NEURO 20

EFFICIENT HEALTH

Electrical Muscle Stimulation

NEURO20 PRO System
OPERATING MANUAL

Version 1.6

This Neuro20 PRO System belongs to:

_____

Owner

_____

Address

_____

City, State/Province, Country

_____

Telephone

Neuro20 PRO System Operating Manual

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www.neuro20.com

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Product No. Neuro20 PRO System 1.1 Operating Manual: N20PRO-OM-V1.6 02/23

Neuro20® PRO System
OPERATING MANUAL

N20PRO-OM-V1.6 02/23

See symbols glossary in the
TECHNICAL SPECIFICATIONS
section of the User Manual.

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SYMBOLS DESCRIPTION

The symbols and their descriptions will appear throughout sections of the Operating Manual. These symbols are associated with the Contraindications, Warnings, Precautions, and potential Adverse Effects. When seeing a symbol read carefully and consider the information prior to operating the equipment.

Symbol	Description
	CAUTION The “CAUTION” symbol indicates text that will explain possible safety hazards that could potentially cause injury or damage to equipment.
	DANGER The “DANGER” symbol indicates potential imminent hazardous safety situations that could result in death or serious injury.
	EXPLOSION HAZARD The “Explosion Hazard” symbol indicates possible safety hazards if this equipment is used in the presence of flammable materials.
	DANGEROUS VOLTAGE The “Dangerous Voltage” symbol indicates possible hazards resulting in the electrical charge delivered in certain program configurations of waveforms.
	BIOHAZARDOUS MATERIALS The “Biohazard” symbol indicates possible hazards resulting from the improper handling of components and accessories that have come in contact with bodily fluids or components that need proper disposal.
	NON-IONIZING ELECTROMAGNETIC RADIATION The “Non-ionizing Electromagnetic Radiation” symbol indicates possible hazards resulting from elevated, potentially dangerous levels of non-ionizing radiation.
	KEEP DRY The “Keep Dry” symbol indicates possible hazards resulting when the suit is operated in water.
	BF COMPONENTS “BF Components” are devices with conductive contact to the User.

INTRODUCTION

Congratulations on your purchase of the Neuro20 PRO System.

Neuro20 Technologies suggests that operators learn the contents of this manual. Owners must register the manufacturing number of the product online at www.neuro20.com. The System will only be activated following product registration.

Neuro20 Technologies suggests that the manual is kept with the System and stored in a safe place. The manual is also available at www.neuro20.com.

Do not operate the System if there is any possibility of damage. If damage is a concern, first refer to Troubleshooting (pg.59). If troubleshooting does not resolve the concern, please contact technical support via email at support@neuro20.com or by phone at +1.917-503-6876. Proper use and maintenance of the System is the sole responsibility of the registered owner/operator.

The Neuro20 PRO System is a medical device not intended for resale, loan, or lease to any third-party operator. Any resale, lease, loan, or distribution of the Neuro20 PRO System may only occur with the written consent of Neuro20 Technologies. If authorized consent is obtained, then the new owner must re-register the device with the company.

Caution! Federal Law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of this device.

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The Neuro20 PRO System should only be used by professional users on patients as prescribed. .

INDICATIONS OF USE

The Neuro20 PRO System is intended to stimulate muscles in order to improve or facilitate muscle performance. Other indications for use include:

- Re-educating muscles
- Increasing local blood circulation
- Maintaining or increasing range of motion
- Relaxation of muscle spasm
- Retarding or preventing disuse atrophy

INTENDED USE ENVIRONMENT

The Neuro20 Pro System is intended to be used in a professional setting such as physicians' office, physical therapist, professional sports setting, and nursing homes, as well as in the home healthcare environment.

SAFETY

Contraindications, Warnings, Precautions, Potential Adverse Effects

Device User Manual
Do not operate this device until the User Manual with the Indications of Use, Contraindications, Warnings, Precautions, and potential Adverse Effects are carefully read and understood. If there are any questions, contact Neuro20 Technologies at info@neuro20.com or call customer support at +1 (917) 503-6876 prior to use.

ADVERSE REACTIONS

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators. Discontinue use and treat appropriately if this occurs. Lower the intensity of the stimulation during any subsequent session.

Reporting Adverse Reactions

Neuro20 encourages all patients to report any adverse reactions to their healthcare professional and then via email to info@neuro20.com. Neuro20 will keep a record of all adverse reaction reports in order to maintain updates, transparency, and public safety at all times and only share information to meet any necessary regulatory requirements.

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

Report Online at
www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Consumer Reporting Form FDA 3500B.
Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at
www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

Call FDA at **1-800-FDA-1088** to report by telephone.

Reporting Form FDA 3500 commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf.

CONTRAINDICATIONS

Pacemaker
Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

WARNINGS

Long Term Effects
The long-term effects of electrical stimulation are unknown.

Application of Electrodes to Other Body Locations
Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus. Stimulation should not be applied across or through the head (transcerbally), directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus). Severe spasm of the laryngeal and pharyngeal muscles may occur if placed on the neck and the contractions may be strong enough to close the airway or cause difficulty in breathing. Stimulation should not occur from electrodes placed on the chest and the upper back or crossing over the heart (transthoracic) in that the introduction of electrical current into the heart may cause cardiac arrhythmias. **Note!** *The pectoralis and the complex of back muscles are superficial and electrical stimulation to these muscles is not considered trans-thoracic.*

Fever/Infection /Acute Inflammation
Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

Active Cancer
Stimulation should not be applied over, or in proximity to, cancerous lesions. Electrical stimulation should not be applied directly over an area of the body where malignancy is known to be present.

WARNINGS (continued)

Implanted Defibrillator
Do not use electrical stimulation on patients with an implanted defibrillator, because this may cause electric shock, burns, electrical interference, or death.

Implanted Medical Device
Do not use electrical stimulation on patients who have an implanted metallic or electronic device because this may cause electric shock, burns, electrical interference, or death.

Patient Cognition / Cooperation/Children
Do not apply if the patient does not understand the potential risks of treatment.

Muscle Breakdown or Bruising coupled with Delayed Onset Muscle Soreness
Over working a muscle can result in some muscle breakdown. This condition results in muscle fiber disruption and small muscle cellular contents, such as myoglobin, exits the fiber and can appear as a bruise. Myoglobin also enters the blood stream is eventually cleared by the liver and kidneys. Urine can appear quite dark as the myoglobin clears. Discontinuation of the Neuro20 System and a review by a physician is important if this occurs. Resuming treatment requires clearance by a physician. Reducing the intensity of stimulation in future sessions and reducing overall exercise is warranted. Delayed Onset Muscle Soreness may also be noted without signs of muscle breakdown. This uncomfortable experience is very often noted after the first few sessions of electrical stimulation coupled with exercise. It can also be noted with increased exercise alone. Please review the physiology of DOMS. Soreness does not mean that stimulation should be discontinued, BUT reducing the intensity, and reducing the concurrent exercise is important as your treatment continues. If DOMS continues for more than a few days following electrical stimulation and exercise, then discuss this with your healthcare practitioner. We suggest waiting until the soreness is eliminated, or markedly reduced, before continuing use.

Skin Preparation
Apply electrical stimulation only to normal, clean, healthy skin.

Pregnancy
Do not apply electrical stimulation over the lumbar or abdominal region, or over the uterus during pregnancy (to prevent uterine contraction).
Precaution: Safety of powered muscle stimulators for use during pregnancy has not been established.

Menstruation
Do not use the Neuro20 electrical System over the lumbar or abdominal regions or over the uterus during menstruation as stimulation may temporarily increase menstrual flow.

Reproductive Organs
Do not apply electrical stimulation treatment over the testes. Electrical stimulation may affect organ function.

WARNINGS (continued)

DVT / Thrombophlebitis
Neuromuscular electrical stimulation should not be applied directly over or near Deep Vein Thrombosis (DVT) since it activates muscles causing contractions. This should be avoided in areas following an acute DVT when the thrombosis is not completely resolved. Follow treating physician guidelines on recommended activity levels and stimulation use. If the patient or subject is not permitted exercise, NMES therapy should be avoided.
Note! *Generally, NMES over a DVT of six weeks or less should be avoided altogether.*

Cardiac Disease
Only low intensities and short treatment times should be used since stimulation of practically any afferent autonomic nerve (especially the Vagus nerve) in the body may cause a change in cardiac rate. **Note!** *Consult with the patient's physician before using electrical stimulation because the stimulation System may cause lethal rhythm disturbances to the heart in susceptible individuals.*

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

Diathermy/Microwave
Operation in close proximity (e.g.1m) to a shortwave or microwave therapy medical equipment may produce instability in the stimulator output.

Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

Monitoring Equipment
Electrical stimulation should not be applied to patients connected to patient monitoring equipment, as the simulation may influence the proper operation of the monitoring equipment.

Explosion hazard exists if the Neuro20 PRO System is used in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.

External Stimulator Systems
Electrical stimulation should not be applied directly over external stimulator Systems with lead wires.

To safely terminate operation of this device, press the red STOP button on the Neuro20 PRO Control box.

WARNINGS (continued)

User Activity
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. Do not use when bathing or swimming. Do not apply powered muscle stimulators while falling asleep.

No modification of this equipment is allowed. Modification of the equipment may cause improper functioning which could lead to injury or death.

PRECAUTIONS

Epilepsy
Caution should be used in persons with suspected or diagnosed epilepsy or seizures. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.

Healing Bones
Caution should be used with electrical stimulation when there is a tendency to hemorrhage following acute trauma, or fracture, in the presence of recent surgical procedures, or healing bone and soft tissue when muscle contraction may disrupt the healing process. Caution should be used when applying electrical stimulation over areas of the body which lack normal sensation. Absent or diminished sensation areas should be avoided or, if needed, to be treated with caution. Always determine acceptable intensity levels for desensitized areas that are likely to be less than intensity levels tolerated on normal skin in the opposite or related body parts.

Hypersensitivity
Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement. Slightly increase electrode hydration and /or add normal saline spray to improve conductance. Adjusting the suit electrode placement may also reduce hypersensitivity.

Prescribing Practitioner
Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

Children or Unqualified Persons
Powered muscle stimulators should be kept out of reach of children. Powered muscle stimulators should be kept out of reach of unqualified persons.

Pets and pests
Powered muscle stimulators should be kept out of reach of pets and away from pests.

PRECAUTIONS (continued)

Lead Wires
Never connect lead wires to a power line or electro-surgery equipment. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

User Activity
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. Do not use when bathing or swimming. Do not apply powered muscle stimulators while falling asleep.

Output Intensity
Gradually increase the output intensity (power for each electrode) to the desired level, or to user tolerance, while monitoring the Operating Tablet display and asking for verbal feedback from the patient. To prevent startling do not apply greater power than tolerated. The output intensity should be increased gradually as user responses may vary greatly.

Conductive Mediums
An appropriate amount of coupling water in the electrodes and on the skin is important to ensure safe and optimal energy transmission to the tissue. Use of hand or body lotions or gels or ultrasound gels are not appropriate for use with the Neuro20 System and may temporarily or permanently interfere with stimulation function.

Bleeding Tendency
Use caution with electrical stimulation when a patient tends to bleed internally, such as following an injury or fracture.

Treatment Monitoring
Treatment areas should be self-checked before and after application, and if there is evidence of pain or irritation, adjust the output lower until it is tolerated.

Medicated Patches, Salves, Creams
The effect of electrical stimulation may be altered by the presence of these materials applied to the skin.

Hot / Cold Packs
Caution is recommended when treatment follows the application of hot or cold therapy, which may alter user sensation. Application of thermal agents over areas of impaired circulation should be performed with caution as the circulation may be insufficient to heat or cool the tissue, altering the patient's perception of warmth and pain.

PRECAUTIONS (continued)

Skin Inspection
Inspect and cleanse the skin prior to application. Following treatment, check the skin for evidence of irritation and if present, treat as appropriate. If there is skin irritation following treatment, shorten treatment time at the next treatment and/or reduce intensity, and if necessary, discontinue use.

Service / Repair Shock Hazard
A potential electric shock hazard exists once the device's outer casing is in part or fully removed. Only qualified service personnel should perform service and repairs. Do not Tamper with or remove the outer casing.

Cleaning
The Control Box must be disconnected from the Smart Suit before washing. When cleaning the electronic Control Box never immerse or wash with water or other liquids. Avoid oil, water, metal, or foreign substances to penetrate the battery compartment, charger, Control Box, or suit connection.

Condensation
Sudden temperature changes can cause condensation to build up inside of the stimulator, allow for the Neuro20 PRO Control Box to reach ambient temperature before use.

Strangulation can occur due to length of exposed component materials. Do not wrap any exposed component part around the throat or neck area. Keep out of the hands/reach of children at all times.

The Neuro20 PRO System contains small parts that will be harmful if swallowed and no part or component is intended for human consumption. Seek medical attention if swallowed.

Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.

Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when electrical stimulation is in use.

Do not operate this unit in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner.

PRECAUTIONS (continued)

Medical electrical equipment needs special precautions regarding EMC. Portable and mobile RF communication equipment can be affected by other medical electrical devices. If you believe interference is occurring, please consult the ELECTROMAGNETIC COMPATIBILITY section to assist in removing the interference.

Common RF emitting devices and electromagnetic security Systems (cellular phones, two-way radios, cordless phones, paging transmitters, RFID devices, etc.) may interfere with the operation of the Neuro20 PRO System. The Neuro20 PRO System has been tested in the presence of these types of devices and while no adverse event occurred, the device should not be operated within the vicinity or environment as another RF emitting device.

See symbols glossary in the TECHNICAL SPECIFICATIONS section of the User Manual.

CONTACT

For assistance, if needed, in setting up, using or maintaining the Neuro20 PRO, or to report unexpected operation or events, contact:

Neuro20 Technologies,
3802 Spectrum Blvd, Suite 116E,
Tampa
FL 33612

Email: support@neuro20.com
Tel: +1 (917) 503 6876
Website: www.neuro20.com

PRODUCT DESCRIPTION

The Neuro20 PRO System is a powered muscle stimulator designed for individual or group rehabilitation and recovery. The System can create co-contraction muscle resistance as well as optimized sequenced movement patterns. The involuntary muscle activation can be voluntarily over-ridden through intentional exercise. Individual intensity levels can be modulated for each muscle group. One to ten patients may be treated within a session.

The Neuro20 PRO System is a wearable textile and supporting software platform, that provides electrical muscle stimulation interventions. The System utilizes electrical stimulation to create a motor neuron recruitment of muscle fiber (involuntary contraction), thereby bypassing the neural pathway that occurs during voluntary muscle recruitment. When combined with a voluntary movement, the contractions create enhanced performance and recovery.

Users may be actively engaged within a variety of training modes while the clinician/operator is controlling the software; or a User can receive therapeutic intervention at a respective physical rehabilitation facility.

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Model Number: N20 PRO-SYS

The Neuro20 PRO System is designed to be operated for sessions for 1-10 users at a time. One Control Box is assigned per user and attaches to each user's Smart Suit. The operator controls the software for each user with individual controls for each.

System COMPONENTS AND OVERVIEW

Neuro20 PRO System Components:

- Neuro20 PRO Control Box - Model Number: N20PRO-CB
- Neuro20 PRO Software 1.0 - Model Number: N20PRO-SW
- Neuro20 Smart Suit 1.0 - Model Number: N20-SS
- Neuro20 PRO System Operating Manual: N20PRO-OM-V1.6

Neuro20 PRO System 3rd-Party Components:

- Operating Tablet w/charger
- Battery w/charger
- Protective case

Dispose of all batteries and component parts as per local regulations. Contact local authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories. Do not dispose of any System components in regular trash or recycling bins unless local regulations permit

Protective Case for Neuro20 System (provided by 3rd party)

The Protective case is IP67 certified, water, dust and shock resistant and provides protection for the technology. The Neuro20 PRO System is placed in custom-cut foam to provide an additional layer of protection. The Smart Suit is packaged separately.

To prevent any damage to the components we suggest carrying the Neuro20 PRO System in the provided Protective Case when traveling and during storage.

Neuro20 Protective Case

Neuro20 Smart Suit Packaging

System COMPONENTS AND OVERVIEW (continued)

Neuro20 PRO Control Box - Model Number: N20PRO-CB

The Neuro20 PRO Control Box is a powered muscle stimulator that attaches to the Smart Suit. The Control Box generates electrical impulses and is controlled by the operator through the Software installed on the Operating Tablet. The Control Box wirelesly connects to operating tablet. The power supply of the Control Box is provided through a rechargeable, replaceable battery.

To determine whether the device has sufficient power to safely and effectively complete a session, please check page 33

Neuro20 PRO Control Box

2 RGB LEDs are located at the top of the cabinet and indicate the following states:

Left LED
Blinking Red – Battery is too hot or battery is not connected properly.
Blinking Yellow – Remaining battery capacity is too low
Blinking Blue – the device is ready for connection
Blue – the device has an active wireless connection
Purple – the device is in firmware update mode
Blinking Purple – firmware update in progress
Blinking Green – device is performing initial self-test

Right LED
Green – the device is switched ON and in the idle state
Purple – Stimulation is ON
White – Rest Period of Stimulation

Both LED's Blinking Red - failure of one or more stimulation components

System COMPONENTS AND OVERVIEW (continued)

Battery & Charger

The battery & charger (LP-E5 battery, model LF7.4900) for the Neuro20 PRO Control Box are provided by a 3rd party provider.

No other batteries other than model LP-E5 Li-ion should be used in the Neuro20 PRO Control Box.

Typical operation time for a fully charged battery is 6 hours of use. Typical shelf life for the battery is one year after full charge, and 500 charging cycles. Charging time for full charge is 3 hours. Once the battery percentage drops to 10%, in Device Management and when assigning devices for training sessions, the icon and text turn red. At this point, the battery should be replaced.

Dispose of all batteries and component parts as per local regulations. Contact local authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories.Do not dispose of any System components in regular trash or recycling bins unless local regulations permit

Battery & Charger

Battery
Contact Points

USB/USB-C Charging cable

System COMPONENTS AND OVERVIEW (continued)

Operating Tablet – (Apple iPad, 9th generation)

The Operating Tablet comes with pre-installed Neuro20 PRO Software. The tablet wirelessly connects to the Neuro20 PRO Control Box and operates the Neuro20 PRO Software.

Neuro20 Operating Tablet

Neuro20 PRO Software - Model Number: N20PRO-SW

Software updates are issued on a regular basis. Keep your Operating Tablet's iOS updated by ensuring that the App Store's automatic updates are ON. We suggest that sole utilization of the provided Operating Tablet is reserved for the Neuro20 PRO Software.

Note- Neuro20 Technologies is not responsible for maintaining or installing any software or application other than the Neuro20 PRO Software.

System COMPONENTS AND OVERVIEW (continued)

Neuro20 Smart Suit - N20-SS

The Neuro20 Smart Suit is equipped with a slide and guide connection System for the Neuro20 PRO Control Box. Inside the Neuro20 Smart Suit there are specially designed electrodes which are placed to fit over various muscle groups. The suits are unisex in sizes ranging from XS to XXXL.

Do not use, or attempt to use any other stimulation suit with the Neuro20 PRO System. The Neuro20 Smart Suit is for single patient use only! Do not share Neuro20 Smart Suits between different users.

Neuro20 Smart Suit

Neuro20 Smart Suit - Size Chart

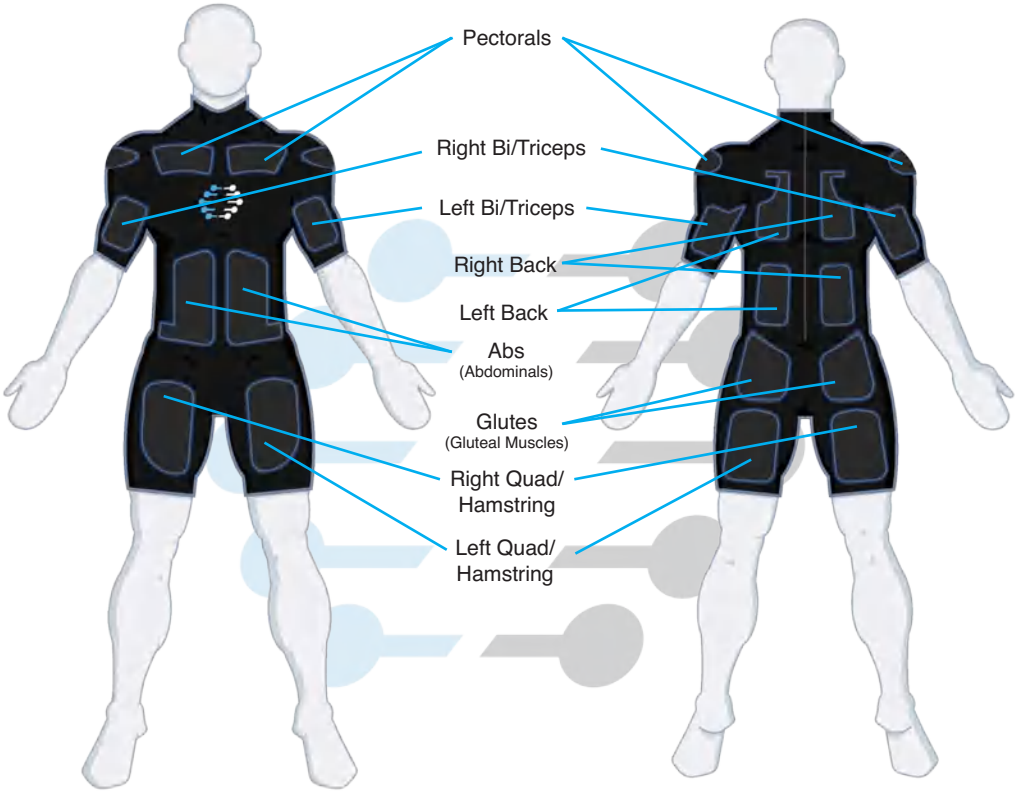
Mesurement	Size	XS	S	M	L	XL	2XL	3XL
Chest	inch	31.5 - 35	35 - 37.5	37.5 - 41	41 - 44	44 - 48.5	48.5 - 53.5	53.5 - 58
	cm	80 - 88	88 - 96	96 - 104	104 - 112	112 - 124	124 - 136	136 - 148
Waist (in)	inch	25.5 - 29	29 - 32	32 - 35	35 - 38	38 - 43	43 - 47.5	47.5 - 52.5
	cm	65 - 73	73 - 81	81 - 89	89 - 97	97 - 109	109 - 121	121 - 133
Hip (in)	inch	31.5 - 35	35 - 37.5	37.5 - 41	41 - 44	44 - 47	47 - 50.5	50.5 - 53.5
	cm	80 - 88	88 - 96	96 - 104	104 - 112	112 - 120	120 - 128	128 - 136

System COMPONENTS AND OVERVIEW (continued)

Neuro20 Smart Suit - Model Number: Neuro20-SS (continued)

Electrodes (pads) on the Neuro20 Smart Suit fit over the following muscle groups.

Neuro20 Smart Suit - Electrodes / Muscle Group Diagram



Neuro20 (PRO) System Operating Manual: N20PRO-SOM-Ver 1.6 02/23

Neuro20 System Operating Manual

Neuro20 PRO System Operating Manual is a guide for safe operation and maintenance.

You can find a digital version of the manual at www.neuro20.com

OPERATING MODES

The Neuro20 PRO System features four operating modes: Strength, Cool Down, Massage and Patterned Movements.

Operating Mode	Stimulation (Work) Period		Rest Period		Max. Output
Strength	84 Hz	175 µs	*No stimulation*	*No stimulation*	200 mA
Cool Down	100 Hz	75 µs	*No stimulation*	*No stimulation*	200 mA
Massage	84 Hz	175 µs	7 Hz	175 µs	200 mA
PEMS - Patterned Movements (all)	84 Hz	175 µs	*No Stimulation*	*No Stimulation*	200 mA

Selecting the program mode is decided by the prescribing physician. To assist with deciding which mode is best for desired patient outcomes, please refer to the following descriptions of the operating modes:

Strength contracts and then releases the muscle based on the set stimulation time and rest periods.

Cool Down is a light contraction and release operating mode.

Massage contracts the muscle, followed by a gentler stimulation period.

PEMS stimulates muscles involved in specific movements. It includes a quick contraction followed by a rest period.

OPERATING MODES (continued)

The programs are to be used to reach the proposed indications in the following ways:

Indication	Mode
The Neuro20 PRO System is intended to stimulate muscles in order to improve or facilitate muscle performance.	• Strength • Massage • Cool Down • PEMS - Patterned Movements (all)
Other indications for use include: • Re-educating muscles • Increasing local blood circulation • Maintaining or increasing range of motion • Relaxation of muscle spasm • Retarding or preventing disuse atrophy	

INSTRUCTIONS OF USE

Each operating mode is to be utilized as prescribed by the physician based on the condition of the patient. This includes any increases in usage of the operating modes, as well as the choice of operating mode.

The prescribing physician is responsible for determining how often stimulation should be used, based on the condition of the patient. It is the manufacturer's recommendation that stimulation parameters at the beginning of the course of treatment be conservative. It is recommended to not exceed 10 minutes of stimulation within the first patient session, or as tolerable to the patient. Shorter sessions may need to be prescribed by the prescribing physician, depending on the patient needs. It is recommended that increases in stimulation time should not go beyond 30 minutes overall.

Treatment and use of the Neuro20 PRO System should be terminated at the physician's discretion.

The physician should be aware of all warnings and precautions listed in this manual.

The setting of the stimulation time and rest time is determined by the prescribing physician based on the desired outcome and condition of the patient.

It is suggested to begin treatment with a 1:2 ratio of stimulation to rest time (10 seconds on, 20 seconds off), however the final decision regarding use is solely at the discretion of the prescribing physician based on patient needs. The prescribing physician may change the ratio of stimulation to rest based on their discretion and patient tolerability.

INSTRUCTIONS OF USE (continued)

Strength, Cool Down, Massage, Patterned Movements

Trainings should be separated by a regeneration phase of at least 3 days between the sessions. Depending on the athlete's/patient's physical condition and fitness level, the regeneration phase may have to be longer. Do not exceed a training time of 30 minutes per session and do not exceed 2 sessions per week for no more than 15 weeks of device use.

If clarification is necessary, physicians can provide information about the optimum regeneration phase for optimum training results.

RUNNING A SESSION

This User Manual describes how to set-up and control a stimulation session. For information regarding this, please refer to the Operating Procedures section on page 38.

Medical providers should increase stimulation until the patient either reports active muscle recruitment or until active recruitment is noticeable to the professional operator. The operator may accomplish this by pressing the muscle group and then the (+) button on the tablet.

Note! For smaller muscle groups, smaller stimulation levels should be considered than for larger muscles.

The operator should continually communicate with their patient to ensure patient comfort and tolerability. The operator may decrease stimulation at any time by pressing the muscle group and then the (-) button on the tablet. The medical professional may pause the stimulation by pressing the Pause button on the tablet or stop the session at any time by pressing the Stop button. Also, the patient may stop the session at any time by pressing the Stop button on the Control Box, which is patient override control.

OPERATING PROCEDURES

Neuro20 Smart Suit

Upon opening the package inspect the suit to ensure there are no exposed wires, holes, or tears.

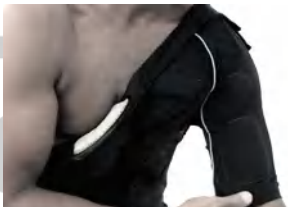
Putting on the Neuro20 Smart Suit

- Pull the suit over your legs.
- Gently pull it over your hips.
- Once the suit is over your waist, slip in one arm. (photo 1.)
- Pull up the suit with that arm sleeve over your shoulder. (photo 2.)
- Adjust the sleeve, so electrodes are in place.
- Follow the same procedure with the other arm. (photo 4. & 5.)
- Once the suit is over your shoulders, hold the loop beneath the zipper with one hand and use the other hand to pull the zipper cord upward, until fully zipped. (photo 6.)
- Secure the magnet tab at the end of the zipper cord to the magnet located at the bottom of the zipper. (photo 7.)

1.

2.

3.



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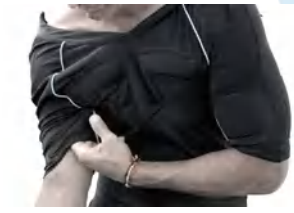

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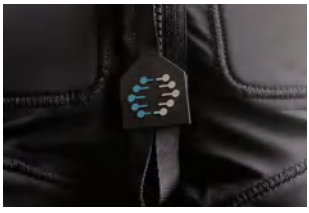


OPERATING PROCEDURES (continued)

Neuro20 PRO Control Box

1. Insert/Ensure a charged battery is in the Neuro20 PRO Control Box.
2. Ensure that the battery cover is properly secured.
3. Twist the grey battery lock button to the closed position.

Attaching Neuro20 PRO Control Box

1. Ensure the Velcro strap on the suit is not in the fastener and out of the way prior to connecting the Control Box. Make sure that the latch at the top of the hip clip is open (in the vertical position).
2. Align the slide and guide rails of the of the Neuro20 PRO Control Box with the rails on the hip clip of the Smart Suit.
3. Connect the Control Box to the Smart suit by gently guiding the USB male connection into the female connection point on the hip clip of the Smart Suit. Make sure that the Control Box is in the proper position.
4. Secure the Control Box by gently pressing down on the latch (horizontal position). Then take the Velcro fastening strap attached to the suit and place it over the Neuro20 PRO Control Box and through the fastener and close to better secure the Neuro20 PRO Control Box to the Neuro20 Smart Suit.

OPERATING PROCEDURES (continued)

Attaching Neuro20 PRO Control Box (continued)

OPERATING PROCEDURES (continued)

Detaching the Neuro20 PRO Control Box

1. Press the Neuro20 PRO Control Box Power Button and ensure that the indicator lights are off.
2. Open the Velcro fastening strap attached to the suit, close the hook and pile strap to each other and ensure that it is no longer through the fastener.
3. Open the latch at the top of the hip clip (vertical position) and slide the box downward off the guide rails. Do not pull on the box outward from the suit as this may result in a tear. Close the latch back into a horizontal position.

Refer to General Maintenance for the proper storage of the Neuro20 PRO Control Box.

OPERATING PROCEDURES (continued)

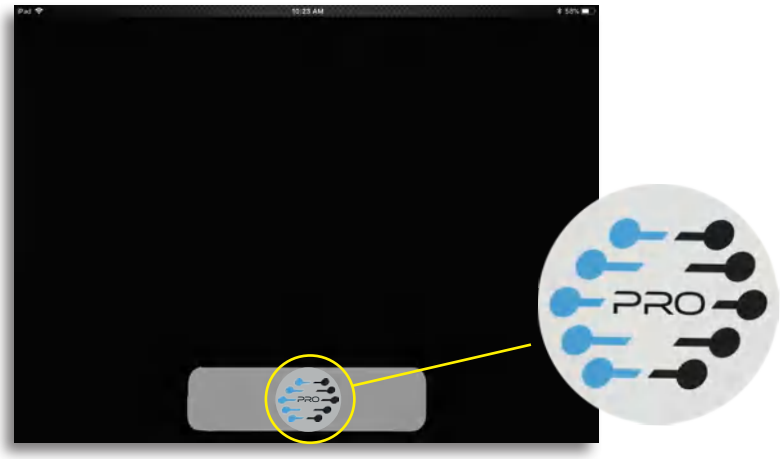
INITIAL SOFTWARE SET-UP (For System Owner Only)

Please observe all safety instructions prior to starting up the System. This start-up configuration needs to be completed only the first time. Use the e-mail of the owner of the System to set-up the Neuro20 PRO Software. The owner will have full access to this e-mail account. All rights for the use of the software and Neuro20 PRO Control Boxes will be registered and assigned to the e-mail used during this procedure. During the registration process a reply to an e-mail from Neuro20 Technologies will be required to confirm registration of the device. A username and temporary password will be sent to the Owner. The Owner will then be able to change the Password.

Software Registration and Owners Profile Setup

1. Power on the Operating Tablet by pressing the power button, then press the home button..

2. Open the Neuro20 PRO Software by tapping the icon at the bottom of the screen.



OPERATING PROCEDURES (continued)

Log-In Screen

Once the user opens the tablet app, the following screen shall appear:

Once the device is registered at www.neuro20.com then

Enter your e-mail and Password and press Sign-In.

If an error occurs refer to the Troubleshooting section of this manual.

OPERATING PROCEDURES (continued)

Main screen

After logging in, the following main screen appears:

The software version of the tablet software appears in the bottom-left corner.

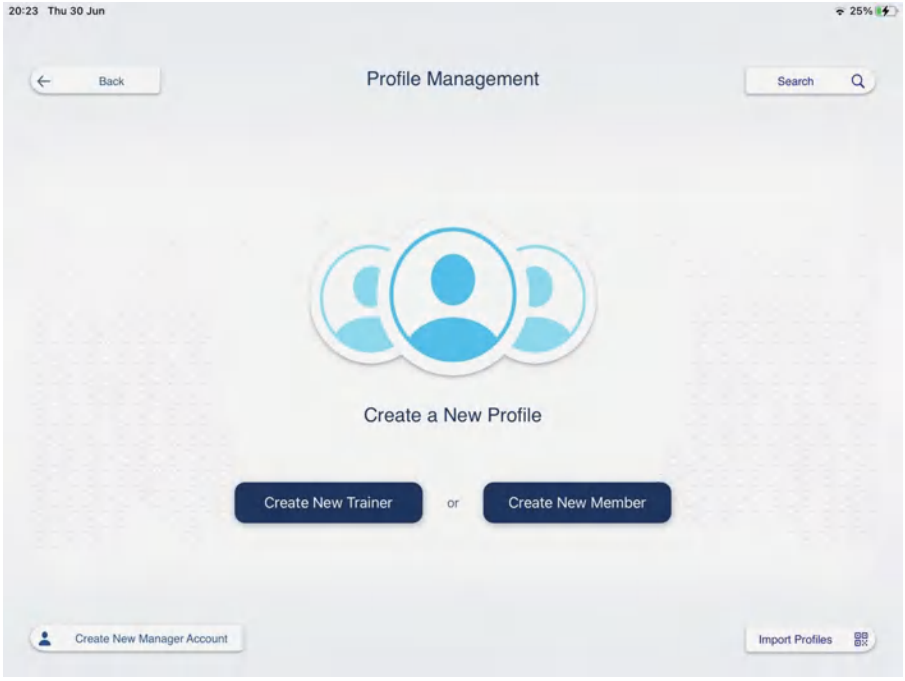
Three buttons appear: Manage Profiles, Manage Devices and Start Training.

OPERATING PROCEDURES (continued)

Profile Management

This section describes the Profile Management functionality of the Neuro20 PRO Software. This section allows the Owner/Manager to control and manage those assigned to the individual Neuro20 PRO Control Boxes and suits.

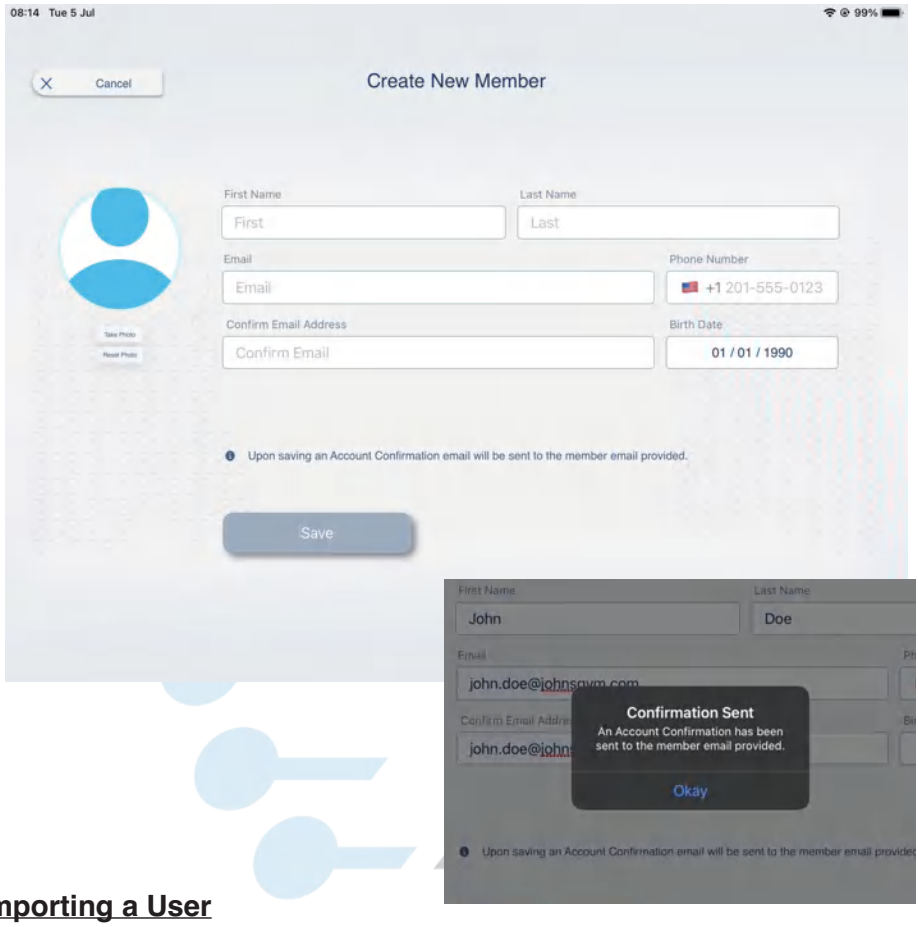
If the user is in an account with Manager permissions, the screen shall appear as follows:



Note! *The Manager Account has the same authorizations and permissions as the Owner.*

1. Create a Profile- click Manage Profiles.
2. Press either Create New Trainer or Create New Member. Fill out all Fields. **Note!** the only difference in the Create New Trainer Field is that there is a toggle choice to have the Trainer be a Member as well.
3. Press the Save button- a dialogue box will appear on the screen (with the background being greyed out), as follows: Press Okay.
4. The New Trainer or Member will need to verify their e-mail and set a password through their registered e-mail account.

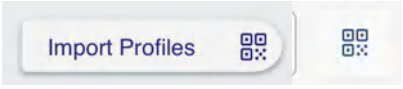
OPERATING PROCEDURES (continued)



Importing a User

This option allows the user to import a member assigned to a different Neuro20 PRO System.

The import function is accessible via the Import Profile or QR code buttons:

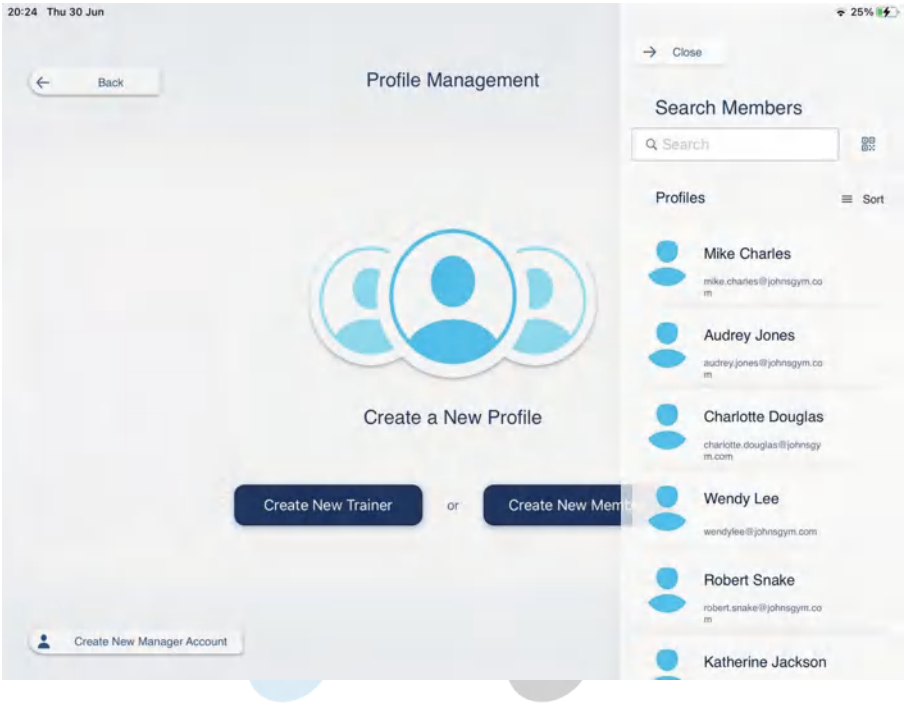


1. Click the Import Profile button to open the Operating Tablet's camera.
2. Scan the member's QR code and the device will import the member's profile and add it to the list of members on the device.

OPERATING PROCEDURES (continued)

Search function

If the user clicks the Search Icon, a pane shall appear on the right-hand side, showing the profiles in the device database.



The Search tool allows the manager to look for specific profile names.

The search box shows only entries on the list which are those where the name or e-mail address contains the given text.

Note! *Exit the profile management section to the main screen by pressing the back button.*

OPERATING PROCEDURES (continued)

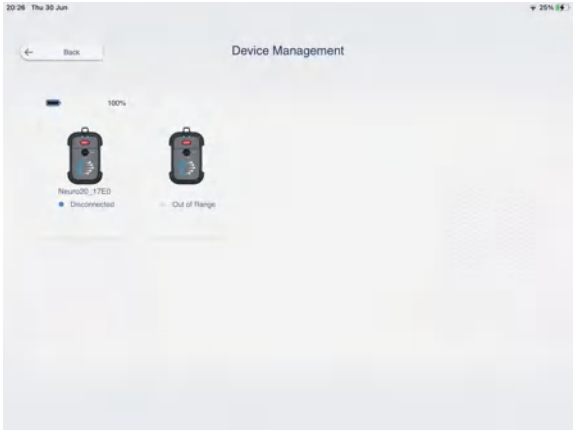
Device management

The Device Management screen shows all Neuro20 PRO Control Boxes connected to the device.

Prior to first connection

Before the first device is connected to the tablet the screen appears as follows:

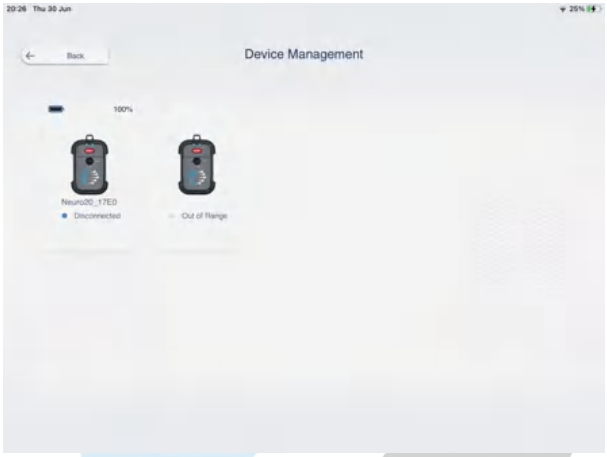
1. Press Red Stop Button to turn on the Control Box.
2. The Control Box with the Wireless ID number will appear.
3. The Owner will be prompted to Activate the Control Box to the Software by Pressing the Activate Device button.
4. Once this occurs the Control Box icon will show as Disconnected. This means that the Control Box is Activated to the Owner but is not Connected for Training. The Owner/Operator will Connect each Control Box during the Start Training Session steps.



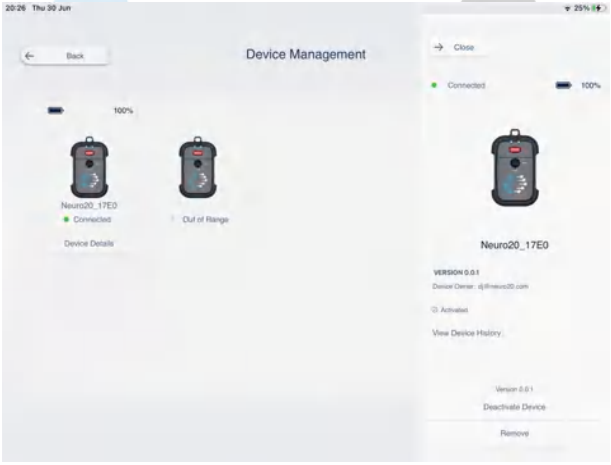
OPERATING PROCEDURES (continued)

After first connection

Once a device is Activated to the Software, the Control Box will appear. The Owner can Activate up to 10 Control Boxes.



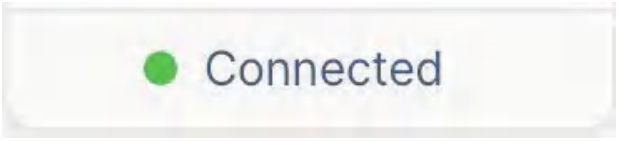
Once all boxes are Activated, the Owner may choose to Press the Disconnected button to see Device Details. This will show the Software version, the Owner account and the Device History. This step is not necessary however it may be used in the future to get this information.



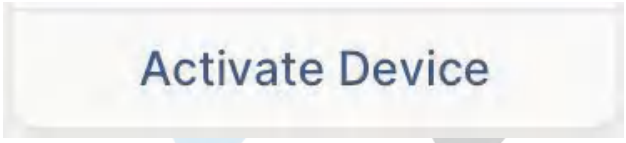
As the System is used, the Control Box icons will state varied Statuses such as Update Firmware, Disconnected, Connected, Out of Range so that the Owner/ Operator may know if the Control Box is ready for operational use.

OPERATING PROCEDURES (continued)

The connection status of the device is shown at the bottom of each block. If the Control Box is correctly connected, a green dot appears and reads “Connected”.

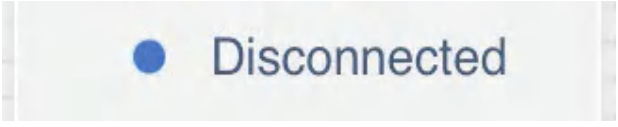


If the Control Box is not activated, no dot will appear, and reads “Activate Device”.



If the Control Box firmware needs to be updated, an amber dot appears and the text reads “Update Firmware”.

If the Control Box is disconnected, a blue dot appears, and the screen reads “Disconnected”.

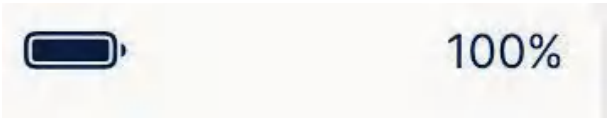


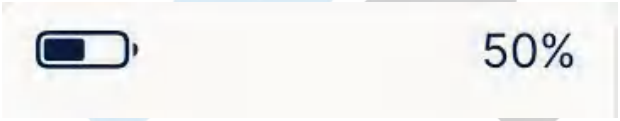
If the Control Box is Activated to the Software but is out of wireless connection range the scree will read “Out of Range”.

OPERATING PROCEDURES (continued)

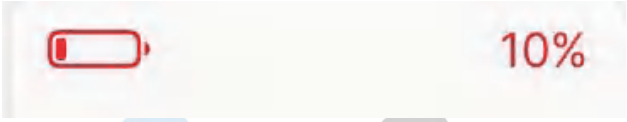
Each device features the percentage battery charge, a picture of the Control Box with serial number, and the connection status.

The upper section of each block shows the charge level of the Control Box. The battery indication on the symbol is proportional to the charge level of the device. The battery charge level is expressed as a percentage on the right-hand side of the block.





Once the battery percentage drops to 10%, in Device Management and when assigning devices for training sessions, the icon and text turn red.



When the battery level drops to 0%, the text and icon is greyed out and the bar in the battery symbol disappears.

Battery consumption will be affected by the selected intensity of stimulation. To ensure that you can finish the session, we suggest that the battery be charged above 25% before use. Once the battery reaches 10%, the battery must be charged to prevent the device from shutting down during session.

OPERATING PROCEDURES (continued)

Firmware Updates

Executing firmware updates for Control Boxes occur in the Device Management screen. Press the Update Firmware button and the update will occur. The following prompt will appear (refer to picture) and press Okay. If necessary, press Device Details to verify the newest Firmware version was installed.

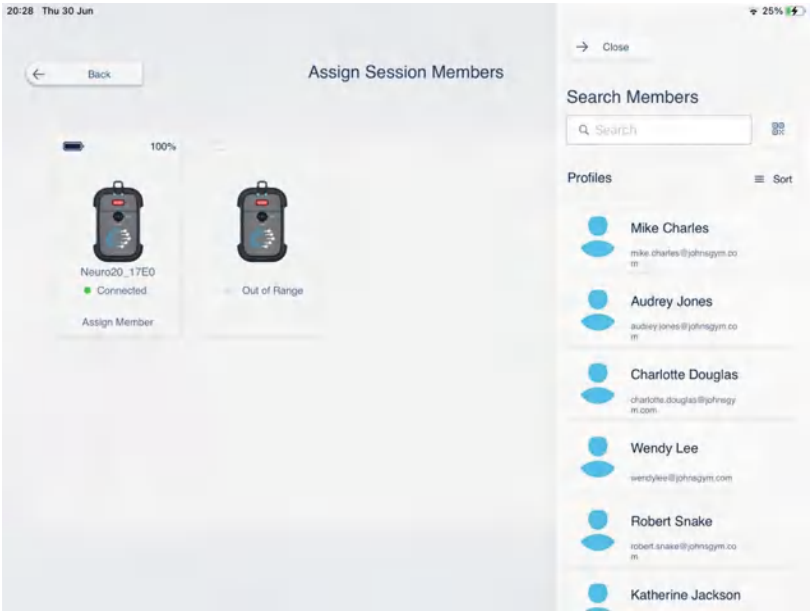
Starting a Training Session

Press Start Training on the Main Screen.

OPERATING PROCEDURES (continued)

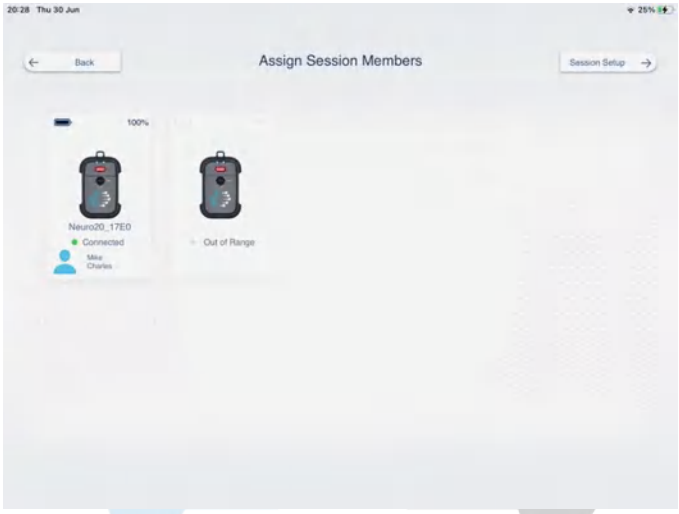
To Assign a member to each Control Box:

1. Power on the Control Box by pressing the red Stop button. Turn on and Assign one Control Box at a time prior to adding another Member.
2. A Control Box picture, the Wireless Connection ID number and an 'Assign Member' button appears on each tile.
3. Press the 'Assign Member' button and a pane will open on the right- hand side of the Software.
4. Select a member to assign to the given Control Box.
5. Repeat steps 1-4 for all remaining members in the Training Session.



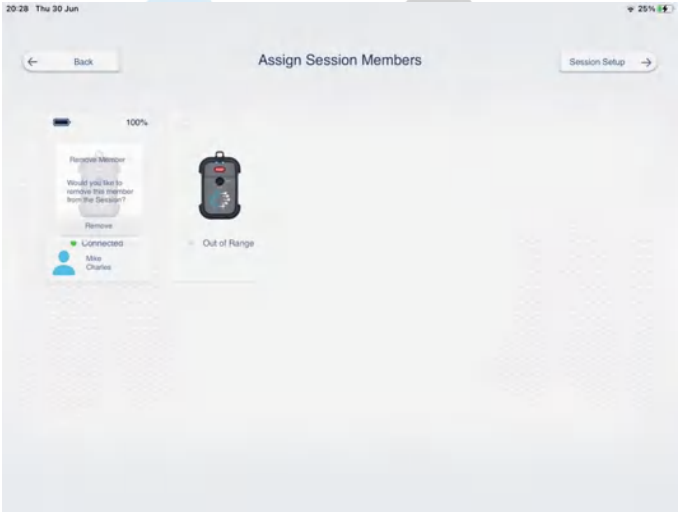
OPERATING PROCEDURES (continued)

The member Assigned to a Control Box will have their profile appear beneath the box like so



Note! Any member accounts that are not activated through the registration process, cannot be assigned to a device.

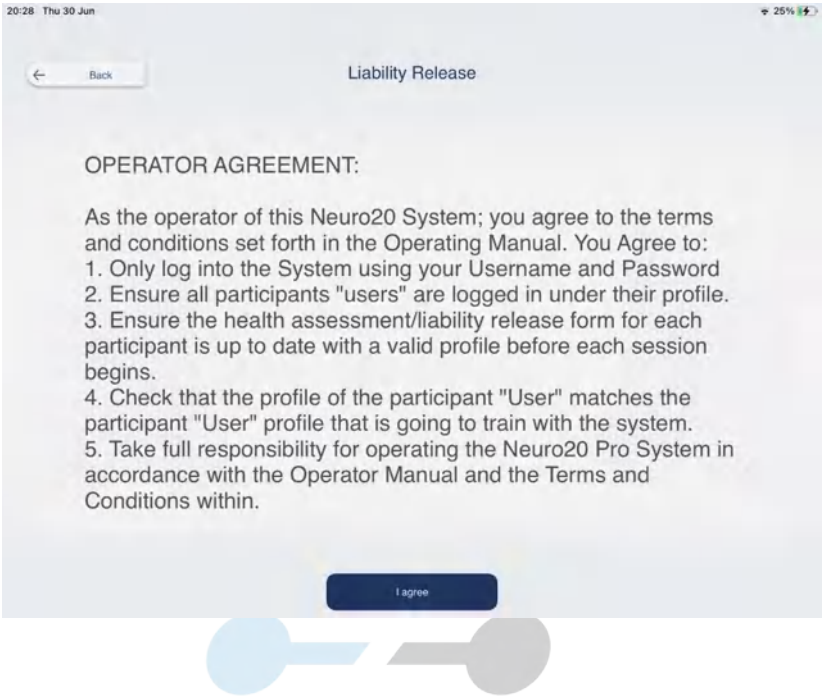
If an operator presses a tile to which a member is already assigned, a notice appears on top of the device picture to allow the operator to remove the member assigned to the Control Box.



OPERATING PROCEDURES (continued)

Liability Release

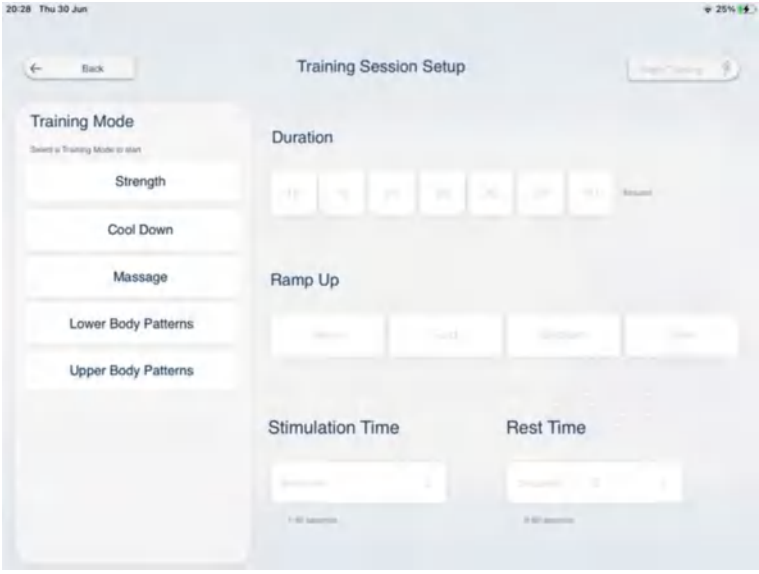
Prior to every training session the operator must read the liability release form shown on the Device Screen and press “I agree” button to proceed.



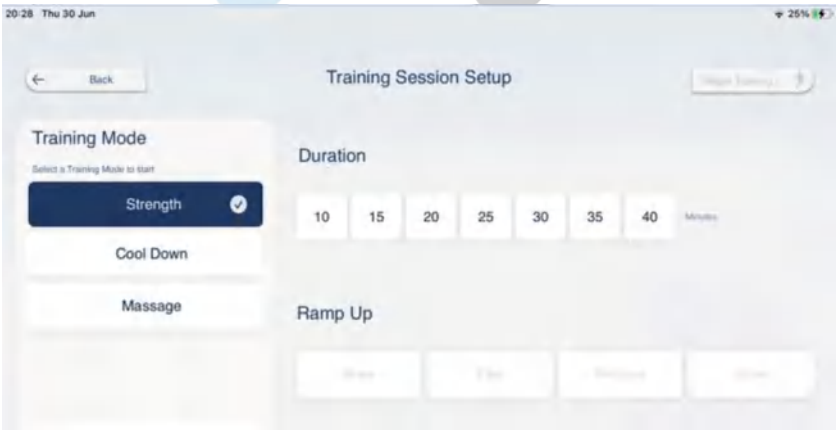
OPERATING PROCEDURES (continued)

Training Session Setup

The following screen appears:



1. Select a Training Mode, and the chosen mode will appear on a blue background with a checkmark to indicate its selection.



OPERATING PROCEDURES (continued)

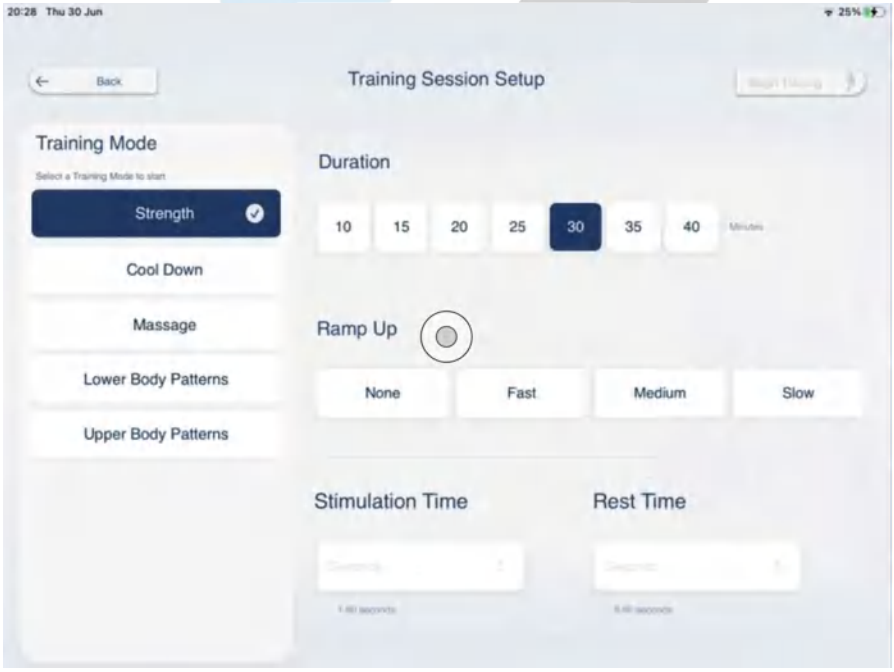
The Training Modes are Strength, Cool Down, Massage, and Patterned Movements.

Note! *Some Patterned Movements signal the User to initiate their voluntary movement over-ride (Rt./Lft. Throwing, Rt./Lft. Batting, Jumping, Rt./Lft. Kicking) while other Patterned Movements do not require a signal to initiate the voluntary movement (Cycling, Walking, Jogging, Running, Sprinting).*

Note! *The difference between the Walking, Jogging, Running, and Sprinting movements are timing speeds of the Patterned stimulation.*

Also, the various modalities have different set-up functions for the operator. For all patterned movements except for Throwing, Batting, Jumping, and Kicking the Duration for the session must be selected (See picture).

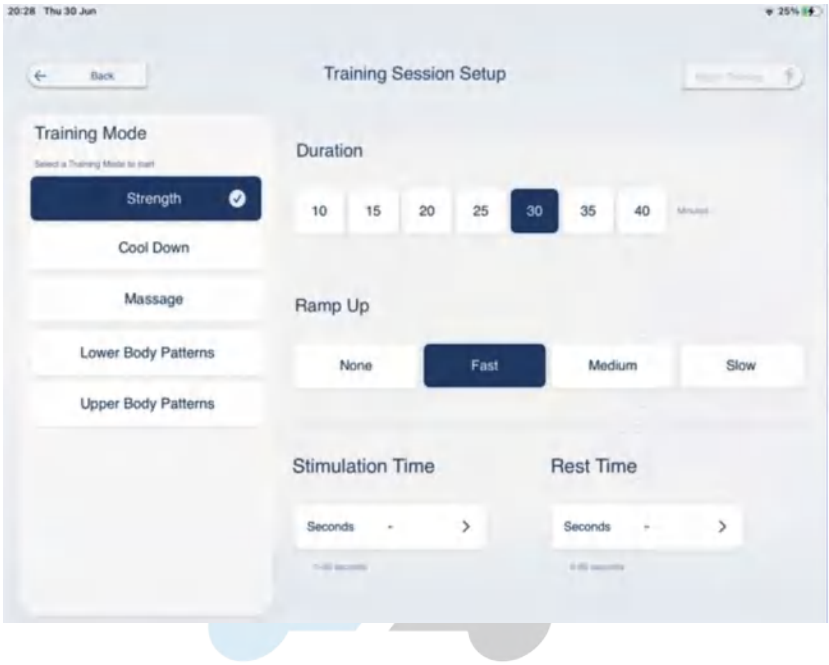
2. Select the desired Duration of the training session. The selectable durations range from 10-40 minutes with five-minute increments.



OPERATING PROCEDURES (continued)

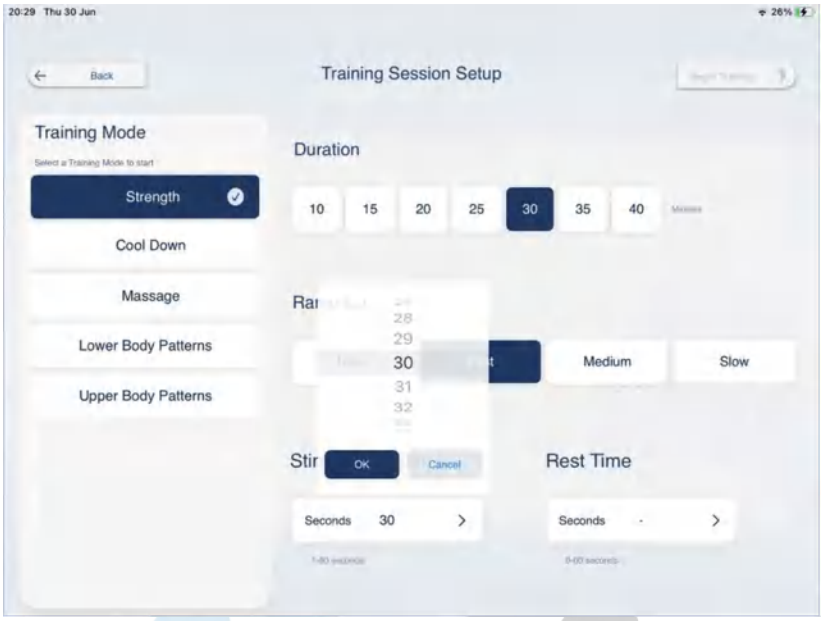
3. Select the desired Ramp Up setting

- None – no ramp.
- Slow – 3-second ramp.
- Medium – 2-second ramp.
- Fast – 1-second ramp.

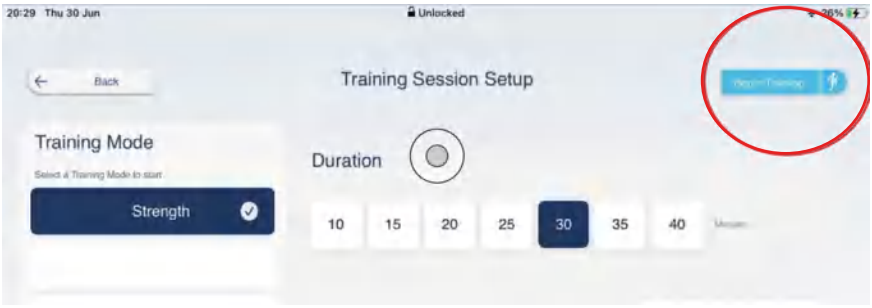


OPERATING PROCEDURES (continued)

4. Select the Stimulation and Rest Time values to determine the length of the muscle stimulation and the length of rest between stimulation. Press the “seconds” boxes and a scrolling menu appears to set the respective times for Stimulation and Rest Time between 1-60 seconds.



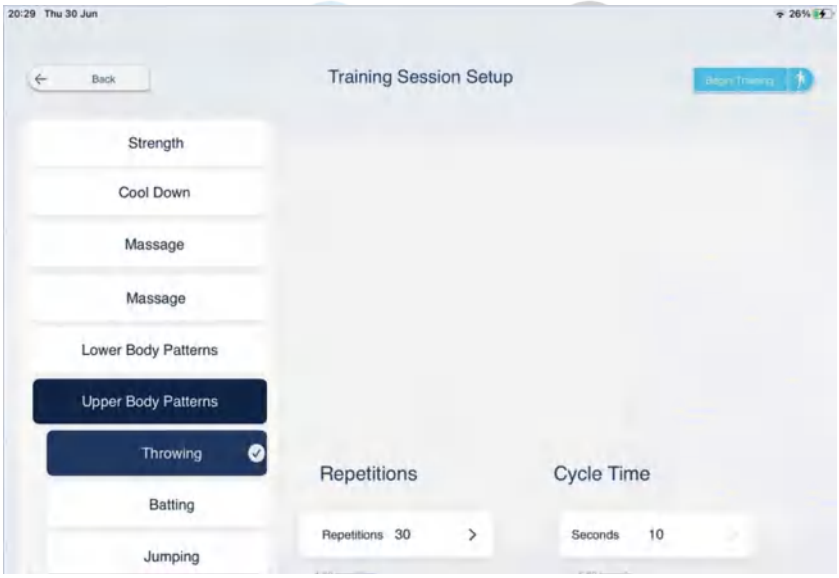
5. Press the ‘Begin Training’ button in the top right corner to open the Training Session.



OPERATING PROCEDURES (continued)

Set Up for Patterned Movements that Signal the User when to voluntarily move with the pattern (Throwing, Batting, Jumping, Kicking).

Instead of selecting Duration of the training session like the other modes, the operator will be prompted to select the number of Repetitions and Cycle Time. The Cycle Time is the time of the contraction plus the time rest time without the contraction to reset the User's body position for the next repetition of the desired movement. For example, in the Batting program the User would reset their stance to swing properly timed with the stimulation.



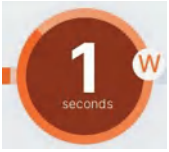
OPERATING PROCEDURES (continued)

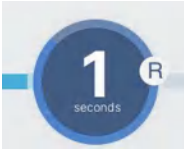
Training Session Screen

The training screen appears with all the Assigned Members and the selected Training Mode in the top center of the screen. This screen will appear different for Patterned Movements.

Training Timer

For all modes, except for Patterned Movements that require a Cycle Time rather than a Duration, the bottom of the software features a timer showing the Elapsed Time and Remaining Time of the training session and a countdown within the circle for the remaining Stimulation Time (orange) and remaining Rest Time between stimulation (blue).





OPERATING PROCEDURES (continued)

Training Timer Petterned Movement

For Patterned Movements that operate with a Cycle Time, the timer on the bottom of the screen will show a 5 minute Stimulation Adjustment period in which the operator will change the intensity percentage of the stimulation. Following the Stimulation Adjustment period, the operator may adjust the stimulation at any time. The time on the bottom of the screen appears as.

Following the five minutes Stimulation Adjustment period the orange time bar/ circle will indicate the Cycle Time and the Remaining Time. The Remaining Time is calculated by multiplying the Cycle Time by the number of Repetitions remaining..

OPERATING PROCEDURES (continued)

Adding Stimulation

1. Press on the member's profile picture at the top of the screen, or press Select All in the top right of the screen. A blue circle will appear around the User's picture. To deselect a User, press on their image again and the blue circle will disappear.
2. Press Start Session (play button) in the bottom right corner of the screen.
3. Stimulation intensity can now be adjusted from the session screen once the session is started.
4. Select body part(s) in the circle, or press Select All to adjust the intensity of the stimulation for said body part(s). The selected body part(s) appear in blue.

Prior to any adjustment the intensity is 0%. Additionally, on the body diagrams, the chosen body part selected appears in blue (even if stimulation is 0%).

OPERATING PROCEDURES (continued)

5. Adjust stimulation intensity with the + and – buttons on screen. The percentage value will increase or decrease by 0.5% increments.

   Note! When increasing stimulation, 1% equates to a 2 mA current.

6. Once the operator reaches the desired intensity of stimulation percentage for a body part for any user deselect the body part for that user by pressing the body part button, turning the body part button to grey. This action will freeze the stimulation intensity at its current level for that user. Repeat this step for each body part for each user until all body parts are at a comfortable level for each User. The operator will monitor and communicate with each User throughout the training session and adjust stimulation parameters as necessary.

OPERATING PROCEDURES (continued)

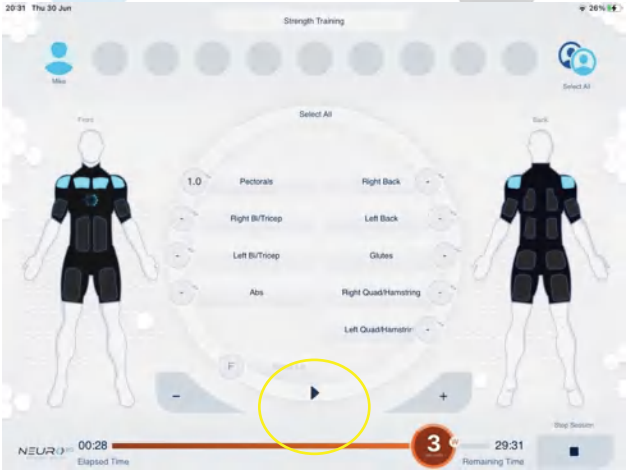
Deselect any body part by pressing the button again, turning the button grey. This action will freeze the stimulation intensity at its current level.

OPERATING PROCEDURES (continued)

Pausing the Training

Press the Pause button located at the bottom center of the circle to freeze the program for the selected user (highlighted blue circle around the user's profile photo). Press Select All to Pause and freeze the training session for all users simultaneously.

When the training session is paused, the timer freezes. Press the Play button to resume the session. **Note!** When the session resumes the timer resumes from where it left off.



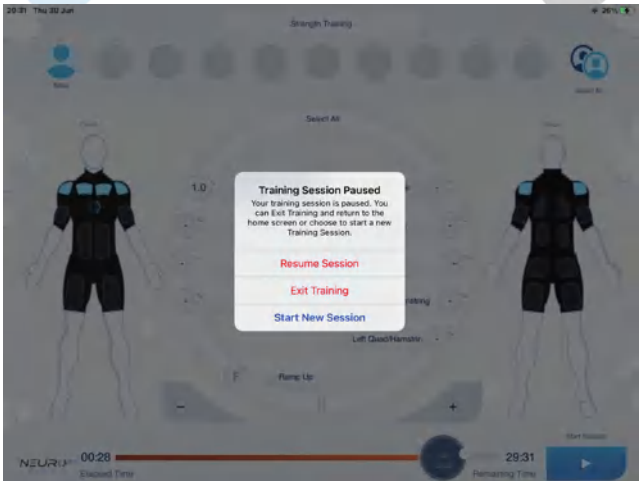
The pause button shall be replaced with a Start button. If this start button is pressed, the protocol shall resume with the previously set treatment parameters.

OPERATING PROCEDURES (continued)

Training Session Stop

Training Session Stop allows the session to be stopped for all users.
To stop the session, press the Session Stop button in the bottom-right of the screen.

When the protocol is stopped, a dialogue box shall appear, as follows:



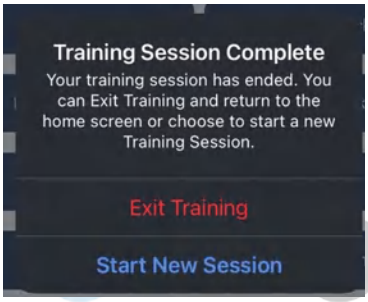
If the operator presses End Session, the session will end, and the device returns to the Assign Training Members screen. If the user presses Resume Session, the session will resume where it left off.

OPERATING PROCEDURES (continued)

Session end

Once the elapsed time ends and the remaining time becomes zero, stimulation intensities are reduced to zero and all users are deselected.

Then, an extra dialogue box shall appear, as follows:



Press Exit training to open the Main Screen. If ending the session remember to press the red Stop button on the Control Boxes to turn them off, detach from the Smart Suit as per directions and store properly. Press Start New Training Session to open the Training Session Setup Screen.

ELECTROMAGNETIC COMPATIBILITY

This device uses Bluetooth Low Energy (IEEE 802.15.1) on the 2.4 GHz frequency and at a maximum of 8 dBm.

The Neuro20 PRO System was tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The guidelines below are intended to help promote electromagnetic compatibility (EMC) in the identified use environment for the Neuro20 PRO System.

- Make use of available resources such as EMC professionals and publications and Internet web pages on the subject of medical device EMC;
- Assess the electromagnetic environment of the facility (e.g., identify radio transmitters in around the facility) and identify areas where critical medical devices are used;
- Manage the electromagnetic environment, RF transmitters and all electrical and electronic equipment, including medical devices, to reduce the risk of medical device electromagnetic interference (EMI) and achieve EMC;
- Coordinate the purchase, installation, service, and management of all electrical and electronic equipment used in the facility to achieve EMC;
- Educate healthcare facility staff, contractors, visitors, and patients about EMC and EMI and how they can recognize medical device EMI and help minimize associated risks;
- Establish and implement written policies and procedures that document the intentions and methods of the healthcare institution for reducing the risk of medical device EMI and achieving EMC;
- Report EMI problems to the US FDA MedWatch program and communicate EMI/EMC experiences to colleagues in open forums such as medical/technical publications and conferences.

More information is contained within a comprehensive guidance document for EMC in healthcare facilities, developed, with FDA participation, by the Association for the Advancement of Medical Instrumentation (AAMI): Technical Information Report (TIR) 18, Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers. AAMI TIR 18-1997. Arlington, Virginia: Association for the Advancement of Medical Instrumentation; 1997.
The Neuro20 PRO complies with the requirements of IEC 60601-1-2:2014 [Including AMD 1:2021] (EMC Collateral Standard) including the E-field susceptibility requirements at a level of 10 volts per meter, at frequencies from 80 MHz to 2.7 GHz.

ELECTROMAGNETIC COMPATIBILITY (continued)

Caution:
Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption. If this occurs, survey the site of disruption, and take the following actions to eliminate the source(s).

- Remove devices that are highly susceptible to EMI.
- Lower power from internal sources within the facility control (such as paging Systems).
- Label devices susceptible to EMI.
- Educate clinical staff to recognize potential EMI-related problems.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- Purchase medical devices that comply with IEC 60601- 2 EMC Standards (3V/meter EMI immunity, limit interference level to 0.0014 V/meter).

FCC requirements

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the Neuro20 Control Box.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced technician for help.

ELECTROMAGNETIC COMPATIBILITY (continued)

Table 201: Guidance and manufacturer's declaration - electromagnetic emission		
The Neuro20 PRO System is intended for use in the electromagnetic environment specified below. The customer or the user of the Neuro20 PRO System should ensure that it is used in such environment		
Emission test	Compliance	Electromagnetic environment guidance
RF emission CISPR 11	Group 1	The Neuro20 PRO System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emission CISPR 11	Class B	The Neuro20 PRO System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

ELECTROMAGNETIC COMPATIBILITY (continued)

Table 202: Guidance and manufacturer's declaration – electromagnetic immunity

The Neuro20 PRO System is intended for use in the electromagnetic environment specified below. The customer or the user of the Neuro20 PRO System should ensure that it is used in such an environment, and that precautions regarding that environment are heeded.

Emissions Tests	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Risk assessment on the Neuro20 PRO indicates the compliance levels claimed are acceptable when ESD-precautionary measures are taken.
Electrical fast transient/ burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not Applicable - Battery powered Not Applicable - signal lines less than 3 meters	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+1kV differential mode (line to line) +2kV common mode (line to ground)	Not Applicable - Battery powered	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000- 4-11	UT =0% 0,5 cycle (0,45,90,135,180, 225,270 and 315 degrees) U_T =0% ; 1 cycle U_T =70%; 20/30 cycles (@ 0 degrees) U_T =0% ;250/300 cycle	Not Applicable - Battery powered	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Neuro20 PRO System requires continued operation during power mains interruptions, it is recommended that the Neuro20 PRO System be powered from an uninterrupted power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60Hz	30 A/m 50 or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note! U_T is the AC mains voltage prior to application of the test level.

ELECTROMAGNETIC COMPATIBILITY (continued)

Table 204: Guidance and manufacturer's declaration – electromagnetic immunity

The Neuro20 PRO System is intended for use in the electromagnetic environment specified below. The customer or the user of the Neuro20 PRO System should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6V (ISM&Amateur)	[V_1] V, where V_1= 3V or 6V [E_1] V/m, where E_1= 10V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Neuro20 PRO System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz 80% @ 1 kHz AM Modulation	9V/m to 28 v/m 15 specific frequencies	Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{V_1}]\sqrt{P}$ - 80 MHz to 800 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$ - 800 MHz to 2,7 GHz
Proximity Field from Wireless Transmitters (test per IEC61000-4-3)	9V/m to 28 v/m 15 specific frequencies		where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Neuro20 PRO System is used exceeds the applicable RF compliance level above, the Neuro20 PRO System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Neuro20 PRO System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

ELECTROMAGNETIC COMPATIBILITY (continued)

Table 206: Recommended separation distances between portable and mobile RF communications equipment and Neuro20 PRO System

The Neuro20 PRO System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Neuro20 PRO System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Neuro20 PRO System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$ (where V_1 = 3V)	80 MHz to 800 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$ (where E_1 = 3V/m)	80 MHz to 2,7 GHz $d = [\frac{7}{V_1}]\sqrt{P}$ (where E_1 = 3V/m)
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

TECHNICAL SPECIFICATIONS

Technical specification

Height: 126 mm (4.96 in) Width: 75.5 mm (2.97 in)
Depth: 37.6 mm (1.48 in) Mass: 160 g (5.6 oz)

Power

Voltage: 7.4 V Mode of Operation: Continuous Battery run time: 6 hours
Power Source: Rechargable Li-ion battery
Battery pack model number: Type LP-E5, Model LF7.4900
Battery pack specification: 7.4 volts 900mAh, IEC62133-2 cert
Note! The battery life above is only an estimate. Actual battery life will vary depending on the training mode used, the length of the session, the stimulation intensity and the speed at which intensity is adjusted. Once the battery percentage drops to 10%, in Device Management and when assigning devices for training sessions, the icon and text turn red. At this point, the battery should be replaced.

STIM (Neuromuscular Stimulation)

Maximum amplitude: 200mA into 300 Ohms 120mA into 500 Ohms
Note! Depending on the skin impedance and connectivity between the skin and the suit, the maximum amplitude may be less than indicated.
Type: Constant current, maximum output voltage 55 Volts +/- 10%
Waveform: Symmetrical, rectangular, bi-phasic with net zero DC current

Pulse Widths: 75 - 200 µs (10% accuracy) (75 µs, 175 µs, 200 µs)
Pulse Rate Selection: 7-100 Hz (5% accuracy) (7 Hz, 40 Hz, 80 Hz, 84 Hz, 100 Hz)
Stimulation (Work) Time: 1 - 60 seconds
Rest Time: 0 - 60 seconds
Training Session Duration: 5 Seconds – 1 Hour
Ramp time: 0-3 seconds.
Number of trials are variable according to the selected parameters.
Pre-set training modes.
Automatic output shut off with detection of open electrode at and above 5% (10 mA).
Expected service life: 5 years. Careful use and maintenance extends the life of the unit over the service life limit.
Calibration Requirements: No re-calibration or periodic maintenance is required for the unit. Unit characteristics do not vary under normal conditions. The unit is calibrated during the manufacturing process and is ready to be placed into service upon delivery.

Environmental Conditions for Use:
+5 to +40 °C (+41 to +104°F). 15-90% Humidity.
Environmental conditions for Storage & Transport:
-25 to +70 °C (-13 to +158°F). 15-90% Humidity.

During intended use, the user should wear the Neuro20 PRO Smart Suit, whilst the trainer should adjust stimulation intensity on the Neuro20 PRO Operating Tablet, in liaison with the user. The Neuro20 Smart Suit is for single patient use only! Do not share Neuro20 Smart Suits between different users.

TECHNICAL SPECIFICATIONS (continued)

Symbols on the Unit and Case	
	Caution! (electrical output)
	Patient's shock protection type: BF (Body Floated) Equipment. This equipment is not earthed but contains a battery within an insulated unit.
	Refer to Instructional Manual Booklet.
	Manufacturer's LOT/Batch number. Present it together with SN number when you report a technical fault or claim a warranty return.
	Manufacturer's serial number of the unit. Present it together with LOT number when you report a technical fault or claim a warranty return.
	Date of manufacture
	This product should be kept dry.
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Name and address of Manufacturer.
IP22	This is an indication for protection ageainst ingress of water and particulate matter. The IP22 mark on your unit means that your unit is protected against solid foreign objects of 12.5mm diameter and greater and is protected against dripping water when tilted at 15°.

TROUBLESHOOTING

1. What if my Neuro20 Operating Tablet does not turn on?
    a. Check to ensure the Neuro20 Operating Tablet is properly charged. If not, plug in and ensure that the charging indication light and charging symbol are on.
    b. Ensure the Neuro20 Operating Tablet is free from debris, water, etc.
    c. If the problem persists, then contact Neuro20 technical support at support@Neuro20.com

2. What if the Neuro20 PRO Software does not launch?
    a. Ensure you have proper contact with the touch pad by cleaning the screen and your finger.
    b. Check to ensure there are no cracks to the screen - if there are cracks or damage discontinue use immediately and contact Neuro20 technical support at support@Neuro20.com
    c. Check the App Store and the e-mail account provided to verify if there are any outstanding mandatory updates - such as Error Message - ISO update version, Firmware update, or Software verification. If there are e-mails from or Neuro20 technical support team, then follow directions as prescribed in the e-mail. If there is no e-mail , ensure that your current e-mail address is registered with and then contact technical support at support@Neuro20.com

3. What if the Neuro20 PRO Software does not launch?
    a. Press the “Forgot Username or Password?” and enter your e-mail into the text-box prompt.
    b. Press “Send” for an e-mail reset to be sent. The tablet shall return to the home screen

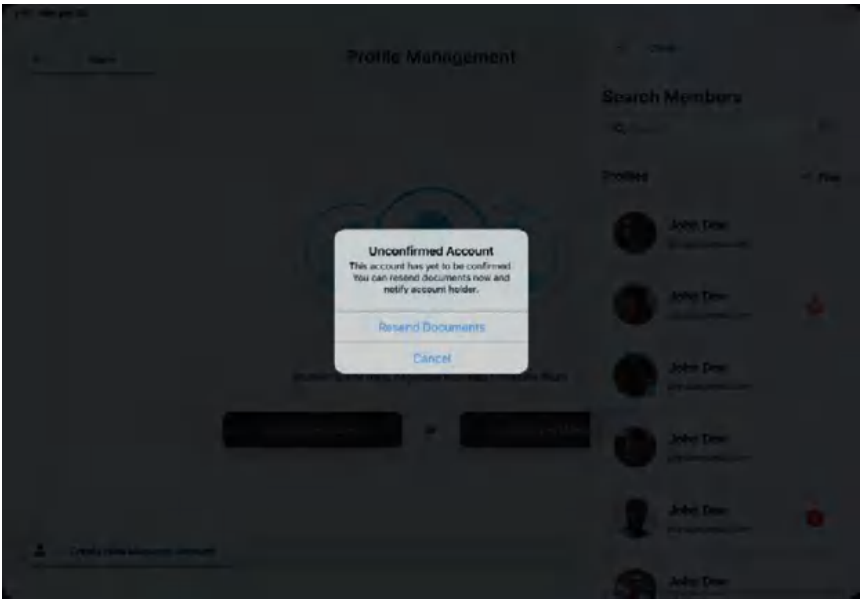
    If the given e-mail is not associated with any entry in the database, a message will appear to prompt e-mail registration

TROUBLESHOOTING (continued)

4. What if an Orange Exclamation Point in a Triangle appears when searching for Members?

   If the user's account is not confirmed, an orange exclamation mark will appear next to the member's name and e-mail address in the search.

If the operator clicks on the exclamation mark, a dialogue box will appear:



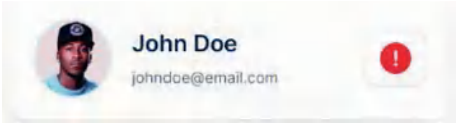
If the user clicks the "E-mail Form" button, an e-mail will be sent to the e-mail recorded under the member account asking the user to activate the account.

If the user clicks the "Cancel" button, the dialogue box will close with no further action.

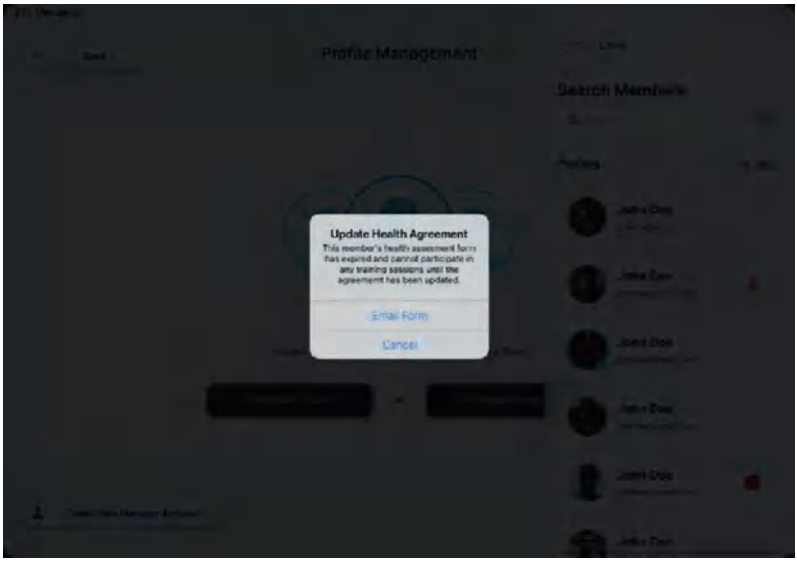
TROUBLESHOOTING (continued)

5. What if a red exclamation point in a Circle appears?

   This warning means that the Health Assessment Form is either expired or missing for this member.



If the Operator clicks on the exclamation mark, the following dialogue box will appear:



If the Operator clicks the “E-mail Form” button, the health agreement will be re-sent to the user.
If the user clicks the “Cancel” button, the dialogue box shall close with no further action.

TROUBLESHOOTING (continued)

6. What if the Neuro20 PRO Control Box is not connecting to the Operating Tablet?
   a. Check the Indicator Light on the Neuro20 PRO Control Box to ensure that the Control Box is on. Also, make sure the Control Box is in the designated range.
   b. Check that the battery is properly charged, if not, exchange the battery with a fully charged battery and turn on.
   c. If the problem persists, go to "Device Management" and check that the Control Box is connected and reading "Activated"
   d. If the problem still persists, contact Neuro20 technical support at support@neuro20.com

7. What if the Client doesn't feel the stimulation during an Active Training Session?
   a. Check the Neuro20 PRO Control Box is on and connected.
   b. Check if the Neuro20 PRO Control Box is attached properly to the Neuro20 Smart Suit. If not, reattach and restart the training program.
   c. Verbally ensure that the User is not wearing anything under the Neuro20 Smart Suit, which could obstruct proper connection of the pads with the skin ... i.e. undergarments or bra.
   d. Check the levels of the muscle groups for the User in question. If the User accidentally or purposely pressed the red Start button on the Control Box during the active training session, it automatically resets all the muscle groups to 0%. If this occurs the Training Session will need to be reset.
   e. If the problem still persists, have the user change the Neuro20 Smart Suit.
   f. If the problem still persists, contact support@neuro20.com.

8. What if during the training session an electrode on the suit diagram turns Yellow?
   a. Verbally ensure that the User is not wearing anything under the Neuro20 Smart Suit which could obstruct proper connection of the electrodes with the skin ... i.e. undergarments or bra.
   b. Ensure Users are in the proper size suit. (See sizing chart pg.15)
   c. Ensure that there is moisture on the electrode either from sweat or use a spray bottle to wet the electrodes.
   d. If the Yellow signal on the suit diagram still persists, then change out the Neuro20 PRO Control Box.
   e. If the Yellow still persists, then close and restart the Software.
   f. If the Yellow still persists then change the Neuro20 Smart Suit.
   g. If the Yellow persists, discontinue training and contact Neuro20 technical support at support@neuro20.com.

TROUBLESHOOTING (continued)

9. What if one or more of the User's icons shows a warning indication?
    a. Warning indications may appear for multiple reasons.
    b. This feature occurs when the Control Box is out of range of the Operating Tablet, is turned OFF, or the battery runs out.
    c. Ensure the User is in range of the device - max. 330ft/100 meters and free of obstructions and that no more than 10 devices are within this range.
    d. Ensure the device is not operating near electromagnetic or microwave potentially interfering devices. More information can be found in the ELECTROMAGNETIC COMPATIBILITY section of this user Manual.
    e. Ensure the wireless connection on the Operating Tablet is not disabled in settings.
    f. Ensure the Control Box was not turned off (check indication light).
    g. If the problem persists, discontinue training and contact Neuro20 technical support at support@neuro20.com.

    Note! *Once the issue is fixed and Control Box reconnects with the Operating Tablet it will automatically join the session. Trainer may need to re-adjust the levels on the Client's muscle groups.*

10. What if the battery is not charging?
    a. Check the connection of the charger and the placement of the battery in the charger.
    b. Disconnect the charger from the power source, then check the connection points of the charger and the battery. Check that they are dry, free from debris, dust or lint. If needed, gently clean the charger and battery contact points with a nylon brush.
    c. Unplug the charger and plug it into an outlet that is proven to be actively working.
    d. Try charging a different battery, if that does not charge, try a different charger.
    e. If the problem persists, contact technical support at support@neuro20.com.

GENERAL MAINTENANCE

It is expected that all operators maintain the Neuro20 PRO System and all of the component parts by using the guidelines provided herein. Neuro20 recommends that the Neuro20 PRO System is only operated after the owner is comfortable and knowledgeable of all contents within the Operating Manual. Please handle all System components with care. The Neuro20 PRO System is an electrical computerized device and should not be thrown, dropped, banged, or stored with items that can damage the product. If there is any evidence, or appearance of damage, or tampering to any component of the Neuro20 PRO System, immediately remove the component from service, discontinue use and contact support@neuro20.com.

Keep the Neuro20 Operating Tablet Dry at all times. Optimal storage conditions are to place the Neuro20 Operating Tablet into the padded case provided at the time of purchase whenever the System is not in operation. Operating Tablet work best at 0° to 35° C (32° to 95° F). Place your device in a cool, moisture-free environment that's less than 90° F (32° C). For Best General Performance Tups refer to: https://www.apple.com/batteries/maximizing-performance/ Use only the charger, cord, and battery components provided and do not alter or stack any other non-authorized product with this device. Always ensure that the Neuro20 Operating Tablet is charged appropriately for the training session and only charge the Neuro20 Operating Tablet in a safe environment away from flammable enriched atmosphere, pets, pests, and children. Limit direct exposure to light, sunlight, when not in operational use and keep away from lint, dust and debris. Never use any liquid or chemical cleaning solution on any System component. When cleaning the Neuro20 Operating Tablet wipe gently with a microfiber cloth. If any damage occurs to the Neuro20 Operating Tablet, stop operation instantly and contact support@neuro20.com.

Software Maintenance:
Regular required Neuro20 PRO Software updates on the tablet may occur. This will require an active internet connection. The software updates will be possible for any registered Owner/Manager to install through the Device Management tab in the software. All registered owner/managers will receive an e-mail to notify them of software updates.

Neuro20 PRO Control Box:
Do not change or alter any labels, components, charger, batteries, or stack electrical unauthorized products with the Neuro20 PRO Control Box as it may cause a malfunction of the device. The temperature range for use of the device is +5 to +40 °C (+41 to +104°F) and the humidity range is 15-90% Humidity. The temperature range for Storage & Transport is -25 to +70 °C (-13 to +158°F) and the humidity range is 15-90% Humidity. Neuro20 PRO Control Boxes should be stored in the padded case provided at the time of purchase.

GENERAL MAINTENANCE (continued)

Keep the Neuro20 PRO Control Box dry at all times. Limit direct exposure to light, sunlight, whenever the System is not in operational use. Keep away from lint, dust and debris. To clean the Neuro20 PRO Control Box use a soft, clean, lint free, dry, nylon brush and gently wipe the surface. If there is any visible damage to a Neuro20 PRO Control Box, remove the item in question from use, store properly, and immediately contact at support@neuro20.com.

Keep the battery and charger dry. Limit direct exposure to light, sunlight, whenever the System is not in operational use. Keep away from lint, dust, and debris, especially the battery and charger contact points. Never use any liquid or chemical cleaning solution on any component part. Keep away from children, pests, and pets.

When the battery is charging, the charger indicator light in the charger is red while charging, and green when charging is complete. If there is any visible damage to the battery or charger remove the item in question from use, store properly, and immediately contact technical support at support@neuro20.com.

Neuro20 Smart Suit:
is a complex technology wearable which requires specific maintenance guidelines.

The Neuro20 Smart Suit is machine washable. We recommend washing the suit regularly after use in order to prepare it for future sessions.
Prior to washing ensure that the suit is right side out (logo visible).

Ensure that the Velcro Strap is out of the loop and securely closed to prevent the hooks of the Velcro causing damage to the suit.

Fold the suit to the proper size to fit into the provided mesh laundry bag and close zipper.

Use a mild, bleach free detergent
(i.e. high performance sports detergent or baby shampoo).

GENERAL MAINTENANCE (continued)

The Neuro20 Smart Suit must be washed on a regular wash cycle, not to exceed a spinning speed of 800 RPM, and in a water temperature at 30 degree C or below.

The Neuro20 Smart Suit must is HANG DRY ONLY, do not place in dryer.

Do Not!

1. Do not dry clean or clean chemically.
2. Do not bleach or use any fabric softener or fragrance enhancer.
3. Do not tumble dry or wring out by hand.
4. Do not dry in direct sunlight.
5. Never iron.
6. Never hand scrub or hand wash or use any abrasive, or brush on the suit.

Always inspect the Neuro20 Smart Suit for physical damage, loose threading, and wear and tear. Any damage or degradation to the electrodes and the connection may cause a malfunction of the technology. Upon recognizing any potential damage to the Neuro20 Smart Suit, remove the suit from serviceability and contact customer support at support@neuro20.com.

The Neuro20 Smart Suit should be stored indoors in a clean, dry, pest free environment away from pets and children, and never stored in direct sunlight. The suggested temperature guidelines for storage of the Neuro20 Smart Suit is above +10° to +40° C (50° to 104° F)d, 5% to 80% RH, non-condensing and atmospheric pressure range of 700 hPa to 1060 hPa.

Note! The Neuro20 Smart Suit should not be altered, patched, or have any logos added to the suit as this may cause a device malfunction.

The Neuro20 Smart Suit is for single patient use only!
Do not share Neuro20 Smart Suits between different users.

GENERAL MAINTENANCE (continued)

Neuro20 Operating Manual:
is available in PDF format on the Neuro20 Operating Tablet located in the "Books" App.

It is also available for download at
https://www.neuro20.com/assets/doc/Manual.pdf
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Service Life and Shelf Life for All Component Parts

Model Number	Description	Shelf Life	*Service Life*
iPad 9th generation	Neuro20 Operating Tablet	5 years	4 years
N20PRO-CB	Neuro20 PRO Control Box	N/A	5 years
N20-SS	Neuro20 Smart Suit	3 years	1 year
Battery & Charger	Battery w/Charger	1 year	N/A

PRODUCT REGISTRATION

It is mandatory for all Neuro20 product owners (System and suits) to register their items with Neuro20 at ***www.neuro20.com/registry.*** Please register your new Neuro20 System and/or Smart Suits with the Serial Number printed on the label of the product. The Neuro20 warranties activate immediately upon date of purchase and will not be considered valid unless product registration is completed.

Ensure that your account password features a mix of uppercase and lowercase letters, symbols and numbers.

At the point of sale of the Neuro20 PRO System requires that certain information is collected and stored in an internal database to be used for certification, tracking and shipment purposes. The model number of the System, the owner's information, and the information for any individual that will operate the System will need to be provided prior to operational use. Any additional or future operators of the Neuro20 PRO System will need to register as well.

This information will be used for Neuro20 to provide updates, potential recall information, additional product information opportunities, and to ensure warranty activation.

LIMITED WARRANTY

Neuro20 Technologies Corp. ("Manufacturer") warrants the Neuro20 PRO System Control Box to be free from manufacturer defects in material and workmanship for a period of three (3) years from the original date of purchase. Seller also warrants the Neuro20 PRO System "Smart Suit" (the "Smart Suit") to be free from manufacturer defects in material and workmanship for a period of six (6) months from the original date of purchase. Together, the Smart Suit and Control Box shall be referred to herein as the "Product".

This Limited Warranty shall be void unless Product is registered with the Manufacturer within thirty (30) days of purchase.

This warranty does not cover any damage caused by misuse, abuse, accidents, wear and tear from normal use, alterations to the Product, or use of the Product with components made by any manufacturer other than Neuro20 Technologies Corp. Failure to comply with all storage, use, cleaning, and other instructions in the Neuro20 PRO System Operating Manual, including but not limited to the System Component and Overview section, shall void this Limited Warranty. This Limited Warranty does not apply to any component of the Neuro20 PRO System other than the Control Box and the Smart Suit.

LIMITED WARRANTY (continued)

Should the Purchaser believe that any portion of the Product is defective within the scope of this warranty, the Purchaser must immediately stop using the defective Product, and inform Manufacturer in writing, via e-mail at ***warranty@neuro20.com*** of the suspected defect within thirty (30) days of discovery of the alleged defect, or this warranty is deemed waived by the exclusive for any and all claims by the Purchaser or any person claiming through the Purchaser against Manufacturer, whether based on contract, negligence, tort, strict liability, warranty, or under any statute or on any other basis.

TO THE FULLEST EXTENT ALLOWED BY LAW, IN NO EVENT SHALL MANUFACTURER BE LIABLE, WHETHER BASED ON CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY, WARRANTY, OR UNDER ANY STATUTE OR ON ANY OTHER BASIS, FOR SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY, PUNITIVE, MULTIPLE OR CONSEQUENTIAL. DAMAGES ARISING OUT OF OR CAUSED BY THE PRODUCT OR THE POSSESSION OR USE OF THE PRODUCT BY THE PURCHASER OR ANY PERSON CLAIMING THROUGH THE PURCHASER.

IN ALL CASES ABOVE WHETHER OR NOT FORESEEABLE AND WHETHER OR NOT SELLER IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, INCLUDING WITHOUT LIMITATION DAMAGES ARISING FROM OR RELATED TO PERSONAL DAMAGES, LOSS OF USE, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, OR FOR LOSS OF REVENUE, PROFITS, EARNINGS, OR GOODWILL. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY. DAMAGES FOR ANY CLAIM, INCLUDING A WARRANTY CLAIM, MADE ON ANY BASIS ARE LIMITED TO THE PURCHASE PRICE OF THE PRODUCT FOR WHICH DAMAGES ARE CLAIMED.

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Some states do not allow limitations on how long an implied warranty lasts, therefore the above limitation may not apply. Manufacturer neither assumes, nor authorizes any person to assume for it, any additional liability or responsibility with respect to the Product beyond this Limited Warranty.

NON-WARRANTY REPAIR SERVICE: Non-warranty repair service may be available for a fee. Contact Manufacturer for further information.

LIMITED WARRANTY (continued)

All limitations and exclusions herein are agreed to and accepted by the Purchaser upon purchase of the Product. Purchaser agrees that any dispute regarding this warranty shall be resolved by arbitration in Hillsborough County, Florida. Purchaser agrees that Florida law shall be the governing law. If arbitration is deemed inapplicable by a court of competent jurisdiction, Purchaser agrees that Florida courts have proper personal jurisdiction over the parties to this Limited Warranty.

Address for notification of claims under this Limited Warranty:

warranty@neuro20.com

Corporate Address:

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