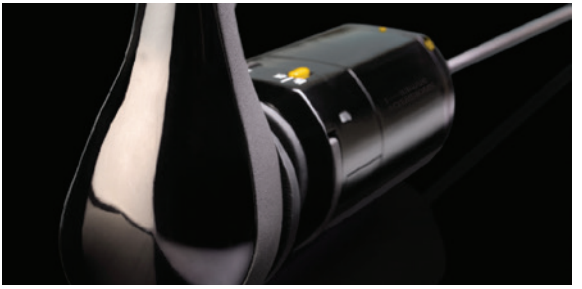
INSTRUCTIONS FOR USE

Doc No. 40-48-012-01 Rev 17, 05/25

POWERED LAPAROSCOPIC DEVICE



Manufactured by HumanTouch Surgical Ltd.
Grand Netter Building,
4 Meir Ariel St., Netanya, 4250574, Israel
Telephone: +(972)-77-3630300

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

US CUSTOMER SERVICE: cs-us@human-x.com

COMPONENTS OF THE HANDX™

COMPONENT	DESCRIPTION
HandX Contains: • HandX case • HandX Handpiece • Power adapter	2 Handpieces 2 Adapters
HandX Disposables Contains: • HandX Arc & Finger Pads • HandX Power cable • Release Key	Disposable, Sterile, Single Use 1 Arc with 1 Spacer, 2 Finger Pads Cable Length- 3.5m Release Key
HandX Needle Holder instrument	5 mm/Disposable Single Use
HandX Fenestrated Grasper instrument	5 mm/Disposable Single Use
HandX Monopolar Hook instrument	5 mm/Disposable Single Use
HandX Self-Righting Needle Holder instrument	5 mm/Disposable Single Use
HandX Monopolar Spatula instrument	5 mm/Disposable Single Use
HandX Monopolar Scissors instrument	5 mm/Disposable Single Use

STANDARD CONVENTIONS USED

The Use of CAUTION, WARNING, and NOTE Statements.

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a Caution, a Warning, or a Note statement. These statements are found throughout the documentation.

These statements should be read before continuing to the next step in a procedure.

WARNING: : A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.

CAUTION: A Caution statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in damage to or destruction of the equipment.

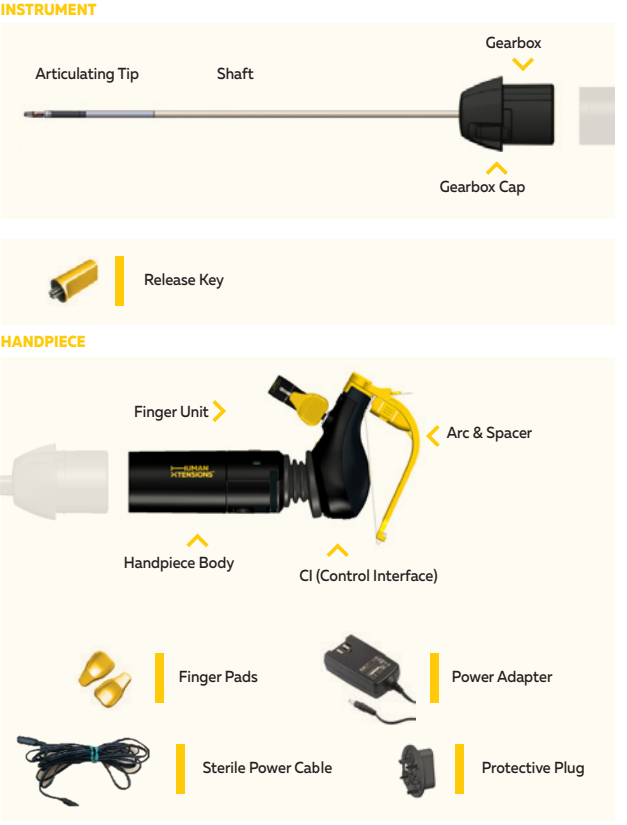
NOTE: A Note statement indicates an operating or maintenance problem, practice, or condition that is necessary to accomplish a task efficiently.

HandX DESCRIPTION

The Human Xtensions HandX is a hand held powered laparoscopic device.

The HandX™ is electromechanically controlled it includes hardware and software and comprises of two major parts, the Handpiece and the Instrument (Figure 1).

Figure 1: Main HandX Components



Main HandX Components as Illustrated in Figure 1:

INSTRUMENT: Articulating Tips - 5 mm Fenestrated Grasper | 5 mm Needle Holder | 5 mm Monopolar Hook | 5 mm Self-Righting Needle Holder | 5 mm Monopolar Spatula | 5 mm Monopolar Scissors | Shaft | Gearbox Cap | Protective Plug | Gearbox.

HANDPIECE: Handpiece Body | CI (Control Interface) | Finger Unit Arc, Finger Pads & Spacer | Power Adapter | DC Power cable | Release Key.

NOTE: The HandX is compliant with IEC 60601-1 and IEC 60601-1-2

INDICATION

The HandX is intended to assist in the control of Human Xtensions laparoscopic Instruments including needle holder , grasper and monopolar instruments, for endoscopic manipulation of tissue, including grasping, approximation, ligation, suturing, cutting and/or coagulation, during laparoscopic surgical procedures. The HandX™ monopolar instruments are connected by a standard cable to a standard electrosurgical power source. It is intended to be used by trained physicians in an operating room environment in accordance with its Instructions For Use.

CONTRAINDICATIONS

1. Where laparoscopic surgery is contraindicated.
2. The monopolar instruments with monopolar activation are NOT intended for contraceptive coagulation of fallopian tissue but may be used to achieve hemostasis following transection of the fallopian tube.
3. This device is intended for use only as indicated.

WARNINGS

1. The disposable components of the device are provided STERILE and are intended for use in a single procedure only. DISCARD AFTER USE DO NOT RESTERILIZE. Reuse reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that in return may result in patient injury, illness or death.
2. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques.
   A thorough understanding of the operating principles, risk versus benefits, and the hazards involved in an endoscopic approach is necessary to avoid possible injury to the user and/or patient.
3. Never use a HandX Handpiece, Instrument or Disposables if the device is damaged or the package is damaged or opened.
4. Do not use past the expiry date.
5. Used HandX Instruments and Handpiece Disposables should be disposed according to bio-hazard disposal practices in accordance with the facility disposal procedure.
6. HandX Handpiece must not be disposed as unsorted waste. Handpiece must be collected separately. Please contact your dealer or supplier for further information.
7. Verify mechanical and electrical compatibility of devices from different manufacturers prior to using them together with the HandX.
8. Do not connect wet accessories to the HandX Handpiece.
9. HandX reusable handle should be stored in a cool and dry place between uses.
10. Never drop the equipment or subject it to severe impact, as it could compromise the functionality and/or safety of the equipment or system.
11. No modification of this device is allowed without authorization of the manufacturer.
12. Recovery time after defibrillation is 1 second.
13. The HandX system shall maintain control of the articulation tip movement at all times. In case of an autonomic articulation tip movement, stop using the device.
14. The HandX Handpiece shall only be used with the accessories provided by HumanTouch Surgical.
15. Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the HandX, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could be resulted.
16. Do not disconnect the instrument during operation. In case of unintended instrument disconnection, replace the instrument.
17. In addition to the listed warnings, the use of the HandX system may cause/lead to the following side effects:
    - Uncommon side-effects (1-10 out of 1,000):
      - Inability to perform the intended surgical task due to a damaged or non-functional device.

- Bleeding or tissue damage due to un-intentional HF energy burst.
- Damage to the trocar seal, loss of intra-abdomen pressure during surgery.

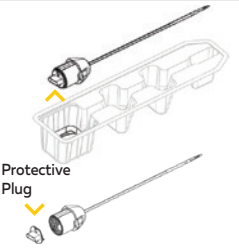
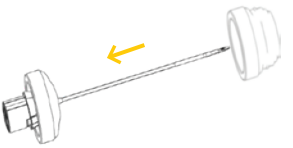
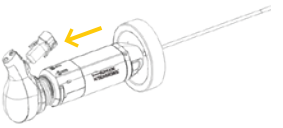
o Rare side-effects (1-10 out of 10,000):

- Patient inflammation or infection caused by a reaction from foreign materials.
- Bleeding and tissue damage due to loss of performance or tip control.

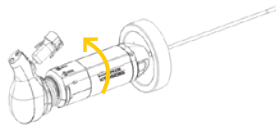
Note: Defibrillation was tested and in compliance with IEC 60601-1.

⚠ **WARNING:** The non-sterile Handpiece Body and the Control Interface must be covered with a standard sterile cover with an opening of at least 8.5 cm (3.5") inner diameter For USA users: use only FDA cleared equipment covers/drapes.

USING THE DEVICE

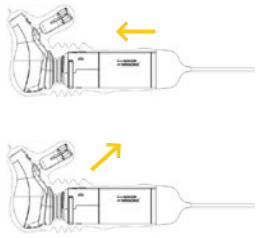
Pre-operative Assembly	
1. Prior to use, remove the Instrument from the blister and remove the Protective Plug from the proximal end of the Gearbox. 2. Remove the protective plug from the instrument.	
3. SCRUB PERSON: After aseptically removing the sterile cover from its packaging, hold the open side of the sterile cover so its opening is facing the tip of the instrument. SCRUBBED PERSON: Maintaining aseptic transfer techniques, carefully slide the instrument into the sterile cover opening.	
4. SCRUBBED PERSON: Secure the distal end of the sterile cover around the instrument's shaft using standard sterile OR tape.	
5. SCRUBBED PERSON: Identify the flat surface of instrument Gearbox' inner part and the flat surface of the Handpiece.	
6. SCRUBBED PERSON: Insert the instrument Gearbox' inner part into the Handpiece Held by the CIRCULATING PERSON, aligning the flat surfaces of both.	

7. SCRUBBED PERSON: While pressing the instrument Gearbox into the Handpiece, rotate it clockwise until a “clicking” sound is heard.



8. While the CIRCULATING PERSON is holding the Handpiece the SCRUBBED PERSON roll the sterile cover to cover the Handpiece Body and the CI, taking care not to touch the Handpiece Body and the CI leaving 15-20 cm extra at the top of the CI.

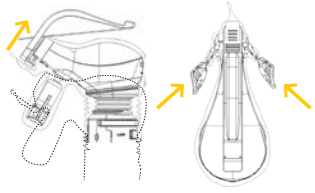
   SCRUBBED PERSON: Secure the proximal end of the cover using standard sterile operating room tape or the tape provided with the sterile cover.



HandX™ Disposables (Arc & Finger Pads) Assembly

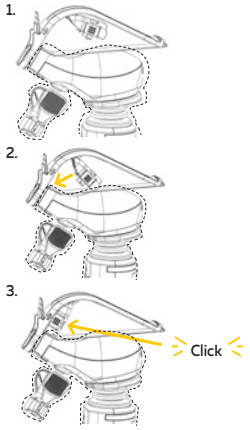
9. SCRUBBED PERSON: Carefully, pull down the extra sterile cover spare in a way that there is no slack around the CI.

10. SCRUBBED PERSON: Slide the Finger Pads and Arc over the sterile cover on to the Control Interface, according to the figure.



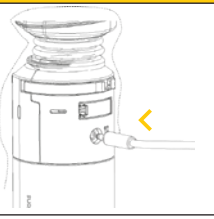
11. SCRUBBED PERSON: Attach the Arc Spacer to the silicone strap. The Spacer is then adjusted to accommodate surgeon's hand comfortability.

    NOTE: The Spacer is packed in the Arcs & Finger Pads pouch.



Pre-operative Assembly

12. SCRUBBED PERSON: Connect the proximal plug of the sterile Power Cable to the Handpiece's power jack, through the sterile cover.

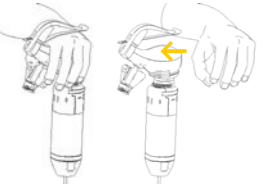


13. CIRCULATING PERSON Connect the distal part of the Power Cable to the power adapter and plug the adapter into the wall socket.

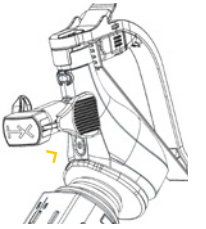
Using the Device (see Device Status Indication Table)

1. Slide the: ON/OFF power switch to the ON or OFF position.

2. Slide your hand onto the device's gripping handle between the Handpiece distal surface and the Arc.

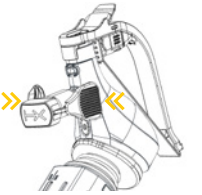


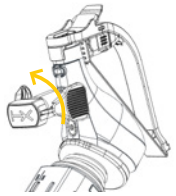
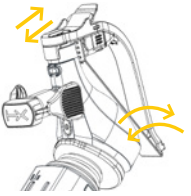
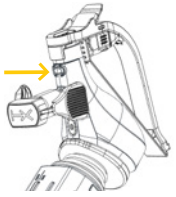
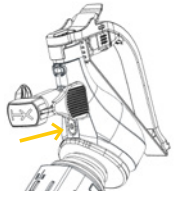
3. Double click the DIALOG Button to access the device's "OPERATING" mode.



4. Pre-Check while the device is in Free Motion – verify device operation following the instructions below, verify that the tip moves properly.

a. Close / Open – pressing/ releasing 3 times the finger pads using your fingers.



b. Roll – Slide the Roll switch in both directions using your fingers.	
c. Articulation – rotate the whole CI unit "Up", "Down", "Clockwise" "Counterclockwise".	
d. Stop Button – short press to activate Standby state.	
e. DIALOG Button – double click to activate Operating mode.	

5. Before inserting the device into the trocar, long press and hold the DIALOG Button (3 seconds) to straighten the tip.

6. Double click the DIALOG Button to access "Operating" mode and unlock the Control Interface.

7. The device is now ready for use.

8. If required, a press on the "DIALOG" button for 1 second will lock the CI unit.

9. Additional Features:

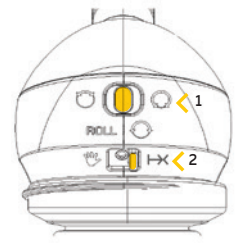
a. Roll Range Switch – "1"

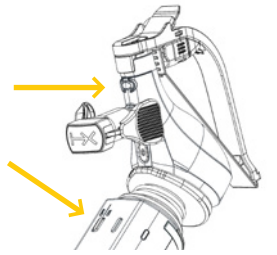
- ± 90° (left position)
- ± 180° (middle position)
- ± 270° (right position)

b. Free/Planar Switch – "2"
- Free motion – full range articulation (right position)
- Planar motion – Articulation in the "Left" and "Right" directions only (left position)

c. CI control style – Changing from La-pro (default) style to Ro-bo style:

- Make sure the system is OFF
- Press and hold the STOP button while turning the system ON.
- Make sure the LEDs are flashing blue.
- To change back to CI default mode (La-pro style), turn the system off and remove the instrument.• NOTE: When turning the system back ON it will load in La-pro style (LEDs flashing green).





10. ⚠ **WARNING**: If cracks or other flaws are observed on sterile cover, replace the sterile cover before using the HandX.

Removal Procedure

11. Press and hold the DIALOG button until the instrument's tip reaches a straight position.

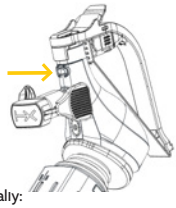
12. Close the Finger Pads to reach a closed grasping position.

13. Gently retract the instrument from within the trocar.

⚠ **CAUTION:** Do not attempt to insert or remove the instrument from the trocar in the articulated position. The tip of the instrument must be straight, parallel to the shaft. Failure to straighten the instrument will result in difficult insertion or withdrawal and may result in damage to the instrument.

Prompt Release Options

14. When prompt release is required follow the subsequent steps:



a. Loose Tip Function – Press and hold the "STOP" Button until the Tip is loosened, and can safely removed. Repeat the step if necessary.

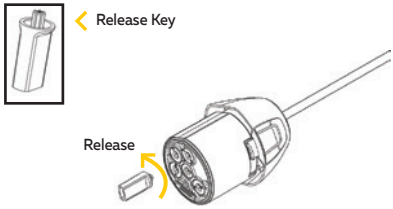
b. Release Key – If "Loose Tip Function" fails, use the "Release Key" (provided in the HandX Disposables set) to loosen the Tip manually:

   i. Release the Gearbox from the Handpiece Body by rotating it counterclockwise.

   ii. Screw the Release Key into the sockets located in the proximal end of the Gearbox rotating it counterclockwise starting with the middle socket (releasing the jaws) following to the rest of the sockets (loosening the articulation). Rotate clockwise the middle socket to close the jaws.

⚠ **CAUTION:** Do not attempt to insert or remove the instrument through the trocar in the articulated position or if the jaws are open. The tip of the instrument must be straight, parallel to the shaft. Failure to straighten the instrument will result in difficult insertion or withdrawal and may result in damage to the instrument

The instrument cannot be used for any subsequent use if this functions has been utilized.



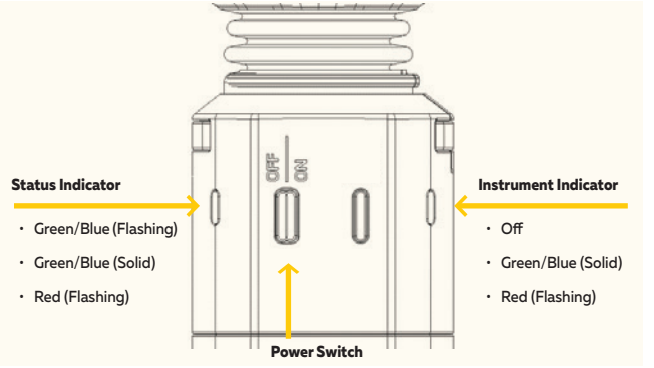
Device Disassembly

15. SCRUBBED PERSON: Disassemble and dispose the Finger Pads, Remove the Spacer from its position before removing the Arc carefully roll and remove the sterile cover from the CI off down to the Instrument.

16. SCRUBBED PERSON: with clean gloves Detach the Instrument from the Handpiece and dispose it according to operating room routine procedure.

17. Using clean gloves, immediately clean and disinfect the Handpiece according to the "Reprocessing Instructions" section.

DEVICE STATUS INDICATIONS TABLE



LA-PRO STYLE

STATUS INDICATOR		INSTRUMENT INDICATOR	
Power switch OFF			
Handheld device powered, instrument registered			
Power switch ON			No instrument Registered
			Standby Mode
			Operating Mode
			System Failure
			Loose Tip

RO-BO STYLE

STATUS INDICATOR		INSTRUMENT INDICATOR	
Power switch OFF			
Handheld device powered, instrument registered			
Power switch ON			No instrument Registered
			Standby Mode
			Operating Mode
			System Failure
			Loose Tip

TROUBLESHOOTING

STATUS	LED'S		Indicator Light Status	Device Status
	Status Indicator	New instrument indicator		
Device is not powered ON			If power is switch OFF:	Turn power switch on.
			If power switch is ON:	Check connection of DC Power Cable and Power Adaptor as well as wall source.
Device is powered, but instrument either does not respond to CI movements or does not respond properly			If the instrument indicator is OFF	
			If the power and instrument indicators are "flashing" GREEN/ BLUE:	Double click the DIALOG button to activate Operating Mode.
			If power and instrument indicators are "solid" GREEN/ BLUE	First check if CI movement is being hindered by sterile drape. If there is no mechanical blocking, re-assemble the system with a new instrument.
			The instrument indicator is "flashing" RED:	The instrument has failed. Re-assemble the system with a new instrument.
The instrumen only articulates left-right.	N/A		Is the free/planar switch set to planar? If YES:	Set to free mode.
The instrument roll range is limited.	N/A		Check The roll range switch.	Set the roll range switch to the desired range.
The instrument cannot be removed from the trocar.	N/A		If the instrument Indicator is solid green and the instrument does not respond to the straight instrument command (3 sec on the DIALOG button).	Use The loose tip command (3 sec) on the stop button as explained in the Prompt Release Section Loose Tip Function(a).
	N/A		If the loose tip function does not loosen the instrument tip.	Use the release key to manually straighten the instrument as explained above in the manual release section (14. b.).

POTENTIAL ADVERSE EVENTS

Unknown.

HANDX CLEANING AND DISINFECTING

⚠ **CAUTION**: Do not use hospital sterilization equipment to sterilize or disinfect the HandX Handpiece.

⚠ **WARNING**:HandX™ Instruments are intended for single use only; do not attempt to reuse or re-sterilize.

⚠ **WARNING**: The multi-use HandX Handpiece handle must be properly reprocessed by cleaning and disinfecting before its first use and after each subsequent use according to the protocol in this section. Using a handle that has not been properly reprocessed presents an acute infection-control risk to both the patient and medical personnel performing or assisting in the procedure.

⚠ **CAUTION**: Clean the multi-use HandX Handpiece handle immediately after use in a procedure. Although covered by sterile cover failure to do so may cause debris to harden on the handle's external surfaces, which can become difficult to remove.

The handle reprocessing procedure is made up of a series of discrete steps, each of which is essential to successful reprocessing. Closely adhere to the reprocessing instructions given in this chapter.

These reprocessing instructions have been validated as being capable of cleaning and disinfecting the multi-use handle. It is the responsibility of the user/medical facility to ensure that reprocessing is performed using the appropriate equipment and materials.

Reprocessing Instructions:

1. Remove the sterile cover and disassemble the Instrument from the Handpiece before cleaning as detailed in the "Using the Device- Device Disassembly" section.

   ⚠ **CAUTION:** Handpiece should NOT be submerged in water or cleaning solutions.

2. Use lint free cloth damped with filtered water (RO water) to clean the Handpiece surfaces.
3. Ensure areas containing crevices are scrubbed thoroughly.
4. Perform visual inspection to verify debris is removed.
5. Use lint free cloth damped with 70% ethanol to disinfect the whole Handpiece surface. The cleaning procedure will continue at least 30 seconds.
6. Ensure areas containing crevices are scrubbed thoroughly.
7. Repeat steps 5&6.
8. Final wipe - Use lint free cloth damped with 70% ethanol to disinfect the whole Handpiece surface.

NOTE: 70% disinfection ethanol wipes may be used as well.

SERVICE AND MAINTENANCE

HumanTouch Surgical, its distributor, or a third party acting on their behalf, provide a one-year warranty for the Handpiece and will service the Handpiece during the warranty period in accordance with the terms of the warranty.

SYMBOL DEFINITIONS

Following are the graphical symbols and their descriptions used in the HandX™:

Rx Only	Federal (USA) law restricts the device to sale by or on the order of a physician	STERILE EO	Ethylene Oxide Sterilized
	Do not use if package is damaged or open	SN	Serial Number
	Follow instructions for use		Class II Equipment
	Defibrillation-Proof Type BF Applied Part	LOT	Batch Code
	Manufacturer		Date of manufacture
	Use by (+date)		Single Use Only
IPX1	Ingress Protection Marking		Direct current
	Keep dry		Temperature limit
QTY	Quantity		Humidity limitation
	Caution. There are specific precautions related to the device, refer to IFU		Atmospheric pressure limitation

Medical device

Sterile packaging

Non-sterile protective packaging with a sterile barrier system inside

Transport Conditions

HandX disposable Instrument & HandX Handpiece disposables:

- Temperature: -10°C to 50°C (14°F to 122°F)
- Humidity: 10% - 85%

HandX handpiece:

- Temperature: -10°C to 50°C (14°F to 122°F)
- Humidity: 10%-85%
- Pressure: 60-102 kPa

Storage Conditions

HandX disposable Instrument & HandX Handpiece disposables:

- Temperature: 15°C to 30°C (59°F to 86°F)
- Humidity: 10% - 85%

HandX handpiece:

- Temperature: -10°C to 50°C (14°F to 122°F)
- Humidity: 10% - 85%

Operation Environment Conditions

- Temperature: 10°C – 35°C (50°F – 95°F)
- Humidity: 30% – 75%
- Adapter input: 100V-240V (AC), 0.6A, 50 Hz-60 Hz
- Adapter output: 0.9V, 2.2A
- Rated input: 9V (DC), 1.5A
- Pressure: 80 - 102 kPa

Cybersecurity

- HumanTouch Surgical takes cybersecurity control measures during the development and the production of the device. In case of potential threat please contact Customer Service: cs-us@human-x.com

Electromagnetic Compatibility (EMC) Declarations

The HandX System was tested according to EMC requirements of IEC 60601-1-2 4.1 edition.

Guidance and manufacturer's declaration – electromagnetic emissions

The HandX™ is intended for use in the electromagnetic environment specified below. The customer or the user of the HandX should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The system uses Radio Frequency (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 HandX is 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. Warning: This equipment/system is intended for use by healthcare professionals only.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

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

IMMUNITY test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment–guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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	±2 kV for power supply lines N/A	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	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

IMMUNITY test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment–guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	UT = 0%, 0.5 Cycle UT = 0%, 1 Cycle UT = 70%, 25/30 cycles UT = 0%, 250/300 cycles	At 100 VAC and 230 VAC: 0% UT for 10 ms 0% UT for 20 ms 70% UT for 500 ms 0% UT for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz, 6 Vrms in ISM bands	3 & 6 Vrms on 0.15 ÷ 80 MHz, 80% AM, at 1kHz	Field strengths from fixed RF transmitters, as deter- mined 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: 
Radiated RF Immunity IEC 61000-4-3	3.0 V/m 80 MHz ÷ 2.7 GHz, 80% AM, 1 KHz	3.0 & 10.0 V/m 80 MHz ÷ 2.7 GHz, 80% AM, 1 KHz	
RF wireless communications equipment fields Immunity	Frequencies and levels as specified at IEC 60601-1-2 table 9	Frequencies and levels as specified at IEC 60601-1-2 table 9 Max –28V/m	

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 System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

human-x.com