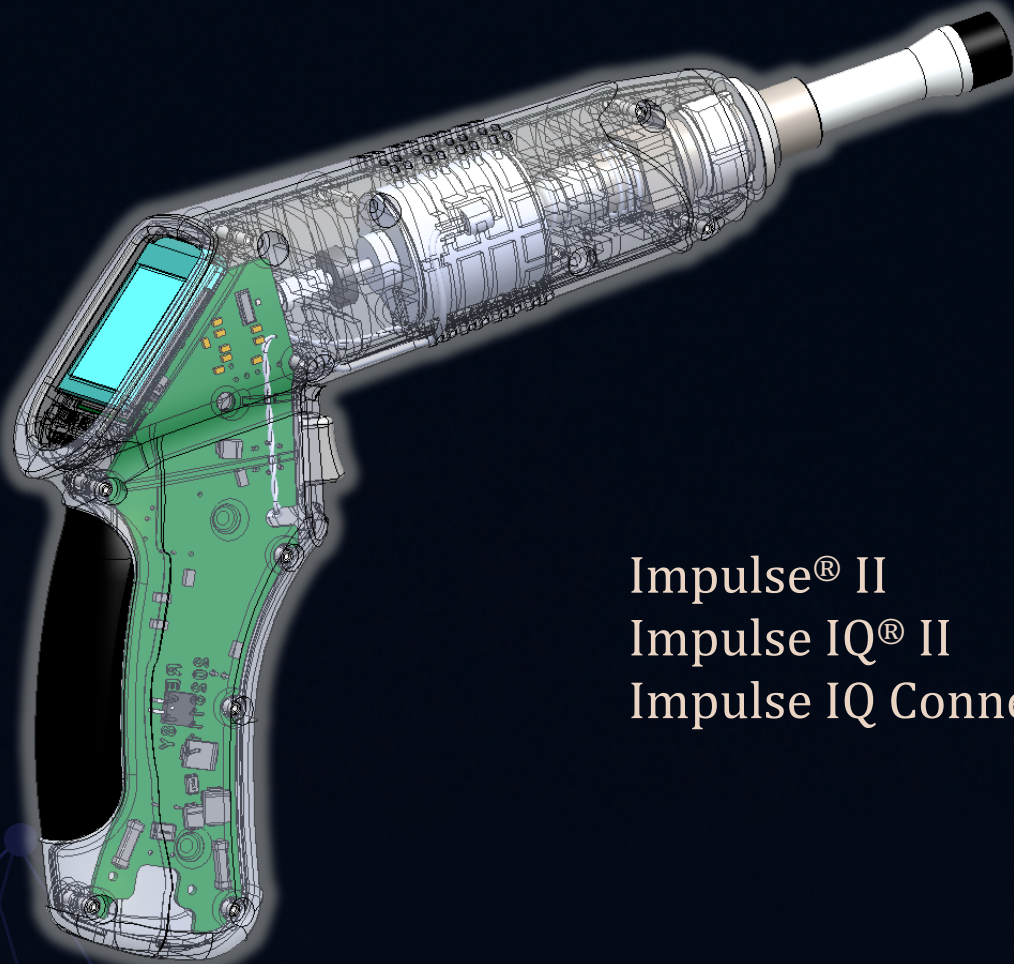


Impulse 2.0 Platform

IFU

Instructions For Use



Impulse® II
Impulse IQ® II
Impulse IQ Connect®

Adjust to the Frequency

ImpulseAdjusting
SYSTEM®

Instructions for Use (IFU)

Device Identification

Device: Impulse 2.0 Platform

Applies to: **Impulse 2.0 • Impulse iQ 2.0 • Impulse iQ Connect**

Manufacturer: Neuromechanical Innovations
9831 S. 51st Street
Phoenix, AZ 85044
www.neuromechanical.com

Revision: Rev. 001

Intended Environment: Professional healthcare settings (clinics, offices)

Associated Software for Impulse iQ Connect device: FDA-registered Impulse iQ Connect Graphical User Interface (GUI)

Date: 9-16-2025

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Device Overview

The Impulse 2.0 platform is a powered, handheld instrument for the therapeutic adjustment/mobilization of musculoskeletal structures (see Section 2).

Variations and distinguishing features:

Feature	Impulse 2.0	Impulse iQ 2.0	Impulse iQ Connect
Output modes	[]	Single-impulse & closed-loop multiple-impulse	[]
Feedback	[]	Closed-loop feedback from the patient's acceleration response	[]
Multi-impulse frequency	[]	≈4–12 Hz (auto-adjusts to maximize acceleration response)	[]
Force settings	[]	Six settings, ≈25–400 N	[]
User interface	[]	LCD overlay switch with force-adjustment arrows	[]
Accessories	[]	Standard single stylus, cervical & lumbar dual styluses	[]
Connectivity	None	None	Wireless to companion GUI

Intended Use / Indications / Users / Environment

Indications for Use — Impulse iQ 2.0

Impulse 2.0 Platform Devices are intended for adjustment, mobilization, or manipulation of the musculoskeletal joints of the spine and/or extremities, or for soft-tissue musculoskeletal mobilization by a licensed health care professional only. For external use only.

Intended users & training

- Licensed health care professional only.
- **Training recommended:** Use only after receiving instruction on usage, indications, and contraindications provided in IFU. Additional postgraduate educational courses available.
- Course information: <https://neuromechanical.com/product-category/online-training>
- Before first use: Review this IFU and the online new-user video content to become familiar with device features and operation.

Use environment

Clinical/office settings (and other environments as cleared). Device is not suitable for use in the presence of flammable mixtures.



Use in dry environment, non-submersible.




















Limit exposure to humidity or moisture.

Symbols & Definition (Glossary)

Symbols and Abbreviations

Symbol	Meaning	Standard Reference
	Manufacturer	ISO 15223-1
	Country of manufacture (USA)	ISO 15223-1

	Distributor	ISO 20417-2020
	Medical Device	ISO 15223-1
	Model	ISO 15223-1
	Unique Device Identifier	ISO 20417-2020
	Warning – consult Instructions for Use	ISO 15223-1
	Consult Instructions for Use	ISO 15223-1
	Patient Information Website	ISO 7000
	Power on/off	IEC 60417-5009
	Device in operation / processing	IEC 60601-1
	Dry Environment Use	ISO 20417
	Humidity Limitation	IEC 60601-1
	Type B applied part	IEC 60417-5009
	International Device Disposal	IEC 63395
	External power connection	IEC 60417-5007
	Adjustment successful (mobility maximized)	Device convention (Connect Only)

	Adjustment successful audible beep (mobility maximized)	Device convention (Impulse IQ Only)
	Adjustment unsuccessful	Device convention
Tx	Times (number of applications delivered to a level)	Device convention
N	Newtons – unit of force	SI Unit

Definitions

Impulse 2.0 Platform – Refers to the family of products encompassing a line of products containing multiple variations (Models) using the same fundamental base Device.

Level – Refers to the body part or spinal level being treated.

Side – Refers to the side of the body, or the side of a specific level, when the level does not have a left/right orientation.

Vector – The angle of drive at which the thrusts are delivered to the level.

Application – Applying the treatment instrument to the patient for one complete cycle.

Cycle – The application of the treatment device to the patient in which a variable number of thrusts are delivered until the device stops thrusting, as defined in the device IFU.

Adjustment Chart – The bottom section of the “Adjust and Review” screen, where adjustment data is populated horizontally on a single line for each application of treatment within a level.

Protocol(s) – One or more defined treatment applications delivered to specific anatomical levels.

Thrusts – The number of times the instrument cycles in a forward motion into the level.

Force – The Newtons (N) of thrust force used during the application of treatment.

Visit – Patient encounter

Session – Active adjustment data collection during a single visit

PTS (Patients) – Visit number for the current Session

ADJ (Adjustment) – Indicates which sequential number indicating the level is being reviewed or treated.

Dose – The total number of thrusts delivered to the level.

Count – Total number of thrusts delivered to current patent.

Adjustments (ADJ) – Refers to the overall number of levels treated during the visit.

Adjustment Frequency Meter – Visually represents the frequency/speed of thrusts in real time.

Result – Indicates whether the adjustment maximized mobility at the conclusion of the application, represented by a audible beep.

Contraindications

Do not use the Device on:

- Acute fractures
- Pathological bones or joints incapable of load sharing during weight bearing
- Soft tissues such as the eyes, mammary glands, ovaries, testicles, or auditory canals

Warnings

- ⚠ Read and understand this IFU and complete the recommended training before use.
- ⚠ Electrical safety: Keep away from liquids; do not immerse or rinse. If liquid is spilled on the device, disconnect from power immediately.
- ⚠ Do not autoclave the instrument.
- ⚠ Do not clean with strong aromatic, chlorinated, ketone or ether solvents; avoid sharp tools/abrasives.
- ⚠ Flammability: Not suitable for use in the presence of flammable mixtures.
- ⚠ Use only approved accessories and replacement parts.
- ⚠ If unexpected device behavior or patient adverse effects occur, stop use and evaluate.

Precautions

- Before applying to a patient, familiarize yourself with the six force settings and preload-nosepiece spring tension by placing the stylus on your own fingertip and delivering a test thrust.
- Between patients, disinfect patient-contact components.
- Keep out of reach of water; do not submerge.
- Follow facility policies for cleaning, disinfection, and (for connected models) data handling.

Device Identification & Contents

- Impulse 2.0 Platform Models covered:

Impulse 2.0

Impulse iQ 2.0

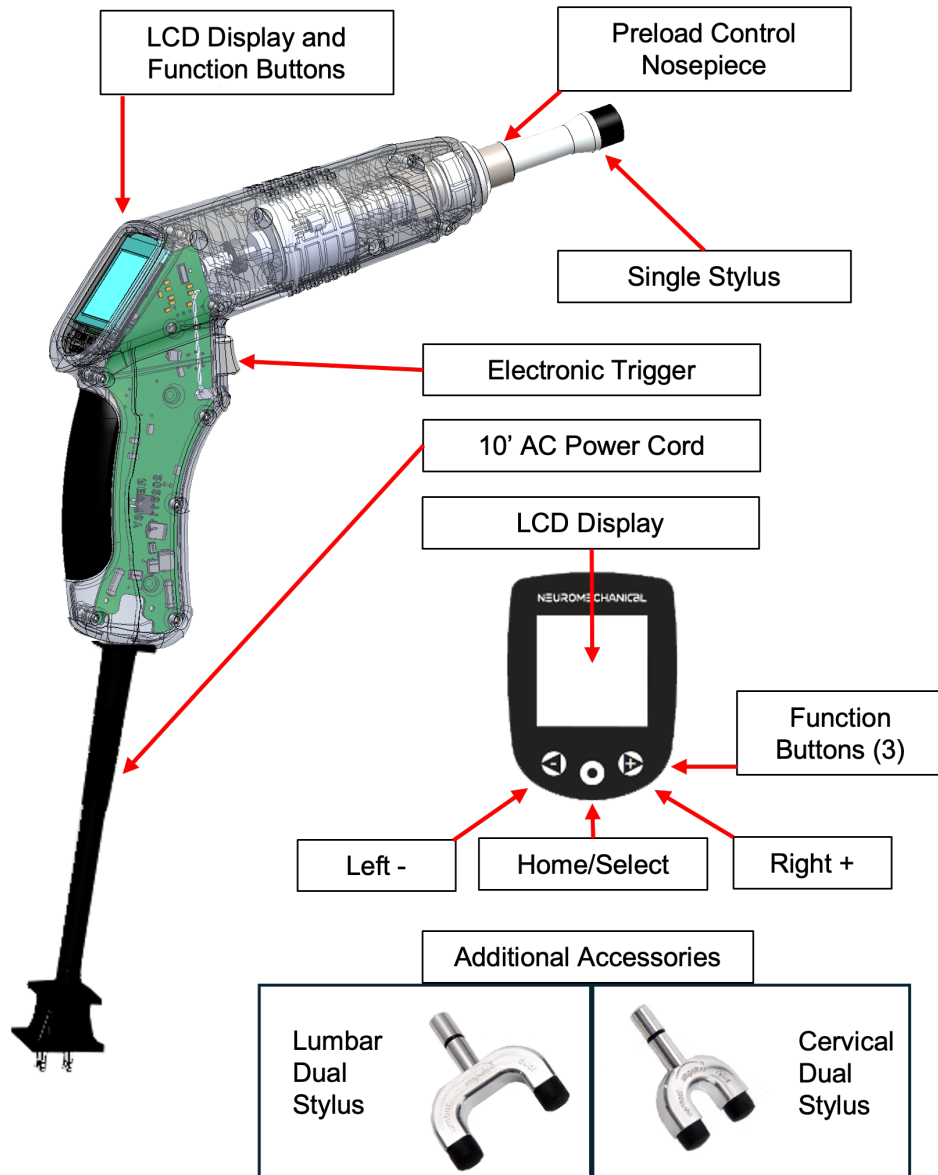
Impulse iQ Connect

- Package contents (iQ 2.0): Instrument body, single stylus with neoprene tip, power supply/cord, IFU, quick start guide, UDI number on cord label
- Additional accessories: Cervical dual stylus and lumbar dual stylus (included)
- Specifications: Six force settings ($\approx 25\text{--}400\text{ N}$), single-impulse and closed-loop multiple-impulse modes ($\approx 4\text{--}12\text{ Hz}$), LCD overlay switch with force-adjustment arrows. Include full specs and tolerances in your spec table.

Setup

- Unpack and verify contents; retain packaging for transport.
- Inspect cables, connectors, stylus, and tip; do not use if damaged.
- Attach the desired stylus; confirm secure engagement.
- Power the device per Start Up
- For iQ Connect only: install and pair the companion GUI.

Figure 1. Schematic of Impulse 2.0 Platform Adjusting Instrument(s) and control layout.



Operation Overview

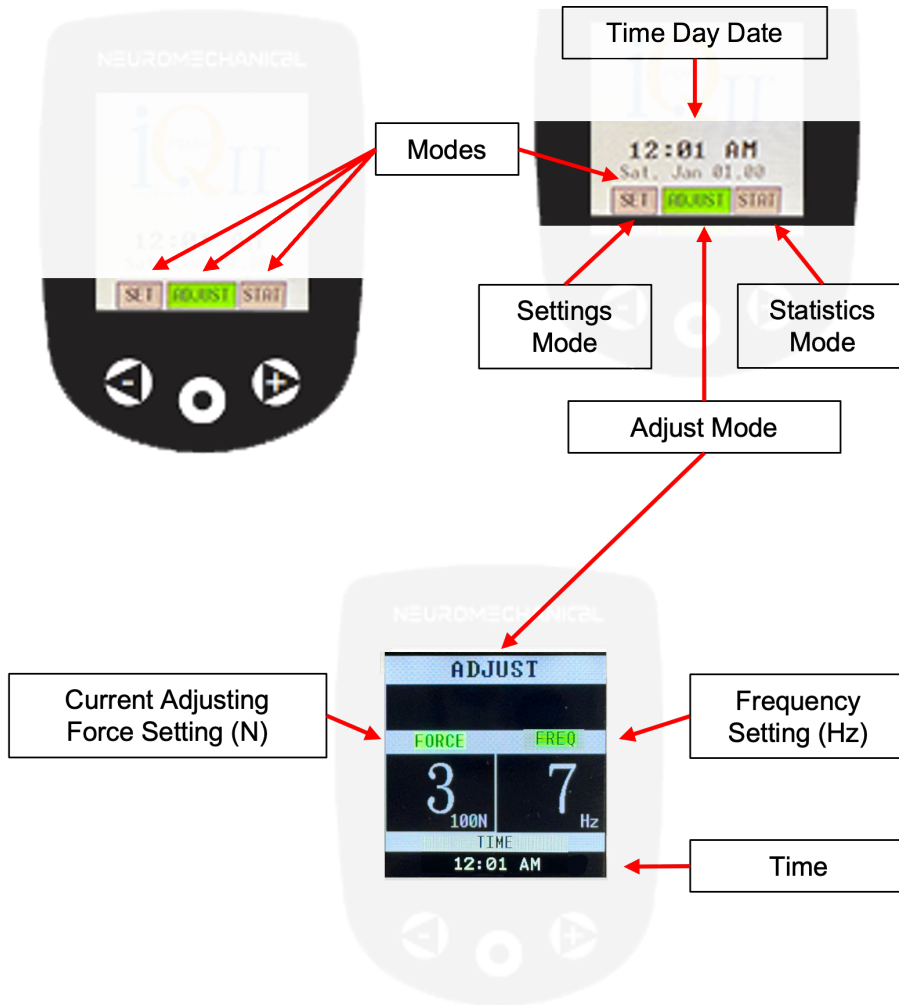
Display Overview

A. Impulse ii (2.0)

Device Logo:



Impulse ii - Display Function Overview:



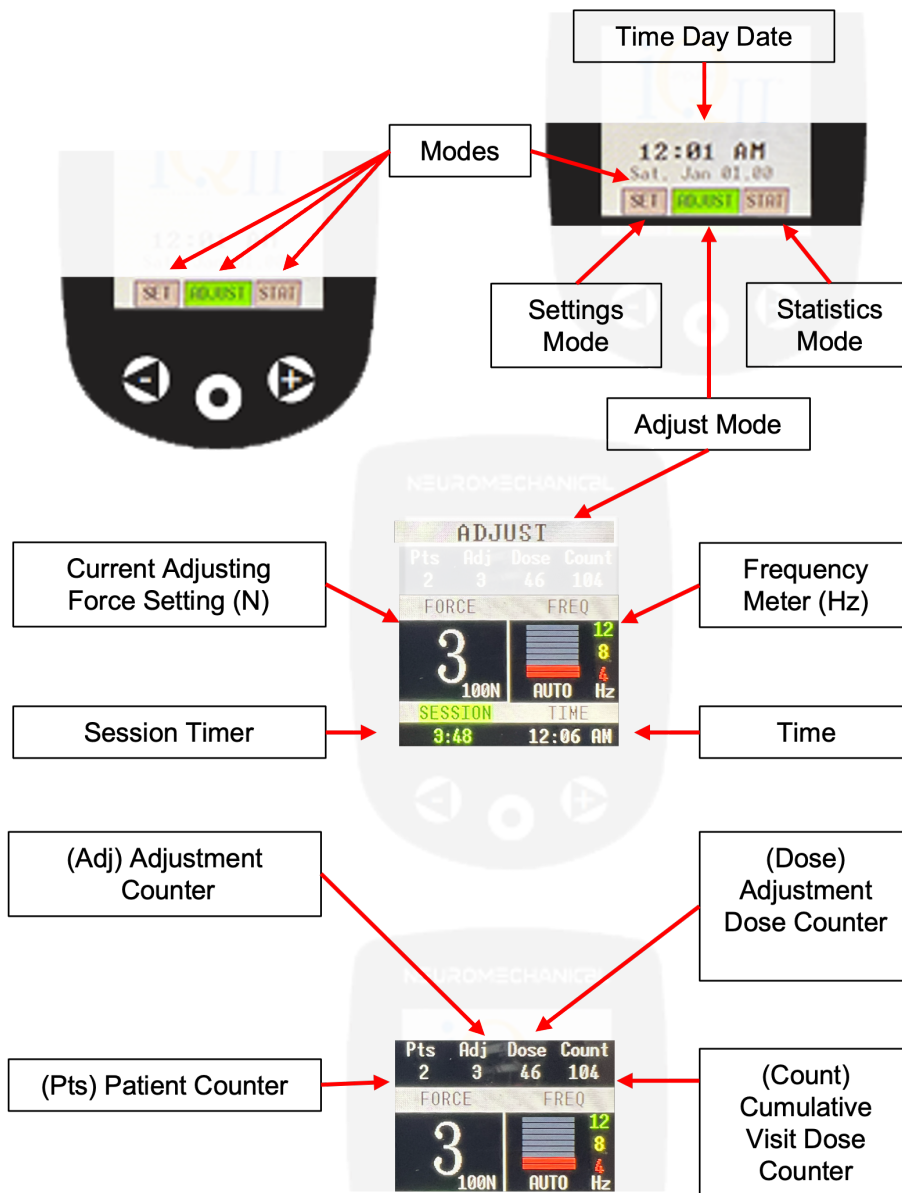
[Insert device-specific steps and settings for Impulse 2.0.]

B. Impulse iQ ii (2.0)

Device Logo:



Impulse iQ ii - Display Function Overview:

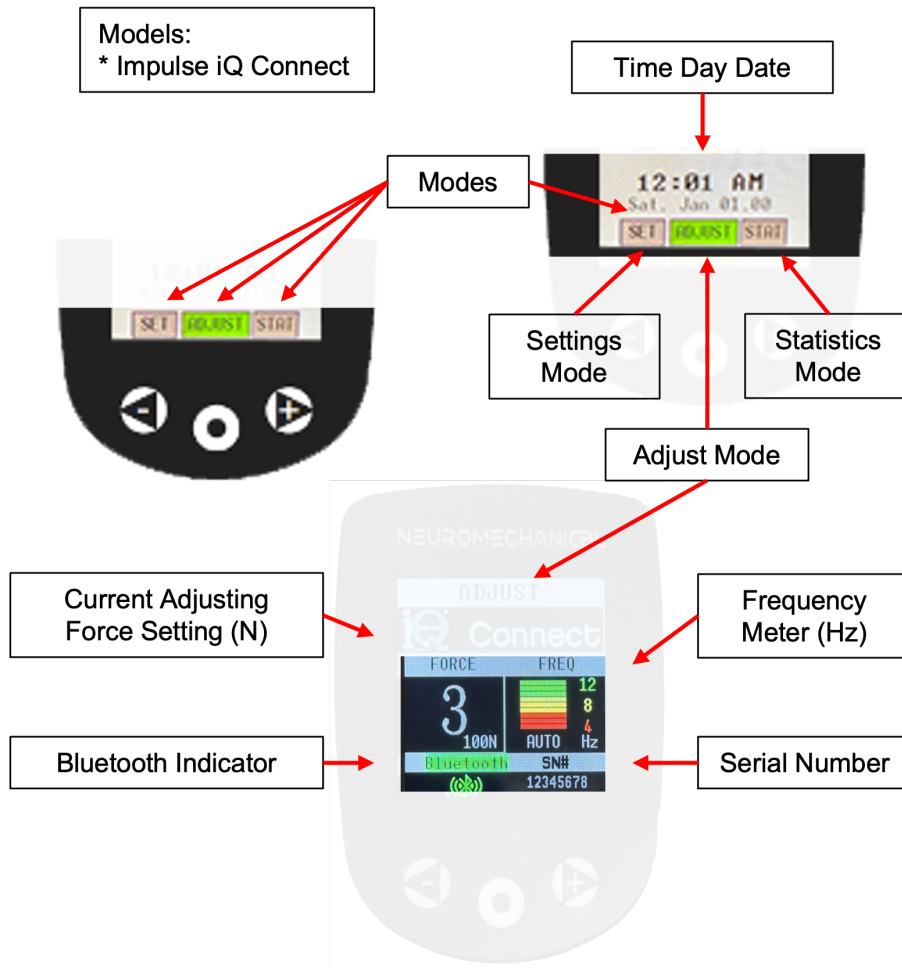


C. Impulse iQ Connect

Device Logo:



Impulse iQ Connect - Display Function Overview:



Bluetooth See: [Impulse IQ Connect Special Features](#)

Start Up

Power On/Off

Turn On: Device will power on once connected to a suitable power supply.

The display screen will illuminate to the Home Screen (Instrument Logo) and transition by default to the ADJUST Screen.

Turn Off: Unplug to turn off

Examples Screens:

Home



Adjust



Setup Setting Mode

From the Home Screen navigate to “SET” using the arrow Button(s) (Left - or Right +)

Once SET is highlighted in green, press the Center Home/Select button to enter settings mode. Upon entering settings mode, use Left – or Right + buttons to navigate through settings functions.

Once the desired setting is highlighted in green use the center Home/Select button to adjust settings. Select Done to Return to Home Screen



Device Setting Time & Date

Time: In Settings Mode use using the arrow Button(s) (Left - or Right +) to highlight “SET TIME” and Center Home/Select button to enter time Set Mode.

Use arrow Button(s) (Left - or Right +) to increase or decrease Hour time value.

Note: Hour value will change AM/PM setting.

Center Home/Select button to accept. Adjust minute value use Center Home/Select button to accept and Save Time.

Setting Screen



Hour AM/PM

Minute

Save Time



Setting Date: Use arrow Button(s) (Left - or Right +) to increase or decrease date values. Center Home/Select button to accept and Save.



Device Adjust Mode

Default Force Setting

Ready To Adjust:

Upon Strat Up, FORCE is highlighted in Green. Device will default to Force Setting three (3) of six (6) settings.

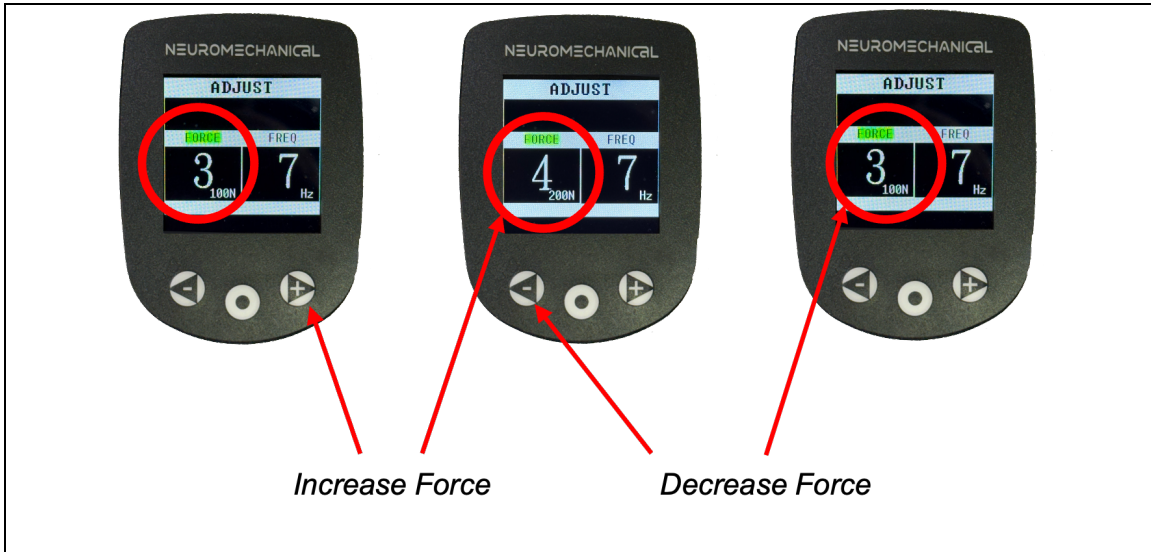
Note: Force Settings are detailed Under Force Settings and within Force Settings Diagram [Changing Force Setting](#)

Impulse II Adjust Screen



Changing Force Setting


Changing Force Settings: Use arrow Button(s) (Left - or Right +) to increase or decrease force setting.



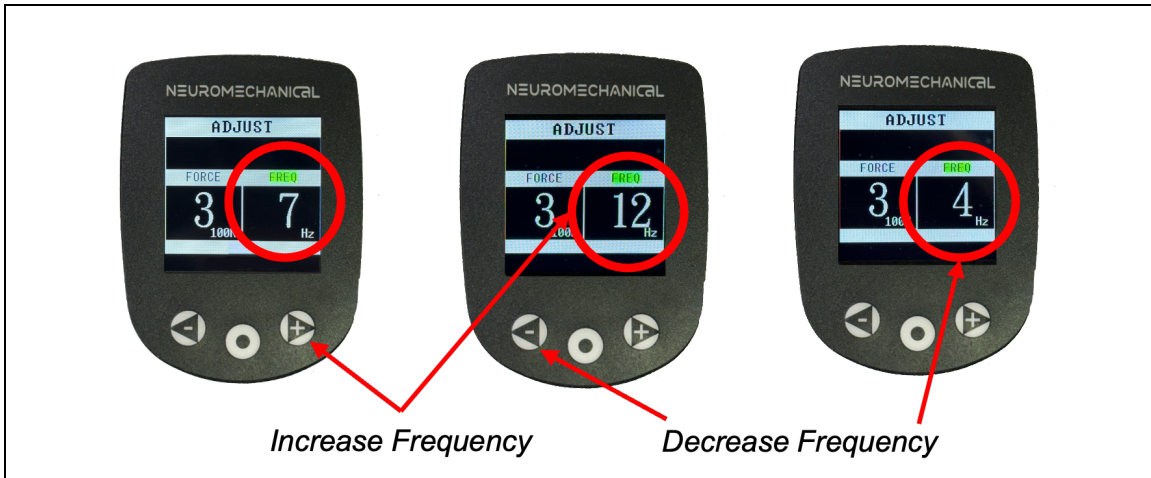
Impulse Device Force Settings Diagram

Setting	Newtons	Force
6	400N	High
5	300N	Medium High
4	200N	Medium
3	100N	Low
2	50N	Light
1	25N	Subtle

Impulse II Frequency Adjustment (Impulse II Only)

<p>Impulse II Frequency Select:</p> <p>Impulse II has a manually adjustable frequency ranging from 4 – 7Hz.</p> <p>Upon start up device will default to 7 Hz.</p> <p>To change FREQUENCY, use the Center button to toggle between FORCE and FREQ</p>	<p><i>Impulse II Adjust Screen</i></p>  <p>The image shows the 'Impulse II Adjust Screen' on a handheld device. The screen displays 'NEUROMECHANICAL' at the top, followed by 'ADJUST'. Below this, there are two columns: 'FORCE' with a value of '3' and '10%' below it, and 'FREQ' with a value of '7' and 'Hz' below it. A red circle highlights the '7 Hz' value. A red arrow points from the 'FREQ' label to the '7 Hz' value. Another red arrow points from the center button on the device's control panel to the 'FREQ' column.</p>
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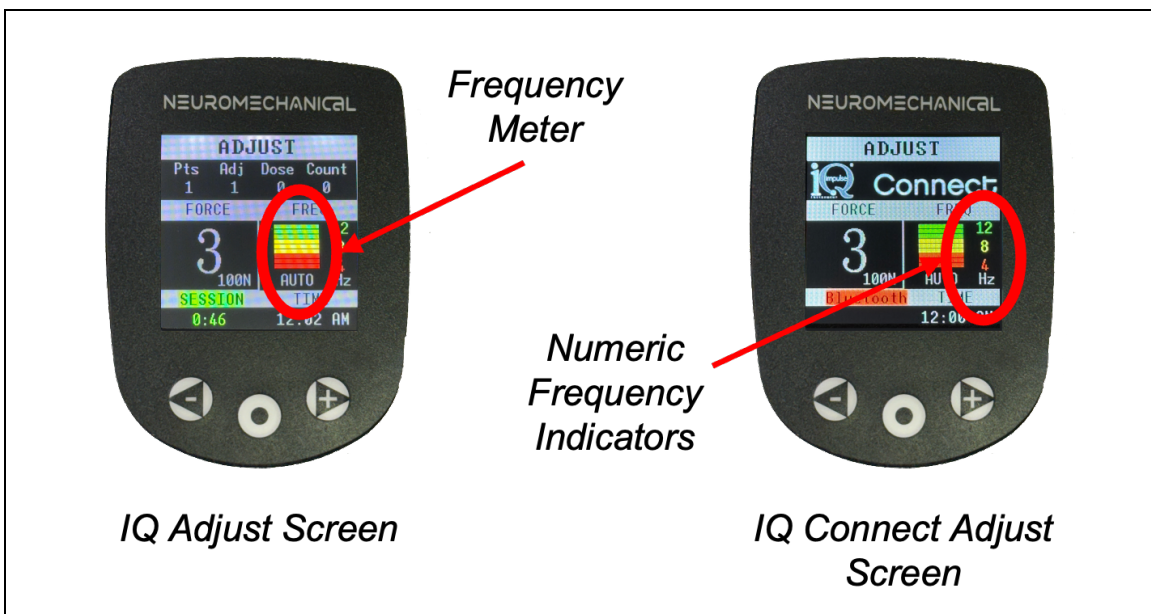
Frequency Change Illustration:



Frequency Meter (Impulse IQ II & Impulse IQ Connect Only)

“IQ” designated instruments have proprietary Intelli-Adjust® and Auto-Sense® smart technology. These technologies work together to adjust trust frequency in real time using biofeedback response.

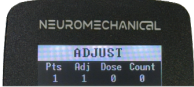

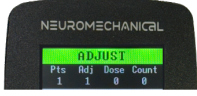
Frequency will be displayed in the FREQ window using lighted bars to indicate real time frequency. Numeric Frequency indicators 4 - 12 appear vertically on the left side of the window.



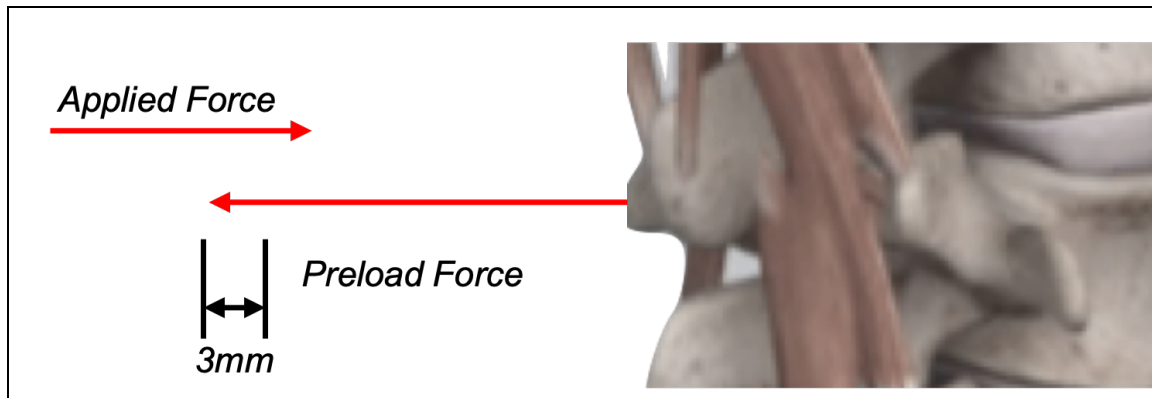


Additional features and visual representations using the companion GUI will be described within the Impulse IQ Connect GUI IFU.

Adjusting

<p>Adjusting:</p> <p>Prior to patient contact ensure finger is removed from trigger.</p> <p>Instrument will not fire until proper preload has been achieved.</p> <p>To properly preload instrument, with finger of the trigger, place Stylus on adjustment area as appropriate and applying slight pressure to actuate.</p> <p>While applying (Approx 20N) pressure, Device Adjustment Indicator will transition for White-Yellow-Green.</p>	<p><i>Preload Color Indications:</i></p> <p><i>White = Rest</i></p>  <p><i>Yellow = Caution</i></p>  <p><i>White = Adjust</i></p> 
---	--

Preload Stylus Tip against patient body (Adjustment Area)



Delivering the Adjustment:

Once Preload is appropriately achieved, maintain firm preload pressure using clinical judgement and squeeze trigger.

Impulse Instruments: will thrust 13 times at the force and frequency as determined by the user.

IQ Instruments: will thrust at force determined by the user at an optimal frequency until maximum mobility has been achieved or mobility improvement potential is limited, as determined real-time proprietary sensors and frequency analysis technologies.

Set-by-step Adjustment Delivery

Administering treatment application should be performed by a trained healthcare professional. Additional training can be accessed through Neuromechanical Online and in person seminar courses.

Turn On: Device will power on once connected to a suitable power supply.

The display screen will illuminate to the Home Screen (Instrument Logo) and transition by default to the ADJUST Screen.

- Following clinical assessment, place the neoprene tip of the stylus on the selected musculoskeletal area.
- Compress the preload control spring housed within the nosepiece to achieve the desired tissue compression. See [Adjusting](#)
- Pull the trigger and release for a single thrust.
- Multiple-impulse mode: Holding the trigger down longer than $\sim\frac{1}{4}$ second initiates closed-loop multiple-impulse thrusts. In this mode, the instrument delivers thrusts at a rate determined by the patient's acceleration response ($\approx 4\text{--}12$ Hz) until the acceleration response is maximized.
- Force selection: Choose among six (6) impulsive force settings ($\approx 25\text{--}400$ N) using the force-adjustment arrows on the LCD overlay switch.

Adjustment Result:

IQ designated instruments (Impulse IQ II & Impulse IQ Connect) report an Adjustment Result.

Success: When the Instrument stops, an adjustment disposition is reported with an audible beep when the adjustment has been successful. A successful adjustment indicates the instrument sensors have detected an appreciable mobility improvement of the adjustment area.

Unsuccessful: When the instrument has not detected an appreciable mobility improvement of the adjustment area the instrument will stop, no audible beep is emitted. Readjusting may be applied consistent with Impulse Adjusting System(r) training and clinical judgement.



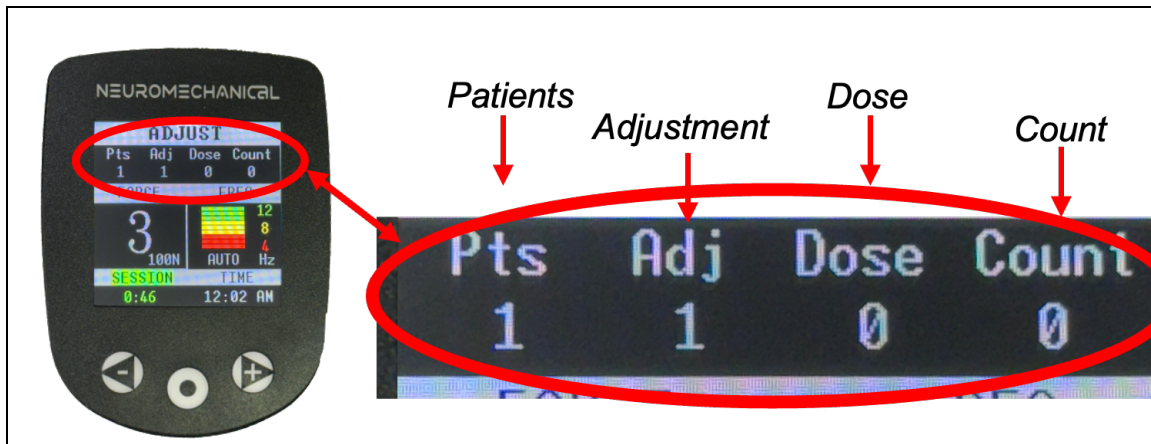
Additional features and visual representations using the companion GUI will be described within the Impulse IQ Connect GUI IFU.

Impulse IQ Special Features



Data Fields

Impulse IQ II Device: Features exclusive visual adjustment data and visit session timer on the Device LCD Screen.



Pts - Adj - Dose - Count:

Pts: Patients - Displays the number of patient sessions today. The system resets at midnight based on the time setting. The visible number indicates the number sequence of the patient being adjusted in the current Session.

Adj: Adjustments - The instrument will report the number of individual (anatomy area) adjustments delivered to the patient during the current Session.

Dose: Dose - The number of thrusts delivered at the completion of an Adjustment.

Count: Count - The cumulative number of thrusts derived during the current Session.

Note: The instrument displays Adjustment #, Dose and Count at the conclusion of an adjustment for visual reference until the instrument is Preloaded again. Once Preloaded, Adjustment (Adj) will advance and Dose will reset to zero. Count will remain unchanged until the conclusion of a subsequent Adjustment.

Sessions

Sessions:

Impulse IQ ii (2.0) has a Session mode that enables advanced features and provides clinical feedback pertaining to Patients, Adjustments and Clinical Efficiency.

Adjust Screen “Sessions” highlighted in red indicates Session Mode is not active.



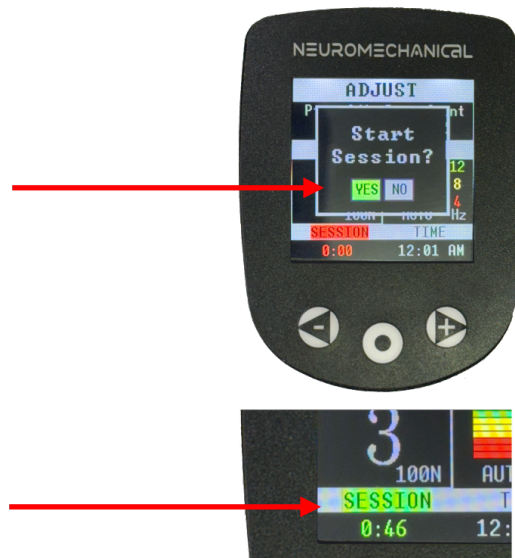
Start Sessions

Start Sessions:

To Adjust with Sessions Enabled press the center Home/Select button while on the Adjust Screen. “Start Session?” pop-up will be displayed.

“YES” is highlighted in green. Press center Home/Select button to accept selection. (use arrows to highlight and select NO)

Session and timer highlighted in Green indicates Session is Active.



End Sessions

END Sessions:

While Session is active, press center Home/Select button to End Sessions Mode. "END SESSION?" pop-up will be displayed.


"YES" is highlighted in green. Press center Home/Select button to accept selection. (use arrows to highlight and select NO)




Impulse IQ Connect Special Features




Bluetooth

<p>Bluetooth:</p> <p>IQ Connect broadcasts a Bluetooth signal which may be paired with proprietary Connect System Software for the purpose of transmitting encrypted Adjustment Data for visual display.</p> <p>Bluetooth will be highlighted Red when ready to be paired with Connect System Software device.</p>	 <p>The image shows the IQ Connect device screen. At the top, it says 'NEUROMECHANICAL'. Below that is 'ADJUST'. The main display area is divided into 'FORCE' and 'FREQ'. Under 'FORCE', it shows '3' and '100N'. Under 'FREQ', it shows a bar graph with '12', '8', and '4' Hz, and 'AUTO'. At the bottom of the screen, 'Bluetooth' is highlighted in red, and 'TIML' is shown as '12:00 AM'. A red arrow points to the 'Bluetooth' text.</p>
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Pairing Bluetooth

<p>Pair Bluetooth:</p> <p>Pairing Bluetooth is only possible through the proprietary Connect System Software. Pairing is described in the Connect Software IFU.</p> <p>Bluetooth and Symbol will be highlighted in green once connected.</p>	 <p>The image shows the IQ Connect device screen. At the top, it says 'NEUROMECHANICAL'. Below that is 'ADJUST'. The main display area is divided into 'FORCE' and 'FREQ'. Under 'FORCE', it shows '3' and '100N'. Under 'FREQ', it shows a bar graph with '12', '8', and '4' Hz, and 'AUTO'. At the bottom of the screen, 'Bluetooth' and the Bluetooth symbol are highlighted in green, and 'SN#' is shown as '12345678'. A red arrow points to the 'Bluetooth' text.</p>
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Serial Number

<p>Serial Number:</p> <p>The Instrument Serial Number is displayed for reference when pairing Bluetooth using the proprietary Connect System Software.</p> <p>Pairing is described in the Connect Software IFU.</p>	
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Pairing, Bluetooth & Connectivity



Pairing with the companion GUI further described within the Impulse IQ Connect GUI IFU.

Power / Electrical

- Impulse iQ 2.0 input: 90–120 V~ (4 A max) or 90–240 V~ (4 A max), depending on model.
- Use only the supplied/approved power supply and cords.
- Disconnect from power before cleaning; never operate if the device or cord is wet or damaged.
- Internal battery has a 10-year life expectation and does not require charging or replacement (IQ Connect Only).

Cleaning, Disinfection & Reprocessing

Owner cleaning (instrument body)

- Cleaning is the only maintenance recommended for owners.
- Wipe the device exterior with a dry cloth.
- Never submerge or rinse the device. Do not autoclave.
- Do not use strong aromatic, chlorinated, ketone, or ether solvents; avoid sharp tools/abrasives.

Between-patient disinfection (patient-contact parts)

- Wipe the neoprene tip of the stylus with a sanitary disinfectant such as 70% isopropyl alcohol (or similar agent appropriate for external human use).
- Allow to dry fully before next use.

Maintain documentation of validated cleaning/disinfection methods consistent with risk analysis and material compatibility.

Accessory owner maintenance (stylus, tips, O-rings)

- The Impulse iQ 2.0 supports three (3) interchangeable stylus attachments.
- Each stylus includes a neoprene tip and rubber O-ring.
- Tips and O-rings can be purchased from the Neuromechanical Innovations online store: neuromechanical.com
- Tip replacement: Owner may remove and replace tips.
- O-ring replacement & lubrication: Owner may replace O-rings and lubricate per Section 11.4.

Lubrication (stylus O-rings only)

- The Impulse iQ 2.0 instrument does not require internal lubrication.
- Stylus O-rings may be lubricated periodically or at replacement with a pin-head-sized drop of sewing machine oil.

Electromagnetic Compatibility (EMC) & Wireless

Provide tested IEC 60601-1-2 edition, immunity/emissions levels, and recommended separation distances. If performance degrades (unexpected outputs/resets), increase distance from RF sources, re-orient, or relocate.

Software, Cybersecurity & Updates

(For iQ Connect / any software-based functionality.) Describe software version visibility, update method (e.g., via app), data stored/transmitted, authentication/access controls, and user responsibilities (installing updates, using approved networks/devices).

Troubleshooting

Symptom	Possible cause	Corrective action
No thrust on trigger pull	Preload not achieved; incorrect attachment	Compress preload spring firmly; confirm stylus seated
Multiple-impulse not starting	Trigger release too soon	Hold trigger > ~0.25 s to initiate multi-impulse mode
Force feels too high/low	Wrong force setting	Adjust via LCD overlay arrows to appropriate setting
Excessive vibration/heat	Extended high-duty operation	Pause to cool; inspect stylus/tip; verify settings
Device feels wet or was spilled on	Liquid exposure	Disconnect from power immediately; allow to dry; inspect before reuse

Adverse Effects / Complications

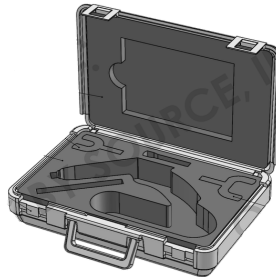
- Skin changes (e.g., redness or ecchymosis) may occur in sensitive individuals after use.
- Muscle soreness may be reported by some users.

- Allergic reactions may occur in individuals sensitive to rubber compounds.

If adverse effects occur, discontinue use and evaluate the patient.

Storage, Transportation & Operating Environment

- Operating (normal use): +10 °C to +40 °C, 30%–75% RH, 700–1060 hPa atmospheric pressure.
- Least favorable work conditions: Avoid extreme cold/heat and/or humidity.
- Handling: Keep dry; protect from shock/vibration; do not immerse or rinse. If liquid is spilled on the device, disconnect from power.
- Do not autoclave; do not use strong aromatic, chlorinated, ketone or ether solvents; avoid sharp tools/abrasives.
- Flammable atmospheres: Not suitable for use in the presence of flammable mixtures.
- Device is shipped in custom molded plastic case:



- Device must be shipped to manufacturer in its original custom molded case for service inspection or repair.

Disposal

Dispose of device, and accessories per local regulations.

Warranty & Service

Routine owner actions

- Cleaning (Section 11) is the only owner-performed maintenance recommended.

Service maintenance & warning

- All other maintenance/repair is performed by Neuromechanical Innovations.

- No authorized third-party service or repair facilities or agents.
- Opening or attempting to open the instrument voids the manufacturer warranty.
- Unauthorized service by the owner or third parties voids the warranty and may create unnecessary risk to patients, practitioners, and the practice.
- Regulatory note provided by manufacturer: “Impulse iQ 2.0 Adjusting Instrument is a Class II medical device registered with the FDA.” (Include clearance/registration details as appropriate.)

Requests & warranty resources

- Service Request: neuromechanical.com/return-and-repair-forms
- Warranty Registration: neuromechanical.com/warranty-registration
- Warranty Information: neuromechanical.com/warranty-information

Adverse Event Reporting & Product Complaints

- Stop use and evaluate the patient if adverse effects occur.
- Report incidents to the manufacturer using the contact details on page 1.
- For U.S. distribution: report serious adverse events through FDA MedWatch as applicable; user facilities/manufacturers follow MDR/eMDR requirements.

Document Control

This IFU supersedes: 0.0

Revision / Date

Summary of Changes

[Rev. 001] / [10-1-2025]

Initial Document



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