INSTRUCTIONS FOR USE

BM-780 II

Radio Frequency Generator

REF: 36 00 80 - 01

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1 Explanation of symbols and abbreviations

	Temperature limit
	Humidity limitation
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Ω	Ohm
A	Ampere
BF	Body floating (not suitable for application on the heart)
dB	Decibel
hPa	Hectopascal
Hz	Hertz
kHz	Kilohertz
MDD 93/42 (EEC)	EU Medical Device Directive
MHz	Megahertz
MPG	Medical Devices Act (Germany)
LF	Low frequency
P	Power
HF	High frequency
RF	Radio frequency
V	Volt
VAC	Volt alternating current
VA	Volt-ampere

(also see chapter 4)

2 Mode of action and intended use

2.1 General information about the mode of action of electrosurgery

Electrosurgery is a surgical method that uses electric current to achieve surgical effects. To prevent this current from causing nerve stimulation (electric shocks), alternate current with a sufficiently high frequency (over 300 kHz) is used so that nerve stimulation no longer occurs (Nernst equation). One therefore also speaks of **"high-frequency surgery" (HF)** or, since the frequency is in the range of radio waves, of **"radio frequency surgery" (RF)**. These terms are used synonymously in the following.

If the current is supplied to the surgical area by an electrode and conducted away from the body again outside the surgical area using a large-scale electrode with no electrosurgical effect, one speaks of **monopolar application**. The electrode in the surgical area is called the active electrode, the current return electrode is called the neutral electrode. If on the other hand the current is conducted away from the body and back to the device by an electrode directly within the surgical area – which is usually symmetrical to the supply electrode – then one speaks of **bipolar application**.

In principle, one differentiates between two electrosurgical effects:

- **Electrosurgical cutting**
- **Electrosurgical coagulation**

With **electrosurgical cutting**, a high current concentration occurs at the transition between the electrode and tissue, leading to very rapid heating at that point. This causes water vapor to escape from the tissue. The release of vapor separates the tissue from the electrode, creating an insulating layer. This layer needs to be electrically penetrated by ionizing the steam so the current can continue to flow. Now physical effects occur in this water vapor layer, which has become electrically conductive, leading to tissue separation. If the tissue contains only little or no water, then this cutting process only works moderately or not at all. This method is used to sever or resect tissue using blade or needle-shaped electrodes, or wire or tape loops.

Two active principles are generally differentiated for **electrosurgical coagulation**. When the current from the electrode enters the tissue, the tissue at that point is heated by electrothermal energy conversion (resistive heating). This is used to denature (coagulate) tissue during surgery or to stop major bleeding (hemostasis). This type of electrosurgical coagulation is called **contact coagulation**, and is carried out using a ball or plate-shaped electrode or the flat side of a blade-shaped electrode, or indirectly through contact with a hemostat.

Another possible application is the targeted destruction of tissue using piercing electrodes, which in this case can postoperatively lead to a desired **tissue volume reduction**.

In bipolar applications, the electrode pair is frequently carried out as tweezers or forceps, often designed for special preparations.

A different coagulation effect occurs when the voltage on the active electrode is so high that sparks can form between the electrode and tissue. Low ends form at the ends of these sparks. Within them, the temperature is extremely high, but the temperature gradient from the inside to the outside is also extreme so that coagulation only takes place in a thin layer on the surface. This allows large-scale hemostasis with only minor depth damage to the tissue to be achieved. This type

of coagulation is called **spray coagulation** and can be carried out with a needle electrode or the pointed end of a blade electrode.

2.2 Intended use of the BM-780 II

The BM-780 II with its output power of max. 80 watts in monopolar application and max. 70 watts in bipolar application is a device for all electrosurgical procedures in ear, nose, and throat medicine practices, plastic/cosmetic surgery, dermatology, gynecology, general medicine, and by registered (accident) surgeons and in clinics. It is suitable for electrosurgical cutting and coagulating.

Exclusions are application immersed in liquids and applications on the open heart and directly on the central nervous system, as well as all applications that require a higher RF output than the maximum output specified in the technical data for the respective current type.

The BM-780 II may only be used by persons that have been trained in the proper and safe use of the device. The instructions for use must be observed for training and application.

The safe application of electrosurgery requires the user to be familiar with the technology and forms of application.

Any change to the product or deviation from these instructions for use waives the liability of Sutter Medizintechnik.

2.3 Contraindications and side effects

2.3.1 Contraindications

Applications that require a higher RF output than the maximum output specified in the technical data for the respective current type are contraindicated.

In case of procedures on body parts with a small cross-section in proportion to their dimensions (filamentary structures and skin flaps), using bipolar technology or forgoing the use of RF surgery is recommended to prevent unwanted coagulation in other areas.

No contraindications that apply to the product directly are known at this time. The attending doctor has to decide whether the intended application can proceed, based on the patient's general condition. The safety measures described in section **Fehler! Verweisquelle konnte nicht gefunden werden.** have to be observed in addition.

2.3.2 Side effects

No side effects that apply to the product directly are known at this time. Observe the safety measures in order to avoid unwanted effects – see section **Fehler! Verweisquelle konnte nicht gefunden werden.**.

3 Transportation and packaging

3.1 Receiving inspection

3.1.1 Transport damage

The device and accessories must be inspected for possible transport damage and defects on receipt.

Scope of delivery: BM-780 II, mains cable, instructions for use

3.1.2 Claims for compensation

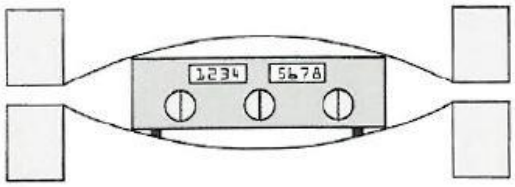
Claims for compensation can only be asserted if the seller or shipper is notified promptly. A record of damages must be prepared immediately. The record of damages has to be submitted to the nearest Sutter representative or directly to Sutter so that claims for compensation can be reported to the insurer.

3.2 Returns

If possible, the original packaging must be used to return a device to Sutter or a Sutter service center. If this is not available, packaging that properly protects the device being returned is mandatory. In case of improper packaging, liability rests exclusively with the sender. The following accompanying documents must be included:

- Name and address of the sender/return recipient
- Model and device number
- Description of the defect
- The version of these instructions for use
- The most recent inspection record for the safety-related inspection

When returning or shipping an RF generator, please ensure that the membrane packaging is correctly inserted.

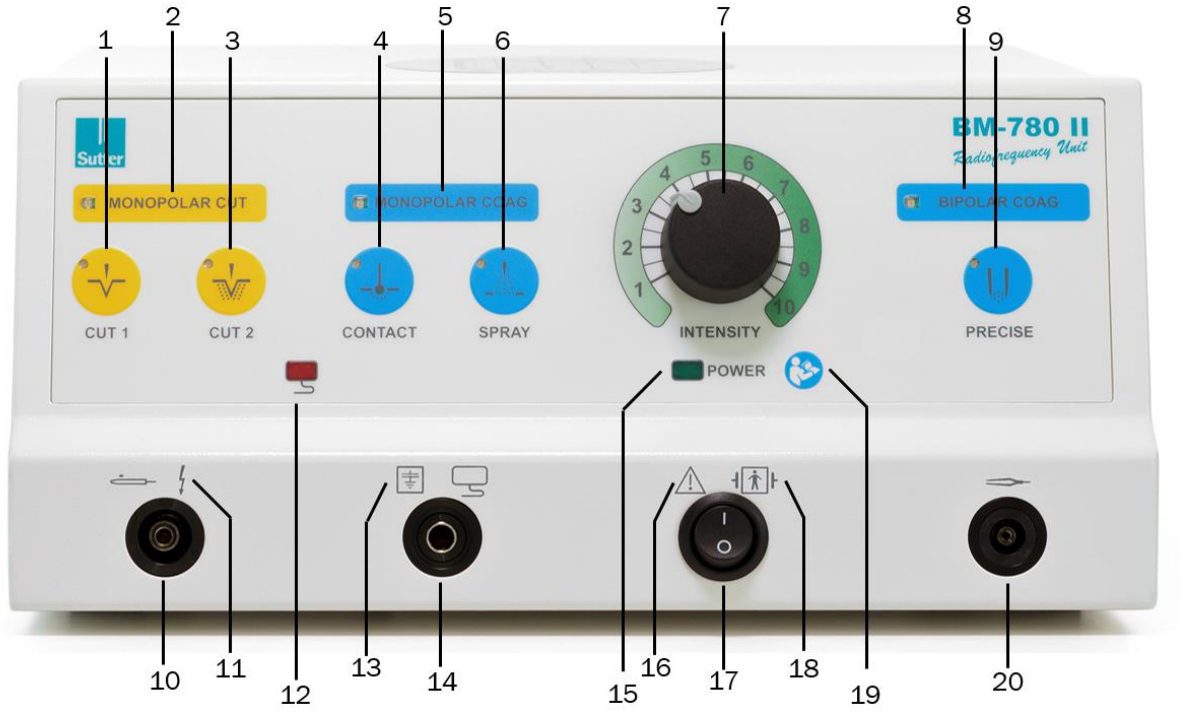


The packaging can be reordered under the following article number: **989118**

4 Commissioning

4.1 Function of the control elements and indicator lamps on the BM-780 II

Front of the device:



1 CUT 1 selection button for monopolar cutting
2 Indicator lamp for monopolar cutting
3 CUT 2 selection button for monopolar cutting with coagulation zone
4 CONTACT selection button for monopolar contact coagulation
5 Indicator lamp for monopolar coagulation
6 SPRAY selection button for spray coagulation
7 Rotary knob for output setting
8 Indicator lamp for bipolar coagulation
9 PRECISE selection button for bipolar coagulation
10 Connection socket for monopolar instruments
11 Notification symbol “CAUTION – HIGH-FREQUENCY CURRENTS, DANGER HIGH VOLTAGE”
12 Indicator lamp for neutral electrode alarm
13 Neutral electrode connected to ground for RF currents, not for LF currents.
14 Neutral electrode connection

15 Device operational indicator lamp

16 Notification symbol “CAUTION!”

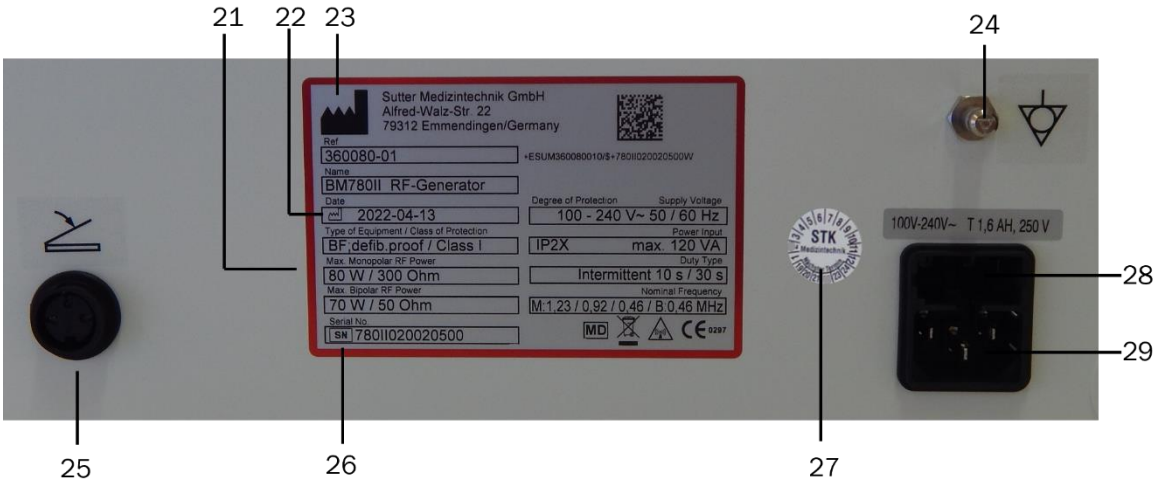
17 Power switch

18 Notification symbol for classification of the device: BF

19 Notification symbol “CAUTION! NOTE THE INSTRUCTIONS FOR USE!”

20 Connection for bipolar instruments

Back of the device:



21 Type plate

22 Manufacturing date

23 Manufacturer

24 PE connection for electric potential equalization

25 Connection socket for foot switch

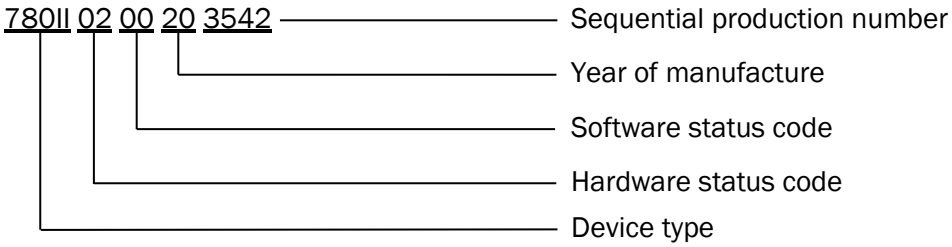
26 Serial number (encoding see below)

27 Safety-related inspection seal of approval

28 Device fuse

29 Mains cable connection socket

The serial number encodes the following information about the respective device:



4.2 Mains supply

Before switching the device on for the first time, check whether your mains network matches the device voltage setting identified on the label (above the connection socket (29) for the mains cable). Please notify your dealer if this is not the case.

(1) Mains fuse 100 – 240 VAC, 2 x T 1.6 AH 250 V G, 5x20 mm

(2) Mains connection 100 – 240 V; 50/60 Hz

The fuses are located in the slot (28) on the mains connection socket.

Connect the mains cable to the connection socket (29) and connect the other end of the mains cable to an outlet.

For the all-phase, full disconnection of the device in case of danger, either the connection socket on the device or the outlet where the mains cable is plugged in should be left accessible.

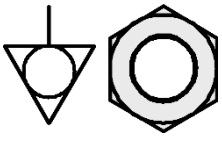
No special measures are required to take the device out of operation.

WARNING

Risk of electric shock!

To exclude the risk of electric shock, this device may only be connected to a mains network with protective conductor.

4.3 Potential equalization connection



Potential equalization is a connection of device housings with good electrical conductivity. It is intended to ensure that the devices consistently maintain the same electrical potential, even in case of an electrical defect. Potential equalization is prescribed for certain operating rooms, for instance for intercardial procedures, and can be established via the potential equalization connection (24). The required connecting cable is not included in the scope of delivery and can be obtained from us if needed.

4.4 Turning the device on and off

POWER

After turning on the power switch (17), the device is operational. The display window above the switch has to light up green.

4.5 Connecting accessories

4.5.1 Connecting the neutral electrode

Connect the neutral electrode to the connection (14). One-piece neutral electrodes or versions with two partial areas that make it possible to monitor the contact to the patient may be connected.

If no neutral electrode is connected, the red neutral electrode indicator lamp (12) flashes in the monopolar operating mode (this is not the case in the bipolar operating mode). If an attempt is made to activate the device with the finger or foot switch in monopolar operating mode in this state, an audible warning sounds in addition. RF current cannot be activated.

This has no influence on the bipolar coagulation current.

When an electrode with more than one surface is connected, the indicator lamp (12) only turns off after the safe application state is reached. Since individual warm-up times can be expected here, the additional required time must be taken into account when such electrodes are used.

NOTE

Insufficient contact between the neutral electrode and patient only triggers an acoustic warning signal when a neutral electrode that supports monitoring is used with the contact quality monitor.

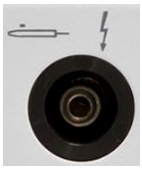
Also see chapter 6.3 for further information about the proper use of neutral electrodes.

WARNING

Risk of burns due to improper handling of the neutral electrode!

Also see chapter 6.3 for further information about the proper use of neutral electrodes.

4.5.2 Connection of monopolar handles



A handle with finger switch or a handle without finger switch in combination with a foot switch can be connected for monopolar cutting and coagulating. Handles are connected to the connection (10). The desired active electrode must be inserted into the surgery handle so that it is held securely.

The foot switch is connected to the connection (25) on the rear of the device.

WARNING

There is a risk of burns due to the use of inadequately insulated instruments when working with monopolar coagulation currents!

In case of inadequate or damaged instrument insulation, there is a risk of exposing the user to HF voltages. A surgery glove does not constitute defined electrical insulation. It does not protect against possible electrical discharge.

In case of indirect application using a handheld instrument (surgical tweezers), the instrument should be insulated so the user is not exposed to the HF voltage transmitted to it.

4.5.3 Connecting bipolar accessories

An instrument connection cable is connected to the jack (20) for bipolar coagulation. A variety of bipolar instruments can be connected to this cable.

Activation is exclusively with the foot switch connected to the jack (25) on the back of the device.

The neutral electrode does **not** have to be connected for bipolar coagulation.

However, simultaneously applying the neutral electrode has no influence on the safety and effectiveness of bipolar coagulation.

WARNING

Risk of burns!

Risk of electric shock due to contact with live components!

Activating the high-frequency current is not permitted while inserting the electrode and during electrode replacement.

4.5.4 Selecting the current type

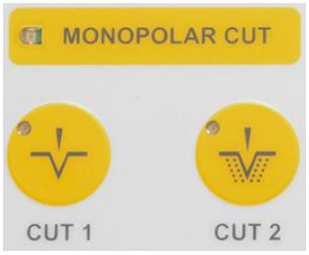
The BM-780 II has three operating modes:

Monopolar CUT (monopolar cutting)

Monopolar COAG (monopolar coagulation)

Bipolar COAG (bipolar coagulation)

To differentiate between these operating modes, the front is divided into three operator panels:



In the “Monopolar CUT” operator panel identified in yellow on the front plate, a lamp (2) indicates the activation of the cutting current and two different current types are available for cutting:

CUT 1 (1)	Smooth cut with no coagulation zone
CUT 2 (3)	Cutting current with coagulation zone

In the “Monopolar COAG” operator panel identified in blue on the front plate, a lamp (5) indicates activation of the monopolar coagulation current and two current types are available for coagulation:

CONTACT (4)	Coagulation with depth effect on direct contact between the electrode and tissue.
SPRAY (6)	Coagulation current with low depth effect for surface coagulation with sparks (fulguration).

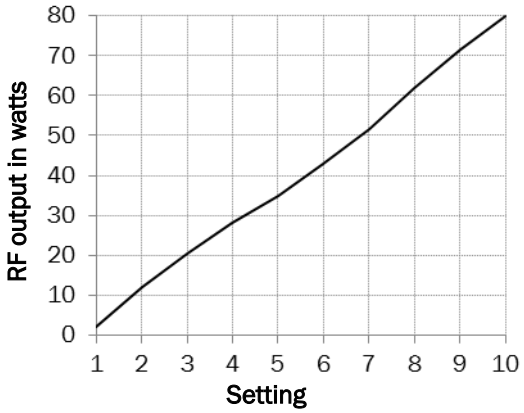
In the “Bipolar COAG” operator panel identified in blue on the right of the front plate, a lamp (8) indicates activation of the bipolar coagulation current. One current type is available for bipolar coagulation:

PRECISE (9)	Local contact coagulation in the area of the bipolar electrode pair.

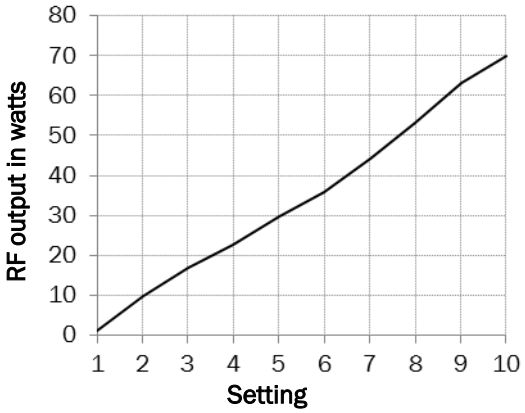
4.5.5 Setting the output power

The output adjuster (7) is used to set the output power. The output setting ranges from a specified minimum value up to a maximum value depending on the selected current type (see technical data, chapter 9.1). Here the increase in the output power is close to linear with the rotation angle. See the diagrams below for the relationship for each current type.

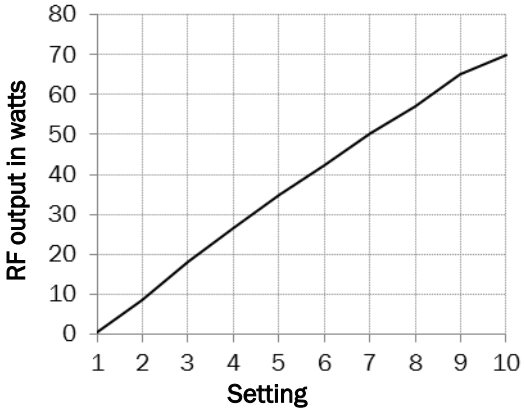
CUT 1



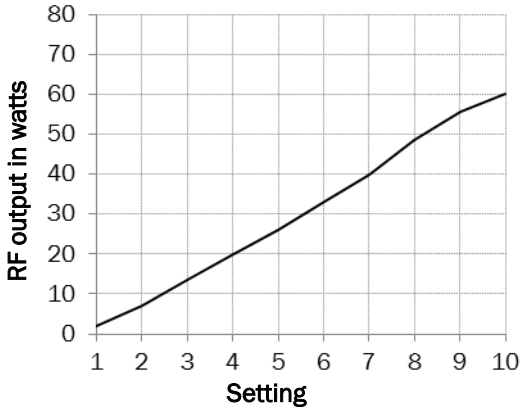
CUT 2



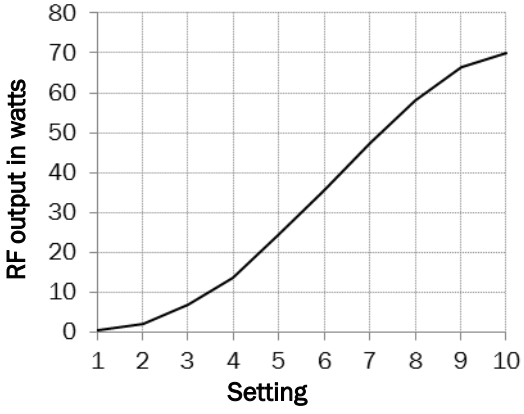
CONTACT



SPRAY



PRECISE



5 Operation

Upon activation, the RF current is turned on according to the previously selected operating mode by operating the switch on the handle or the foot switch. The RF current is produced according to the previously selected output setting. A continuous audible signal accompanies activation and the indicator lamp corresponding to the operating mode lights up.

NOTE

For safety reasons, always perform a functional test of the foot switch prior to surgical application. Activate the pedal with the electrosurgery device turned on. To prevent unintentional burns, perform the functional test without electrode cables connected to the electrosurgery device.

WARNING

The rules for electrosurgery application described in chapter 6 for patients and users generally have to be observed. In particular, ensure safe application of the neutral electrode and proper positioning of the patient.

WARNING

An active accessory that withstands the RF peak voltages in the respective selected mode must be used for safe application.

Only accessories in sound condition may be used.

WARNING

HF current application for a long time with a high output can cause the surface of the device to become very hot.

5.1 Special function

The device is equipped with the following special function.

The AutoRF™ function monitors and controls the power output of the device depending on the state of the tissue.

5.2 Function test

All device functions should be checked before using the device. Please perform the following function tests:

1. Pull the plug of the connection cable for the neutral electrode out of the connection socket (14). The red warning lamp (12) flashes. When attempting to activate a monopolar RF current, an intermittent acoustic warning signal sounds instead of the continuous activation current. RF current activation is blocked. On the other hand, the bipolar current can be activated if selected; in this case, the red warning lamp will not flash.
2. Connect the plug of the connection cable for the neutral electrode to the connection socket (14) again. The red warning lamp (12) has to stop flashing. If a segmented neutral electrode is used, it must be correctly applied to the patient for the warning lamp to turn off.
3. Connect the connection cable with the electrode handle to the jack (10). Activate the chosen current with the finger switch on the electrode handle or the foot switch. The indicator lamps assigned to the current types (2), (5) or (8) have to light up according to the selected current type and the RF activation signal has to sound.

   Please note that bipolar coagulation can only be activated using the foot switch.

WARNING

If the HF activation signal sounds without the foot switch or electrode connected, the device is defective and may not be operated. A technical inspection is required.

If the RF activation signal sounds with the foot switch or electrode handle connected **without** activating one of the control elements, one of these accessories is defective. Continuing to operate this accessory is not permitted. It must be replaced.

6 Safety measures

6.1 General information

Electrosurgery devices are high-frequency generators that generate high voltages and currents for their intended application. To avoid danger for the patient, operating personnel, or third parties, this method must be applied carefully and strict compliance with the operating and safety instructions is required.

A medical device record must be maintained according to the operator ordinance.

Any serious-incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

WARNING

Risk of burns due to high HF current concentration!
The hazard potential of electrosurgery increases with the applied output.

Failure to comply with the safety measures listed below results in the possibility of severe or even fatal injury to the patient or user!

- A defect in an electrosurgery device can cause an unwanted increase in the output power. In order to prevent this, a protective circuit against overdosing is integrated into the BM-780 II.
- Risks due to high electric voltage!
- The RF output should be set as low as possible for the respective application.
  - ➔ Note however that setting the output too low can also constitute a risk, for instance because a first cut is not made due to excessively low output so that local coagulation occurs where it is not desirable or even dangerous.
- An inadequate effect with the usual setting may for instance be due to poor application of the neutral electrode, poor contact in plug connections, cables broken underneath the insulation, or encrusted electrodes. This needs to be checked and defective components must be replaced as needed.
- The use of RF surgery devices may generate sparks on the active electrode.
  - ➔ Consequently, the use of ignitable anesthetics, nitrous oxide (N_2O), and oxygen should be avoided.
  - ➔ Combustible substances used as cleaning agents, disinfectants, or solvents must evaporate before the application of RF surgery.
  - ➔ There is a risk that combustible liquids may accumulate under the patient or in body recesses such as the navel or body cavities such as the vagina. Liquids that have accumulated in these places must be wiped up before the RF surgery device is used.
  - ➔ There is a risk that endogenous gases may ignite.
  - ➔ Materials saturated with oxygen such as cotton wool and gauze may be ignited by the sparks that form during the intended use of the RF surgery device.
- The application of a current type with a high voltage, in particular a monopolar high-voltage coagulation current type, can cause neuromuscular stimulation on the patient.

- Combinations with other devices may only be realized by the manufacturer or with the manufacturer's consent.
- The operation of the RF surgery device may interfere with other electromedical devices.

6.2 Patient positioning

For monopolar applications, the electric current supplied to the patient by the electrosurgery device via the active electrode can travel either

- along the regular path that leads through the neutral electrode, which conducts the current from the patient to the device over a large area and therefore without the heating effect that occurs on the active electrode, or
- along an unwanted bypass that can form when the patient is in contact with conductive components that are connected to ground potential.
  - ➔ These are all large-scale metal components such as the frames of treatment tables, operating tables, chairs with metal frames, and the housings of electrical equipment supplied by the mains network.
  - ➔ The patient must not have any contact with grounded metal components, otherwise there is a risk of point burns at the contact points. Especially the patient's limbs should not be in contact with metal fixtures.

The following information also has to be observed when using an RF generator:

- If the patient is lying on an operating table or treatment table with a metal frame, high-frequency insulation to the metallic surface should be ensured by a sufficient number of pads (drapes).
- If moisture, perspiration, and the like is expected during the operation, wetting of the pads serving as high-frequency insulation must be prevented with waterproof film where applicable.
- The accumulation of fluids under the patient must be prevented under all circumstances. Additional dry cloth layers must be used as needed.
- Route the supply cables to the RF electrodes without loops so that they touch neither the patient nor other cables. This applies in particular to the cable for the neutral electrode. Only the cables intended for the device by the manufacturer may be used.
- The RF current flowing through the body must reach the neutral electrode along the shortest possible path.
  - ➔ Ensure that the current does not leave the body and re-enter it in a different place on the way to the neutral electrode, for example in case of contact between the hand and thigh or elbow and torso. This current bypass causes a risk of burns at such contact points.
  - ➔ Accordingly, areas with high levels of perspiration should be kept dry with drapes, limbs in contact with the trunk or skin-to-skin contact should be separated with layers of drapes (arm/torso, leg/leg, mammae).

After repositioning the patient, the electrodes, cables, and insulating layers must be checked to verify they are correctly positioned.

WARNING

Risk of burns due to stray currents!

If HF current concentrates in small areas, this can cause burns. For concurrent monopolar and bipolar application, ensure that a minimum distance of 10 cm is maintained between the respective cables. All cables must be routed without strain and loops.

6.3 Application of neutral electrodes

Attach neutral electrodes and cables carefully. The following points in particular have to be observed:

- Secure contact of the neutral electrode must be ensured for the entire RF application duration. The circulation must not be impaired by the application of the neutral electrode to limbs.
- The neutral electrode has to be applied as close as possible to the surgical area, reliably, and with its entire surface in contact with the patient's body.
- The neutral electrode has to be applied in a suitable, prepared location on the patient's body.
- The current paths in the body must be as short as possible and run lengthwise or diagonal to the body, not crosswise, the latter under no circumstances on the thorax.
- Any metal components in and on the body must be removed if possible, insulated, or require special attention.
- To ensure continuous application of the neutral electrode during the entire duration of the operation, we recommend a split disposable adhesive neutral electrode. Continuous monitoring of the patient is only ensured with a split adhesive neutral electrode.
  - ➔ Monitoring is not possible with a one-piece neutral electrode. No warning signal is triggered in case of poor contact! Monitoring is not possible when non-compatible neutral electrodes that support monitoring are used.
- When using disposable adhesive electrodes, ensure that the expiry date has not passed.
- Second and third-degree burns can occur when using adhesive electrodes with a damaged gel layer. Pulling adhesive electrodes off quickly can cause skin injuries.
  - ➔ Adhesive electrodes with a damaged gel layer may not be used under any circumstances.
  - ➔ Ensure that the gel-free connecting lugs of an adhesive electrode are entirely covered by the cable connection clip so they cannot come into contact with the patient's skin.
- The risk of a burn under the neutral electrode is particularly great when monopolar cutting or contact coagulation currents with an especially high output power and long activation time are used.
- Since methodical switching between bipolar and monopolar application can be expected during the course of an operation, we recommend applying the neutral electrode in all cases.
- Applying the neutral electrode to implants and other metal components, or to bony protrusions and scar tissue, is not permitted. The application site may have to be prepared by cleaning and degreasing, and the removal of heavy hair growth. Substances that dry out the skin (such as alcohol) may not be used for removal.

- When RF surgery and monitoring screens are used simultaneously on a patient, only monitoring electrodes with supply cables that contain protective resistors or RF inductors may be used. Needle electrodes for monitoring may not be used. The active surgery electrode must not be used in the vicinity of the ECG electrodes (minimum distance 15 cm).
- Do not pull on the cable or connecting lug to remove the neutral electrode. Pulling adhesive electrodes off quickly can cause skin injuries.
- Observe the instructions for use provided for the neutral electrode.

6.4 Pacemaker, active and passive implants

WARNING

For patients with metallic implants, RF current paths generally may not pass through these implants. This must be taken into account for the application of the active and neutral electrode. Applying the neutral electrode via endoprostheses or metallic implants is prohibited.

NOTE

Patients with active implants such as pacemakers or implanted electrodes may be endangered by the application of the RF surgery device. Irreparable damage to the active implant or an impairment of its function are possible effects. Because of these uncertainties, electrosurgery should only be used on such patients when there is no equivalent alternative. The guidelines that follow must be observed.

- The implant manufacturer's instructions for use have to be observed.
- Monitoring such patients with suitable monitoring devices is recommended.
- Keep a defibrillator and external pacemaker ready for use.
- The following applies for the electrosurgery device:
  - ➔ Choose the lowest possible output power setting.
  - ➔ The active electrode of the electrosurgery device should not be used closer than 15 cm to the active implant or its electrodes.
  - ➔ Carefully follow the instructions for use, such as the application of the neutral electrode.

NOTE

Use bipolar technology if possible.

6.5 Handling electrosurgery instruments

Please observe the following information when using RF instruments:

- The supply lines and instruments used must be designed for the RF voltages of the BM-780 II and these must not be exceeded (see the voltage diagrams in chapter 9.2.2).
- A visual inspection of accessories should always be performed prior to use.
- No electrosurgery instruments of any kind may be set down on the patient during application pauses.

- Parallel connections for the HF current or concentrated leakage current paths can form if the active electrode makes contact with metallic components. This can cause burns.

WARNING

Risk of burns! Unintentionally operating a finger or foot switch can cause uncontrolled HF activation. This can lead to an unwanted thermal effect on a part of the body, for example when a surgery instrument is connected.

6.6 Risks due to electromagnetic interference

WARNING

The intended use of electrosurgery instruments that generate a high-frequency current, such as the BM-780 II, may interfere with other electromedical equipment (such as ECG monitoring) and electronic equipment (such as telephones or PCs) during the activation of the HF current.

WARNING

Radio equipment, mobile telephones, or other transmitters operated in the immediate vicinity of the RF generator may impair its safe functioning.

See chapter 9.3 for the minimum distances from transmitters.

The following steps can be taken to reduce this interference:

- Connect the mains cable of the BM-780 II to a different outlet.
- Increase the distance between the BM-780 II and the other device (not directly adjacent to each other or stacked).
- If devices are operated next to each other or stacked with the BM-780 II, the functioning of both devices must be monitored.
- Ensure the potential equalization bolt (24) is connected to a proper ground.
- Route instrument cables so that they are not close to other devices and their connection cables, to the extent possible.
- Route connection cables so that they are not close to other devices if possible.

6.7 Accessories

Sutter Medizintechnik recommends the following tested accessories:

- Bipolar silicone cable, length 4.5 m (REF 370138 L)
- Monopolar electrode handle for electrode shaft Ø 2.4 mm, cable length 4 m (REF 360218)
- Connection cable for single use neutral electrodes, length 4.5 m (REF 360236)
- Foot switch (REF 360105, 360109)
- Single-use patient plate, split, for adults and children (REF 29 00 - 5)

Products shown in this IFU are subject to regulatory approval in individual markets. Products may therefore not be available in all markets.

NOTE

The device may only be used with accessories, wear parts and single use products for which safe, unproblematic use is confirmed by a declaration of conformity.

Using untested accessories from other manufacturers may lead to increased electromagnetic interference emissions or reduced electromagnetic interference resistance of the device and to faulty operation.

If you use accessories from other manufacturers, it is therefore particularly important to ensure that the accessories are in fact suitable. Indicators of legitimate manufacturers and suitable accessories include the following points:

- The manufacturer has a declaration of conformity for the accessory.
- The manufacturer has proof of compatibility for the accessory, or is willing to confirm this for you.
- The accessory includes instructions for use that clearly describe the scope of functionality in easily comprehensible terms.
- The accessory has suitable plug connections that can be connected to the device without excessive force and problems.
- The manufacturer is willing to confirm testing of the accessory according to the international IEC 60601-2-2 standard on request.
- The accessory products are labeled, clearly legible, e.g. with information about the manufacturer and their maximum dielectric strength.
- The manufacturer provides you with additional technical data and specifications on request, and is available for your inquiries during regular business hours.

Ask your specialist dealer or the manufacturer in case of doubt.

WARNING

Avoid settings on the device where the maximum output voltage exceeds the rated voltage for the accessory (see the voltage diagrams in chapter 9.2.2).

If components form a system together with the BM-780 II (for instance connection of a flushing pump or joint connection on one power strip), these have to meet the requirements of the respective medical environment. IEC/EN 60601-1 (3rd edition, section 16) in particular must be taken into account. Contact the manufacturers of the components or equipment in case of doubt.

7 Safety-related inspections

The following inspections must be carried out on this device at least every 24 months by persons who, based on their education, knowledge, and experience gained through practical activity, are able to perform such safety-related inspections properly and who are not subject to any directives in regards to this inspection activity.

NOTE

No maintenance tasks may be carried out on the BM-780 II while it is in use.

NOTE

The product may only be repaired by the manufacturer or an agent expressly authorized by the manufacturer. Otherwise the warranty and any possible additional liability claims against the manufacturer are voided.

The following safety-related inspections have been established:

- Inspect the device and accessories for mechanical damage that impairs functionality.
- Check safety-related labeling for legibility.
- Check the nominal current and melting characteristics of fuse links for the equipment fuses.
- Perform a functional test according to the instructions for use (see chapter 5.2).
- Check the concordant increase in the energy output according to the rotational direction of the output adjuster (7).
- Perform a nominal/actual value comparison of the maximum energy output on both outputs for the available operating modes with the corresponding nominal load resistors specified in chapter 9.2.
- Check audible and visual feedback during output.
- Electrical inspection according to the test report for recurring safety-related inspections.
- Leakage currents must not be greater than 1.5 times the initially measured value and simultaneously not exceed the limit value.

  ➔ See the supplied test reports from the initial installation for the initially measured value.

We recommend recording the safety-related inspections in a medical device record and documenting the inspection results.

If the safe functioning and/or operation of the device is not given, it must be repaired or the operator must be notified of the hazard emanating from the device.

The manufacturer will gladly perform the safety-related inspections properly and provide you with a replacement device in the interim. A fee is charged for performing the inspections and for the replacement device. Please contact the manufacturer or your specialist dealer.

8 Care instructions

8.1 Cleaning and disinfection

Disconnect the device from the mains network for cleaning and disinfection. Liquids must not be allowed to get into the interior of the device when applying or spraying cleaning agents and disinfectants.

All exterior surfaces of the device, including the front plate, can be cleaned with conventional cleaning agents that do not contain alcohol.

Never clean the device with scouring agents, disinfectants, or solvents that my scratch the housing or damage the device.

The surfaces of the device and accessories that cannot be sterilized can be disinfected using disinfectants commonly used in medical practices and surgery departments.

Disinfectant residues must be removed entirely before putting the device into operation.

NOTE

Accessories for electrosurgery devices must be kept in flawless, functional condition at all times. Non-functional, damaged, or defective accessories may pose a hazard for the patient or the user, and can impair the proper functioning of the electrosurgery device. Accessories that are not suitable for use must be separated.

8.2 Sterilization of accessories

Be sure to observe the information provided with accessories for their care and reconditioning.

8.3 Accessories that cannot be sterilized

Accessories that cannot be sterilized, such as the foot switch, also require regular disinfection by wiping.

The instructions for use of the BM-780 II do not replace the instructions for use of the accessories.

9 Technical information

9.1 Technical data, standards, certification

Mains supply	100 – 240 V; 50/60 Hz	
Power consumption	without RF output	approx. 16 VA
	at max. output power	approx. 120 VA
Protection class	I	
Protection level	IP2X	
MPG classification	II b	
LF and RF leakage currents	according to IEC 60601-1 and IEC60601-2-2	
Type	BF; defibrillator safe	

RF output parameters:

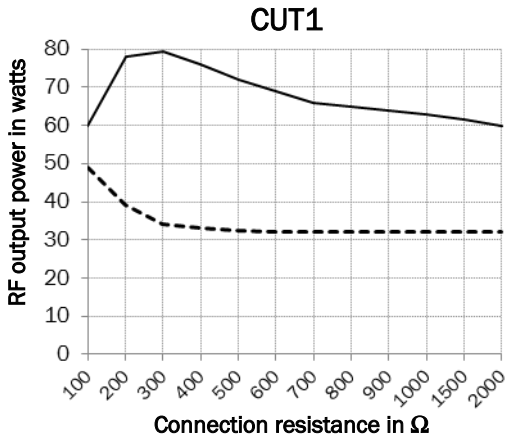
Current type	Output	On load resistor	Max. HF output current	Nominal frequency	Modulation frequency
CUT 1	Max. 80 W	± 20 % on 300 Ω	510 mA	0.92 MHz	-
CUT 2	Max. 70 W	± 20 % on 300 Ω	480 mA	0.92 MHz	58 kHz
CONTACT	Max. 70 W	± 20 % on 200 Ω	600 mA	1.23 MHz	77 kHz
SPRAY	Max. 60 W	± 20 % on 300 Ω	450 mA	0.46 MHz	58 kHz
PRECISE	Max. 70 W	± 20 % on 50 Ω	1200 mA	0.46 MHz	-

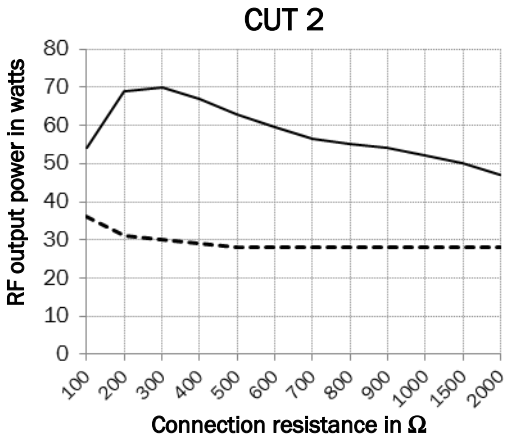
Operating mode	Intermittent INT 10 s /30 s corresp. 25 % ED
Mains fuses	100 – 240 VAC, 2 x T 1.6 AH 250 V G 5x20mm
Signal level	RF indicator: 55 dB(A) Alarm: 65 dB(A)
Weight	Approx. 3.9 kg
Dimensions	W x H x D 295 mm x 136 mm x 280 mm
Standards	IEC 60601-1: 2005 + Cor.:2006 + Cor.:2007 + A1:2012 IEC 60601-1-2: 2014 IEC 60601-2-2: 2017
CE 0297	Conforming to article 120(3) of Council Regulation (EU) 2017/745 (MDR)

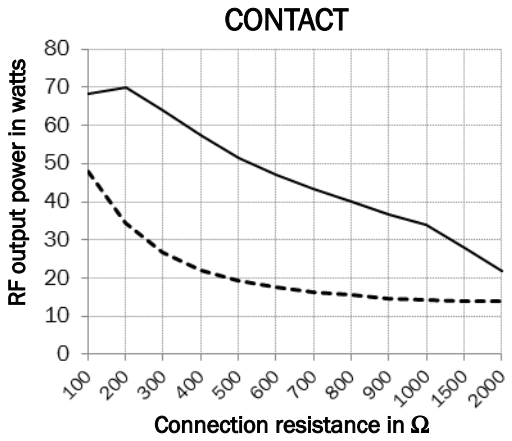
Environmental conditions for transportation and storage	Ambient temperature	-25 °C to +70 °C
	Relative humidity	10% to 100%
	Atmospheric pressure	500 hPa to 1060 hPa
Environmental conditions for operation	Ambient temperature	+10 °C to +40 °C
	Relative humidity	30% to 75%
	Atmospheric pressure	700 hPa to 1060 hPa

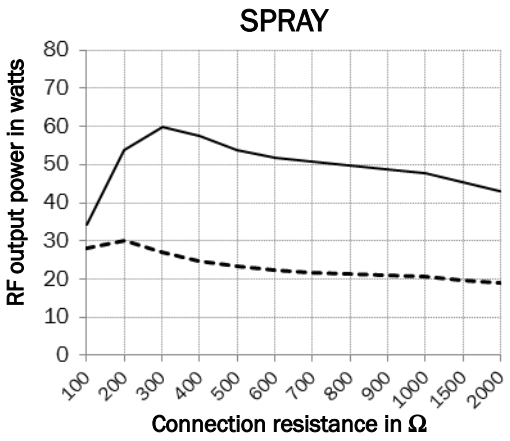
9.2 Diagrams

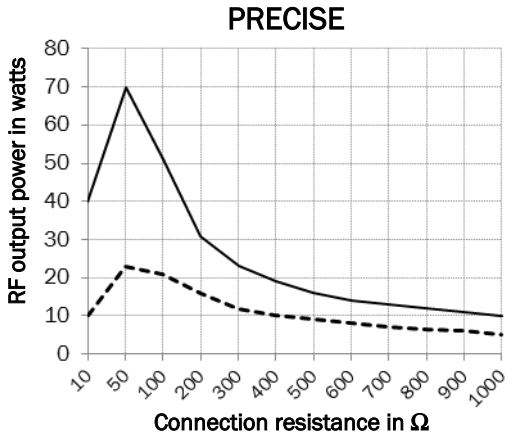
9.2.1 RF output





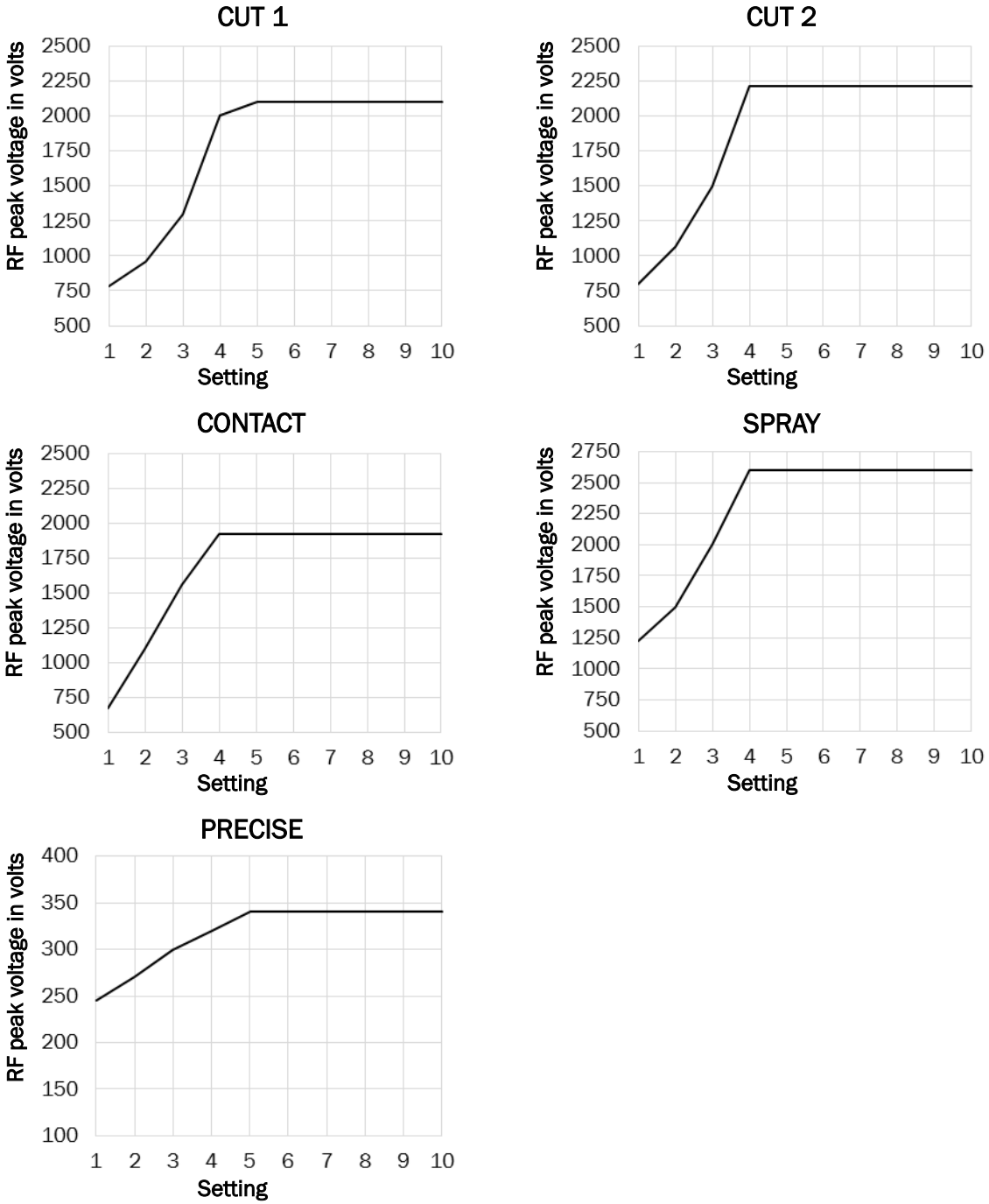






——— Setting “10” (maximum output power)
- - - - Setting “5” (half output power)

9.2.2 RF voltage



WARNING

An active accessory that withstands the RF peak voltages in the respective selected mode must be used for safe application.

9.3 Guidelines and manufacturer declaration for electromagnetic compatibility

Guidelines and manufacturer declaration according to IEC 60601-1-2:2014, section 7: Electromagnetic emissions		
The BM-780 II is intended for operation in an electromagnetic environment as specified below. The customer or user of the BM-780 II must ensure that it is operated in such an environment.		
Interference resistance tests	**Compliance level**	**Electromagnetic environment – guidelines**
HF emissions according to CISPR 11	Group 2	The BM-780 II has to emit electromagnetic energy for its intended function. Interference with devices in the vicinity is possible.
HF emissions according to CISPR 11	Class B	Compliance with the class only in operational readiness without the activation of HF current!
Emission of harmonics according to IEC 61000-3-2	Class A	The BM-780 II is suitable for use in all facilities, including residential facilities and those connected directly to the regular, public supply network for residential buildings.
Emission of voltage fluctuations/flicker according to IEC 61000-3-3	Complies	

Guidelines and manufacturer declaration according to IEC 60601-1-2:2014, section 8.9: Electromagnetic emissions			
The BM-780 II is intended for operation in an electromagnetic environment as specified below. The customer or user of the BM-780 II must ensure that it is operated in such an environment.			
Interference resistance tests	**Test level according to IEC 60601**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be made of wood or concrete, or covered in ceramic tiles. If synthetic floor coverings are installed, the relative humidity must be at least 30 %.
Fast transient electrical interference/burst according to IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a normal commercial or hospital environment.
Impulse voltage/surges according to IEC 61000-4-5	±1 kV differential mode voltage ±2 kV common mode voltage	±1 kV differential mode voltage ±2 kV common mode voltage	The quality of the supply voltage should correspond to a normal commercial or hospital environment.
Voltage drops, brief disruptions, and fluctuations in the supply voltage according to IEC 61000-4-11	0 % U_T (100 % drop of U_T) for ½ period at 0, 45, 90, 135, 180, 225, 270, 315 degrees 0 % U_T (100 % drop of U_T) for 1 period 70 % U_T (30 % drop of U_T) for 25/30 periods, single phase at 0 degrees 0 % U_T (100 % drop of U_T) for 250/300 periods	0 % U_T (100 % drop of U_T) for ½ period at 0, 45, 90, 135, 180, 225, 270, 315 degrees 0 % U_T (100 % drop of U_T) for 1 period 70 % U_T (30 % drop of U_T) for 25/30 periods, single phase at 0 degrees 0 % U_T (100 % drop of U_T) for 250/300 periods	The quality of the supply voltage should correspond to a normal commercial or hospital environment. If the user of the BM-780 II requires continuous functioning even in case of energy supply interruptions, supplying the BM-780 II from an uninterruptible power supply is recommended.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields for the mains frequency should correspond to the typical values found in commercial or hospital environments.
NOTE: U_T is the AC mains voltage prior to application of the test levels.			

Guidelines and manufacturer declaration according to IEC 60601-1-2:2014, section 8.9: Electromagnetic interference resistance			
The BM-780 II is intended for operation in an electromagnetic environment as specified below. The customer or user of the BM-780 II must ensure that it is operated in such an environment. Radio equipment, mobile telephones or other transmitters operated in the immediate vicinity may impair the functioning of the device.			
Interference resistance tests	**Test level according to IEC 60601**	**Compliance level**	**Electromagnetic environment – guidelines**
Conducted HF interference according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz 6 V_{eff}[a] in ISM frequency bands 150 kHz to 80 MHz	3 V_{eff} 150 kHz to 80 MHz 6 V_{eff}[a] in ISM frequency bands 150 kHz to 80 MHz	Portable and mobile radio devices should not be used closer to the BM-780 II (including cables) than the recommended separation distance of **30 cm**. The field strength of stationary radio transmitters for all frequencies should be lower than the compliance level[b] according to on-site testing.[b]. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated HF interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
NOTE	These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		

[a] The ISM bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; 40.66 MHz to 40.70 MHz

[b] The field strength of stationary transmitters such as base stations of mobile telephones and mobile radio devices, amateur radios, AM and FM radio and TV transmitters cannot be theoretically determined exactly in advance. In order to determine the electromagnetic environment in regards to the stationary transmitters, a site survey should be considered. If the measured field strength at the location where the BM-780 II is used exceeds the aforementioned compliance level, the device should be monitored to ensure it is functioning properly. Should unusual performance characteristics be observed, additional measures may be required, such as changing the alignment or location of the BM-780 II.

Recommended separation distances between portable and mobile HF telecommunications devices and the BM-780 II according to IEC 60601-1-2:2014, section 8.10				
Specification for high-frequency wireless communication equipment				
Frequency band (MHz)	Test frequency (MHz)	Modulation	Compliance level (V/m)	Distance (m)
380 - 390	385	Pulse modulation[a] 18 Hz	27	0,3
430 - 470	450	FM[b] ±5 kHz deviation or pulse modulation[a] 18 Hz	28	0,3
704 – 787	710, 745, 780	Pulse modulation[a] 217 Hz	9	0,3
800 – 960	810, 870, 930	Pulse modulation[a] 18 Hz	28	0,3
1700 – 1990	1720, 1845, 1970	Pulse modulation[a] 217 Hz	28	0,3
2400 - 2570	2450	Pulse modulation[a] 217 Hz	28	0,3
5100 - 5800	5240, 5500, 5785	Pulse modulation[a] 217 Hz	9	0,3
NOTE	The minimum safety distance of 30 cm between portable HF communication devices transmitting in the specified frequency band and the BM-780 II should be maintained. This includes cellular phones, WiFi, RFID, and Bluetooth devices among others. Failure to comply can impair the performance characteristics of the device.			
[a] Pulse modulation	Pulse modulation is defined as a square wave signal with a pulse-duty factor of 50 %.			
[b] FM	Frequency modulation			

10 Environmental notices

10.1 Packaging

The entire packaging can be returned to the seller for recycling.
Otherwise dispose of the packaging as waste paper and/or household garbage.

10.2 Environmentally friendly device operation

During the vaporization of tissue, you should avoid the concentrated, longer-term inhalation of the burn-off that occurs during intended use. Hazardous substances other than the aforementioned burn-off do not develop during the intended use of the device. A flue gas extraction system may be used for burn-off extraction.

Not only from the perspective of improved occupational safety but in particular also in the interest of energy conservation, we recommend turning off the device during longer treatment pauses.

If disposable products are used in the course of treatment, please note that these shall only be disposed of in household garbage or as hazardous waste after careful cleaning, disinfection and if applicable sterilization. Infected sharp components of disposable instruments are treated like other “sharps” (cannulas, needles, and scalpels) according to the applicable directive (disposal in germ-proof and puncture-proof containers).

10.3 Device disposal

The use of composite materials was largely avoided in designing the device. This enables a high degree of recycling when the device reaches the end of its service life. The requirements of the electronic scrap directive must be met in the course of disposal, or the device has to be returned to the manufacturer/distributor for proper disposal.

Labeling of electric and electronic equipment according to Directive 2002/96/EC (WEEE) and the German Electrical and Electronic Equipment Act (ElektroG)

The symbol on the product or its packaging indicates that this product may not be disposed of as regular household garbage.

Notes

Notes

Address of the manufacturer

Distributed by:

Manufacturer:

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