Certification Exhibit

FCC ID: 2AD2U-MI001
IC: 12752A-MI001

FCC Rule Part: 15.247
ISED Canada's Radio Standards Specification: RSS-247

TÜV SÜD Project Number: 72135816

Manufacturer: DJO, LLC
Model(s): 11-4000-0-06000 and 11-4001-0-06000

Manual

DONJOY®

X4™ Knee Brace
Instructions for Use

DJO®

TABLE OF CONTENTS

BEFORE USING THE DEVICE, PLEASE READ THE FOLLOWING INSTRUCTIONS COMPLETELY AND CAREFULLY. CORRECT APPLICATION IS VITAL TO THE PROPER FUNCTIONING OF THE DEVICE.

INTENDED USER PROFILE

The intended user should be a licensed medical professional, the patient, the patient's caretaker, or a family member providing assistance. The user should be able to read, understand and be physically able to perform and follow the directions, warnings and cautions provided in the information for use. This device is not intended for use by children.

INTENDED USE/INDICATIONS

The X4™ brace is intended to provide post-operative knee support during the rehabilitation process. The Motion Intelligence™ platform together with X4 is intended to be used to measure and evaluate knee joint range of motion during rehabilitation and exercise in the pre-operative and post-operative phases of reconstructive knee surgery.

CONTRAINDICATIONS

None.

WARNINGS AND CAUTIONS

Brace is intended to be worn during waking hours in direct contact with skin or as directed by a medical professional. If you experience any pain, swelling, sensation changes, or any unusual reactions while using this product, consult your medical professional immediately.

Do not wear brace while swimming, in the shower or bath or while sleeping.

Warning: Equipment contains CR2032 lithium coin cell battery. There is danger of explosion if lithium ion batteries are incorrectly replaced. The patient should not replace the original battery and the sensor is not intended to be serviced.

SYMBOLS

	**WARNING!** Read and understand all warnings and Instructions for Use before using this device.		Manufacturer
	Temperature range		Non-ionizing electromagnetic radiation
	Atmospheric pressure range		Humidity range
IP22	Indication for protection against water and particular matter	$\mathbb{R}_{\text{X Only}}$	Prescription only (USA)

ENVIRONMENTAL CONDITIONS

Operating Conditions	Temperatures	+41°F (5°C) to +104°F (40°C)
	Relative Humidity	15% to 93% non-condensing
	Atmospheric Pressure	700hPa to 1060 hPa
	Altitude	Maximum of 3000m
Transport and Storage Conditions	Temperatures	-13°F (-25°C) without relative humidity control, up to 158°F (70°C)
	Relative Humidity	15% - 93% non-condensing
	Atmospheric Pressure	500 hPa to 1060 hPa

When operating after transporting or storage in Elevated or Low temperature conditions, please keep sensor at ambient temperature for 15 min. prior to operation.

Motion Intelligence™ system consists of - 1 regular hinge, 1 hinge with sensor, 1 thigh strap, 1 calf strap, 1 software app for smart device.

APPLICATION SET UP AND PAIRING

1. Download Motion Intelligence™ App from the App store.
2. Follow in-app instructions to setup. Enter Application Key as provided by the clinician.
3. To pair the device with your mobile phone or tablet:
   a. Ensure Bluetooth is enabled in your phone or tablet Settings. **Settings** > **Bluetooth** > **On**.
   b. In the Motion Intelligence App: **Settings** > **Sensors** > **Connect**.
   c. On Brace device: With app open, press button on the front of the lateral (outside) hinge until the blue LED light blinks.
   d. Click "Yes" to pairing request prompt in app on your mobile phone or tablet.
   e. Screen will show "Connected" and provide battery life.

Note: This step only needs to occur one time. Brace will pair automatically while wearing the brace and standing in full extension.

BRACE APPLICATION INFORMATION

1. In a seated position bend leg at about 20 degrees, align the MI 360™ hinge on lateral or outside of the knee at the center of the knee joint. (Figure 1)

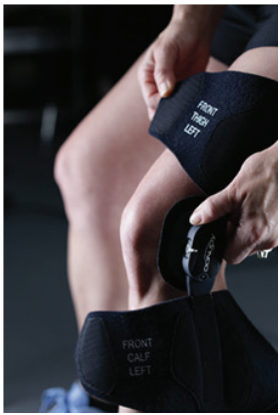

Figure 1

2. Wrap on thigh strap and secure. Clinician may trim excess material as needed. (*Figure 2a* and *2b*)

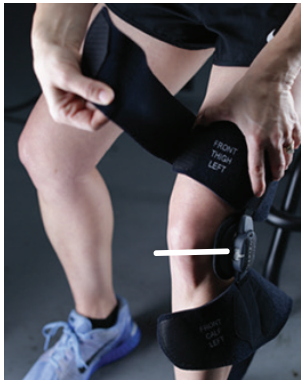

Figure 2a

Figure 2b

3. Wrap on calf strap and secure. Clinician may trim excess material as needed. (*Figure 3a* and *3b*)

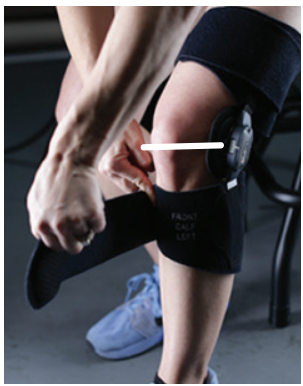

Figure 3a

Figure 3b

4. Secure the opposite hinge on the medial or inside of the knee at the center of the knee joint. (*Figure 4a* and *4b*)

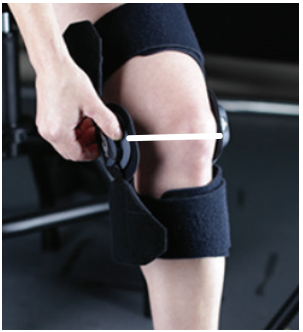

Figure 4a

Figure 4b

5. Stand and walk, make adjustments to straps as needed to ensure hinges are centered on the knee joint.

   After you have successfully paired the device to the app the first time, subsequently when the brace is worn, the MI 360™ sensor will automatically collect data on the exercises and steps.

6. Follow the in-app instructions and go through each exercise and answer the survey questions when prompted. (*Figure* 5)

   NOTE: If needed, a clinician may use a Goniometer to determine proper leg angle for thigh and calf uprights and custom bend uprights to proper leg angle.

Figure 5

If you are having any medical issues or need an urgent response, please call your doctor's office directly.

If assistance is needed with the brace or setting up or using the App, please call or email:

Phone: (844)279-0200/ (760)734-4740
Email: MIsupport@djoglobal.com
Visit: www.djoglobal.com/MI

CLEANING INSTRUCTIONS

Remove softgoods from the brace by sliding the straps off the top and bottom of the hinge bars.

Wash softgoods in water (86°F/30°C) using soap. Rinse thoroughly, air dry.

Do not wash the hinge component containing the electronic sensor.

Brace Re-assembly

Place thigh bar with label in thigh wrap slot such that the LED light on the hinge is facing forward and text "Thigh Front" on wrap facing forward. Repeat on calf portion.

MATERIAL CONTENTS

Hinge Bars: Aluminum, Steel, Nylon

Softgoods: Nylon, Polyester

FCC AND IC STATEMENTS

FCC Statements

Warning: Changes or modifications to this device not expressly approved by (DJO LLC) could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, 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 antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with radiation exposure limits set forth for an uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating conditions. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IC Statements

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Cet équipement est conforme aux limites d'exposition aux radiations dans un environnement non contrôlé. Cet équipement est en contact direct avec le corps de l'utilisateur dans des conditions de fonctionnement normales. Cet émetteur ne doit pas être co-localisées ou opérant en conjonction avec tout autre antenne ou transmetteur.

ELECTROMAGNETIC COMPATIBILITY (EMC)

The X4™ Knee Brace MI 360™ Sensor is intended for use in the electromagnetic environment specified below. The customer or user of the X4 Knee Brace MI 360 Sensor should assure that it is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions Tests	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11	Group 1	The X4 Knee Brace Sensor is equipment where there is intentionally generated, or used, conductively-coupled Radio Frequency (RF) energy that is necessary for the internal functioning of the equipment .
RF Emissions CISPR 11	Class B	The X4 Knee Brace Sensor is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A. Battery Powered.	N/A
Voltage Fluctuations/ emission oscillations IEC 61000-3-3	N/A. Battery Powered.	N/A

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 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	N/A. Battery Powered.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A. Battery Powered.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U (>95% dip in TU) for 0.5 cycle 40% U (60% dip in TU) for 5 cycles 70% U (30% dip in TU) for 25 cycles <5% U (>95% dip in TU) for 5 sec	N/A. Battery Powered.	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60Hz) Magnetic Fields IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Portable and mobile RF communications equipment should be used no closer to any part of the X4™ Knee Brace Sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity Test	IEC 60601 Test Level	Compliance Level	Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3V	1.2√P
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	10 V/m	0.35√P 80MHZ to 800MHZ 0.7√P 800MHZ to 2.5GHZ
			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 X4™ Knee Brace Sensor is used exceeds the applicable RF compliance level above, the X4 Knee Brace Sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the X4 Knee Brace Sensor.

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

TECHNICAL SPECIFICATIONS

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the X4 Knee Brace Sensor

The X4™ Knee Brace Sensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X4 Knee Brace Sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X4 Knee Brace Sensor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	**Separation distance according to frequency of transmitter (Meters)**		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.12	0.03	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7

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

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

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

WARRANTY

DJO, LLC will repair or replace all or part of the unit and its accessories for material or workmanship defects for a period of six months from the date of sale. To the extent the terms of this warranty are inconsistent with local regulations. The provisions of such local regulations will apply.

DISPOSAL

Sensor is electronic equipment and may include substances that can damage the environment. Do not dispose of the device in municipal waste. Do not puncture. Do not dispose in fire or incinerate. Dispose of the unit according to national, state, and local regulations.

Expected life is six months.

Rx ONLY.
INTENDED FOR SINGLE PATIENT USE.
NOT MADE WITH NATURAL RUBBER LATEX.

NOTICE: WHILE EVERY EFFORT HAS BEEN MADE IN STATE-OF-THE-ART TECHNIQUES TO OBTAIN THE MAXIMUM COMPATIBILITY OF FUNCTION, STRENGTH, DURABILITY AND COMFORT, THERE IS NO GUARANTEE THAT INJURY WILL BE PREVENTED THROUGH THE USE OF THIS PRODUCT. THIS DEVICE IS NOT INTENDED TO PREVENT INJURY, BUT AS AN ADJUNCT TO POST-OPERATIVE THERAPY. USE CAUTION AND FOLLOW YOUR DOCTOR'S ADVICE.

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