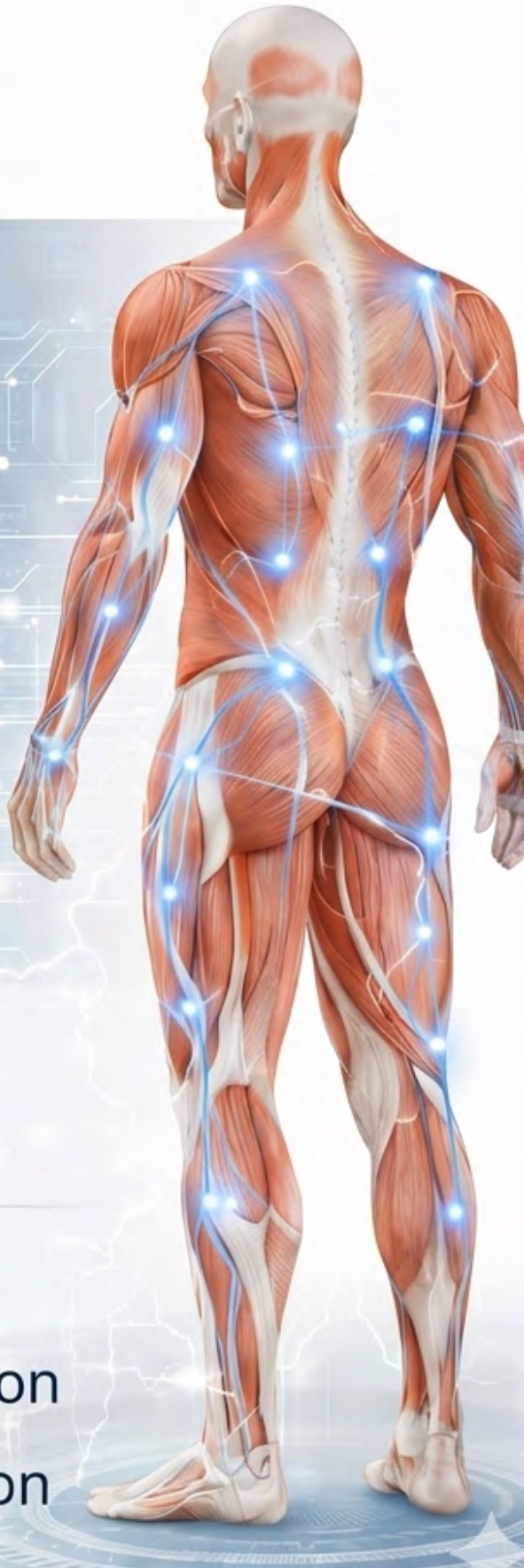
WHOLE-BODY

NEUR20
TECHNOLOGY THAT MOVES YOU

# ELECTRICAL NEUROMUSCULAR MODULATION (ENM)



## CLINICAL PROTOCOL FRAMEWORK

- ☑ Physiological Signaling
- ☑ Coordinated Motor Activation
- ☑ Neuromuscular Re-Education


**Neuro20® PRO System Clinical Protocol Framework**

***For professional use only.***



*Published by Neuro20 Technologies Corp.*
*140 Pine Ave N,*
*Oldsmar, FL 34677 USA*

*+1 (917) 503-6876*
*info@neuro20.com*

*www.neuro20.com*

*Document Version: N20-PT-00 rev. 01*
*Publication Date: March 2026*

*Copyrighted in the United States of America*

# Table of Contents

# Introduction

The Neuro20 PRO System is an FDA-cleared Whole-Body Electrical Neuromuscular Modulation (WB-ENM) system designed to support neuromuscular activation, functional movement training, and the management of physical impairments that affect mobility and activities of daily living (ADLs).

This guide provides clinical protocol recommendations developed in collaboration with physicians, physical therapists, and rehabilitation professionals currently using Neuro20 technology in clinical practice. The protocols are intended to assist clinicians in selecting appropriate Neuro20 stimulation strategies based on patient presentation, functional impairments, and therapeutic goals.

The protocol section is designed for **rapid clinical reference**, allowing clinicians to proceed directly to the condition-specific protocol pages.

A detailed explanation of the **clinical reasoning framework and proposed physiological mechanisms** behind the protocols is provided in the **Clinical Logic and Mechanisms section at the end of this document.**

This guide should be used in conjunction with the **Neuro20 PRO System User Manual**, which contains complete instructions for use, warnings, precautions, and contraindications.

## How to Use This Guide

1. **Identify the patient's primary condition or functional limitation.**
2. **Refer to the corresponding protocol section** for that condition.
3. **Select the appropriate protocol type** (Sensory, Motor, or Patterned) based on patient presentation and therapeutic goals.
4. **Adjust stimulation parameters** according to patient tolerance and clinical judgment.

For additional explanation of the clinical reasoning supporting these protocols, refer to the **Clinical Logic and Mechanisms section** at the end of this document.

Protocols should be used as **clinical frameworks rather than rigid prescriptions**, and may be adjusted based on patient response.

## Clinical Guidance Notice

This protocol guide was developed by Neuro20 Technologies in collaboration with medical professionals currently using the Neuro20 PRO System in clinical practice. The content reflects clinical experience, observational insights, and proposed physiological reasoning intended to support therapeutic decision-making.

The Neuro20 PRO System is **not intended to diagnose, treat, cure, or modify underlying disease processes**. Instead, the system supports neuromuscular activation, functional training, and the management of physical impairments affecting mobility and activities of daily living (ADLs).

This document is a **supplementary clinical guidance resource** and does not replace the official Neuro20 PRO System User Manual, which contains all device operation instructions, warnings, precautions, contraindications, and safety information.

# CONTRAINDICATIONS, WARNINGS & SAFETY

*Read fully before use. For professional use only. Always refer to the full Neuro20 PRO System User Manual.*

## CONTRAINDICATIONS - DO NOT USE

**Cardiac Demand Pacemaker**

Do not use on patients with a cardiac demand pacemaker.

## ADVERSE REACTIONS

Skin irritation or burns beneath electrodes have been reported with similar electrical stimulation devices. Discontinue use and treat appropriately if observed. Reduce stimulation intensity in subsequent sessions. Refer to User Manual for adverse event reporting.

## WARNINGS & PRECAUTIONS

**Fever / Infection / Acute Inflammation** - Do not stimulate over swollen, infected, or inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins).

**Active Cancer / Malignancy** - Do not stimulate over or in proximity to cancerous lesions.

**Medical & Implanted Devices** - Do not use with implanted devices; if deactivation is possible, obtain physician clearance before each session. Avoid simultaneous use with high-frequency medical equipment due to risk of burns or device damage.

**Epilepsy** - Use with caution; consult the patient's physician prior to use.

**Muscle Breakdown (DOMS / Rhabdomyolysis Risk)** - Overstimulation may cause muscle breakdown, including rare cases of rhabdomyolysis (e.g., dark urine). Discontinue use and consult a physician if this occurs, and resume only with physician clearance at reduced intensity. If soreness persists beyond a few days, reduce intensity. Ensure adequate hydration.

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

**Pregnancy** - Do not apply over the lumbar, abdominal region, or uterus during pregnancy. Safety of powered muscle stimulators during pregnancy has not been established.

**Menstruation -** May increase menstrual flow; avoid lumbar, abdominal, and uterine regions during menstruation cycle.

**DVT / Thrombophlebitis** - Do not apply directly over or near Deep Vein Thrombosis. Avoid in areas of acute DVT until fully resolved. If the patient is not permitted to exercise, avoid NMES therapy. NMES over a DVT of six weeks or less should be avoided altogether.

**Cardiac Disease** - Use low intensity and short treatment durations. Stimulation may affect heart rate; consult the patient's physician prior to use.

**Monitoring Equipment** - Do not use on patients connected to monitoring equipment; stimulation may interfere with device function.

## STOP SESSION IF

- Abnormal pain or discomfort
- Skin irritation or burns
- Dizziness, nausea, or unusual symptomps

**Emergency Stop** The patient or operator can press the ***red STOP button*** on the Control Box at any time to immediately terminate the session.

## IMPORTANT REMINDERS

- Inspect Smart Suit before each use.
- Ensure proper electrode contact before starting session.
- Use only as prescribed by a licensed healthcare professional.

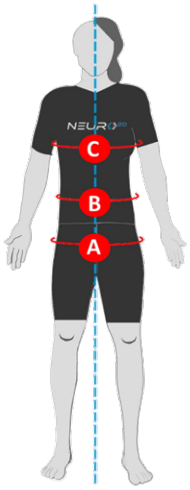
***Refer to the User Manual for full contraindications, warnings and precautions.***

***www.neuro20.com/manual***

# SIZING, FIT & CARE

*Follow all guidelines to maintain device performance, safety, and warranty coverage.*

**KEY RULE:** ***HIP measurement (A) is the PRIMARY sizing factore*** - always size by hips first. If upper/lower body measurements differ, use compression garments over the suit. Never adjust suit size for comfort.




| SIZE | MEASUREMENT | | | | | |
|---|---|---|---|---|---|---|
| | A HIPS | | B WAIST | | C CHEST | |
| | inch | cm | inch | cm | inch | cm |
| XXS | 31.5 - 35 | 80 - 88 | 25.5 - 29 | 65 - 73 | 31.5 - 35 | 80 - 88 |
| XS | 35 - 37.5 | 88 - 96 | 29 - 32 | 73 - 81 | 35 - 37.5 | 88 - 96 |
| S | 37.5 - 41 | 96 - 104 | 32 - 35 | 81 - 89 | 37.5 - 41 | 96 - 104 |
| M | 41 - 44 | 104 - 112 | 35 - 38 | 89 - 97 | 41 - 44 | 104 - 112 |
| L | 44 - 47 | 112 - 120 | 38 - 43 | 97 - 109 | 44 - 48.5 | 112 - 124 |
| XL | 47 - 50.5 | 120 - 128 | 43 - 47.5 | 109 - 121 | 48.5 - 53.5 | 124 - 136 |
| XXL | 50.5 - 53.5 | 128 - 136 | 47.5 - 52.5 | 121 - 133 | 53.5 - 58 | 136 - 148 |

*Smart Suit Key Features*

*Smart Suit Components*

*Preparing Smart Suit*

*Putting on Smart Suit*

- Measure standing with flexible measuring tape directly on body or over thin clothing.
- Do not size up or down for comfort, use compression garments instead.
- Neuro20 is not responsible for sizing errors outside published guidelines.
- Must be worn directly on the body, no underwear underneath.
- Re-measure after significant body changes (weight loss / muscle gain).

## QUICK CHECKLIST — BEFORE EVERY SESSION

- ✓ **Skin clean & dry** — No lotions, oils, or creams applied
- ✓ **Electrodes aligned** — Correct position over muscle groups
- ✓ **USB-C connected** — Plug removed, connection solid
- ✓ **Suit is snug** — No gaps between electrodes and skin
- ✓ **Battery charged** — Green light = fully charged
- ✓ **Control Box secured** — Latch closed, Velcro strap fastened

## CARE & MAINTENANCE

### WASHING THE SMART SUIT

1. **Suit right-side out** (logo visible). Velcro strap securely closed.
2. **Insert silicon plug into USB-C** connector before placing in wash bag.
3. **Fold suit** lengthwise in half, fold ends to centre, fold in half again.
4. **Place** folded suit **in the provided Wash Bag.**
5. **Machine wash:** regular cycle, max 30°C / 86°F, max 1200 RPM.
6. **Use mild, ecologic, sensitivae** or bleach-free sports detergent (e.g. ECOS, HEX, Biokleen).
7. **HANG DRY ONLY** - never tumble dry, iron, wring, or dry in sunlight.

### CONTROL BOX & BATTERY CARE

- **Keep dry at all times.** Never immerse or wash with liquids.
- **Clean gently.** Use a soft, dry, lint-free nylon brush only.
- **Avoid direct sunlight.** Store in padded case when not in use.
- **Temp (use)** +5°C to +40°C (+41°F to +104°F)
- **Temp (storage)** -25°C to +70°C (-13°F to +158°F)
- **Battery charging.** Red = charging | Green = fully charged (battery charger indicator lights)
- **Damage visible?** Remove from use immediately & contact support.

## TROUBLESHOOTING & SUPPORT

*Troubleshooting & Support:* ***support.neuro20.com***

*For full care instructions, detergent recommendations & service life details, refer to the Maintenance Guide or User Manual -* ***www.neuro20.com/manual***

*Washing Smart Suit*

*Smart Suit How to Videos*

*Smart Suit Table Test*

*Maintenance Guide (PDF)*

*Smart Suit Size Chart (PDF)*



# Neuro20 Protocol Framework

The Neuro20 protocol categories are designed to address functional impairments rather than specific disease processes. Patients with different diagnoses may present with similar neuromuscular dysfunctions such as impaired muscle activation, altered movement coordination, fatigue, or reduced activity tolerance.

For this reason, Neuro20 protocols are organized into three primary stimulation strategies - **Sensory, Motor, and Patterned** - allowing clinicians to select the approach most appropriate for the patient's functional presentation and therapeutic goals.

A detailed explanation of the clinical reasoning framework and proposed physiological mechanisms supporting these protocols can be found in the **Clinical Logic and Mechanisms section at the end of this document.**

# Neuro20 Protocol Categories

How do you determine what protocol to use with Neuro20? The protocols are broken down into three main categories:

- **Sensory Protocol**
- **Motor Protocol**
- **Patterned Protocol**

Let's break down the categories of protocols at their simplest form.

***Sensory Protocol*** - Using a setting that has a variable frequency. The stimulation is increased throughout the entire body to a *"sensory or sub-sensory"* level, to positively alter spinal cord excitability via sensory interneurons. Recommended to activate all channels/pads when using this protocol.

***Motor Protocol*** - Using any setting where involuntary muscle contractions are performed to lead to voluntary movement, pushing neuroplastic adaptation of motor pathways. Recommended to activate all channels/pads when using this protocol.

***Patterned Protocol*** - Using the Patterned programs (walking, cycling, swinging, etc.) to reinforce movement patterns that are limited not primarily by strength or endurance, but by impaired neuromuscular coordination. These programs apply sequenced muscle activation to support neuromuscular re-education and improved motor pattern integration — commonly described in clinical practice as helping to *"retrain the body and brain"*.

# Clinical Protocol Selection Process

## Step 1: Identify Clinical Systems and Physical Impairments

List all the physical and systems impairments that are clinically relevant to the current state of the patient that are creating functional limitations and making activities of daily living (ADLs) challenging.

| PHYSICAL IMPAIRMENTS | | SYSTEMS IMPAIRMENTS | |
|---|---|---|---|
| • Active Range of Motion<br>• Passive Range of Motion<br>• Muscle Strength<br>• Muscle Endurance<br>• Muscle Power | • Sensation<br>• Joint Mobility<br>• Flexibility<br>• Nerve Mobility | • Activity Intolerance<br>• Cardiopulmonary Vital Signs<br>  • Blood Pressure<br>  • Heart Rate<br>  • Blood O2 levels<br>  • Respiration Rate | • Sleep-Wake Regulation<br>• Sexual Dysfunction<br>• Speech Impairments<br>• Vision Impairments |

## Step 2: Identify the Disease State / Medical Condition

This step guides protocol selection into one of four clinical reasoning categories. ***(Reminder:** Neuro20 PRO System is not intended to treat, modify, or cure the underlying disease. The section below is only to help guide the protocol process as it relates to the systems and physical impairments).*

| LOCAL / STABLE | SYSTEMIC / STABLE |
|---|---|
| Spinal Cord Injury<br>Traumatic Brain Injury<br>Amputee<br>Stroke<br>Orthopedic<br>Post-Surgical<br>Cerebral Palsy | Chronic Pain<br>Fibromyalgia<br>Complex Regional Pain Syndrome<br>Functional Neurological Disorder |
| **LOCAL / PROGRESSIVE** | **SYSTEMIC / PROGRESSIVE** |
| Parkinson's<br>ALS<br>Dementia | Multiple Sclerosis<br>Neuropathy<br>Rheumatoid Arthiritis<br>Long Covid<br>Dysautonomia / POTS |

## Step 3: Understand the 4 Different Protocols Combinations for Neuro20

| MOTOR PROTOCOL WITH EXERCISE | SENSORY PROTOCOL WITH EXERCISE |
|---|---|
| Stim - Slight Involuntary Contractions<br>Therapy exercises as recommended | Stim - Mild to Moderate "Buzz" (No contractions)<br>Therapy exercises as recommended |
| **PATTERNED PROTOCOL WITH EXERCISE** | **SENSORY PROTOCOL NO EXERCISE** |
| Stim - Slight Involuntary Contractions<br>Therapy exercises as recommended | Stim - Mild to Moderate "Buzz" (No contractions)<br>No active therapy (use with ADLs, going for a walk, passive) |

## Step 4: Review to Determine if Clinical Reasoning Fits with Protocol

***Local/Stable*** - The injury/medical disease is located in a specific area and is generally stable in nature, in that the underlying injury or damage is not progressing. Individuals often present with a mix of physical and system impairments, but protocol focus should be on movement, strength, and improving motor pathways to maximize improvement with functional limitations and ADLs. Start with **Sensory Protocol / With Exercise** for 1-3 sessions and then, if tolerated, move to **Motor Protocol/ With Exercise** and **Patterned Protocol / With Exercise.**

***Local/Progressive*** - The injury/medical disease is limited to a specific pathway, but can continue to deteriorate over time. Individuals should prioritize moving towards the Motor Protocol to maintain muscle strength, balance, and functional ability, but may require additional time on the Sensory Protocol to start. Recommend starting with **Sensory Protocol / With Exercise** for 3 sessions to set foundation to push towards more functional gains with **Motor Protocol / With Exercise.**

***Systemic/Stable*** - The presentation is more widespread in nature but not characterized by ongoing structural progression. Individuals may report challenges such as pain, muscle spasm, fatigue, or reduced activity tolerance. Initial protocol selection should prioritize modulation of these impairments to allow progression toward movement-based and strength-focused goals.

Begin with **Sensory Protocol / No Exercise** for 3 sessions. If tolerated, transition to **Sensory Protocol / With Exercise** for 3 sessions. If improvements in muscle activation and functional tolerance are observed, cautiously trial **Motor Protocol / With Exercise** when clinically appropriate. Some individuals may remain best suited for Sensory-based protocols depending on response.

***Systemic/Progressive*** - The condition is widespread and generally will continue to progress with time. These individuals can have a negative response to pushing with too much activity or exercise. Start with **Sensory Protocol / No Exercise** for 3 sessions and then progress to **Sensory Protocol / With Exercise** for 3 sessions. If the patient is responding positively, test the **Motor Protocol / With Exercise**, but do so with very close attention to impairments. Patients in this category have conditions that can respond inconsistently if pushed too hard with electrical activity combined with exercise. In some cases, the Neuro20 system may provide the most benefit when used just at **Sensory Protocol / No Exercise** for the duration. With this patient population, ensure you are exercising caution but also listening to the patient.

For example, in Multiple Sclerosis, demyelination may affect the peripheral nerves, spinal cord, brain, either individually or in combination. Pushing too much electrical current for some MS patients can cause impairments, like spasms, to worsen – but, in others, can actually create improvement.

***IMPORTANT NOTE:*** *The discussion above reflects clinical variability, not contraindication. These patient populations often present with complex and multi-factorial impairments. When applied with appropriate clinical judgment and dosing, Whole Body Electrical Neuromuscular Modulation may meaningfully support improvements in impairments, functional limitations, and activities of daily living (ADLs).*

## Step 5: Select the Protocol to Use with Patient

***SENSORY PROTOCOL EXAMPLES***

**CONDITIONING Mode** (Sensory Protocol)
(Frequency preset at 40/7 Hz)

- **Session Duration:** 30–40 minutes
- **Ramp Up:** Medium
- **Stimulation Time:** 20 seconds
- **Rest Time:** 15 seconds

Stimulation should produce a mild to moderate sensory "buzzing" without visible muscle contraction; intensity and perception will vary between individuals. In patients with reduced or absent sensation (e.g., certain spinal cord injuries), subjective feedback may not be reliable, and dosing should be guided by visible motor response, autonomic signs, and clinical judgment.

**** Use these settings for all new patients or when the clinical presentation does not clearly indicate a Motor or Patterned approach.***

**MASSAGE Mode** (Sensory Protocol)
(Frequency preset at 84/7 Hz)

- **Session Duration:** 30–40 minutes
- **Ramp Up:** Medium
- **Stimulation Time:** 20 seconds
- **Rest Time:** 15 seconds

Stimulation should produce a mild to moderate sensory buzzing without visible muscle contraction; intensity and perception will vary between individuals. In patients with reduced or absent sensation (e.g., certain spinal cord injuries), subjective feedback may not be reliable, and dosing should be guided by visible motor response, autonomic signs, and clinical judgment.

**** Use these settings when Conditioning mode produces limited observable response or when increased sensory variability is desired.***

## Step 5: Select the Protocol to Use with Patient *(continued)*

### ***MOTOR PROTOCOL EXAMPLE***

Available Modes:

**CONDITIONING / STRENGTH / COOL DOWN / MASSAGE / PATTERNED MOVEMENT**

For the Motor Protocol, any of the above modes may be used.
The key difference compared to the Sensory Protocol is that stimulation intensity is increased to produce a light, visible muscle contraction.

Recommended Setup Range:

- **Session Duration:** 30–40 minutes
- **Ramp Up:** Fast or Medium
- **Stimulation Time:** 10–20 seconds
- **Rest Time:** 20–30 seconds

If the Motor Protocol results in increased pain, muscle spasms, excessive fatigue, or worsening of system impairments, reduce the intensity or transition back to a Sensory Protocol and continue therapy or exercises at a sensory-level stimulation.

### ***PATTERNED PROTOCOL EXAMPLE***

**Select the appropriate movement program (Walking, Cycling, Swinging, etc.)** and increase stimulation intensity to produce a light, visible muscle contraction before initiating the sequence.

Patterned programs are ideally used in conjunction with active movement to reinforce coordinated motor patterns. In individuals with limited or absent voluntary control, these programs may still be applied to provide structured, sequenced neuromuscular input and afferent signaling, even when observable movement is minimal.

Refer to the **Operating Manual** for specific parameter settings for **each individual PEMS program.**

# TBI/STROKE PROTOCOL

## Neuro20 Medical Category for Protocol Progression

Local / Stable

## Recommended Starting Protocol

Sensory / Exercise 1-3 Sessions. Progress as tolerated to Motor / Exercise and Patterned / Exercise.

## Protocol Review Specific to TBI/Stroke

The presentation of the Stroke/TBI patient is critical in determining the protocol and direction. Always consider the stroke location, weakness patterns, sensation, tone, elasticity, and contractors.

- Ensure all electrodes are used consistently to maximize neural activation.
- Combine stimulation with movement, balance exercises, and complex vestibular/visual activities to enhance brain activity.
- Pay close attention to tone and potential contractures during treatment.
- Initial focus should be on increasing nervous system activity before progressing to improved movement.

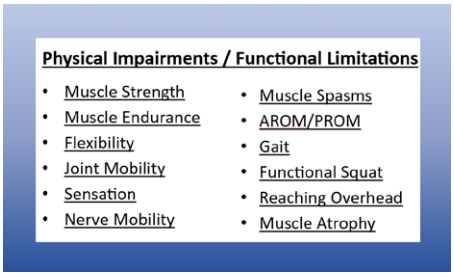
First, prioritize enhancing nervous system activity, then progressively focus on improving movement.

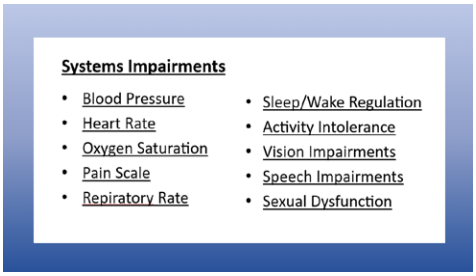
## *FIRST 1-3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Exercises as Guided / Directed by Rehab |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.




## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what the patient is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *6-8%* |
| *Biceps & Triceps* | 8-10% |
| *Abdominals & Back* | 10-15% |
| *Glutes* | 15-20% |
| *Quads & Hamstrings* | 15-20% |

***IMPORTANT NOTE:***

***These percentages are a baseline.***

***Individual tolerance varies.***

*Communication is key.*

*Adjust settings to maintain comfortable contractions.*

*Tolerance typically increases after the first few sessions.*

## TBI/STROKE PROTOCOL continued

### *SUCCESSIVE SESSIONS 2-6 ( Training Flow: STRENGTH)*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 25-40 minutes | 15-20 seconds | 30-40 Seconds | Medium | Moderate/ Strong** | Standing/Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and the patient should still have 100% motion in all directions.

### IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

**If patient is having difficulty with specific movement pattern past 6 sessions, test Patterned Protocol to address functional limitation. Do not initially combine with Strength Protocol as this could exhaust the patient. Ensure there is adequate space and supervision when using Patterned Protocols to help facilitate change in neuromuscular coordination.**

TBI/Stroke patients need to be pushed to Motor Protocols as soon as they tolerate it. The goal with these patients to is strengthen the activation of dormant or dysfunctional movement communication systems.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **PATTERNED** | 20-30 minutes | 15-20 seconds | 15-20 seconds | Medium | Moderate/ Strong** | Muscles Active to Facilitate Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

Clinical Reminder: Always be sure to consider patient sensation throughout the process, as well as their overall state of reconditioning / atrophy when starting. Injuries to the brain do not present the same and consistent clinical evaluation of SYSTEMS and PHYSICAL IMPAIRMENTS is always important throughout treatment with Neuro20.

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# SPINAL CORD INJURY (SCI) PROTOCOL

## Neuro20 Medical Category for Protocol Progression

Local / Stable

## Recommended Starting Protocol

Sensory / Exercise 1-3 Sessions. Progress as tolerated to Motor / Exercise and Patterned / Exercise.

## Protocol Review Specific to Spinal Cord Injury (SCI)

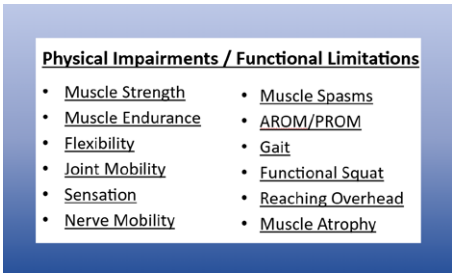
Spinal cord injuries can vary greatly in presentation, from the level of injury, to complete/incomplete cord damage, to the underlying diagnosis that caused it (spinal stroke, car accident, viral attack, etc.). It is important to remember to pay close attention to physical and system impairments at all time. It is recommended to push the patient to motor protocols as soon as possible but be mindful of the current state of muscle atrophy, duration since SCI, and experience with electrical stimulation. VERY IMPORTANT: If patient is lacking sensation, always error on the side of caution when starting them with Neuro20.

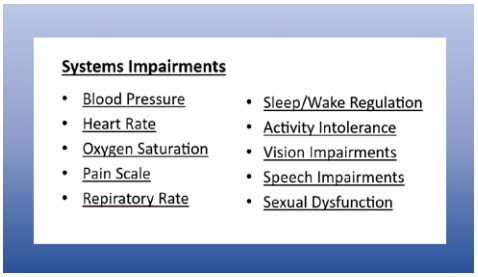
## *FIRST 1-3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Exercises as Guided / Directed by Rehab |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.




## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what the patient is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *6-8%* |
| *Biceps & Triceps* | 8-10% |
| Abdominal & Back | 10-15% |
| *Glutes* | 15-20% |
| *Quads & Hamstrings* | 15-20% |

***IMPORTANT NOTE:***

***These percentages are a baseline.***

***Individual tolerance varies.***

*Communication is key.*

*Adjust settings to maintain comfortable contractions.*

*Tolerance typically increases after the first few sessions.*

## SPINAL CORD INJURY (SCI) PROTOCOL continued

### *SUCCESSIVE SESSIONS 2-6 ( Training Flow: STRENGTH)*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 25-40 minutes | 15-20 seconds | 30-40 Seconds | Medium | Moderate/ Strong** | Standing/Movement |

**Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

### IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

Inform the patient:
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominal

ADVISE PATIENT to STAY HYDRATED!

**If patient is having difficulty with specific movement pattern past 6 sessions, test Patterned Protocol to address functional limitation. Do not initially combine with Strength Protocol as this could exhaust the patient. Ensure there is adequate space and supervision when using Patterned Protocols to help facilitate change in neuromuscular coordination.**

If the patient is able to ambulate, using walking Patterned Protocols can be very helpful but ensure the patient has enough strength and endurance to accomplish the movement.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **PATTERNED** | 20-30 minutes | 15-20 seconds | 15-20 seconds | Medium | Moderate/ Strong** | Muscles Active to Facilitate Movement |

**Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

**Clinical Reminder: Always be sure to consider patient sensation throughout the process, as well as their overall state of deconditioning / atrophy when starting. Injuries to the spine do not present the same and consistent clinical evaluation of SYSTEMS and PHYSICAL IMPAIRMENTS is always important throughout treatment with Neuro20.**

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# MULTIPLE SCLEROSIS PROTOCOL

## Neuro20 Medical Category for Protocol Progression

*Systemic / Progressive*

## Recommended Starting Protocol

Sensory / No Exercise for 3 sessions. If Positive impact to Systems/Physical Impairments, progress to Sensory / Exercise

## Protocol Review Specific to Multiple Sclerosis

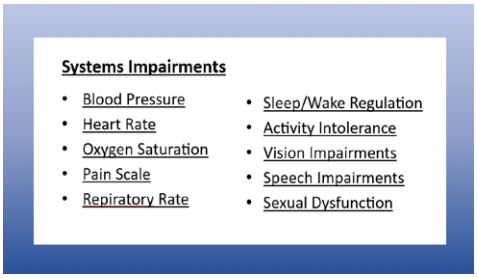
Individuals with multiple sclerosis are going through a "waxing and waning" of "damage and growth" to the myelin that covers the peripheral nerves, spinal cord, and within the brain. This impacts the ability to coordinate movement that then leads to a sequela of other problems associated with weak muscles, risk of falls, difficulty with gait, fatigue, and coordination of muscles. Patients with a Systemic/Progressive condition can have variable responses to whole body electrical stimulation. Be sure to pay close attention to physical and systems impairments during treatment.

## *FIRST 3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Slow functional movements |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.


## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what the patient is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *4-6%* |
| *Biceps & Triceps* | *5-8%* |
| *Abdominals & Back* | 8-12% |
| *Glutes* | 12-15% |
| *Quads & Hamstrings* | 12-15% |

***IMPORTANT NOTE:***

***These percentages are a baseline.***

***Individual tolerance varies.***

*Communication is key.*

*Adjust settings to maintain comfortable contractions.*
*Tolerance typically increases after the first few sessions.*

## *SUCCESSIVE SESSIONS 4-6 ( Training Flow: Massage )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **MASSAGE** | 25-40 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Standing/Movement |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

## IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

## SESSIONS 6+ (If patient is showing progress, progress to Motor Protocol)

Multiple Sclerosis patients may benefit more from remaining at Sensory Protocol / with Exercise for the duration but it is important to still test if a Motor Protocol would be beneficial. Continue to monitor Systems and Physical Impairments.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 20-30 minutes | 15 seconds | 30-45 seconds | Medium | Moderate / Strong ** | Functional Movements / Muscles to Fatigue |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

Clinical Reminder: Multiple Sclerosis is a progressive disease with systemic impact to myelin that could be in the peripheral nerves, the spinal cord, and/or the brain. Make sure to consult with patient's treating physician to determine where the body is being impacted as to help guide the proper protocol for Neuro20.

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# PARKINSONS PROTOCOL

## Neuro20 Medical Category for Protocol Progression

Local / Progressive

## Recommended Starting Protocol

Sensory / Exercise 3 Sessions. Progress as tolerated to Motor / Exercise and Patterned / Exercise.

## Protocol Review Specific to Parkinson's

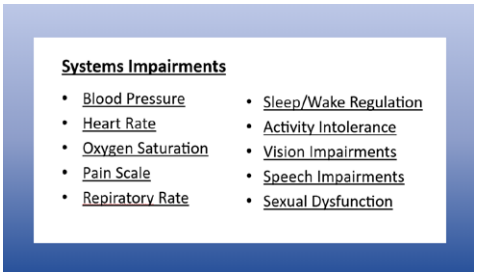
Parkinson's patients, due to a lack of dopamine, have difficulty initiating and maintaining coordinated movement. As the neurological system is intact (sensation / motor pathways), it is important to recognize that depending on the severity and duration of dopamine reduction (note: most don't see symptoms until about a 70% loss in dopamine), there is likely significant deconditioning and a high risk of falls. Patients commonly experience a decrease in tremors for a few hours after use, but these may come back. For lasting results, the patient may require prolonged Neuro20 use.

## *FIRST 3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Exercises as Guided / Directed by Rehab |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.


## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what person is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *6-8%* |
| *Biceps & Triceps* | 8-10% |
| Abdominal & Back | 10-15% |
| *Glutes* | 15-20% |
| *Quads & Hamstrings* | 15-20% |

***IMPORTANT NOTE:***

***These percentages are a baseline.***

***Individual tolerance varies.***

*Communication is key.*

*Adjust settings to maintain comfortable contractions.*

*Tolerance typically increases after the first few sessions.*

## *SUCCESSIVE SESSIONS 4-6 ( Training Flow: STRENGTH)*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 25-40 minutes | 15-20 seconds | 30-40 Seconds | Medium | Moderate / Strong ** | Standing/Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

## IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

**Parkinson's patients generally have challenges due to lack of strength, muscle atrophy, tremors, muscle spasms, and general fatigue. There are times when Patterned Protocols would be beneficial but ensure that other SYSTEMS and PHYSICAL IMPAIRMENTS are the actual limiting factor clinically.**

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **PATTERNED** | 20-30 minutes | 15-20 seconds | 15-20 seconds | Medium | Moderate / Strong ** | Muscles Active to Facilitate Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

**Clinical Reminder: Neuro20 supports neuromuscular activation in individuals experiencing movement challenges related to dopaminergic dysfunction, but it is not intended to replace dopamine or provide medical management. The main goal is to provide enough strength, endurance, and balance to reduce risk of falls and overall improve patient ability to living functionally independent.**

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# CHRONIC PAIN PROTOCOL

## Neuro20 Medical Category for Protocol Progression

Systemic / Stable

## Recommended Starting Protocol

Sensory / No Exercise for 3 sessions. If Positive impact to Systems/Physical Impairments, progress to Sensory / Exercise

## Protocol Review Specific to Chronic Pain

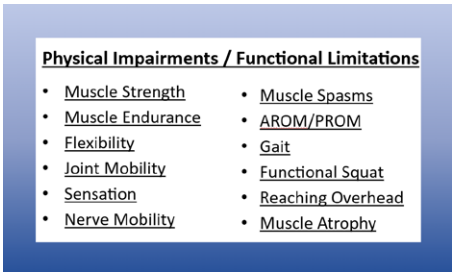
Chronic pain can present with variable underlying causes, from mechanical to nocioplastic. Commonly, the physical and system impairments associated with Chronic Pain are rooted in a combination of muscle spasms, weak or dysfunctional muscles, fatigue, or a cyclical combination the facilitates the underlying condition. It is important to closely pay attention to what is driving the underlying dysfunction to determine the proper protocols to utilize.

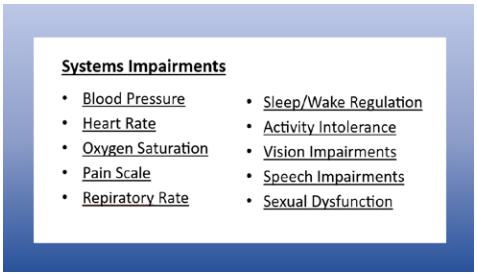
## *FIRST 3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Slow functional movements |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.




## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what person is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *4-6%* |
| *Biceps & Triceps* | *5-8%* |
| *Abdominals & Back* | 8-12% |
| *Glutes* | 12-15% |
| *Quads & Hamstrings* | 12-15% |

***IMPORTANT NOTE:***

***These percentages are a baseline.***
***Individual tolerance varies.***
*Communication is key.*
*Adjust settings to maintain comfortable contractions.*
*Tolerance typically increases after the first few sessions.*

## CHRONIC PAIN PROTOCOL continued

### *SUCCESSIVE SESSIONS 4-6 ( Training Flow: Massage )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **MASSAGE** | 25-40 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Standing/Movement |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

### IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

### SESSIONS 6+ (If patient is showing progress, progress to Motor Protocol)

Chronic Pain patients may benefit more from remaining at Sensory Protocol / with Exercise for the duration, but it is important to still test if a Motor Protocol would be beneficial. Continue to monitor Systems and Physical Impairments.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 20-30 minutes | 15 seconds | 30-45 seconds | Medium | Moderate / Strong ** | Functional Movements / Muscles to Fatigue |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

**Clinical Reminder: If the underlying issue associated with Chronic Pain is mechanical in nature, it will be important to progress with Motor Protocols to re-establish functional ability to support movement. Patterned movements are commonly not needed as the underlying issue for neuromuscular activation dysfunction is the cycle of pain.**

* Note: This protocol serves as a general outline only. The clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# ORTHOPEDIC PROTOCOL

## Neuro20 Medical Category for Protocol Progression

Local / Stable

## Recommended Starting Protocol

Sensory / Exercise 1-3 Sessions. Progress as tolerated to Motor / Exercise and Patterned / Exercise.

## Protocol Review Specific to Orthopedic

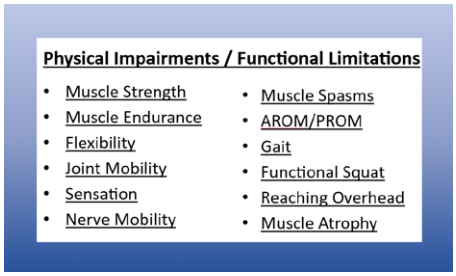
For common problems such as sprains, strains, back spasms, sore muscles, and all patients that have non-surgical injuries and don't present with neurological diagnosis, clinical move the patient into STRENGTH protocols as seen appropriate by clinical evaluation. Having full sensation and no underlying systemic or progressive conditions means the device requires less caution with use. Continue to evaluate physical and systems impairments but the verbal reports of how the patient feels will likely guide the treatment progression.

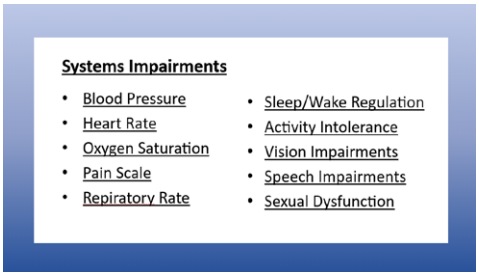
## *FIRST 1-3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Exercises as Guided / Directed by Rehab |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.




## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what person is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *6-8%* |
| *Biceps & Triceps* | 8-10% |
| *Abdominals & Back* | 10-15% |
| *Glutes* | 15-20% |
| *Quads & Hamstrings* | 15-20% |

***IMPORTANT NOTE:***

***These percentages are a baseline.***
***Individual tolerance varies.***
*Communication is key.*
*Adjust settings to maintain comfortable contractions.*
*Tolerance typically increases after the first few sessions.*

## ORTHOPEDIC PROTOCOL continued

### *SUCCESSIVE SESSIONS 2-6 ( Training Flow: STRENGTH)*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 25-40 minutes | 15-20 seconds | 30-40 Seconds | Medium | Moderate/ Strong** | Standing/Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

### IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

**If patient is having difficulty with specific movement pattern past 6 sessions, test Patterned Protocol to address functional limitation. Do not initially combine with Strength Protocol as this could exhaust the patient. Ensure there is adequate space and supervision when using Patterned Protocols to help facilitate change in neuromuscular coordination.**

Orthopedic patients you can push harder than those with neurological diagnoses but it is still important to not over fatigue them by trying to make gains too fast, no different than any other exercise regiment.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **PATTERNED** | 20-30 minutes | 15-20 seconds | 15-20 seconds | Medium | Moderate/ Strong** | Muscles Active to Facilitate Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

**Clinical Reminder: If the patient is progressing quickly, make sure to do exercises with suit on and off to ensure there is carry over into daily activities. Non-neurological patients will likely need the device for only a short duration (2-8 weeks) before being discharged from use on a regular basis.**

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# POST SURGICAL PROTOCOL

## Neuro20 Medical Category for Protocol Progression

Local / Stable

## Recommended Starting Protocol

Sensory / Exercise 1-3 Sessions. Progress as tolerated to Motor / Exercise and Patterned / Exercise.

## Protocol Review Specific to Post Surgical

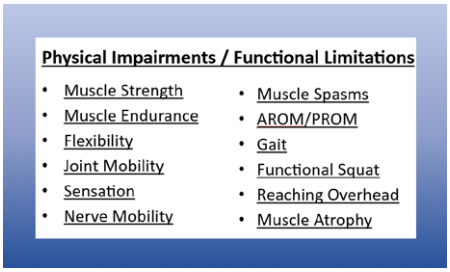
Any post surgical patient it is important to consult with the surgeon before using Neuro20. With some conditions it may be appropriate to use immediately, others may not be appropriate due to the procedure, healing wound, or requirement to have minimal to no muscle activation. Post surgical patients commonly will follow same pathway as common orthopedic injury patients.

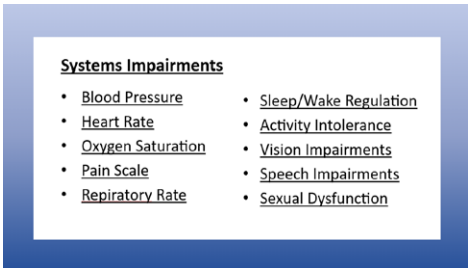
## *FIRST 1-3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Exercises as Guided / Directed by Rehab |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS impairments when using Neuro20 with your patient to determine the course of treatment with the device.




## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what person is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *6-8%* |
| *Biceps & Triceps* | 8-10% |
| *Abdominals & Back* | 10-15% |
| *Glutes* | 15-20% |
| *Quads & Hamstrings* | 15-20% |

***IMPORTANT NOTE:***

***These percentages are a baseline.***

***Individual tolerance varies.***

*Communication is key.*

*Adjust settings to maintain comfortable contractions.*

*Tolerance typically increases after the first few sessions.*

## POST SURGICAL PROTOCOL continued

### *SUCCESSIVE SESSIONS 2-6 ( Training Flow: STRENGTH)*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 25-40 minutes | 15-20 seconds | 30-40 Seconds | Medium | Moderate / Strong ** | Standing/Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

### IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

**If patient is having difficulty with specific movement pattern past 6 sessions, test Patterned Protocol to address functional limitation. Do not initially combine with Strength Protocol as this could exhaust the patient. Ensure there is adequate space and supervision when using Patterned Protocols to help facilitate change in neuromuscular coordination.**

Neuro20, if cleared by surgeon, for assistance with common post surgical problems associated with blood flow, muscle spasms, and muscle weakness.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **PATTERNED** | 20-30 minutes | 15-20 seconds | 15-20 seconds | Medium | Moderate/ Strong** | Muscles Active to Facilitate Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

**Clinical Reminder: If the patient still has a healing wound that is weeping, oozing, or still in early stages of healing, ensure you communicate this with the surgeon to determine if Neuro20 is appropriate. The technology can be an adjunct to restoring function faster but is variable depending on the surgery. Always consult the surgeon before starting treatment.**

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# AMPUTEE PROTOCOL

## Neuro20 Medical Category for Protocol Progression

Local / Stable

## Recommended Starting Protocol

Sensory / Exercise 1-3 Sessions. Progress as tolerated to Motor / Exercise and Patterned / Exercise.

## Protocol Review Specific to Amputees

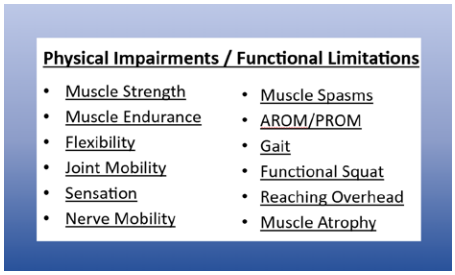
Amputations can occur at various levels which can significantly increase oxygen consumption with exercises, as well as quality of gait. When ambulating with a new limb there is a mix of both orthopedic and neurological challenges. Neuro20 is exceptionally helpful in activating the muscular kinetic chain to restore movement while also creating ample signal to assist with balance and restoring normal movement patterns.

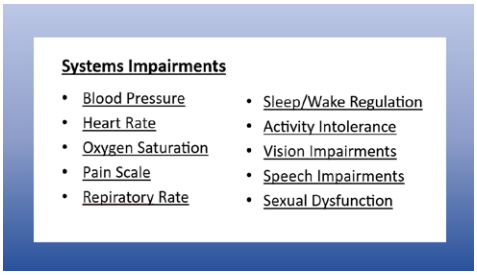
## *FIRST 1-3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Exercises as Guided / Directed by Rehab |

**Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.




## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what the patient is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *6-8%* |
| *Biceps & Triceps* | 8-10% |
| *Abdominals & Back* | 10-15% |
| *Glutes* | 15-20% |
| *Quads & Hamstrings* | 15-20% |

***IMPORTANT NOTE:***

***These percentages are a baseline.***
***Individual tolerance varies.***
*Communication is key.*
*Adjust settings to maintain comfortable contractions.*
*Tolerance typically increases after the first few sessions.*

## AMPUTEE PROTOCOL continued

### *SUCCESSIVE SESSIONS 4-6 ( Training Flow: Massage )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **MASSAGE** | 25-40 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Standing/Movement |

** Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

### IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

### SESSIONS 6+ (If patient is showing progress, progress to Motor Protocol)

Patients commonly have challenges with exercising due to blood pressure dysregulations. It is important to pay attention to systems and physical impairments as you progress with Neuro20 protocols.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 20-30 minutes | 15 seconds | 30-45 seconds | Medium | Moderate / Strong ** | Functional Movements / Muscles to Fatigue |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

**Clinical Reminder: This patient population has challenges with variety of symptoms that can change day to day. Progression to the Motor Protocol may be difficult for some patients, but it is important to test to determine if it is beneficial.**

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# RHEUMATOID ARTHRITIS PROTOCOL

## Neuro20 Medical Category for Protocol Progression

*Systemic / Progressive*

## Recommended Starting Protocol

Sensory / No Exercise for 3 sessions. If Positive impact to Systems/Physical Impairments, progress to Sensory / Exercise

## Protocol Review Specific to Rheumatoid Arthritis

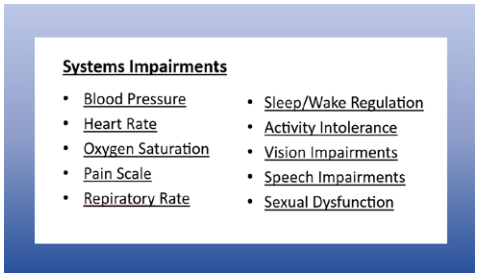
Rheumatoid arthritis is an auto-immune, degenerative condition that traditionally progresses with time. Patients will commonly report "flare ups" associated with various environmental factors, stressful events, and particular activities that are reported to "set off their symptoms". In using Neuro20, it is important to recognize that the device does not cure, modify, or treat the underlying condition but can be very helpful managing the physical and systems impairments that are created secondary to the disease state.

## *FIRST 3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Slow functional movements |

**** Intensity Mild/Moderate (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.***

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.


## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what the patient is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *4-6%* |
| *Biceps & Triceps* | *5-8%* |
| *Abdominals & Back* | 8-12% |
| *Glutes* | 12-15% |
| *Quads & Hamstrings* | 12-15% |

***IMPORTANT NOTE:***

***These percentages are a baselines.***
***Individual tolerance varies.***
*Communication is key.*
*Adjust settings to maintain comfortable contractions.*
*Tolerance typically increases after the first few sessions.*

## RHEUMATOID ARTHIRITIS PROTOCOL continued

### *SUCCESSIVE SESSIONS 4-6 ( Training Flow: Massage )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **MASSAGE** | 25-40 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Standing/Movement |

**** Intensity Mild/Moderate (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.***

### IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

### SESSIONS 6+ (If patient is showing progress, progress to Motor Protocol)

Ensure with this patient population to maximize their "strengthening" with the device in a sensory capacity but if benefits are maxed out with Sensory Protocol, progress to Strength Protocol to see if additional benefits are possible.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 20-30 minutes | 15 seconds | 30-45 seconds | Medium | Moderate / Strong ** | Functional Movements / Muscles to Fatigue |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

Clinical Reminder: Be aware of "all" factors that set off Rheumatoid arthritis patients. Paying attention to physical and systems impairments is important to know how to progress the patient to maximize function while minimizing symptoms.

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# CEREBRAL PALSY PROTOCOL

## Neuro20 Medical Category for Protocol Progression

Local / Stable

## Recommended Starting Protocol

Sensory / Exercise 1-3 Sessions. Progress as tolerated to Motor / Exercise and Patterned / Exercise.

## Protocol Review Specific to Cerebral Palsy

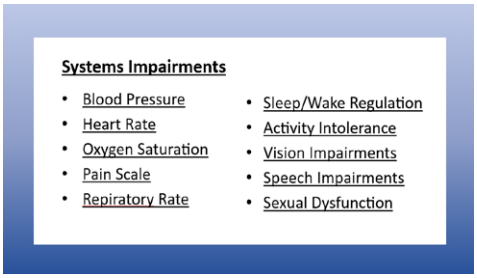
Cerebral palsy patients can have a high variability of presentation depending on the extent of neuron damage and age of patient. Certain patterns of movement may be difficult to address with Neuro20, or any additional technology, but there are potential benefits to stimulating the entire kinetic chain. IMPORTANT: If the patient has a contracture associated with Cerebral Palsy, Neuro20 is not recommended as a treatment to improve active range of motion. If the limited ROM is due to muscle spasm, Neuro20 can potentially assist with reducing tone as well as strengthen muscles that are difficult to exercise.

## *FIRST 1-3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Exercises as Guided / Directed by Rehab |

**** Intensity Mild/Moderate (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.***

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.


## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what the the patient is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *6-8%* |
| *Biceps & Triceps* | 8-10% |
| *Abdominals & Back* | 10-15% |
| *Glutes* | 15-20% |
| *Quads & Hamstrings* | 15-20% |

***IMPORTANT NOTE:***

***These percentages are a baseline.***

***Individual tolerance varies.***

*Communication is key.*

*Adjust settings to maintain comfortable contractions.*

*Tolerance typically increases after the first few sessions.*

## CEREBRAL PALSY PROTOCOL continued

### *SUCCESSIVE SESSIONS 2-6 ( Training Flow: STRENGTH)*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 25-40 minutes | 15-20 seconds | 30-40 Seconds | Medium | Moderate / Strong ** | Standing/Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

### IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

**If patient is having difficulty with specific movement pattern past 6 sessions, test Patterned Protocol to address functional limitation. Do not initially combine with Strength Protocol as this could exhaust the patient. Ensure there is adequate space and supervision when using Patterned Protocols to help facilitate change in neuromuscular coordination.**

**IMPORTANT:** Patterned Protocol is appropriate for patients that have sufficient strength and active range of motion to facilitate motions like gate. If any contractures, do not attempt to use Neuro20 to "push through" limited range of motion.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **PATTERNED** | 20-30 minutes | 15-20 seconds | 15-20 seconds | Medium | Moderate/ Strong** | Muscles Active to Facilitate Movement |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

Clinical Reminder: Cerebral Palsy is a mix of orthopedic and neurological injuries so it important to understand change may take longer than a standard orthopedic patient. Never having established "normal" movement patterns can make progress slow but ensure you are consistent with treatment for 12+ weeks to determine potential beneficial outcomes.

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# NEUROPATHY PROTOCOL

## Neuro20 Medical Category for Protocol Progression

*Systemic / Progressive*

## Recommended Starting Protocol

Sensory / No Exercise for 3 sessions. If Positive impact to Systems/Physical Impairments, progress to Sensory / Exercise

## Protocol Review Specific to Neuropathy

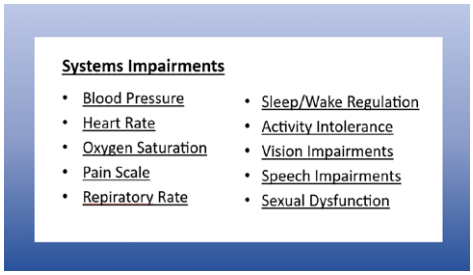
There are many forms of neuropathy but this specific protocol is associated with a diseased state that is non-mechanical in nature (ex. Neuropathy associated with Diabetes). IMPORTANT: If neuropathy is associated with a mechanical reasoning at the spine, refer to ORTHOPEDIC protocol.

## *FIRST 3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Slow functional movements |

** Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.


## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what the patient is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *4-6%* |
| *Biceps & Triceps* | *5-8%* |
| *Abdominals & Back* | 8-12% |
| *Glutes* | 12-15% |
| *Quads & Hamstrings* | 12-15% |

***IMPORTANT NOTE:***

***These percentages are a baselines.***

***Individual tolerance varies.***

*Communication is key.*

*Adjust settings to maintain comfortable contractions.*

*Tolerance typically increases after the first few sessions.*

## *SUCCESSIVE SESSIONS 4-6 ( Training Flow: Massage )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **MASSAGE** | 25-40 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Standing/Movement |

** Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

## IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***

*Over-stimulation could cause:*

- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**

Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

### SESSIONS 6+ (If patient is showing progress, progress to Motor Protocol)

It is important to remember that Neuropathic patients commonly have significant physical impairments (blood flow, weakness, muscle spasms) associated with their reports of pain.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 20-30 minutes | 15 seconds | 30-45 seconds | Medium | Moderate / Strong ** | Functional Movements / Muscles to Fatigue |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

**Clinical Reminder: Neuropathic patients may find the Motor Protocol challenging as many parts of their peripheral nervous system are in a state of excitability but it is important to test. If the secondary issues associated with fear and pain with movement are addressed, pushing to strengthen could be beneficial in improving ADLs.**

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# LONG COVID PROTOCOL

## Neuro20 Medical Category for Protocol Progression

*Systemic / Progressive*

## Recommended Starting Protocol

Sensory / No Exercise for 3 sessions. If Positive impact to Systems/Physical Impairments, progress to Sensory / Exercise

## Protocol Review Specific to LONG COVID

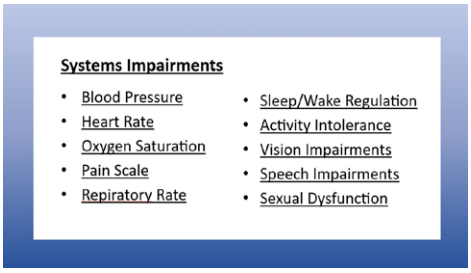
Long COVID results a variety of systems and physical impairments that vary from person to person. In using Neuro20, it is important to recognize that the device does not cure, modify, or treat the underlying condition but can be very helpful managing the physical and systems impairments that are created secondary to the disease state.

## *FIRST 3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Slow functional movements |

** Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.


## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what the patient is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *4-6%* |
| *Biceps & Triceps* | *5-8%* |
| *Abdominals & Back* | 8-12% |
| *Glutes* | 12-15% |
| *Quads & Hamstrings* | 12-15% |

***IMPORTANT NOTE:***

***These percentages are a baselines.***
***Individual tolerance varies.***
*Communication is key.*
*Adjust settings to maintain comfortable contractions.*
*Tolerance typically increases after the first few sessions.*

## LONG COVID PROTOCOL continued

### *SUCCESSIVE SESSIONS 4-6 ( Training Flow: Massage )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **MASSAGE** | 25-40 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Standing/Movement |

** Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

### IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

### SESSIONS 6+ (If patient is showing progress, progress to Motor Protocol)

Similar to Multiple Sclerosis, Long COVID patient may have difficult with Motor Protocol as it stresses the muscular system to the point of increasing systems associated with muscle spasms and fatigue.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 20-30 minutes | 15 seconds | 30-45 seconds | Medium | Moderate / Strong ** | Functional Movements / Muscles to Fatigue |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

**Clinical Reminder: As a diagnosis that is relatively new to medicine, it is important to pay close attention to systems and physical impairments.**

* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

# DYSAUTONOMIA/POTS PROTOCOL

## Neuro20 Medical Category for Protocol Progression

*Systemic / Progressive*

## Recommended Starting Protocol

Sensory / No Exercise for 3 sessions. If Positive impact to Systems/Physical Impairments, progress to Sensory / Exercise

## Protocol Review Specific to Dysautonomia/POTS

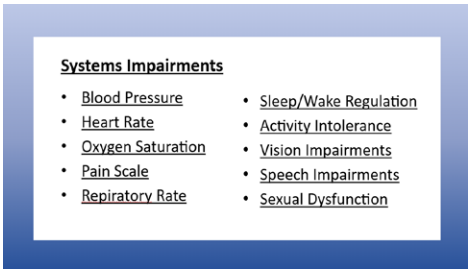
Dysautonomia / POTS are systemic conditions that have a variety of symptoms. In using Neuro20, it is important to recognize that the device does not cure, modify, or treat the underlying condition but can be very helpful managing the physical and systems impairments that are created secondary to the disease state.

## *FIRST 3 SESSIONS ( Training Flow: Conditioning )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **CONDITIONING** | 20-30 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Slow functional movements |

** Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

**IMPORTANT:**
Neuro20 is not designed to treat, cure, or modify medical conditions or diseases. It is important to evaluate all PHYSICAL and SYSTEMS *impairments* when using Neuro20 with your patient to determine the course of treatment with the device.


## *ESTIMATED STARTING INTENSITIES*

The intensity of stimulation in a Sensory Protocol involves a "mild to moderate" buzz without involuntary muscle contractions at rest. When starting, for the first 3 sessions, make sure there is no activity / exercise outside of what the patient is already able to do.

| Muscle Group | Intensity (%) |
|---|---|
| *Deltoids & Pecs* | *4-6%* |
| *Biceps & Triceps* | *5-8%* |
| *Abdominals & Back* | 8-12% |
| *Glutes* | 12-15% |
| *Quads & Hamstrings* | 12-15% |

***IMPORTANT NOTE:***

***These percentages are a baselines.***
***Individual tolerance varies.***
*Communication is key.*
*Adjust settings to maintain comfortable contractions.*
*Tolerance typically increases after the first few sessions.*

## *SUCCESSIVE SESSIONS 4-6 ( Training Flow: Massage )*

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **MASSAGE** | 25-40 minutes | 20 seconds | 15 seconds | Medium | Mild/ Moderate* | Standing/Movement |

** Intensity **Mild/Moderate** (Sensory) = Increase stimulation until a mild to moderate buzzing sensation is felt through the pads without causing involuntary muscle contractions at rest.*

## IMPORTANT WARNINGS

***DO NOT Over-Stimulate!!!***
*Over-stimulation could cause:*
- *Delayed Onset Muscle Soreness (DOMS)*
- *Rhabdomyolysis (often requires hospitalization)*

**Inform the patient:**
Post-exercise soreness may occur, especially in:
Biceps, Gluteal Muscles, Abdominals

**ADVISE PATIENT to STAY HYDRATED!**

## SESSIONS 6+ (If patient is showing progress, progress to Motor Protocol)

Patients commonly have challenges with exercising due to blood pressure dysregulations. It is important to pay attention to systems and physical impairments as you progress with Neuro20 protocols.

| Training Mode | Training Duration | Stimulation Time | Rest Time | Ramp | Intensity | Position / Activity |
|---|---|---|---|---|---|---|
| **STRENGTH** | 20-30 minutes | 15 seconds | 30-45 seconds | Medium | Moderate / Strong ** | Functional Movements / Muscles to Fatigue |

** Intensity Moderate/Strong = Increase stimulation to cause light, involuntary muscle contraction through all pads. Muscle should be visibly active and patient still has 100% motion in all directions.

- If the patient experiences exhaustion for more than a day, reduce session time.
- Stick to initial session settings until recovery improves.
- Adjust session length based on recovery: If exhaustion lasts >1 day, reduce session time and revert to initial settings.

**Clinical Reminder: This patient population has challenges with variety of symptoms that can change day to day. Progression to the Motor Protocol may be difficult for some patients, but it is important to test to determine if it is beneficial.**

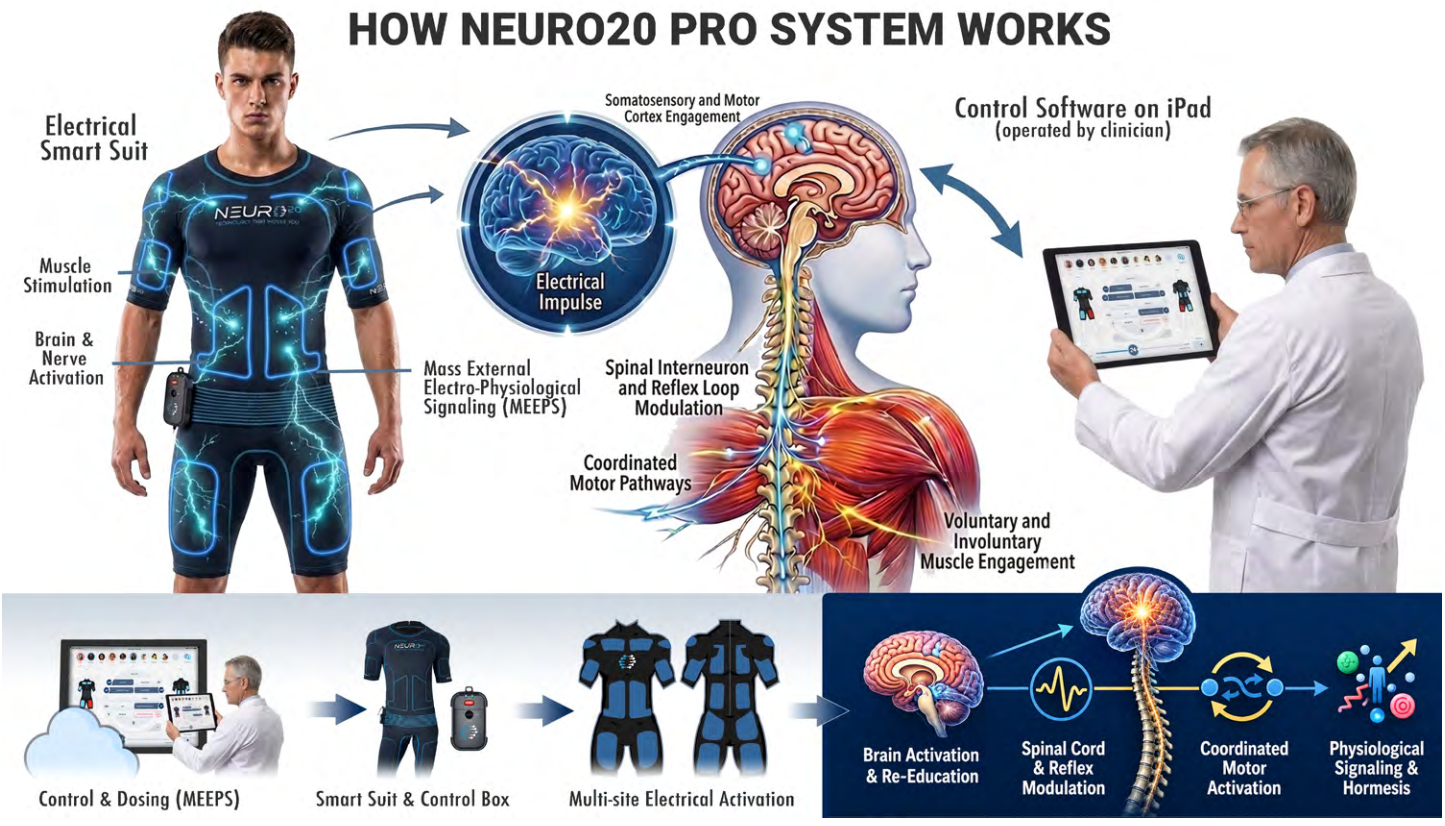
* Note: This protocol serves as a general outline only. Clinician must refer to the official Neuro20 PRO System Operating Manual for detailed safety guidelines, including maximum usage limits, prior to prescribing or initiating use.

## What Is Neuro20?

Neuro20 is the first **Whole Body Electrical Neuromuscular Modulation (WB-ENM)** device that, since FDA clearance in 2023, has been used by 1,000+ individuals globally, with patients and clinicians reporting meaningful improvements in function and quality of life in real-world settings. From improved walking, to less fatigue, to observable physiological changes in neuromuscular and sensory-motor signaling patterns that may reflect shifts in nervous system regulation, this incredible technology is rapidly expanding our understanding of how a single device can **BOTH** incorporate the benefits of exercise while also modulating disabling neurological sequelae.

The Neuro20 Smart Suit is an advanced whole-body wearable textile integrating embedded technology that uses Whole Body Electrical Neuromuscular Modulation (WB-ENM) to stimulate sensory and motor pathways, utilizing 20 large contoured electrodes to engage the maximum amount of nervous signaling pathways.

If you were to break down the suit into 2” x 2” electrodes/pads, it would be the equivalent of 131 pads on the body simultaneously. That covers a lot of area! On average, a Neuro20 Smart Suit actively stimulates 16.7% of the surface of the skin, allowing a clinician to impact almost the entire sensory nervous system, as well as over 44+ muscles offering clinical opportunities to address the majority of the kinetic chain simultaneously.



## Why is Neuro20 referred to as a Whole Body Electrical Neuromuscular Modulation (WB-ENM) device?

If you do a quick scan on the internet or pull out one of your old textbooks, you are likely going to see there are some common categories of therapeutic electrical medical devices.

***Transcutaneous Electrical Nerve Stimulation (TENS)*** is the most popular and well known of all the types of devices. From complex systems in the clinic that offer a variety of frequencies, pulse widths, and wave forms with the goal of reducing pain, to the variable plethora of low voltage at home devices you can find on Amazon, TENS is built on our knowledge and acceptance of Gate Theory. TENS can be in the form of conventional (high frequency / low intensity), acupuncture-like (low frequency / high intensity), burst, modulated, and intense (high frequency / high intensity). Mechanistically, at its simplest form, TENS, as understood as a device to modulate pain, is believed to be acting on the ascending inhibitory pathways within three key areas.

- Periaqueductal Gray (PAG)
- Rostral Ventromediala Medulla (RVM)
- Spinal Cord (As a Whole) and Spinal Cord (Inhibitory Interneurons)

***Interferential Current (IFC)*** is a crossing of very high frequency electrical pathways (often 4,000 Hz or higher) to allow deeper penetration into tissue. This application creates a “net” lower frequency by intersecting currents, allowing for reduction in pain along these same mechanisms understanding of Gate Theory. It is also used for treating muscle spasm, muscle atrophy, reducing swelling, and even gastrointestinal disorder like Irritable Bowel Syndrome (IBS), constipation, and bladder dysfunction/spasticity. The involvement of the autonomic nervous system (ANS) in intestinal and bladder regulation will be explored in greater detail later.

***Neuromuscular Electrical Stimulation (NMES)*** is the application of pads around known motor points, areas where it is easiest to create muscle contractions. Stimulating either Type I (slow twitch) or Type II (fast twitch) muscle fibers, NMES’s intended goal is to rebuild strength, endurance, and size of muscles after injury, surgery, or disuse, as well as improve the activation of muscle groups to facilitate functional motion.

***Functional Electrical Stimulation (FES)*** is a rehabilitative form of treatment using controlled electrical pulses sufficient to stimulate nerves and induce contractions in paralyzed or weak muscles. Common movements like walking, grasping, and cycling are enhanced through a variety of electrical leads over specific muscles. This same electrical treatment is used to reduce muscle spasms, increase strength, and improve circulation.

Neuro20 technology is an evolution of the application of technologically driven electrical stimulation. Neuro20’s different settings range from 7-100 Hz frequency, 75-175 microsecond pulse width, and stimulation can be controlled via up to 10 channels, allowing different intensities by body part.

One additional feature of Neuro20 is also including an additional patented application of **Patterned Electrical Muscle Stimulation (PEMS).**

***Neuro20 PEMS (Patterned Electrical Muscle Stimulation)*** is an evolved variant of Functional Electrical Stimulation (FES) that delivers stimulation in a coordinated, sequential pattern designed to mimic the natural order of muscle activation during functional movements such as walking, cycling, or throwing. Rather than stimulating isolated muscles, PEMS engages only the muscle groups required for a specific movement and activates them in physiologically timed sequences. These externally generated contractions provide afferent sensory feedback to the central nervous system, with the goal of reinforcing motor pathways and supporting neuromuscular re-education.

In real-world clinical use, patients and clinicians have documented observational reports of outcomes occurring during periods of consistent Neuro20 use. These reports are case-based and hypothesis-generating and are not presented as cleared treatment claims.

- Chronic Pain patients returning to daily, functional life with using suit only 1-2x a week.
- Muscle spasms in SCI patients staying away for 2-3 days in between treatments.
- Patients coming off blood pressure medication, baclofen, and gabapentin permanently.
- Individuals losing 8-10 pounds of weight in a month without increasing activity level.
- Sleep improving on first day of use across multiple medical conditions
- Post Traumatic Stress Disorder (PTSD) symptoms lessening to the point of being more functional at home and the community.

This suggests there is more happening than just traditional “stimulation”. Neuro20 is having a positive benefit to patient quality of life days and weeks in between uses, indicating that one device is both a supplement to “exercise” and “beneficial modulation” at the same time.

For this reason, Neuro20 is better defined as a **Whole Body Electrical Neuromuscular Modulation (WB-ENM)** medical technology.

- Whole Body - Entire kinetic chain
- Electrical - Therapeutic delivery system
- Neuromuscular - Activating muscle via exercise for positive functional outcomes
- Modulation - Interacting with physiological neurological systems for the better

## What is Mass Internal Dysfunctional Physiological Signaling (MIDPS)?

The purpose of this section is to utilize new terminology as a foundation for clinical reasoning in describing observable secondary physiological patterns as it relates to the Neuro20 protocols. Nothing below is a diagnosis and does not replace established pathology.

**What do the following conditions have in common?**

Multiple Sclerosis, Parkinson’s, Spinal Cord Injury, Type II Diabetes, and Chronic Pain. The connection may not be immediately obvious but will become clearer as the discussion progresses.

***Multiple Sclerosis*** is an autoimmune disorder that attacks myelin and presents in a dozen+ different ways throughout the brain, spinal cord, and peripheral nervous system.

***Parkinson’s*** is the destruction or dysfunction of dopamine production in the substania nigra that results in profound movement dysregulations

***Spinal Cord Injuries*** have a wide variety of presentations, depending on the level of injury, complete vs. incomplete, and so many other factors we can’t label them all here.

***Type II Diabetes*** is the result of desensitized insulin receptors, resulting in high amounts of glucose floating around the blood stream.

***Chronic Pain*** has thousands of presentations and can be the result of injury, surgery, psychological trauma, a bad reaction to medication, a hard day at work, having a fight with a friend....so many variables to account for.

The common thread is all of them may be influenced by **internal communication dysfunction.**

Pharmacologically, the approach would be to figure out how to control the mechanism of disease/problem and then the cascading benefits exist. But are the problems the DIRECT result of the disease state or a SECONDARY result of a dysfunctional system?

- If myelin is damaged, what does that do to the communication system between the body and brain?
- If dopamine is not present to regulate the movement patterns, how does that communication impact your ability to walk?
- If the spinal cord is damaged, how does an intact brain and body get communication back and forth?
- If there is dysregulation of glucose signaling that creates damage to nerve ending (neuropathy) how many other cascading communication systems fall with it?

All of the above present ongoing secondary physiological patterns that alter neuromuscular excitability, autonomic imbalance, fatigue, spasticity, pain, and several other system-related dysfunctions, which, for the purposes of teaching the protocols of Neuro20, we will refer to as **Mass Internal Dysfunctional Physiological Signaling (MIDPS):**

***Mass:*** The whole body

***Internal:*** Systems that maintain life

***Dysfunctional:*** Abnormal, none beneficial mechanisms

***Physiological:*** Systemic process that facilitate function

***Signaling:*** Functional inter-cellular communication

Moving forward in this document, MIDPS will be the framework to direct the decision making process for Neuro20 as it relates to its delivery mechanism that acts both as a means to improve muscle activity, while managing negative neurological sequelae that hinder progress with functional limitations and ADLs.

## What is Mass External Electro-Physiological Signaling (MEEPS)?

Continuining the clinical guide of MIDPS as the hypothesized problem, how does Neuro20 support improvement in neuromuscular signaling patterns observed in these conditions?

Moving forward, this technological delivery of Neuro20 will be referred to as
**Mass External Electro-Physiological Signaling (MEEPS):**

***Mass:*** The whole body

***External:*** Over the skin, non Invasive, drug-free

***Electro:*** Electrical delivery of various frequencies, pulse widths, and intensity

***Physiological:*** Intervening on systemic processes that facilitate function

***Signaling:*** Enhancing the natural sensory and motor communication pathway

Just as we use Gate Theory, first presented by Ronald Melzack and Patrick Wall in the 1960s, to guide decision making and treatment for chronic pain conditions using electrical stimulation, the relationship of these concepts (MIDPS and MEEPS) serves as a framework for Neuro20 protocols. This relationship, postulated by *Dr. Keith J. Cronin, DPT,* serves as theoretical bridge between the work of Melzack and Wall and the evolution of technology today, is as follows:

*The use of multi-site, non-invasive electrical input to potentially systemically influence sensory integration, autonomic function, and re-establish dormant or dysfunction motor pathways.*

Now that we have the terminology in place and have established where this technology fits as a treatment tool as compared to current devices and the markets, let's dive into the proposed physiological mechanisms that will define the usage of Neuro20 with a variety of medical conditions. The combination of all this will allow the clinician to understand the "why" when determining:

*"What are the best Neuro20 settings (program, stimulation, on/off time) for a patient who has (medical condition) and suffers from "list of systemic dysfunction/ impairments/ functional limitations" with a goal of "what clinically you intend to accomplish"?*

## Proposed Physiological Mechanisms of Neuro20

We didn't know the potential possibilities of whole-body electrical stimulation until the Neuro20 PRO System was cleared for medical use in February 2023. If similar devices have been used in the fitness market for over a decade, why are we just discovering these breakthroughs today? The positive impacts of Mass External Electro-Physiological Signaling (MEEPS) would not be known to have potential impact on Mass Internal Dysfunctional Physiological Signaling (MIDPS).

For centuries, pharmacologic therapies have been used to influence physiological systems by altering biochemical pathways throughout the body. Electrical interventions date back to using electric eels for treatment and more recently with Amazon devices and implanted batteries to control bladder function, pain, and even motor control. The two directions of thought exist as follows:

*"Use pharmacological interventions to impact the entire ecosystem when injected or digested or localized on skin or body cavity openings with creams, droplets, or suppositories."*

*or*

*"Use electrical interventions to impact specific pathways, temporarily with external devices and permanently with internal devices."*

The Neuro20 approach of Whole Body Electrical Neuromuscular Modulation (WB-ENM) now creates a new offering to the non-invasive, drug-free, electrical intervention possibilities based on ***FOUR*** main principles that differ from all other technologies to date. We will cover those ***FOUR*** principles a little bit later, but for now, we will cover the proposed ***TWO*** primary mechanisms that Neuro20 is acting on.

1. Somatosensory and Motor Cortex Neurons to Stimulate Movement Pathways
2. Spinal Cord Sensory Interneurons as Gate Theory to Modulate Excitability

Historically, evaluating this in the United States has been limited by technological and regulatory constraints. The Neuro20 PRO System now enables the potential for a single device to both promote the benefits of exercise and address negative impacts associated with dysfunctional neurological systems.

## Somatosensory and Motor Cortex Neurons to Stimulate Movement Pathways

The first primary mechanism for Neuro20 is facilitating motor pathway activity to restore, augment, or maintain functional muscle activity. This understanding of neuromuscular action via electrical activity is more accepted in medical practice but now is evolving into a functional application of the technology.

After a stroke or TBI, is it that the neuron death has resulted in a permanent dysfunction for movement, or is it that the pathway communication systems are merely offline? Neuroplastic models following brain injury for decades indicated the time for best change was early, 3-6 months after damage occurs, to restore function. Emerging technology and treatment techniques have shown there is far more neuroplasticity than once believed. The time frame from injury is a factor, but another factor is the **aggregate signaling** to the brain to generate enough stress to create positive change.

A stroke resulting in paresis to the left side of the body causes functional limitations and disabilities that can permanently affect the quality of life of the patient. For patients that, years later, suffer from disability - is this the result of the brain injury itself, or is it also a steady decline of other systems due to a lack of signaling? Does the patient generate enough day to day signaling of the **motor pathways** to force the body to create and connect more pathways?

## Physiological Framework Defining WB-ENM

In the American health care system, the average inpatient stay for someone with a stroke, TBI, or spinal cord injury is 11-15 days of intense care. That word "intense" is underlined because that is combination therapy 3+ hours a day to help restore as much function as possible. Each encounter with rehab is another **signaling** event to push sensory and motor pathways to restore function. This is often why there are significant gains early on, but then a plateau or regression upon leaving. Why is this? Because the **signaling** event was not long enough to create permanent adaptation. Just consider the following in a rehabilitation setting:

- In 1-2 weeks, changes in neuromuscular patterns can be achieved.
- In 4-6 weeks, measurable changes in strength are noted with consistent rehab.
- In 8-12 weeks, muscle growth can occur from pushing the body to adapt.

These ranges can be adjusted a bit, but overall, there are regular norms for development and building strength, endurance, and muscle. So only 11-15 days after a serious stroke event, the intense treatment drops off? Rewiring circuits require **consistent** and **measured** pressures and challenges to make permanent changes, no different than why toddlers that start learning to walk have to take 2-3 hour naps. It is a lot of pressure on the brain!

Neuro20 directly stimulates 44+ different muscles, with particular attention to those that control the posterior kinetic chain, which is necessary for balance, gait, and functionally living independently. Electrical stimulation is well known for the ability to create involuntary muscle contraction, but with Neuro20, this can be accomplished at a **systemic** level. Why does this matter?

Kinetically, we don't operate any system in isolation, and this is particularly true for movement. Functional limitations and Disabilities that affect patients are the result of a combination of Impairments that result in the inability to move freely.

Neuro20 can accomplish the following 4 (four) important criteria:

- An **Effective Therapeutic Dosage** of muscle and sensory pathway stimulation.
- **Large Electrical Pads** to spread out the energy to reduce noxious stimulus
- **Free Range of Motion** in all directions.
- **Patterned Electrical Muscle Stimulation** to focus on specific movements.

The next section will focus on these 4 main differentiators of Neuro20 compared to other interventions. For now, these criteria will help explain the primary mechanism of Somatosensory and Motor Pathway activation.

→ If there is enough stimulation to make body parts move as a whole....

→ And the stimulation doesn't cause pain...

→ And there is ability to move in all planes of motions without limitations.....

→ And if necessary, stimulation patterns that replicate normal Neuro-Muscle axis communication...

Then it makes sense that this type of rehabilitative technology is showing promise to make a **profound** impact on restoring or developing movement patterns. Asking a patient to walk that is having difficulty connecting the brain and the body is challenging, but if the signal is pushing afferently to support the efferent intent, what would this mean for progress with rehab?

*Simple: More signal into the motor pathway results in adaptive changes that carry over into permanent restoration of movement related inter-cellular communication. Just consider that walking, once developed early in life, is not stored in the brain; it is more centered in the spinal cord. If the inputs and outputs are impacted by neuronal death, it makes sense to push more signal through the brain, spinal cord, and body to restore normalization of movement.*

## 1. Effective Therapeutic Dosage

*"If you took 5% of the therapeutic dose of Tylenol, would it help you with your pain"?* This example was brought up earlier, but now let's dive in a bit deeper.

Any doctor out there will be quick to chime in and say, *"Well, it depends on a lot of things."*

- How much Tylenol has the patient taken previously?
- Are they currently taking other drugs?
- Is the person naturally sensitive or not to the medications?
- When was the last time the person ate?
- Was the medication taken in the morning or night?

All this makes perfect sense. With a drug, we can test and account for a lot of variables all at the same time. This determines the dosage, and off we go to saying "take one 400mg pill in the morning and one 400mg before bed for the next two weeks. If symptoms don't improve, please contact your doctor."

The dosage was determined by a lot of variables taken into consideration and the ability to manufacture that dosage specific to the patient. But what if they only manufactured 20mg doses? No problem! Just take 20 pills each time, and we have achieved the same dosage.

Now let's take this same illustration to Neuro20. Would you put many devices on the body, coordinate all them at the same time, and then go ahead and do therapy? No, that would be highly impractical and inefficient in a clinical setting.The time required to set up and manage such a system would be unrealistic for routine use! But the reality is this if the FIRST principle of WB-ENM that Neuro20 resolves: the dosage of electrical stimulation that is easy to administer and control. To make a therapeutic change in electrophysiology, no different than a Tylenol at the bio-mechanical level, there needs to be enough dosage and Neuro20 technologically is demonstrating the potential to meet that criteria.

## 2. Large Electrical Pads

Traditional science shows there are ideal “motor points” that exist within each muscle, tiny focused points where the muscle is easier to stimulate to create a contraction. Is the motor point based on the actual physiology, or did we create maps based on the technology available? **Probably a combination of both.**

Traditional electrical stimulation to create a motor response commonly relies on small 2” x 2” electrodes placed over specific motor points. To recruit deeper nerves or muscle fibers, intensity must be increased. However, because the stimulation is concentrated into a small surface area, the current density is high, often resulting in localized discomfort before broader or deeper tissue recruitment can occur.

Electricity does not remain confined to a single point; it disperses through surrounding tissue. With a small electrode, the effective transfer area is limited, concentrating more energy into a smaller region. This often narrows stimulation to a focused zone and can increase sensory discomfort at the skin and superficial nerve level.

Neuro20 utilizes significantly larger contoured electrodes that distribute current over a much broader surface area. By spreading the stimulation across more tissue, higher overall output can be delivered while maintaining tolerability. This wider dispersion allows recruitment across larger motor territories simultaneously and supports engagement of deeper neuromuscular structures without the concentrated discomfort commonly associated with small-pad stimulation.

Equally important, achieving therapeutic dosage systemically should not create excessive localized sympathetic irritation. By distributing current more broadly, Neuro20 aims to balance sufficient intensity for neuromuscular activation with improved comfort, supporting both functional recruitment and patient tolerance.

## 3. Free Range of Motion in All Directions

Traditional passive electrical stimulation is commonly done in a seated, supine, or sometimes stationary standing position. Newer technologies, not fixed to a large box that is on a wheeled platform, allow for full movement in all directions, but only one body part can be stimulated. The newer and traditional technologies don’t meet the Neuro20 comparative advantages of:

1. Effective Therapeutic Dosage
2. Large Electrical Pads

and while these technologies do allow for full range of motion, they involve wires hanging out and movement that is still “artificially adjacent”. Neuro20 solves this with an intelligently designed Smart Suit, an advanced whole-body wearable textile integrated with completely wireless and wire-free embedded technology that delivers electrical stimulation through 20 different pads simultaneously, allowing complete freedom of movement without restrictions. Often the question is asked: *“If you stimulate the hamstrings and quads at the same time, won’t it result in just an isometric contraction with no movement?”* Yes, it would...if there wasn’t cortical (brain) control for reciprocal inhibition.

Neuro20 does not show signs of potential interference with normal physiological principles for movement; it appears, to date, to create proposed mechanisms to enhance it. If the goal is to push motor pathways and increase muscle strength, endurance, and size, the individual muscle units have to be pushed to adapt. With Neuro20, this is easier to accomplish, particularly for people who struggle to move in the first place.

## 4. Patterned Electrical Muscle Stimulation (PEMS)

What happens if, no matter how much you instruct a patient on the proper way to walk, they just can't progress? This happens a lot. Establishing functional movement patterns is a lot of neural load, and sometimes, the two don't connect. Neuro20's FOURTH principle of how it makes a significant impact on quality of life is the ability to incorporate Patterned Electrical Muscle Stimulation (PEMS).

The Neuro20 PEMS programs are designed to "mimic" the same electrical and muscle firing patterns of common movements like:

- Walking
- Sit to Stand
- Cycling
- Swinging.

Where the Neuro-Muscle axis may have difficult connecting, these programs push the connection to be as close to normalized as possible. If the Systems and Physical Impairments are what is holding back progress with Functional Limitations, this technological evolution of electrical stimulation is an incredible adjunct.

## Spinal Cord Sensory Interneurons as Gate Theory

Traditional application of Gate Theory is based on a "one to one" relationship when understood from the use of devices like TENS for pain control.

- Place 2" x 2" electrodes on either side of the site of pain.
- Use a high or low frequency setting (depending on toleration).
- Increase stimulation to a mild to moderate "buzz".
- Afferent stimulation goes from peripheral nerves -> Spinal cord
- Signal is modulated at the local spinal cord level to "block" signal
- Use every time there is pain to provide relief during use a few hours after.

Previous research has indicated this stimulation is acting on a variety of mechanisms at the same time, which include, but aren't limited to:

- Activation of large-diameter afferents (e.g., A-beta mechanoreceptive input) to modulate nocioceptive transmission
- Inhibitory activation of Periacqueductal Grey and Rostra Ventromedial Medulla to minimize excitatory activation of the spinal cord
- Altering voltage-gated channels to inhibit transmission of signaling

Expanding Gate Theory beyond "only pain" and extending it to what sensory nerves accomplish as a whole, the picture of Neuro20 starts to become clearer. The "gate" of pain at a single location is part of a vast network of "gates" or communication centers that regulate the flow of information for the betterment of physiological function. Muscle reflex loops, whether short latency (monosynaptic) or medium latency (long loop / multi segment), communicate with each other at a local level, where improper interaction can result in muscle spasms.

There are many number of “gates” that are functionally intertwined at any time within the human body. With this understanding of “multiple gates” as a guideline, the second postulated primary mechanism for Neuro20 is the expansion of the TWO-dimensional model of Afferent - Efferent to the following FOUR-dimensional model:

- Mass Afferent Pathway Volume (Multi-Segmental Signaling)
- Significant Pre Cortex Activation (Somatosensory/Motor)
- Modulated Efferent Spinal Pathway
- Continuation of Hormesis driven Physiological Signaling

Simply put, the more pathways that are signaled at the same time may support the allocation of resources to be dedicated to operate, maintain, and regulate spinal cord excitability. This is a physiological mechanism that is done without conscious thought or action; it is at the reflexive, neurotransmitter level.

Using Tylenol example. If you only had 5% of a Tylenol, would it have a therapeutic effect? *Not likely.*

To date, if we used a single TENS unit on one part of the body, could it have a systemic lasting effect? Research is mostly conclusive: No, that is not possible, as the physiological impact remains localized to the area of application. What about if there were 10+ non-invasive electrical channel inputs operating simultaneously, would the dosage be enough to create therapeutic change in the sensory system of the body? *It would seem this hypothetical theory is becoming more of a practical possibility.*

*By taking our understanding of Gate Theory and adding increase Volume (more pathways), dosage of afferent signaling to generate a strong neuronal response, and stimulating for a therapeutic dosage that creates a sustained physiological response, the possibilities start to unfold.*

These sensory peripheral nerves, neurons, and interneurons don’t just process pain but many things:

- Body position
- Visual/Auditory
- Organ Function
- Respiration
- Digestion
- Metabolic Activity
- Blood pressure
- Heart Rate
- Oxygen Saturation

The sensory gateways for pain operate and exist on a systemic level with many other sensory neurons (Mechanoreceptors, Proprioceptors, Thermoreceptors, Chemoreceptors, etc) to keep all information and communication flowing among all systems. Neuro20, early in its formal research, shows promise in potential positive influence to the Autonomic Nervous System (ANS), resulting in a more relative Parasympathetic Nervous System (PNS) shift from a more dominant Sympathetic Nervous System (SNS) state. The aggregate activation of all spinal cord segments between C4 and S5 simultaneously is, what is believed, to be replicating the inter-cellular communication effects that would be similar to regular exercise. Note, the impact of signaling is only a portion of what exercise offers, but research over decades has concluded exercise is good for overall health. So, if we could replicate the signal, what would the promising benefits be?

Chronic, progressive, or debilitating diseases, injuries, or conditions cause a relative and steady decline in physiological function. This downward drive creates a chronic state of **sympathetic drive**, the relative abnormal balance of sympathetic activation relative to parasympathetic. In short bursts, the sympathetic response is beneficial, saving us from danger of life-threatening events and allowing us to operate with short bouts of heavy stress. Over the long term, this chronic state results in a "fight or flight" response that increases resting blood pressure, decreases fat metabolism, increases inflammation, and makes it difficult for restorative sleep, all issues associated with the previously-described framework of **Mass Internal Dysfunctional Physiological Signaling (MIDPS).**

From Multiple Sclerosis to Spinal Cord Injury to Chronic pain, the proposed common thread to all these medical states (and many more) is a ***relative homeostatic baseline of sympathetic drive at the spinal cord level. In common terminology: Many medical patients are in a constant state of "fight or flight".*** This is believed to be one of Neuro20's Primary Mechanisms of Action to improve patient care is by shifting the neurological system into a state that is more proactive for movement, improved healing, and decreased stress. For Neuro20, the programs of Conditioning (40Hz / 7Hz) and Massage (84Hz / 7Hz) seem to have the most impact on this sensory pathway as there is a varying frequency. This topic was covered in greater depth earlier when discussing the selection of different programs based on protocol criteria.

## Neuro20 Protocols

The most common question asked regarding using Neuro20 is the following

*“What program should I select for my patient getting started with Neuro20?”*

## Neuro20 Protocol Logic

****In the decision modeling to select the appropriate Neuro20 protocol, any reference to medical conditions or diseased states is a part of a logical guide to provide proper treatment with this technology. The Neuro20 PRO System does not treat or cure any underlying pathology, and the mentioning of these various conditions is designed to group common presentations of systems and physical impairments together for the purposes of selecting the most appropriate protocol.****

Neuro20 is a Class II medical device that requires a medical prescription for use. The device has six indications of use as listed below:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Indications for Use**

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223797

Device Name
Neuro20 PRO System

Indications for Use *(Describe)*
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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.
***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The cleared indications are not diagnosis-specific but are based on functional neuromuscular impairments.

Since receiving FDA clearance in February 2023, clinical observations have been reported across a range of patient presentations (discussed earlier in this document). While underlying diagnoses may differ, many patients share neuromuscular impairments consistent with the cleared indications for use. The following three guidelines, as they relate to indications, impairments, and research, are important to identify as they facilitate the logic behind each Neuro20 protocol.

**Patients across many disease states/conditions commonly present ONE or MULTIPLE of the indications listed above.**

Indications that include addressing:

- Activation of muscle to improve strength and facilitate muscular functional ability
- Neuromuscular Re-education
- Increasing local blood flow (which, with 20 electrodes on the body, is addressing local blood flow in many areas)
- Maintaining range of motion and ability to move
- Decreasing muscle spams
- Preventing disuse atrophy of muscles needed to maintain movement

are very common to many neurological and orthopedic conditions.

Following FDA clearance as a Class II medical device, Neuro20 began being utilized under medical supervision across a range of patient populations with diverse diagnoses. The device was not designed or indicated to cure, treat, or modify underlying disease processes, but rather to assist in managing systems and physical impairments that impact functional limitations and activities of daily living (ADLs).

Because it was applied across varied clinical presentations within its cleared scope, clinicians were able to observe consistent patterns in how patients responded at the level of neuromuscular and systems impairments. These observations helped inform the ongoing refinement of protocols and contributed to the development of the conceptual framework described in this document.

**The indications above are commonly associated with OTHER systems and physical Impairments.**

As patient populations can commonly have one or multiple of the indications listed above, it is also common that other systems and physical impairments occur within the same disease set and within the individual. Systems impairments that include

- Pain Level/Quality
- Activity Intolerance
- Sleep-Wake Regulation
- Cardiopulmonary Vital Signs
    - Blood Pressure
    - Heart Rate
    - Blood O2 levels
    - Respiration Rate
- Sexual Dysfunction
- Speech Impairments
- Vision Impairments

have been observed within these patient populations. During periods of Neuro20 use, clinicians and patients have reported subjective or incidental observations related to these areas. These observations were not part of the device's intended use or cleared indications and were not collected as controlled outcome measures. Rather, they were noted anecdotally and contributed to the development of the protocol reasoning framework described below.

## There Are Currently Limited Studies on this Technology Category

While there are combined thousands of studies that have been completed on the known benefits for regular exercise or electrical stimulation (IFC, TENS, FES), there is very limited research on whole body electrical stimulation devices that combine stimulation with physical activity. Until February 2023, a Class II medical device incorporating a whole-body electrical stimulation configuration with 6 (six) indications for use on unhealthy/diseased tissue had not been cleared in its current form. To date, available information regarding this specific configuration and indication set consists primarily of observational case reports and anecdotal reports specific to Neuro20 from patients and clinicians.

Similar whole-body electrical stimulation systems, operated at only a sensory level with significantly lower intensity per channel, began publishing research in 2018 with limited success but by 2023, outcomes for patients with stroke, multiple sclerosis, and cerebral palsy were demonstrating some benefits that have not been demonstrated previously with traditional electrical stimulation technology.

As Neuro20 is designed differently than the aforementioned device, the protocols are built to reflect its specific technological specifications that fall in line with the six indications cleared by the FDA.

## Ongoing Clinical Development

The Neuro20 Clinical Protocol Guide reflects the current collective clinical experience and insights from physicians, physical therapists, and rehabilitation professionals utilizing the Neuro20 PRO System in clinical practice.

As clinical experience with Whole-Body Electrical Neuromuscular Modulation continues to expand, Neuro20 Technologies will continue refining these protocols through collaboration with clinicians, emerging research, and ongoing clinical observations.

Clinicians are encouraged to provide feedback regarding protocol effectiveness, patient response, and potential improvements to further advance the safe and effective use of Neuro20 technology.

## Contact

For clinical feedback, training, or protocol support:

**Neuro20 Technologies Corp.**
Tampa, Florida, USA

clinical@neuro20.com

**www.neuro20.com**



NEURO20
TECHNOLOGY THAT MOVES YOU

NEURO 20
TECHNOLOGY THAT MOVES YOU

# Advancing Neuromuscular Rehabilitation

The Neuro20 PRO System delivers coordinated **whole-body electrical neuromuscular modulation** designed to support neuromuscular activation, functional movement training, and management of physical impairments that affect mobility and activities of daily living.

Clinical protocols within this **guide** were developed through collaboration with physicians, physical therapists, and rehabilitation professionals currently using Neuro20 technology in clinical practice.

As clinical experience continues to expand, Neuro20 Technologies remains committed to **refining** these protocols through ongoing clinician collaboration and emerging scientific research.

**Neuro20 Technologies Corp.**
**Tampa, Florida USA**
**clinical@neuro20.com**
**www.neuro20.com**


*Neuro20 PRO System - FDA 510(k) K223797*
*Neuro20 Clinical Protocol Guide N20-PT-00 rev. 00*