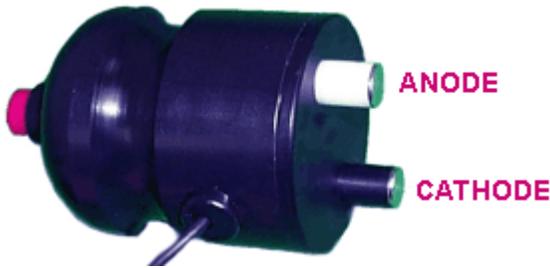


STMHUM HUMAN-SAFE STIMULATOR – DB9



Human stimulation with a superior degree of safety and comfort

The STMHUM is a direct, human-safe stimulator that provides pulse output in the range of 0-100 V. The maximum width pulse that can be generated is limited to 1 msec by hardware, ensuring the STMHUM meets all stimulator safety standards.

The ergonomic design allows the user to focus on the electrode placement instead of worrying about holding the electrode.

- Subjects depress the red safety switch to allow the software-controlled stimulus presentation through
- To stop the stimulus, Subjects simply remove their thumb from the switch and the electrode shuts off.

Cable terminates in a DB9 connector to interface the “Analog out” port on MP36 and MP36R units; not compatible with MP35 or MP30 units. Requires software versions BSL 4.1.1 or AcqKnowledge 4.4.1 or higher.

The STMHUM eliminates the need for an external stimulator—use as a cost-effective alternative for the HSTM01+BSLSTMB/A hardware combination.

BIOPAC software provides an output control panel that allows for the voltage to be specified directly along with pulse frequencies. Set parameters using MP Menu > Output Control > Human Stimulator – STMHUM:



IMPORTANT! Refer to the Stimulation Safety Notes beginning on the next page.

STMHUM SPECIFICATIONS

Stimulus Type:	Voltage
Stimulus Pulse Width:	50 µsec to 1 msec
Step Up Voltage Ratio:	1:10
Maximum output voltage:	100 V
Safety Switch:	Yes (pushbutton)
Isolation Capacitance:	100 pF
Isolation Voltage:	1500 V
Power output:	Watt (instantaneous max.) = (100 V x 100 V)/500 Ohms = 20 Watts Joules (Watts x Seconds) = 20 Watts x 0.001 seconds = 0.020 Joules = 20 mJ
Stimulating Electrodes:	<i>Material:</i> Stainless steel; <i>Diameter:</i> 8 mm; <i>Spacing:</i> 2.54 cm
Dimensions:	<i>Height</i> (electrode bottom to button top): 7.7 cm; <i>Diameter:</i> 4.5 cm; <i>Weight:</i> 170 G
Cable:	<i>Length:</i> 3 m (10'); <i>Connector:</i> DB9 male
Interface:	MP36 or MP36R Analog Out port (DB9 female)

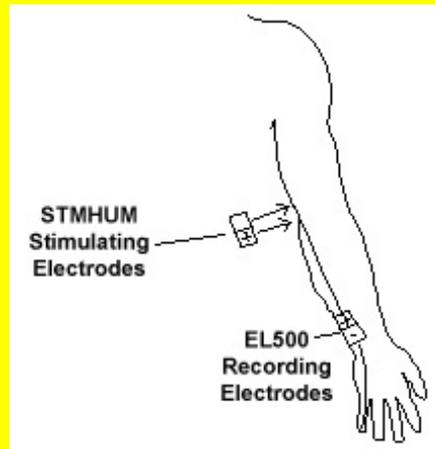
IMPORTANT SAFETY NOTES!

When using the STMHUM, it is possible to generate voltages as high as 100 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 OPPOSITE 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 STMHUM.

Example of correct stimulation electrode placement:



STIMULATION 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 the STMHUM stimulation unit, this standard is quite relevant.

STMHUM 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.

STMHUM units employ stimulus isolation transformers that limit the output pulse width to 1 ms maximum, under 500 ohm load conditions. In addition, the highest available output voltage is 100 V pk-pk under open circuit conditions.

For the pulse energy calculation for STMHUM:

$$\begin{aligned} \text{Joules} &= \text{Watts} \times \text{Seconds} \\ \text{Watt (instantaneous max.)} &= (100 \text{ V} \times 100 \text{ V}) / 500 \text{ Ohms} = 20 \text{ Watts} \\ \text{Joules (Watts} \times \text{Seconds)} &= 20 \text{ Watts} \times 0.001 \text{ seconds} = 0.020 \text{ Joules} = 20 \text{ mJ} \end{aligned}$$

Accordingly, the highest possible energy output using the STMHUM is **20 mJ**, 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 35 mm. 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 “Pulses” output control panel in the BIOPAC software is used to control the STMHUM. Set to the 0% level, prior to the onset of the stimulation protocol. During the protocol, increase the stimulus intensity by increasing the Level in small increments 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.