IEC 60417-5841 Type B Applied Part **IEC 60417-5172 Class II Equipment**

General Warning: Reference to Instruction Manual

Thrust 2 sec. **Rest 40 sec.**

Alternating Current

MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, CAN/CSA C22.2 NO. 601.1 46LP

This symbol on the product or on its packaging indicates that this product must not be disposed of with your other household waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service or Neuromechanical Innovations at info@neuromechanical.com

CE 0086

Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex Street, Sydney, NSW 2000
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United States Food and Drug Administration
Medical Device Listing 510(k): K080261

Neuromechanical INNOVATIONS

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IFU-002 Rev. 2 US Patents 7,144,417 and 8,083,699 and Patents Pending 04/2012

IMPORTANT

READ BEFORE USING INSTRUMENT

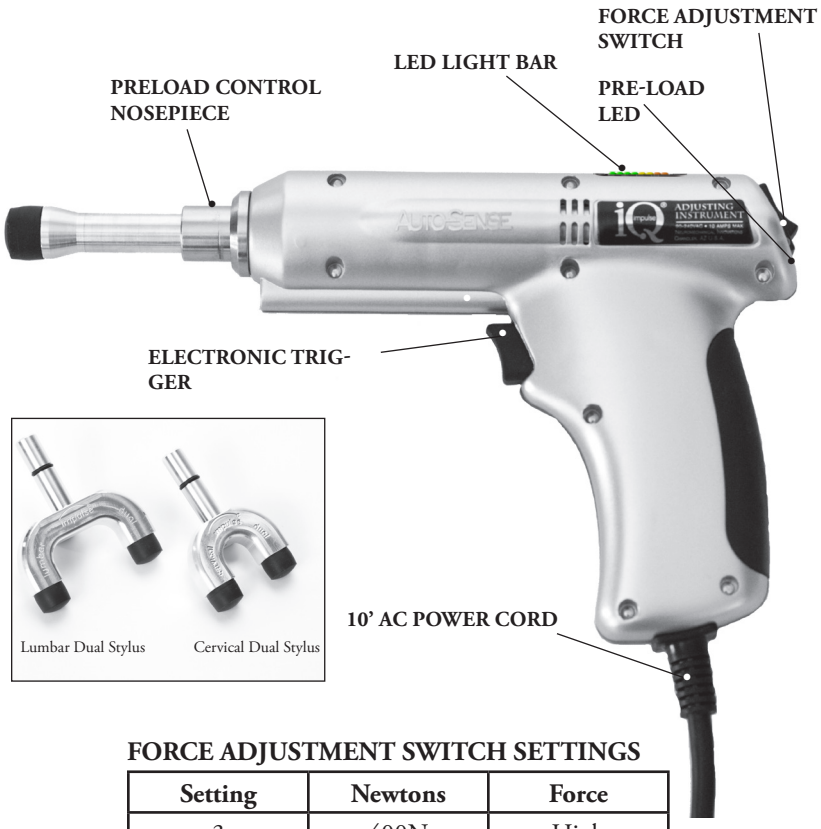
iQ impulse®

ADJUST TO THE FREQUENCY

ACTIVATE WARRANTY NOW!

TURN TO PAGE 11

FIGURE 1. SCHEMATIC OF THE IMPULSE IQ ADJUSTING INSTRUMENT®



FORCE ADJUSTMENT SWITCH SETTINGS

Setting	Newtons	Force
3	400N	High
2	200N	Medium
1	100N	Low

LED LIGHT BAR

LED Color	Green	Green	Green	Green	Yellow	Yellow	Orange	Orange
Pulse Per Second	12	10	9	8	7	6	5	4

WARRANTY INFORMATION

In order to activate warranty, please visit:

http://neuromechanical.com/warranty

NOTES

IMPULSE IQ ADJUSTING INSTRUMENT® DEVICE USAGE

Recommended use of the Impulse iQ Adjusting Instrument® is by a licensed health care professional only. It is further recommended that the device be used only after receiving instruction on usage, indications, and contra indications that are provided in postgraduate educational courses. More information on course offerings can be found at www.neuromechanical.com. Prior to use, the device usage information contained herein and the accompanying CD/video program must be reviewed to familiarize you with the device and its features.

Indications for Use - The Impulse iQ Adjusting Instrument® is 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.

Usage - To provide a thrust, place the silicone tip of the stylus on the selected musculoskeletal area and compress the preload control spring housed within the nosepiece of the instrument to achieve the desired tissue compression, pull the trigger and release for a single thrust. Holding the trigger down longer than ¼ second initiates the multiple-impulse thrust mode. In this mode the instrument will thrust at a multiple-impulse rate from closed loop feedback identified by the patients acceleration response ranging from 4 to 12 Hz until the acceleration response is maximized. High, medium, and low impulsive force settings are available to choose from as clinically indicated using the force adjustment switch. The Impulse iQ Adjusting Instrument® comes standard equipped with interchangeable single stylus and cervical and lumbar dual styluses. Refer to Figure 1 for a schematic of the Impulse iQ Adjusting Instrument® and further details of its operation.

Precautions - Prior to applying the device to a patient, familiarize yourself with the features of the Impulse iQ Adjusting Instrument®, such as the different force settings and spring tension in the preload-nosepiece by applying the stylus to your own fingertip and thrusting. The Impulse iQ Adjusting Instrument® is an electric device accommodating input voltages from 90 - 120 V~ (4A Max) or 90 - 240 V~ (4A Max) based upon model, and thus must be kept out of reach or submersion from water.

Contra indications - The Impulse iQ Adjusting Instrument® is not to be used on acute fractures, pathological bones or joints incapable of load sharing during weight bearing, or soft tissues such as the eyes, mammary glands, ovaries, testicles, or auditory canals.

Adverse Effects or Complications - At times discoloration of the skin, such as redness or ecchymosis may be observed in sensitive individuals following use while others may report muscle soreness. This product contains no latex however, the electrical power cord and plug contain PVC and persons with latex or phthalate allergies should avoid or limit exposure.

Maintenance - Cleaning is the only maintenance recommended to be performed by owner. Cleaning the device can be accomplished by wiping with a dry cloth. In between patients, the silicone tip of the instrument stylus should be inspected for wear and wiped down with a sanitary disinfectant such as Isopropyl Alcohol 70% or similar substance appropriate for external use on humans. Never, under any circumstances, should the device be submerged in water. All other maintenance/repair issues will be performed by Neuromechanical Innovations.

IMPULSE IQ ADJUSTING INSTRUMENT® DEVICE USAGE

Caution - Federal law restricts this device to sale by or on the order of a licensed health care professional.

Storage, Transportation, Operating Environment - Instrument should be maintained at room temperature +10˚C to+40˚C, 30% to 75% humidity, 700hPA to 1060hPA atmospheric pressure during normal operation.

IMPULSE IQ ADJUSTING INSTRUMENT® OPERATION

Force Adjustment Switch. The force of the delivered thrust can be changed by means of a three position Force Adjustment Switch located at the rear of the device, just above the handle grip. In the (1) position, the low force setting is achieved, delivering approximately 100N of force commonly used for the occiput, upper cervical spine, and on excessively tender areas. With the switch in the (2) position, the medium force setting is achieved, delivering approximately 200N of force, commonly used in the lower cervical spine, thoracic and lumbar areas. Placing the switch in the (3) position activates the high force setting, which will administer approximately 400N that is more appropriate for the lumbar, sacrum, and sacroiliac joints. All three force settings have the same pulse duration, approximately 2 msec. Total peak force output is also dependent upon operator preload. The choice of force setting and/or single or rapid pulse thrust to be used is in the clinical judgment of the clinician using the device.

Electronic Trigger. The Electronic Trigger allows the delivery of single thrusts or multiple thrusts. Pulling the trigger and immediately letting go will administer a single thrust. Holding the trigger down will initiate the rapid pulse mode where the instrument will thrust at a multiple-impulse pulse rate near the natural frequency identified by the patients acceleration response ranging from 4 to 12 Hz until the acceleration response is maximized. Once the multiple-impulse pulse mode is activated, discontinuation of the thrusts can be achieved simply by releasing the trigger, enabling the clinician to manually determine how many consecutive thrusts to administer as clinically indicated in the judgment of the clinician.

Preload Control Nosepiece. Tissue compression, commonly known as a tissue pull in chiropractic techniques, is the preload applied while making segmental contact with the patient prior to the application of the thrust. The amount of preload to apply prior to the application of the thrust is in the judgment of the clinician. An LED light adjacent to the Force Adjustment Switch will turn from amber to green when the preload spring is maximally compressed providing visual feedback to the clinician that tissue compression has been achieved.

Styluses. The Impulse iQ Adjusting Instrument® comes standard equipped with interchangeable single stylus and cervical and lumbar dual styluses. The styluses are held in place by a small black o-ring found on the shaft of the stylus. If removal becomes difficult a single drop of a light weight lubricant can be applied to the o-ring to reduce friction. Sewing machine oil can be found at crafts stores and unlike 3 in 1 oil has virtually no aroma. The silicone tips on the ends of the styluses are replaceable should one fail.

ELECTROMAGNETIC COMPATIBILITY

Guidance and Manufacturer's Declaration - Electromagnetic Emissions for Impulse and Impulse iQ

The Impulse and Impulse iQ devices are intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Impulse and Impulse iQ use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Impulse and Impulse iQ are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity for Impulse and Impulse iQ

The Impulse and Impulse iQ are intended for use in the electromagnetic environment specified below. The customer or the user of the Impulse and Impulse iQ should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – guidance
Electromagnetic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Electrical fast transient/burst IEC 61000-4-5	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-11	<5% U_T (>95% dip in U_T) For 0,5 cycle <40% U_T (>60% dip in U_T) For 5 cycles <70% U_T (>30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 seconds	<5% U_T (>95% dip in U_T) For 0,5 cycle <40% U_T (>60% dip in U_T) For 5 cycles <70% U_T (>30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 seconds	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	Not applicable	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE—U_T is the a.c. mains voltage prior to application of the test level.

ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer´s declaration – electromagnetic immunity - for equipment and system that are not life supporting.

The Impulse and Impulse iQ are intended for use in the electromagnetic environment specified below. The customer or the user of the Impulse and Impulse iQ should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Impulse and Impulse iQ, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.2\sqrt{p}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 1.2\sqrt{p}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

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

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c See examples of calculated separation distances in next table.

Recommended separation distances between portable and mobile RF communications equipment and the Impulse or Impulse iQ

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
W	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

FUNCTIONALITY IN MULTIPLE-THRUST MODE

Areas of the body to be treated with Impulse iQ® are determined by the clinical judgment of the licensed health care provider proving care under their scope of practice. Impulse iQ® has a sensor embedded in the nose piece of the instrument to precisely measure acceleration responses. The sensor is connected to a computer microprocessor that controls the functionality of the device. When Impulse iQ® is applied to the musculoskeletal structures of the body (spine and extremity joints) the instrument measures the acceleration response simultaneously during the chiropractic adjustment.

Generally speaking, two basic variables are assessed during the adjustment:
(1) the displacement for the given force (peak acceleration response) and;
(2) the speed or frequency at which the spine moved (peak-to-peak acceleration response duration).

AUDIBLE INDICATORS AND CLINICAL DECISION MAKING

DISCLAIMER

Neuromechanical Innovations (NMI) provides the information in this section in order to assist customers to better understand the use of the Impulse iQ Adjusting Instrument® within the realm of clinical practice. As an example, below are referenced the Medicare PART clinical documentation guidelines (www.cms.gov). These are Centers for Medicare and Medicaid Services (CMS) guidelines that apply to Medicare only. CMS guidelines are not endorsed or approved by NMI and this information is provided only for informational assistance and is strictly advisory in nature. NMI recommends that you direct inquiries to your local Medicare carrier regarding any questions about CMS guidelines and this commentary does not take precedence over any federal regulation or directive. NMI will take no action to enforce or otherwise require customer compliance wIth this information.

As previously stated, the clinical judgment of the operator to determine if treatment with Impulse iQ® is indicated, or successful is to be made independently from the functionality of the device itself. Clinical indicators indicating the need for treatment and its dosage always take precedence over the audible indicators of the device. Treatment can be ceased at any time by simply releasing the trigger of the device. The determination of medical necessity of treatment including treatment dosage is always the responsibility of the clinician and not the device.

Multiple thrust rate is determined from data obtained from the acceleration response of the initial thrust. The computer algorithm inside the instrument processes and analyzes the data and in turn sets the pulse train rate ranging from 4-12 Hz. As the area is being adjusted during Impulse iQ®'s multiple-thrust mode, the thrust rate may stay the same, increase, or decrease dependent upon the acceleration response. Audible (beep) indicators assist the clinician in understanding the responses.

The LED ight bar is intended to guide the operator in interpreting acceleration response. Ideally, during treatment, the light bar will reach the green levels indicating an optimal result. If only the yellow levels are reached attention should be given to reassessing the effectiveness of the treatment. The determination of medical necessity of continuing the treatment including treatment dosage is always the responsibility of the clinician and not the device.

AUDIBLE INDICATORS

Figure 2 provides the three audible indicator categories (single beep, double beep, and no beep). A single beep indicates that the acceleration response has been maximized. A double beep indicates that the acceleration response has not yet been maximized. No beep indicates that no significant change in acceleration response has been sensed. In the figures below, you will find the Impulse iQ Adjusting Instrument® audible indicators and clinical decision making with consideration to other variables that may influence the treatment.

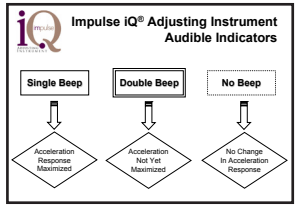


Figure 2

Single Beep: If the instrument beeps once after the adjustment, this indicates that maximum mobility has been reached for pulse train ***(Figure 3).*** Indeed, it is recommended that the clinical indicators that necessitated the treatment be re-assessed prior to further clinical decision making.

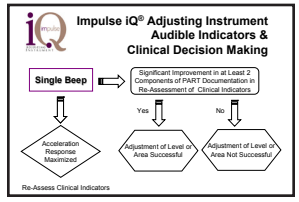


Figure 3

Double Beep: If the instrument beeps twice after the adjustment, this indicates that maximum mobility has not been reached for pulse train ***(Figure 4).*** Of course, it is recommended that the clinical indicators that necessitated the treatment be re-assessed prior to further clinical decision making. It is recommended that special consideration is also given to insure that the contact is correct with consistent preload throughout the adjustment.

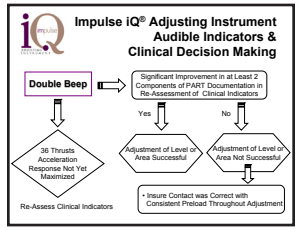


Figure 4

No Beep: If the instrument does not beep after the adjustment, this indicates that no significant improvement in acceleration response has been detected ***(Figure 5).*** In this instance, the clinical indicators that necessitated the treatment must be re-assessed prior to further clinical decision making. Consideration should be given to insure proper segmental contact point, line of drive (adjustment vector), or if area is not receptive to change.

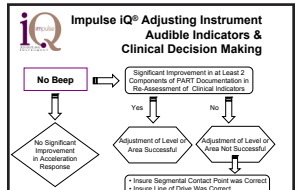


Figure 5

LIMITED WARRANTY

Neuromechanical Innovations guarantees the Impulse iQ Adjusting Instrument® to be free of defects in its materials and workmanship under normal use and service for three (3) years from the date of purchase. A device returned to the manufacturer with the proper documentation will receive a repaired or replaced device. This warranty will be void should the device be opened, tampered with outside of normal use, or found to be damaged outside of normal use and service. The limited warranty described herein is non-transferable and shall be in lieu of any other warranty, whether it be expressed or implied, which is included but not limited to any implied warranty or merchantability of fitness for a particular purpose. Neuromechanical Innovations makes no other warranties, express or implied.

For warranty registration, please visit http://neuromechanical.com/warranty

CUSTOMER SERVICE

If you have any questions about this product you may call:

USA	Toll Free: 888-294-4750	Email: customerservice@neuromechanical.com
AUS	+61 (0)2 8090-7441	Email: customerservice@dynamicare.com.au
AUS	1300 856 118 (Local)	

Please do not return your instrument(s) or any products prior to contacting customer service.

DEVICE SPECIFICATIONS

North American Version	**International Version**
90-120 V~	90-240 V~
50-60 Hz.	50-60 Hz.
4A Max	4A Max

Duty Cycle: Instrument is designed to deliver thrust for 2 (two) seconds; rest for 40 (forty) seconds

ELECTROMAGNETIC COMPATIBILITY

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-1. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.