being recorded. An alert can be muted by selecting ‘Alerts off’. If this is chosen, any active alert on this waveform will be cleared, and an icon signifying alarms are turned off (🔕) will be shown. To reduce alarm fatigue around the alert criteria defined above, a majority voting window called Sliding Window Analysis Test (SWAT) is implemented. A significant change occurs over an 80% majority vote in a window when comparing the recently acquired response to the baseline. This will lead to a maximum alarm delay of 80 seconds for the user interface to

display the alert and a maximum delay of 80 seconds for the user interface to no longer display the alert.
EMG: Free-run activity is defined as a recorded CMAP with a minimum 80µV amplitude. If free-run activity is detected on a channel, the waveform and the frame associated with that myotome will transition to yellow until no activity is detected over a four-second period.

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.

Assembled from tested components
Complete system not tested

COMPLAINT HANDLING/REPORTING:

All product complaints relating to safety, efficacy, or performance of the product should be reported immediately to Alphatec Spine by telephone, e-mail, or letter, per contact information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide his/her name, address, and as many details as possible. You may contact Customer Service directly at: customerservice@atecspine.com.

For Surgical Technique Guides or additional information regarding the products, please contact your local representative or Alphatec Spine, Inc. Customer Service directly at customerservice@atecspine.com.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

For a listing of Symbols and Explanations, see **atecspine.com/eifu**

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