

Application Note 257 Safe Use of Electrical Stimulators

IMPORTANT SAFETY NOTE

When using the STMISOC, STMISOD or STMISOE stimulus isolation adapter, it is possible to generate high peak-peak voltages. These voltages are potentially damaging, especially if the stimulator's high voltage outputs are connected across the subject's heart--meaning that the heart is potentially in the electrical path from lead to lead. This occurs when stimulation electrodes are placed on opposite sides of the subject's body.

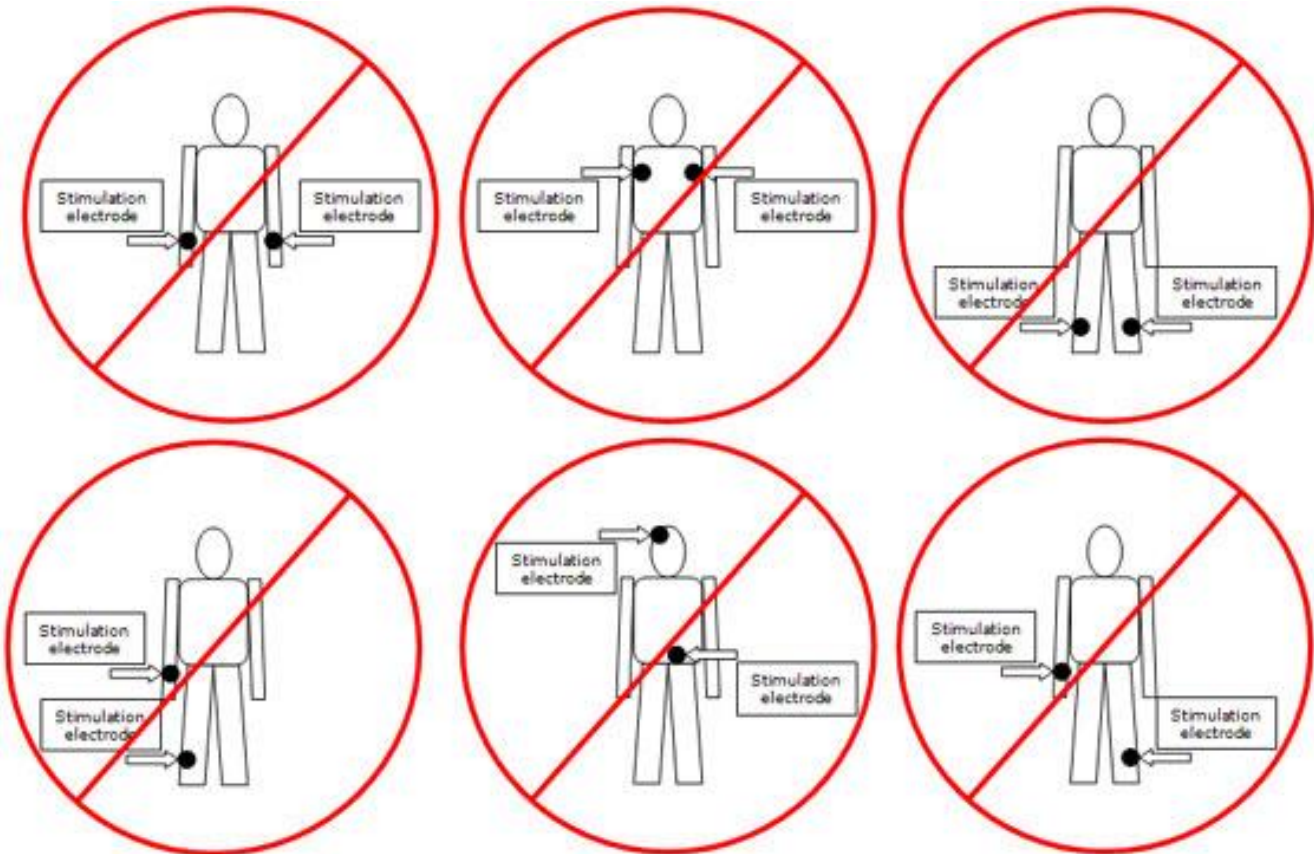
When using a STM200, BSLSTM/A/B, STMISOL, or STMISOLA stimulation unit, it is similarly possible to generate high voltages. With these latter units, however, extra precautions are required when using on subjects.

NEVER PLACE STIMULATION ELECTRODES ON OPPOSITE SIDES OF THE SUBJECT'S BODY

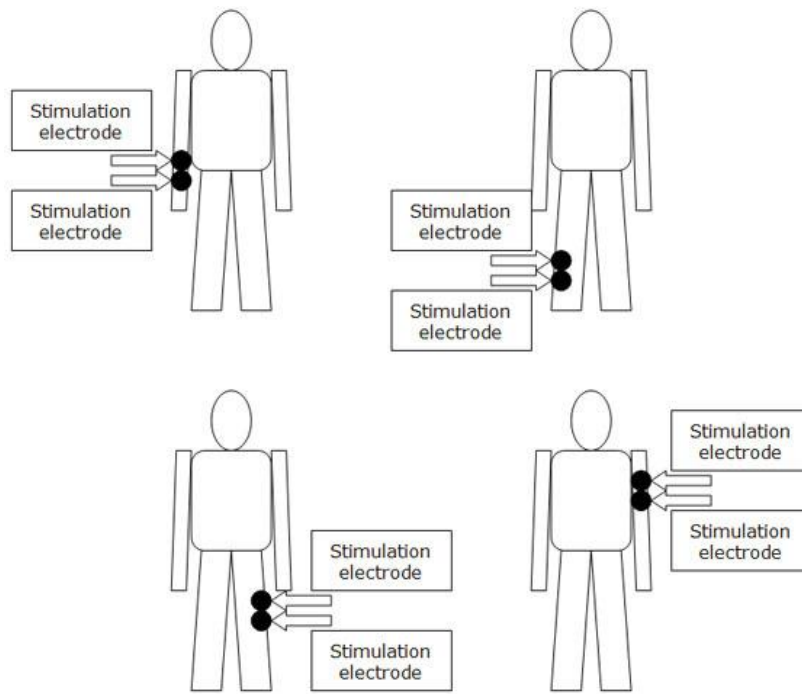
NEVER PLACE STIMULATION ELECTRODES SO STIMULATION CURRENTS ARE PERMITTED TO FLOW THROUGH THE SUBJECT'S HEART

Stimulation electrodes should be placed as far away from the subject's heart as possible on the SAME side of the subject's body. Typically, stimulation electrodes are placed on a subject's single limb. The stimulation (+, -) electrodes should be placed closely together and never more than a few inches apart from each other. Do not place any stimulation electrode on the torso near the heart.

The following six diagrams, with associated red cross-out circles, illustrate UNACCEPTABLE stimulation configurations. In all of these cases, it will be possible for stimulation current to pass through the heart.



The following four diagrams illustrate acceptable stimulation configurations. In all of these cases, stimulation currents are very localized to the stimulation site and are prohibited from flowing through the heart.



REGULATORY STANDARDS

The harmonized, international regulatory standard relating to the safety of nerve and muscle stimulators is IEC 601-2-10. Certain stimulation equipment is excluded from this standard, such as stimulators intended for cardiac defibrillation; however, for the purposes of defining relevant safety metrics for the STMISOC, STMISOD and STMISOE stimulus isolation adapters this standard is quite relevant.

The STMISOC, STMISOD and STMISOE are designed in such a manner that the power available to stimulate the subject is limited. This limitation of power is achieved through the use of a stimulus isolation transformer that has physical constraints (due to its size and construction) that absolutely, in accordance to known physical laws, constrain the maximum transferable energy to be no more than a specific level.

Section 51.104 of the IEC 601-2-10 standard clearly specifies the limitation of output energy for a variety of wave types.

- 1) For stimulus pulse outputs, the maximum energy per pulse shall not exceed 300 mJ when applied to a load resistance of 500 ohms.
- 2) For stimulus pulse outputs, the maximum output voltage shall not exceed a peak value of 500 V, when measured under open circuit conditions.

The STMISOC, STMISOD and STMISOE all employ a stimulus isolation transformer that limits the output pulse width to 2 ms maximum, under 500 ohm load conditions.

The highest available output voltages are indicated as follows, under open circuit and 500 ohm loaded conditions. Also indicated is the maximum pulse energy and pulse width which can be transferred to a 500 ohm load:

STMISO Unit	Open Circuit Max Voltage (V p-p)	500 Ohms Load Max Voltage (V p-p)	Maximum Pulse Energy (mJ)	Maximum Pulse Width (ms)
STMISOC	240	200	160	2
STMISOD	120	100	40	2
STMISOE	240	200	160	2

Example - Maximum pulse energy calculation for STMISOC; with Watts (instant max) and Joules (Watts x Seconds):

$$\text{Watts} = (200 \text{ V} \times 200 \text{ V}) / 500 \text{ ohms} = 80 \text{ W} \quad \text{Joules} = 80 \text{ W} \times 0.002 \text{ seconds} = 0.16 \text{ Joules} = 160 \text{ mJ}$$

HSTM01 Unit	Open Circuit Max Voltage (V p-p)	500 Ohms Load Max Voltage (V p-p)	Maximum Pulse Energy (mJ)	Maximum Pulse Width (ms)
HSTM01 used with STMISOL	220	200	80	1
HSTM01 used with BSLSTM	110	100	20	1
HSTM01 used with STM200	110	100	20	1

The maximum available energy from the STMISOC, STMISOD or STMISOE stimulus isolation adapters is limited to be considerably less than the 300 mJ maximum as specified by IEC 601-2-10.

The STM200, BSLSTM/A/B and STMISOL/LA units from BIOPAC are capable of EXCEEDING the IEC 601-2-10 standard regarding the delivery of electrical pulse energy to a human subject for clinical purposes. Accordingly, if protocols are not rigorously followed and phantom testing not performed, it might be possible that these stimulators will exceed 300 mJ pulse energy, transferred to a subject, during an experiment.

The STM200, BSLSTM/A/B and STMISOL/LA stimulators are designed for a broad range of stimulation requirements, many of which do not involve the use of human subjects, such as tissue field stimulation, organ stimulation, exposed nerve stimulation, etc. These two stimulators can also be employed in research areas that require the use of high voltage or constant current stimulation, such as those associated with ceramic or piezo activation for blood flow equipment development. High voltage stimulation is also used in the area of actuator development for prosthetics research. There are specific life science research requirements that can be addressed by employing the STM200, BSLSTM/A/B or STMISOL/LA, which may not be possible to undertake, using devices such as STMISOC, STMISOD or STMISOE.

STM200, BSLSTM/A/B and STMISOL/LA can also satisfy research stimulation requirements for human studies, such as:

- 1) long stimulation pulse widths (in excess of 2 ms)
- 2) constant current stimulation via program control
- 3) arbitrary wave constant current stimulation
- 4) functional muscle stimulation

BIOPAC wishes to express that EXTREME CAUTION be employed when attempting to use the STM200*, BSLSTM/A/B or STMISOL/LA on human subjects. EXTREME CAUTION is required because these stimulators can be operated programmatically and it's possible that a program failure could result in a situation where the pulse energy delivered to a subject may exceed 300 mJ.

BIOPAC highly recommends that:

- 1) Program software for stimulator control be designed to be safety redundant so as to limit stimulator energy output in the event of operator data entry error.
- 2) Phantom testing be performed, PRIOR to involvement of any human subject. In these situations, an inert object replaces the human in the research study. Also, the stimulation leads to the object are monitored and recorded during the protocol. In this fashion, the expected electrical stimulus can be delivered and then VERIFIED, by the monitoring channel, so proper stimulation behavior can be insured.

Stimulator	Open Circuit Maximum Voltage (Volts)	500 Ohms Load Max Voltage (Volts)	Maximum Pulse Energy (mJ)	Maximum Pulse Width (ms)
STM200	100 (0-pk)	100 (0-pk)	2000	100
BSLSTM/A/B	100 (0-pk)	100 (0-pk)	2000	100
STMISOL/LA	200 (0-pk)	50 (0-pk)	2000	500

Please note that it's possible for STM200, BSLSTM/A/B and STMISOL/LA stimulators to deliver electrical energy stimulation pulses which may exceed the IEC 601-2-10 specified 300 mJ limit by a factor of 2000/300 or 6.667.

The easiest way to constrain the amount of energy delivered to a subject is to place hard limits on the possible stimulator output widths. In the case of STM200 or BSLSTM/A/B, pulse widths should not be allowed to exceed 15 ms.

In the case of STMISOL/LA, pulse widths should not be allowed to exceed 75 ms. However, for general electrical stimulation purposes, it is unusual to have a stimulation pulse width exceed 2 ms.

To check a circumstance where STM200, BSLSTM/A/B and STMISOL/LA can satisfy IEC 601-2-10, then use HSTM01 handheld stimulus isolator. This combination will limit pulse energy to less than 300 mJ in a 500 Ω load.

NOTES REGARDING USE OF ELECTRODES

For electrical stimulation, generally, the lower the electrode salt content, the less skin irritation will be experienced by subject. This is because fewer salt ions are driven into skin during stimulation. This strategy puts more demand on the stimulator, because skin impedances are higher with low salt electrodes. There is no one size fits all requirement. For example, it's possible to help mitigate the undesirable effects of higher salt content electrodes by stimulating the subject with bipolar pulses, instead of unipolar pulses.

[Click here for more details about using BIOPAC electrodes and gels.](#)

ELECTRICAL STIMULATORS IN THE MRI

BIOPAC highly recommends that electrical stimulation in the MRI be performed using the STMISOC, STMISOD or STMISOE. It's possible to perform program control of voltage stimulation using the combination of IPS100C, STM100C and STMISOC/D/E.

BIOPAC has been made aware that the RF energy generated by the MRI can travel through a poorly implemented patch panel and affect stimulator function in the case of STMISOL/LA. BIOPAC has seen several successful implementations of STMISOL/LA used in the MRI, with the appropriately implemented patch panel filters. BIOPAC has also seen one case where very poor patch panel filtering was employed and the STMISOL/LA delivered errant shocks during EPI, as a consequence.

If the STM200, BSLSTM/A/B or STMISOL/LA must be used in the MRI, for research stimulation studies, BIOPAC highly recommends that:

- 1) Program software for stimulator control be designed to be safety redundant so as to limit stimulator output in the event of operator data entry error.
- 2) Patch panel filtering and cabling methods be implemented as per [BIOPAC's connection guide illustrations and connections](#), available online and also in BIOPAC Application Notes 223 and 230. The patch panel must have a very low impedance to MRI ground (less than 1 ohm at $[42.7 \cdot T]$ MHz), where T is Tesla strength of MRI. For a 3T MRI, this means that the patch panel should have less than a 1 ohm impedance to MRI mains ground at 128.1 MHz.
- 3) Only BIOPAC Lead 108 Series Carbon Fiber Radio Translucent leadwires be used in the MRI. For electrode attachments to subject, only BIOPAC EL508 and/or EL509 Carbon Fiber Electrodes should be used. Leads should run straight; they should not be coiled or twisted. Furthermore leads should be insulated from the subject's skin surface with a towel or foam pad.
- 4) Phantom testing be performed, PRIOR to involvement of any human subject. In these situations, an inert object replaces the human in the research study. Also, the stimulation leads to the object are monitored and recorded during the protocol. In this fashion, the expected electrical stimulus can be delivered and then VERIFIED, by the monitoring channel, so proper stimulation behavior can be insured.

STMISOLA: Additional Notes Regarding Use of Current Mode Output

Current Mode stimulus output can appear to demonstrate non-intuitive behavior. This behavior is very different than Voltage Mode stimulus output.

The STMISOLA is a voltage-controlled stimulation system. In the case of Current Mode output, options exist to map the stimulus output current to the input control voltage. These two options are:

Option 1)

+10 V input control voltage maps to +100 ma stimulus output current

-10 V input control voltage maps to -100 ma stimulus output current

Option 2)

+10 V input control voltage maps to +10 ma stimulus output current

-10 V input control voltage maps to -10 ma stimulus output current

For both Option 1) or 2) the behavior is essentially the same, even though the stimulus output current range is different. When the input control voltage is close to 0 V, the stimulus output current is also proportionally close to 0 ma.

IMPORTANT NOTE:

When attempting to set the input control voltage to zero volts, the resulting voltage will most certainly never be exactly zero volts. Instead of zero, the input voltage will simply be close to zero, perhaps on the order of +0.001 V or -0.00001 V.

So, if the input control voltage is non-zero, the current output will also be non-zero!

Example A:

A non-zero input control voltage of 0.001 V will result in a non-zero stimulus output current of 0.001 ma, assuming STMISOLA is set to Option 2). If the STMISOLA stimulus output is connected to an infinite (or very large) impedance, the STMISOLA will attempt to drive 0.001 ma through this very large impedance. Assuming the large impedance is 200 Mohm, then:

$$0.001 \text{ ma} \times 200,000,000 \text{ ohms} = 200 \text{ V (estimate)}$$

Accordingly, in practical operation, if the STMISOLA is used in current mode and is attached to electrodes that are making intermittent contact to the tissue of the subject, intermittent shocks may be felt by subject, even if 0 V is applied to the input control voltage. This is because the STMISOLA will drive directly to the compliance voltage limit and start to behave as a voltage stimulator. Intermittent contact with electrodes will result in intermittent +/- 200 V shocks being applied to the subject. These possible transient shocks may be felt, but only when skin electrodes dislodge and reconnect to the subject's tissue.

This possible +/- 200 V stimulus will be present on STMISOLA output leads at the point when the electrodes reconnect with the tissue, assuming the electrodes had dislodged previously. At the point of reconnect, the voltage level falls back below the compliance threshold and the errant stimulus goes away, but this process takes a few microseconds. If transient connects and reconnects happen over a period of time, many bursts of voltage will impact the electrode sites.

This potential safety issue can be mitigated through a couple of methods:

- 1) Employ a bipolar voltage clamp across the stimulus output current leads.
- 2) Employ an added parallel resistance across the stimulus output current leads.

In method 1), the bipolar voltage clamp simply limits the compliance voltage to a deemed safe level. Two, oppositely directed, diode and Zener diode series circuits are used to define the voltage clamp maximum value, assuming the stimulus electrodes may become dislodged.

In method 2), the maximum load impedance will be dictated by the chosen added parallel resistance.

Also, these two methods can be used together, for additional safety consideration.

Example B:

Using the Example A, also assume that a parallel resistance of 1Mohm is employed across the stimulus output current leads. Accordingly, the reference equation becomes:

$$0.001 \text{ ma} \times 1,000,000 \text{ ohms} = 1 \text{ V (estimate)}$$

In this case, the maximum stimulus voltage received by the subject, in the event of sporadic electrode contact, would be on the order of 1 V, instead of 200 V. Alternatively, if the parallel loading represented by the additional 1 Mohm resistance is not desired, a voltage clamp could be used to limit the maximum output voltage level in the event of sporadic electrode contact.

The STMISOLA has the capability of acting as a nearly ideal current stimulator, with very high performance. Adding a parallel resistance or a voltage clamp reduces performance from ideal, but enhances safety. Please contact BIOPAC Systems, Inc. at www.biopac.com for more information.