BIOPAC Systems, Inc.
Registered to ISO 9001:2015

APPLICATION NOTE

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Application Note 175 Using the STMISOC Stimulus Isolator

The MP160/150 System stimulation features provide a powerful vehicle for outputting a variety of waveforms of varying duration, coincident with the data acquisition process. Often, a stimulation voltage in excess of 20 V (p-p) is required to perform nerve or muscle stimulation. This application note will focus on using the STMISOC for either voltage or current stimulation, when higher stimulation voltages or compliance is important. This note will also detail the hardware and software setup procedures for using the STMISOC with the MP System.

To use the STMISOC, an MP System with minimally one STM100C Stimulator module is required. The STMISOC plugs directly into the EXT STIM jack on the STM100C module. Use two of the LEAD110 electrode leads to connect the stimulus output to the subject. The LEAD110 electrode leads are required because they have the proper plug type for the new safety lead standard used on the STMISOC module. (1.6 mm pin connectors).

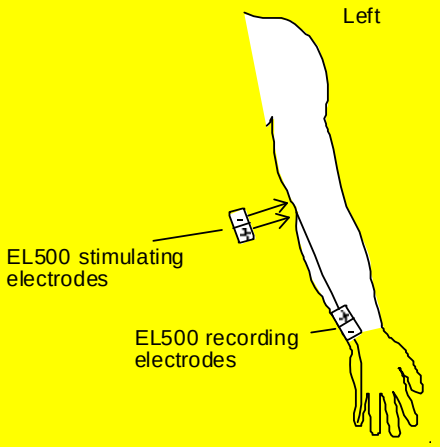
IMPORTANT SAFETY NOTES!

When using the STMISOC, STMISOD, or STMISOE, it is possible to generate voltages as high as 200 v p-p. These voltages are potentially dangerous, especially if the stimulator's high voltage outputs are connected across the subject's heart. Across the heart means that the heart is potentially in the electrical path from lead to lead. This situation occurs when the stimulation electrodes are placed on opposite sides of the subject's body.

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

Always use the stimulator with the leads placed in relatively close proximity to each other and relatively far from the heart, and with the leads placed only on the **SAME** side of the body. The figure to the right illustrates correct connection techniques when using the STMISOC/D/E.

Example of correct stimulation electrode placement:



STMISO SAFETY

The harmonized, international regulatory standard relating to the safety of nerve and muscle stimulators is **IEC 60601-2-10:2015**. 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 STMISOC, STMISOD, or STMISOE stimulation units, this standard is quite relevant.

STMISOC, STMISOD, and STMISOE stimulation units 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 stimulus isolation transformers which have physical constraints (due to their size and construction) which absolutely —in accordance to known physical laws — constrain the maximum transferable power to be no more than a specific level.

The IEC 60601-2-10:2015 standard clearly specifies the **limitation of output power** for a variety of wave types.

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

STMISOC, STMISOD, and STMISOE units employ stimulus isolation transformers that limit the output pulse width to 2 ms maximum, under 500 ohm load conditions. In addition, the highest available output voltage is 200 V pk-pk (STMISOC or STMISOE) under open circuit conditions.

For the pulse energy calculation for STMISOC and STMISOE:

Joules = Watts x Seconds
Watts (instantaneous maximum) = (200 V x 200 V) / 500 ohms = 80
Joules = 80 W x 0.002 seconds = 0.16 Joules = 160 mJ

Accordingly, the highest possible energy output using the STMISOC or STMISOE is **160 mJ**.

The remaining stimulus isolation unit, STMISOD, has a maximum voltage output of 100 V. In this case, the maximum energy output is:

Watts (instantaneous maximum) = (100 V x 100 V) / 500 ohms = 20
Joules = 20 W x 0.002 seconds = 0.04 Joules = 40 mJ

In all cases the maximum available energy, from the STMISO series stimulus isolation units, is limited to be considerably **less than the 300 mJ maximum** as specified by IEC 60601-2-10:2015.

CAUTIONS FOR USE!

Even the safest stimulation units, if used incorrectly, can cause serious harm. The following points illustrate fundamental rules for using stimulus isolation units to stimulate subjects.

1) **NEVER APPLY THE STIMULUS SIGNAL IN SUCH A MANNER AS TO CAUSE CURRENT TO FLOW THROUGH THE HEART**.

   Primarily considered, this rule implies that stimulation leads should never be split apart so as to be able to touch opposing sides of the body surrounding the heart.

   For example: NEVER CONNECT THE STIMULUS ISOLATION UNIT SO THAT ONE LEAD TOUCHES THE LEFT ARM AND THE OTHER LEAD TOUCHES THE RIGHT ARM.

   Both stimulus leads [(+) and (-)], should be applied to the SAME side (left or right) of the subject's body. Furthermore, always stimulate AWAY from the heart. Stimulation probes (such as BIOPAC's EL350 or the EL351), which constrain the distance from the positive stimulation output to the negative stimulation output, should always be used for skin surface stimulation of nerve or muscle.

   The EL350 or the EL351 stimulation probes fix the distance between stimulation outputs to 35mm. It is not recommended that this distance be increased for skin surface stimulation of nerve or muscle. An increase in this distance simply allows stimulation currents to circulate over a larger area, which is usually not necessary for nerve or muscle stimulation scenarios.

2) **Always start the stimulation process with the stimulator control set the LOWEST possible level**. The control for the STMISO series stimulus isolation units is located on the STM100C stimulation module. Set the control knob to the 0% level, prior to the onset of the stimulation protocol. During the protocol, increase the stimulus intensity by SLOWLY turning the control knob towards the 100% level. Stop increasing the intensity at the first sign of subject discomfort.

IMPORTANT NOTES!

A) It takes as little as **15 micro-amps** directed across the heart to instigate ventricular fibrillation. This situation can be readily achieved by using sub-surface stimulation needle electrodes that insert directly into the heart. It is considerably more difficult to achieve ventricular fibrillation on the same heart using surface electrodes, but it is possible to do so, evidenced by the performance of cardiac defibrillation units used in hospitals or by paramedics.

B) **Qualified experienced professionals** should supervise any protocols where electrical stimulation is applied to human subjects. Electrical stimulation protocols are not simple.
Please contact BIOPAC Systems for any questions regarding the use of BIOPAC's stimulation units or accessories.

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.

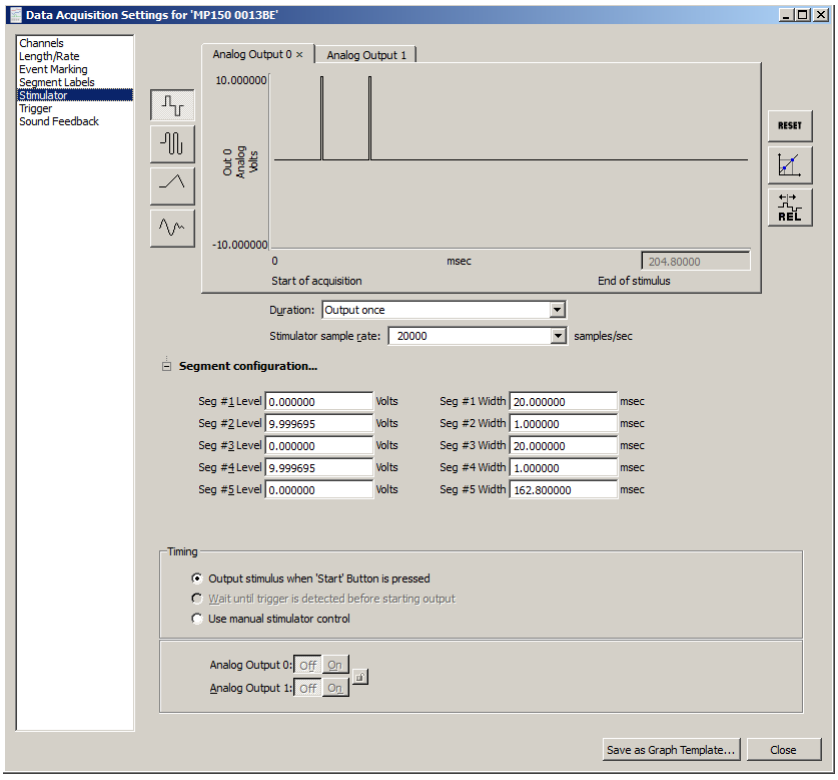
When using the STMISOC, the MP System is typically operated in MP storage mode. In MP mode, input data is stored to the MP unit's internal input data buffer and downloaded to the computer only **after** acquisition is completed. MP mode is useful when acquiring data at very high rates (in excess of 10 kHz, or so). When operating in this mode, input data acquisition lengths are limited to 4,365,311 samples or less.

If MP storage mode is selected, waveform outputting (simultaneous with the acquisition) is limited to short files. However, it is possible to "wrap around" the output data file so that the waveform is output continuously during the MP acquisition. This mode is selectable by choosing this function in the Stimulator Setup dialog box.

MP storage mode is used when data needs to be input and output at high speed, and when relatively short duration acquisitions are suitable. These requirements are typically used when performing general stimulus/response tests.

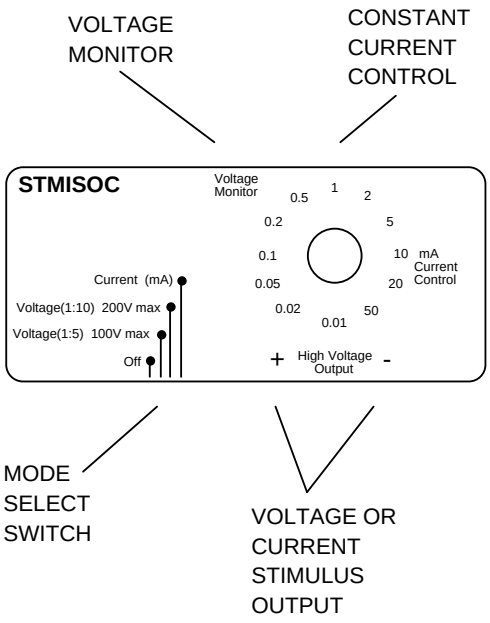
If the stimulator dialog setup is used to create the output waveform, the waveform will always be a short term wave. Namely, the canned waveform constructed by the dialog will always fit into the 4096 point short term wave limit. Selecting "Output Once" or "Output Continuously" makes no difference as to the type of wave. In both cases, the wave output will be a short term wave.

The following setup illustrates a double 1 ms stimulation pulse:



Output Once in MP160/150 Mode

From this source setup, it's possible to output a pulse amplitude up to 100 V to the subject. The stimulation voltage can be adjusted manually by using the LEVEL control on the STM100C module, allowing control over the output stimulation voltage from 0 - 100% of the expected maximum voltage. Generally, the LEVEL control would be set to 0% prior to the acquisition, and then slowly increased as the acquisition is repeated in order to evoke a response.



STMISOC Controls

STMISOC Mode	*Signal output if STM100C LEVEL control is set to 100%*
OFF	No signal will be output from the STMISOC.
Voltage (1:5) 100 V Max	Signal output will be 5x the values shown in the Stimulator Setup dialog (acts like a STMISOD).
Voltage (1:10) 200 V Max	Signal output will be 10x the values shown in the Stimulator Setup dialog (acts like a STMISOE).
Current	Signal output will be positive constant current output; set signal value with the Current Control rotary switch. When using the STMISOC in Current mode, it's important to output **positive pulses** only. Pulses should have a height of at least 10 V because pulse height output determines the voltage compliance of the current stimulation signal. The compliance of the current stimulation signal is determined by multiplying the pulse voltage amplitude by 10. For a 10 V pulse, the compliance would be 100 V. This means that the STMISOC can output a current of up to 100 V/R load. If R load = 5 k ohms, in this case the maximum output current would be 100 V/5 k = 20 ma. The maximum pulse height can be as much as 20 V, so it's possible to have a compliance as high as 200 V.

In the **Voltage** output modes, the STMISOC can be used with bipolar stimulation. Furthermore, the STMISOC can be used with different waveform types (square, sin, triangle) in Voltage output mode.

The Voltage Monitor output provides a proportional output of the exact voltage used to stimulate the subject. If the Current mode is selected, the Voltage Monitor Output will be disabled. The Voltage Monitor output will provide the following output:

Voltage (1:5) 100V Max setting: 1/10 proportional output

Voltage (1:10) 200V Max setting: 1/20 proportional output

For example, if the mode is set to Voltage (1:10) 200 V Max setting, then the Voltage Monitor output will output a voltage which is 1/20 of the actual stimulation voltage.

To Isolate the Voltage Monitor Feedback Signal from the MP160/150 Input:

The Voltage monitor output on the STMISOC shares output stimulus ground (Vout-). In cases where continuous output stimulus monitoring also requires isolation from MP160/150 input, it's recommended to use one each of:

CBL100, INISO, HLT100C

STMISOC Specifications

Stimulus Pulse Width:	50 µsec to 2 msec (voltage and current)
Stimulus Sine Wave Range:	100 Hz to 5 kHz (voltage only)
Step Up Voltage Ratio:	Selectable: (1:5) or (1:10)
Maximum Output Voltage:	(1:5) mode 100 V (p-p); (1:10) mode 200 V (p-p) into 5 k ± load
Constant Current Range:	0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1.0, 2.0, 5.0, 10.0, 20.0, 50.0 ma (unipolar only)
Current Source Compliance:	200 V maximum
Current stimulation mode:	Positive current only
Isolation Capacitance:	150 pf
Isolation Voltage:	1500 VDC (from amplifier ground)
Cable Length:	1.8 meters
Weight:	190 grams
Dimensions:	10 cm (wide) x 5 cm (deep) x 4.5 cm (high)
Interface:	STM100C
Off mode:	Turns off Voltage or Current stimulation to subject.
Voltage Monitor output:	
Output via	3.5 mm mono phono jack
(1:5) mode	1:10 of stimulation voltage
(1:10) mode	1:20 of stimulation voltage
Current mode	disabled
OFF Reports a signal of approximately 50% of the voltage indicated in the stimulator setup window	