SafeOp 3: Neural Informatix System™
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The SafeOp System consists of the SafeOp Patient Interface with power supply and IV pole mount, the Windows AIX™ Tablet with docking station, power supply, and a USB data cable. Disposable system components include electrode kits with surface and/or subdermal needle electrodes, stimulating probe and clips, and an MEP activator.
The SafeOp 3: Neural Informatix System (SafeOp 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 transcranial motor evoked potentials (MEP), 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.

CONTRAINDICATIONS:
There are several conditions and situations where the use of transcranial Motor Evoked Potential (MEP) monitoring is contraindicated. These contraindications include:

Epilepsy, cortical lesions (abnormalities in the brain's outer layer), convexity skull defects (defects in the skull's outer surface), raised intracranial pressure (increased pressure inside the skull), cardiac disease, the use of medications or anesthetics that promote seizures (proconvulsant medications or anesthetics), the presence of intracranial electrodes (electrodes placed inside the skull), the presence of vascular clips or shunts (used to redirect blood flow), and having cardiac pacemakers or other implanted biomedical devices.

Patients with a history of head injury, cerebral aneurysm, stroke, seizures, other neurological impairments, or those who have metal plates or fragments in their head are contraindicated for the use of Motor Evoked Potentials (MEP).

If intraoperative seizures occur without a clear explanation or if arrhythmias (abnormal heart rhythms) arise during monitoring, it is advisable to discontinue MEP stimulation.

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 Patient Interface is a Class 1 device. The mode of operation is Continuous Operation. For protection against electric shock the Patient Interface requires a properly grounded electrical outlet. The internal isolation transformer must not be bypassed under any circumstances.

The SafeOp Patient Interface is type BF because it has medium or long-term contact with the patient. The SafeOp Patient Interface 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 Patient Interface is removed.

Electrical Shock Hazard. Do not connect electrode inputs to earth ground. The SafeOp Patient Interface 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 Patient Interface shall be used only with SafeOp 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 near 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 connect a power cord to the Patient Interface.

⚠ Do not remove the AIX Tablet from the room where the SafeOp Patient Interface is in use. This assures proper connection of the tablet and Patient Interface and minimizes potential disruptions in wireless data transfer between them.

⚠ To prevent the risk of electric shock, it is essential to handle MEP scalp stimulation electrodes with caution. Never touch both electrodes simultaneously. Prior to conducting any tests, confirm that both electrodes are securely and correctly attached to the patient. By following these safety measures, the potential for shock can be effectively minimized.

⚠ MEP stimulation can create the possibility of tongue or lip laceration, mandibular fracture, seizures, cardiac arrhythmias, and scalp burns. It is important to be aware of these potential risks associated with MEP stimulation to protect the safety of the patient.

⚠ Patients must be fitted with oral gauze before MEP stimulation to avoid bite injuries.

⚠ MEP stimulation has the potential to cause forceful muscle contractions in the patient's entire body. For the patient’s safety, it is crucial to employ appropriate physical restraints and halt

surgical operations both before and during MEP stimulation. It is important to inform the surgeon well in advance of any MEP testing to facilitate necessary preparations. Follow these guidelines diligently to prioritize patient well-being and minimize risks during MEP stimulation.

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.

Electrode Warnings

Only use the SafeOp Electrodes provided with the system. Use of other electrodes has not been qualified with the SafeOp Patient Interface 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.

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 Patient Interface is in use. This avoids improper pairing of the Tablet and Patient Interface and minimizes potential disruptions in wireless data transfer between the Patient Interface 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.

⚠ The SafeOp Patient Interface (PN AIX11240) can only be powered up by the SafeOp Patient Interface power supply (PN AIX11241).

⚠ 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 Patient Interface is intended only for connection to the AIX Tablet provided with the SafeOp System.

⚠ Do not turn on the power to the SafeOp Patient Interface 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 Patient Interface 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 Patient Interface 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 Patient Interface 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 Patient Interface 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 Patient Interface, 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 Patient Interface 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 Patient Interface 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 Patient Interface or cables.

⚠ Installing or inserting an HDMI or audio-out AUX cable to the AIX Tablet may lead to missed audible tones, notifications, and alerts and should be avoided.

⚠ External accessories such as mouse and keyboard are not supported or recommended for use with the SafeOp System.

⚠ Improperly placed stimulating electrodes may result in weak or no potentials regardless of stimulation level.

⚠ Avoid touching the connection ports on the AIX Tablet and touching the patient at the same time.

⚠ The SafeOp System should be operated in relative humidity conditions of 20-75%.

⚠ The SafeOp Patient Interface should completely power on before starting a case on the SafeOp application.

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.

Cybersecurity Cautions

⚠ Unauthorized access to the ports, including Wi-Fi network, of the physical system creates the potential for malware to be uploaded which could result in the system malfunctioning or becoming inoperable.

User Consent Statement

By using the SafeOp System for a surgical procedure, the user consents to the cybersecurity related cautions outlined above.

MRI SAFETY INFORMATION

The SafeOp 3: Neural Informatix 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

POSSIBLE ADVERSE EFFECTS:

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.

CLEANING, DISINFECTION, AND MAINTENANCE:

Maintenance:

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. The device should also be sent back to Alphatec any time there is physical damage, the appearance of system dysfunction, or when recommended by ATEC technical support.

Contact ATEC Customer Service in the instance that any cyber incident occurs.

Cleaning and Disinfection

The SafeOp Patient Interface 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 electrodes, harnesses, probe, clip, MEP activator are for single patient use only and should be disposed of after use following hospital protocol.

AIX Tablet Battery

The AIX 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 Alphatec customer service for instructions on returning the Tablet for battery replacement.

REPROCESSING OF REUSABLE INSTRUMENTS:

Reprocessing is not applicable to SafeOp 3 system. Refer to INS-114 for reprocessing instructions for SafeOp accessories.

STERILIZATION AND RESTERILIZATION:

Sterilization and resterilization is not applicable to SafeOp 3 system components. Refer to INS-114 for sterilization instructions for SafeOp accessories.

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
	No Patient Interface connection		tEMG saturation

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 with the following options: Low, Medium, and High. The “Low” setting is equivalent to 60% of maximum volume, “Medium” is 80% and “High” is 100%. The audible tones related to individual modalities or globally can be muted. A red bell with an ‘X’ will appear in the top right corner of the screen next to the volume icon if any or all modalities are muted. Underneath the bell will be text to describe if all, EMG only, SSEP only or both EMG & SSEP audible tones are 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 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).

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 Patient Interface and Tablet are powered down. A Tablet shutdown or Patient Interface shutdown will be logged by the system. If a total loss of power greater than 30 seconds occurs, the system will log a Patient Interface 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 compound muscle action potential (CMAP) with a minimum 80µV amplitude. If free-run EMG 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.

FC
Assembled from tested components
Complete system not tested

RETURNING INSTRUMENTS TO ALPHATEC SPINE:

All used products returning to Alphatec Spine must undergo all steps of cleaning, inspection, and terminal sterilization before being returned to Alphatec Spine. Documentation of decontamination should be included.

UDI CONSTRUCTION

To compile a unique device identifier (UDI) for reusable, reprocessed devices, the device identifier (GTIN) may be ascertained by searching for the part number in the FDA GUDID at https://accessgudid.nlm.nih.gov/. The production identifier(s) (e.g., lot number, serial number) may be found directly marked on the device.

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 their 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 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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