# Instructions for use

# ASTOPAD®

## Patient warming system

**DUO310**
**COV070**
**COV105**
**COV150**
**COV155**
**COV180**
**SOF2**
**SOF4**
**SOF5**
**SOF7**
**ROE4**
**ROE8**

**STIHLERELECTRONIC**

STIHLER ELECTRONIC GmbH • 70771 Leinfelden-Echterdingen • Germany

0315.7200.12, Rev.08, 03/2021

***To be completed by the user:***

**Serial number** _____

**Registration number** _____

**Equipment location** _____

**Start-up date** _____

**Manufaturer:** **STIHLER ELECTRONIC GmbH**
**Gaussstrasse 4**
**70771 Leinfelden-Echterdingen**
**GERMANY**
**Tel. +49 (0) 711-720670**
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**E-mail: info@stihlerelectronic.de**



CE 0124

STIHLER ELECTRONIC GmbH declares under its sole responsibility that this product conforms to EC Directive 93/42/EEC on medical devices.
Notified body: DEKRA Certification GmbH, registration number 0124.

## CONTENTS

# 1 Information about these instructions

- Carefully read the entire instructions for use before using the device.
- Correct and safe operation can only be guaranteed if the instructions for use are observed.
- Incorrect use can result in damage to the product or to other property and/or personal injury.
- Keep the instructions for use for future reference.
- Only use the device for the intended purpose as described in these instructions for use. Please refer to section **4 Intended use**.

# 2 General information

## 2.1 Guarantee conditions

The guarantee period is 12 months. During this guarantee period, the manufacturer will repair or replace free of charge all defects caused as a result of material or manufacturing errors.

Other damage is not subject to this guarantee. The guarantee does not include cases of misuse or incorrect handling, use of force or damage caused by normal wear and tear. This also applies to changes undertaken by persons who are not authorised by the manufacturer and to modifications to the original condition.

If the equipment is damaged during the guarantee period, send the cleaned equipment to the nearest sales point or directly to STIHLER ELECTRONIC GmbH. The sender is responsible for any transport and packaging costs.

## 2.2 Liability

The manufacturer is only liable for the safety, reliability and performance of the equipment

- if all operating, servicing, and calibration procedures are carried out by trained and qualified persons according to the procedures published by the manufacturer;
- if only original spare parts are used to replace components as needed;
- if the assembly and repairs are carried out by authorised personnel or an authorised service centre;
- if the electrical installations satisfy the locally applicable regulations and the IEC/EN requirements and
- if the equipment is used for its intended purpose and at a suitable location in accordance with the instructions for use.

## 2.3 Disposal of the equipment

Electrical devices are recoverable waste and should not be disposed of in domestic waste at the end of their service life. Please follow the local rules for the disposal of used products, or send the cleaned and disinfected equipment with a corresponding note to STIHLER ELECTRONIC GmbH or your closest sales point. This will ensure the most cost-efficient and proper disposal of your old equipment.

| | |
|---|---|
|  | Follow the national regulations on the disposal of medical devices. |

## 2.4 Information on battery disposal

Batteries must not be disposed of in domestic waste. The user is obliged to ensure proper disposal. Returns can be made to public communal collection points or wherever the batteries are sold.

The battery can be removed by loosening the 4 screws on the underside and opening the housing.

## 2.5 Return of a used product

A report must be sent together with the equipment, detailing the precise reasons, circumstances, and, if known, the cause of the return. To prevent transportation damage, the equipment should be shipped either in the original packaging or in other, well-protected packaging.

**Transport regulations for returning devices with a built-in battery:**
When returning the ASTOPAD DUO310 control units, it is essential to ensure that the control unit is in a state in which it can be stored/transported (see section **7.6.3 Switch to storage/transport mode**).

| **⚠WARNING** |
|---|
| **Risk of infection!**<br>Clean and disinfect the equipment after every use and before you return the equipment for repairs. |

| ***NOTICE*** |
|---|
| The customer is responsible for the proper packaging and labelling of returns. |

## 2.6 Service information

For service or technical support, please contact your local sales point or the following:

STIHLER ELECTRONIC GmbH
Gaussstrasse 4
70771 Leinfelden-Echterdingen
GERMANY

Tel. +49 (0) 711-720670
Fax +49 (0) 711-7206757
www.stihlerelectronic.de
E-Mail: info@stihlerelectronic.de

# 3 Important safety information

These instructions for use define and refer to the following safety information.

| **DANGER** |
| --- |
| Describes a risk from a situation which, if not avoided, will result directly in severe or fatal injuries. |

| **WARNING** |
| --- |
| Describes a dangerous situation which, if not avoided, may result in severe or fatal injuries. |

| **CAUTION** |
| --- |
| Describes a dangerous situation which, if not avoided, may result in minor to moderate injuries. |

| ***NOTICE*** |
| --- |
| Indicates information considered important, but that does not relate to risks (e.g. reference to property damage). |

## 3.1 Dangers

**DANGER**

**Explosion hazard!**
Do not use the ASTOPAD patient warming system in an explosive environment or in the presence of flammable anaesthetics.

## 3.2 Warnings

**WARNING**

**Risk of injury!**

- Use of the ASTOPAD must be carried out under the supervision of a physician.
- Read and observe all instructions, stickers, and accompanying documentation that came with the ASTOPAD. Failure to observe the instructions, including warnings and safety information, can result in incorrect handling, patient injury, injury to users or medical personnel, damage to the device, or material damage.
- Operate and service the ASTOPAD only in accordance with the procedures described in these instructions and with the applicable standards, rules, and guidelines. The manufacturer shall not be responsible for the safety of users or patients if any actions/procedures other than those published are carried out during operation, servicing, or repeated inspections.
- The ASTOPAD may only be used by appropriately trained and medically qualified specialists.
- The ASTOPAD may only be serviced by appropriately trained and medically qualified service personnel.
- If the OR table top is tilted (adjusted through the longitudinal axis), there is a danger that the patient will slip off. The patient must be sufficiently secured against slipping before the OR table top is tilted or otherwise moved out of the horizontal position!
- Due to the physico-chemical properties of disinfectants, please ensure that no disinfectants accumulate beneath the patient. During use, the patient must not be damp or even wet when lying on the ASTOPAD applied part. This presents a chemical burn hazard.
- When RF surgical instruments or endocardial catheters are used, the patient must also be properly insulated. This insulation must not be damp. The equipment manufacturer’s instructions for use must be observed at all times.
- With transdermal drug applications (patches), the additional heat can increase the uptake of the drugs and result in injury to the patient.

**⚠WARNING**

**Risk of injury!**

- In the case of arterial occlusion, the applied parts of ASTOPAD must not be used distal to this area.
- Overheating of ischemic extremities can occur when ASTOPAD applied parts are used.
- The ASTOPAD does not contain any parts the user can repair. Therefore, do not attempt to repair the ASTOPAD yourself. Contact your local sales point.
- Any repairs to the equipment may only be carried out by persons authorised and qualified by the manufacturer.
- Modifications to the ASTOPAD are not permitted.
- When ASTOPAD COV applied parts are used as an over-blanket, please ensure that they do not obstruct the patient's field of vision.
- Do not use the ASTOPAD until the following error conditions have been remedied through appropriate corrective action:
  - Damaged or worn cables, plugs, or connecting socket.
  - Damaged housing, damaged or loose control panel.
  - Damaged or missing labels/safety signs/warnings.
  - Damaged outer cover of the ASTOPAD applied parts.
  - No visual or audible alarm activated after switching on via the Standby button (self-test defective).
  - Button(s) which do not function correctly.
  - ASTOPAD has been exposed to mechanical impact or extreme exposure to a liquid.
  - ASTOPAD has given someone an electric shock.
  - ASTOPAD appears to have overheated.
  - ASTOPAD has triggered an alarm shutdown.
- The extension connection cable and the mains cable should not touch the patient and should not hinder the treating personnel.
- Do not cover the labelled SENSOR ZONE of the ASTOPAD applied part ROE (patient, their extremities or objects).
- If the ASTOPAD control unit with battery installed is not to be used for a longer period of time, the battery must be removed.
- Keep the ASTOPAD outside the MRI area. The ASTOPAD is not designed for use in a magnetic resonance imaging (MRI) environment.

**⚠WARNING**

**Danger of overheating!**

- For patients from 35 to 90 cm in height, use only the ASTOPAD applied parts COV070 and SOF7.
- Do not use the ASTOPAD applied parts COV105, COV150, COV155, COV180, SOF2, SOF4, SOF5, ROE4 or ROE8 for patients under 90 cm in height.

**⚠WARNING**

**Risk of infection!**

- Use aseptic procedures.
- Clean and disinfect the ASTOPAD after every use and before you return the ASTOPAD for repairs.
- Place the extension connection cable between the ASTOPAD applied part and the ASTOPAD control unit so that it is protected from blood and bodily fluids.
- Please ensure that the cables do not touch the floor.
- It is recommended that a water-tight and absorbent barrier is always placed between the patient and the ASTOPAD applied part.

**⚠WARNING**

**Risk of decubitus ulcer!**

- Regardless of the treatment duration, aged, paralysed, comatose, and cachectic patients are particularly at risk of decubitus ulcers. Critical points should therefore also be constantly examined by medical personnel.
- Never operate ASTOPAD applied parts when folded or bent under the patient.
- Do not place the patient on the connection block of the ASTOPAD applied part.
- When the ASTOPAD applied parts COV are used as an under-blanket, please ensure that they are placed flat underneath the patient, are secured, and will not crease.
- In all surgical procedures, it is important to ensure that sufficient measures are taken to avoid bed sores in accordance with the patient position.
- The risk of skin irritation caused by an accumulation of surgical preparation solutions under the patient may increase with warming; please ensure that the instructions for use for surgical preparation solutions are followed.
- Reduce or eliminate the risk of skin warming under pressure-loaded bony protrusions.
- Do not place ANY hard objects (such as connection cables, ECG cables, hard reusable neutral electrodes, patient fluid lines, etc.) between the ASTOPAD applied part and the patient.
- ASTOPAD applied parts COV can be wrapped around the patient. However, take care that the applied part will not form creases.

**⚠WARNING**

**Risk of electric shock!**

- To prevent the risk of an electric shock, only connect the ASTOPAD to a mains power supply with an earth conductor.
- Do not use mains adapters that interrupt the earth conductor.
- Do not open the ASTOPAD control unit casing.
- If several pieces of equipment are combined or connected (e.g., in multiple socket outlets), the sum of the leakage currents may not exceed the permissible limits (please see the respective national regulations). Observe the requirements as stipulated in IEC/EN 60601-1 regarding medical electrical equipment.
- All electrical installations must conform to the applicable electrical standards and the specifications defined by the manufacturer.
- Before every use, check to make sure that the ASTOPAD control unit and the ASTOPAD applied parts are undamaged.
- The mains plug must be removed from the socket to fully disconnect the ASTOPAD from the mains.

**⚠WARNING**

**Risk of radio interference!**

- Use of the ASTOPAD in the immediate vicinity of other equipment or stacked with other devices should be avoided, as this may result in incorrect operation. If use in the form described is necessary nevertheless, the ASTOPAD and the other equipment must be observed to confirm that they are functioning correctly.
- Use of accessories other than those specified by the manufacturer of the ASTOPAD may cause increased electromagnetic interference or reduced electromagnetic immunity and result in incorrect operation.
- Do not use portable RF communication devices (radio equipment) (including their accessories such as antenna cables and external antennas) within 30 cm of the parts of the ASTOPAD and cables stipulated by the manufacturer. Failure to observe this may cause a reduction in the performance of the ASTOPAD.

## 3.3 Cautions

**⚠CAUTION**

**Risk of injury!**

- When installing the ASTOPAD control unit on an infusion stand, please observe the instructions from the infusion stand manufacturer regarding maximum load and tilting stability.
- When the ASTOPAD applied parts are used on the OR table, the OR table must be prepared according to the customary national regulations and guidelines.
- Never insert pointed or sharp objects into the ASTOPAD applied parts or damage the surface of the parts in any other way.
- Damage to the ASTOPAD applied part may result in overheating. For this reason:
  - Only disinfect the ASTOPAD applied part with an alcohol-based disinfectant or one of the approved disinfectants.
  - Do not use bleach solution containing hypochlorite to disinfect the ASTOPAD applied parts.
  - Do not carry out cleaning or disinfection procedures other than those specified in this manual without the express permission of the manufacturer.

**⚠CAUTION**

**Risk of hypothermia!**

- If an ASTOPAD alarm shutdown is triggered at one output, the heating process is interrupted at both outputs.
- If thermally conductive materials, such as water, gel, and similar substances, are used and were not pre-heated, the patient’s body temperature may cool down as a result once the ASTOPAD applied parts are switched off.
- When ASTOPAD is used, the patient’s body temperature must be monitored at regular intervals.
- The temperature control of the ASTOPAD regulates and monitors the temperature of the applied parts, but not the patient’s body temperature.
- If the ASTOPAD cannot be started or if the patient's temperature balance is insufficient, consider using alternative warming methods to prevent or reduce hypothermia or to improve the patient's comfort.
- When this product is used in combination with other heat sources, an overheating alarm or an overheating alarm shut-off may occur on the ASTOPAD control unit.

**CAUTION**

**Misinterpretation!**

Shadows of the internal cables and sensors may be captured in diagnostic images (CT, X-ray) taken when the patient is using the ASTOPAD applied parts. The images should be assessed by clinical experts to determine the quality and diagnostic suitability of the image.

**CAUTION**

**Risk of radio interference!**

- Due to the presence of electromagnetic interference, essential performance characteristics may be unusable or only usable to a limited extent. This results in a risk of hypothermia for the patient.
- According to Standard IECEN 60601-1-2, medical electrical equipment requires special precautionary measures in regard to electromagnetic compatibility (EMC).
- The ASTOPAD may cause radio interference or may interfere with the operation of equipment in close proximity. It may be necessary to take appropriate corrective action, such as a realignment, a new configuration of the ASTOPAD or shielding.

## 3.4 Notices

***NOTICE***

- The specified moisture resistance IPX2 for the ASTOPAD applied parts is ensured only when the connector
  - is connected to a suitable extension cable, or
  - the attached protective cap is used.
- Actions to avoid damaging the ASTOPAD:
  - Do not immerse the ASTOPAD control unit, the applied parts or the plugs of the connection cables in liquid.
  - Do not disinfect the ASTOPAD control unit and/or the applied parts with:
    - Steam (e.g. in autoclaves)
    - Hot air
    - Thermochemical cleaning solutions
  - The ASTOPAD applied parts must not be disinfected with bleach solution (hypochlorite or other agents containing chlorine).
  - Do not use any cleaning or decontamination methods other than those recommended by the manufacturer.
- The customer is responsible for the proper packaging and labelling of returns.
- The specified defibrillation protection is ensured only when the ASTOPAD applied part is connected to the extension connection cable and the ASTOPAD control unit.

# 4. Intended use

Patient warming system with reusable applied parts, used for body warming.

## 4.1 Intended medical indications

ASTOPAD can be used in all areas used for medical purposes for prophylaxis against the patient cooling down or for treating hypothermia. The individual ASTOPAD applied parts can be used as over-blankets and/or under-blankets, pads (OR table pad) or a mattress. The OR table pads and mattresses are also used to relieve pressure on the patient.

## 4.2 Contraindications

There are no known contraindications for patient warming.

## 4.3 Possible adverse effects

With proper use, no side effects are expected from the ASTOPAD. For longer surgical procedures, there is an increased risk of decubitus ulcers. To reduce the risk of decubitus ulcers, the additional use of a pressure-relieving pad is recommended if the operating time exceeds two hours.

## 4.4 Intended patient group

ASTOPAD must not be used for patients with a height of less than 35 cm.

Only the ASTOPAD applied parts COV070 and SOF7 may be used for patients with a height of between 35 and 90 cm.

For all other patients with a height greater than 90 cm, all ASTOPAD applied parts may be used.

## 4.5 Intended body part

ASTOPAD applied parts COV are designed for use under or over the patient, completely or partially (upper body and extremities) and the head (without field of vision).

ASTOPAD applied parts SOF and ROE are designed for use under the patient, fully or partially (upper body and extremities).

ASTOPAD applied parts may have direct skin contact. It is recommended that a thin, water-tight and absorbent pad is used between the ASTOPAD applied part and the patient.

ASTOPAD control unit and connection cables are not designed for direct skin contact.

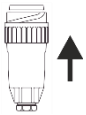
## 4.6 Intended user profile

Only medically trained professionals may use the patient warming system.

## 4.7 Intended environment of use/operation

- ASTOPAD may only be used in professional health care facilities (e.g. hospitals, emergency care, dialysis, or near HF surgical devices).
- The ASTOPAD can be used in surgical, intensive care or inpatient areas in which there is a risk of cooling for the patient, or where the patient requires external warming.
- ASTOPAD is reusable, but must be cleaned/disinfected between uses.
- The ASTOPAD control unit is designed to be secured to round pipes (such as infusion stands) or on medical standard rails.
- ASTOPAD is not designed for use in incubators.
- ASTOPAD is not designed for use in a magnetic resonance imaging (MRI) environment.
- ASTOPAD may not be used in a potentially explosive environment or in the presence of flammable anaesthetics.
- ASTOPAD is not designed for use in a domestic environment or in veterinary medicine.

# 5 Symbols

| Symbols and indications on the control panel | |
|---|---|
|  | Standby button: Switches between **Standby mode** and **On mode.** When the blue LED is lit, ASTOPAD is in **Standby mode**. |
|  | Start button: Starts the heating process. |
|  | Plus button: Temperature increase set value. |
| | Minus button: Temperature decrease set value. |
|  | Stop button: Stops the heating process. |
|  | Alarm condition when the yellow LED is lit or flashing. |
|  | No ASTOPAD applied part is connected to the control unit. |
|  | Wait until the temperature of the applied part rises to reach the set temperature. |
|  | Wait until the temperature of the applied part drops to reach the set temperature. |
|  | Battery charge level<br>(control unit not connected to mains power). |
|  | Battery charge level<br>(control unit connected to mains power and battery is being charged). |
|  | Battery status<br>(defective or incorrect battery). |

| Where applicable, these symbols appear at the appropriate location on the ASTOPAD, on the packaging, on the type plate or in the accompanying documentation. | |
|---|---|
|  | Defibrillation protected applied part type BF in accordance with IEC/EN 60601-1. |
| **IPX2** | Protected against dripping water in accordance with IEC/EN 60529 . |
|  | Follow the instructions for use. |
|  | General warning/danger symbol. |
| REF | Reference (part) number. |
| SN | Serial number. |
| LOT | Batch designation. |
| MD | Medical device. |
|  | Year of manufacture. |
|  | Manufacturer. |
|  | Information for the position of the locking ring on the cable plug of the extension connection cable. |
|   | Battery. |
|  | Margins of the heated area. |
|   | The SENSOR ZONE symbol marks the area containing the sensors for controlling the mattress temperature. This zone must not be covered under any circumstances, not even partially. |
|  | Symbol on plug connector for potential equalisation in accordance with IEC/EN 60601-1. |
|  | Dry at low heat. |
|   | Boil-proof, delicate wash cycle. |
|  | Do not use chlorine bleach. |
|  | Do not iron. |
|  | Dry-cleaning possible, with limitation of mechanical stress. |

| | |
|---|---|
|  | Additional information. |
|  | Electrical devices are recoverable waste and should not be disposed of in domestic waste at the end of their service life. |
|  | Batteries and rechargeable batteries are recoverable waste and should not be disposed of in domestic waste at the end of their service life. |
|  | Symbol for the permitted temperature range for storage and transport. |
|  | Symbol for the permitted moisture range for storage and transport. |
|  | Symbol for the permitted atmospheric pressure range for storage and transport. |
|  | Transport upright with the arrows pointing up. |
|  | Keep dry. |
|  | Fragile, protect against impacts. |
|  | Packaging labelling for transporting lithium batteries according to ADR SV 188 or IATA - DGR International Dangerous Goods Regulations,Packing Instruction 965, II. SECTION II 43416. |
|  | Labelling for the individual shipment of lithium-ion batteries via air freight according to IATA - DGR International Dangerous Goods Regulations, Packing Instruction 965, II. SECTION II II.2 Additional requirements 43418/v4. |
| CE 0124 | This device conforms to EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. The notified body, DEKRA Certification GmbH (identification number 0124), monitors the manufacturer's quality management system. |
| CLASSIFIED c UL us 75JA | MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH standards ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012,<br>CAN/CSA-C22.2 No. 60601-1:14. Control No. 75JA. |
|  | Tilt of the OR table top. |
|  | Acoustic alarm signal. |
|  | No acoustic alarm signal. |

| | |
|---|---|
|  | Prohibited: Do not cover SENSOR ZONE - risk of overheating! |
|  | Prohibited: Do not clamp ASTOPAD applied parts - risk of damage and possible overheating! |
|  | Prohibited: Never pierce the ASTOPAD applied parts with pointed or sharp objects - risk of damage and possible overheating! |
|   | Prohibited: Do not disinfect with hypochlorite solution. Chlorine and peroxides and all other oxidising disinfectants have a negative effect on the materials, therefore the use of these disinfectants is not recommended. Product life is significantly shortened by disinfectants of this kind. |
|   | Prohibited: Keep the ASTOPAD outside the MRI area. |

# 6 Product description

## 6.1 Introduction

The ASTOPAD consists of a control unit and optionally one or two applied parts (blankets, pads, OR table pads or mattresses).

**⚠WARNING**

**Danger of overheating!**

- For patients from 35 to 90 cm in height, use only the ASTOPAD applied parts COV070 and SOF7
- Do not use the ASTOPAD applied parts COV105, COV150, COV155, COV180, SOF2, SOF4, SOF5, ROE4 or ROE8 for patients under 90 cm in height.

## 6.2 Technical description

The ASTOPAD control unit can be secured to a round pipe (e.g. infusion stand) or a medical standard rail.

The ASTOPAD control unit has two outputs (connecting sockets) A and B for connecting the ASTOPAD applied parts. The required set temperature of each connected applied part can be selected, independently of one another, in a range from 32.0°C to 39.0°C in 0.5°C increments. Optionally, the system can also be operated with only one of the outputs A or B connected. The selected set temperature and the actual temperature of each applied part are displayed on the control panel.

The ASTOPAD control unit can also be operated via the battery option, independent of the mains. With battery inserted, operation is possible for about 2 hours independent of the mains.

With the exception of the COV155 heating blankets, which were exclusively designed as blankets for the upper body, the ASTOPAD applied parts COV can be used as over-blankets for warming the patient from above and/or as under-blankets for warming the patient from below.

The heated, pressure-relieving OR table pad ASTOPAD applied part SOF or ROE offers a combination of hypothermia and decubitus prophylaxis.

The key component of the ASTOPAD applied part SOF is a visco-elastic foam, combined with a dynamic foam base for the best possible decubitus prophylaxis on the OR table.

The special ASTOPAD applied part ROE is X-ray permeable and based on an optionally 40 mm or 80 mm thick visco-elastic foam with a maximum sensor-free zone.

Together with a pressure-relieving gel pad or a conventional visco-elastic OR table pad, the ASTOPAD applied part COV helps to prevent hypothermia and to relieve pressure in the surgical field. It should, however, be noted that the ASTOPAD applied part COV is placed over the gel pad to prevent the patient from cooling down due to the cold gel pad. This transfers the heat to the patient as soon as the ASTOPAD is started. A long warm-up time for the gel pad is not needed.

ASTOPAD does not regulate the patient's actual body temperature and does not display it. It only shows the current temperature of the active applied part.

Temperature regulation of the ASTOPAD applied parts is performed with several integrated sensors.

Safety of the ASTOPAD is ensured by the following measures for each output:

- Several temperature sensors for each applied part
- Double independent sensor monitoring
- Heater monitoring
- Time shut-off
- Visual and acoustic alarm signals
- Overheating and low-temperature alarm if the contact surface temperature deviates from the temperature controller setting

## 6.3 Components of the ASTOPAD

### Control unit

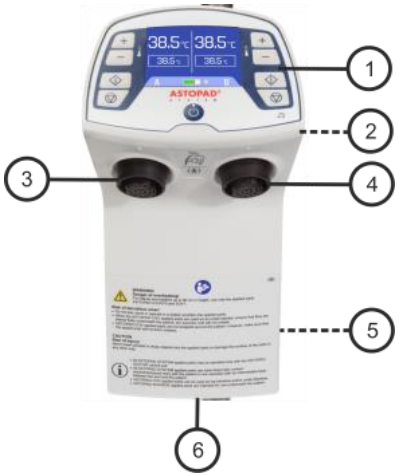



**Fig. 1 Control unit**

| No. | Designation | Description |
|---|---|---|
| **1** | Control panel | Operating buttons and temperature displays. |
| **2** | Fastening device | For secure attachment of the ASTOPAD control unit. |
| **3** | Output A (connecting socket) | Plug-in connection to connect the applied part. |
| **4** | Output B (connecting socket) | |
| **5** | Connection for potential equalisation | The additional potential equalisation has the task of equalising potentials of various metal parts which can be touched at the same time or of reducing potential differences that can arise in the application between the body, electromedical equipment and foreign conductive parts.<br>The connection is made via green-yellow insulated cables (min. 4 mm²) on standardised connection bolts and connection sockets.<br>When connecting/combining ME devices to form an ME system, the requirements of IEC/EN 60601-1 must be observed. |
| 6 | Device plug for detachable mains connection cable with mains plug | The mains connection cable supplies the control unit with mains voltage via a plug. The device is disconnected from the power supply by pulling out the mains plug. |

## Applied parts


**Fig. 2 ASTOPAD COV/SOF/ROE applied parts**

| No. | Designation | Description |
|---|---|---|
| **1** | ASTOPAD COV | Example of an ASTOPAD applied part COV |
| **2** | ASTOPAD SOF | Example of an ASTOPAD applied part SOF |
| **3** | ASTOPAD ROE | Example of an ASTOPAD applied part ROE |
| **4** | Connection cable | Connection cable for connecting to the extension connection cable. |
| **5** | End cap | The attached end cap is closed when no extension connection cable is connected. It protects the contacts and guarantees the IPX2 moisture protection. |
| **6** | Extension connection cable | The applied parts can be connected to the control unit with the extension connection cable. |

## 6.4 Control panel

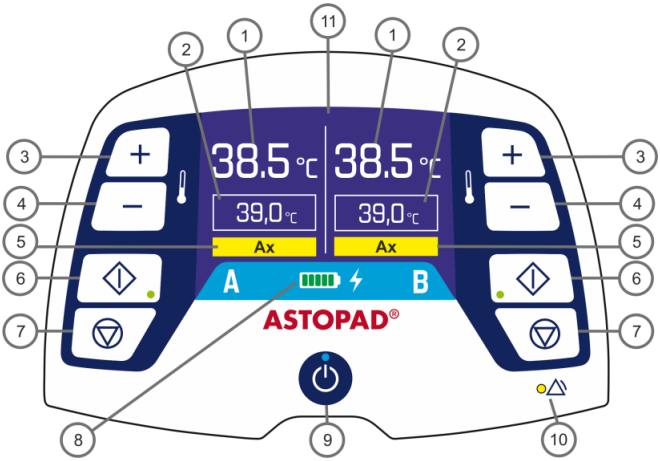


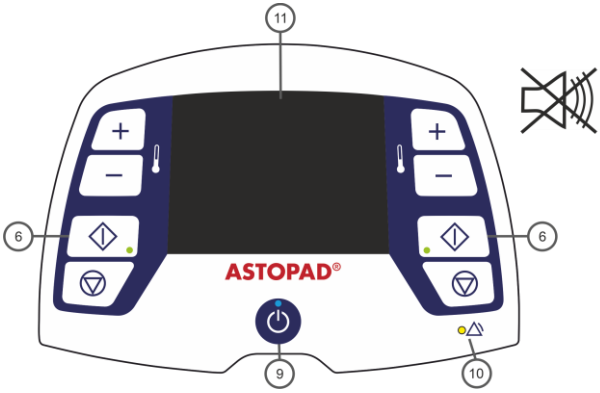

**Fig. 3 Control panel**

| No. | Designation | Description |
|---|---|---|
| **1** | Actual temperature A or B | Displays the actual temperature of the applied part. |
| **2** | Set temperature A or B | Displays the selected set temperature of the applied part. |
| **3** | Plus button A or B | Press this button to increase the set temperature in increments of 0.5°C. |
| **4** | Minus button A or B | Press this button to decrease the set temperature in increments of 0.5°C. |
| **5** | Alarm indicator | Displays the corresponding alarm code in an alarm situation. |
| **6** | Start button Start LED (green) A or B | Press this button to start the heating process. or Press this button to confirm a change made to the set temperature. |
| **7** | Stop button A or B | Ends the heating process and switches off the respective output. |
| **8** | Battery indicator | Shows the current battery charge level or battery status. |
| **9** | Standby button Standby LED (blue) | The Standby button switches between **Standby mode** and **On mode**. |
| **10** | Alarm LED (yellow) | LED flashes or lights up and the acoustic alarm signal sounds when there is an alarm situation. |
| **11** | Display | Informs the user of temperatures and fault conditions. |

# 7 Operating states

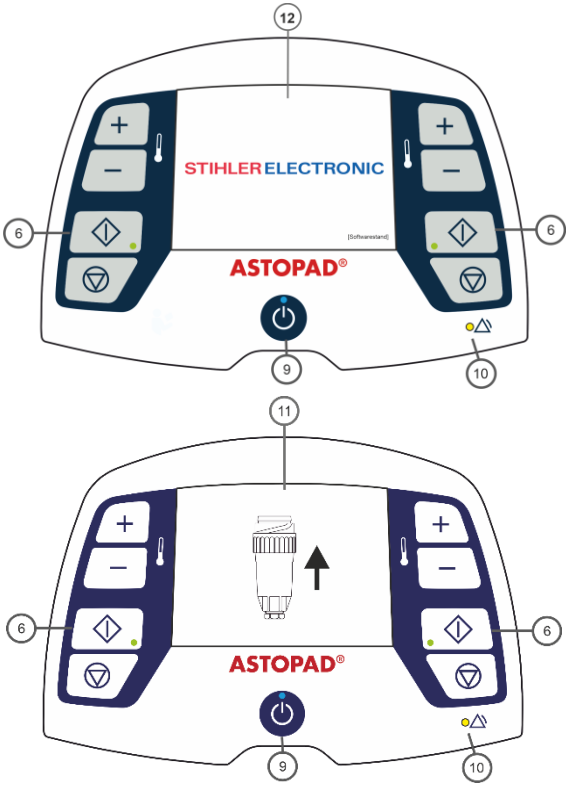
With a few exceptions, the operating states when only one applied part is connected to the ASTOPAD control unit at output A and is being operated are described below.
The description of the operating states applies to the connection and operation of a second applied part to output B of the ASTOPAD control unit.

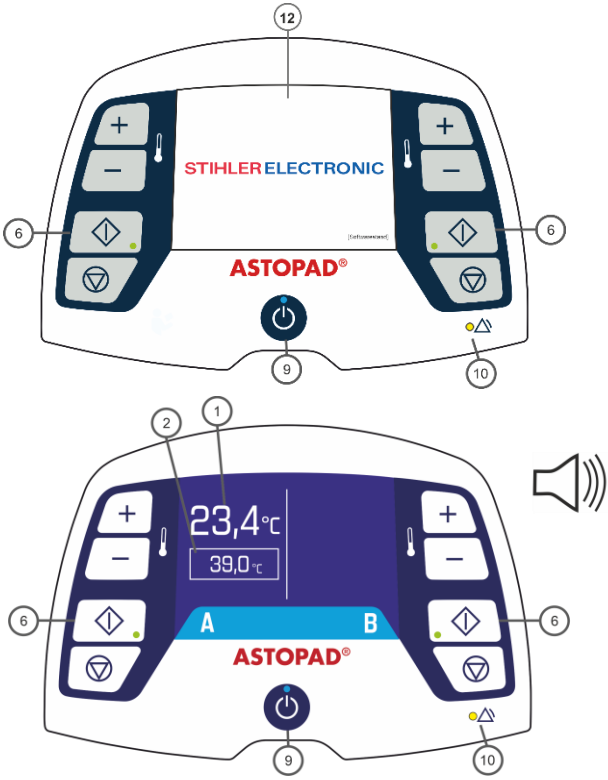
## 7.1 Standby mode

| | |
|---|---|
| Control panel |  |
| Action | After connecting the mains plug to the mains socket, the control unit is in **Standby mode**. |
| Device response | • The Standby LED (9) lights up.<br>• The display (11) shows the symbol for battery status (only for equipment with built-in battery). |
| | • Press the Standby button (9) to switch the equipment from any mode to **Standby mode**.<br>• In **Standby mode** only the electronics and the applied parts are disconnected from the power supply. The control unit remains connected to the mains.<br>• For equipment with a built-in battery, the battery is charged in **Standby mode**.<br>• After a power failure, the equipment automatically switches to **Standby mode**. |

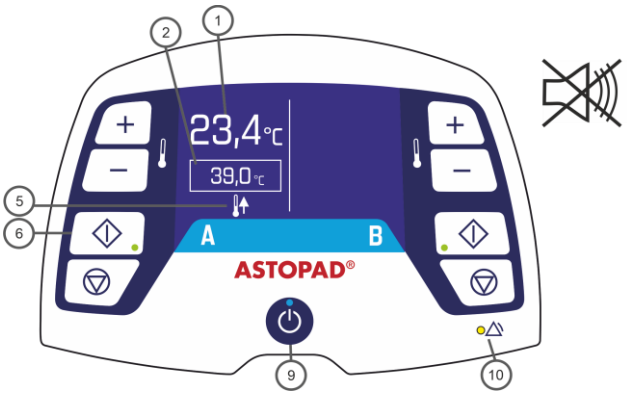
## 7.2 On mode

### 7.2.1 On mode (no applied part connected)

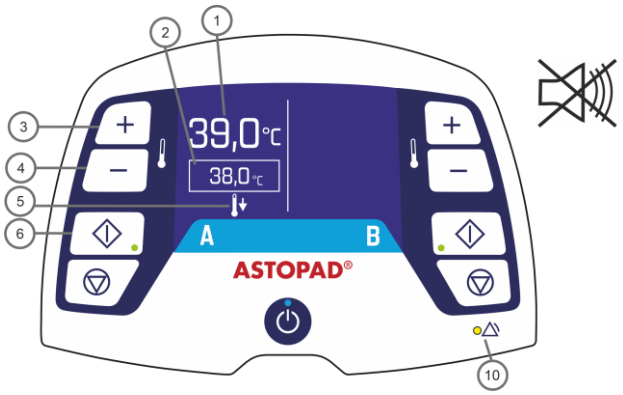
| | |
|---|---|
| Control panel |  |
| Action | Press the Standby button (9) to switch the control unit from **Standby mode** to **On mode**. |
| Device response | • The Standby LED (9) goes out.<br>• The Start screen (12) is displayed for 1 second.<br>• The equipment performs a self-test. The LEDs (6), (10) flash once and the acoustic alarm signal sounds once, to confirm that the control unit is working properly.<br>• If no applied part is connected to the control unit, the display (11) shows the symbol Connect applied part. |
| ⓘ | • The current software version is displayed in the bottom right corner of the Start screen.<br>• The display remains until at least one applied part is connected to the control unit. |

| **7.2.2 On mode** (an applied part connected) | |
|---|---|
| Control panel |  |
| Action | Press the Standby button (9) to switch the control unit from **Standby mode** to **On mode**. |
| Device response | • The Standby LED (9) goes out.<br>• The Start screen (12) is displayed for 1 second.<br>• The equipment performs a self-test. The LEDs (6), (10) flash and the acoustic alarm signal sounds, to confirm that the control unit is working properly.<br>• The display shows the current actual temperature (1) and the stored set temperature (2). |
|  | • The current software version is displayed in the bottom right corner of the Start screen.<br>• The self-test remains active until the heating process is started.<br>• By pressing the Standby button and simultaneously holding the Stop output B button, the Start screen is displayed for as long as the Stop button is pressed. |

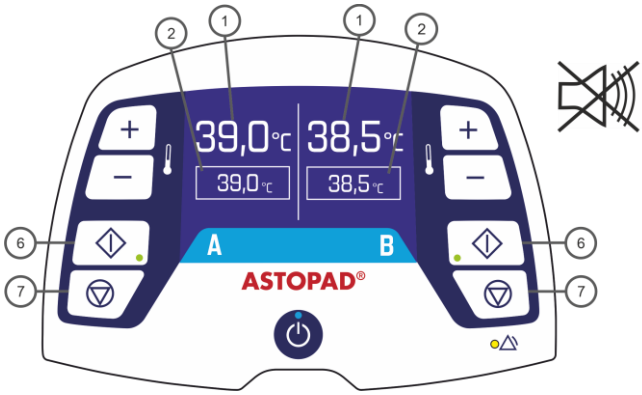
## 7.3 Heating mode output A and/or B

| | |
|---|---|
| Control panel |  |
| Action | Press the Start button (6) to start the heating process. |
| Device response | • The last set temperature (2) is loaded.<br>• Acoustic alarm switches off, and the alarm LED (10) goes out.<br>• When the applied part is started, the display (5) shows the applied part heating symbol, until the difference with regard to the set temperature (2) is less than 1°C.<br>• LED Start (6) lights up green.<br>• Temperature control is active. |
| ⓘ | If no applied part is connected to an output (A or B) or the heating process does not start, displays (1), (2) and (5) go off. |

## 7.4 Increasing/decreasing the set temperature

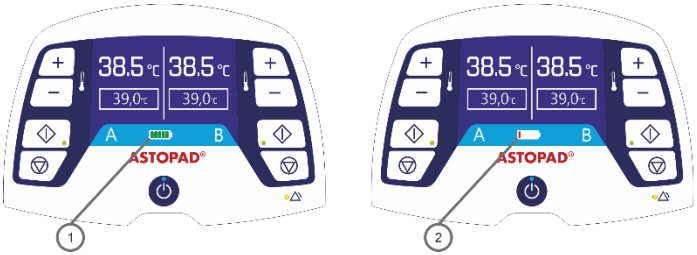
| | |
|---|---|
| Control panel |  |
| Action | 1. Press the Plus (3) / Minus (4) buttons to raise or lower the selected set temperature in 0.5°C increments.<br>2. Confirm the new set temperature by pressing the Start button (6). |
| Device response | • The Start LED (6) flashes green until confirmation by pressing the Start button (6).<br>• The selected set temperature (2) is saved.<br>• When the applied part is started, the display (5) shows the symbol or , until the difference with regard to the set temperature (2) is less than 1°C.<br>• LED Start (6) lights up green.<br>• Temperature control is active. |
| | • If no applied part is connected to an output (A or B) or the heating process does not start, the display (1) and (2) go off.<br>• The set temperature can be set independently for each output A and B in the range from 32.0°C to 39.0°C. |

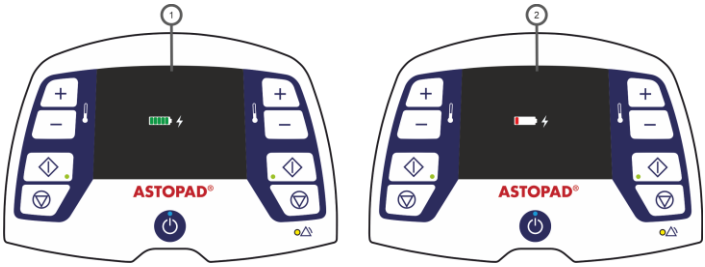
## 7.5 Switching off an output (A or B)

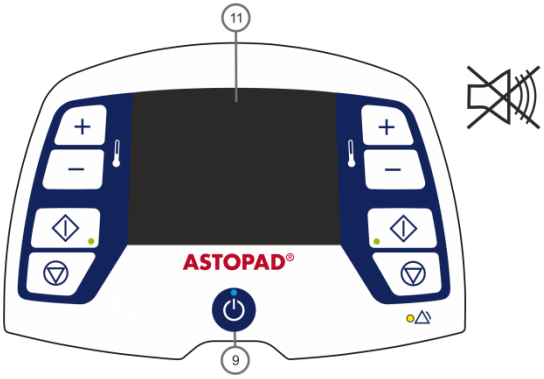
| | |
|---|---|
| Control panel |  |
| Action | Press the Stop button (7) to switch off an output. |
| Device response | • The Start LED (6) goes out.<br>• Displays (1) and (2) go off for the output that was switched off. |
|  | • If only one output is active, pressing the Stop button (7) will deactivate the heating process of this output and activate the self-test.<br>• Pressing the Start button (6) can reactivate the heating process with the last set temperature setting (2).<br>• Press the Standby button (9) to switch the equipment into **Standby mode**. |

## 7.6 Operation independent of the mains (only for devices with a battery)

The ASTOPAD control unit can also be operated independent of the mains with the battery option, to retain heat after the heating phase of the applied part. In this case, the device can be operated for about 2 hours independent of the mains.

| 7.6.1 Display battery charge level | |
|---|---|
| Control panel |  |
| Action | Operate control unit with one or two applied parts. |
| Device response | • Display shows the symbol battery charge level (1) 100%<br>• Display shows the symbol battery charge level (2) 10% |

| 7.6.2 Charge battery | |
|---|---|
| Control panel |  |
| Action | Connect the control unit to the mains (control unit is in **Standby mode**). |
| Device response | Battery fully charged:<br>• Display (1) shows the symbol battery charge level 100% and control unit connected to the mains.<br><br>Battery is <u>not</u> fully charged:<br>• Display (2) shows the symbol battery charge level 10% and control unit connected to the mains. Battery is being charged. |

| 7.6.3 Switch to storage/transport mode | |
|---|---|
| Control panel |  |
| Action | Hold down Standby button (9) for at least 3 seconds. |
| Device response | • The Standby LED (9) goes out.<br>• The display (11) turns off. |
| | Battery discharge is reduced.<br>Press the Standby button (9) for at least 3 seconds to switch on the control unit again (**On mode**). |

# 8 Installation

## 8.1 Initial start-up

Prior to first use, perform the following inspections:

- Visual inspection (see Section **13.1 Recurrent tests**).
- Check the mains voltage (compare the details on the type plate with the available mains voltage). An incorrect mains voltage may destroy the equipment.

National regulations may require different inspections for the initial start-up. If additional tests are required for electrical safety, these must be carried out according to Section **13.1 Recurrent tests**.

## 8.2 Installing the control unit

For safe installation, the ASTOPAD control unit is fitted with a universal mounting device. The device can be securely fixed to the infusion stands, round pipes and medical standard rails.

**⚠CAUTION**

**Risk of injury!**

When installing the ASTOPAD control unit on an infusion stand, please observe the instructions from the infusion stand manufacturer regarding maximum load and tilting stability.

### 8.2.1 Attaching to infusion stand / round pipe

**Fig. 4 Attaching to infusion stand / round pipe**

1. Turn the handwheel anticlockwise to open the fastening device.
2. Select a maximum height of 165 cm on the infusion stand (ASTOSTAND: 180 cm) and place the opened clamping area of the fixing device on the infusion stand.
3. Turn the handwheel clockwise to tighten the fastening device to the infusion stand.
4. Check that the ASTOPAD control unit is securely fitted.

### 8.2.2 Attaching to medical standard rail

**Fig 5 Attaching to medical standard rail**

1. Hook the ASTOPAD control unit at an angle from above into the standard rail using the fastening device.
2. Turn the handwheel clockwise to tighten the fastening device to the medical standard rail.
3. Check that the ASTOPAD control unit is securely fitted.

| | |
|---|---|
| ⓘ | To secure to the medical standard rail, it may be necessary to reposition the universal mounting device. To do this, release the two fixing screws. Once the position is changed, the screws must be screwed in again according to their positioning. |

# 9 Getting started

**⚠WARNING**

**Risk of electric shock!**
Before every use, check to make sure that the ASTOPAD control unit and the applied parts are undamaged.

**⚠WARNING**

**Risk of infection!**
- Use aseptic procedures.
- Route the extension connection cable between the ASTOPAD applied part and the control unit so that it is protected from blood and bodily fluid.
- Please ensure that the cables do not touch the floor.
- It is recommended that a water-tight and absorbent barrier is always placed between the patient and the ASTOPAD applied part.

**⚠WARNING**

**Risk of injury!**
- Do not use the ASTOPAD until the following error conditions have been remedied through appropriate corrective action:
  - Damaged or worn cables, plugs, or connecting socket.
  - Damaged housing, damaged or loose control panel
  - Damaged or missing labels/safety signs/warnings.
  - Damaged outer cover of the ASTOPAD applied parts.
  - No visual or audible alarm activated after switching on via the Standby button (self-test defective).
  - Button(s) which do not function correctly.
  - ASTOPAD has been exposed to mechanical impact or extreme exposure to a liquid.
  - ASTOPAD has given someone an electric shock.
  - ASTOPAD appears to have overheated.
  - ASTOPAD has triggered an alarm shutdown.
- When RF surgical instruments or endocardial catheters are used, the patient must also be properly insulated. This insulation must not be damp. The equipment manufacturer's instructions for use must be observed at all times.
- With transdermal drug applications (patches), the additional heat can increase the uptake of the drugs and result in injury to the patient.
- In the case of arterial occlusion, the applied parts of ASTOPAD may not be used distal to this area.
- Overheating of ischemic extremities can occur when ASTOPAD applied parts are used.

**⚠WARNING**

**Risk of injury!**

- When ASTOPAD COV applied parts are used as an over-blanket, please ensure that they do not obstruct the patient's field of vision.
- The extension connection cable and the mains cable should not touch the patient and should not hinder the treating personnel.
- The marked SENSOR ZONE of the ASTOPAD applied part ROE must not be covered by heat-conducting materials.

**⚠WARNING**

**Risk of decubitus ulcer!**

- Regardless of the treatment duration, aged, paralysed, comatose, and cachectic patients are particularly at risk of decubitus ulcers. Critical points should therefore also be constantly examined by medical personnel.
- Never fold, bend the ASTOPAD applied parts or operate in a folded condition.
- Do not place the patient on the connection block of the ASTOPAD applied part.
- When the ASTOPAD applied parts COV are used as an under-blanket, please ensure that they are placed flat underneath the patient, are secured, and will not crease.
- In all surgical procedures, it is important to ensure that sufficient measures are taken to avoid bed sores in accordance with the patient position.
- The risk of skin irritation caused by an accumulation of surgical preparation solutions under the patient may increase with warming; please ensure that the instructions for use for surgical preparation solutions are followed.
- Reduce or eliminate the risk of the skin warming under pressure-loaded bony protrusions.
- Do not place ANY hard objects (such as mattress cables, ECG cables, hard reusable neutral electrodes, leads of patient fluid lines, etc.) between the ASTOPAD applied part and the patient.
- ASTOPAD applied parts COV can be wrapped around the patient. However, take care that the applied part will not form creases.

| | |
|---|---|
|  | • All ASTOPAD applied parts may be operated only with the ASTOPAD control unit.<br>• All ASTOPAD applied parts may have direct skin contact with the patient. It is recommended that a thin, water-tight and absorbent pad is used between the applied part and the patient. ASTOPAD control unit and connection cables are not designed for direct skin contact.<br>• ASTOPAD applied parts COV can be used as over-blankets and/or under-blankets.<br>• ASTOPAD applied parts SOF or ROE are intended for use underneath the patient.<br>• Do not install the ASTOPAD so that disconnection from the mains via the mains plug is difficult to carry out.<br>• The ASTOPAD control unit can also be operated independent of the mains with the battery option, to retain heat after the heating phase of the applied part. In this case, the device can be operated for about 2 hours independent of the mains. |

## 9.1 Preparation for use

- Before use, please clean and disinfect the product according to the instructions (see Section **9.6 Cleaning and disinfection**).
- Apply the ASTOPAD control unit according to Section **8.2 Installing the control unit.**

### 9.1.1 Using ASTOPAD applied part COV070, COV105, COV150, COV180 as an under-blanket

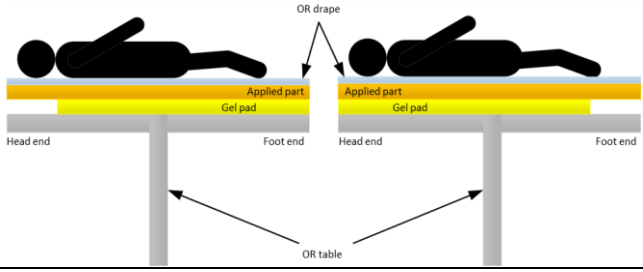
**⚠WARNING**

**Danger of overheating!**

- For patients from 35 to 90 cm in height, use only the ASTOPAD applied part COV070.
- Do not use the ASTOPAD applied parts COV105, COV150, COV155 or COV180 for patients under 90 cm in height.

1. Protect the ASTOPAD applied part from mechanical damage by inserting it in a reusable cover (COV40XXX/COV45XXX).
2. The pressure-relieving gel pad may also be placed on the OR table.
3. Place the ASTOPAD applied part lengthwise on the table with the cable connection side
   facing the outside edge of the OR table/treatment table.
4. Secure the ASTOPAD applied part to the table with the fixation straps of the cover so that it is flat underneath the patient and will not crease. If combining a pressure-relieving gel pad and an ASTOPAD applied part, place the gel pad under the applied part.
5. Align the gel pad and the ASTOPAD applied part flush with the head or foot end.

6. Use a thin, water-tight and absorbent pad between the ASTOPAD applied part and the patient.




**WARNING**

If the OR table top is tilted (adjusted through the longitudinal axis), there is a danger that the patient will slip off. The patient must be sufficiently secured against slipping before the OR table top is tilted or otherwise moved out of the horizontal position!

### 9.1.2 Using ASTOPAD applied part COV as a over blanket

**WARNING**

**Risk of injury!**
When ASTOPAD applied parts COV are used as an over-blanket, please ensure that they do not obstruct the patient's field of vision.

Place the ASTOPAD applied part lengthwise over the patient with the cable connection side facing away from the patient. If areas of the patient are to be made accessible, the direction of the ASTOPAD applied part can be adjusted according to the operation field.

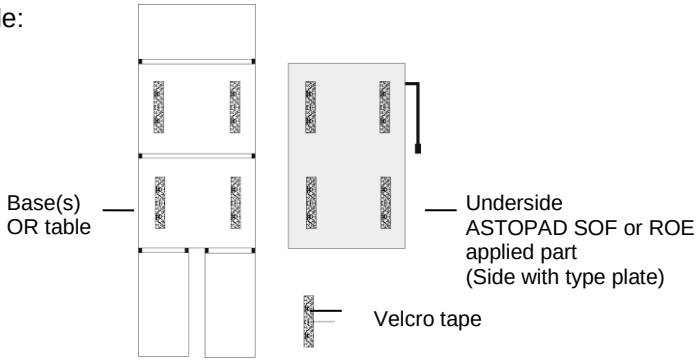
### 9.1.3 Use with ASTOPAD applied part SOF, ROE without fixation cover

**WARNING**

**Risk of injury!**
Do not cover the labelled SENSOR ZONE of the ASTOPAD applied part ROE (patient, their extremities or objects).

The ASTOPAD applied part SOF/ROE comes with Velcro tape, approximately 2 m long (self-adhesive). The Velcro tape must be cut to fit the OR table and applied to the underside of the ASTOPAD applied part when it is commissioned/installed (see example below).

For example:




| | |
|---|---|
| | Wait 5-6 hours before using for the first time to ensure the best possible adhesion. |

### 9.1.4 Use with ASTOPAD applied part SOF with fixation cover

When the ASTOPAD applied part SOF is placed on the existing OR table pad without Velcro, the applied part must be secured with the SOF45X fixation cover.

1. Push the ASTOPAD applied part SOF into the fixation cover (type plate on the blue side).
2. Position the ASTOPAD applied part SOF on the existing OR table pad with the blue side facing down.
3. Run the fixation straps underneath, between the OR table and the standard rail, and use the D-rings for securing.

## 9.2 Starting the heating process

- The user should be positioned in front of the ASTOPAD control unit, able to easily see the displays and operating elements.
- For optimum warming of the ASTOPAD applied part ROE, start the heating process shortly after placing a new patient on the heated mattress.

1. Plug the mains plug for the ASTOPAD control unit into the socket.
2. Place the patient as specified and attach the ASTOPAD applied parts according to the application and section
3. **9.1 Preparation for** use.
4. For ASTOPAD applied parts COV or SOF, connect the extension connection cable to the connection cable of the applied parts. Then secure the bayonet connector by turning it to the right.
5. Place the extension connection cable/connecting cable in either output A or B; taking care that the two white dots on the plug are facing upwards. Secure the plug connection by turning it a quarter rotation to the right.
6. Switch on the ASTOPAD control unit with the Standby button .
7. Check whether the self-test is automatically activated (display illuminates, all LEDs flash, and the acoustic alarm sounds). Only then is the ASTOPAD ready for use.

**WARNING**

**Risk of injury!**
Do not use the ASTOPAD if no visual or acoustic alarm is activated when it is switched on via the Standby button (self-test faulty).

8. Press the Start button to start the heating process at output A or B with the displayed set temperature.

## 9.3 Selecting a new set temperature

1. Press the Plus or Minus buttons to raise or lower the selected set temperature in 0.5°C increments.
2. Confirm the new set temperature by pressing the Start button .
   The selected set temperature is stored.

## 9.4 Switching off an output

Press the Stop button to end the heating process at output A or B. The display turns off.

If only one output is active, pressing the Stop button will deactivate the heating process and activate the self-test.

## 9.5 Switching off the ASTOPAD

1. Press the Standby button of the ASTOPAD control unit to switch off (all displays are turned off, the Standby LED illuminates).
2. Disconnect the ASTOPAD control unit from the applied part(s).

| | |
|---|---|
| | Operate the ASTOPAD applied part ROE:<br>To achieve optimum heating conditions for the next patient, end the heating process after each use. |

## 9.6 Cleaning and disinfection

During use, ASTOPAD and its accessories may be unintentionally contaminated with organic contaminants (such as blood or bodily fluids) or micro-organisms. The following cleaning and disinfection procedures should therefore be followed after each use.

- Wear gloves when cleaning and disinfecting (chemical-resistant).
- Always work from top to bottom and from clean to dirty areas.
- When using wipes, only use for as long as they leave a closed film of fluid on the surface.
- Please observe the defined contact time of the disinfectant.
- Work methodically to disinfect each area of the ASTOPAD.

### 9.6.1 Preparation

For routine disinfection, only use alcohol-based disinfectants or one of the following approved disinfectants:

| Disinfectant | Manufacturer |
|---|---|
| acryl-des | Schülke + Mayr, Austria |
| ANIOSURF CITRON | Laboratoires ANIOS, France |
| Bacillol Plus | BODE CHEMIE HAMBURG, Germany |
| BIGUAMED PERFEKT N | Desomed-Dr. Trippen GmbH, Germany |
| ClearSurf | Fresenius Medical Care, Germany |
| Mikrobac forte | BODE CHEMIE HAMBURG, Germany |
| mirkrozid sensitive liquid | Schülke + Mayer, Germany |
| Terralin protect | Schülke + Mayer, Germany |
| Incidin Plus | Ecolab GmbH, Germany |
| Incidin Pro | Ecolab GmbH, Germany |
| Meliseptol Foam pure | B. Braun Melsungen AG, Germany |

**NOTICE**

To prevent damage:

- Do not immerse the ASTOPAD control unit, the applied parts or the plug of the connection cable in liquid.
- Do not disinfect the ASTOPAD control unit and/or the applied parts with:
  - Steam (e.g. in autoclaves)
  - Hot air
  - Thermochemical cleaning solutions
- Please observe the specific instructions for using the disinfectant.


Prohibited: Do not disinfect with hypochlorite solution.
Chlorine and peroxides and all other oxidising disinfectants have a negative effect on the materials, therefore the use of these disinfectants is not recommended. Product life is significantly shortened by disinfectants of this kind.

## 9.6.2 Applied part

**⚠CAUTION**

**Risk of injury!**

Damage to the ASTOPAD applied part may result in overheating. For this reason:

- Only disinfect the ASTOPAD applied part with an alcohol-based disinfectant or one of the approved disinfectants.
- Do not use bleach solution containing hypochlorite to disinfect the ASTOPAD applied parts.
- Do not carry out cleaning or disinfection procedures other than those specified in this manual without the express permission of the manufacturer.

Clean and wipe-disinfect the ASTOPAD applied part according to the following procedure:

1. Disconnect the ASTOPAD applied part from the control unit.
2. Close the plug with the sealing cap to protect the electrical contracts from penetrating liquids.
3. Visually inspect all surfaces (from all sides) including the terminal block and connecting cable for wear, cuts, holes, cracks and other unacceptable impairments.

**NOTICE**

Cleaning and disinfection is only possible if no damage is present. Damaged components cannot be used.

4. Thoroughly clean all surfaces (from all sides), including the connection block and the connection cable, according to the instructions of the disinfectant manufacturer, to remove all residues of bodily fluids and other contamination.

| NOTICE |
| --- |
| If the surfaces are not clean at the end of the cleaning step, either repeat the cleaning processes or safely dispose of the applied part. |

5. Disinfect all surfaces (from all sides), including the connection block and the connecting cable, according to the instructions of the disinfectant manufacturer.
6. When disinfecting the ASTOPAD applied parts SOF and ROE, wipe from the head end to the foot end.
7. Allow all parts and all sides to air dry thoroughly before continuing to use or store.

### 9.6.3 Control unit

Clean and wipe-disinfect the ASTOPAD control unit according to the following procedure:

1. Disconnect the ASTOPAD control unit from the mains.
2. Visually inspect the control panel and the housing from all sides for wear, holes, cracks and other impermissible damage.

| NOTICE |
| --- |
| Cleaning and disinfection is only possible if no damage is present. Damaged components cannot be used. |

3. Thoroughly clean all surfaces (from all sides) according to the instructions of the disinfectant manufacturer to remove all residues of bodily fluids and other contamination.

| NOTICE |
| --- |
| If the surfaces are not clean at the end of the cleaning step, the cleaning process should be repeated until the housing is visibly clean. |

4. Disinfect all surfaces (from all sides) according to the instructions for the disinfectant.
5. Allow the ASTOPAD control unit to air dry before continuing to use or store.

# 10 Alarms and troubleshooting

The ASTOPAD does not require continuous supervision by the user, but must be inspected at regular intervals (depending on the condition of the patient). For this, the intended operating location is immediately in front of the control panel of the ASTOPAD control unit.

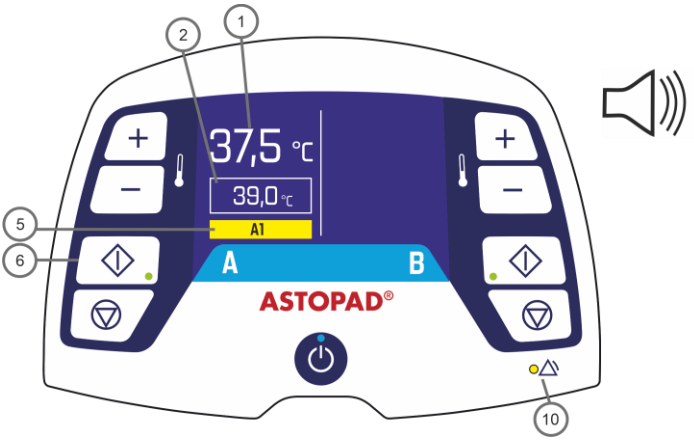
In the event of failure of the ASTOPAD, possible injury to the patient is delayed and the user has sufficient time to provide alternative warming methods.

To guarantee the safe operation of ASTOPAD for patients and users, ASTOPAD is equipped with a series of independent alarm systems. The alarms are the result of consistent implementation of the standards listed in Section **15 Conformity with international standards.**

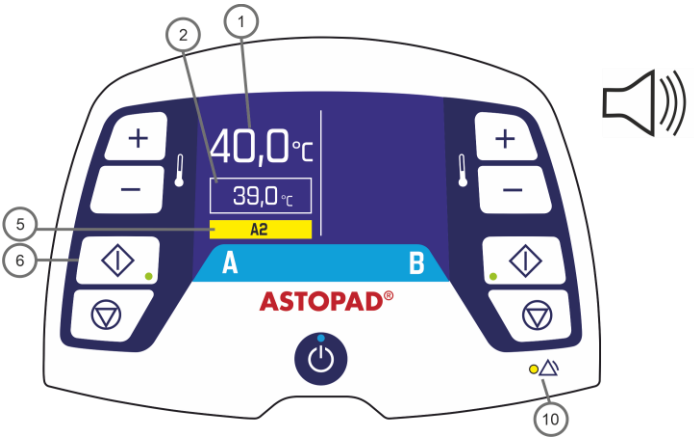
The alarm signal is output visually and acoustically.

The following only describes the behaviour of the ASTOPAD control unit under alarm conditions for output **A**. The ASTOPAD control unit behaves in the same way under alarm conditions for output **B**.

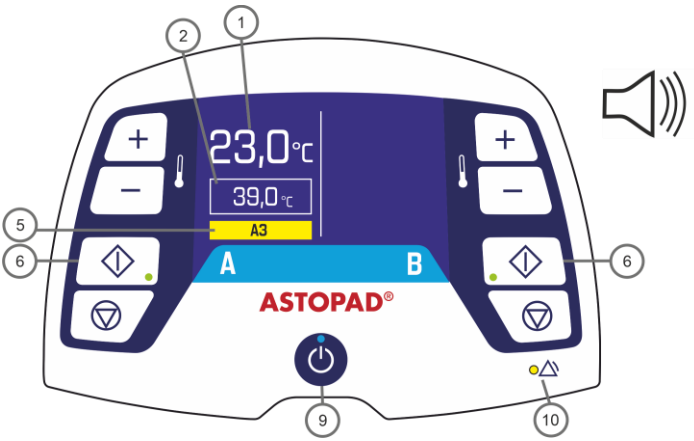
## 10.1 Low temperature alarm A1 (low priority alarm)

| | |
|---|---|
| Control panel |  |
| Alarm condition | The set temperature was reached once. After that, the actual temperature (1) drops by at least 1°C below the set temperature (2). $T_{Set} - T_{Actual} \geq 1°C$.<br>This condition remains for at least 10 minutes. |
| Device response | • Display (5) shows **A1** (flashing).<br>• The Start LED (6) flashes.<br>• The alarm LED (10) lights up yellow.<br>• An acoustic alarm signal is triggered. |
| Possible reasons<br>►Required action(s) | The applied part is influenced by the environmental conditions (cooled).<br>►Stop cooling. |
| | Applied part defective.<br>►Send the applied part to the local sales point. |
| Required action(s) for resetting | Press the Start button (6).<br>The overheating alarm **A1** is reset. |
| ⓘ | If the alarm conditions are not met, the display **A1** and the acoustic alarm signal is automatically reset. The alarm LED continues to light up yellow to indicate a low-temperature alarm that has already been triggered. |

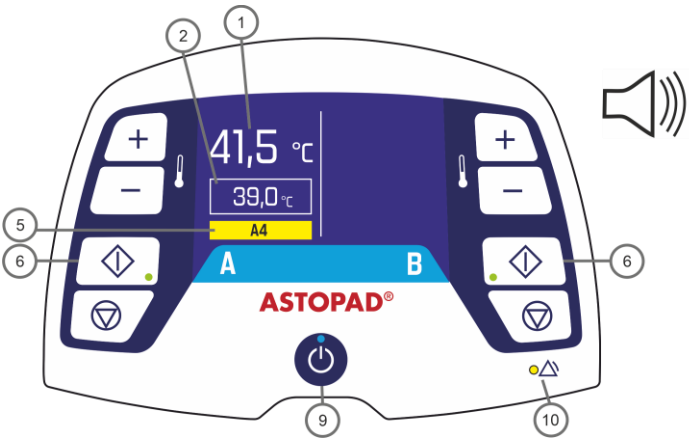
## 10.2 Overheating alarm A2 (low priority alarm)

| | |
|---|---|
| Control panel |  |
| Alarm condition | The set temperature was reached once. After that, the actual temperature (1) rises by at least 1°C above the set temperature (2) and remains below 41°C.<br>$T_{Actual} - T_{Set} \geq 1°C$ and $T_{Actual} < 41°C$.<br>This condition remains for at least 10 minutes. |
| Device response | • Display (5) shows **A2** (flashing).<br>• The Start LED (6) flashes.<br>• The alarm LED (10) lights up yellow.<br>• An acoustic alarm signal is triggered. |
| Possible reasons<br>►Required action(s) | Set temperature was lowered.<br>►Cooling phase, no action necessary. |
| | The applied part is influenced by the environmental conditions (heat source).<br>► Remove heat source. |
| | Applied part defective.<br>►Send the applied part to the local sales point. |
| Required action(s) for resetting | Press the Start button (6).<br>The overheating alarm **A2** is reset. |
| ℹ | If the alarm conditions are not met, the display **A2** and the acoustic alarm signal are automatically reset. The alarm LED continues to light up yellow to display an overheating alarm that has already been triggered. |

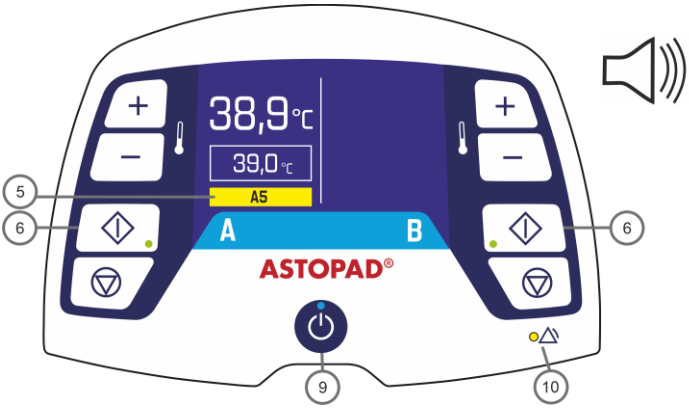
## 10.3 Time alarm A3 (low priority alarm)

| | |
|---|---|
| Control panel |  |
| Alarm condition | The set temperature (2) is not reached during 60 minutes of uninterrupted heating. |
| Device response | • **A3** (flashing) appears on the display (5).<br>• The Start LED (6) flashes.<br>• The alarm LED (10) lights up yellow.<br>• An acoustic alarm signal is triggered.<br>• The heating process is not interrupted. |
| Possible reasons<br>►Required action(s) | A layer of thermally conductive materials (water or gel) is situated on the applied part.<br>►Remove the pad or place it underneath the applied part. |
| | Applied part defective.<br>►Send the applied part to the local sales point. |
| Required action(s) for resetting | Press the Start button (6) to reset the alarm. |
| ⓘ | If the set temperature is not reached during 60 minutes of uninterrupted heating, the alarm is triggered again. |

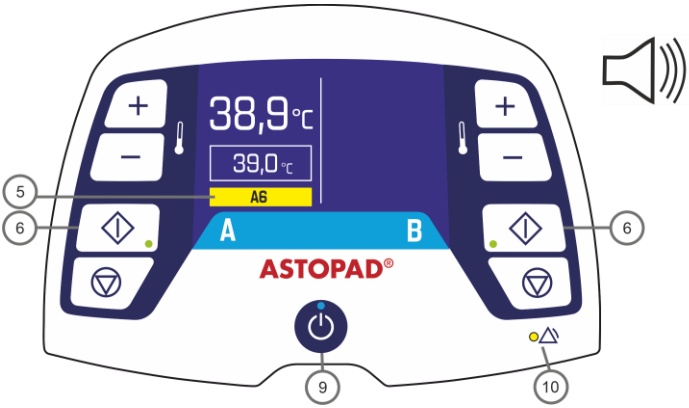
## 10.4 Overheating alarm shut-off A4 (medium priority alarm)

| | |
|---|---|
| Control panel |  |
| Alarm condition | The actual temperature (1) is higher than 41°C. |
| Device response | • **A4** (flashing) appears on the display (5). If both outputs are active, **A4** is displayed for both outputs.<br>• The Start LED (6) and the Alarm LED (10) flash.<br>• An acoustic alarm signal is triggered.<br>• The heating process is interrupted at the two outputs. |
| Possible reasons<br>►Required action(s) | Set temperature is increased. Applied part produces a temperature overshoot.<br>►1. Switch off the control unit with the Standby button (9).<br>2. Allow the applied part to cool.<br>3. Restart the heating process. |
| | The applied part is influenced by the environmental conditions (heat source).<br>►Remove heat source. |
| | Applied part defective.<br>►Send the applied part to the local sales point. |
| Required action(s) for resetting | Switch off the control unit with the Standby button and allow the applied parts to cool down. |

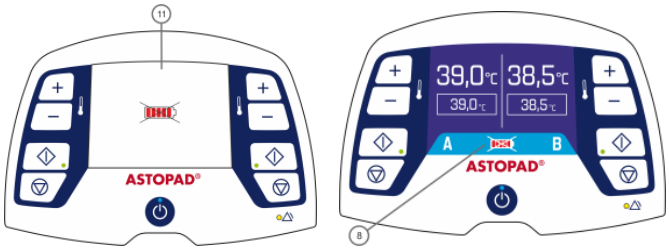
## 10.5 Sensor defect alarm A5 (medium priority alarm)

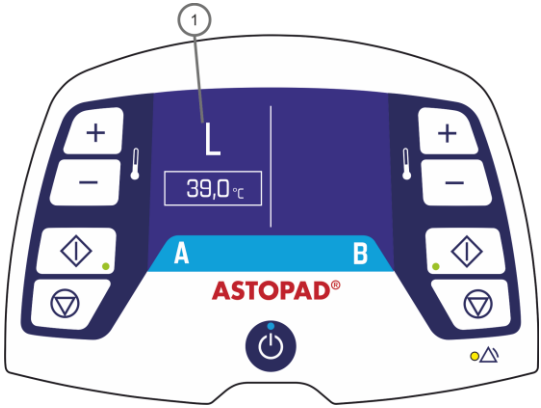
| | |
|---|---|
| Control panel |  |
| Alarm condition | At least one temperature sensor supplies a value outside the permissible range. |
| Device response | • **A5** (flashing) appears on the display (5). If both outputs are active, **A5** is displayed for both outputs.<br>• The Start LED (6) and the Alarm LED (10) flash.<br>• An acoustic alarm signal is triggered.<br>• The heating process is interrupted at the two outputs. |
| Possible reasons<br>►Required action(s) | Defective sensor(s) in the applied part.<br>►Send the applied part to the local sales point. |
| | Defective connection cable on the applied part.<br>►Send the applied part to the local sales point. |
| | Defective cable plug on the applied part.<br>►Send the applied part to the local sales point. |
| | Defective extension connection cable.<br>►Replace the extension connection cable. |
| | Defective connecting socket for output A or B on the control unit.<br>►Send the control unit to the local sales point. |

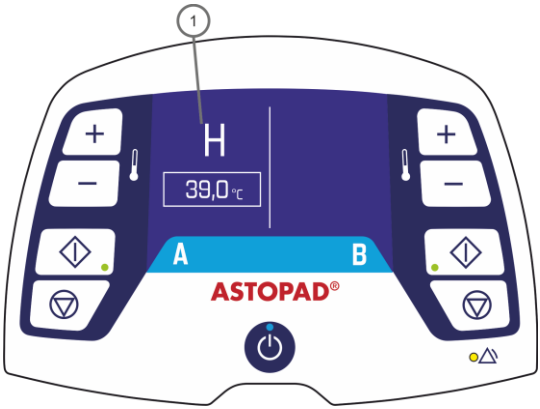
## 10.6 Heating defect alarm A6 (medium priority alarm)

| | |
|---|---|
| Control panel |  |
| Alarm condition | The heater of the applied part is defect. |
| Device response | • **A6** (flashing) appears on the display (5). If both outputs are active, **A6** is displayed for both outputs.<br>• The Start LED (6) and the Alarm LED (10) flash.<br>• An acoustic alarm signal is triggered.<br>• The heating process is interrupted at the two outputs. |
| Possible reasons<br>►Required action(s) | Heater resistance too high or low.<br>►Send the applied part to the local sales point. |
| | Defective connection cable on the applied part.<br>►Send the applied part to the local sales point. |
| | Defective cable plug on the applied part.<br>►Send the applied part to the local sales point. |
| | Defective extension connection cable.<br>►Replace the extension connection cable. |
| | Defective connecting socket for output A or B on the control unit.<br>►Send the control unit to the local sales point. |

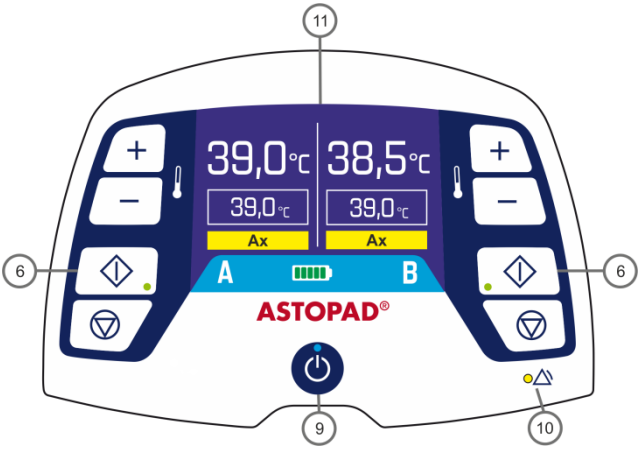
# 11 Information messages and troubleshooting

| 11.1 Battery status (only for devices with a battery) | |
|---|---|
| Control panel |  |
| Information condition | The battery is defect or no original battery is inserted. |
| Device response | After the Start screen in mains operation and in **Standby mode**, the display (11, 8) shows the crossed-out battery symbol. |
| ►Required action(s) | ►Insert new original battery. |
| ⓘ | The battery should be replaced every 3 years to ensure adequate battery capacity. |

| 11.2 Applied part temperature too low | |
|---|---|
| Control panel |  |
| Information condition | The actual temperature (1) is lower than 20°C. |
| Device response | Display (1) shows **L**. |
| Possible reasons<br>►Required action(s) | The actual temperature is outside the display range<br>►Heat applied part. |

| 11.3 Applied part temperature too high | |
|---|---|
| Control panel |  |
| Information condition | The actual temperature (1) is higher than 45°C. |
| Device response | Display (1) shows **H**. |
| Possible reasons<br>►Required action(s) | The actual temperature is outside the display range<br>►Allow the heating element to cool. |

# 12 Brief overview of operating states and alarms




## 12.1 Overview of operating states

| Operating state | Display (11) | Start LED Output A or B Green (6) | Alarm LED Yellow (10) | Standby LED Blue (9) | Acoustic alarm signal | Possible reasons |
|---|---|---|---|---|---|---|
| Standby mode | | ○ | ○ | ● | | - |
| | | ○ | ○ | ● | | Battery is charging |
| | | ○ | ○ | ● | | Battery defective or no original battery inserted |
| On mode | | ○ | ○ | ○ | | Battery defective or no original battery inserted |
| | | ○ | ○ | ○ | | No applied part connected |
| | **Actual temperature Set temperature** | ☼ | ☼ | ○ | | Self-test |
| | **L Set temperature** | ☼ | ☼ | ○ | | Self-test and Actual temperature < 20°C |
| | **H Set temperature** | ☼ | ☼ | ○ | | Self-test and actual temperature > 45°C |

○ = LED off ● = LED on ☼ = LED flashes

| Operating state | Display (11) | Start LED Output A or B Green (6) | Alarm LED Yellow (10) | Standby LED Blue (9) | Acoustic alarm signal | Possible reasons |
|---|---|---|---|---|---|---|
| Heating mode | Actual temperature Set temperature | ● | ○ | ○ | | Warm-up phase |
| | Actual temperature Set temperature A5 | ☼ | ☼ | ○ | | No applied part connected or defect sensor |
| | Actual temperature Set temperature A6 | ☼ | ☼ | ○ | | No applied part connected or defect heating |
| | | ○ | ○ | ○ | | Output heating process not started |
| | L Set temperature | ● | ○ | ○ | | Warm-up phase and actual temperature < 20°C |
| | Actual temperature Set temperature | ● | ○ | ○ | | Cooling phase |
| Mode Increase/ decrease set temperature | Actual temperature Set temperature | ☼ | ○ | ○ | | New set temperature not confirmed |
| Mode Switching off an output | | ○ | ○ | ○ | | Output heating process switched off |
| | Actual temperature Set temperature | ☼ | ☼ | ○ | | Only one output was started, control unit is in self-test |
| Switching off the control unit | | ○ | ○ | ● | | See Standby mode |
| Off mode | | ○ | ○ | ○ | | Mains plug pulled out |
| Storage/ transport | | ○ | ○ | ○ | | Mains plug disconnected and Standby button was pressed for more than 3 sec. (only for battery-operated equipment) |

○ = LED off ● = LED on ☼ = LED flashes

## 12.2 Overview of alarms

| Alarm | Display (11) | Start LED Output A or B Green (6) | Alarm LED Yellow (10) | Standby LED Blue (9) | Acoustic alarm signal | Possible reasons |
|---|---|---|---|---|---|---|
| Low temperature alarm **A1** | **Actual temperature** **Set temperature** **A1** | ☼ | ● | ○ | 🔊 | Actual temperature is at least 1°C lower than the set temperature for at least 10 minutes. |
| Overheating alarm **A2** | **Actual temperature** **Set temperature** **A2** | ☼ | ● | ○ | 🔊 | The actual temperature is at least 1°C higher than the set temperature for at least 10 minutes. |
| Time alarm **A3** | **Actual temperature** **Set temperature** **A3** | ☼ | ● | ○ | 🔊 | Set temperature not reached within 60 minutes of uninterrupted heating. |
| Overheating alarm shut-off **A4** | **Actual temperature** **Set temperature** **A4** | ☼ | ☼ | ○ | 🔊 | The actual temperature is higher than 41°C |
| | **H** **Set temperature** **A4** | ☼ | ☼ | ○ | 🔊 | The actual temperature is higher than 45°C |
| Sensor defect Alarm **A5** | **Actual temperature** **Set temperature** **A5** | ☼ | ☼ | ○ | 🔊 | Connection between control unit and applied part interrupted or sensor defective |
| Heater defect alarm **A6** | **Actual temperature** **Set temperature** **A6** | ☼ | ☼ | ○ | 🔊 | Connection between control unit and applied part interrupted or heating defective. |

○ = **LED off** ● = **LED on** ☼ = **LED flashes**

# 13 Maintenance

To ensure sufficient battery capacity in ASTOPAD control units with a battery, the battery should be replaced every 3 years. Replacing the battery is described in Section **13.2 Replacing the battery**.

ASTOPAD does not require preventative servicing (e.g. replacing fluids or components), but it does require repeated inspections in accordance with Section **13.1 Repeated inspections**.

No service or maintenance work may be carried out on the ASTOPAD during use on the patient.

**WARNING**

**Risk of injury!**

- The ASTOPAD may only be serviced by appropriately trained and medically qualified service personnel.
- The ASTOPAD does not contain any parts the user can repair. Therefore, do not attempt to repair the ASTOPAD yourself. Contact your local sales point.
- Any repairs to the equipment may only be carried out by persons authorised and qualified by the manufacturer.
- Modifications to the ASTOPAD are not permitted.

On request, STIHLER ELECTRONIC GmbH will provide service instructions that will allow properly trained and qualified persons to repair the parts of the equipment that the manufacturer has designated as repairable.
Provision of technical documents and/or spare parts from the manufacturer is not an authorisation to open or repair the equipment.

## 13.1 Recurrrent tests

A recurrent test of the ASTOPAD (applied part and control unit) must be performed at least every 12 months.

For the test, you can either purchase the required test equipment and instructions from the manufacturer, or you can commission the manufacturer or your local dealer to perform the inspection of the ASTOPAD.

Also, please observe all other applicable regulations (e.g. IEC/EN 62353) on monitoring the safety of medical devices and the use of calibrated testing equipment.

The inspection of the Essential Performance characteristics and all other safety-relevant functions are described in the ASTOPAD testimg instructions:

- Testing instructions ASTOPAD, German (Order no. 1731.9045.11)
- Testing instructions ASTOPAD, English (Order no. 1731.9045.12)

The following test equipment is required to carry out the repeated inspection:

- System test box for ASTOPAD (Order no. 1715.9040)

| | |
|---|---|
| ⓘ | The test instructions are included in the scope of delivery of the ASTOPAD system test box. |

## 13.2 Replacing the battery

1. Disconnect the ASTOPAD control unit completely from the power supply (by pulling out the mains plug).
2. Press the Standby button until the Standby LED goes out.
3. Disconnect the mains connection cable from the control unit, flipping the lock (red button) of the mains plug in the direction of pull.
4. Remove the housing cover (Fig. 6) by releasing the four housing screws.
5. Remove the battery (Fig. 7) and insert a new battery as far as it will go.
6. Replace the housing cover and secure with the four housing screws.

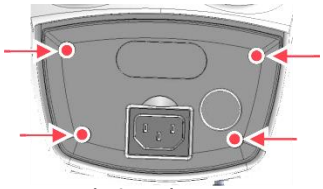


Fig. 6 Housing cover

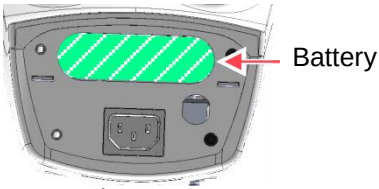



Fig. 7 Battery

# 14 Technical Data

<table>
<tr><th colspan="5">ASTOPAD DUO310 control unit</th></tr>
<tr><td>Electrical connection</td><td colspan="4">100 – 240 VAC, 50 – 60 Hz</td></tr>
<tr><td>Rated current</td><td colspan="4">110 V = 1.6 A, 240 V = 0.8 A</td></tr>
<tr><td>Primary fuses</td><td colspan="4">2 x 3.15 A</td></tr>
<tr><td>Power consumption</td><td colspan="4">max. 160 W</td></tr>
<tr><td>Classification (IEC/EN 60529)</td><td colspan="4">IPX2</td></tr>
<tr><td>Classification (IEC/EN 60601-1)</td><td colspan="4">Protection Class I, defibrillation-protected applied part type BF</td></tr>
<tr><td>Classification (MDD 93/42/EEC)</td><td colspan="4">Class IIb</td></tr>
<tr><td>Code UMDNS</td><td colspan="4">10-414(COV), 11-989(SOF/ROE)</td></tr>
<tr><td>Code GMDN</td><td colspan="4">37329</td></tr>
<tr><td>Dimensions (mm)<br>Height<br>Width<br>Depth</td><td colspan="4">max.<br>300<br>155<br>130</td></tr>
<tr><td>Weight (kg)</td><td colspan="4">2.0 (without battery)<br>2.5 (with battery)</td></tr>
<tr><td>Operating mode</td><td colspan="4">Continuous operation</td></tr>
<tr><td>Permissible environmental conditions</td><td>Moisture</td><td>Temperature</td><td colspan="2">Atmospheric pressure</td></tr>
<tr><td>In operation/storage</td><td rowspan="2">10% to 75%<br>non-condensing</td><td>+16°C to +26°C</td><td colspan="2" rowspan="2">700 hPa to 1060 hPa</td></tr>
<tr><td>In transport</td><td>-20°C to +50°C</td></tr>
<tr><td>Regulation of the contact surface temperature (Essential performance characteristics according to IEC/EN 80601-2-35)</td><td colspan="4">32.0°C to 39.0°C in 0.5°C increments<br>Tolerance ± 1.0°C</td></tr>
<tr><td>Display precision of the contact surface temperature</td><td colspan="4">± 0.7°C</td></tr>
<tr><td>Overheating shut-off</td><td colspan="4">41.0°C (± 0.5°C)</td></tr>
<tr><td>Acoustic alarm volume level</td><td colspan="4">approx. 60 dB(A)</td></tr>
<tr><td>Expected operating life</td><td colspan="4">The expected operating life is 10 years from the date of first use, providing the product is subject to misuse, negligence, damage or inappropriate use and the equipment is used and serviced properly and as intended.</td></tr>
</table>

| **ASTOPAD all applied parts** | | | |
|---|---|---|---|
| Electrical connection | 24 VDC | | |
| Classification (IEC/EN 60529) | IPX2 | | |
| Permissible environmental conditions | **Moisture** | **Tempera-ture** | **Atmospheric pressure** |
| In operation/storage | 10% to 75% non-condensing | +16°C to +26°C | 700 hPa to 1060 hPa |
| In transport | | -20°C to +50°C | |
| Heating-up period from 23.0°C to 37.0°C | Approx. 10 minutes | | |
| Expected operating life | The expected operating life is 5 years from the date of first use, providing the product has not been subject to misuse, negligence, damage or inappropriate use and the equipment is used and serviced properly and as intended. | | |

| **ASTOPAD** | **COV 070** | **COV 105** | **COV 150** | **COV 155** | **COV 180** |
|---|---|---|---|---|---|
| Power consumption (W) | 60 | 115 | 150 | 85 | 150 |
| Dimensions (mm) | | | | | |
| Length | 680 | 1050 | 1500 | 1500 | 1800 |
| Width | 480 | 500 | 500 | 500 | 800 |
| Height | 30 | 30 | 30 | 30 | 30 |
| Weight (kg) | 0.7 | 1.1 | 1.4 | 1.3 | 2.2 |
| Connection cable | 50 cm PVC cable | | | | |
| Standard extension connection cable | 2 m | | | | |

| ASTOPAD | SOF2 | SOF4 | SOF5 | SOF7 |
|---|---|---|---|---|
| Power consumption (W) | 105 | 115 | 150 | 60 |
| Dimensions* (mm)<br>Length<br>(with sacral)<br>Width<br>Height | approx.<br>1710-2300<br><br>480-600<br>40-100 | approx.<br>810-1300<br>(910-1300)<br>480-600<br>40-100 | approx.<br>1310-1700<br><br>480-600<br>40-100 | approx.<br>600-800<br>(660-900)<br>450-600<br>40-100 |
| Weight (kg) | Approx. 7.5 | Approx. 2.7 | Approx. 3.2 | Approx. 2.0 |
| Connection cable | 50 cm PVC cable | | | |
| Standard extension connection cable | 2 m | | | |

* according to ordering information

| ASTOPAD | ROE4 | ROE8 |
|---|---|---|
| Power consumption (W) | 105 | |
| Dimensions* (mm)<br>Length<br>Height | approx.<br>2400-2800<br>40 | approx.<br>2400-2800<br>80 |
| Weight (kg) | Approx. 6.5 | Approx. 13.0 |
| Connection cable | 200 cm PVC cable | |

* according to ordering information

| ASTOPAD | Integrable rechargeable battery for the ASTOPAD DUO310 control unit (optional) |
|---|---|
| Type | Li-Ion |
| Energy content (Wh) | 99.4 |
| Dimensions (mm)<br>Length x width x height | 150 x 77 x 22 |
| Weight (g) | 430 |

***NOTICE***

The specified defibrillation protection is ensured only when the applied part is connected to the extension connection cable and the control unit.

**DANGER**

**Explosion hazard!**
Do not use the ASTOPAD patient warming system in an explosive environment or in the presence of flammable anaesthetics.

# 15 Conformity with international standards

| Standard | Title |
|---|---|
| IEC/EN 60601-1<br>ANSI/AAMI ES 60601-1<br>CAN/CSA C22.2 No. 60601-1 | Medical electrical equipment – Part 1: General requirements for basic safety, including essential performance |
| IEC/EN 60601-1-2 | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility – Requirements and tests |
| IEC/EN 60601-1-8 | Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance - collateral standard: Alarm systems – General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| IEC/EN 80601-2-35 | Medical electrical equipment Part 2-35: Particular requirements for basic safety and essential performance of heating devices using blankets, pads, or mattresses and intended for heating in medical use. |
| IEC/EN 60601-1-6<br>(IEC/EN 62366-1) | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - collateral standard: Usability. |

**Definitions according to IEC/EN 80601-2-35:**

| Term | Definition | ASTOPAD applied parts |
|---|---|---|
| Over-blanket | Blanket for use on top of patient. | COV070, COV105, COV150, COV155, COV180 |
| Under-blanket | Blanket for use underneath patient. | COV070, COV105, COV150, COV180 |
| Pad | Applied part of a heating element that may be bent, but not folded. | SOF4, SOF5, SOF7 |
| Mattress | Applied part of a heating element that supports the patient’s entire body resiliently. | SOF2, ROE4, ROE8 |

# 16 Ordering information and accessories

| REF | Variant | Description |
|---|---|---|
| DUO310 | XX | ASTOPAD DUO310 control unit, 100-240 VAC, 50-60 Hz |
| 1831.0001 | - | Integrable rechargeable battery for the ASTOPAD DUO310 control unit |

XX = -EU Mains connection cable with Schuko plug
-AU Mains connection cable with Australia plug
-CN Mains connection cable with China plug
-CH Mains connection cable with Switzerland plug
-DK Mains connection cable with Denmark plug
-GB Mains connection cable with Great Britain plug
-EU110 Mains connection cable with Hospital Grade plug
-Not for sale or use in the USA and Canada-

| REF | Description |
|---|---|
| **Applied parts (incl. standard extension connection cable COV50200)** | |
| COV070 | ASTOPAD COV070 heating blanket 680 x 480 mm |
| COV105 | ASTOPAD COV105 heating blanket 1050 x 500 mm |
| COV150 | ASTOPAD COV150 heating blanket 1500 x 500 mm |
| COV155 | ASTOPAD COV155 arm-chest heating blanket 1500 x 500 mm (with cutout) |
| COV180 | ASTOPAD COV180 heating blanket 1800 x 800 mm |
| SOF7 | ASTOPAD SOF7 heated, pressure-relieving OR table pad, length 600 to 800 mm (with Sacral 660 to 900 mm), width 450 to 600 mm, height 40 to 100 mm |
| SOF4 | ASTOPAD SOF4 heated, pressure-relieving OR table pad, length 810 to 1300 mm (with Sacral 910 to 1300 mm), width 480 to 600 mm, height 40 to 100 mm |
| SOF5 | ASTOPAD SOF5 heated, pressure-relieving OR table pad, length 1310 to 1700 mm, width 480 to 600 mm, height 40 to 100 mm |
| SOF2 | ASTOPAD SOF2 heated, pressure-relieving OR table mattress, length 1710 to 2300 mm, width 480 to 600 mm, height 40 to 100 mm |
| **Applied parts with 2 m connection cable** | |
| ROE4 | ASTOPAD ROE4 heated, pressure-relieving OR table mattress, height 40 mm, length 2200 to 2800 mm |
| ROE8 | ASTOPAD ROE8 heated, pressure-relieving OR table mattress, height 80 mm, length 2200 to 2800 mm |

| Accessories | |
|---|---|
| COV40070 | Reusable cover for COV070 |
| COV40105 | Reusable cover for COV105 |
| COV40150 | Reusable cover for COV150 |
| COV40155 | Reusable cover for COV155 |
| COV40180 | Reusable cover for COV180 |
| COV45070 | Fixation cover for COV070 |
| COV45105 | Fixation cover for COV105 |
| COV45150 | Fixation cover for COV150 |
| SOF407 | Reusable cover for SOF7 |
| SOF404 | Reusable cover for SOF4 |
| SOF405 | Reusable cover for SOF5 |
| SOF402 | Reusable cover for SOF2 |
| SOF457 | Fixation cover for SOF7 |
| SOF454 | Fixation cover for SOF4 |
| SOF455 | Fixation cover for SOF5 |
| SOF452 | Fixation cover for SOF2 |
| ROE454 | Mattress cover for ROE4 |
| ROE458 | Mattress cover for ROE8 |
| COV50200 | Standard extension connection cable 2.0 m |
| COV50400 | Extension connection cable 4.0 m |
| STA100 | ASTOSTAND STA100, stainless steel infusion stand, heavy-duty version |

**We reserve the right to modify design and technical data without notice.**

# 17 Guidelines and manufacturer's declaration

| Guidelines and manufacturer's declaration - electromagnetic emissions | | |
|---|---|---|
| ASTOPAD is intended for use in the electromagnetic environment specified below. The customer or user of ASTOPAD should assure that the system is used in such an environment. | | |
| **Emission test** | **Compliance** | **Electromagnetic environment - guidelines** |
| RF emissions in accordance with CISPR 11/EN 55011 | Group 1 | ASTOPAD uses RF energy only for its internal function. Therefore, its RF emissions are very low, and it is unlikely that nearby electronic devices will be affected. |
| RF emissions in accordance with CISPR 11/EN 55011 | Class A | The emission characteristics of this device permit its use in industrial and hospital environments (CISPR 11, Class A). If used in domestic settings (which usually requires Class B according to CISPR 11), this device may not offer suitable protection of radio services. The user may have to take corrective action such as relocation or re-orientation of the equipment. |
| Harmonic components in accordance with IEC 61000-3-2 | Class A | |
| Voltage fluctuations and flicker in accordance with IEC/EN 61000-3-3 | Complies | |

| Guidelines and manufacturer's declaration - electromagnetic immunity | | | |
|---|---|---|---|
| ASTOPAD is intended for use in the electromagnetic environment specified below. The customer or user of ASTOPAD should assure that the system is used in such an environment. | | | |
| **Immunity test** | **Test level** | **Compliance level** | **Electromagnetic environment - guidelines** |
| Electrostatic discharge (ESD) according to IEC 61000-4-2 | ± 8 kV contact<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air | Complies | The floor should be a wood, concrete, or ceramic tile floor. If the floor is made of synthetic material, the relative humidity must be at least 30%. |
| Electrical fast transients and bursts according to IEC 61000-4-4 | ± 2 kV<br>100 kHz repetition frequency | Complies | Mains power quality should be that of a typical commercial or hospital environment. |
| Surges according to IEC 61000-4-5 | ± 0.5 kV, ± 1 kV Line to line<br><br>± 0.5 kV, ± 1 kV, ± 2 kV line to ground | Complies | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips in accordance with IEC 61000-4-11 | 0 % $U_T$; ½ cycle At 0, 45, 90, 135, 180, 225, 270 and 315 degrees<br><br>0 % $U_T$; 1 cycle and<br><br>70 % $U_T$; 25/30 cycles Single-phase at 0 degrees | Complies | Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation even in the event of mains power interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or battery. |
| Voltage interruptions in accordance with IEC 61000-4-11 | 0 % $U_T$; 250/300 cycles | Complies | |
| Magnetic fields with energy rated frequencies according to IEC/EN 61000-4-8 | 30 A/m<br>50 Hz or 60 Hz | Complies | Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment. |
| NOTE: $U_T$ is the AC mains voltage prior to application of the test level. | | | |

**Guidelines and manufacturer's declaration - electromagnetic immunity**

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

| Immunity test | Test level | Compliance level | Electromagnetic environment – recommended separation distance |
|---|---|---|---|
| Conducted disturbances induced by high-frequency fields according to IEC/EN 61000-4-6 | 3 $V_{eff}$<br>0.15 MHz to 80 MHz<br><br>6 $V_{eff}$ in ISM frequency bands between 0.15 MHz and 80 MHz<br>80 % AM at 1 kHz | Complies | $d = 1{,}2\sqrt{P}$ |
| Radiated RF disturbances<br>IEC 61000-4-3 | 3 V/m / 10 V/m<br>80 MHz to 2.7 GHz<br>80% AM at 1 kHz | Complies | $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2{,}3\sqrt{P}$ 800 MHz to 2.7 GHz |

Portable and mobile RF communication equipment should not be used at a distance from ASTOPAD (including its cables) that is less than the recommended separation distance calculated from the equation applicable to the frequency of transmission.

Where P is the maximum output power rating of the transmitter in watts (W) as specified by the transmitter manufacturer and **d** is the recommended separation distance in meters (m).
At all frequencies according to an on-site test **a**, the field strength of fixed RF transmitters is lower than the compliance level **b**
Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher value applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic wave propagation is affected by absorption and reflection from structures, objects and people.

**a** The field strength of fixed transmitters, e.g. base stations of mobile phones and land mobile services, amateur radio stations AM and FM radio and television transmitters, cannot be theoretically determined precisely beforehand. To assess the electromagnetic environment due to fixed RF transmitters, a site survey is recommended. If the measured field strength at the location in which the ASTOPAD is used exceeds the compliance level specified above, the ASTOPAD should be observed to verify normal operation at that application site. If abnormal performance is observed, additional measures may be necessary, such as reorientation or relocation of the ASTOPAD.
**b** Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and ASTOPAD**

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

| Maximum output power rating of transmitter in watts (W) | Separation distance according to frequency of transmitter in meters (m) | | |
|---|---|---|---|
| | 150 kHz to 80 MHz<br>$d = 1{,}2\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1{,}2\sqrt{P}$ | 800 MHz to 2.7 GHz<br>$d = 2{,}3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters whose maximum output power rating is not specified in the above table, the distance can be determined using the equation applicable to the respective column, where P is the maximum output power rating of the transmitter in Watts (W) as specified by the transmitter manufacturer.
NOTE 1: For the calculation of the recommended separation distance from the transmitters in the frequency range of 80 MHz to 2.7 GHz, an additional factor of 10/3 was used to reduce the likelihood of interference occurring due to a mobile/portable communication device used unintentionally in the patient area.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic wave propagation is affected by absorption and reflection from structures, objects and people.