ATMOS RS 221
Radiosurgical unit
with automatic switchoff
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Notes on operating instructions

These operating instructions contain important notes on how to operate the ATMOS RS 221 safely, correctly and effectively. Their reading helps to avoid risks, and also to reduce repair costs and down-time. That increases, amongst other things, the reliability and service-life of the device. These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. Reprints (also in extracts) only with permission in written form by ATMOS.

These operating instructions must always be kept available near the device.

Care and safety inspections in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS RS 221 and are therefore a must besides regular cleaning. Repair work and safety inspections may be carried out only by expert personnel authorised by ATMOS. By applying only original spare parts you will have the guarantee that operational safety, readiness for work and the value of your ATMOS RS 221 will be preserved.

- The product ATMOS RS 221 bears CE marking CE according to the EU guideline of the council for medical products 93/42/EWG and meets the basic requirements of annex I of this guideline.
- The product ATMOS RS 221 complies with all applicable requirements of the directive 2011/65/EC restricting the use of certain hazardous substances in electrical and electronic equipment ("RoHS")
- The declaration of conformity can be obtained on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 9001 and EN ISO 13485.
- Prior to start-up please peruse chapter 2.0 „For your safety", in order to be prepared for any possible dangerous situations.

To cope with their different applications, modern radio frequency surgical units have to provide currents that must be reproducible in intensity and curve (wave form) to a larger degree and more dependable than is known for older devices.

Radiosurgery is an atraumatic method to cut and coagulate soft tissue.
The cutting effect - known as electrosection - is achieved without manual pressure or cellular contusion. This results from the heat generated by the radio frequency current running against the tissue’s electric resistance. The current is induced into the tissue by means of a delicate electrode called a surgical or active electrode. The heat separates and vaporizes the cells located in the way of the current in immediate proximity to the active electrode. This results in a cutting of tissue just as a scalpel would do. The radio frequency current then flows off at the surface of the body, thus preventing electrical shock.

Radio frequency coagulation is a destruction of tissue without evaporation of cells caused by radio frequency currents. The atraumatic nature of radio surgery offers remarkable advantages. Avoiding traumatization leads to a healing of the tissue without generating fibrous, contractile scar tissue that would be typical for the healing process of wounds caused by manual cutting. An equally significant advantage is in the sterilizing effect of high frequency surgery. Summing up these advantages, radio frequency surgery eases, quickens and improves all surgical measures. It further helps to eliminate unfavorable post-operative symptoms such as pain, swelling and infection. The application of radio surgery prevents post-operative shock through excessive loss of blood that is often encountered after comparable measures where traditional methods were used.

Please pay attention to the special operating instructions enclosed regarding the application of the handle, electrodes and other accessories.
Name: ATMOS® RS 221

Main functions:
Radiosurgery device for cutting and coagulation

Med. indications/ application:
In surgeries for the opening and coagulation as well as for the volume reduction and dehydration of tissue.

Specification of the main function:
The current is induced into the tissue by means of a delicate electrode called a surgical or active electrode. The heat separates and vaporizes the cells located in the way of the current in immediate proximity to the active electrode. This results in a cutting of tissue just as a scalpel would do (max. 100 watt). The radio frequency current then flows off at the surface of the body, thus preventing electrical shock. During the coagulation (max. 90 watt) the supplied heat serves for haemostasis.

Application organ: Tissue, skin

Application time:
Temporary use on the patient (< 60 minutes).

Application site:
The application site is the clinical, outpatient as well as the practices area.
The application of the device may only be performed by medical trained and introduced staff.

Contraindications:
No application on patients with active implant devices or systems (exception: regulations chapter 3 user manual will be adhered).
No application in explosive or flammable areas.

The product is: X active □ not active

Sterility: Not necessary

Single use product / reprocessing:
The device and the accessories are partially reusable. For information on reprocessing, cleaning and disinfection see user manual.
2.0 Scope of supply and connections

Scope of supply
Basic device, line cord, operating manual, instruction manual, ENT accessories, set of electrodes

Options

ATMOS RS 221 monopolar set  REF 506.5850.0
Handpiece with yellow release button
Handpiece with blue release button
Standard set of electrodes (7 electrodes)
Neutral electrode with rubber fixation
Cable for the neutral electrode

ATMOS RS 221 bipolar set  REF 506.5860.0
Bipolar tweezers, bayonet, L=195 mm
Foot switch
Bipolar cable, length 2.5 m

Accessories:

Handpiece, cutting (for 2,4mm electrodes), cable length 2,5 m  506.5851.0
Handpiece, coagulation (for 2,4mm electrodes), cable length 2,5 m  506.5852.0
Neutral electrode  506.5853.0
Cable for the neutral electrode  506.5854.0
Rubber bandage for neutral electrode 0,5 m  506.5855.0
Foot switch with 2,5 m cable  506.5861.0
Bipolar cable, length 2,5 m  506.5862.0
Bipolar tweezers, bayonet, L=195, width of tip 1.0 mm, length of tip 6.0 mm  506.5863.0

Consumables:

ATMOS RS 221 monopolar set
Handpiece with yellow release button
Handpiece with blue release button
Standard set of electrodes (7 electrodes)
Neutral electrode with rubber fixation
Cable for the neutral electrode

ATMOS RS 221 bipolar set
Bipolar tweezers, bayonet, L=195 mm
Foot switch
Bipolar cable, length 2,5 m

Options

Connection
monopolar COAG
Connection
monopolar cut
Connection
bipolar COAG
2.0 Operating elements

- **ON** I
- **OFF** 0

**Symbol for operating mode neutral electrode**

**Symbol for neutral electrode (glows red at malfunction)**

**Symbol for type of device according to EN 60601**

---

**MONO CUT**

1. Cutting monopolar
2. Monopolar cutting with coagulation / setting of coagulation degree
3. Output / coagulation degree lower
4. Output / coagulation degree higher
5. Display output / coagulation degree

**MONO COAG**

1. Permanent coagulation monopolar / setting of coagulation degree
2. Pulse coagulation monopolar / setting of pulse duration
3. Output / coagulation degree / pulse duration shorter
4. Output / coagulation degree / pulse duration longer
5. Display output / coagulation degree / pulse duration

**BIPOL COAG**

1. Permanent coagulation bipolar / setting of coagulation degree
2. Pulse coagulation bipolar / setting of pulse duration
3. Output / coagulation degree / pulse duration shorter
4. Output / coagulation degree / pulse duration longer
5. Display output / coagulation degree / pulse duration
The icons displayed on the device and the identification plate carry the following meaning:

- Device classification: Type BF and defibrillator proof.
- Device emits non-ionizing radiation. RF radiation.
- Neutral electrode, grounded
- Attention: See operations manual!
- 0482 CE mark in conformity with 93 / 42 EEC
- On / off switch
- Short time rating
- Foot switch
- Connection for equipotential bonding
- Fuse
- Button for increasing  Button for reduction
- Connection for neutral electrode
- Manufacturing date
- „Trigger out“ Connection socket for triggering a smoke evacuation device
The device is destined for proper use by physicians. It is equipped with 3 channels for the following medical applications (operating modes):

**Channel 1 - Mono Cut**
Unipolar Channel

1 a) Mode Cut - high frequency current not modulated
Intended for cutting with minimal heat development into the adjoining tissue.

1 b) Mode Cut With Coagulation - high frequency current modulated for simultaneous coagulation effect
Intended for cutting with simultaneous coagulation of the tissue, thereby achieving a hemostasis along the cut. The coagulation degree may be adjusted in 9 steps (from 1-9).

**Channel 2 - Mono Coag**
Unipolar Channel

2 a) Mode Permanent Coagulation - high frequency current modulated for coagulation effect
Intended for coagulation without cutting. The coagulation degree may be adjusted in 9 steps.

2 b) Mode Pulse Coagulation - high frequency current modulated for coagulation effect
As under 2 a); in addition, the duration of the pulse for coagulation may be adjusted in 9 steps (from 1-9).

**Channel 3 - Bip Coag**
Bipolar Channel

3 a) Mode Bipolar Permanent Coagulation - high frequency current modulated for coagulation effect
Intended for bipolar coagulation without cutting. The degree of bipolar coagulation may be adjusted in 10 steps (from 0-9).

3 b) Mode Bipolar Pulse Coagulation - high frequency current modulated for coagulation effect
As under 3 a); in addition, the duration of the pulse for bipolar coagulation may be adjusted in 9 steps (from 1-9; 0.05 up to 0.45 sec) as well as the automatic switchoff „A“.

A warning sound will be heard while the RF voltage is active. The volume may be adjusted (within the legally required limits) with a screw driver on the bottom of the device. In case an error is made the sound is always heard at maximum volume.

*The coagulation degree and adjustments are outlined on the next page.*
2.0 Technical Data

Coagulation Degree

The coagulation degree may be adjusted in the operating modes

- **Unipolar Cut**
  - Cut with Coagulation

- **Unipolar Coagulation**
  - Permanent Coagulation and Pulse Coagulation

- **Bipolar Coagulation**
  - Bipolar Permanent Coagulation and Bipolar Pulse Coagulation from c1 through c9.

The device is delivered with the following settings:

- **Channel Mono Cut**
  - Operating mode: Cut With Coagulation preset at c2 - maximum power 80 Watts

- **Channel Mono Coag**
  - Operating modes: Permanent and Pulse Coagulation

- **Channel Bip Coag**
  - Operating modes: Bipolar Permanent and Bipolar Pulse Coagulation preset at c4 - maximum power 60 Watts

### Technical Data and Adjustments of the Coagulation Degree

<table>
<thead>
<tr>
<th>Coagulation Effect *</th>
<th>Setting</th>
<th>Modulation of RF output</th>
<th>Maximum Power Selectable</th>
</tr>
</thead>
<tbody>
<tr>
<td>low</td>
<td>c0**</td>
<td>100% unmodulated</td>
<td>99W</td>
</tr>
<tr>
<td>I</td>
<td>c1</td>
<td>90%</td>
<td>90W</td>
</tr>
<tr>
<td>II</td>
<td>c2</td>
<td>80%</td>
<td>80W</td>
</tr>
<tr>
<td>III</td>
<td>c3</td>
<td>70%</td>
<td>70W</td>
</tr>
<tr>
<td>IIII</td>
<td>c4</td>
<td>60%</td>
<td>60W</td>
</tr>
<tr>
<td>IIIII</td>
<td>c5</td>
<td>50%</td>
<td>50W</td>
</tr>
<tr>
<td>IIIIII</td>
<td>c6</td>
<td>40%</td>
<td>40W</td>
</tr>
<tr>
<td>IIIIIII</td>
<td>c7</td>
<td>30%</td>
<td>30W</td>
</tr>
<tr>
<td>IIIIIII</td>
<td>c8</td>
<td>20%</td>
<td>20W</td>
</tr>
<tr>
<td>high</td>
<td>c9</td>
<td>10%</td>
<td>10W</td>
</tr>
</tbody>
</table>

* The crest refers to the modulation of a wave. The higher the crest, the more the wave differs from the uniform sine wave. Increasing the crest, which is adjusted by the degree of coagulation from C 1 up to C 9, decreases the maximum power output of 90 Watt (at C 1) up to 10 Watt (at C 9). We recommend a degree of coagulation between C 2 - C 4, and to adjust the required output power in Watt.

** The crest factor c0 is only available in the bipolar channel.

The **Maximum Power Selectable in Watts** given in the chart is the maximum performance of the device at that setting. The actual output depends on the load resistance, i.e. the electrical resistance against RF currents by the tissue. Resistance is determined by the kind and condition of the tissue (muscle, fat, moisture, etc.); thus the performance may vary. The connections between load resistance and output are displayed in the graphs on the subsequent pages.

To correctly assess the effects of the coagulation degrees, it is suggested to exercise cuts with the different settings on a beef model.
The graphs displayed on the subsequent pages are designed to assist the user in assessing the suitability and the selection of settings for the individual application.
2.0 Technical Data

Operation Mode: Cut

RF Performance in Operating Mode Cut at 1 kΩ Load

Performance Display

RF Performance in Operating Mode Cut vs. Load

Maximum Voltage Output in Operating Mode Cut Performance Display
Operation Mode: Cut/Coag and Coag only Coagulation degree: c2

RF Performance vs. Display in Operating Mode Cut/Coag or Coag at 1kΩ Load, Coagulation degree: c2

RF Performance vs. Load in Operating Mode Cut/Coag or Coag at selected performance settings, Coagulation degree: c2

Maximum Voltage Output vs. Display in Operating Mode Cut/Coag or Coag, Coagulation degree: c2
Operation Mode: Cut/Coag and Coag and Coagulation

RF Performance vs. Display in Operating Mode
Cut/Coag or Coag at 1 kΩ Load, Degree of Coagulation: c4 - Performance Display

RF Performance vs. Load in Operating Mode
Cut/Coag or Coag at selected performance settings, Coagulation degree: c4

Maximum Voltage Output vs. Display in Operating Mode Cut/Coag or Coag, Coagulation degree: c4 - Performance Display
Operating Mode: Bipolar Coagulation Coagulation degree: c4
## Technical Data

### ATMOS RS 221

<table>
<thead>
<tr>
<th>Nominal Voltage:</th>
<th>230 V / 115 V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal Frequency:</td>
<td>50 Hz / 60 Hz</td>
</tr>
<tr>
<td>Nominal Performance:</td>
<td>220 VA</td>
</tr>
<tr>
<td>Protection Class:</td>
<td>I</td>
</tr>
<tr>
<td>Protection Degree:</td>
<td>BF</td>
</tr>
<tr>
<td>Operating Mode:</td>
<td>DAB / 25 % ED</td>
</tr>
<tr>
<td>Ambient Temperature:</td>
<td>+ 10° C bis + 40° C in operation</td>
</tr>
<tr>
<td></td>
<td>- 40 ° C bis + 70° C during storage</td>
</tr>
<tr>
<td>Fuses:</td>
<td>2 x T 1,6 A / H for 230 V</td>
</tr>
<tr>
<td></td>
<td>2 x T 3,15 A / H for 115 V</td>
</tr>
</tbody>
</table>

### High Frequency

**Unipolar:**
- Cutting: max. 100 W on 1kΩ load
- Cutting/Coagulation: max. 90 W on 1kΩ load
- Permanent Coagulation: max. 90 W on 1kΩ load
- Pulse Coagulation: max. 90 W on 1kΩ load

**Bipolar:**
- Permanent Coagulation: max. 99 W on 250Ω load
- Pulse Coagulation: max. 99 W on 250Ω load

**HF frequency:** 2.2 MHz
**HF voltage:** 500 V maximum peak voltage output
**HF operation modes:**
- Unipolar Cutting via finger or foot switch
- Unipolar Coagulation via finger or foot switch
- Bipolar Coagulation via foot switch
- Unipolar Cutting:
  - a) Cutting only
  - b) Cutting with coagulation, coagulation degree selectable * in 9 steps
- Unipolar Coagulation:
  - a) Permanent coagulation, coagulation degree selectable * in 9 steps (from 1-9)
  - b) Pulse Coagulation as a), additionally selectable pulse duration in 9 steps (0.05-0.45 seconds)
- Bipolar Coagulation:
  - a) Bipolar Permanent Coagulation selectable coagulation degree *in 10 steps (from 0-9)
  - b) Bipolar Pulse Coagulation as a), additionally selectable pulse duration in 9 steps (0.05-0.45 seconds)
  - and in addition setting „A“ for automatic switchoff

**Neutral Electrode Connection:** Grounded
**Electrode Connection:** Defibrillator proof
**Dimensions/Mass/Weight:**
- H x W x D: 138 x 285 x 230 mm
- 5.8 kg / 58 Newton

**Color of Case:** RAL 9002 / 514 dove-blue
**GMDN-Code:** 32811
**UMDNS-Code:** 11-490
**Classification acc. to Annex IX EEC directions 93/42/EEC:** II b
General Safety Precautions for the Use of Radiosurgical Devices

- Do not use radiosurgical devices on persons having a pacemaker, an implanted defibrillator or an implanted neurostimulator, or consult with the responsible physician prior to their use in order to ensure that the radio frequency currents of the surgical device do not negatively interfere with the device. Radio frequency surgical devices may also influence devices connected to the patient (hearing aids, for example). During radiosurgical operations, those devices should be switched off or removed.

- Do not use inflammable or explosive anesthetics, or aspirate them. Take special care that no such liquids accumulate in hollows of the body (as in the navel). Inflammable substances like cleaning detergents or disinfectants must be evaporated prior to using a high frequency surgical device.

- **Warning:**
  Please note that high frequency currents may interfere with other vital electromedical devices used during surgery.

- This device is intended for producing „HF with intent“. Interference from other high frequency devices cannot be excluded. Therefore, activation via handpiece or foot switch should be limited to the medical requirements. The device meets the requirements of Directive 89/336/EEC regarding electromagnetic compatibility in connection with EN 60601-1-2 (see also Notes on EMC, Chapter 12).

- At simultaneous use of radiosurgical devices and physiological monitoring devices, the monitoring electrodes should be mounted as remotely as possible from the electrosurgical electrodes, especially if the monitoring electrodes do not have an restricting device to limit the radio frequency current.

- Cables leading to a radiosurgical device should not touch the patient or other cables.

- Take special care during surgery on thin tissue layers to prevent undesired coagulation or desication of the tissue.

- Intensity settings should be kept as low as possible to prevent an undesired destruction of tissue.

- Skin-to-skin contact (for example, between arms and body or between thighs) should be avoided. Always place a layer of gauze between parts of the body that may touch.

- The patient should not have unprotected contact with grounded metal parts. It is recommended to use anti-static cloth. The entire neutral electrode must have skin contact and should be covered by the patient's body. It is to be placed as closely as possible to the operation field.

- If the radiosurgical device seems to emit insufficient power, inspect all operating elements, cable connections, and the position of the neutral electrode. For further helpful advice in case of defects see chapter 10.

- The cables of hand pieces, bipolar forceps, and neutral electrode must not be rolled up, shortened, placed tightly parallel, crossed, or tangled. The electrode which is not in use should be kept separately at a safe distance.

- This product is not re-sterilisable. Repeated reuse of components which are marked with a ☓ is forbidden. In case of repeated reuse these components lose their function and there is a high of risk infection.
3.0 General safety

- The consulting doctor must be consulted prior to applying the radiofrequency device on patients with an active implanted medical device or system (AIMDS). For the duration of the operation with the radiofrequency device all these types of devices or systems must be removed.

  The following precautionary measures must be observed:
  1. If possible deactivate the AIMDS (Active Implantable Medical Devices and systems)
  2. Use the lowest device strength compatible with an acceptable diagnostic or therapeutic outcome and keep the path of device output as far from the AIMDS as possible
  3. Monitor the patient closely during the medical procedure
  4. Stop the procedure immediately in the case of an adverse incident
  5. Verify the continued proper function of the AIMDS during and after the medical procedure

- The ATMOS RS 221 may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments, especially intestinal and stomach gases as well as oxygen.

- The device may only be used with the probes which were specially designed for this device. The application of minimally invasive electrodes from other manufacturers is prohibited.

- When the device is in the cutting mode it must be ensured that the electrodes have at least 1 cm distance to the tissue and under no circumstances should any damage be caused to the tissue.

- During operations which require a continuous function of the device a second device should be ready to use.

- It is important to note that during cutting and coagulation cell liquid evaporates and within closed cavities, it could lead to an increase in pressure with the danger of tissue rupture.

- The ATMOS RS 221 may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments.
3.0 General safety

Please note:
A medical insulating transformer with earth leakage monitor or any similar safety system acc. to EN 60 601-1 is required, if several devices are connected to one common power supply. The transformer must correspond to the power consumption of all the devices to be connected.

Precautions for Use of Attachments for the Radiosurgical Unit

Only use the original attachments supplied with the unit and/or offered by the manufacturer to achieve maximum security for patient and user. The characteristics of the parts and cables are matched to the performance and voltage output of the unit in order to ensure a safe operation for all modes of operation and all settings.

Each connected attachment must be designed at least for the RF peak output voltage shown in the graphs (see Technical Data pages 6-8).

Examining the Condition of Unit and Attachments

The unit should be regularly examined to make sure it is mechanically intact. Especially the electrodes and their cables should be checked for impeccability of the insulation.

Every mechanical damage to case, cables, plugs, operating elements and parts call for a technical checkup and repair.

Discovered defects are to be repaired or - in case of doubt - a technical checkup should be arranged. For further advice in case of defects see chapter 10.

Operating Regulation

The device is classified as IIb according to guide line “Medical products” 93/42/EWG. The regulations of the Operating Regulations for Medical Devices, including those of Annex I, are applicable,

§ 5: Operation and Application
§ 6: Safety-regulated Control
§ 7: Medical Device Log

Safety-regulated Control:
The user is obligated to arrange for periodical technical checkups according to the following instructions.

Period: Every 12 months after delivery, and following every maintenance procedure.

Extent: Visual screening of device and attachments

Inspection according to VDE 0751 of
- conductor resistance
- substitute device abduction current
- substitute patient’s abduction current

Functional Inspection
Measurement of the RF output performance at 1 kΩ load, respectively the bipolar outlet at 250 Ω load,

The test results according to VDE 0751 must be documented in the Medical Device Log under consideration of the initial measurements.

Should the checkup reveal defects, the operator is responsible to arrange for their correction.
Use of the accessories

**Handpieces and cables**

RF cables and hand pieces are used to connect auxiliary instruments for cutting and unipolar / bipolar coagulation to radiosurgical devices. Prior to use, cables, plugs, and hand pieces are to be screened for visible flaws. Cables with brittle or defect insulation must not be used. These products are subject to normal technical wear and tear that is inevitable. If the product shows visible flaws or does not function as described in the manual, please notify the manufacturer or the responsible representative immediately.

Cables and hand pieces are generally not to be repaired, but must be replaced with new parts.

**Electrodes**

All electrodes are available in a flexible version to easily access every region. The shaft of these electrodes can be repeatedly bent without breaking.

Electrodes with yellow coating are intended for cutting and for cutting with simultaneous coagulation; electrodes with blue coating for coagulating.

Always insert the electrode into the hand piece as far as it will go. Never use electrodes with defective coating. You could injure yourself and your patient.

**Bipolar forceps and bipolar needle electrodes**

Bipolar forceps are available in different lengths and with different bends and tips. Only connect two-pole bipolar forceps and bipolar needle electrodes (stitch electrodes) to the bipolar cables which are recommended by the manufacturer.

**Neutral electrode**

The neutral electrode is essential when working with the channels Mono Cut and Mono Coag. While working with these channels, the neutral electrode must be connected to the unit via the neutral electrode cable. If the neutral electrode is missing or the cable interrupted (cable not plugged in or defect), nE appears in the displays for Mono Cut and Mono Coag, and the warning symbol N (neutral electrode) lights up red. If Mono Cut or Mono Coag is selected during this condition, a buzzer interval will be heard. If contact to the neutral electrode is lost while working with Mono Cut or Mono Coag, the output is switched off, the same indications as above will be displayed, and the buzzer sounds.

The channel Bip Coag can be used regardless of the condition of the neutral electrode or even without any neutral electrode and the aforementioned warning indications and the buzzer will not be activated.

The neutral electrode is to be placed underneath or next to the patient with full surface contact. It is recommended to place the neutral electrode as closely as possible to the location of the operation. Skin contact is mandatory. It may be necessary to partially undress the patient. Conduction gel (ECG gel) may be evenly spread over the complete surface of the neutral electrode to increase abduction of the RF current. Cables must never be put on the patient's thorax. The patient must be insulated against all electrically conductive parts, and rest on a dry and electrically insulating sheet. Skin-to-skin contact (in the armpits, for example) is to be avoided and should be prevented by using layers of gauze.

Prior to the planned operation, please refer to your operating instructions in order to set the necessary settings on the HF-/radiofrequency device, regarding the condition of the neutral electrodes, the applied electrodes, bipolar forceps etc. Never apply HF-radiofrequency surgery on patients with cardiac pacemakers or in the presence of flammable or explosive liquids or gases.

Neutral electrode cable              autoclave cycles: minimum 300
**Maintenance of device and accessories**

**Recommended disinfectants**

Maintenance and care for device and accessories

**Cleaning the Unit**

The case is especially designed for easy cleaning and maintenance. The fire glazed powder coating resists the most common cleaning detergents and disinfectants. The foil keys are smooth and tightly fitted into the carefully shaped case to permit wiping with liquid disinfectants. The sockets for the cable plugs at the front side of the case are sunk. Should any cleaning detergent flow into the cable sockets, it can drain through the open bottom of the case without seeping into the sockets. The robust steel sheet design of the unit ensures stability and easy recycling.

Wipe the unit with mild cleaning detergents or disinfectants. Never use cleaning agents that are aggressive or contain quartz sand. Since the composition of plastics, varnishes, and paints constantly change, cleaning detergents and disinfectants should be tested on the bottom side of the unit prior to use.

Information regarding reprocessing can be found in the instructions for reprocessing, which is enclosed with the accessories.
4.0 Introduction to Radiosurgery

Introduction to Radiosurgery

Definition of a Fine Technology:

Damage to tissue caused by radio frequency surgery can only happen if the heat in the tissue reaches a level causing extreme dehydration of the tissue, thereby destroying the tissue. Avoiding such heat accumulation is the basic goal of the high frequency surgical technology. The accumulation of heat in the lateral tissue depends on several factors which are explained below.

Lateral heat depends on:
1. The chosen level of intensity
2. The length of time the electrode is in contact with the tissue
3. The size of the electrode
4. The mode of operation

1. Intensity Level
   a) Intensity set too high - intense accumulation of lateral heat.
   b) Insufficient intensity setting - intense accumulation of lateral heat due to strong resistance to the electrode. Additionally, excessive bleeding occurs while cutting, caused by the tearing of tissue due to increased resistance
   c) Correct intensity setting - lateral heat reduced to the minimum required for the evaporation of cells. The electrode can be moved through the tissue evenly and smoothly without sparks and resistance, and coagulation occurs fast.

2. The length of time the electrode is in contact with the tissue
   (at the same intensity setting)
   a) Slow passage of the electrode through the tissue - more lateral heat.
   b) Fast passage of the electrode through the tissue - less lateral heat.

3. The size of the electrode
   (at the same settings for operation mode and intensity)
   a) Large electrode - higher intensity setting needed - more lateral heat.
   b) Small electrode - lower intensity setting needed - less lateral heat.

4. The mode of operation
   Available are modulated and non-modulated RF currents; their heat generation in the tissue varies in development. Generally, the non-modulated RF current strictly used for cutting generates the least lateral heat; this heat increases according to the modulation of the RF current and the duration of effect on the tissue.
4.0 Correct Choice of Operating Modes

Cutting (Channel 1 - Mono Cut - Operation Mode 1.a)
This non-modulated RF wave is ideal for a clean separation of tissue without coagulation; it is also suitable for the removal of tissue for histological examination. The RF current is emitted as long as the foot switch or finger switch are activated.

Cutting with Coagulation (Channel 1 - Mono Cut - Operation Mode 1.b)
This modulated RF wave is intended for cutting with simultaneous coagulation of the incision surface. The coagulation degree is adjustable from light to intense. The RF current is emitted as long as the foot switch or finger switch are activated.

Permanent Coagulation (Channel 2 - Mono Coag - Operation Mode 2.a)
This modulated RF wave is used for instant hemostasis, either directly by means of a coagulation electrode, or indirectly using a clamp. The coagulation degree is adjustable from light to intense. The RF current is emitted as long as the foot or finger switch is activated.

Pulse Coagulation (Channel - Mono Coag - Operating Mode 2.b)
This modulated RF wave is used for instant hemostasis either directly by means of a coagulation electrode, or indirectly using a clamp. The coagulation degree is adjustable from light to intense. The RF current is emitted for the duration selected by activating the foot or finger switch.

Bipolar Permanent Coagulation (Channel 3 - Bip Coag - Operating Mode 3.a)
This modulated RF wave is used for instant hemostasis by means of bipolar forceps. The coagulation degree can be varied from 0.05 to 0.45 seconds. The coagulation degree "0" is also suitable for cutting, e.g. with bipolar scissors. The RF current is emitted as long as the foot or finger switch is activated.

Bipolar Pulse Coagulation (Channel 3, Bip Coag - Operating Mode 3.b)
This modulated RF wave is used for instant hemostasis by means of bipolar forceps. The coagulation degree is adjustable from light to intense, pulse duration can be varied from 0.05 to 0.45 seconds. The RF current is emitted for the duration selected by activating the foot or finger switch. When the setting "A" is preselected, the device switches off automatically as soon as a certain tissue resistance is reached. Please note the instructions stated on page 23.
4.0 Anesthesia

Utilizing the Radio Frequency Surgical Unit

Anesthesia

During all high frequency surgical operations either local or general anesthesia is to be applied.

Cutting and Cutting with Coagulation
Channel 1 (Mono Cut)

Radio frequency surgery is performed applying practically any pressure to achieve the cutting. A gentle touch, dexterity, smooth movement of the wrist, and a contact to the tissue which is as light as a feather are prerequisites for efficient radiosurgery.

During the cutting process it is important to cut in a flowing, smooth, continuous way, applying a steady and light pressure. Such movement should not be too slow. If too slow, accumulated heat may injure the adjoining tissue, causing necrosis and scabbing.

The tissue should be moist. If the tissue is too dry, the surface could be charred. Extremely dry tissue may be moistened with a wet strip of gauze, with water spray, or with conduction gel (as used with an ECG). Prior to surgical procedures, the area to be worked on should be studied to choose the correct electrode, the suitable radio frequency and the appropriate intensity for the surface to be treated.

The finger or foot switch must be activated prior to touching the tissue for cutting or cutting with coagulation.

Should you want to place a second or third cut in the same area, allow about 10 seconds for the tissue to cool down before touching the area with the electrode again. Every rule of surgical technique as well as clinical assessment aspects also apply to radio frequency surgery. The major difference compared to cutting with a scalpel lies in cutting without pressure. This rule is to be observed by all means. Contrary to the scalpel, a light, smooth, continuous stroke should be developed. Only then will the surgeon fully appreciate the overwhelming advantages of the radiosurgical technique.
Unipolar and Bipolar Coagulation
Channel 2 (Mono Coag) and Channel 3 (Bip Coag)

Bleeding presents no problem in radiosurgery.

Coagulation can be achieved by various techniques (direct method, indirect method, bipolar method). Coagulation can avoid bleeding during the first invasion of the electrode into the tissue. All forms of hemorrhage must be stopped by using either direct pressure, air, compression or a clamp. Once the bleeding is momentarily suppressed, capillaries as well as large blood vessels can be permanently sealed with a brief application of a modulated RF current. Ball electrodes, thick needles, blade electrodes and bipolar forceps are available for the coagulation. It is possible to coagulate blood vessels up to a diameter of 1.5 - 2.0 mm. Thereby a ligature may become unnecessary in many cases.

Direct Method of Coagulation
The direct method is applied by putting the coagulation electrode (ball or thick needle) very gently onto the area to be coagulated and then activating the foot switch or finger switch. For smaller blood vessels, the modulated RF pulse wave is recommended.

Indirect Method of Coagulation
Using the indirect method, the bleeding vessel is seized with the bipolar forceps and slightly pulled out of the adjoining tissue. The foot switch is pressed until the seized blood vessel has taken on a paler hue. For smaller blood vessels, the modulated RF pulse wave is recommended.

Bipolar Method of Coagulation
Using the bipolar method, the bleeding vessel is seized with the bipolar forceps and is gently pulled out of the adjoining tissue. The foot switch is pressed until the seized blood vessel has taken on a paler hue. For smaller blood vessels, the modulated RF pulse wave is recommended.

Bipolar Method of volume reduction and tissue tightening
Using the bipolar method for volume reduction and tissue tightening of the soft palate, the lingual tonsils or the nasal concha a bipolar stitch electrode is penetrated into the tissue, the coagulation degree is adjusted to c1 or c2 and the impulse period to dA (automatic). The foot switch should be kept pressed until the device switches off automatically thus when a certain tissue resistance is reached.

IMPORTANT: Prior to starting treatment please take care that at the channel Bip Coag the below right LED is illuminated because otherwise the automatic switch off is not activated.

We recommend practicing cutting and coagulating on a beef model prior to first use. See „Cutting and Coagulation Exercise on a Beef model“, Chapter 9.
Place the overview chart in front of the unit, and proceed as follows:

1. On the rear side, plug the power cable into the right socket (as seen from above). Ensure that the flat side of the plug is on top. This is the only way to insert the plug into the jack.

2. Ensure that the voltage of your power outlet complies with the 230 Volt at 50 Hz required for the device; otherwise the device may not be put into operation. Only then should the safety plug be inserted into the wall socket.

3. If you operate the unit using the unipolar channels **Mono Cut** and **Mono Coag** with the foot switch (these outlets can also be operated by using the finger switch) or if you want to work bipolarly, insert the round plug of the foot switch into the socket at the right side of the device (as seen from above). Ensure that the pins of the plug point upwards, and the recess is on the lower side. This is the only way to insert the plug into the socket. Turn the safety nut to the right. The plug is now locked safely. If you want to remove the plug firstly, you have to turn the nut to the left; otherwise the plug will not come off.

4. Now insert the desired hand piece connections and, if desired, the bipolar cable into the pertinent sockets.

   4.a) Insert the cable of the hand piece with the yellow finger switch into socket B under channel **Mono Cut**.

   4.b) Insert the cable of the hand piece with the blue finger switch into socket C under channel **Mono Coag**.

   4.c) Insert the bipolar cable into socket D under channel **Bip Coag**.

   4.a) through 4.c): The device is equipped according to the intended use; you do not have to connect all hand pieces and the bipolar forceps.

5. Now plug the cable of the neutral electrode into socket A.

6. Connect the end of the neutral electrode cable to the plug of the neutral electrode.

7. Activate the device with the push button „I“ of the power switch. The device reports itself as operational with a short signal tone.

8. The unit is now operational. The display of the preset channel or the unipolar/bipolar channel used last time is brightly lit.

A warning signal resounds if the device is switched on and the neutral electrode is not connected to the device. The monopolar outlets Mono Cut and Mono Coag are only activated when the neutral electrode is connected to the device. If the neutral electrode is missing, the red N-lamp and the performance displays of both monopolar outlets show nE. The Bip Coag (bipolar) outlet can be used without neutral electrode.
The unit memorizes the operational condition. When the unit is restarted, it is automatically set to the channel, operation mode, intensity, coagulation degree, and pulse duration last used.

If you have last worked with the unipolar channels, a permanent and intermitting tone sounds when the unit is activated without the neutral electrode and the neutral electrode cable. The sound is terminated only when both the neutral electrode cable and the neutral electrode are properly connected or operation mode Bip Coag is selected. If the unit was last used in the bipolar mode, only a short signal is given since in bipolar mode it can be operated without the neutral electrode.

A warning tone sounds if the RF current is active. The volume of this sound can be adjusted within the regulated limits with a screwdriver on the bottom of the unit.

In case of system malfunction, the warning tone always sounds at the maximum volume.
5.0 Switching Channels

When the unit has been started up and is switched on, a short tone sounds, and the display of the last channel used lights up.

4 operating buttons and a numeric display are assigned to each channel.

The two upper buttons 3+ 4 are used to change settings, the lower buttons 1+ 2 are for switching operating modes.

Only one channel can be operated at a time

If another channel is desired, please proceed as follows:

a) Press the appropriate buttons for the operation mode (lower buttons 1+ 2), or
b) tap against the yellow or blue finger switch of the unipolar hand pieces, or

c) briefly short-circuit the bipolar forceps.

For all channels, the operating modes can be selected using the lower buttons 1 2.

If the channel selection is changed by tapping the colored finger switch on the hand pieces or by short-circuiting the bipolar forceps, the last operating mode used on the chosen channel is selected.

A warning tone sounds if the RF current is active. The volume of this sound can be adjusted within the regulated limits with a screwdriver on the bottom of the unit. This sound goes off automatically when the automatic switchoff is activated and a certain tissue resistance is reached. With it the end of the coagulation procedure is indicated.

In case of system malfunction, the warning tone always sounds at the maximum volume.
Channel 1 - Mono Cut

1.1 Prepare the unit as outlined under „Starting Up“.

Channel Mono Cut can be activated by:
- pressing one of the operation mode buttons 1 + 2, or by
- a short tapping to the yellow finger-switch on the handpiece.

1.2 Ensure that the unit is set to the intended operating mode.

Channel Mono Cut has two different operating modes:
- RF current non-modulated - for cutting
- RF current non-modulated - for cutting with simultaneous coagulation

**Operating mode: Cutting.**
Cutting only, with the least heat development in the adjoining tissue

This operation mode is selected by pressing the left button 1. At the same time, the display 5 shows the set output of 1-100 Watts.

By pressing the arrow buttons 3+ 4 the output can be increased or decreased.

Arrow down 3 - output is decreased.
Arrow up 4 - output is increased.

One tap against the arrow buttons alters the output by one Watt. Keeping the arrow buttons pressed continuously increases or decreases the output; after about 2 seconds of pressing the buttons, the displayed settings start to change at accelerated pace.

Maximum output of non-modulated RF current at 1 kΩ load is 100 Watts.
6.0 Unipolar Cutting

Operating mode: Cutting with Simultaneous Coagulation

For cutting with simultaneous coagulation along the incision.

This operation mode is selected by pressing the right button \( \text{②} \).

After switching, the display \( \text{③} \) briefly shows the set output, then the selected coagulation degree from c1 to c9, and then again the set output, which in this mode is adjustable from 1 to 90 Watts.

By pressing the arrow buttons \( \text{⑤} + \text{④} \) the output can be increased or decreased.

Arrow down \( \text{⑤} \) - output is decreased.

Arrow up \( \text{④} \) - output is increased.

One tap against the arrow buttons alters the output by one Watt. Keeping the arrow buttons pressed continuously increases or decreases the output; after about 2 seconds of pressing the buttons, the displayed settings start to change at accelerated pace.

Checking and Changing the Coagulation degree

A continuous pressing of the right button \( \text{②} \) displays the set coagulation degree from c1 to c9. Keeping this button pressed and at the same time tapping the arrow buttons \( \text{⑤} + \text{④} \) the coagulation degree can be increased or decreased.

Arrow down \( \text{⑤} \) - output is decreased.

Arrow up \( \text{④} \) - output is increased.

The coagulation degree can only be changed in single steps.
The maximum output selectable in the operation mode Cutting with simultaneous coagulation depends on the selected coagulation degree.

<table>
<thead>
<tr>
<th>Coagulation effect*</th>
<th>Setting</th>
<th>Modulation of RF output</th>
<th>Maximum of power adjustable</th>
</tr>
</thead>
<tbody>
<tr>
<td>low</td>
<td>c1</td>
<td>90%</td>
<td>90W</td>
</tr>
<tr>
<td>I</td>
<td>c2*</td>
<td>80%</td>
<td>80W</td>
</tr>
<tr>
<td>II</td>
<td>c3</td>
<td>70%</td>
<td>70W</td>
</tr>
<tr>
<td>III</td>
<td>c4</td>
<td>60%</td>
<td>60W</td>
</tr>
<tr>
<td>IIII</td>
<td>c5</td>
<td>50%</td>
<td>50W</td>
</tr>
<tr>
<td>IIIII</td>
<td>c6</td>
<td>40%</td>
<td>40W</td>
</tr>
<tr>
<td>IIIIIII</td>
<td>c7</td>
<td>30%</td>
<td>30W</td>
</tr>
<tr>
<td>IIIIIII</td>
<td>c8</td>
<td>20%</td>
<td>20W</td>
</tr>
<tr>
<td>high</td>
<td>c9</td>
<td>10%</td>
<td>10W</td>
</tr>
</tbody>
</table>

* Preset is coagulation degree c2.

After setting the desired coagulation degree, the display shows the selected wattage. Should this appear unsuitable, it can be decreased or increased to the wattage corresponding with the coagulation degree by using the arrow buttons + (as described previously).

Switching to a higher coagulation degree causes an intensified coagulation during cutting and therefore a higher degree of scabbing on the surface of the cut, accompanied by a contraction of some cell layers.

The last setting is stored in the system memory.

**Important notice for working with channel Mono CUT**

Please note that the operation mode Mono Cut can only be used if the neutral electrode is properly connected. The neutral electrode is placed underneath the patient, as close to the operating area as possible. The patient’s body should completely cover the neutral electrode and the complete surface of the neutral electrode must be in contact with the patient's skin. If necessary, the pertinent parts of the patient's body should be undressed.

Always insert the electrode into the hand piece as far as it will go. Ensure that the blank (not coated) metal shaft is completely inserted into the hand piece. Only use the manufacturer’s original electrodes.
Activating the output in channel Mono Cut

The unit is activated by either pressing the yellow finger switch at the hand piece or by using the foot switch. The output selected is applied as long as the finger switch or foot switch remain pressed.

Activate the device prior to cutting or to cutting with simultaneous coagulation by pressing the foot switch or the yellow finger switch at the hand piece prior to touching the tissue.

The selected output and the selected coagulation degree cannot be changed while the device is being activated by pressing the finger switch or foot switch.

Changes are only possible when the device supplies no power output to the electrode, that is, when neither the finger switch nor the foot switch are being pressed.
Channel 2 - Mono Coag

2.1 Prepare the unit as outlined under „Starting Up“.

Channel Mono Coag can be activated by:
- pressing one of the operation mode buttons 1 + 2, or by
- short tapping of the blue finger switch on the hand piece.

2.2 Ensure that the unit is set to the intended operating mode.

Channel **Mono Coag** has two different operating modes:
- RF current modulated - for continuous coagulation with adjustable degrees -
- RF current modulated - for pulse coagulation with adjustable degree and selectable pulse duration

**Operating mode: Continuous coagulation Continuous coagulation with selectable coagulation degree**

This operation mode is selected by pressing the left button 1.

After switching, the display 5 briefly shows the set output, then the selected coagulation degree from c1 to c9, and then again the set output, which in this mode is adjustable from 1 to 90 Watts.

By pressing the arrow buttons 3 + 4 the output can be increased or decreased.

**Arrow down** 3 - output is decreased.
**Arrow up** 4 - output is increased.

By tapping on the arrow buttons the output is altered by one watt. Keeping the arrow buttons continuously pressed increases or decreases the output; after about 2 seconds of pressing the buttons, the displayed settings start to change at accelerated pace.

Maximum output of the modulated high frequency current at 1 kΩ load is 90 Watts.
Checking and changing the coagulation degree

By continuously pressing the left button 1, the display 5 shows the set coagulation degree from c1 to c9. Keeping this button pressed and tapping on the arrow buttons 3 + 4 at the same time, the coagulation degree can be increased or decreased.

Arrow down 3 - coagulation degree is decreased.
Arrow up 4 - coagulation degree is increased.

The coagulation degree can only be changed in single steps.

The maximum output selectable in operation mode **Continuous coagulation** is determined by the selected coagulation degree.

<table>
<thead>
<tr>
<th>Coagulation effect *</th>
<th>Setting</th>
<th>Modulation of RF output</th>
<th>Maximum of power adjustable</th>
</tr>
</thead>
<tbody>
<tr>
<td>low</td>
<td>C1</td>
<td>90%</td>
<td>90W</td>
</tr>
<tr>
<td>I</td>
<td>C2</td>
<td>80%</td>
<td>80W</td>
</tr>
<tr>
<td>II</td>
<td>C3</td>
<td>70%</td>
<td>70W</td>
</tr>
<tr>
<td>III</td>
<td>C4</td>
<td>60%</td>
<td>60W</td>
</tr>
<tr>
<td>IIII</td>
<td>C5</td>
<td>50%</td>
<td>50W</td>
</tr>
<tr>
<td>IIIII</td>
<td>C6</td>
<td>40%</td>
<td>40W</td>
</tr>
<tr>
<td>IIIIIII</td>
<td>C7</td>
<td>30%</td>
<td>30W</td>
</tr>
<tr>
<td>IIIIIII</td>
<td>C8</td>
<td>20%</td>
<td>20W</td>
</tr>
<tr>
<td>high</td>
<td>C9</td>
<td>10%</td>
<td>10W</td>
</tr>
</tbody>
</table>

*Preset is coagulation degree c4.

After setting the desired coagulation degree, the display 5 shows the selected wattage. Should this appear to be unsuited, it can be decreased or increased up to the wattage corresponding with the coagulation degree by using the arrow buttons 3 + 4 (as described previously).

Switching to a higher coagulation degree causes a more massive coagulation while cutting and thereby a more massive scabbing on the surface of the cut, accompanied by a contraction of some cell layers.

The last setting is stored in the system memory.
Operating mode: Pulse coagulation

Pulse coagulation with selectable coagulation degree and adjustable pulse duration

This operation mode is selected by pressing the right button ②.

After switching, the display ③ briefly shows the set output, then the coagulation degree from c1-c9, then briefly the set pulse duration from d1-d9 and then again the set output, which in this mode is adjustable from 1-90 watts.

By pressing the arrow buttons ③ + ④ the output can be increased or decreased.

Arrow down ③ - coagulation degree is decreased.
Arrow up ④ - coagulation degree is increased.

By one tap on the arrow buttons the output is altered by one Watt. Keeping the arrow buttons pressed continuously increases or decreases the output; after about 2 seconds of pressing the buttons, the displayed settings start to change at accelerated pace.

Maximum output of the modulated RF current at 1 kΩ load is 90 Watts.

Checking and changing the coagulation degree

The coagulation degree on outlet Mono Coag can only be changed with the left button ① and is also selectable for continuous as well as pulse coagulation with the left button ①.

Setting and adjustment of the coagulation degree are outlined on the previous page.
Checking and adjusting the pulse duration for pulse coagulation

By persistently pressing the right button 2 the display 5 shows the selected pulse duration from d1 to d9. By keeping this button pressed and tapping on the arrow buttons 3 + 4 the pulse duration can be increased or decreased.

Arrow down 3 - coagulation degree is decreased.
Arrow up 4 - coagulation degree is increased.

The pulse duration can only be changed in single steps.

The pulse duration is determined by the adjustment factor.

<table>
<thead>
<tr>
<th>Adjustment factor</th>
<th>Pulse duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>d1</td>
<td>0.05 seconds</td>
</tr>
<tr>
<td>d2</td>
<td>0.10 seconds</td>
</tr>
<tr>
<td>d3</td>
<td>0.15 seconds</td>
</tr>
<tr>
<td>d4*</td>
<td>0.20 seconds</td>
</tr>
<tr>
<td>d5</td>
<td>0.25 seconds</td>
</tr>
<tr>
<td>d6</td>
<td>0.30 seconds</td>
</tr>
<tr>
<td>d7</td>
<td>0.35 seconds</td>
</tr>
<tr>
<td>d8</td>
<td>0.40 seconds</td>
</tr>
<tr>
<td>d9</td>
<td>0.45 seconds</td>
</tr>
</tbody>
</table>

*Pulse duration is preset at d4.

After setting the desired coagulation degree, the display 5 shows the selected wattage. Should this appear to be unsuited, it can be decreased or increased up to the wattage corresponding with the coagulation degree by using the arrow buttons 3 + 4 (as described previously).
Important notice for working with channel Mono Coag

Note that channel Mono Coag can only be used if the neutral electrode is properly connected. The neutral electrode is placed underneath the patient as closely as possible to the operating area, and the electrode should be completely covered by the patient's body. The complete surface of the neutral electrode must be in contact with the patient's skin. If necessary, the pertinent parts of the patient's body are to be undressed.

Insert a blue-coated coagulation electrode into the hand piece as far as it will go. Ensure that the blank (not coated) metal shaft is completely inserted into the hand piece. Only use the manufacturer's original electrodes.

Activating the output in channel Mono Coag

The unit is activated by either pressing the yellow finger switch at the hand piece or by using the foot switch. The output selected is applied as long the finger switch or foot remain pressed. For pulse coagulation, the duration is determined by the pulse duration selected.

For direct coagulation, first gently touch the blood vessel to be coagulated, and then activate the finger or foot switch.

The selected output, the coagulation degree, and the pulse duration cannot be changed while the device is being activated by the finger or foot switch. Changes are only possible when there is no power supply from the device to the electrode, that is, when neither the finger nor the foot switch are being pressed.
Channel 3 - Bip Coag

3.1 Prepare the unit as outlined under „Starting Up“.

Channel Bip Coag can be activated by:
- pressing one of the operation mode buttons ① + ②, or by
- short-circuit of the bipolar forceps.

3.2 Ensure that the unit is set to the intended operating mode.

Channel Bip Coag has two different operating modes:
- RF current modulated - for continuous bipolar coagulation with adjustable degrees
- RF current modulated - for bipolar pulse coagulation with adjustable degree, selectable pulse duration and automatic switchoff.

**Operating mode: Continuous bipolar coagulation**

Continuous bipolar coagulation with selectable coagulation degree

This operation mode is selected by pressing the left button ①.

After switching, the display ⑤ briefly shows the set output, then briefly the selected coagulation degree from c0 to c9, and then again the set output, which in this mode is adjustable from 1 to 99 Watts.

By pressing the arrow buttons ③ + ④ the output can be increased or decreased.

Arrow down ③ - coagulation degree is decreased.
Arrow up ⑤ - coagulation degree is increased.

By one tap on the arrow buttons the output is altered by one Watt. Keeping the arrow buttons pressed continuously increases or decreases the output; after about 2 seconds of pressing the buttons, the displayed settings start to change at accelerated pace.

Maximum output of the bipolar RF current at 250 kΩ load is 99 Watts.
Checking and changing the coagulation degree

By persistently pressing the left button, the display shows the selected coagulation degree from c0 to cd9. By keeping this button pressed and tapping on the arrow buttons + the coagulation degree can be increased or decreased.

Arrow down - coagulation degree is decreased.
Arrow up - coagulation degree is increased.

The coagulation degree can only be changed in single steps.

The maximum output selectable in operation mode Bipolar continuous coagulation is determined by the selected coagulation degree.

<table>
<thead>
<tr>
<th>Coagulation effect</th>
<th>Modulation of RF Output</th>
<th>Maximum of Power adjustable</th>
</tr>
</thead>
<tbody>
<tr>
<td>low c0**</td>
<td>100% unmodulated</td>
<td>99W</td>
</tr>
<tr>
<td>I c1</td>
<td>90%</td>
<td>90W</td>
</tr>
<tr>
<td>II c2</td>
<td>80%</td>
<td>80W</td>
</tr>
<tr>
<td>III c3</td>
<td>70%</td>
<td>70W</td>
</tr>
<tr>
<td>IIII c4</td>
<td>60%</td>
<td>60W</td>
</tr>
<tr>
<td>IIIII c5</td>
<td>50%</td>
<td>50W</td>
</tr>
<tr>
<td>IIIIIII c6</td>
<td>40%</td>
<td>40W</td>
</tr>
<tr>
<td>IIIIIIIII c7</td>
<td>30%</td>
<td>30W</td>
</tr>
<tr>
<td>high c8</td>
<td>20%</td>
<td>20W</td>
</tr>
<tr>
<td>high c9</td>
<td>10%</td>
<td>10W</td>
</tr>
</tbody>
</table>

* Preset is coagulation degree c4.

After setting the desired coagulation degree, the display shows the selected wattage. Should this appear to be unsuited, it can be decreased or increased up to the wattage corresponding with the coagulation degree by using the arrow buttons + (as described previously).

Switching to a higher coagulation degree causes a more intensive coagulation while cutting and thereby an intensified scabbing on the surface of the cut, accompanied by a contraction of some cell layers.

The last setting is stored in the system memory.
**8.0 Bipolar coagulation**

**Operation mode:**
**Bipolar pulse coagulation**

Bipolar pulse coagulation with selectable coagulation degree and adjustable pulse duration

This operation mode is selected by pressing the right button 2.

After switching, the display briefly shows the set output, then the selected coagulation degree from d0 to d9, then briefly the selected pulse duration from dA to d9, and then again the set output, which in this mode is adjustable from 1 to 99 Watts.

By pressing the arrow buttons 3 + 4 the output can be increased or decreased.

Arrow down 3 - coagulation degree is decreased.
Arrow up 4 - coagulation degree is increased.

By one tap on the arrow buttons the output is altered by one Watt. Keeping the arrow buttons pressed continuously increases or decreases the output; after about 2 seconds of pressing the buttons, the displayed settings start to change at accelerated pace.

Maximum output of the modulated RF current at 250 kΩ load is 99 Watts

**Checking and changing the coagulation degree**

The coagulation degree of operation mode Bip Coag can only be changed with the left button 1 and is only selectable for bipolar continuous as well as bipolar pulse coagulation only with the left button 1.

Setting and adjustment of the coagulation degree are outlined on the previous page.
8.0 Bipolar coagulation

Checking and adjusting the pulse duration for bipolar pulse coagulation

On persistently pressing of the right button 2 the display 5 shows the selected pulse duration from dA to d9. By keeping this button pressed and tapping on the arrow buttons 3+ 4 the pulse duration can be increased or decreased.

Arrow down 3 - coagulation degree is decreased.
Arrow up 4 - coagulation degree is increased.

The pulse duration can only be changed in single steps.

The pulse duration is determined by adjustment factor.

<table>
<thead>
<tr>
<th>Adjustment factor</th>
<th>Pulse duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>dA</td>
<td>automatic switch off</td>
</tr>
<tr>
<td>d1</td>
<td>0,05 seconds</td>
</tr>
<tr>
<td>d2</td>
<td>0,10 seconds</td>
</tr>
<tr>
<td>d3</td>
<td>0,15 seconds</td>
</tr>
<tr>
<td>d4*</td>
<td>0,20 seconds</td>
</tr>
<tr>
<td>d5</td>
<td>0,25 seconds</td>
</tr>
<tr>
<td>d6</td>
<td>0,30 seconds</td>
</tr>
<tr>
<td>d7</td>
<td>0,35 seconds</td>
</tr>
<tr>
<td>d8</td>
<td>0,40 seconds</td>
</tr>
<tr>
<td>d9</td>
<td>0,45 seconds</td>
</tr>
</tbody>
</table>

*Pulse duration is preset at d4.

After setting the desired pulse duration, the display 3 shows the selected wattage. Should this appear to be unsuited, it can be decreased or increased up to the wattage corresponding with the coagulation degree by using the arrow buttons 3 4 (as described previously).

Important notice for working with channel Bip Coag

Please note that the operation mode Bip Coag can be used without neutral electrode. It is however mandatory that the unit is equipped with a foot switch since the operating channel Bip Coag can only be activated with the foot switch.

For haemostasis please attach the bipolar forceps to the bipolar cable. Only use the manufacturer’s original bipolar forceps.

For tissue-dehydrogenation and volume reduction only use the bipolar needle electrodes and the setting dA (automatic switch off).

Activating the output in channel Bip Coag

Activating can only be done by pressing the foot switch. At continuous bipolar coagulation, the output selected is applied as long the foot switch remains pressed; at bipolar pulse coagulation, the duration is determined by the pulse duration selected. In case dA (automatic switch off) is preselected the device goes off automatically as soon as a certain tissue resistance is reached. With it the end of the coagulation procedure is indicated.

At bipolar coagulation and at bipolar pulse coagulation, the vessel to be coagulated is seized with the tips of the bipolar forceps and slightly lifted up. Only then should the foot switch be pressed. When the tissue around the tips of the forceps turns slightly white, the coagulation is completed, and in most cases the bleeding is stopped. Should the vessel continue to bleed, repeat the procedure.

The selected output, coagulation degree and pulse duration cannot be changed while the device is being activated by pressing the foot switch. Changes are only possible when there is no power supply from the device to the bipolar forceps, that is, when the foot switch is not pressed.
Prepare the device for work (as outlined under „Starting Up”), and proceed as follows:

1. Chose a piece of fresh, lean beef. Do not take veal as it does not change color when cut with an electrode. Pork is unsuited for this exercise due to its cellular structure. Wait for the meat to assume room temperature.

**Important:** It is absolutely mandatory to place the meat on the neutral electrode (which, in turn, must be connected to the device) otherwise, power abduction and thereby system operation is impossible.

2. Insert a yellow coated electrode of your choice (needle, loop, lozenge, etc.) into the hand piece with the yellow finger switch.

3. On the left channel 1 (yellow), switch the unit to mode „Cutting“ (button 1), and select the strongest output of 100 Watts with the arrow button 4. For details on settings, please see the previous chapters.

4. Press the finger switch or the foot switch, and with even movements, perform several incisions of different length and depth. View the results. The intensity setting was too high, if sparking occurs and remarkable color changes occur along the incision.

5. Reduce the intensity with arrow button 3 to 10 Watts, and try to repeat the exercise as described under step 4. You will note that the electrode will either not cut at all, or that it only does so after some pulling and straining and that if a cut is achieved at all, shreds of tissue keep sticking to the electrode.

**Important:** Always take care that the electrode wires are free from residues!

6. Repeat the process described above with increased settings until no changes of color and no visible sparking is observed. The tip of the electrode should encounter no resistance.

Continue this exercise cutting with slow, medium, and fast speed at each of the different settings to obtain the skill and the confidence you will need for doing actual surgery on a patient.

**Important:** When cutting and cutting with coagulation always first activate the unit by pressing the finger or foot switch, and then touch the tissue.

**ATTENTION:**
The different settings and the relevant results achieved from the beef may deviate on patients and can only be considered as recommendations! The required settings depend on the nature of the tissue, the age of the patient, the position of the neutral electrode (not required when working in the channel Bip Coag), the electrodes used and the wave form. The manufacturer cannot be held liable for wrong settings.
10.0 Coagulation exercises

10.1 Unipolar coagulation exercises on a beef model

Prepare the device for work (as outlined under „Starting Up“), and proceed as follows:

1. Choose a piece of fresh, lean beef. Do not take veal as it does not change color when cut with an electrode. Pork is unsuited for this exercise due to its cellular structure. Wait for the meat to assume room temperature.

**Important:** It is absolutely mandatory to place the meat on the neutral electrode (which, in turn, must be connected to the device); otherwise, power abduction and thereby system operation is impossible.

2. Insert a blue coated electrode of your choice (rigid needle, ball, blade, etc.) into the hand piece with the blue finger switch.

3. On the central channel 2 (blue), switch the unit to mode „Continuous coagulation“ (button 1), and select the strongest output of 90 Watts with the arrow button 4, and the lowest coagulation degree of c1. For details on settings see the previous chapters.

4. Gently place the electrode onto the meat and then press the finger or the foot switch. View the results. The intensity setting was too high, if remarkable color changes occur along the incision. This coagulation would have led to tissue necrosis.

5. Reduce the intensity to 10 Watts with the arrow button 3, and increase the coagulation degree to c9. Try to repeat the exercise as under step 4. Very likely, no coagulation (white coloring underneath the electrode) will occur, or it would take very long until it happens.

6. Repeat the process described above with increased settings until a quick change of color (coagulation/protein precipitation) is achieved. This is the ideal setting for the beef model.

7. Continue the coagulation exercise at the determined ideal setting by pressing the coagulation electrode strongly onto the meat. You will note that it takes much longer to achieve a coagulation because the initial electric resistance in the tissue is too high.

Continue this exercise with different settings until you have obtained the skill and the confidence you will need for doing actual surgery on a patient.

Also repeat these exercises in mode „Cutting with coagulation“ (button 2) with different coagulation degrees from c1 to c9. The maximum output selectable is limited by the set coagulation degree. For further details on settings see the previous chapters.

**Important:** For unipolar coagulation always touch the area to be coagulated very gently - do not press down the electrode. Only then press the finger or foot switch.

The intensity setting found best on the beef model can be different on an actual patient due to the position of the neutral electrode or the texture of the tissue.
10.2 Cutting exercises on a beef model

Prepare the device for work (as outlined under „Starting Up”), and proceed as follows:

1. Choose a piece of fresh, lean beef. Do not take veal as it does not change color when cut with an electrode. Pork is unsuited for this exercise due to its cellular structure. Wait for the meat to assume room temperature.

   Important: It is absolutely mandatory to place the meat on the neutral electrode (which, in turn, must be connected to the device) otherwise, power abduction and thereby system operation is impossible.

2. Insert a bipolar forceps of your choice onto the bipolar cable.

3. On the left channel 1 (blue), switch the unit to mode „Continuous coagulation“ (button 1), and select the strongest output of 90 Watts with the arrow button 4 and in the lowest coagulation degree of c1.

4. Gently place the electrode onto the meat and then press the finger or foot switch. View the results. The intensity setting was too high if remarkable colour changes occur along the incision. This coagulation would have led to tissue recribus.

5. Reduce the intensity with arrow button 3 to 10 Watts, and increase the coagulation degree to c9. Try to repeat the exercise as under step 4. Very likely, no coagulation (white colouring underneath the electrode) will occur, or it would take very long until it happens.

6. Repeat the process described above with increased settings until no changes of color and no visible sparking is observed. The tip of the electrode should encounter no resistance.

   Continue this exercise cutting with slow, medium, and fast speed at each of the different settings to obtain the skill and the confidence you will need for doing actual surgery on a patient.

   Also repeat these exercises in mode „Cutting with coagulation“ (button 2) with different coagulation degrees from c1 to c9. The maximum output selectable is limited by the set coagulation degree. For further details on settings see the previous chapters.

   Important: When cutting and cutting with coagulation always first activate the unit by pressing the finger or foot switch, and then touch the tissue.

The intensity setting found best on the beef model can be different on an actual patient due to the position of the neutral electrode or the texture of the tissue.
# 11.0 Application-specific information

## 11.1 Notes and recommendations

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<th>Type of treatment</th>
<th>Monocut channel 1</th>
<th>Mono coag channel 2</th>
<th>Bipolar coag channel 3</th>
<th>Recommended setting</th>
<th>Recommended electrode form</th>
<th>Recommended REF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>THROAT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uvuloplasty / palatoplasty</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 28-32 watts</td>
<td>n.B. multi-tip, needle, UPP special electrode</td>
<td>506.5870.0 (#41) 506.5886.0</td>
</tr>
<tr>
<td>Lingual tonsils</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 18-22 watts</td>
<td>rigid special needle electrode coated, multi-tip</td>
<td>506.5884.0 (#36) 506.5870.0 (#41)</td>
</tr>
<tr>
<td>Tonsillectomy</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 22-28 watts</td>
<td>a.r. Multi-Tip</td>
<td>506.5870.0 (#41)</td>
</tr>
<tr>
<td>Tonsillotomy</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 30-40 watts</td>
<td>a.r. rigid special needle electrode coated</td>
<td>506.5884.0 (#36)</td>
</tr>
<tr>
<td>Coagulation of the lingual tonsils</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 15-25 watts</td>
<td>rigid needle electrodes</td>
<td>506.5881.0 (#32)</td>
</tr>
<tr>
<td>Tightening of the soft palate with automatic switch-off</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 5-15 watts</td>
<td>A bipolar needle electrodes palate</td>
<td>506.5887.0 (#04)</td>
</tr>
<tr>
<td>Tightening of the lingual tonsils with automatic switch-off</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 5-15 watts</td>
<td>A bipolar needle electrodes palate</td>
<td>506.5887.0 (#04)</td>
</tr>
<tr>
<td><strong>NOSE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperplastic mucosa</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 25-27 watts</td>
<td>a.r. ENT sling</td>
<td>506.5882.0 (#35)</td>
</tr>
<tr>
<td>Polyposis nasi</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 26-30 watts</td>
<td>a.r. ENT sling</td>
<td>506.5882.0 (#35)</td>
</tr>
<tr>
<td>Rhynophyma</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 28-30 watts</td>
<td>n.B. multi-tip, sling</td>
<td>506.5870.0 (#41) 506.5871.0 (#43)</td>
</tr>
<tr>
<td>Concha treatment / epistaxis</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 22-24 watts</td>
<td>10-15 sec multi-tip, rigid needle electrode, bayonet shaped, adjustable fine-wire electrode</td>
<td>506.5870.0 (#41) 506.5885.0 (#52)</td>
</tr>
<tr>
<td><strong>EAR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radioconcho therapy</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 15-25 watts</td>
<td>8-18 sec rigid needle electrodes</td>
<td>506.5885.0 (#52)</td>
</tr>
<tr>
<td>Volume reduction of the nasal concha with automatic switch-off</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 5-15 watts</td>
<td>A bipolar needle electrode concha</td>
<td>506.5888.0 (#03)</td>
</tr>
<tr>
<td>Otoplasty</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 28-30 watts</td>
<td>a.r. multi-Tip</td>
<td>506.5870.0 (#41) 506.5886.0</td>
</tr>
<tr>
<td>Paracentesis</td>
<td>x</td>
<td></td>
<td></td>
<td>approx. 20-30 watts</td>
<td>1-2 sec rigid special electrode, coated</td>
<td>506.5884.0 (#36)</td>
</tr>
</tbody>
</table>

*A = automatic  
a. r. = as required*

**IMPORTANT INFORMATION!**
The manufacturer cannot be held liable for any wrong settings. The notes are simply recommendations! The required settings depend on the consistency of the tissue, the age of the patient, the position of the neutral electrode, the electrode used, the type of wave and the device settings. For any questions, please do not hesitate to contact us.
11.0 Application-specific information

11.2 Radioconchotherapy (RCT)

- Place neutral electrode as closely as possible to the OT field and make sure that the patient completely covers the neutral electrode.
- Anaesthetise OT field as usual.
- Insert special electrode into the hand piece with the blue button.
- Adjust unit to monopolar Mono continuous coagulation, coagulation degree C3, 22-23 Watts.
- Penetrate the mucosa without bone contact parallel to the bone. Activate device with finger or foot switch for 2-3 seconds.
- Repeat this procedure along the concha 2-3 times (according to requirements) until the shrinking effect occurs.

In case the mucosa at the concha is hyperplastic and has to be removed, we recommend the ENT loop electrode No. 35 with bendable shaft. The hyperplastic mucosa is removed in layers.

Recommendations for the patient
The patient should be advised to use a saline solution spray 4 times a day and nasal ointment (Dispanthenol), and to refrain from physical exertion for 2 days.

ATTENTION:
The manufacturer cannot be held liable for an erroneous choice of settings. The information above is strictly based on experience and should be considered as a recommendation only. The correct settings depend on the tissue consistency, the age of the patient and the placement of the neutral electrode, the electrodes used, kind of mode and settings.

11.3 Coagulation of the lingual tonsils

- Place neutral electrode as closely as possible to the OT field and make sure that the patient completely covers the neutral electrode.
- Anaesthetise OT field as usual. ATTENTION: Do not use any anaesthetics containing adrenalin as this may cause impaired cerebral blood flow.
- Insert the bent special needle electrode (with partially coated needle) REF 506.5884.0 into the handpiece with the blue button.
- Adjust unit to monopolar Mono continuous coagulation, coagulation degree C3, 22-23 Watts.
- Penetrate the needle at full length into the lingual tonsils.
- Activate device with finger or foot switch for 5-15 seconds.
- Repeat this procedure 2-3 times (according to requirements).

Postoperative treatment
Examinations: 1 week and 4 weeks postoperative

Is it necessary to repeat the treatment?
Results may vary from case to case.

ATTENTION:
The manufacturer cannot be held liable for an erroneous choice of settings. The information above is strictly based on experience and should be considered as a recommendation only. The correct settings depend on the tissue consistency, the age of the patient and the placement of the neutral electrode, the electrodes used, kind of mode and settings.
11.4 Tightening the lingual tonsils with automatic switch-off

- Place neutral electrode as closely as possible to the OT field and make sure that the patient completely covers the neutral electrode although this is not necessary when using bipolar instruments. However, in case that monopolar instruments are used during the intervention - where a neutral electrode is obligatory - it cannot be forgotten.

- Anaesthetise OT field as usual. Normally an anesthetic spray is used first and after a short while 1-2 ccm anaesthetics are injected.

- Insert the bipolar electrode REF 506.5887.0 into the bipolar cable of the ATMOS RS 221 and the bipolar cable into the BIPCOAG outlet of the device.

- Switch the unit to „continuous bipolar coagulation“ mode, recommended coagulation degree c1 - c2. For impulse coagulation please select impulse duration dA for automatic switch-off. Select an output power of 15 - 20 W. The higher the performance, the smaller the dehydrated area, the lower the performance the larger the dehydrated tissue because with low power the device switches off later.

- Penetrate the electrode on the left and on the right parallel to the lingual tonsils and not too deeply into the tissue. Please take care that the electrode is penetrated thus far enough so that the thin coating (isolation) disappears partly or even fully into the tissue because the bare metal might cause necrosis on the tissue surface. The radiosurgical device may only be activated after correct positioning of the electrode. Activate the device via foot switch until the procedure is completed with an acoustic signal. This happens when the lingual tonsils are tightened, the volume is reduced and the tissue has the required resistance.

- If after the healing period it is noticed that the first treatment was not completely successful, the treatment can be repeated after approx. 3 to 6 weeks.

This information refers to the treatment of the lingual tonsils with our radiosurgical device ATMOS RS 221. If this type of treatment is performed with the bipolar electrode REF 506.5887.0 but with an external device without automatic switch-off every penetration takes approx. 9 seconds.

For all interventions a patient consent sheet should be signed by the patient.

Postoperative behaviour and care of the patient

Slight oedema may occur within the first 3 days.

As a precaution it is recommended to prescribe a standard analgetic in case the patient suffers from pain or oedema. The preventive administration of antibiotics is recommendable.

Recommendations to the patient

The patient has to see the doctor again after 24 hours.

The patient is advised to eat only soft, lukewarm and less spicy food for the following 2-3 days. The swallowing reflex might be slightly abnormal for 1-2 days.

The patient has to be informed that in the first days after the intervention snore noise could be louder than before. This phenomenon disappears during the healing process.

Normal activities may resume immediately. However, the patient should not smoke within the first days after the intervention.

In the patient information and consent form which the patient has to sign, he should be advised of possible incidents and complications during surgical procedures in the nose/oral/pharyngeal area. This patient information sheet should also contain the above mentioned recommendations.

ATTENTION:
The manufacturer cannot be held liable for an erroneous choice of settings. The information above is strictly based on experience and should be considered as a recommendation only. The correct settings depend on the tissue consistency, the age of the patient and the placement of the neutral electrode, the electrodes used, kind of mode and settings.
11.5 Volume reduction of the nasal concha with automatic switch off

- Place neutral electrode as closely as possible to the OT field and make sure that the patient completely covers the neutral electrode although this is not necessary when using bipolar instruments. However, in case that monopolar instruments are used during the intervention - where a neutral electrode is obligatory - it cannot be forgotten.

- Anaesthetise OT field as usual. Normally an anesthetic spray is used first and after a short while 1-2 ccm anaesthetics are injected.

- Insert the bipolar electrode REF 506.5888.0 into the bipolar cable of the ATMOS RS 221 and the bipolar cable into the BIPCOAG outlet of the device.

- Switch the unit to „continuous bipolar coagulation“ mode, recommended coagulation degree c1 - c2. For impulse coagulation please select impulse duration dA for automatic switch-off. Select an output power of 15 - 20 W. The higher the performance, the smaller the dehydrated area, the lower the performance the larger the dehydrated tissue because with low power the device switches off later.

- Penetrate the electrode parallel to the bone into the nasal mucosa but without contact to the bone. Please take care that the electrode is penetrated far enough so that the thin coating (isolation) disappears partly or even fully into the tissue because the bare metal might cause necrosis on the tissue surface. The radiosurgical device may only be activated after correct positioning of the electrode. Activate the device via foot switch until the procedure is completed with an acoustic signal. This happens when the nasal mucosa is tightened, the volume is reduced and the tissue has the required resistance.

- Repeat the procedure once or twice (if necessary) until the desired shrinking effect is reached. The punctures should then be 1 to 1.5 cm be kind the first puncture.

- If after the healing period it is noticed that the first treatment was not completely successful, the treatment can be repeated after approx. 3 to 6 weeks.

This information refers to the treatment of the nasal concha with our radiosurgical device ATMOS RS 221. If this type of treatment is performed with the bipolar electrode REF 506.5888.0 but with an external device without automatic switch-off every penetration takes approx. 5 to 9 seconds.

In case the mucosa at the concha is hyperplastic and has to be removed, we recommend the ENT loop electrode No. 35 with bendable shaft. The hyperplastic mucosa is removed in layers. In this case the Cut/Coag mode is used, coagulation degree 3, approx. 25 to 27 Watt in order to prevent unnecessary bleedings.

For all interventions a patient consent sheet should be signed by the patient.

**Postoperative care of the patient**

As a precaution it is recommended to prescribe a standard analgetic in case the patient suffers from pain or oedema. The preventive administration of antibiotics is recommendable.

**Recommendations to the patient**

The patient has to see the doctor again after 24 hours.

Normal activities may resume immediately. However, the patient should not smoke within the first days after the intervention.

In the patient information and consent form which the patient has to sign, he should be advised of possible incidents and complications during surgical procedures in the nose/oral/pharyngeal area. This patient information sheet should also contain the above mentioned recommendations.

**ATTENTION:**

The manufacturer cannot be held liable for an erroneous choice of settings. The information above is strictly based on experience and should be considered as a recommendation only. The correct settings depend on the tissue consistency, the age of the patient and the placement of the neutral electrode, the electrodes used, kind of mode and settings.
11.6 Bipolar exercises with the automatic switchoff at a beef model

Prepare the device for work (as outlined under „Starting Up“), and proceed as follows:

1. Choose a piece of fresh, lean beef. Do not take veal as it does not change color when cut with an electrode. Pork is unsuited for this exercise due to its cellular structure. Wait for the meat to assume room temperature.

Please note that it is not absolutely mandatory to place the meat on the neutral electrode (which, in turn, must be connected to the device) because there is no bipolar electrode required when working in the bipolar mode.

2. Attach a bipolar needle electrode (stitch electrode) of your choice to the bipolar cable.

3. Switch the unit to „continuous bipolar coagulation“ mode at the right channel 3 (blue, button 1), and select an output power of 15 W and a coagulation degree of either c1 or c2 with the arrow button 4. For further details on settings see the previous chapters.

4. Switch the unit to the operation mode „bipolar impulse coagulation“ at the right channel (blue, button 2), and activate the automatic switch of dA with the arrow buttons 3 and 4.

5. Penetrate the bipolar needle electrode into the meet phantom so that at least part of the isolation of the needle disappears into the meet. This way discoloration and necrosis on the tissue surface is avoided. Operate the foot switch until the device switches off automatically, the coagulation process is finalised. Shortly before a bang can be heard. In order to examine the treated area you have to cut it open either with a scalpel or by using the device in the mono cut channel with the unfiltered wave and a needle electrode. The subjacent area must have a white colouration.

6. Repeat the process described above with increased output power. You will see that the result changes. The higher the settings, the quicker the coagulation and the smaller the dehydrated, tightened area. The lower the output power, the larger is the dehydrated area because with low power the tissue liquid vapourises slowerly and the device switches off later.

**ATTENTION:**
The different settings and the relevant results achieved from the beef may deviate on patients and can only be considered as recommendations! The required settings depend on the nature of the tissue, the age of the patient, the position of the neutral electrode (not required when working in the channel Bip Coag), the electrodes used and the, wave form. The manufacturer cannot be held liable for wrong settings.
11.7 Tightening the soft palate with automatic switch-off

- Place neutral electrode as closely as possible to the OT field and make sure that the patient completely covers the neutral electrode although this is not necessary when using bipolar instruments. However, in case that monopolar instruments are used during the intervention - where a neutral electrode is obligatory - it cannot be forgotten.

- Anaesthetise OT field as usual. Normally an anasthetic spray is used first and after a short while 1-2 ccm anaesthetics are injected.

- Insert the bipolar electrode REF 506.5887.0 into the bipolar cable of the ATMOS RS 221 and the bipolar cable into the BIPCOAG outlet of the device.

- Adjust continuous bipolar coagulation, recommended coagulation degrees is c1 - c2. Select impulse duration dA for automatic switch off during impulse coagulation. Adjust a performance of 15-20 Watt. The higher the performance, the smaller the dehydrated area, the lower the performance the larger the dehydrated area because with lower performance the device switches off later.

- Penetrate the electrode and take care that the electrode is penetrate thus far that the thin coating (isolation) disappears partly or even fully in the tissue because the bare metal might cause necrosis on the tissue surface. Please take care not to puncture the musculus levator veli palatini nor the musculus veli palatini. Go easy on the uvula as this may lead to necrosis. The first puncture is made approx. 2.5 cm above the lowest point of the uvula. The second and third puncture is made on the left and the right, parallel to the first puncture. The radiosurgical device may only be activated after correct positioning of the electrode. Activate the device via foot switch until the procedure is completed with an acoustic signal. This happens when the palate is tightened, the volume is reduced and the tissue has the required resistance.

- If after the healing period it is noticed that the first treatment was not completely successful, the treatment can be repeated after approx. 3 to 6 weeks.

This information refers to the treatment of the soft palate with our radiosurgical device ATMOS RS 221. If this type of treatment is performed with the bipolar electrode REF 506.5887.0 but with an external device without automatic switch-off every penetration takes approx. 9 seconds.

For all interventions a patient consent sheet should be signed by the patient.

Postoperative behaviour and care of the patient

Slight oedema may occur within the first 3 days. Hyperemia of the palate can be observed during 4 to 6 days. In the puncture area a white-yellow discoloration may occur during the procedure which then disappears within the following 2 weeks.

As a precaution it is recommended to prescribe a standard analgetic in case the patient suffers from pain or oedema. The preventive administration of antibiotics is recommendable.

Recommendations to the patient

The patient has to see the doctor again after 24 hours.

The patient is advised to eat only soft, lukewarm and less spicy food for the following 2-3 days. The swallowing reflex might be slightly abnormal for 1-2 days.

The patient has to be informed that in the first days after the intervention snore noise could be louder than before. This phenomenon disappears during the healing process.

Normal activities may resume immediately. However, the patient should not smoke within the first days after the intervention.

In the patient information and consent form which the patient has to sign, he should be advised of possible incidents and complications during surgical procedures in the nose/oral/pharyngeal area. This patient information sheet should also contain the above mentioned recommendations.

ATTENTION:
The manufacturer cannot be held liable for an erroneous choice of settings. The information above is strictly based on experience and should be considered as a recommendation only. The correct settings depend on the tissue consistency, the age of the patient and the placement of the neutral electrode, the electrodes used, kind of mode and settings.
Possible malfunctions and their rectification

The device has extensive self-test routines for safe operation. A malfunction is reported by an error code on the LED displays Mono Cut and Mono Coag. Since those outlets are automatically cut off, the displays are also switched off. The error message shines dimly.

Error messages include:
Err in the display of the left channel Mono Cut, and a
Number in the display of the center channel Mono Coag

Two categories of errors can occur:
Category 1 Error in external elements and attachments Codes Err 07 and Err 11 to Err 29
Category 2 Internal system error Codes Err 01 to Err 06, Err 08 to Err 10, Err 30 to Err 62

Possible causes of errors in category 1 include:
Defect finger switch and/or foot switch, defect buttons, or buttons already pressed at start-up.

Rectification of category 1 errors:
In case of errors reported with codes Err 07 and Err 11 to Err 29 the operator may himself try to rectify the error. In order to do this, switch off the device and remove the defective part from the device according to the Error Table (see next page). Then switch on the device. If the error is no longer reported, the defective part should be replaced.

Important: Error code Err 07 may be caused by a tangling of the cables of hand pieces and/or bipolar forceps, or by accidental contact of active and inactive electrodes during operation. A so-called overspill of RF current to other channels may occur. If the voltage on an inactive channel outgrows a certain limit, the unit goes out of operation and displays error code Err 07.

The cables of hand pieces, bipolar forceps, and neutral electrode should not be rolled up, shortened, placed tightly parallel, crossed, or tangled. The electrode which are not in use should be kept at safe distance.

Rectification of category 2 errors:
Errors reported with codes Err 01 to Err 06, Err 08 to Err 10, and Err 30 to Err 62 indicate a device system error demanding immediate technical checkup and repair.
## Table of Error Codes

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<thead>
<tr>
<th>Code Err</th>
<th>Type of Error</th>
<th>Remarks</th>
</tr>
</thead>
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<tr>
<td>01-06</td>
<td>internal system error</td>
<td>Immediate service mandatory.</td>
</tr>
<tr>
<td>07</td>
<td>wrong outlet active</td>
<td>Voltage in an inactive outlet.</td>
</tr>
<tr>
<td>08-10</td>
<td>internal system error</td>
<td>Immediate service mandatory.</td>
</tr>
<tr>
<td>11</td>
<td>foot switch: short circuit</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>finger switch Mono Cut - short circuit</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>finger switch Mono Coag - short circuit</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>bipolar forceps Bip Coag - short circuit</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>several errors code 11 to 14</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>button Mono Cut + short circuit</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>button Mono Cut - short circuit</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>button mode Cut - short circuit</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>button mode Cut/Coag - short circuit</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>button Mono Coag + short circuit</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>button Mono Coag - short circuit</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>button mode Mono Coag - continuous coagulation - short circuit</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>button mode Mono Coag - pulse coagulation - short circuit</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>button Bip Coag + short circuit</td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>button Bip Coag + short circuit</td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>button mode Bip Coag - continuous bipolar coagulation: short circuit</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>button mode Bip Coag - bipolar pulse coagulation: short circuit</td>
<td></td>
</tr>
<tr>
<td>28</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>several errors code 16 to 27</td>
<td></td>
</tr>
<tr>
<td>30-62</td>
<td>Internal system error</td>
<td>Immediate service mandatory.</td>
</tr>
</tbody>
</table>
Warranty

The manufacturer assumes a warranty for 24 months from the day of delivery. The manufacturer will repair or, at their discretion, replace parts and material proven faulty or being of poor workmanship with new items. Assumption of this guarantee excludes other claims (cancellation of sales contract, depreciation, compensation, etc.).

The warranty is void in case of faults caused by improper treatment, bad maintenance, repair by technicians other than those of ATMOS MedizinTechnik GmbH & Co. KG, use of incorrect accessories, normal wear and tear, or transport.

This warranty is not extended to electrodes, hand pieces, hand piece cables, bipolar pincers, bipolar cables, neutral electrodes, and neutral electrode cables.

Repair

Should the device not function impeccably even though all recommendations and instructions were observed, please send it together with all accessories to the manufacturer or their representatives for repair.

Describe your complaint on the delivery note and state whether the malfunction is a permanent one or appears only occasionally, and when you noted the fault for the first time. This will make it easier to locate the fault and to return the device to you as soon as possible.

Pack the device and all accessories very carefully. Send it as parcel or insured parcel post prepaid. The manufacturer or their representatives will not assume liability for devices lost in the mail. Unfranked shipments will not be accepted.

Should the inspection show no fault in the device, the manufacturer or their representatives regret having to charge you for the time, postage, and packing plus VAT.
14.0 Notes on EMC

- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.

14.1 Guidelines and Manufacturer’s Declaration - Emissions

The ATMOS RS 221 is intended for use in the electromagnetic environment specified below. The customer or user of the RS 221 should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The RS 221 has to emit electromagnetic power, to ensure its intended function. Nearby electromagnetic devices can be influenced.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class B</td>
<td>The RS 221 is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonics IEC 61000-3-2</td>
<td>Inapplicable</td>
<td></td>
</tr>
<tr>
<td>Flicker IEC 61000-3-3</td>
<td>Inapplicable</td>
<td></td>
</tr>
</tbody>
</table>

14.2 Guidelines and Manufacturer’s Declaration - Immunity

The ATMOS RS 221 is intended for use in the electromagnetic environment specified below. The customer or user of the RS 221 should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601- Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESD IEC 61000-4-2</td>
<td>± 6 kV Contact</td>
<td>± 6 kV Contact</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>± 8 kV Air</td>
<td>± 8 kV Air</td>
<td></td>
</tr>
<tr>
<td>EFT IEC 61000-4-4</td>
<td>± 2 kV Mains</td>
<td>± 2 kV for mains cables</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>± 1 kV I/Os</td>
<td>± 1 kV I/Os</td>
<td></td>
</tr>
<tr>
<td>Surges IEC 61000-4-5</td>
<td>± 1 kV Differential</td>
<td>± 1 kV symmetric</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>± 2 kV Common</td>
<td>± 2 kV symmetric</td>
<td></td>
</tr>
<tr>
<td>Power Frequency 50/60 Hz Magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be that of a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
14.0 Notes on EMC

### Immunity Test

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage Dips / Dropout IEC 61000-4-11</td>
<td>&lt; 5 % $U_T$ (&gt; 95 % Dip of the $U_T$) for 0.5 Cycle</td>
<td>&lt; 5 % $U_T$ (&gt; 95 % Dip of the $U_T$) for 0.5 Cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the RS 221 demands continued function even in case of interruptions of the energy supply, it is recommended to supply the RS 221 from an uninterruptible current supply or a battery.</td>
</tr>
<tr>
<td></td>
<td>40 % $U_T$ (60% Dip of the $U_T$) for 5 Cycles</td>
<td>40 % $U_T$ (60% Dip of the $U_T$) for 5 Cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% $U_T$ (30 % Dip of the $U_T$) for 25 Cycles</td>
<td>70% $U_T$ (30 % Dip of the $U_T$) for 25 Cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5 % $U_T$ (&gt;95 % Dip of the $U_T$) for 5 s</td>
<td>&lt; 5 % $U_T$ (&gt;95 % Dip of the $U_T$) for 5 s</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE** $U_T$ is the mains alternating current prior to application of the test levels.

### 14.3 Guidelines and Manufacturer’s Declaration - Immunity

The ATMOS RS 221 is intended for use in the electromagnetic environment specified below. The customer or user of the RS 221 should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>3 $V_{eff}$ 150 kHz to 80 MHz</td>
<td>3 $V_{eff}$ 150 kHz to 80 MHz 80% AM 1kHz</td>
<td>Portable and mobile communications equipment should be separated from the RS 221 incl. the cables by no less than the distances calculated/listed below.</td>
</tr>
</tbody>
</table>
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m 80 MHz to 2.5 GHz | **Recommended distances:**
| | | | $d = 1.17 \sqrt{P}$
| | | | $d = 1.17 \sqrt{P}$ for 80 MHz to 800 MHz
| | | | $d = 2.33 \sqrt{P}$ for 800 MHz to 2.5 GHz
| | | | where $P$ is the max. power in watts (W) and D is the recommended separation distance in meters (m). |
| | | | Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b). |
| | | | Interference may occur in the vicinity of equipment containing following symbol. |
14.0 Notes on EMC

NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines may not to be applicable in all cases. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.

a The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be exactly predestined. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS RS 221 is used exceeds the above compliance level, the ATMOS RS 221 is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the device.

b Within the frequency range of 150 kHz to 80 MHz the field strength is to be below 3 V/m.

14.4 Recommended separations between portable and mobile RF Communications equipment and the ATMOS RS 221

The ATMOS RS 221 is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS RS 221 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS RS 221 as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Nominal output of the transmitter W</th>
<th>Separation distance, depending on transmit-frequency m</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz d = 1,17 \sqrt{P}</td>
<td>80 MHz to 800 MHz d = 1,17 \sqrt{P}</td>
</tr>
<tr>
<td>0.1</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.69</td>
</tr>
<tr>
<td>100</td>
<td>11.67</td>
</tr>
</tbody>
</table>

For transmitters for which the maximum nominal output isn’t indicated in the above table, the recommended separation distance $d$ in meters (m) can be determined using the equation belonging to the respective column whereas $P$ is the maximum nominal output of the transmitter in watts (W) acc. to manufacturer’s specification.

NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines may not to be applicable in all cases. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.
1. General: Our General Standard Terms and Conditions apply exclusively. Client’s terms and conditions which are contrary to or deviate from our General Standard Terms and Conditions are not recognised unless their validity is explicitly confirmed in writing. Our General Standard Terms and Conditions also apply even if we deliver to clients without reservation, in the delivery of all our products and in any future business with that client.

2. Proposal - Order Confirmation: Our proposals are subject to change without notice unless otherwise stated in our order confirmation. Each order is only accepted by us following our written order confirmation.

3. Orders: Every order requires an exact description of all of our product’s details. We assume no liability for errors and damage caused by inaccurate or incomplete ordering details.

4. Prices: Unless otherwise stated in the order confirmation, our prices in the order confirmation are ex factory prices and exclude packaging and value added tax. Packaging is charged separately at cost price in the invoice. Value added tax is charged separately in the invoice according to the legal rate on the invoice date. We reserve the right to change prices appropriately should price reductions or increases, especially due to wage settlements, changes in the price of materials or currency fluctuations, be incurred. Proof of such changes will be provided for the client on request.

5. Payment Conditions - Balancing: Unless otherwise stated in the order confirmation, our invoices are payable with a 3% discount within 10 days (except for repair and assembly services) or within 21 days from the invoice date net cash. Money received is decisive for complying with this term. We are entitled to charge interest after the due date at a rate 2% above the relevant basic interest rate of the German Federal Bank. Should the client have payment arrears, we are entitled to charge interest on arrears at a rate 5% above the relevant basic interest rate of the German Federal Bank. Should we be able to prove higher damages due to arrears, we are also entitled to claim these. The client only has the right to balance invoices against its own claims should such claims be confirmed in a court of law or recognised by us. The client does not have the right of retention due to disputed counterclaims.

6. Delivery Periods: Fulfillment of our delivery duties requires the punctual and proper fulfillment of the client’s duties. The right to defense on the grounds of an unfulfilled contract is reserved. Should the client default in accepting the goods delivery or breach other cooperation duties, we are entitled either to demand the payment of the contract price for any delivered goods and the costs incurred up to that time without setting a further deadline. The right to make further claims is reserved. Furthermore, in such cases, the risk of coin-vidential damage or a coincidental deterioration in the quality of the delivered goods is transferred to the client in the case of default in accepting such goods or payment arrears. Acts of God or stoppages (due to insufficient supplies of material, industrial disputes etc.) entitle us either to demand an appropriate extension of delivery periods or to partly or entirely dissolve the delivery contract. This does not give the client the right to claim damages. We have fulfilled delivery periods if the delivery goods have left our factory or the client has been informed of the goods’ readiness for delivery within such delivery periods. Delivery periods stipulated by the client are not recognised by us unless they form part of our order confirmation. We adhere to legal terms and conditions in cases where, as a result of an undue delay in the delivery for which we are liable, the client is entitled to claim that his interests in a continued fulfillment of the contract have ceased. We also adhere to legal terms and conditions should a delay in delivery be caused by deliberate or grossly negligent action by us or our representatives for which we are responsible. We are also responsible for such actions by our representatives or agents. Should the delivery delay not be caused by our deliberate or grossly negligent action for which we are responsible, our liability is limited to damage which is regarded as typical for that case. We are liable according to the legal terms and conditions if and as far as the delivery objects apart from our product itself, except in the case of an act of deliberate or grossly negligent actions by us or our representatives or agents. Should no deliberate breach of contract be claimed, our liability is limited to damage which is regarded as typical for that case.

7. Delivery - Familiarisation: In the case of the delivery of devices for the medico-technical industry which require assembly and/or familiarisation for the final customer using specialist trade personnel (such as Ear, Nose and Throat Apparatus and Suction Units), we reserve the right to deliver the goods exclusively to the relevant specialist traders. Should the trader not carry out assembly and/or familiarisation for the final customer, this is carried out by us. In such cases, we reserve the right to charge the client for the additionally created costs. Our specialist traders operate a recording system so that, if necessary, our products can be traced to the final customer. The specialist trader undertakers to immediately report to us all events and risks which must be reported in connection with our products.

8. Passage of Risk - Packaging: Unless otherwise stated in our order confirmation, delivery is agreed ex factory. The risk of the goods’ damage or loss is therefore transferred to the client as soon as the goods leave the factory or the client is in default of acceptance of the goods. This also applies to cases where we confirm prepaid carriage. Transport packaging and all other packaging according to the packaging regulations is not returnable. Our client is responsible for disposing the packaging at its own cost. Our deliveries are also insured by us at the client’s expense unless explicitly otherwise agreed. No insurance is arranged in the case of goods which are collected by our clients. In the case of transport damage, claims are only handled if the client receives confirmation of any damage, reduced weight or lost or by the shipping company before accepting the delivery.

9. Warranty: The client is responsible for examining the delivered goods immediately after receiving them to determine any eventual deficiencies or delivery errors, and to report these immediately. Should the client fail to examine the delivery and reporting responsibility, and should payment conditions be fulfilled, we shall be liable to the client within the scope of legal regulations. Our period of warranty shall at all cases be two years. Our client can make use of the warranty as follows, so long as he can provide first buyer proof (in the form of an invoice or delivery note) and provided that the product still has the original, unaltered serial number:
   a. We choose whether to fulfil our guarantee by providing repair services free of charge - either on the client’s premises in our factory or - or replacing the product. We can also provide these guarantee services through an authorised company.
   b. Should a product be returned to us, the client agrees to send the product in its original or similar packaging, offering the same protection as the original packaging, to our address or any address notified by us.
   c. Our guarantee ceases to apply if changes of any kind have been made to our product, unless such changes have been made by us or a company authorised by us, or have been previously agreed upon in writing by us. Our guarantee also ceases to apply if third parties have carried out repairs to our products or replaced parts thereof. This applies regardless of the fact whether these measures individually or collectively led to a deficiency of the product;
   d. We accept no responsibility for damage defects caused by:
      - operational wear and tear;
      - incorrect installation or incorrect or insufficient maintenance;
      - incorrect operation of the product (in contradiction to the operating instructions delivered with the product); - improper use or operating faults;
      - inappropriate or negligent handling and care, especially with respect to dirt, lime, suction of fluids, inappropriate cleaning and sterilisation; - using accessories and/or replacement parts which are not explicitly approved;
      - incorrect assembly and/or initial operation by the client or third parties;
      - the client’s negligence in handling the product; - unacceptable operating conditions, such as humidity, temperatures, the power supply, vibrations;
      - accidents, acts of God, especially lightning, fire, water, public unrest and insufficient ventilation. We are not liable for damage to the delivery objects apart from our product itself, except in the case of an act of deliberate or grossly negligent actions by us or our representatives or agents.

10. Reservation of Ownership: We retain ownership of our products until the receipt of all payments arising from the business relationship, including all demands arising from instalment orders, subsequent orders, repairs, accessory deliveries and replacement orders. Should we have agreed upon payment on the basis of cheque and bill transactions, the ownership reservation applies until the cheque received by us has been paid in, and does not expire through our credit upon receiving the client’s cheque. In the case of a breach of contract by the client, especially payment arrears, we are entitled to repossess our goods. Repossession of our goods represents a withdrawal from the contract, unless explicitly declared in writing by us. We have the right to utilise the product after its repossession, whilst the income form such use is balanced against the client’s arrears, after deducting appropriate utilisation costs. The client is responsible for handling the goods with care. Should maintenance and inspection work be necessary, the client must carry these out punctually at his own cost. Our client is entitled to sell the goods he has bought from us in a proper sale transaction. However, he must immediately assign all outstanding claims to the value of the final invoice sum (including value added tax) of our claims to his customers or third parties. The client is entitled to collect this claim even after such assignment. Our right to collect the claim ourselves remains unaffected thereby. We undertake to release the securities to which we are entitled if requested to do so by the client should the realisable value of the securities be more than 10 percentage points higher than the outstanding claims. We reserve the right to choose the securities to be released.

11. Plans and Illustrations: We retain ownership of copyrights to all plans, illustrations, calculations and other documents which are attached to our proposals. The client must receive explicit written permission before passing these on to third parties. Imitating our legally patented products is forbidden and will be prosecuted.

12. Jurisdiction and Place of Performance: Our central office is the place of performance for all disputes in connection with these General Standard Terms and Conditions and the contracts closed with clients under them. This jurisdiction excludes other jurisdiction relating to persons or subject-matter. Furthermore, our client is not entitled to bring charges against us in another court should he file counter-charges, carry out counterclaiming or declare retention. We, however, are entitled to bring charges against our client at their general place of jurisdiction or at another relevant court recognised by German or foreign law. Unless otherwise stated in the order confirmation, our central office is the place of performance.

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