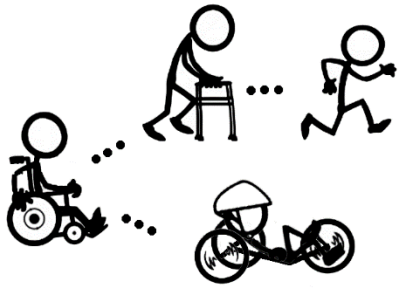


MOTIMOVE STIMULATORS

by

3F-Fit Fabricando Faber

www.3-x-f.com

Model: MOTIMOVE Arduino Module

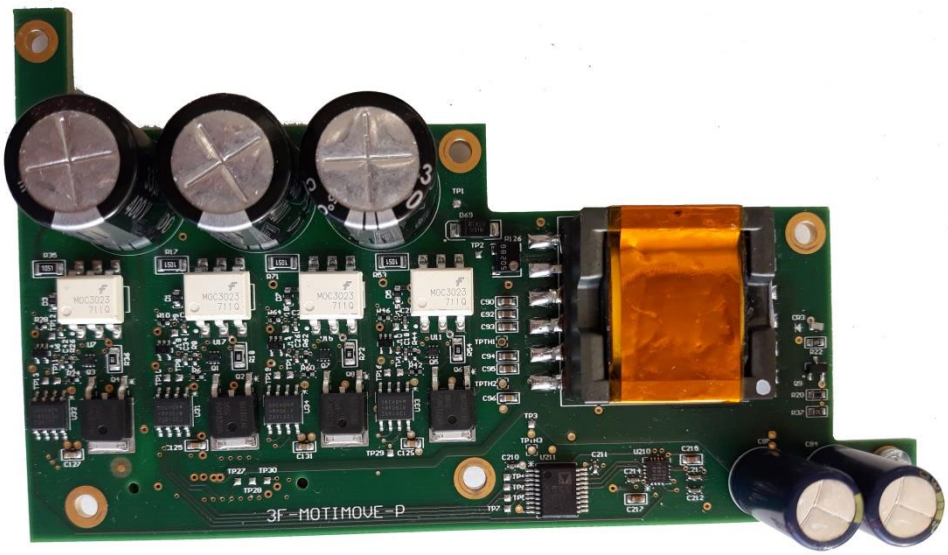


Table of content

1. General Description

1.1. The 3F-MOTIMOVE Arduino module

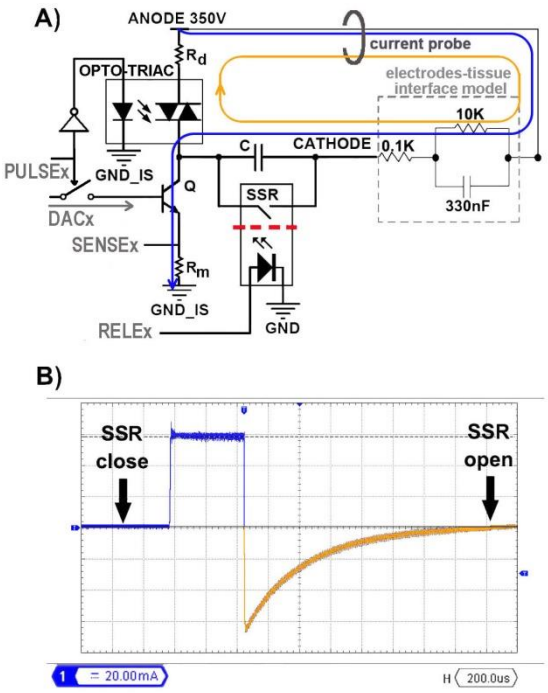
- Is a four-channel pulse generator for functional electrical stimulation (FES).
- **The Motimove Arduino Module must be handled by experts only! The Module, when not used as integral part of the Motimove 8 stimulator, does not hold a CE mark.**
- It requires precise control of timings and pulse intensities from an external controller.
- **Wrong timings of control signals can lead to damage of the electronic circuits and to serious injuries of the user. Maximum supported parameters are listed in Technical Specifications.**
- **The selection of stimulation parameters, control and mode of application is the sole responsibility of the operator!**
- **3F-Fit Fabricando Faber holds no liability for any damage of the equipment of user that may arise from the improper use of the MOTIMOVE Arduino module or selection of the stimulation parameters above the limits listed in Technical Specifications.**
- For use in humans or animals, if MOTIMOVE Arduino module is controlled from the external controller other than those provided by 3F-Fit Fabricando Faber, the positive results of safety tests must be obtained from a certified test laboratory.

1.2. Technical Specification

Absolute Maximum Values	
Pulse control	Regulated current
Pattern of stimulation	Compensated biphasic with spontaneous exponential discharge
Pulse amplitude	170mA
Frequency	500Hz [1]
Pulse duration	1000µs [1]
Maximum voltage reserve	350V [2]
Maximum load impedance	2kΩ (for 50Hz, 500µs, 170mA)
Number of Channels	4
Estimated consumption during stimulation **Never stimulate continuously with current intensities higher than 120mA for longer than 10 minutes. It may lead to overheat, distortion of pulses and stimulator shutdown. For larger amplitudes, recommended ON-OFF periods are at least 50%.**	standby - 350mA high voltage turned on, zero stimulation - 170mA 4ch 50Hz, 500us, 17mA - 400mA 4ch 50Hz, 500us, 34mA - 450mA 4ch 50Hz, 500us, 51mA - 530mA 4ch 50Hz, 500us, 68mA - 600mA 4ch 50Hz, 500us, 85mA - 650A 4ch 50Hz, 500us, 102mA – 770 1.12A 4ch 50Hz, 500us, 119mA – 850 1.2mA 4ch 50Hz, 500us, 138mA – 950 1.3mA 4ch 50Hz, 500us, 155mA – 1030 1.38mA 4ch 50Hz, 500us, 170mA – 1050 1.4A 8ch 50Hz, 500us, 170mA - 2.14A 8ch 40Hz, 350us, 170mA - 1.44A 8ch 40Hz, 350us, 68mA - 980mA

[1] **The product of frequency and pulse width must be limited to 0.025 (e.g. 100Hz and 250µs; 500Hz and 50µs; 25Hz and 1ms). Higher values may lead to damage of electronic circuits.**
[2] **Voltage is determined by the position of the trimmer. Do not turn the trimmer. Higher voltages may damage electronic circuits!**

1.3. Essential Performance



In normal operating mode MOTIMOVE generates charge-imbalanced asymmetric biphasic pulses with a rectangular positive pulse, adjustable in amplitude and width, followed by a passive discharge phase with opposite polarity and exponential decay (Fig.B). The exponential phase is generated immediately after the positive rectangular pulse as a result of the passive discharge of the excessive accumulated charge in the tissue and electrodes through the discharge resistor R_d in the output stage (Fig.A) and is considered as best for preventing potentially skin-damaging galvanic processes at the electrode contact area[2]. Pulse shown in the Fig.B is generated for the following parameters: pulse width 500µs, current intensity 60mA, frequency 50Hz measured on the electrical model of two electrodes-tissues interfaces shown in Fig.A. If the load is purely resistive there will be no exponential compensation pulse, and only rectangular part will remain.

Each output stage (channel) can be separately controlled. The independent sources allow for generating synchronous stimulation pulses on all channels.

Rectangular pulse intensity is determined by the value from an isolated digital-analog converter (DAC60504BRTET, Texas Instruments) which defines the output transistor base current, and pulse duration is determined by the duration of digital input (PULSEx) high level, both controlled by the external microprocessor. Switching of PULSEx from high to low level turns off the transistor and triggers the opto-triac in Fig.A and passive discharge of the accumulated charge through the resistor R_d. Opto-triac automatically closes when the current drops below 100µA. Discharge shape and time depend on the impedance of tissue and electrode-tissue interface and can last up to 3 times the pulse length till the DC component in the output current gets close enough to zero. This discharge interval determines the minimum interval between adjacent pulses on one channel.

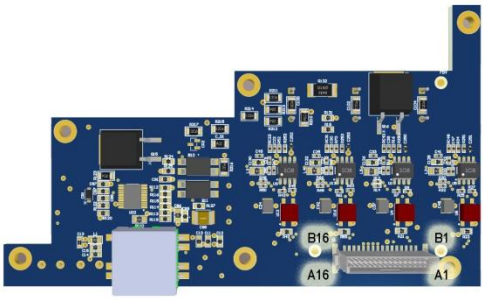
Each output stage includes a serial blocking capacitor, C, of 220pF for blocking potentially harmful DC components in the electrode current in a period when the pulses are not generated. This capacitor is short-circuited by a parallel solid-state relay (SSR) which should be closed by a digital input (RELEx) at least 300µs before the leading edge of the rectangular pulse and opened at least three pulse durations after the end of the rectangular pulse (marked with black arrows in Fig.B). This limits the minimum time delay to the next pulse (i.e. if the pulse width is 350µs, then the minimum delay before next pulse is 300µs+4*350µs =1.7ms). This circuit allows conduction of pulses through the SSR and prevents any DC conduction in periods between the pulses. In case of a fault of the system, if any DC-current would be generated between the pulses it would immediately charge the

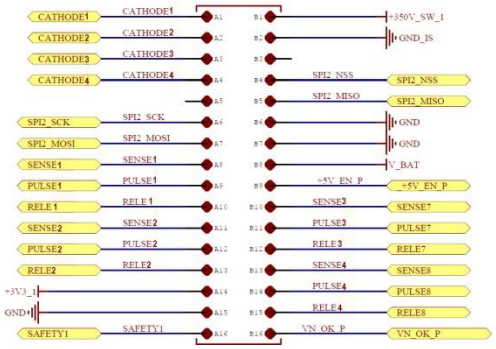
[2] Merrill, D.R., Bikson, M. and Jefferys, J.G., 2005. Electrical stimulation of excitable tissue: design of efficacious and safe protocols. *Journal of neuroscience methods*, *141*(2), pp.171-198.

blocking capacitor and prevent any further DC-current flow into the skin. Each channel has a current measuring resistor, R_m, which is used to detect whether the electrode was detached from the active channel (digital output SENSEx).

Pulses are current controlled. Voltage on the common anode is always high (350V), and voltage on each cathode depends on the pre-set current intensity and connected load. For maximum current set to 170mA the pulse shape is preserved for pure resistive load of maximum 2KΩ. In case of a larger load, the essential performance is lost and the amplitude of the rectangular part of the pulse is reduced and distorted.

1.4. Connector pinout





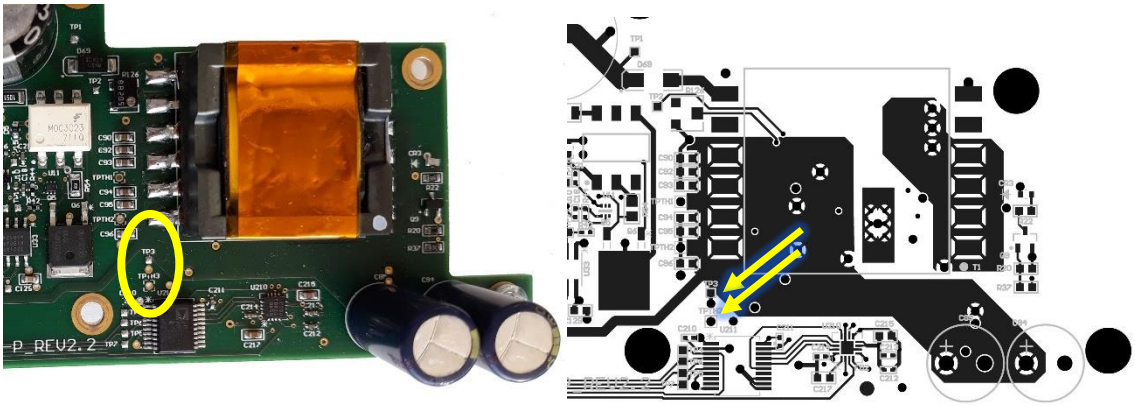
- +3V3_1: regulated 3.3V
- V_BAT (7-8.4V): use 2 x Li-Ion cells of 3.7V. For voltages bellow 7V generation of full rectangular pulses is not guaranteed!
- GND: negative pole of the battery
- GND_IS: v
- +350V_SW_1 (AO, 350V): anode/constant voltage
- CATHODE5-8 (AO, 0-350V): cathodes (channels 5-8)/current sources
- +5V_EN_P (DI, 3.3V): enables generation of isolated 5V on isolation DC-DC converter
- SAFETY1 (DI, 3.3V): enables 350V capacitor charge (voltage reserve) after enable of 5V DC-DC converter (be sure to first enable DC-DC converter!). SAFETY1 line is convenient for low voltage emergency stop. Reset of SAFETY1 will disable charge of capacitor and they the voltage reserve (anode) will decrease to zero after 0.5-3s (depending of the connected load). Setting of SAFETY1 will enable capacitor charge in less than 1s.
- SPI2 (SPI bus): setting the value on DAC for control of pulse intensity
- PULSE5-8 (DI, 3.3V): setting the start and stop (duration) of the pulse
- RELE5-8 (DI, 3.3V): to close the solid state relay in the output stage 300us before the pulse and open after minimum 4 pulse durations (see 1.3.). Opening will end the exponential discharge, but it should not be done before the value of exponential discharge is close to zero.
- SENSE5-8 (D0, 3.3V): detection of the open circuit on the channel that is set to be active (detection of the detached electrode). Works only for currents >15mA.

1.5. Getting started

To avoid damage of the device and ensure safety of the operator, follow the initial steps of the device setup.

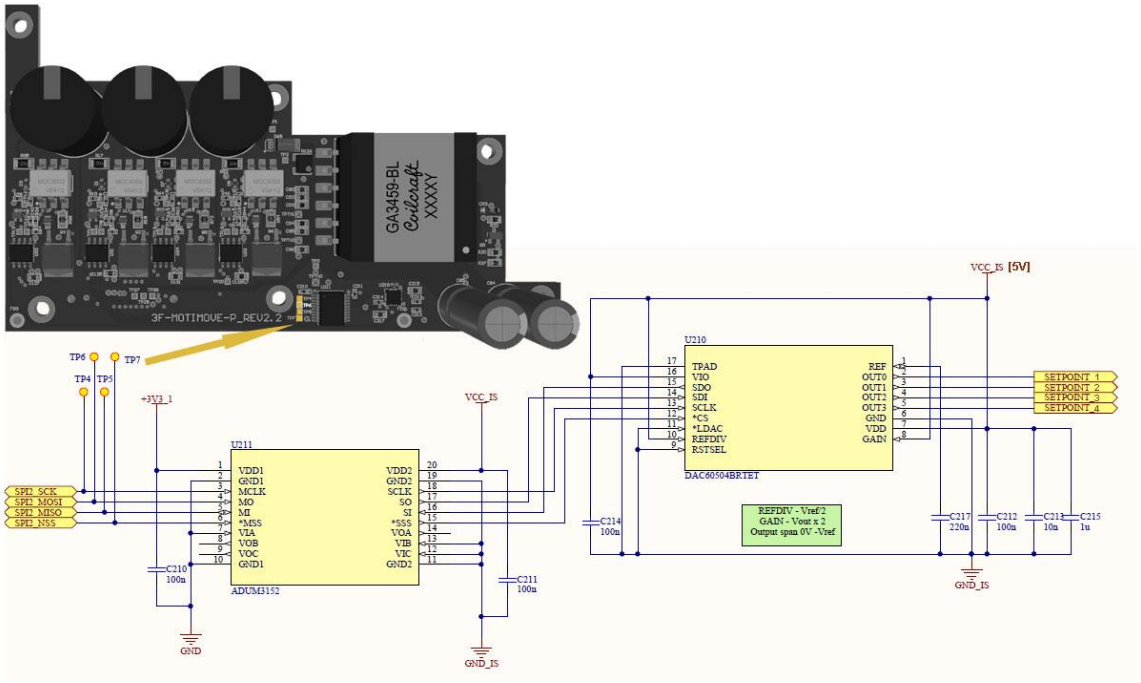
1.5.1. Enable isolated 5V supply

Bring +5V_EN_P pin to high level (3.3V). Check the voltage between pins TPTH3 (isolated GND) and TP3. It should be 5V. This supply is needed for all functions of the module.



1.5.2. Control the DAC for pulse current intensity

The output of 4-channel 12-bit DA converter (DAC60504BRTET, Texas Instruments) defines the intensity of the pulse on the selected channel. DAC is controlled by SPI (see the scheme below).



For example, if the voltage on the output 1 from DAC has value of SETPOINT_1 = 1050mV then the pulse intensity on stimulation channel 1 will be 100mA, for 550mV → 50mA, for 1750mV → 170mA.

The behaviour of DAC is not fully linear, hence we recommend using a different coefficient for calculating DAC control for amplitudes of 0-50mA (coef=16.9) and amplitudes from 51-170mA

(coef=17.75). For instance, to generate pulse amplitude of 100mA you need to set DAC control to 16.9*50=845. For amplitude of 170mA you need to set DAC to 17.65*170=3000.

Be aware that setting output values of DAC to the value >3000 will generate pulses of more than 170mA which may damage the equipment and induce injuries to the user for long durations of the pulses!

CODE EXAMPLE with Cortex M4 connected to DAC

```
current_out = pulse_current_mA *  coef;

void writeSPI_Arduino(uint8_t channel, uint16_t current_out)
{
   uint8_t spiTxBuf[3];
   uint16_t temp16 = current_out << 4;
   uint8_t temp8 = channel;
   spiTxBuf[0] = 0x08;
   spiTxBuf[1] = (temp16 & 0xFF00)>>8;
   spiTxBuf[2] = temp16 & 0x00FF;

   HAL_GPIO_WritePin(SPI_NSS_GPIO_Port, SPI_NSS_Pin, GPIO_PIN_RESET );
   HAL_SPI_Transmit(&hspi, spiTxBuf, 3, 50);
   HAL_GPIO_WritePin(SPI_NSS_GPIO_Port, SPI_NSS_Pin, GPIO_PIN_SET );
}
```

If you are using some other platform you'll need to send SPI transaction to communicate with DAC you should refer to
https://www.ti.com/lit/ds/symlink/dac80504.pdf?ts=1662386956387&ref_url=https%253A%252F%252Fwww.ti.com%252Fproduct%252FDAC80504
CHAPTER 8.5 Programming

For example if you want to write value to :

8.6.1 NOP Register (address = 0x00) [reset = 0x0000]

Figure 65. NOP Register

15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	0
NOP															
W															

LEGEND: R/W = Read/Write; R = Read only; -n = value after reset

Your SPI Transaction should have 24 bits of data:

- SS to LOW
- First 8 bits of address and 16 bits of register data.
- SS to HIGH

For better understanding refer to **FIGURE 62. 63. 64** Timing Diagrams for READ/WRITE

1.5.3. Pulse control

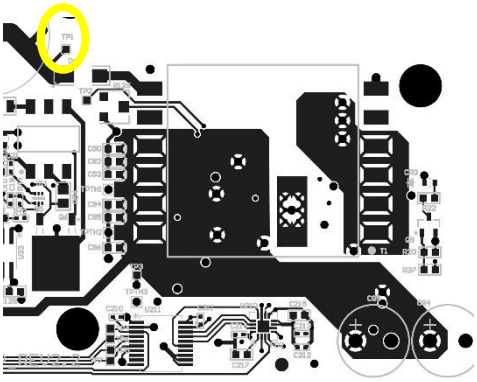
PULSEx lines control the duration of the pulses (see figure in 1.3.). PULSEx are digital inputs (0-3.3V). Pulses are generated on the corresponding channel with the amplitude defined by SETPOINT_x only during the high value of the PULSEx line.

Pulses can only be generated if the corresponding SSR (solid-state relay) is closed. Otherwise the capacitor on the output line will prevent or distort the delivery of pulses. SSR should be closed (line RELEx to high value) at least 300µs before the PULSEx rise edge, and opened after more than four durations of the pulse width (measured from the PULSEx rise edge).

1.5.4. Generate high voltage reserve for the common anode

Before generating high voltage double check if your SPI control of pulse intensities operates well, and PULSEx and RELEx lines have the appropriate timings.

Never turn the trimmer marked with red circle!!! Changing trimmer value will change the output of the transformer and may cause damage to the circuits or damage to the tissue of the user.



After you enable high-voltage, by setting SAFETY1 to high value, double check the between pins TPTH3 (isolated GND) and TP1 (easy access point is on the top of the coil marked with yellow arrow). If the high-voltage was recently enabled it should show +300V. After warm-up period it will increase for about 15% more (to about 350V).

1.6. Indications and Contraindications

Functional electrical stimulation (FES) is an established method of therapy that activates the sensory-motor systems. The FES can generate or assist compromised cyclic movements and goal-oriented movements in persons after an injury or disease of the central nervous system. MOTIMOVE can generate contractions of paralyzed innervated muscles.

The envisioned applications of the MOTIMOVE are:

- The assistance of the volitional exercise of cyclic and goal-oriented functional movements;
- Generation of missing movement that is the prerequisite for cyclic or goal-oriented functional movements;
- exercise aiming to increase muscle strength and mass;
- an exercise that can decrease the level of spasticity;
- an exercise that can increase the range of motion;
- an exercise that prevents complications of no-use pattern;
- exercise increasing the local and overall blood circulation;
- an exercise required to allow the standing and walking (loading of the skeleton and bodily liquids by gravity).

The absolute contraindications for the use of MOTIMOVE:

- Implanted stimulators of any kind that are active;
- Pregnancy. Adverse effects are still unknown;
- Open wound below the electrode placement;
- Unhealed fracture of the bone of the body part that is exposed to FES;
- Tear of the muscle that is exposed to FES.

The relative contraindications for the use of MOTIMOVE:

- Denervated muscles. MOTIMOVE cannot activate denervated muscles;
- Severe spasticity. Stretching before use may help to reduce likelihood of spasms occurring;
- Severe osteoporosis. Therapist should be consulted to adjust the FES parameters.
- Recently implanted plates, pins, screws and other near the muscles that are exposed to FES;
- Epilepsy due to possible adverse effects of unknown kind.

1.7. Security Notes

Read the manual carefully before using this device!

The modification of the MOTIMOVE components is not allowed. The repair or any other technical modification of the MOTIMOVE must be performed by the manufacturer only! An unauthorized modification of the equipment may lead to electrical shock and death if connected to mains supply.

A technical inspection of the MOTIMOVE must be carried out by the 3F – Fit Fabricando Faber licensed staff member only. 3F – Fit Fabricando Faber provides circuit diagrams, component part lists, descriptions, calibration instructions to its authorized services.

Do not put/connect any cables or other contacts on the stimulator into/to AC mains power outlets.

Before use isolate all contacts to Motimove Arduino Module from potential touch of the user, operator or other equipment, and especially from the AC mains supply or other high-voltage sources.

Before use protect Motimove Arduino Module from contact with water.

Use Motimove Arduino Module only with battery supply!

1.8. Use environments

MOTIMOVE Arduino Module can be used in professional laboratory environment; however, use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 m (12 inches) to any part of the MOTIMOVE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The vicinity of the following equipment should be avoided:

- active HF SURGICAL EQUIPMENT and the RF shielded room for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high
- close proximity (e.g. 1m) to a shortwave or microwave therapy equipment which may produce instability in the stimulator output.
- electrical monitoring devices (e.g. ECG or EEG) simultaneously connected to the client, because the treatment can disturb signals on the monitoring devices.

Potential hazards:

- Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.

1.9. Intended operator

MOTIMOVE Arduino Module is a research device; thereby, the operator is responsible for selecting the protocol and adjusting the stimulation parameters.

The patient must not touch the electrodes on the body with a contralateral hand while the stimulator is in use, to avoid generating a current path across the hearth.

1.10. Warnings

If the user's blood pressure or heart rate reaches a level that the operator considers a compromise to safety, or if the user feels faint or nauseated, the training should be stopped immediately, and appropriate medical action should be taken.

If the user needs more information on how to use the device, he/she should contact the manufacturer to ensure that the user's safety is not at risk.

- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur, and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias and fibrillations.
- Stimulation should not be applied transcerebrally or directly on the eyes.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 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 MOTIMOVE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- In case of unexpected events or operations, report such events to the manufacturer.

1.11. Precautions

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used for patients with any implanted device.
- Caution should be used in the presence of the following:
    - When there is a tendency to hemorrhage following acute trauma or fracture;
    - Following recent surgical procedures when muscle contraction may disrupt the healing process;
    - Over the menstruating or pregnant uterus; and
    - Over areas of the skin which lack normal sensation.
    - history of uncontrolled autonomic dysreflexia;
    - history of limb stress fractures;
    - history of severe spasticity or spastic response to application of electrical stimulation;
- Some users may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- If the stimulator is to be used near the ribcage, consider and analyse the risk of cardiac fibrillation.
- Protect the Module from water. If the device falls into water do not use it any longer and contact manufacturer for further instructions.
- Store the device in the packaging to protect it from damage and dirt.
- Users should be always accompanied by an assistant.
- Always reduce output power to zero before removing the electrodes
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Powered muscle stimulators should be kept out of the reach of children.
- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

1.12. Adverse Reactions

Skin irritations or chemical burns may occur if there is insufficient contact between the skin and electrodes or if the parameters have been adjusted incorrectly. When using stimulation for the first time, **check the area underneath the electrodes after 2 minutes**! If you find that there is bad electronic contact, please use contact gel available from medical suppliers.

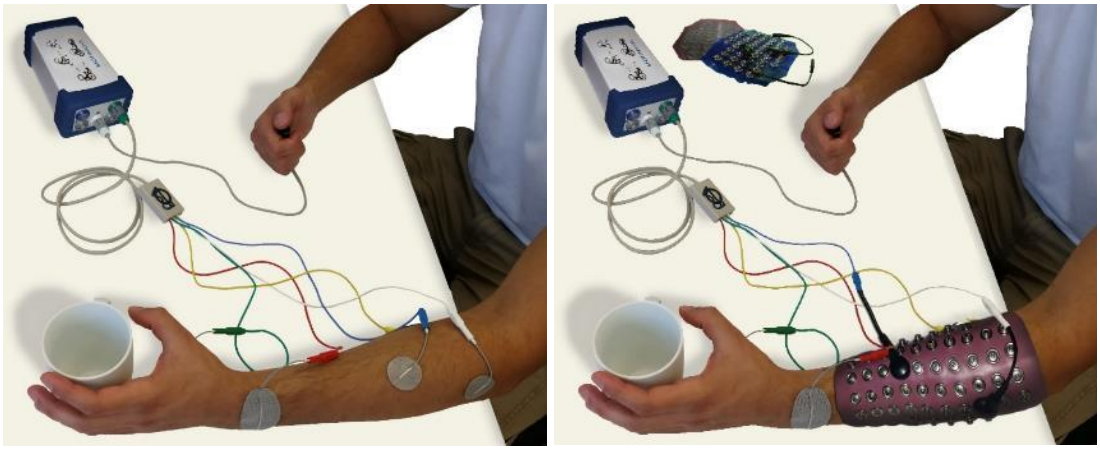
Choose the appropriate electrode size and make sure not to exceed power density of 0.1 Watts/cm² (e.g. if maximum voltage of the stimulator is 350V, for pulse intensity I=170mA, pulse width T=500µs, and frequency f=40Hz, the power is U*I*duty cycle= 350V*150mA*500µs*40Hz= 1.19 Watts; therefore, the size of the electrode should be minimum 11.9cm^2).

2. How to use MOTIMOVE Arduino Module

2.1. Electrode Size Recommendation

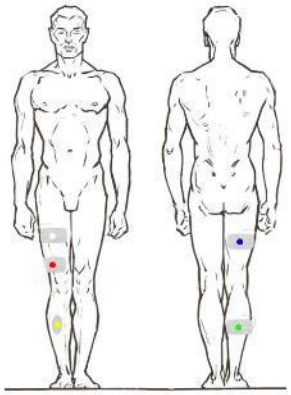
For stimulation of lower extremities, the electrode size should be equal or larger than 16cm^2. Recommended size for the anode is 5x10cm. The anode should be positioned on the frontal side of the upper leg, close to the knee. The cathodes should be positioned over the bulks of desired muscles.

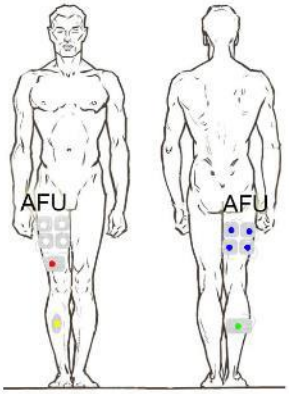
For stimulation of upper extremities, the recommended anode size should be equal or larger than 6 cm^2 and other electrodes should be equal or larger than 3 cm^2. It is recommended to position the anodes close to the wrist. Cathodes should be positioned over the motor points on the dorsal or volar side of the forearm to produce finger and wrist extension and flexion, respectively. One channel should be positioned on the thenar group to stimulate thumb flexion.



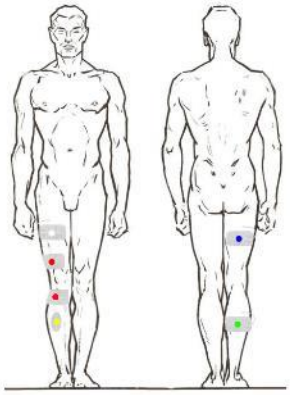
Any electrodes that have current densities exceeding 2mA/cm^2 may require special attention of the operator

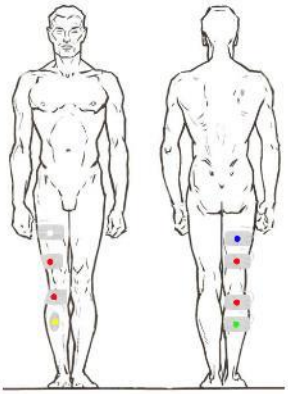
2.2. Electrode Placement Recommendation



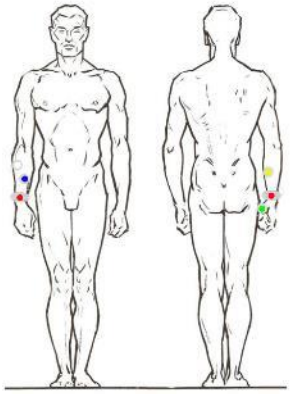


Walking, cycling & rowing (single anode per leg)

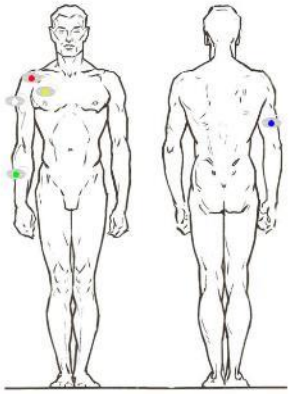




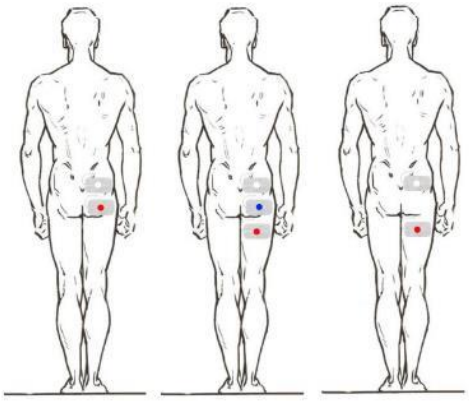
Walking, cycling & rowing (with anode splitters)



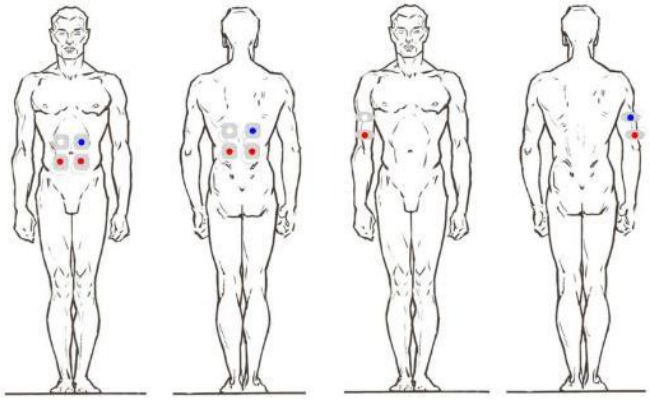
Grasping
(with anode spliter)



Arm exercise
(shoulder abduction,
elbow extension
shoulder horizontal adduction,
finger extension)



Exercise against pressure ulcers



Execrise examples

Warranty

3F-Fit Fabricando Faber provides free service for 30 days after receipt of the device. In case of personal misuse, vandalism, accidental damage (such as breaking or short circuit of the components), intervention by unauthorized service or person and other equipment damage, the warranty is void and 3F-Fit Fabricando Faber is not obliged to provide free service.

Warranty is void in case of:
1) Damage during transport (out of control of 3F-Fit Fabricando Faber)
2) Use of accessories and attachments other than those provided or explicitly permitted by 3F-Fit Fabricando Faber
3) Abuse, misuse or brutal use done as an intentional act that violates this manual
4) Influence of the environmental conditions, temperature, humidity or force majeure (such as lightning and/or other natural disasters) or other factors that are out of control of 3F-Fit Fabricando Faber
5) Repair in the facilities or by personnel not authorized by 3F-Fit Fabricando Faber

The warranty is void and 3F-Fit Fabricando Faber cannot be held responsible for malfunction caused by (including but not limited to):
1) Unauthorized assembly, removal or readjustments of components
2) Unauthorized components replacement
3) Repair by unauthorized service or personnel

3F-Fit Fabricando Faber will provide a consulting support for connecting the Arduino module.

In case of suspicion in device malfunction please contact the manufacturer or authorised service.

Manufactured by:

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