



Instructions for use

English

Ref. No. 400.01



DC IMPULSE

DC Impulse
Instructions for use
Revision 04
Date 2016-04-15

For DC Impulse generators
Version 1.XX
REF: 400.01

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1 About this document

These instructions for use refer to the following product:

| Product | Manufacturer |
|---|---|
| DC Impulse Ref. No. 400.01 Version 1.XX | Ovesco Endoscopy AG Dorfackerstr. 26 72074 Tuebingen Germany |

The instructions for use are part of the product.

When using the instructions for use, please observe the following:

1. Read the instructions for use carefully before first use of the product. Before first use, users should fully understand how the product works, how to handle the product and which possible risks are connected to use of the product.
2. Store the instructions for use in a place accessible to medical staff.
3. Pass on the instructions for use to every subsequent owner or user of the product.
4. Update the instructions for use according to all amendments and revisions issued by the manufacturer.

These instructions for use include proprietary information subject to copyright law. It is not permitted to duplicate this document or portions of this document by photocopying or other means of replication without prior written consent by the manufacturer of the product.

The manufacturer assesses the right to alter the contents of these instructions for use without prior notice. Due to continuous further development of the product, it is possible that technical specifications and figures in this document are not up-to-date.

Maintenance and repair may only be performed by the manufacturer or by any person or persons authorized by the manufacturer. Unauthorized opening or performance of services by any non-authorized person or persons voids the warranty and the manufacturer's liability with regards to operational safety.

The manufacturer's warranty does not cover primary or secondary damage and defects resulting from improper or unreasonable use or maintenance, especially resulting from failure to follow the instructions for use.

2 Components

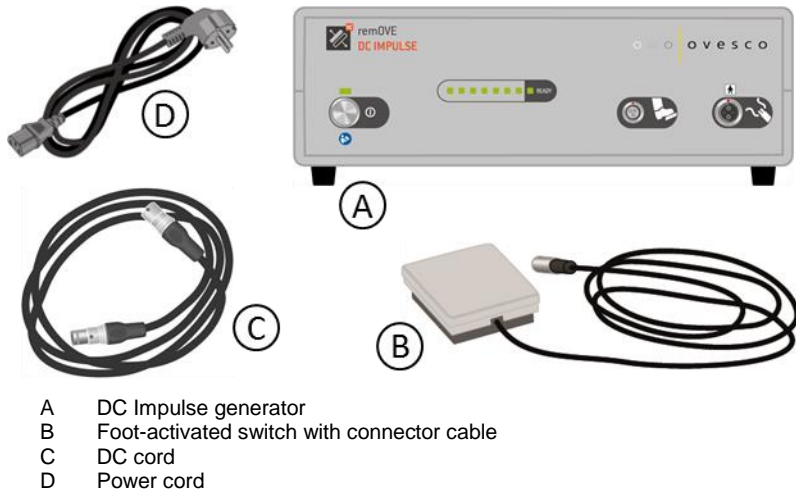


Figure 1: Components of the DC Impulse generator (Ref. No. 400.01)

The DC Cutter Set (Ref. No. 400.02.01) is not included with the DC Impulse generator and has to be ordered separately.

3 Accessories / replacement parts

Please only use original parts or parts certified by the manufacturer as compatible with the DC Impulse generator as accessories or replacement parts. Otherwise safety and functionality cannot be guaranteed.

The following accessories / replacement parts for the DC Impulse generator may be ordered separately:

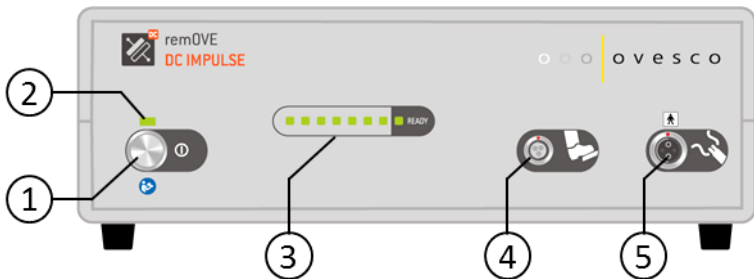
| Accessory / replacement part | max. length | Ref. no. |
|--|-------------|------------|
| Foot-activated switch with connector cable | 2 m | 400.03 |
| DC cord | 2 m | 400.04 |
| Power cord | 2.5 m | 400.10.XX* |

* When ordering the power cord, please note the country of use.

The DC Cutter Set is not included with the DC Impulse generator and has to be ordered separately:

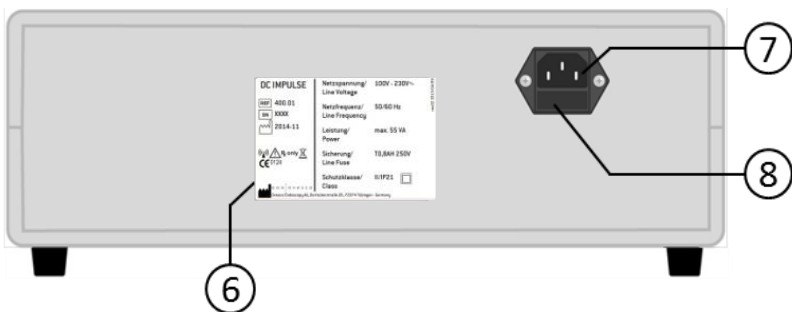
| Product | Ref. no. |
|--|-----------|
| remOVE DC Cutter Set (remOVE DC Cutter, remOVE SecureCap, remOVE Grasper, remOVE Shield) | 400.02.01 |

4 Description



- 1 ON/OFF switch
- 2 ON/OFF display
- 3 Status display: charge of battery / ready for use / error
- 4 Connection foot-activated switch
- 5 Connection DC cord

Figure 2: Front view of the DC Impulse generator



- 6 Name plate
- 7 Connection to power supply
- 8 Fuse

Figure 3: Back side view of the DC Impulse generator

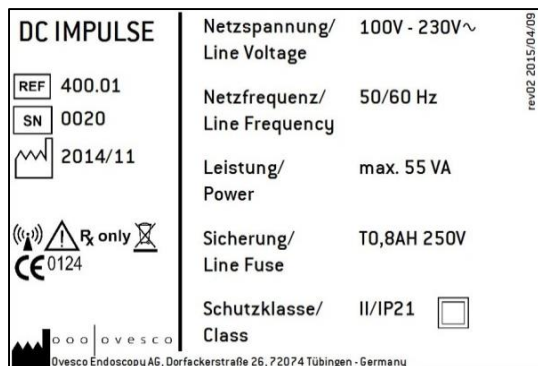


Figure 4: Name plate of DC Impulse generator

5 Intended use / indication

The DC Impulse generator is a medical electrical device for fragmentation of OTSC® and FTRD® clips made by Ovesco Endoscopy AG for the digestive tract.

Clips produced by Ovesco Endoscopy AG are:

| Product | Ref. No. |
|------------------|--|
| OTSC® System Set | 100.03, 100.04, 100.05, 100.06, 100.07, 100.08, 100.09, 100.10, 100.11, 100.12, 100.13, 100.14, 100.27, 100.28, 100.29, 100.30, 100.31 |
| OTSC® Reloader | 200.37, 200.38, 200.39, 200.40, 200.41, 200.42, 200.43 |
| FTRD® System Set | 200.70 |
| OTSC® Proctology | 200.60 |

It is not permitted to use the DC Impulse generator outside of its intended use as specified above. Using the DC Impulse generator for fragmentation of objects other than the products specified above may lead to defects and damages to the DC Impulse generator, destruction of the DC Cutter instrument and permanent bonding of DC Cutter instrument to the object.

6 Contraindications

Do not use the DC Impulse generator if flexible endoscopic interventions are contraindicated and/or when fragmentation and removal of an OTSC® or FTRD® clip made by Ovesco are contraindicated. Clip fragmentation and removal of the clip are also contraindicated if the clinical effect of the clip is still necessary.

7 Complications / warnings / precautions



The following complications may occur even if the product is used as intended.

Damage of tissue in the digestive tract. This includes in particular:

- Thermal damage of the wall of the respective digestive organ
- Bleeding due to injury
- Perforations; these may occur time-delayed after intervention
- Consider that by official Definition of the applicable norm the following statement applies to electromedical devices in general: “any value of current, however small, has some probability of causing ventricular, fibrillation” (IEC 60601-1, section 8.7.3, A.14).

Before use of product, always check for completeness and possible defects of all components. Incomplete or defect components must be replaced. Defective or missing components may lead to malfunction of the system. E.g. defective isolation of power lines may lead to electrocution of patient and/or user.

Ignition and/or explosion of flammable gases, amongst others e.g. high concentration of oxygen, inside or outside the digestive tract may be caused by sparks generated during use of the product. Before use of the product, please make sure that no flammable gases/materials are present in the vicinity of the device and/or the application site.

Power lines/parts must not be in touch or contact with the DC Cutter instrument. Defective power lines may lead to electrocution of patient/user.

All fragments of the clip must be removed from the patient's body. If sharp-edged fragments of the clip remain inside, this may lead to injury of the digestive tract organ or other abdominal organs. These injuries may occur delayed after the intervention.

Clips with incomplete cuts that remain in the patient's body do not anymore comply with the requirements of their intended use. These clips might break which results in sharp-edged fragments of the clip. This can cause injuries of digestive organs or other abdominal organs. These injuries may occur delayed after the intervention.

Due to the physical working principle and technical design of the system neuromuscular irritation is highly improbable during application, but cannot be ruled out completely. During application in the esophagus, there is a residual risk of neuromuscular irritation, particularly of the myocardium. Interference with active cardiac implants cannot be ruled out entirely. Before use of the product in the esophagus, it is advised to:

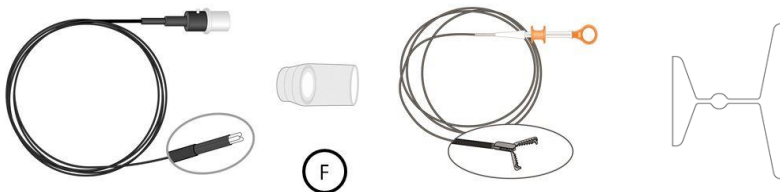
- adjust/compensate for any clinically relevant imbalance of the electrolyte metabolism, particularly hypokalemia. If applicable, a cardiologist should be consulted.
- consult with a cardiologist in patients with implanted cardioverter defibrillator (ICD) and evaluate whether to switch off the ICD for the duration of treatment (monitoring of patient might be advised).

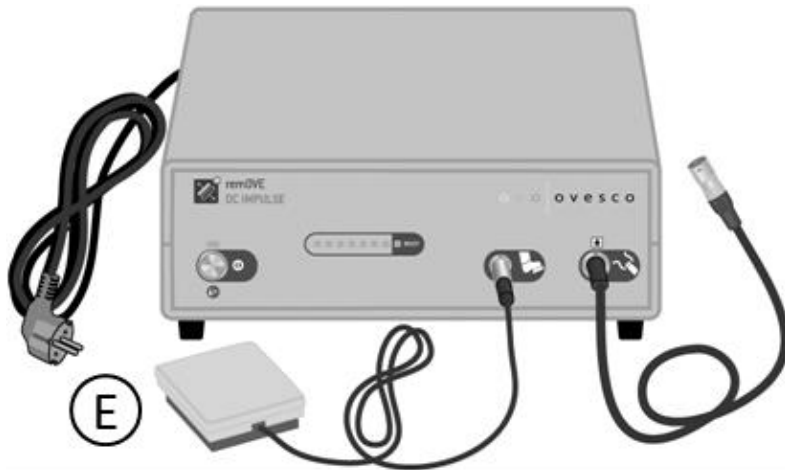
Applied parts and generator are not defibrillation-proof. Remove instrument before defibrillation of patient.

8 Components and products required for use

The DC Impulse generator may only be used in conjunction with manufacturer-approved accessories and products as detailed in the instructions for use.

The use of accessories, cables and transducers, other than those the DC Impulse generator was designed for, can significantly increase emissions and reduce immunity of the DC Impulse generator against interference.





- | | | |
|---|--|--------------------|
| E | remOVE DC Impulse generator incl. accessories | Ref. No. 400.01 |
| F | remOVE DC Cutter Set (remOVE DC Cutter, remOVE SecureCap, remOVE Grasper, remOVE Shield) | Ref.-No. 400.02.01 |

Figure 5: Products required for use

9 Preparation

Additional devices to be connected to medical electric devices have to be in compliance with IEC or ISO norms. Additionally, all configurations have to be in compliance with normative requirements for medical systems (see IEC 60601-1-1 or Section 16 of the third revision of IEC 60601-1, respectively). The person or persons who connect additional devices to medical electric devices are system configurators and are thus responsible for ensuring that the system is in compliance with the normative requirements for systems. Be advised that local law takes precedence over the normative requirements detailed above.

When setting up the DC Impulse generator please make sure that the user has clear, unobstructed line of sight to the status display.

When setting up the DC Impulse generator please make sure that environmental factors do not impair the user's perception of acoustic signals generated by the DC Impulse generator.

Do not connect the DC Impulse generator to the power supply unless a protective earthing conductor is present in order to avoid electrocution.

Before use of product please follow the steps detailed below:

1. Place the device on a stable surface in sufficient distance to the wall, ensuring that the device can immediately be disconnected from the power supply if necessary.
2. Connect the power cord to the DC Impulse generator and connect the power cord to the power supply.
3. Connect the foot-activated switch and the DC cord to the DC Impulse generator.
4. Connect the DC Cutter instrument to the DC cord.

In order to connect the DC Cutter instrument with the DC cord, align the two markings (red and white dot) on both devices in such a way that the white dot on the plug of the DC Cutter instrument and the red dot on the plug of the DC cord are opposite to each other, see figure below.



Figure 6: left: DC Cutter instrument; right: DC cord

5. Activate the DC Impulse generator by pressing the ON/OFF switch. The ON/OFF switch lights up to indicate that the device is activated.

The status display indicates the charge of the DC Impulse generator through green flashing LEDs

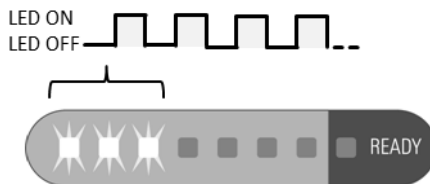


Figure 7: Status display indicates charge during charging phase by flashing green LEDs corresponding to the charge level.

If the DC Impulse generator has not been in use for more than two days, the internal energy storage is fully charged over a time period of about 10 minutes. If the DC Impulse generator has been in use in the past two days, the device might charge faster.

Successful completion of charging cycle is indicated through three short acoustic signals in quick succession. The status display indicates operational readiness through emitting constant green light from all eight LEDs.



Figure 8: Status display indicates operational readiness through emitting constant green light from all eight LEDs.

6. As soon as all eight green LEDs are constantly on, the DC Impulse generator is ready for use.

10 Use of product



The user must make sure that set-up, assembly and use of the DC Impulse generator, all accessories and endoscopic instruments are carried out in accordance with the respective instructions for use.

Always use only one DC cord to connect the DC Cutter instrument and the DC Impulse generator. If connection is established without a DC cord or with more than one DC cord, functionality may be impaired.

Make sure it is possible to remove the clip. If the clip is ingrown into tissue, superficial dissection and tissue removal in order to expose clip may be necessary.

When recovering clip fragments, make sure all clip fragments are located completely inside the SecureCap. Protruding sharp parts of a clip fragment may lead to injuries of organs of the digestive tract. Perforations may occur time-delayed after intervention.

When introducing and removing DC Cutter instrument, make sure neither the endoscope nor the DC Cutter instrument is being damaged, e.g. by kinking of the instrument shaft.

Coiling up of the DC Cutter instrument to small diameters can cause pre-bending of the instrument tip. A pre-bending can complicate the positioning/contacting at the clip during the application.

Check that the remOVE Shield is affixed to the lens before starting the cutting process and keep a minimum distance of 30-40 mm between the endoscope tip and the clip during the cutting process. The endoscope tip can be damaged by sparks during the cutting process. Affixing the remOVE Shield to the lens and maintaining the maximum possible distance between the endoscope tip and instrument tip reduce the risk of damage.

Be advised that the DC Cutter instrument tip might heat up during cutting. Thus contact between instrument tip and skin directly after use may cause superficial burns of the skin. The temperature at the instrument tip may reach 130 °C.

Using CO₂ Atmosphere during application may reduce efficiency of the clip fragmentation.

Even when using the product according to its intended use, adverse effects might occur. Thus Ovesco products should only be used by persons who are qualified and trained in the respective field of application.

Make sure that the foot-activated switch is not permanently pressed. A single DC pulse is only triggered when the foot-activated switch is pressed during an acoustic contact signal. Permanent activation of the foot-activated switch may cause unintended triggering of a DC pulse.

When removing material residue from the instrument tip through a DC pulse, the instrument tip must be shielded from patient, user and any third parties because sparks might occur.

If user suffers from red-green color blindness, make sure that the user understands the status display.

For use of the product, the following steps have to be observed:

1. Maneuver the endoscope to the site of the clip to be removed.
2. Introduce the DC Cutter instrument through the working channel and establish contact with the clip. A continuous acoustic signal indicates sufficient electrical contact between the instrument and the clip.
3. When a continuous acoustic signal occurs, press the foot-activated switch once in order to start cutting. Once the clip has been cut, the acoustic signal will stop and the status display will flash green for about 6 seconds. Next, three short acoustic signals in quick succession occur and the status display switches back to "ready for use".

In order to create easily removable clip fragments, each clip has to be cut in two spots on opposite sides of the teeth.

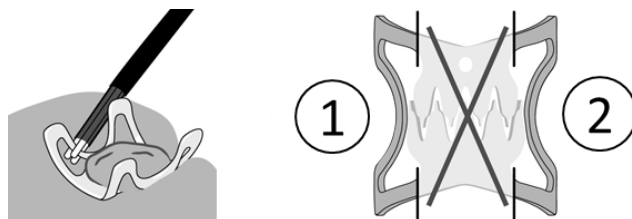


Figure 9: Spots on the clip suitable for clip fragmentation: first cut at (1), second cut at the opposite side (2)

After cutting, residue of clip material might be present in the DC Cutter instrument tip. This residue might create a conductive contact between the electrodes. This is indicated by a continuous acoustic signal without contact between the instrument tip and the clip. This material residue may be removed through another application of a direct current pulse.

For this purpose, remove the DC Cutter instrument from the working channel and apply a DC pulse by pressing the foot-activated switch. This should remove the residue. When applying a DC pulse, position the DC Cutter instrument in a way that patients, users and other persons are protected from sparks that might occur.

4. Make sure fragmentation of clip at two spots has been successfully accomplished by endoscopic visualization.
5. Pull back the endoscope and mount the SecureCap onto the endoscope tip. Maneuver the endoscope with the mounted SecureCap to the site of the clip fragments.
6. Use the grasper to pull one clip fragment into the SecureCap and remove it from patient's body. During endoscope retraction, keep the clip fragment with the grasper inside the SecureCap. Repeat this maneuver for the second and, if applicable, any additional clip fragments.



Figure 10: Clip with grasper inside SecureCap

7. Turn off the DC Impulse generator by pressing the ON/OFF switch.

11 Mode of operation

The DC Impulse generator is designed to send an electrical direct current pulse of typically $I_s = 155 \text{ A}$ for the duration of 60 ms through the bipolar, endoscopic instrument DC Cutter instrument.

This DC pulse flows through the clip segment the DC Cutter instrument is establishing contact with, resulting in localized melting of the clip material.

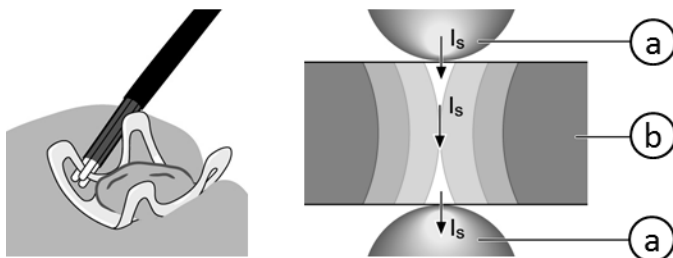


Figure 11: Left: Establishment of contact between clip segment and DC Cutter instrument. Right: Cross-section of clip segment to be cut (b) and marking of current path I_s between electrodes (a)

The DC Impulse generator is equipped with internal energy storage, allowing the device to generate a DC pulse without additional load on the power supply. This internal energy storage is charged before the DC Impulse generator generates the DC pulse.

The DC Impulse generator is designed to ensure that a direct current pulse can only be generated when sufficient contact with a segment of the clip is established. Sufficient contact is indicated through an acoustic signal.

Should contact break off between the DC Cutter instrument and the clip during the application of a DC pulse, the output of the DC Impulse generator will be deactivated within less than 500 μs . Breaking-off of contact might occur, for example, if one or both electrodes lose contact with the clip due to successful clip fragmentation.

During a DC pulse, the voltage drop between the electrodes of the DC Cutter instrument is between 1.3 V and 2.0 V. During loss of contact, short-term (max. 500 μs) voltage spikes max. 22 V may occur. These spikes might be transferred into the tissue if both electrodes of the DC Cutter instrument are in contact with tissue.

12 Error message

The DC Impulse generator is equipped with a failure detection system. Technical failures are indicated via the status display. Failure detection is implemented to ensure user/patient safety.

If a failure message occurs, the device casing may not be opened. Life-threatening electrocution could occur.

If a failure message occurs, the device may no longer be used in order to ensure the safety of users and/or patients. If a failure occurs, all eight LEDs of the status display are flashing orange, see figure below.

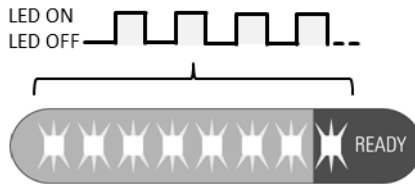


Figure 12: Status display flashes orange during failure message.

If a failure message is displayed by the DC Impulse generator, acoustic contact detection between instrument and clip is deactivated. A DC pulse can no longer be generated, and the internal energy storage of the DC Impulse generator can no longer be recharged.

In the case of failure message or malfunctioning of the device, please contact manufacturer.

13 Cleaning and disinfection

As part of your responsibility to ensure hygiene and cleanliness of all product components during use, please make sure that only suitable devices and procedures validated specifically for this product are used for cleaning and disinfection of the product. Please follow the respective local and/or national legislation as well as hygiene regulations pertaining to medical practices or hospitals.

Before cleaning the DC Impulse generator, disconnect the device from the power supply. For cleaning the surfaces, please use approved cleaning/disinfection

supplies and only in accordance with instructions by the respective manufacturer. Make sure no fluids enter the device casing. Non-compliance may result in burning hazard and/or electrocution.

1. Apply alcohol-based cleaning/disinfection agent. Do not use benzyl-alcohol-based and/or any other agents because it can cause damages to the DC Impulse generator materials.
2. Wet a sponge or cloth in clean water and wipe off the cleaning/disinfection agent.
3. Dry the device using a clean, lintfree cloth.

14 Transport and shipping / storage

14.1 Transport and shipping

Perform surface disinfection and properly package device for shipping. Add another form of packaging, to avoid bacterial contamination and infections once you leave the doctor's office or hospital.

Be advised to transport / ship the DC Impulse generator in its original, undamaged packaging.

Make sure the packaging is not damaged and/or wet. Otherwise, the device might get damaged during transport / shipping, which may lead to malfunction during the next use. This, in turn, may endanger the user/patient.

When transporting / shipping the device, make sure to follow the respective terms of transport.

14.2 Storage

If the DC Impulse generator is not stored properly, customer claims may not be considered. Improper storage may also lead to malfunction, which may endanger the user/patient.

It is recommended to store the DC Impulse generator in its undamaged original packaging.

It is recommended to thoroughly clean the DC Impulse generator before storing it.

Do not expose the DC Impulse generator to direct or indirect sunlight or other types of UV radiation.

Do not store the DC Impulse generator in the vicinity of chemicals, disinfectants and/or sources of radioactive radiation.

Do not place heavy objects on top of the DC Impulse generator or its packaging.

Make sure to store the DC Impulse generator in a dry and clean space, ensuring appropriate storage conditions.

14.3 Transport and storage conditions

When transporting or storing the DC Impulse generator, please make sure that the following environmental requirements are met:

| Environmental factors | Storage | Transportation |
|------------------------------|-----------------------------------|-----------------------------------|
| Temperature | 0 °C to +50 °C | -20 °C to +50 °C |
| Relative humidity | 0 % to 90 %, RH non-condensing | 0 % to 90 %, RH non-condensing |
| Air pressure | 500 to 1060 hPa | 500 to 1060 hPa |

15 Maintenance / repair

15.1 In general

After every use of the DC Impulse generator and its accessories, please check for damages or defects. Pay special attention to intact isolation of all cords and cables.

Never use a damaged DC Impulse generator or damaged accessories. Immediately replace defective accessories.

Make sure that a safety inspection of the DC Impulse generator is performed annually.

15.2 Safety inspection

Safety inspections have to be performed annually.

Consider that national regulations might call for more frequent safety inspections and make sure to have the inspections performed accordingly.

When performing a safety inspection, please make sure all national requirements and rules are met.

Safety inspections of the device and its accessories may only be performed by qualified personnel with all required knowledge and experience, who are authorized to perform safety inspections without supervision.

The inspector documents all testing results and measurements according to the printable inspection record (see appendix of the instructions for use).

If considerable deviations or abnormalities are recorded, please contact the manufacturer.

15.3 Repair

If repairs are needed, please contact the manufacturer. Do not attempt to repair the device yourself under any circumstances.

Ovesco accepts liability with regards to safety, reliability and functionality of the device under the following circumstances:


- All instructions with regards to installation and intended use given in this document have been followed properly.
- Modifications, repairs, etc. were only performed by personnel authorized for these tasks by Ovesco.
- Electrical installations in the space concerned are in accordance with local and national rules and regulations.

In your repair request, please include the following information. Correct and complete information ensures quick and successful repair work.

- Complete address
- Order number of DC Impulse generator
- Serial number of DC Impulse generator
- Describe the problem, the act of use when the problem occurred and all accessories used.

16 Disposal

When disposing or recycling the product or its components, please make sure to follow national rules and regulations.

| Symbol | Description |
|---|--|
|  | Products with this symbol have to be delivered to a separate collection for electrical and electronic equipment. Inside the European Union, the manufacturer will dispose of the product free of charge. |

17 Operating conditions

When using the DC Impulse generator, please make sure the following operating conditions are met:

| Environmental factors | Value |
|-----------------------|------------------------------------|
| Temperature | +10 °C to +40 °C |
| Relative humidity | 25 % to 75 %, RH non-condensing |
| Air pressure | 700 to 1060 hPa |
| Operation level | ≤ 4000 m |

If the DC Impulse generator has been stored or transported at a temperature of less than + 10 °C, it must be acclimated to room temperature for at least 3 hours.

18 Specifications

| Isolation / Classification | |
|---|---|
| EMC | IEC 60601-1-2:2007 |
| Type of protection, through casing | IP 21 |
| Type of protection, through foot-activated switch | IPX8 |
| Type of protection according to EN 60601-1 | II with functional earth |
| Type of applied part according to 60601-1 | BF |
| Compliance with standards | IEC 60601-1: 2005+Cor.: 2006 + Cor.: 2007 + A1 2012 IEC 60601-1-2: 2007 IEC 60601-1-6:2010 ISO 14971: 2007 ISO 13485: 2003 + AC 2009 |
| Classification according to 93/42/EEC | IIB |

| Power input | 100V – 230 V | |
|--|---------------------|----------------------|
| Power supply voltage | 220V - 230 V | 100 V – 120 V |
| Power consumption in standby mode once fully charged | 6 W / 17 VA | 6 W / 10 VA |
| Power consumption in standby mode | 60 mA | 90 mA |
| Max. power consumption | 50 W / 55 VA | 50 W / 50 VA |
| Mains fuse | T 0.8 A H 250 V | T 0.8 A H 250 V |
| Line frequency | 50 / 60 Hz | 50 / 60 Hz |

| Measurements and weight | |
|----------------------------------|---------------------------|
| Measurements of product | 340 x 340 x 110 mm |
| Net weight | 5.0 kg |
| Type of packaging / measurements | Carton 400 x 400 x 300 mm |
| Gross weight | 7.5 kg |

| Operating conditions | |
|-----------------------------|---|
| State of charge | Indicated by green flashing LEDs on status display. |
| Ready for use initial | Indicated by three short acoustic signals in quick succession and continuous glowing of all LEDs on status display in green once operating voltage is reached. Initial charge when device energy storage is completely discharged takes ca. 10 minutes. |
| Ready for use signal | Indicated by three short acoustic signals in quick succession once operating voltage is reached or 6 seconds after DC pulse. |
| Ready for use visual | Indicated by all LEDs on the status display being lit in green. |
| On/Off signal | Yes. Green LED display above on/off switch. |
| Overheating protection | Yes. |
| Error message | Yes. All LEDs are flashing orange on status display. |

| Documentation | |
|----------------------------------|---|
| Log and record of number of uses | Yes. Readout by qualified personnel only. |

| Specifications | |
|--|--------------------------|
| Instrument type DC Cutter instrument | Bipolar / direct current |
| One-time duration of impulse during activation | ≤ 65 ms |
| Output current DC Cutter instrument | ≤ 165 A |
| Output voltage DC Cutter instrument | 1.3 – 2.0 V |
| Interval between activations | ≥ 6 s |

| Compatibility | |
|-----------------------|--------------------|
| DC Cutter Set | Art.-Nr. 400.02.01 |
| Foot-activated switch | Art.-Nr. 400.03 |
| DC cord | Art.-Nr. 400.04 |
| Power cord | Art.-Nr. 400.10.XX |

| Environmental conditions for operation, transport and storage | Operation | Storage | Transportation |
|--|--------------------------------|--------------------------------|--------------------------------|
| Temperature | +10°C to +40°C | 0 °C to +50 °C | -20 °C to +50 °C |
| Relative humidity | 25 % to 75% RH, non-condensing | 0 % to 90 %, RH non-condensing | 0 % to 90 %, RH non-condensing |
| Air pressure | 700 to 1060 hPa | 500 to 1060 hPa | 500 to 1060 hPa |
| Operation level | ≤ 4000 m | - | - |

19 Electromagnetic compatibility (EMC)

Make sure no electronic devices which could be compromised by electromagnetic fields are present in the vicinity of the DC Impulse generator. A compromised device could lead to malfunction and/or failure of respective device and thus may endanger user and/or patient.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

| Guidance and manufacturer's declaration - electromagnetic emissions (IEC 60601-1-2, Table 1) | | |
|---|-------------------|--|
| The DC Impulse generator is intended for use in the electromagnetic environment specified below. The customer or the user of the DC Impulse generator should assure that it is used in such an environment. | | |
| Measurements of electromagnetic emissions | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR11 | Group 1 | The DC Impulse generator uses 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 CISPR11 | Class A | The DC Impulse generator is suitable for use in all establishments other than domestic 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 (IEC 60601-1-2, Table 2)**

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

| Immunity testing | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|--|---|---|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact | ± 6 kV contact | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| | ± 8 kV air | ± 8 kV air | |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines | ± 2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s) | ± 1 kV line(s) to line(s) | Mains power quality should be that of a typical commercial or hospital environment. |
| | ± 2 kV line(s) to earth | ± 2 kV line(s) to earth | |
| Voltage dips, short interruptions and voltage variations on power supply input lines 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 s | <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 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the DC Impulse generator requires continued operation during power mains interruptions, it is recommended that the DC Impulse generator be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | 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.

Guidance and manufacturer's declaration
- electromagnetic immunity (IEC 60601-1-2, Table 4)

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

| Immunity testing | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|---|-----------------------------|------------------|---|
| Conducted RF disturbances IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 10 V | Portable and mobile RF communications equipment can affect the DC Impulse generator and should be used no closer to any part of the DC Impulse generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated RF disturbances IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | |

Recommended separation distance

$d = 0.35 \times \sqrt{P}$ for 150 kHz to 80 MHz

$d = 1.2 \times \sqrt{P}$ for 80 MHz to 800 MHz

$d = 2.3 \times \sqrt{P}$ for 800 to 2.5 GHz

where P is the rated maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (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 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. |
| 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 reorienting or relocating the device. |
| b | Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m. |

Recommended separation distances between portable and mobile RF communications equipment and the DC Impulse generator (IEC 60601-1-2, Tabelle 6)

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

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m) | | |
|--|---|--|---|
| | 150 kHz to 80 MHz; $d = 0.35 \times \sqrt{P}$ | 80 MHz to 800 MHz; $d = 1.2 \times \sqrt{P}$ | 800 MHz to 2.5 GHz; $d = 2.3 \times \sqrt{P}$ |
| 0.01 | 0.035 | 0.12 | 0.23 |
| 0.1 | 0.11 | 0.38 | 0.73 |
| 1 | 0.35 | 1.2 | 2.3 |
| 10 | 1.1 | 3.8 | 7.3 |
| 100 | 3.5 | 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. | | |

20 Warranty

Ovesco Endoscopy AG, the manufacturer, grants a 24 month warranty on material and construction of the DC Impulse generator, starting from date of purchase.




















The warranty covers any faults occurring in the product due to the materials used in the manufacturing process or faulty installation by the manufacturer. Faults the manufacturer is notified of within the warranty period will be fixed free of charge.

The warranty is void if the buyer or non-authorized third parties have interfered with the device. The warranty does not cover defects due to incorrect handling, use, storage, transport, force majeure or other external forces.


All other warranty claims are excluded.

Faults corrected under the manufacturer's warranty will not engender any incidental expenses. Shipping costs inside the Federal Republic of Germany will be borne by the manufacturer or distributor.

21 Symbols

| | |
|---|--|
|  | CE-mark and identification number of Notified Body |
|  | See instructions for use |
|  | Caution: please observe |
|  | Serial number |
|  | Reference or order number |
|  | Date of manufacturing |
|  | Manufacturer |
|  | When operating this device, electric energy is used, resulting in electromagnetic radiation. |
|  | Protection class II device with functional earth |
| Rx only | Caution! Must be used by qualified staff |
|  | ON/OFF switch |
|  | Ready for use |
|  | Connection foot-activated switch |
|  | DC Cutter instrument connection |
|  | Applied part type BF |
|  | Do not use if package is damaged |
|  | Air pressure limit |
|  | Humidity limit |
|  | Temperature limit |
|  | Marking of electrical and electronic equipment according to applicable guideline 2002/96/EG (WEEE), see disposal |

Appendix 1

| Inspection Record DC Impulse generator <i>Annual Safety Inspection</i> | | |
|---|--|--|
| Date _____ <i>(dd.mm.yyyy)</i> | Inspector _____ <i>Name of Inspector</i> | Signature _____ |
| Test | | Result |
| 1. Are all cable insulations intact? → Insulation has to be intact. | | <input type="checkbox"/> OK <input type="checkbox"/> not OK <input type="checkbox"/> attachment (if required) |
| 2. Are all accessories present? → Accessories have to be complete. | | <input type="checkbox"/> OK <input type="checkbox"/> not OK <input type="checkbox"/> attachment (if required) |
| 3. Do all displays function as intended (On/Off switch, status display)? → All displays have to function in accordance with the instructions for use. | | <input type="checkbox"/> OK <input type="checkbox"/> not OK <input type="checkbox"/> attachment (if required) |
| 4. Do three short acoustic signals in quick succession indicate the device is fully charged? → The three-time acoustic signal has to indicate completion of charge. | | <input type="checkbox"/> OK <input type="checkbox"/> not OK <input type="checkbox"/> attachment (if required) |
| <div style="display: flex; align-items: center;">  <p>If any deviations, faults and/or failure messages occur, please contact the manufacturer.</p> </div> | | |

CE 0124

CE-marking according to
EC directive 93/42 EEC



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