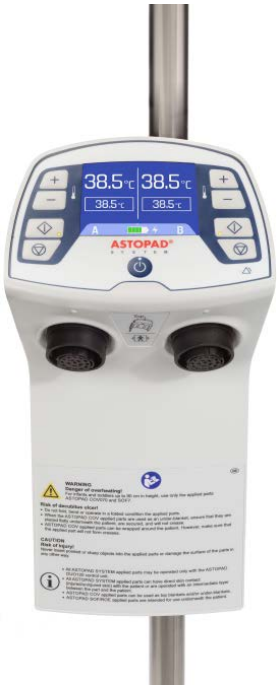
Instructions for use

ASTOPAD®

Patient Warming System



Part no. 0315.7200.12NA Rev. 01_draft 02/2020

STIHLERELECTRONIC

STIHLER ELECTRONIC GmbH • 70597 Stuttgart • Germany

To be completed by the user:

Serial number _____

Registration number _____

Device location _____

Start-up date _____

Manufacturer: **STIHLER ELECTRONIC GmbH**
Julius-Hoelder-Strasse 36
70597 Stuttgart
GERMANY
Tel. +49 (0) 711-720670
Fax +49 (0) 711-7206757
www.stihlerelectronic.de
E-Mail: info@stihlerelectronic.de

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. Refer to the section “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 applies also to changes undertaken by persons who are not authorized 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 have been carried out by trained and qualified persons according to the procedures published by the manufacturer;
- if only original spare parts have been used to replace components as needed;
- if assembly and repairs are only carried out by authorized personnel or an authorized service center;
- 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 products.

2.4 Information about the Battery

Batteries must not be disposed of in domestic waste. The user is obliged to carry out 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 rule for the return of device with built-in battery:
When returning ASTOPAD DUO310 control units, it is essential to ensure that the control unit is in storage / transport condition (see chapter 7.6 "Storage / transportation").

WARNING
Risk of infection! 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 in United States and Canada, please contact your local sales point or the following:

Gentherm Medical LLC.	Telephone	1-513-772-8810
12011 Mosteller Road	Toll Free (U.S.)	1-888-437-5608
Cincinnati, OH 45241	Fax	1-513-772-9119
USA	E-Mail	medical@genthermcsz.com

Visit our Web Site at www.gentherm.com

Before you call a service …
To help us better serve you, please have the serial numbers of your ASTOPAD system (control unit & applied part) ready when you call for parts or service. The serial number is located on the type label attached the control unit's rear and on the backside of the junction block of the applied parts.

3 Important safety information

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

DANGER
DANGER indicates a hazardous situation which, if not avoided, will result in death or serious injury.

WARNING
WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION
CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE
NOTICE indicates a property damage message.

3.1 Dangers

DANGER
Explosion hazard! Do not use the ASTOPAD patient warming system in an explosion-hazard environment or in the presence of flammable anesthetics.

3.2 Warnings

⚠WARNING

Risk of injury!

- ASTOPAD is only to be used under the direction of a Licensed Healthcare Practitioner.
- Read and observe all instructions, stickers, and accompanying documentation enclosed with the medical device. 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 this equipment 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 recurrent test.
- This device may only be operated by appropriately trained and medically qualified healthcare professionals.
- The service personnel must be appropriately trained and qualified.
- If the OR table top is tilted (adjusted through the longitudinal axis), there is a chance 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, ensure that disinfectants do not accumulate beneath the patient. During use, the patient must not be moist or even wet when lying on the mattress. 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.
- In the case of arterial occlusion, the applied parts of the ASTOPAD may not be used distal to this area.
- Overheating of ischemic extremities can occur with the use of the ASTOPAD applied parts.
- 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 authorized and qualified by the manufacturer.
- Modifications to the ASTOPAD are not permitted.

⚠WARNING

Risk of injury!

- When applied parts ASTOPAD COV are used as a top blanket, 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 markings/safety signs/warnings.
  - Damaged outer cover of the applied parts.
  - Alarm testing equipment defective. No optical or acoustic alarm after switching on using the Standby button (self-test).
  - Button(s) which do not function correctly.
  - A system that has been exposed to mechanical impact or liquid ingress into internal electronic system components.
  - A system that has previously delivered an electric shock to a person.
  - A system that appears to be overheating.
  - If at least one of the applied parts in a system triggers or has triggered an alarm shut-off.
  - If the self-test does not activate automatically after switching on with the Standby button and the heater does start operation immediately.
- The extension connection cable and the mains cable should not touch the patient and should not hinder the treating personnel.
- If the ASTOPAD DUO control unit with installed battery is not used for a longer period, the battery must be removed.

⚠WARNING

Risk of overheating!

- For pediatrics under 90 cm in length/height, use only the applied part ASTOPAD COV070.
- Do not use ASTOPAD COV105 or COV155 or COV180 for pediatrics under 90 cm in length/height.

⚠WARNING

Risk of infection!

- Use aseptic procedures.
- Clean and disinfect the equipment after every use and before you return the equipment for repairs.
- Route the extension connection cable between the applied part and the control unit in such a way that it is protected from soiling of blood and body fluids.
- Prevent the cables from coming into contact with the floor.
- It is recommended to always place a waterproof and absorbent barrier between the patient and the ASTOPAD applied part.

⚠WARNING

Risk of decubitus ulcer!

- Regardless of the treatment duration, aged, paralyzed, comatose, and cachectic patients are particularly at risk of decubitus ulcers. Critical points should therefore also be constantly examined by medical personnel.
- Do not fold, bend, or operate the applied parts in a folded condition.
- Do not place the patient on the connection block of the applied part.
- When the ASTOPAD COV applied parts are used as an under-blanket, ensure that they are placed flatly underneath the patient, are secured, and will not crease.
- Care must be taken during any surgical interventions to ensure that sufficient measures are taken to prevent decubitus ulcers in accordance with the patient's positioning.
- The risk of skin irritation caused by pooling of surgical prep solutions under the patient may increase with warming; ensure that surgical prep solution instructions for use are followed.
- Alleviate or remove the risk of heating skin under pressurized bony prominences.
- DO NOT place any hard objects (e.g., mattress cables, ECG cables, hard cautery return pads, patient fluid lines, etc.) between the ASTOPAD applied part and the patient.
- ASTOPAD COV applied parts can be wrapped around the patient. However, take care that the applied part will not form creases.

⚠WARNING

Risk of electric shock!

- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not use mains adapters that interrupt the earth conductor.
- Do not open the ASTOPAD DUO310 housing.
- If several pieces of equipment are combined or connected together (e.g., in multiple socket outlets), the total leakage currents must not exceed the allowable limits (refer to the respective national regulations). Observe the requirements as stipulated in IEC/EN 60601-1 regarding medical electrical systems.
- 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 DUO310 control unit and the applied parts of the ASTOPAD 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 this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of ASTOPAD, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

3.3 Cautions

⚠CAUTION

Risk of injury!

- Federal law (USA) restricts this device to sale by or on the order of a Licensed Healthcare Practitioner.
- When installing the ASTOPAD DUO310 control unit on an infusion stand, observe the instructions from the infusion stand manufacturer regarding maximum load and tilting stability.
- When ASTOPAD is used on the OR table, the OR table must be prepared according to the customary regulations and guidelines.
- Never insert pointed or sharp objects into the applied parts or damage the surface of the parts in any other way.
- Damage to the Applied part can cause overheating, therefore:
  - Do not use bleach solution with hypochlorite for disinfection of the applied parts.
  - Other than the cleaning and disinfection procedures described in this IFU shall not be applied without the manufacturer's authorization.
- Do not continue to use ASTOPAD applied parts beyond the labeled Use by Date.

⚠CAUTION

Risk of hypothermia!

- If the alarm shut-off of the ASTOPAD is triggered at an output, the entire system will switch off.
- If thermally conductive materials, such as water, gel, and similar substances, are used and were not pre-heated, the patient's body temperature may reduce as a result once the ASTOPAD applied parts are switched off.

⚠CAUTION

Risk of hypothermia!

- When the ASTOPAD is used, the patient's body temperature must be monitored at regular intervals.
- The temperature control of the ASTOPAD controls 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 the use of alternative warming methods in order to avoid or reduce hypothermia or to improve the patient's well-being.
- 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 DUO310 control unit.

⚠CAUTION

Risk of radio interference!

- The essential performance can be lost or degraded due to EM disturbances. As a result, there is the possibility of hypothermia of the patient.
- According the standard IEC/EN 60601-1-2, medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according the EMC information provided.
- The device/system can cause radio interferences or can interfere with the operation of devices in the vicinity. Appropriate measures may be necessary, such as reorienting or relocating of ASTOPAD or shielding.

3.4 Notices

NOTICE

- The specified humidity protection 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 patient warming system:
  - Do not immerse the control unit and/or the applied parts in liquid.
  - Do not disinfect the system using steam (e.g., in autoclaves), hot air, or thermo-chemical cleaning solutions.
  - The applied parts must not be disinfected with bleach solution (hypochlorite or other agents containing chlorine).
  - The operator should 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 applied part is connected to the extension connection cable and the control unit.

4 Intended Use

The ASTOPAD patient warming system is intended to prevent or treat hypothermia and to provide warmth to patients.

4.1 Indications for Use

The ASTOPAD patient warming system is indicated for use in all areas of healthcare facilities for preventing or treating hypothermia or maintaining normothermia. The warming blankets can be used over or under the patient (pediatric and adult) by appropriately trained healthcare professionals.

4.2 Contraindications

No contraindications are known for patient warming.

4.3 Possible adverse effects

In normal use, no side effects arising from ASTOPAD are to be expected. For longer surgical procedures there is an increased pressure ulcer risk for the patient. To reduce the pressure ulcer risk, therefore, the additional use of a pressure-relieving support is recommended after an operating time of two hours.

4.4 Intended patient group

For pediatrics under 90 cm in length/height use only the ASTOPAD applied part COV070.
For all other patients (greater than 90 cm in length/height) all available ASTOPAD applied parts can be used (COV070, COV105, COV155, COV180).

4.5 Intended body part

ASTOPAD applied parts **COV** are intended for use underneath or over the patient, partial or complete (torso and extremities on all sites), head (without visual field).

Control unit, connecting cable and applied parts are not intended for direct skin contact. A thin waterproof and absorbent barrier shall always be used between applied part and patient.

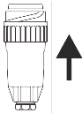
4.6 Intended user profile

The device may only be used by qualified medical personnel.

4.7 Intended environment of use / operation

- ASTOPAD may only be used in professional healthcare facilities (e.g. hospital, emergency care, dialysis, including HF surgical equipment, etc.).
- ASTOPAD is not intended for home healthcare environment.
- ASTOPAD is reusable, but requires cleaning / disinfection between the applications.
- Appropriate medical hygienic factors must be applied for the use of ASTOPAD.
- ASTOPAD must not be used in an environment at risk of explosion or in the present of flammable anesthetics.
- 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.

5 Symbols

Symbols and indications on the control panel	
	The Standby button switches between the **Standby mode** and the **On mode**. The device is in **Standby mode** if the blue LED illuminates.
	“Start” button: Starts the heating process.
	Temperature increase set value.
	Temperature decrease set value.
	“Stop” button.
	Alarm condition when the yellow LED flashes.
	No applied part is connected to the control unit.
	The applied part heats up to the set temperature.
	The applied part cools down to the set temperature.
	Battery capacity indicator.
	Defective or incorrect battery.
	Battery being charged or the device is connected to the mains.

Where applicable, these symbols appear at the appropriate location on the patient warming system, on the packaging, on the identification plate, or in the accompanying documentation.	
	Defibrillation-proof type BF applied part in accordance with IEC/EN 60601-1.
IPX2	Protected against dripping water in accordance with IEC/EN 60529.
	Follow the instructions for use.
	Caution: Federal US law restricts this device to sale by or on order of a Licensed Healthcare Practitioner.
	General warning/danger symbol.
REF	Catalogue number.
SN	Serial number.
LOT	Batch code.
	Year of manufacture.
	Manufacturer.
MD	Medical Device
	Information for the position of the locking ring on the cable plug of the extension connection cable.
	Battery
	Symbol on plug connector for potential equalization in accordance with IEC/EN 60601-1.

	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 humidity range for storage and transport.
	Symbol for the permitted atmospheric pressure range for storage and transport.
	Transport with the arrows pointing up.
	Keep dry.
	Fragile, protect against impacts.
	Packaging Labeling for the transport of lithium batteries according to ADR SV 188 or IATA - DGR International Dangerous Goods Regulations, Packing Instruction 965, II. SECTION II 43416
	Labeling for 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 (registration 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, CAN/CSA-C22.2 No. 60601-1:14. Control No. 75JA
	Tilt of the OR table top.
	Acoustic alarm signal.
	No acoustic alarm signal.
 yyyy-mm	Use by Date, DO NOT USE AFTER.

	Prohibition: Do not clamp – risk of damage and possible overheating!
	Prohibition: Never insert pointed or sharp objects into the applied parts – risk of damage and possible overheating!
	Prohibition: Do not disinfect with hypochlorite solution Chlorine and peroxides and all other oxidizing disinfectants have a negative impact on the materials of the applied parts, therefore the use of such disinfectants is not recommended. The lifetime is significantly reduced by these disinfectants.

6 Product description

6.1 Introduction

The ASTOPAD Patient Warming System is a thermal regulating system which includes a connection cable that attaches to reusable conductive warming blankets for patient warming in clinical environments. The system consists of a control unit (DUO310) and one or optionally two applied parts (warming blankets).

⚠WARNING

Risk of overheating!

- For pediatrics under 90 cm in length/height, use only the applied part ASTOPAD COV070.
- Do not use ASTOPAD COV105 or COV155 or COV180 for pediatrics under 90 cm in length/height.

6.2 Technical description

The ASTOPAD control unit (DUO310) is equipped with a universal mounting clamp for attaching to standard medical equipment rails or an infusion stand, two outputs for connecting one or two applied parts, connection to mains by detachable power supply cord, connector for potential equalization, the electronic boards and the control panel for the user/operator.

The control unit has two outputs (connecting sockets) A and B for connecting ASTOPAD applied parts. The desired set temperature can be selected in the range of 32.0 °C - 39.0 °C in 0.5 °C increments for each connected applied part, independently of each other, on the control panel of the control unit. The control unit can also be used with only one of the outputs, A or B. The selected set temperature and the current temperature are displayed individually for each applied part in the control panel.

The control unit supplies the applied part(s) with electrical current (low voltage) and monitors and controls the temperature of the applied part(s). When error conditions occur, the control unit draws the operator's attention to the error condition by means of alarm signals (optical & acoustical). In the event of failure conditions (overheating, heater defect, sensor defect), the control unit reacts immediately by shutting off the power supply to the applied part.

Optionally the control unit can be fitted with a battery. When the battery is installed, it is possible to operate the device independently from the mains for approximately two hours.

The ASTOPAD DUO310 control unit does not control and indicate the actual temperature of the patient, but rather only the actual temperature of the applied part.

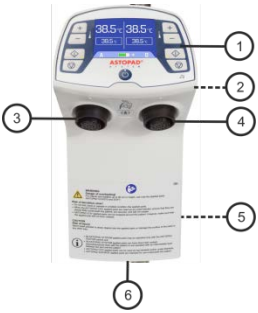
Temperature regulation of the individual applied parts is performed with several integrated sensors.

Safety of ASTOPAD is guaranteed by the following measures per 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



No.	Designation	Description
1	Control panel	Operating buttons and temperature displays.
2	Attachment device	For secure attachment of the ASTOPAD DUO310 control unit.
3	Output A (connecting socket)	Plug connection between control unit and applied part.
4	Output B (connecting socket)	
5	Connector for Potential Equalization	The purpose of additional potential equalization is to equalize potentials between different metal parts that can be touched simultaneously, or to reduce differences of potential which can occur during operation between the body, the medical electrical devices and conductive parts of other objects. The connection is made by green-yellow insulated leads (min. 4 mm²) to standardized plug connectors and receptacles. When connecting/combining medical electrical equipment together to a medical electrical system, the requirements of IEC/EN 60601-1 must be observed.
6	Power input connector for removable power cord with mains plug	Conveys electricity from the wall power outlet to the control unit. Pull the mains plug to disconnect from supply network.

Fig. 1 Control unit

ASTOPAD COV applied parts

No.	Designation	Description
1	ASTOPAD COV	Example of an ASTOPAD COV applied part.
2	Connection cable	Connection cable for connecting to the extension connection cable.
3	End cap	The attached end cap is used to close off the end when an extension cable is not connected. It protects the contacts and guarantees the IPX2 liquid ingress protection.
4	Extension connection cable	The extension connection cable is used to connect the ASTOPAD COV applied parts to the control unit.

Fig. 2 ASTOPAD COV applied parts

6.4 Control panel

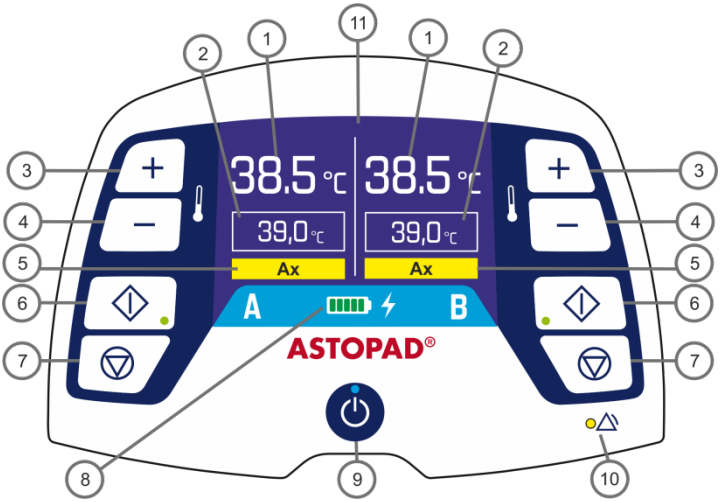
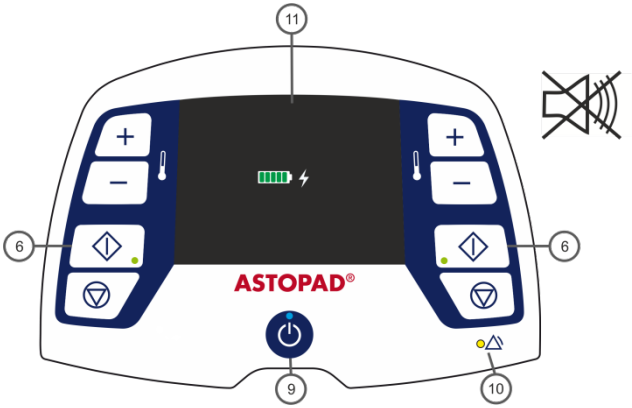


Fig. 3 Control panel

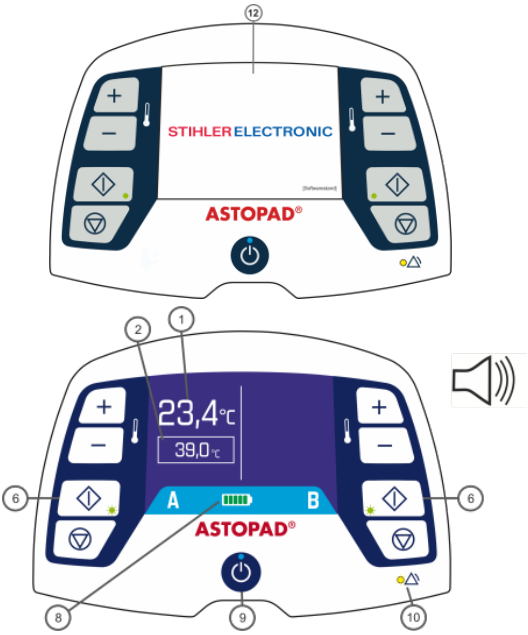
No.	Designation	Description
1	Actual temperature A or B	Displays the actual temperature of the applied part
2	Set temperature A or B	Displays the selected set temperature of the applied part.
3	“Temperature increase” button A or B	Press this button to increase the set temperature in increments of 0.5 °C.
4	“Temperature decrease” 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 status indicator	Indicates the current battery status.
9	“Standby” button “Standby” LED (blue)	The Standby button switches between the **Standby mode** and the **On mode**.
10	“Alarm” LED (yellow)	LED flashes or turns on 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

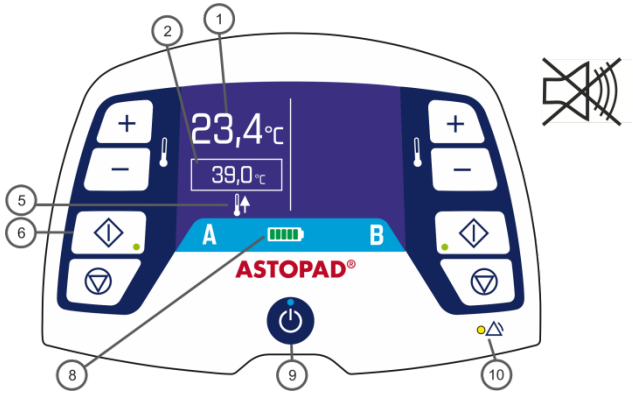
7.1 Standby mode

Control panel	
Action	After connecting the mains plug to the mains socket, the control unit is in **Standby mode** or Press the “Standby” button (9) to switch the device from any **mode** to **Standby mode**.
Device response	• The “Start” LED (6) turns off • The “Alarm” LED (10) turns off • The “Standby” LED (9) illuminates • The display (11) shows the symbol for battery status (only for device with built-in battery)
ℹ	• After a power failure, the device automatically switches to **Standby mode**. • In **Standby mode** only the electronics and the applied parts are disconnected from the power supply. The control unit remains connected to the mains. • For device with a built-in battery, the battery is charged in **Standby mode**.

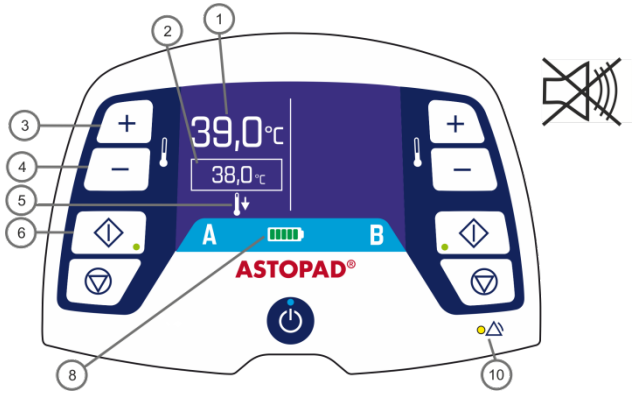
7.2 On mode

Control panel	
Action	Press the “Standby” button (9) to switch the device from **Standby mode** to **On mode**.
Device response	• The Standby LED (9) turns off. • The Start screen (12) is displayed for 1 sec. • The device performs a self-test. The display illuminates, the LEDs (6) (10) flash and the acoustic alarm signal sounds to indicate that the control unit is functioning correctly. • When an applied part is connected, the display (1) shows the current actual temperature. • If no applied part is connected to one of the two outputs A/B, the corresponding display is turned off. • Display of the saved initial set temperature.(2) • For device with a built-in battery the symbol for battery status (8) is displayed.
ⓘ	• The self-test remains active until the heating process is started at one of the two outputs. • By pressing the Standby button and simultaneously holding the Stop Channel B button, the Start screen is displayed for as long as the Stop button is pressed. • The software status can be read at the bottom right corner of the Start screen.

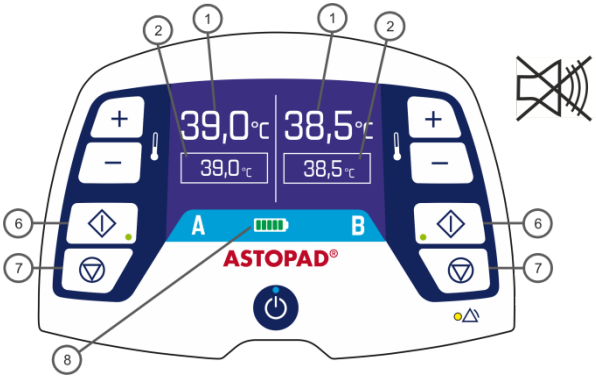
7.3 Heating mode output A and/or B

Control panel	
Action	Press the “Start” button ⑥ to start the heating process.
Device response	• The acoustic alarm switches off, and the “Alarm” ⑩ LED turns off. • When the applied part is started, the display ⑤ shows the symbol “Applied part heating”, until the difference between the set temperature ② is < 1.0 °C. • The “Start” LED ⑥ is green. • Temperature control is active. • For device with a built-in battery the symbol for battery status ⑧ is displayed.
ℹ	If no applied part is connected to an output (A or B) or the heating process does not start, displays ① and ② turn off.

7.4 Increasing/decreasing the set temperature

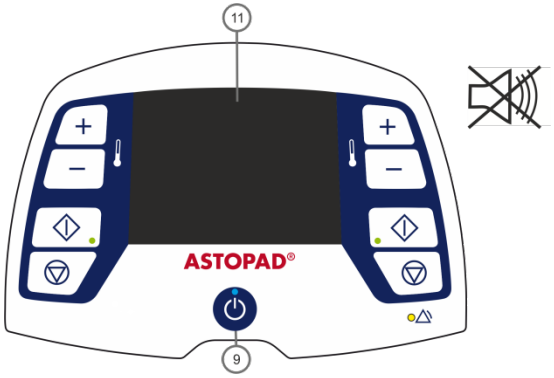
Control panel	
Action	1. Press the “Temperature increase” (3) /“temperature decrease” button (4) to raise or lower the selected set temperature in 0.5 °C increments. 2. Confirm the new set temperature by pressing the “Start” (6) button.
Device response	• The “Start” LED (6) flashes green until confirmation by pressing the “Start” (6) button. • When the applied part is started, the display (5) shows the symbol “Applied part cooling” / “applied part heating”, until the difference between the set temperature (2) is < 1.0 °C. • The “Start” LED (6) is green. • Temperature control is active. • For device with a built-in battery the symbol for battery status (8) is displayed.
ⓘ	• If no applied part is connected to an output (A or B) or the heating process does not start, displays (1) and (2) turn off. • 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” (7) button to switch off an output.
Device response	• The “Start” (6) LED turns off. • Displays (1) and (2) turn off for the output that was switched off.
ℹ	• If only one output is active, pressing the “Stop” (7) button will activate the self-test. • Pressing the “Start” (6) button can reactivate the heating process with the last set temperature setting.

7.6 Storage/transportation

(only for battery-operated equipment)

Control panel	
Action	Press the “Standby” (9) button and hold it for at least 3 sec.
Device response	• The Standby LED (9) turns off. • The display (11) turns off.
ℹ	For devices without batteries, complete switch-off is performed by pulling out the mains plug.

8 Installation

8.1 Putting into service

Before operating this device for the first time:

- Inspect the device visually (***chapter 13.1 Recurrent Tests)***.
- Check the mains voltage (compare the data on the type label with the available mains voltage). An incorrect mains voltage can lead to destruction of the device

National regulations may require other tests before this device can be put into service. If required, additional tests for electrical safety should be carried out according to ***chapter 13.1 Recurrent Tests.***

8.2 Installation of the Control unit

For safe installation, the control unit is equipped with a universal attachment device. With this, the device can be securely attached to infusion stands as well as to medical standard rails.

⚠ CAUTION
Risk of injury! When installing the ASTOPAD DUO310 control unit on an infusion stand, observe the instructions from the infusion stand manufacturer regarding maximum load and tilting stability.

8.2.1 Attachment to infusion stands

Fig. 4 Attachment to infusion stands

1. Turn the hand wheel counterclockwise to open the attachment device.
2. Turn the hand wheel clockwise to lock the attachment device to the infusion stand.
3. Check that the control unit is firmly fixed.

8.2.2 Attachment to medical rails

Abb. 5 Attachment to medical rails

1. Hang the ASTOPAD control unit obliquely from above with the attachment device into the standard rail.
2. Fix the ASTOPAD control unit by tightening the hand wheel to the standard rail.
3. Check that the control unit is firmly fixed.

	For attachment to the medical rail it may be necessary to move the universal attachment device into another position. For this the two mounting screws must be released. After changing the position, the screws must be screwed again according to the positioning of the attachment device.

9 Getting started

WARNING

Risk of electric shock!
Before every use, check to make sure that the ASTOPAD DUO310 control unit and the applied parts are undamaged.

WARNING

Risk of infection!
- Use aseptic procedures.
- Route the extension connection cable between the applied part and the control unit in such a way that it is protected from soiling of blood and body fluids.
- Prevent the cables from coming into contact with the floor.
- It is recommended to always place a waterproof and absorbent barrier between the patient and the ASTOPAD applied part.

WARNING

Risk of injury!
- When RF surgical instruments or endocardial catheters are used, the patient must also be properly insulated. This insulation must not be damp. The device 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 the ASTOPAD may not be used distal to this area.
- Overheating of ischemic extremities can occur with the use of the ASTOPAD applied parts.
- When applied parts ASTOPAD COV are used as a top blanket, ensure that they do not obstruct the patient's field of vision.
- Have the device repaired if the self-test is not activated automatically after the mains switch is switched on and the heating does start immediately.
- The extension connection cable and the mains cable should not touch the patient and should not hinder the treating personnel.

⚠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 markings/safety signs/warnings.
  - Damaged outer cover of the applied parts.
  - Alarm testing device defective. No visual or acoustic alarm after switching on using the Standby button. (Self-test)
  - Button(s) which do not function correctly.
  - A system that has been exposed to mechanical impact or liquid ingress into internal electronic system components.
  - A system that has previously delivered an electric shock to a person.
  - A system that appears to be overheating.
  - If at least one of the applied parts in a system triggers or has triggered an alarm shut-off.

⚠WARNING

Risk of decubitus ulcer!

- Regardless of the treatment duration, aged, paralyzed, comatose, and cachectic patients are particularly at risk of decubitus ulcers. Critical points should therefore also be constantly examined by medical personnel.
- Do not fold, bend, or operate the applied parts in a folded condition.
- Do not place the patient on the connection block of the applied part.
- When the ASTOPAD COV applied parts are used as an under-blanket, ensure that they are placed flatly underneath the patient, are secured, and will not crease.
- Care must be taken during any surgical interventions to ensure that sufficient measures are taken to prevent decubitus ulcers in accordance with the patient's positioning.
- The risk of skin irritation caused by pooling of surgical prep solutions under the patient may increase with warming; ensure that surgical prep solution instructions for use are followed.
- Alleviate or remove the risk of heating skin under pressurized bony prominences.
- DO NOT place any hard objects (e.g., mattress cables, ECG cables, hard cautery return pads, patient fluid lines, etc.) between the ASTOPAD applied part and the patient.
- ASTOPAD COV applied parts 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 DUO control unit.
- All ASTOPAD applied parts should not come in direct skin contact with the patient and must be operated with an intermediate layer between the part and the patient.
- ASTOPAD COV applied parts can be used as top blankets and/or under-blankets.
- Install the device so that disconnection from the mains via the mains plug is difficult to carry out.
- With installed battery, it is possible to operate the ASTOPAD control unit independently to the mains for approx. 2 hours.

9.1 Preparation for use

- Before use, make sure that the device and its applied parts have been cleaned and disinfected according to the instructions for use ***(see Section 9.6 Cleaning and disinfection)***.
- Attachment of the ASTOPAD DUO control unit according to ***Section 8.2 Installation of the Control unit***.

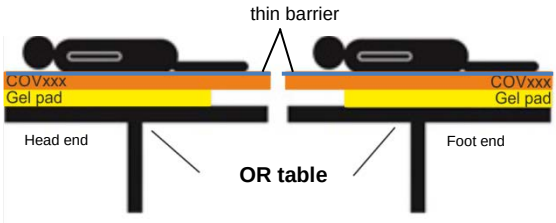
9.1.1 Using ASTOPAD COV070/COV105/COV150/COV180 as an under-blanket

⚠WARNING

Risk of overheating!

- For pediatrics under 90 cm in length/height, use only the applied part ASTOPAD COV070.
- Do not use ASTOPAD COV105 or COV155 or COV180 for pediatrics under 90 cm in length/height.

1. A pressure-relieving gel pad may also be placed on the OR table.
2. Place the blanket lengthwise on the table with the cable connection side pointing to the outside edge of the OR table/treatment table.
3. Position the blanket on the table so that the blanket is flat underneath the patient and will not crease. If a pressure-relieving gel pad is used in combination with the applied parts ASTOPAD COV070/COV105/COV150/COV180 on the OR table, the gel pad must be placed under the ASTOPAD COV. Observe the arrangement of the ASTOPAD COV and the gel pad. The gel pad and COVXXX must be positioned flush with the head or foot end of the OR table.
4. Always place a thin waterproof and absorbent barrier between the ASTOPAD applied part and the patient.



WARNING

Risk of injury!
If the OR table top is tilted (adjusted through the longitudinal axis), there is a chance 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 COV as a top blanket

WARNING

Risk of injury!
When applied parts of the ASTOPAD COV are used as a top blanket, ensure that they do not obstruct the patient's field of vision.

Always place a thin waterproof and absorbent barrier between the ASTOPAD applied part and the patient.

Place the blanket 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 blanket can be adjusted according to the operation field.

9.2 Starting the heating process

The operator should be positioned in front of the ASTOPAD control unit, able to see easily the displays and operating elements.

1. Plug the mains plug for the ASTOPAD DUO310 control unit into the plug socket.
2. Position the patient correctly and apply the applied parts according to the particular case and according to ***Section 9.1 Preparation for use***.
3. Connect the extension connection cable with the connection cable of the applied parts. Then secure the bayonet connector by turning it to the right.
4. Place the extension connection cable/connection 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.
5. Switch on the device with the "Standby" button.
6. 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! Have the device repaired if the self-test is not activated automatically after the mains switch is switched on and the heating does start immediately.

7. 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 arrow button for “temperature increase” (+)/“temperature decrease” (−) to raise or lower the selected set temperature in 0.5 °C increments.
2. Confirm the new set temperature by pressing the “Start” button.

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 activate the self-test.

9.5 Switching off the ASTOPAD

1. Press the “Standby” button of the ASTOPAD DUO310 control unit to switch off (all displays are turned off, the “Standby” LED illuminates).
2. Disconnect the ASTOPAD DUO310 control unit from the applied part(s).
3. Clean and disinfect ASTOPAD.

9.6 Cleaning and disinfection

ASTOPAD components and accessories are not intended to be in direct contact with the patient, but they may inadvertently become contaminated with organic soils (e.g. blood, body fluids) or microorganisms during use.
Therefore after each use the following cleaning and disinfecting procedures shall be followed.

While cleaning and disinfecting, wear gloves with chemical resistance.
- Always work from top to bottom and from clean to dirty areas.
- After removing blood, discard the wet wipe. Use a new one to continue cleaning.
- Use wipes only as long as they leave a closed liquid film on the surface.
- Use adequate numbers of wipes per surface in order to achieve adequate disinfection.
- Dispose of used wipes according the instructions of your facility.
- Follow the specific EPA label disinfectant contact times.
- Work methodically in order to disinfect each area of the device.

	Chlorine and peroxides and all other oxidizing disinfectants have a negative impact on the materials of the applied parts, therefore the use of such disinfectants for routine disinfection is not recommended. The lifetime of ASTOPAD components is significantly reduced by these disinfectants.

9.6.1 Preparation

For an intermediate disinfection use an EPA-registered disinfectant that is labeled as tuberculocidal.

Recommended Product:
Sani-Cloth® GERMICIDAL DISPOSABLE WIPES from Professional Disposables International, Inc. [1]

The surfaces should remain wet with the disinfectant for the tuberculocidal contact time specified in the wipe manufacturer's label instructions.

9.6.2 Applied parts

1. Disconnect applied part from the control unit.
2. Close the connector using the end cap (refer to Fig. 2 ASTOPAD COV applied parts) to protect electrical contacts from entering liquids.
3. Visually inspect all surfaces (all sides) including the junction block and the connecting cable for wear and tear, cuts, holes and cracks and other unacceptable deteriorations.

Cleaning and disinfecting is possible only when no damage exists! Damaged components should not be used.

4. Visually inspect all surfaces (all sides) including the junction block and the connecting cable for residues of body fluids and other soilings.

[1] EPA registration number: 9480-4

When soil or residues of body fluids are visible

5. Clean first according to the instructions of the disinfectant manufacturer and then disinfect in a second step.

If the surface is not visually clean at the end of the cleaning step, the cleaning process should be either repeated or the device should be safely disposed.

When no soil is visible

6. Disinfect all surfaces according to the instructions of the disinfectant. When disinfecting mattresses wipe from head-end to foot-end.

The surfaces should remain wet with the disinfectant for the tuberculocidal contact time specified in the wipe manufacturer's label instructions.

7. Let air dry all parts and all sides well thoroughly before further use or storage.

9.6.3 Control unit

1. Disconnect control unit from mains.
2. Visually inspect control panel and housing from all sides for wear and tear, holes and cracks and other unacceptable deteriorations.

Cleaning and disinfecting is possible only when no damage exists! Damaged components should not be used.

3. Visually inspect all surfaces for residues of body fluids and other soilings.

When soil or residues of body fluids are visible

4. Clean first according to the instructions of the disinfectant manufacturer and then disinfect in a second step.

If the surface is not visually clean at the end of the cleaning step, the cleaning process should be repeated until the housing is visually clean.

When no soil is visible

5. Disinfect all surfaces according to the instructions of the disinfectant.

The surfaces should remain wet with the disinfectant for the tuberculocidal contact time specified in the wipe manufacturer's label instructions.

6. Let air dry control unit before further use or storage.

⚠CAUTION

Risk of injury!
Damage to the applied part can cause overheating, therefore follow the instructions below:

- Only disinfect the applied part with the recommended disinfectant.
- Do not use solutions containing hypochlorite (bleach) for disinfecting the applied part.
- Do not use cleaning and disinfection procedures which differ from the procedure described.

NOTICE

To avoid damage to the Patient Warming System:

- Do not immerse the control unit and/or the applied parts in liquid.
- Do not disinfect the control unit and/or the applied parts with these methods/products:
  - Steam (autoclave)
  - Hot air
  - Thermochemical cleaning solutions
- Refer to the specific instructions for use of the disinfectants.

Do not disinfect with hypochlorite solution
Chlorine and peroxides and all other oxidizing disinfectants have a negative impact on the materials of the applied parts, therefore the use of such disinfectants is not recommended. The lifetime is significantly reduced by these disinfectants.

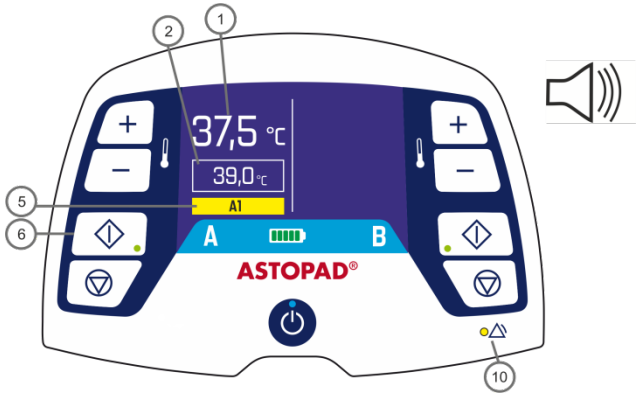
10 Alarms and troubleshooting

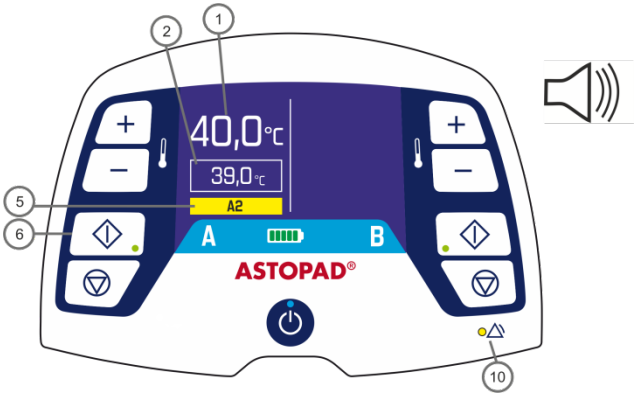
The ASTOPAD does not require continuous supervision by the operator, but must be inspected at regular intervals (depending on the condition of the patient). For this, the intended operating location is immediately in front of the control panel of the control unit.

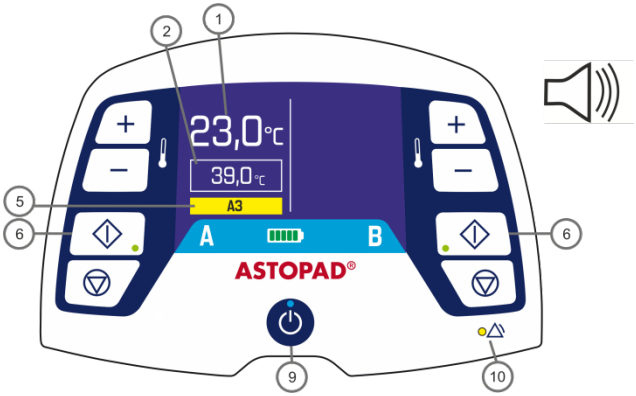
In case of failure of the equipment, possible injury to the patient is delayed and the operator has sufficient time to provide alternative warming methods.

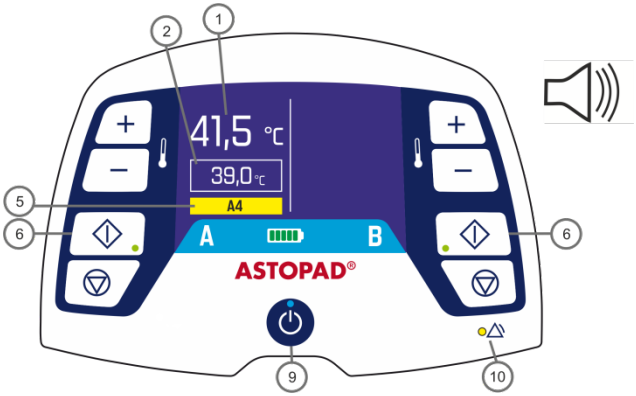
To ensure the safe operation of the ASTOPAD for patients and users, the ASTOPAD is equipped with a series of independent alarm systems. The alarms are the result of consistent implementation of the standards listed in ***Section 15 Conformity with international standards***.

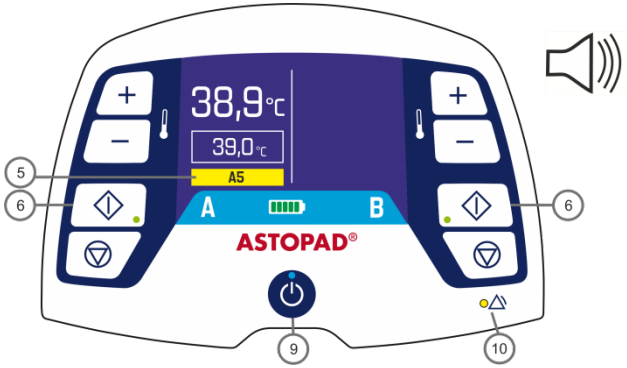
The alarms are only triggered by technical alarm conditions (device faults). The alarm signal is given visually and acoustically.

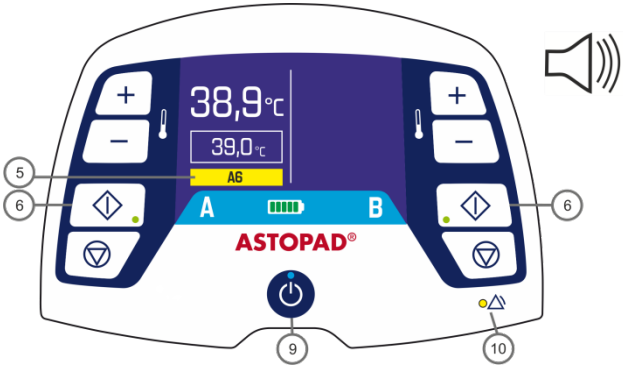
10.1 Low temperature alarm “A1” (low priority alarm condition)	
Control panel	
Device response	• The temperature reduces in controlled state to 1.0 °C below the set temperature ②. • If this condition lasts for more than 10 minutes, the acoustic alarm is triggered, the “Alarm” LED ⑩ turns on and the display ⑤ shows “A1”.
Alarm condition	This alarm is displayed when the difference of the applied part’s actual temperature ① to the set temperature is ② ≥ 1.0 °C lower.
Possible reasons ►Required action(s)	The applied part has not yet reached the set temperature. ►Warm-up phase, no action necessary.
	Applied part defective. ►Send the applied part to the local sales point.
Required action(s) for resetting	Press the “Start” ⑥ button to return the ASTOPAD to the control mode. The acoustic alarm signal is then suppressed for a further 10 minutes and the display ⑤ shows the symbol “Applied part heating”. If the alarm condition recurs, there is a defect in the applied part.
ⓘ	As soon as the set temperature is reached or the alarm is reset, the acoustic low-temperature alarm “A1” will be suppressed for 10 minutes according to IEC/EN 80601-2-35.

10.2 Overheating alarm “A2”	(low priority alarm condition)
Control panel	
Device response	• The temperature increases in controlled state to 1.0 °C above the set temperature ②. • If this condition lasts for more than 10 minutes, the acoustic alarm is triggered, the “Alarm” LED ⑩ turns on and the display ⑤ shows “A2”.
Alarm condition	This alarm is displayed when the difference of the applied part’s actual temperature ① to the set temperature is ② ≥ 1.0 °C higher.
Possible reasons ►Required action(s)	Set temperature is decreasing. ►Cooling phase, no action necessary. ►Press the “Start” ⑥ button to reset the alarm.
	Set temperature is increased. Applied part produces a temperature overshoot. ►Press the “Start” ⑥ button to reset the alarm.
	Applied part is being influenced by an external heat source. ►Remove the external heat source.
	Applied part defective. ►Send the applied part to the local sales point.
Required action(s) for resetting	Press the “Start” ⑥ button to return the ASTOPAD to the control mode.
ⓘ	As soon as the set temperature is reached or the alarm is reset, the acoustic overheating alarm “A2” will be suppressed for 10 minutes according to IEC/EN 80601-2-35.

10.3 Time alarm “A3” (low priority alarm condition)	
Control panel	
Device response	• When the applied part is started, the display ⑤ shows “A3”. • The Start LED ⑥ flashes and the Alarm LED ⑩ turns on. • An acoustic alarm signal is triggered.
Alarm condition	This alarm is triggered if the set temperature ② is not reached during 60 minutes of uninterrupted heating.
Possible reasons ►Required action(s)	A layer of thermally conductive materials (water or gel) is on the applied part. ►Remove the layer or place it underneath the applied part.
	Applied part defective. ►Send the applied part to the local sales point.
Required action(s) for resetting	Start the heating process again with the “START” ⑥ button or if necessary, switch off the control unit with the “Standby” ⑨ button.

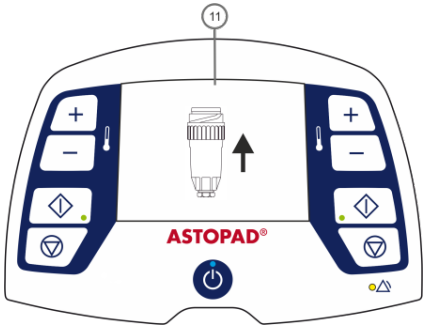
10.4 Overheating alarm shut-off “A4” (medium priority alarm condition)	
Control panel	
Device response	• When the applied part is started, the display (5) shows “A4”. • The Start LED (6) and the Alarm LED (10) flash. • An acoustic alarm signal is triggered. • The heating process is stopped at the two outputs.
Alarm condition	This alarm is triggered if an applied part sensor measures a temperature of > 41.0 °C.
Possible reasons ►Required action(s)	Set temperature is increased. Applied part produces a temperature overshoot. ►1. Switch off the control unit. 2. Allow the applied part to cool. 3. Restart the heating process.
	Applied part is being influenced by an external heat source. ►Remove the external heat source.
	Applied part defective. ►Send the applied part to the local sales point.
Required action(s) for resetting	Switch off the control unit with the “Standby” (9) button and allow the applied parts to cool down.

10.5 Sensor defect alarm “A5”	(medium priority alarm condition)
Control panel	
Device response	• The display (5) for the affected output shows “A5”. • The Start LED (6) and the Alarm LED (10) flash. • An acoustic alarm signal is triggered. • The heating process is stopped at the two outputs.
Alarm condition	This alarm is triggered if one or more sensors in the applied part are defective.
Possible reasons ►Required action(s)	Defective sensor(s) in the applied part. ►Send the applied part to the local sales point.
	Defective connection cable on the applied part. ►Send the applied part to the local sales point.
	Defective cable plug on the applied part. ►Send the applied part to the local sales point.
	Defective extension connection cable. ►Replace the extension connection cable.
	Defective connecting socket for output A or B on the control unit. ►Send the control unit to the local sales point.

10.6 Heater defect alarm “A6”	(medium priority alarm condition)
Control panel	
Device response	• The display ⑤ for the affected output shows “A6”. • The Start LED ⑥ and the Alarm LED ⑩ flash. • An acoustic alarm signal is triggered. • The heating process is stopped at the two outputs.
Alarm condition	This alarm is triggered if there is a defect in the heating conductor in the applied part.
Possible reasons ►Required action(s)	Heater resistance too high or defective. ►Send the applied part to the local sales point.
	Defective connection cable on the applied part. ►Send the applied part to the local sales point.
	Defective cable plug on the applied part. ►Send the applied part to the local sales point.
	Defective extension connection cable. ►Replace the extension connection cable.
	Defective connecting socket for output A or B on the control unit. ►Send the control unit to the local sales point.

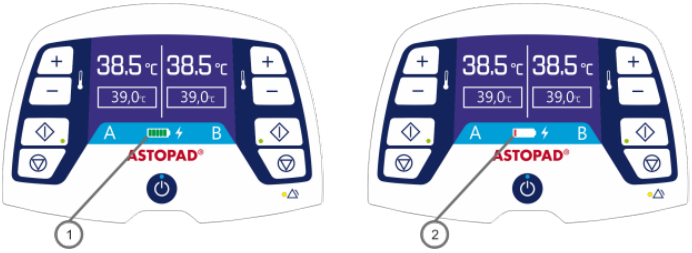
11 Information messages and troubleshooting

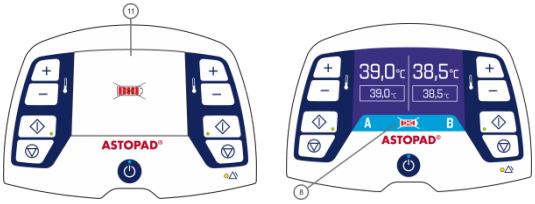
11.1 No applied part connected

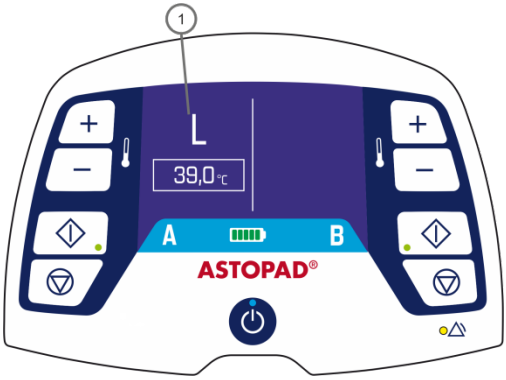
Control panel	
Device response	After the Start screen, the display (11) shows the symbol “Connect applied part”.
Information condition	This message appears if an applied part is not connected to either of the outputs A/B.
Possible reasons ►Required action(s)	No application part connected. ►Connect at least one applied part to one of the outputs A/B.
ⓘ	The display is shown until at least one applied part is connected to the ASTOPAD DUO310 control unit.

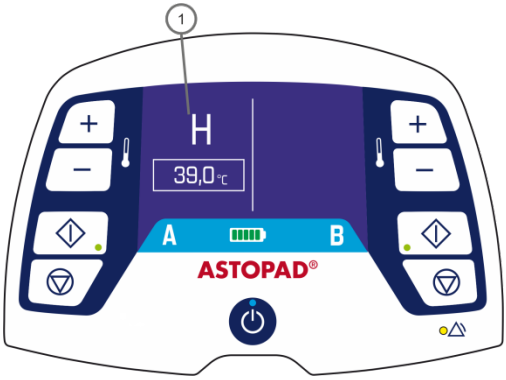
11.2 Battery state

(only for battery-operated equipment)

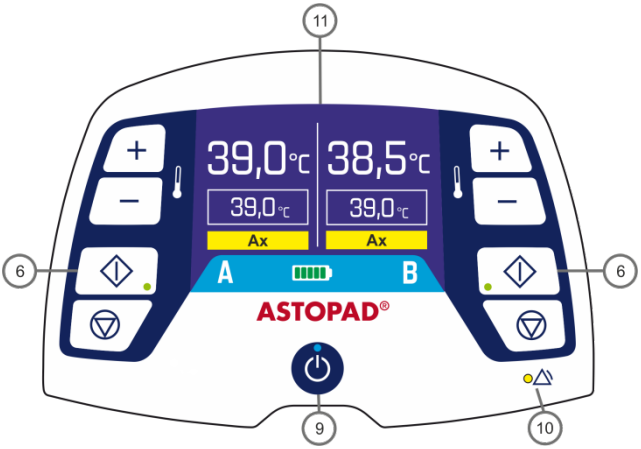
Control panel	
Information condition	Display battery state: (1) Battery capacity 100% (2) Battery capacity 10%

11.2 Battery defective (only for battery-operated equipment)	
Control panel	
Device response	After the Start screen, in mains operation mode and in Standby mode the display (11) (8) shows the crossed-out battery symbol.
Information condition	This display appears if the battery is defective or an original battery has not been inserted.
Possible reasons ►Required action(s)	Battery defective ►Insert a new, original battery.
	Not an original battery ►Insert a new, original battery.
ⓘ	The battery should be replaced every 3 years in order to ensure an adequate battery capacity.

11.3 Applied part temperature too low	
Control panel	
Information condition	The display (1) shows an “L”.
Alarm condition	This display appears if the temperature of the applied part is outside of the display range.
Possible reasons ►Required action(s)	Temperature of the applied part < 20.0 °C ►Heat up the heating element.

11.4 Applied part temperature too high	
Control panel	
Device response	The display ① shows an “H”.
Information condition	This display appears if the temperature of the applied part is outside of the display range.
Possible reasons ►Required action(s)	Temperature of the applied part > 45.0 °C ►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	**OFF**	○	○	●		Standby mode
		○	○	●		Battery is being charged
		○	○	●		Defective or incorrect battery
On mode		○	○	○		Defective or incorrect battery
		○	○	○		No applied part connected
	Actual temperature Set temperature	☼	☼	○		Self-test
	L Set temperature	☼	☼	○		Self-test and temperature of the applied part < 20.0 °C
	H Set temperature	☼	☼	○		Self-test and temperature of the applied part < 45.0 °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 defective sensor in the applied part
	Actual temperature Set temperature A6	☼	☼	○		No applied part connected, or defective heating conductor in the applied part
	OFF	○	○	○		Output not started
	L Set temperature	●	○	○		temperature of the applied part < 20.0 °C
	Actual temperature Set temperature	●	○	○		Cooling phase
	Actual temperature Set temperature	●	○	○		Defective or incorrect battery
Standby Increase/ decrease set temperature	**Actual temperature Set temperature**	☼	○	○		New set temperature not confirmed
Mode Switching off an output	**OFF**	○	○	○		-
	Actual temperature Set temperature	☼	☼	○		Only one output was started; device is in self-test
Switching off the control unit	**OFF**	○	○	●		See Standby mode
Off mode	**OFF**	○	○	○		Mains plug pulled out
Off mode	**OFF**	○	○	○		The "Standby" button has been 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 ≤1.0 °C set temperature
Overheating alarm "A2"	**Actual temperature Set temperature A2**	●	●	○	🔊	Actual temperature ≥1.0 °C set temperature
Time alarm "A3"	**Actual temperature Set temperature A3**	☀	●	○	🔊	Set temperature not reached during 60 minutes of uninterrupted heating
Overheating alarm "A4"	**Actual temperature Set temperature A4**	☀	☀	○	🔊	Actual temperature ≥ 41.0 °C
	H Set temperature A4	☀	☀	○	🔊	Temperature of the applied part > 45.0 °C
Sensor defect alarm "A5"	**Actual temperature Set temperature A5**	☀	☀	○	🔊	Connection interrupted between control unit and applied part or sensor defect in applied part
Heater defect alarm "A6"	**Actual temperature Set temperature A6**	☀	☀	○	🔊	Connection interrupted between control unit and applied part or heater defect in applied part

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

13 Maintenance

To ensure sufficient battery capacity for devices with battery option, the battery should be replaced every 3 years. Replacing the battery is described in chapter 13.2 "Replacing the battery".

Furthermore, ASTOPAD does not require preventative maintenance (e.g., exchange of liquids or components) but recurrent tests in accordance with section 13.1.

	ASTOPAD shall not be serviced or maintained while in use with a patient.

WARNING

Risk of injury!

- The service personnel must be appropriately trained and qualified.
- 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 device may only be carried out by persons authorized 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 device that the manufacturer has designated as repairable.
Provision of technical documents and/or spare parts is not an authorization from the manufacturer to open or repair the equipment.

13.1 Recurrents tests

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

For the inspection, you can either purchase the required test device 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 applicable national regulations (e.g., IEC/EN 62353) on monitoring the safety of medical products and the use of calibrated testing equipment.

Required testing equipment:

System-Test box for ASTOPAD
Order no. 1715.9040

Inspection regulations and set values can be obtained from the inspection instructions for the ASTOPAD.

Inspection of applied part:

- Visual inspection
- Sensor test
- Heating resistance test

Inspection of control unit:

- Visual inspection
- Test of the cable breakage shut-off
- Temperature control test (this test is used to check the essential performance feature)
- Test of the overheating and low temperature alarm
- Test of the heating resistance monitoring
- Electrical safety inspection (in accordance with IEC/EN 62353)
  - Protective Earth resistance
  - Insulation resistance
  - Alternative device leakage current
  - Alternative patient leakage current

ⓘ	The tests must be performed according to the specifications in the test instructions (Scope of delivery of the ASTOPAD test box)

13.2 Replacing the battery

1. Disconnect the device completely from the mains power supply (by disconnecting the mains plug)
2. Press the "Standby" button until the "Standby" LED switches off.
3. Disconnect the mains plug from the device.
4. Remove the housing cover by loosening the four housing screws (Fig. 6).
5. Remove the battery and push the new battery as far as possible (Figure 7).
6. Mount the housing cover and secure with the four housing screws (Fig. 6).

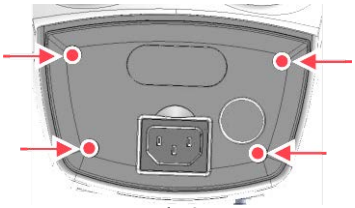


Fig. 6

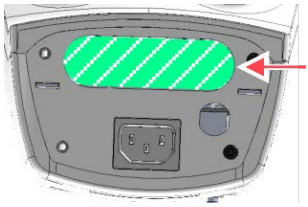


Fig. 7

14 Technical data

ASTOPAD DUO310 **Control unit** compatible with ASTOPAD applied parts COV			
Electrical connection	100 – 240 VAC 50 – 60 Hz		
Rated current	110 V = 1,6 A, 240V = 0,8 A		
Primary fuses	2 x 3.15 A		
Power consumption	max. 160 W		
Classification (IEC/EN 60529)	IPX2		
Classification (IEC/EN 60601-1)	Protection Class I, defibrillation-protected applied part type BF		
Classification (MDD 93/42/EEC)	Class IIb		
Regulatory class as per FDA	II		
Code UMDNS	10-414(COV)		
Code GMDN	37329		
Dimensions (mm) Height Width Depth	max. 300 155 130		
Weight (kg)	2.0 (without battery) 2.5 (with battery)		
Operating mode	Continuous operation		
Tested immunity for environment with “HF Surgical Equipment”	20 V/m 150 kHz – 80 MHz		
Permissible ambient conditions	Humidity	Temperature	Atmospheric pressure
In operation	10% to 75% non-condensing	+16°C to +26°C	700 hPa to 1060 hPa
During storage/transport	10% to 75% non-condensing	-20°C to +50°C	700 hPa to 1060 hPa

ASTOPAD DUO310 **Control unit** compatible with ASTOPAD applied parts COV	
Control of contact surface temperature (Essential Performance according to IEC/EN 80601-2-35)	32.0 °C to 39.0 °C in 0.5 °C increments Tolerance ± 1.0 °C
Contact surface temperature display precision	± 0.7 °C
Overheating shut-off	41.0 °C (± 0.5 °C)
Acoustic alarm volume level	Approx. 60 dB(A)
Service Life	The expected service life is 30 months from the date of first use provided the product is not subject to misuse, negligence, accident or abuse and under the conditions that the device is properly used and maintained as intended.

ASTOPAD	**All applied parts**		
Electrical connection	24 VDC		
Classification (IEC/EN 60529)	IPX2		
Permissible ambient conditions	Humidity	Temperature	Atmospheric pressure
In operation	10% to 75% non-condensing	+16°C to +26°C	700 hPa to 1060 hPa
During storage/transport	10% to 75% non-condensing	-20°C to +50°C	700 hPa to 1060 hPa
Time to heat from 23.0 °C to 37.0 °C	Approx. 10 minutes		
Use by date	30 months (see label on the cable of the applied part)		

ASTOPAD	**COV 070-NA**	**COV 105-NA**	**COV 150-NA**	**COV 155-NA**	**COV 180-NA**
Power consumption	60 W	115 W	150 W	85 W	150 W
Dimensions (mm)	approx.	approx.	approx.	approx.	approx.
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	Approx. 50-cm PVC cable				
Extension connection cable	2 m				

ASTOPAD	Built-in, rechargeable battery for ASTOPAD DUO310 control unit (optional)
Type	Li-Ion
Energy level	99.4 Wh
Dimensions (mm) Length x Width x Height	150 x 77 x 22
Weight	430 g

NOTICE
The specified defibrillation protection is ensured only when the applied part is connected to the control unit.

⚠ DANGER
Explosion hazard! Do not use the ASTOPAD patient warming system in an explosion-hazard environment or in the presence of flammable anesthetics.

15 Conformity with international standards

Standard	Title
IEC/EN 60601-1 ANSI/AAMI ES 60601-1 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, including essential performance – Supplementary standard: Electromagnetic compatibility – Requirements and tests
IEC/EN 60601-1-8 (applicable parts)	Medical electrical equipment – Part 1-8: General requirements for basic safety, including essential performance – Supplementary 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 (IEC/EN 62366)	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 designed to be used over a patient	COV070/COV105/ COV150/COV155/ COV180
Under-blanket	Blanket designed to be used under a patient	COV070/COV105/ COV150/COV180

16 Ordering information and Accessories

Ref. -Variant	Description
Control unit compatible with ASTOPAD applied parts COV/SOF/ROE	
DUO310 -NA	ASTOPAD DUO310 control unit, 100-240 VAC, 50-60 Hz, Hospital Grade plug
1831.0001	Built-in, rechargeable battery for ASTOPAD DUO310 control unit (optional)
Applied parts (incl. standard extension connection cable COV50200)	
COV070-NA	ASTOPAD COV070 warming blanket 680 x 480 mm
COV105-NA	ASTOPAD COV105 warming blanket 1050 x 500 mm
COV150-NA	ASTOPAD COV150 warming blanket 1500 x 500 mm
COV155-NA	ASTOPAD COV155 Arm-chest-warming blanket 1500 x 500 mm (with cut-outs)
COV180-NA	ASTOPAD COV180 warming blanket 1800 x 800 mm
Accessories	
COV50200	Standard extension connection cable, 2.0 m

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

17 Guidelines and manufacturer's declaration

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11/EN 55011	Group 1	ASTOPAD uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11/EN 55011	Class A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	in compliance	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/bursts IEC/EN 61000-4-4	± 2 kV 100 kHz repetition frequency	in compliance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	± 0.5 kV, ± 1 kV Line-to-line ± 0.5 kV, ± 1 kV, ± 2 kV Line- to-ground	in compliance	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips-IEC/EN 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	in compliance	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ASTOPAD requires continued operation during power mains interruptions, it is recommended that the ASTOPAD be powered from an uninterruptible power supply or a battery.
Voltage interruptions IEC/EN 61000-4-11	0 % U_T; 250/300 cycle	in compliance	
Rated power frequency magnetic fields IEC/EN 61000-4-8	30 A/m 50 Hz or 60 Hz	in compliance	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.

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	Test level	Compliance level	Electromagnetic environment – guidance Recommended separation distance
Conducted disturbances induced by RF fields IEC/EN 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	in compliance	$d = 1.2\sqrt{P}$
Radiated RF EM fields IEC/EN 61000-4-3	3 V/m / 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	in compliance	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz

Portable and mobile RF communications equipment should be used no closer to any part of the ASTOPAD, including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter.

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b].
Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE1. At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ASTOPAD is used exceeds the applicable RF compliance level above, the ASTOPAD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating 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 the ASTOPAD

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
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 rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.
NOTE 1: The compliance level between 80 MHz and 2.7 GHz is intended to decrease the likelihood that mobile/portable communication equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in this frequency range.

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