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): K023462

Neuromechanical INNOVATIONS

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IFU-001 Rev. 3 US Patents 7,144,417 and 8,083,699 and Patents Pending 04/2012

IMPORTANT
READ BEFORE USING INSTRUMENT

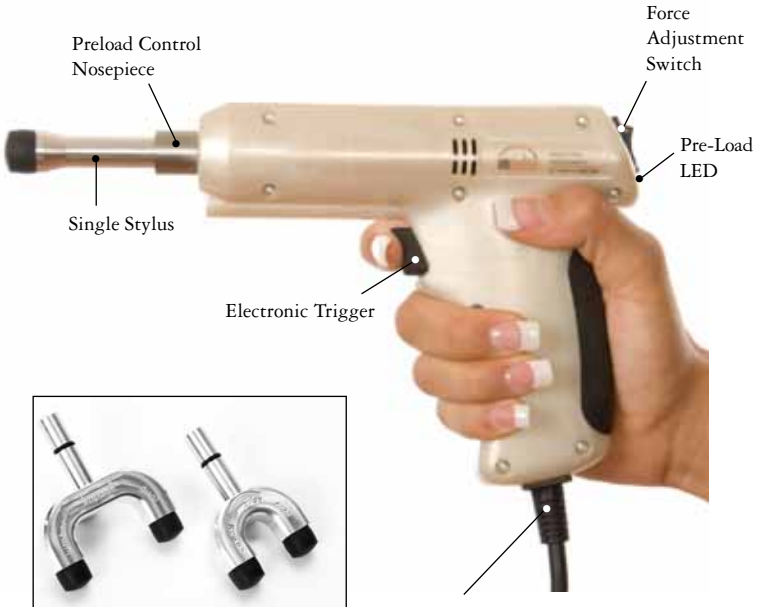
impulse®

ADJUSTING INSTRUMENT

Catch the *New Wave* in Instrument Adjusting

ACTIVATE WARRANTY NOW!
TURN TO PAGE 7

FIGURE 1. SCHEMATIC OF THE IMPULSE ADJUSTING INSTRUMENT®



FORCE ADJUSTMENT SWITCH SETTINGS

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

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.

WARRANTY INFORMATION

In order to activate warranty, please visit:

http://neuromechanical.com/warranty

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. **Recommended separation distance** $d = 1.2\ p$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\ p$ 80 MHz to 800 MHz $d = 1.2\ p$ 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	$d = 1,2\ P$	$d = 1,2\ P$	$d = 2,3\ P$
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.

IMPULSE ADJUSTING INSTRUMENT® DEVICE USAGE

Recommended use of the Impulse 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 **http://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 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 rapid thrust mode, causing the instrument to fire at 6 Hz for 2 seconds. High, medium, and low impulsive force settings are available to choose from as clinically indicated using the force adjustment switch. The Impulse 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 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 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 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 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.

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 ADJUSTING INSTRUMENT® OPERATIONS

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 12 consecutive thrusts will be delivered (6 Hz, 2 sec.). Once the rapid 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 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.

LIMITED WARRANTY

Neuromechanical Innovations guarantees the Impulse Adjusting Instrument® to be free of defects in its materials and workmanship under normal use and service for one (1) year from the date of purchase. A device returned to the manufacturer with the proper documentation will be serviced or replaced. 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 express 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.