# ENDORAIL SYSTEM

COMPONENT OF ENDORAIL MEDICAL DEVICE

## INSTRUCTIONS FOR USE

# DISCLAIMER



Endostart S.r.l. disclaims all liability for injuries or property damage due to improper use of this product and failure to observe the indications, warnings, instructions and precautions laid out in this user manual.

In the event of a serious incident related to the Endorail medical device, the user must notify the manufacturer and the competent authority of the country in which the event occurred.

Endostart S.r.l. cannot be held liable for any injuries or property damage resulting from failure to observe the rules or precautions listed below and generally reported in this user manual.

These instructions for use are provided in hard copy only and must always accompany the Endorail.

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|---|---|
| **WARNING** | To ensure proper use of the device and to prevent injuries to patients, read all information contained in these instructions for use. |
| **WARNING** | Read all the information contained in the Endorail Set instruction for use. |

# 1 GENERAL INFORMATION

## 1.1 INTENDED USE

The Endorail is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope (i.e., an endoscope with an instrument channel that is at least 3.2 mm diameter and is used for standard endoscopic visualization) during endoscopy of the large intestine.

## 1.2 INTENDED POPULATION

Endorail is indicated for adults (>21 years), male and female with BMI≤30 kg/m2.

## 1.3 INTENDED USERS

Endorail is intended for use by digestive endoscopy specialists supported by nursing staff.

## 1.4 INTENDED ENVIRONMENT

Endorail is intended for use in professional healthcare facility environment.

## 1.5 CLASSIFICATION

| | |
|---|---|
| Classification Name: | Endoscope Channel Accessory |
| Regulation Name: | Endoscope and Accessories |
| Regulation Number: | 21 CFR 876.1500 |
| Product Code: | ODC |
| Regulatory Class: | Class II |
| Classification Panel: | Gastroenterology/Urology |

## 1.6 DEVICE DESCRIPTION

Endorail includes two components to be used in combination called: Endorail Set and Endorail System.

Endorail System is reusable and includes the following elements:

- Endorail Handpiece (EH),
- Endorail Cart (EC).

Before the procedure, the operator prepares the syringe containing the ferromagnetic fluid using the Endorail Solution Syringe (ESS), the spike and the Endorail Powder (EP). The Endorail Balloon Guide (EBG) is a balloon catheter that can be introduced as needed through the endoscope instrument channel during the colonoscopy, if the procedure becomes challenging. Endorail Set does not require to be pre-mounted and does

not interfere with the normal examination process. The EBG is advanced beyond the colonoscope tip where the balloon is filled with the ferromagnetic fluid and magnetically anchored with the Endorail Handpiece (EH) placed on the patient's abdomen. Once anchored, the colonoscope can be straightened and guided along the catheter. Afterward the EBG can be unlocked, deflated and retrieved.

### 1.6.1 ENDORAIL HANDPIECE (EH)


Figure 1 EH Front view

Figure 2 EH Back view


Figure 3 EH Top view

a. Handpiece handle
b. Handpiece neck: portion of the handpiece that joins the handle with the handpiece body. The length of the neck varies according to the selected magnetic power level.
c. Magnetic power levels: the scale of the magnetic power levels is shown on the front and back of the neck. The magnetic power levels are represented by horizontal lines and the corresponding numerical value. The thicker lines correspond to the MIN, 20,

25, 30 and MAX levels; the thinnest lines correspond to the intermediate levels (Two full rotations of the handpiece handle allow the switching between two subsequent magnetic power levels).

d. Magnetic power level marker: The red target marker indicates the selected magnetic power level.
e. Handpiece Body: contains the permanent magnet. The front face of the body is distinguished by the presence of the Endorail logo. The back face is characterized by the device label and safety signs.
f. Handpiece base: it is the part that can be put in contact with the intact skin of the patient's abdomen.
g. Handle rotation direction indicator : under the handle there is an arrow which, together with the + and - signs, indicates the rotation direction to increase (clockwise) or decrease (counterclockwise) the level of magnetic power.

### 1.6.2 ENDORAIL CART (EC)

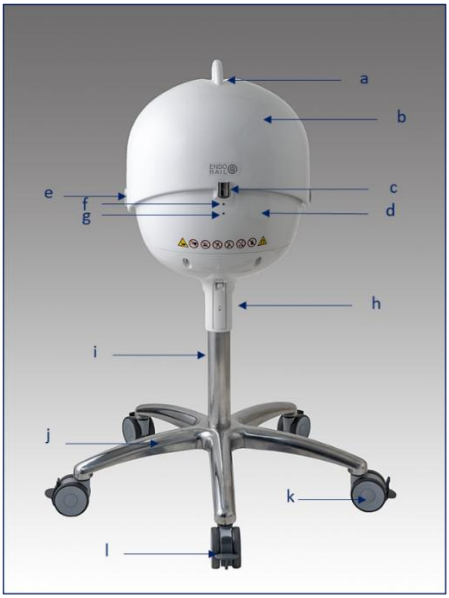


**Figure 4 EC Front view**

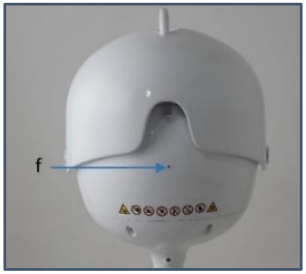


**Figure 5 EC Back view**

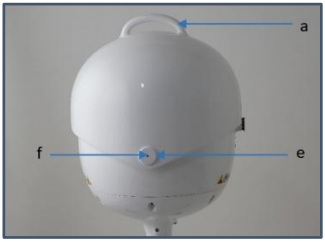


**Figure 6 EC Side view**

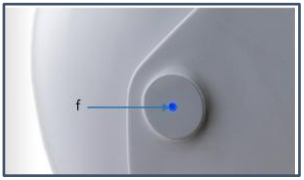


**Figure 7 EC Side view**

a. EC handle: allows to open the case lid and to move the cart.
b. Case lid
c. Buckle: positioned on the front face of the cart. Allows stable closure of the housing cover.

d. Case: contains the handpiece. The handpiece should always be stored in the case except for the time it is used in the endoscopic procedure.
e. Hinges: allow the case lid to be opened
f. Blue indicator lights: on the case there are 4 blue indicator lights.
g. Red indicator light: in the front face of the cart there is a led indicator light that turn on in case battery replacement is required.
h. Battery compartment
i. Leg
j. Basement
k. Wheels
l. Wheels lock

Endorail System embeds an electronic board including the following main components: Hall-effect sensor, microcontroller, acoustic indicator, firmware. The board is connected with the case lights and the batteries. The software is not intended to provide information used to take decisions with diagnosis or therapeutic purposes. The firmware interacts with Hall-effect sensor, the lights and acoustic indicators and the medical device batteries. In particular, when the EH is placed inside the case the Hall-effect sensor measures the intensity of the magnetic field produced by the magnet. According to value of the magnetic field intensity recorded, the microcontroller controls the LED lights and

drives the acoustic output signal. The acoustic signal is activated each time that lights are blinking.
Lights blinks as follows:

BLUE INDICATOR LIGHTS: 4 blue lights are present on the case. These lights indicate whether the handpiece is placed in the case or not and if it has been stored correctly.
The lights blinks in the following cases:

- slow flashing: occurs when the handpiece is not present inside the case;
- rapid flashing: occurs when the handpiece is placed inside the case and magnetic intensity is different from the minimum level (MIN);
- turned on without flashing for 5 seconds: occurs as soon as the handpiece is placed inside the case with the magnetic intensity at minimum level (MIN);

RED INDICATOR LIGHT: it is placed on the front side of the case. This light indicates low battery charge.
In case of low battery charge, the red indicator blinks in the following cases:

- slow flashing: occurs when the handpiece is not present inside the case; The blue lights and the acoustic indicator activate at the same frequency;

- rapid flashing: occurs when the handpiece is placed inside the case and magnetic intensity is different from the minimum level (MIN); The blue lights and the acoustic indicator activate at the same frequency;
- slow flashing for 30 minutes: occurs when the handpiece is placed inside the case with the magnetic intensity at minimum level (MIN). The blue lights and the acoustic indicator don’t activate.

# 2 CONTRAINDICATIONS

Do not use the device:

1. On patients with body mass index (BMI)>30 kg/m$^2$
2. On patients ≤21 years
3. On patients with any contraindication to colonoscopy
4. On patients with known allergy or hypersensitivity to any of the elements of the Endorail Set (e.g.: iron)
5. On patients with permanent or semi-permanent implanted active and/or ferromagnetic/magnetic medical devices
6. On patients with dense diverticulosis
7. On patients with diverticulitis
8. On patients with ferromagnetic/magnetic foreign body
9. On patients with large abdominal hernias
10. On patients with severe thrombocytopenia
11. On patients with severe coagulopathy
12. On patients with peritonitis
13. On patients with peritoneal carcinomatosis
14. On pregnant women
15. On patients with bleeding diathesis
16. On patients with severe splenomegaly
17. On patients with gastrointestinal perforation

18. In conjunction with the use of electrosurgical units or electrocoagulation electrodes
19. In MRI rooms

# 3 WARNINGS

1. Never use the device from Physicians or nursing staff with permanent or semi-permanent implanted active and/or ferromagnetic/magnetic medical devices.
2. Do not modify any part of the device.
3. Never use the device for purposes other than those indicated in this instruction for use.
4. Do not use the device if any component shows evident signs of damage.
5. Do set the handpiece always at the MIN level except when being used in the endoscopy procedure.
6. Never store the handpiece out of its case
7. Never place the handpiece on the abdomen of the patient with not intact skin.
8. Do not leave handpiece in other place other than on patient's abdomen or in its case.
9. Do replace the batteries when the red light is flashing.

# 4 ENDORAIL SYSTEM INITIALIZATION

Before the first use of the Endorail System perform the following operations:

- Remove the device packaging
- Remove the insulating tab from the battery compartment to activate the device
- Verify that the four indicator blue lights switch on for 5s without flashing.

# 5 ENDORAIL SYSTEM PREPARATION

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| **WARNING** | Do check that all lights and acoustic signals are off before initiating the procedure. |

## 5.1 PRELIMINARY OPERATIONS

Before using the device, we recommend:

- Turning the patient into a supine position.
- Uncovering the patient's abdomen and checking that the skin is intact.
- Making certain that there is sufficient space in front of the tip of the colonoscope for the balloon to emerge entirely and advance by an additional 4 cm from the balloon proximal bond.
- Making certain that the tip of the colonoscope has at least reached the descending colon or other more proximal segment (e.g., transverse, ascending, caecum or colic flexures).
- Using the Endorail only if it is possible to advance the balloon under visual control.

## 5.2 STEP 1 - MOVING THE CART

**Fig. 8 Cart wheel lock**

When it is to be used, the cart must be brought near the patient's bed following the instructions given below:

- Release the cart wheels by lifting the lock with your foot. (See Fig. 8).
- Grip the handle on the case lid to move the cart and position it near the patient.
- Engage the Cart wheels lock with your foot.

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| **WARNING** | Do not bring any electromedical, electronic devices or ferromagnetic objects within a distance of 10 cm from the Cart with the EH stored inside and the case lid closed. |
| **CAUTION** | Use the EC handle to move the Cart only when the case lid is closed. |
| **CAUTION** | Do not use the EC handle to lift the Cart. |
| **CAUTION** | Do not place weights on the Cart or rest on it. |

## 5.3 STEP 2 - OPENING THE CART

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|---|---|
| **WARNING** | Never open the case lid, if ferromagnetic objects are within 50 cm from the Cart and from the patient's abdomen. |
| **CAUTION** | Verify that the Cart wheels are locked. |

- Unlock the buckle.
- Grip the handle on the lid to slide it back and open the case. (Fig. 9)

**Figure 9 Opening the case lid.**

# 6 INSTRUCTIONS FOR USE – CLINICAL PHASE

## 6.1 ANCHORING

The handpiece must be placed on the patient's abdomen — on the abdominal quadrant corresponding to the segment of the colon where the Endorail Balloon Guide (EBG) is located — following the steps given below:

- Check whether there is an area of abdominal transillumination indicating the position of the tip of the colonoscope and thus of the balloon.
- According to the clinical-endoscopic situation, determine under which abdominal quadrant the EBG balloon filled with the ferromagnetic fluid should be located; this is called the **anchoring quadrant.**
- Grip the handpiece handle, lift it and verify that the EH magnetic power level is set to minimum (MIN).
- Place the handpiece on the patient’s abdomen so that the base is in contact with the anchoring quadrant.

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| **CAUTION** | Move the handpiece taking it with two hands only by the handle and the neck. |
| **CAUTION** | Keep the handpiece in place on the patient’s abdomen with at least one hand for the entire duration of the procedure. |

### 6.1.1 BALLOON CAPTURE

Set the handpiece on the anchoring quadrant and increase the magnetic power level to 25 by turning the handpiece handle clockwise. Raising the balloon from the lower surface until it comes into contact with the upper surface of the colon mucosa is indication that the balloon has been captured.

**NOTE**

If the balloon cannot be captured, these two situations must be considered:

1) The handpiece is not correctly lined up with the balloon
    a. See the following Zenith sign section
2) The level of magnetic power is not enough to attract and raise the balloon
    a. Increase the magnetic power level up to 30
    b. Press on the abdomen with the handpiece base to decrease the distance between the balloon and the base of the handpiece itself. The operator must apply clinical judgement in the amount of pressure to be applied.

## ZENITH SIGN

If there is any doubt regarding correct abdominal positioning of the handpiece in relation to the balloon inside the colon, better centering can be achieved by observing arrangement of the iron powder particles inside the balloon.

Remember, before applying the handpiece, given the force of gravity, the **EBG balloon filled with the ferromagnetic fluid** tends to rest on the lower surface of the colon mucosa. In addition, the iron powder contained in the ferromagnetic fluid tends to settle and a **sedimentation line (Fig.10)** will be visible, with the sediment at the bottom, the water at the top.

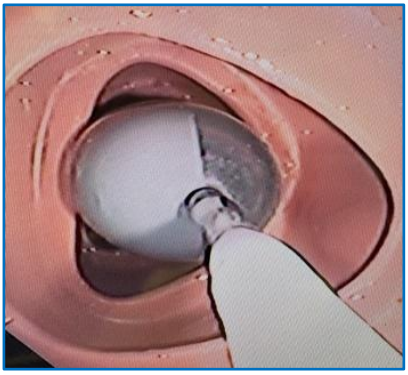

**Fig. 10 Sedimentation line separating sediment at the bottom and water at the top.**

To effectively achieve capture and anchoring, **the EH should be precisely positioned over the balloon.**

When the handpiece is placed near the balloon, the magnetic field interferes with the ferromagnetic fluid and the iron powder arranges

itself in lines parallel to the magnetic field itself **(field lines).** The direction of these lines indicates the position of the magnet relative to the balloon. Therefore, if the handpiece is placed vertically above the balloon, the field lines are parallel to the axis of gravity. In other words, they will be oriented according to the ideal line joining the lower and upper walls of the colon **(Zenith sign). (Fig.11)**.

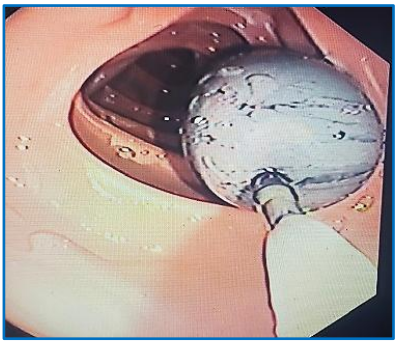

**Fig. 11 Image of the balloon during magnetic anchoring with parallel field lines inside.**

Otherwise, these lines may be oriented differently or may not be visible.

It is worth noting that the absence of the Zenith sign does not preclude stable anchoring of the EBG balloon.

### 6.1.2 ANCHORING

After the balloon has been captured, magnetic power level should be increased up to 30.

### 6.1.3 VERIFICATION OF ANCHORING FORCE AND GUIDED FORWARD MOVEMENT

Once the balloon has been anchored, its stability must be checked by performing the following operations:

- Grip the proximal body of the catheter with two fingers and gently pull on the balloon to check whether it is in contact with the upper surface of the colonic mucosa.
- Once adequately anchored, proceed with traction of the catheter until the tip of the colonoscope comes to within approximately 1 cm of the balloon.

## 6.2 GUIDED ADVANCEMENT/STRAIGHTENING

Should the endoscopist deem it necessary, colonoscope straightening maneuvers may be performed following such reference methods as traction, torsion, etc. These maneuvers should be performed gently so as to limit the risk of releasing the balloon.

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| **NOTE** | If the balloon is released during guided colonoscope forward advancement or straightening maneuvers, the anchoring procedure should be repeated and, if necessary, consider increasing the magnetic power level. |

## 6.3 REMOVAL OF THE HANDPIECE

Once the endoscopic procedure has been completed, perform balloon release and handpiece removal maneuvers as follows:

- Gently turn the handpiece handle counter-clockwise until magnetic power level is set to MIN.
- Grip the handpiece handle with two hands, lift the handpiece from the patient's abdomen and place it in the case while always keeping it vertical.
- Close the case lid, making certain that the buckle is properly secured.
- Unlock the wheels, move the cart away from the patient bed and lock them again pending the cleaning and disinfection procedure.

| | |
|---|---|
| **WARNING** | Do set the handpiece at the MIN level before moving it from the patient's abdomen |
| **CAUTION** | When the handpiece is in the case, verify that the blue indicator lights remain on for 5 seconds. |

## 6.4 CLEANING AND DISINFECTION

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|---|---|
| **CAUTION** | Before disinfecting the device, wear personal uncontaminated protective equipment and follow the |

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|---|---|
| | instructions on the safety data sheet of the disinfectant used. |
| **CAUTION** | During the procedure, avoid any disinfectant deposit on the handpiece surface as it could cause damages. Each phase of the disinfection procedure should last at least for 10 seconds. |
| **CAUTION** | Never spray the disinfectant directly on the surface of the device. |

Upon completion of the endoscopic examination and whenever the Endorail System device is used or handled, it must undergo cleaning and disinfection by the following procedure.

- Moisten a soft cloth with an alcoholic solution at 70% w/w.
- Open the case and clean the handpiece handle.

Figure 12 Opening the buckle.

Figure 13 Cleaning the handpiece handle.

- Grip the handpiece handle with one hand, pull out the handpiece and rest it on the edge of the case. Clean the neck and the surface around the side of the handpiece body.

Figure 14 Cleaning the handpiece handle.

Figure 15 Cleaning the surface around the side of the handpiece.

- Lift the handpiece to clean its base.

**Figure 16 Cleaning the handpiece base.**

- While keeping the handpiece lifted, clean the edge of the case. Rest again the handpiece on the cart edge and clean the inside surface of the case.

- Visually inspect the handpiece at the end of the cleaning procedure. If the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device, so that a visibly soiled device is not used again.

Figure 17 Cleaning the edge of the case.

Figure 18 Cleaning the inside of the case.

- Replace the handpiece inside its case. Close the lid. and clean the outside surface of the case.

Figure 19 Closing the case lid

- Visually inspect the handpiece at the end of the cleaning procedure. If the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device, so that a visibly soiled device is not used again.

# 7 MAINTENANCE

If properly maintained and used, the useful life of the device is 5 years. Battery life is less than 5 years and thus the batteries will need to be replaced periodically (see section 7.2).

## 7.1 INDICATOR LIGHTS AND ACOUSTIC SIGNAL FUNCTIONING CHECK

| VERIFICATION PROCEDURES | FUNCTIONS TO BE CHECKED |
|---|---|
| • Open the case lid.<br>• Grip the handpiece handle with both hands, lift the handpiece up and hold it resting on the edge of the case. | Slow flashing of blue indicator lights and acoustic signal emission (1/sec). |

| | |
|---|---|
| • Open the case lid.<br>• Grip the handle of the handpiece with both hands, lift the handpiece up and hold it resting on the edge of the case.<br>• Gently turn the handle clockwise until the magnetic power level of 20 is selected.<br>• Replace the handpiece in its holder inside the case. | Fast flashing of blue indicator lights and acoustic signal emission (5/sec). |
| • Open the case lid.<br>• Grip the handpiece handle with both hands, lift the handpiece up and hold it resting on the edge of the case.<br>• Make certain that the magnetic power level is set to minimum (MIN).<br>• Replace the handpiece in its holder inside the case. | Persistent illumination of the blue indicator lights (5 sec) without any acoustic signal. |

If the four blue indicator lights and the acoustic signal do not switch on when the handpiece is removed from the case, replace the batteries. If the malfunction persists, contact manufacturer.

## 7.2 REPLACING ENDORAIL CART BATTERIES

| | |
|---|---|
| **CAUTION** | Do not use batteries other than those indicated in the technical characteristics. |
| **CAUTION** | The removed batteries must be disposed of in accordance with the regulation in force. |

When battery charge is no longer optimal, the device warns the operator that the batteries need to be replaced. In particular, the red indicator light flashes for 30 minutes.

To remove the batteries the following operations must be performed:

- Open the cover to the battery compartment
- Remove the batteries by pulling them manually
- Position the new batteries aligning the + and - signs as indicated on the battery holder (Fig. 20)
- Close the cover to the battery compartment
- Verify that the four blue indicator lights switch on for 5s without flashing.

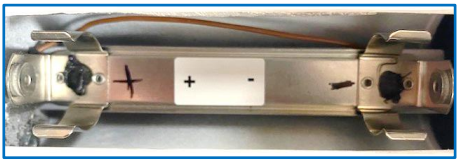


**Fig. 20 Battery Holder**

# 8 TROUBLESHOOTING

| Problem | Solution |
|---|---|
| Ferromagnetic objects have bumped the handpiece because of the magnetic attraction. | Reduce the magnetic power level to MIN. Thus, separate the handpiece from the ferromagnetic object. Verify that the EH has not been damaged. |
| The handpiece cannot be stored inside the Cart due to EC breakage. | Set the magnetic power level to MIN and store the handpiece by keeping it at least at 50 cm from any ferromagnetic and/or electronic device. Contact the manufacturer. |

# 9 DISPOSAL

Do not dispose of this product as general urban wastes. Prepare the product for recycling or separate waste collection in accordance with the local regulation in force.

In hospital facilities, follow the in-house rules for the disposal of electrical and electronic waste.

# 10 STORAGE CONDITIONS

The device must be stored in a cool and dry place.

# 11 TECHNICAL CHARACTERISTICS

**Technical characteristics of the Handpiece**

| Specification | Unit of Measure | Value |
|---|---|---|
| **Dimensions** | mm | Height at MIN magnetic power level: 242<br>Maximum diameter: 116 |
| **Weight** | kg | 2,65 |

**Technical characteristics of the Cart**

| Specification | Unit of Measure | Value |
|---|---|---|
| **Dimensions** | mm | Height: 943<br>Width: 687<br>Depth: 721 |
| **Weight** | kg | 18 |
| **Power supply** | -- | 2 non-rechargeable batteries<br>C (LR14) PC1400<br>Rated voltage 1.5 V |

# 12 ELECTROMAGNETIC COMPATIBILITY

The device complies with collateral standard IEC 60601-1-2 applicable to the product and related to electromagnetic compatibility.

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| **WARNING** | Never use the device from Physicians or nursing staff with permanent or semi-permanent implanted active and/or ferromagnetic/magnetic medical devices. |
| **WARNING** | Do not bring any electromedical, electronic devices or ferromagnetic objects within a distance of 10 cm |

| | |
|---|---|
| | from the Cart with the EH stored inside and the case lid closed. |
| **WARNING** | Never open the case lid, if ferromagnetic objects are within 50 cm from the Cart and from the patient's abdomen. |
| **WARNING** | Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. |
| **WARNING** | Avoid the presence of mobile phones and in general all portable and mobile RF communication equipment in the environment of use as they can affect the operation of the device. |
| **WARNING** | Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation. |
| **WARNING** | Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device. |

| | |
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| **WARNING** | Do not use Wireless power transfer (WPT) and 5G cellular RF emitters in the environment of use as they can affect the operation of the device. |

## 12.1 BASIC SAFETY AND ESSENTIAL PERFORMANCES

| Description of basic safety | How is it monitored during each test | Immunity Pass/Fail Criteria |
|---|---|---|
| No damage or degradation of indicator lights and acoustic signal. | Verify the correct functioning of the indicator lights indicators and the acoustic signal emission after the EMC tests. | No failure of components affecting electrical safety. |

| Description of essential performances | How is it monitored during each test | Immunity Pass/Fail Criteria |
|---|---|---|
| Presence of an alert system to indicate when the device is in use. | Verify that blue indicator lights flash slowly and acoustic signal turns on when the device is in use | Slow flashing of blue indicator lights and acoustic signal emission (1/s) when the device is in use. |

| | | |
|---|---|---|
| Presence of an alert system to indicate if the device is not properly stored. | Verify that blue indicator lights flash rapidly and acoustic signal turns on when the the handpiece is stored not at the minimum level (MIN). | Rapid flashing of blue indicator lights and acoustic signal emission (5/s) when the handpiece is stored not at the minimum level (MIN). |
| Presence of an alert system to indicate that the batteries need to be replaced. | Verify that the red indicator flash slowly for 30 minutes when the handpiece is stored at the minimum level (MIN). | Slow flashing of the red indicator for 30 minutes (1/s) to indicate low battery charge when the handpiece is stored at the minimum level (MIN). |
| Presence of an alert system to indicate when the device is in use in case of low battery charge. | Verify that the blue indicator lights and red indicator flash slowly and the acoustic signal turns on when the device is in use. | Slow flashing of blue indicator lights and red indicator and acoustic signal emission (1/s) when the device is in use. |
| Presence of an alert system to indicate if the | Verify that the blue indicator lights and red indicators flash rapidly | Rapid flashing of blue indicator lights, red indicator and acoustic |

| | | |
|---|---|---|
| device is not properly stored in case of low battery charge. | and the acoustic signal turns on when the handpiece is stored not at the minimum level (MIN). | signal emission (5/s) when the handpiece is stored not at the minimum level (MIN). |
| Presence of not ferromagnetic materials and magnetic shielding to reduce external flux density. | Verify that the external flux density is less than 0,5 mT within a distance of 10 cm from the Cart with the handpiece (EH) stored inside and the housing cover closed. | The external flux density is less than 0,5 mT within a distance of 10 cm from the Cart with the handpiece (EH) stored inside and the housing cover closed. |

## 12.2 PERFORMANCES ACCORDING TO THE GUIDELINE IEC TR 60601-4-2

The Endorail System device was tested according to the recommendations of guideline IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

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| **Description of performances according IEC TR 60601-4-2** | The magnet field and power level remain stable (tolerance ±5%) on the base of the handpiece before and after each EMC test. |

## 12.3 EMC TABLES ACCORDING TO IEC 60601-1-2

| **Guidance and manufacturer's declaration – Electromagnetic emissions** | | |
|---|---|---|
| The device is intended for use only in the electromagnetic environment specified below. | | |
| **Emission test** | **Compliance** | **Electromagnetic environment** |
| RF emissions CISPR 11 | Group 1 | The device uses RF energy only for its internal functions. Therefore, RF emissions are very low and are unlikely to cause interference in nearby electronic equipment. |

| | | |
|---|---|---|
| RF emissions<br>CISPR 11 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the low-voltage power supply network that supplies buildings for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Not applicable | |

| **Guidance and manufacturer's declaration – Electromagnetic Immunity** | | | |
|---|---|---|---|
| The device is intended for use only in the electromagnetic environment specified below. | | | |
| **Immunity test** | **IEC 60601-1-2 Test level** | **Compliance level** | **Electromagnetic environment** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | 8kV in Contact<br>Direct<br>15 kV on Air | Test level compliance to Table 4 of IEC 60601-1-2 | The floors must be wooden, concrete or ceramic. If the floors are covered with synthetic material, |

| | | | |
|---|---|---|---|
| | | | the relative humidity should be at least 30%. |
| Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3 | 385 MHz - 5.785 MHz | Test level compliance to Table 9 of IEC 60601-1-2 | RF wireless communications equipment shall not be used no closer than 30 cm (12 inches) to any part of the device. |
| Electrical fast transient/burst IEC 61000-4-4 | Not applicable | -- | -- |
| Surge IEC 61000-4-5 | Not applicable | -- | -- |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | Not applicable | -- | -- |

| | | | |
|---|---|---|---|
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m (50 Hz) | Test level compliance to Table 4 of IEC 60601-1-2 | Power frequency magnetic fields should have levels characteristic of a typical location in a commercial or hospital environment. |
| Radiated fields in close proximity — Immunity test IEC 61000-4-39 | 8 A/m Frequency: 30 kHz Modulation: CW<br><br>65 A/m Frequency: 134.2 kHz Pulse Modulation: 2,1kHz<br><br>7.5 A/m Frequency: 13.56 MHz Pulse | Test level compliance to Table 11 of IEC 60601-1-2 | The proximity magnetic fields should be no higher than the test levels specified in Table 11. |

| | | | |
|---|---|---|---|
| | Modulation: 50kHz | | |

| **Guidance and manufacturer's declaration – Electromagnetic Immunity** | | | |
|---|---|---|---|
| The device is intended for use only in the electromagnetic environment specified below. | | | |
| **Immunity test** | **IEC 60601-1-2 Test level** | **Compliance level** | **Electromagnetic environment** |
| Radiated RF IEC 61000-4-3 | 3 V/m Frequency: 80 MHz – 2.7 GHz Modulation: 1 KHz/AM 80% | Test level compliance to Table 4 of IEC 60601-1-2 | Portable and mobile RF communications equipment shall not be used no closer than 30 cm (12 inches) to any part of the device. |
| Conducted RF IEC 61000-4-6 | Not applicable | -- | -- |
| NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2: These guidelines may not apply in all situations. | | | |

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| Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.<br>a) Fields generated by fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be accurately estimated through calculations. |
| To evaluate the electromagnetic environment generated by fixed RF transmitters, the need to make measurements in the field of application must be considered. If the measured field strength in the location where the device is used exceeds the established V/m field strength, observe the device to verify that normal operation is maintained. In case of abnormal functioning, additional protection measures must be carried out, such as moving the device away from the emitting element or using a place of use that is more shielded from RF radiation and/or using a more effective filter.<br>b) Over the frequency range of 150 kHz to 80 MHz, the field strength must be less than 3 V/m. |

# 13 SYMBOLS

| | |
|---|---|
|  | Manufacturer |
|  | Medical device |
|  | Consult instructions for use |
|  | WEEE waste disposal |
|  | Caution |
|  | MR Unsafe |
|  | Federal (USA) law restricts this device to sale by or on the order of a physician |
|  | Catalogue number |
|  | Serial number |
|  | Date of manufacture |
|  | Unique Device Identifier |
|  | Type B applied part |
|  | Do not approach magnetic cards |
|  | Warning; Magnetic field |
|  | Do not approach fire extinguishers |

| | |
|---|---|
|  | No activated mobile phones |
|  | No metallic articles or watches |
|  | No access-with active implanted cardiac devices |
|  | Warning; Crushing of hands |
|  | No access for people with metallic implants |