STIHLERELECTRONIC
A GENTHERM Company

Instructions for Use

ThermAffyx™

Patient Safety System

Controller: REF: 360 | **Heated Securement Pad:** REF: 363 | 80385-A | Rev.04, 06/2026, 26.0000.11 | **en**

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To be completed by the user:

Serial number _____

Registration number _____

Equipment location _____

Start-up date _____

Manufacturer:

STIHLER ELECTRONIC GmbH

Gaussstrasse 4
70771 Leinfelden-Echterdingen
GERMANY

Tel. +49 (0) 711-720670
Fax +49 (0) 711-7206757
https://gentherm.com/en/medical
E-mail: info.ste@gentherm.com

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.

You can download all versions of the instructions for use from our website or request them from us: https://gentherm.com/en/medical or using this following QR code:

eIFU Indicator

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

The ThermAffyx™ System consists of the ThermAffyx™ Controller with its Power Supply Cable, the ThermAffyx™ single-use Heated Securement Pad and the ThermAffyx™ Extension Cable to connect the Pad to the Controller. The Pad consists of an anti-slip foam with an integrated heating element. The Pad Kit includes an optional draw sheet and body strap.

Fig. 1 Components of the ThermAffyx Patient Safety System

2.1. Warranty

The warranty period of the Controller, Extension Cable and the Power Supply Cable is 12 months from the date of purchase. During this period, the manufacturer will repair or replace all defects caused by material or manufacturing errors free of charge.

Other damage is not subject to this warranty. The warranty does not include cases of misuse or incorrect handling, use of force or damage caused by normal wear and tear or unauthorized modifications to the device.

If the equipment is damaged during the warranty period, clean and disinfect the equipment per instructions in **section 8.8 Clean and Disinfect** before returning the device to the manufacturer or an authorized service representative. See **section 13.4 Service Information** for mailing instructions. The sender is responsible for the proper return, packaging, and transport and associated costs.

2.2 Liability

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

- all operating and inspection procedures are performed by trained Licensed Healthcare Practitioners or qualified Service Staff according to the procedures published by the manufacturer;
- only accessories listed in **section 16 Ordering Information** and accessories are used with the system;
- service and repairs are only performed by the manufacturer or an authorized service representative;
- the electrical installations satisfy the locally applicable regulations and the IEC requirements;
- the equipment is used for its intended purpose and at a suitable location in accordance with the instructions for use;
- there are no modifications to the System or its components.

3. Important Safety Information

These instructions for use refer to the following design, signal words & colors according to ANSI Z535:

⚠ **WARNING**	Describes a hazardous situation which, if not avoided, may result in severe or fatal injuries.
⚠ **CAUTION**	Describes a hazardous situation which, if not avoided, may result in minor to moderate injuries.
NOTICE	Indicates information considered important, but that does not relate to physical injury (e.g. reference to property damage).

3.1 Warnings

⚠ WARNING

Risk of Injury - General

- The ThermAffyx™ System may only be used by appropriately trained and Licensed Healthcare Practitioners.
- Follow hospital protocols for patient positioning and securement.
- When installing the Controller on an infusion stand or IV pole, please follow the instructions from the infusion stand or IV pole manufacturer regarding maximum load and tilting stability.
- Do not use the System under the following conditions:
  - *Button(s) do not function correctly.*
  - *The Controller, Power Supply Cable or Extension Cable has been exposed to mechanical impact or extreme exposure to a liquid.*
  - *The System has given someone an electric shock.*
  - *The System appears to have overheated.*
  - *The System has triggered an alarm shut-off.*
- Do not use the Pad if its package is damaged.
- Do not use the Pad if it is damaged (foam, straps, connection cable).
- Do not use the Pad as a carrying/transport aid for patients.
- Do not use in the presence of flammable anesthetics – explosion hazard.
- The System may only be serviced or repaired by the manufacturer or authorized service representatives.
- Modifications to the system or its components are not permitted.
- California Proposition 65 Warning: The medical devices and products mentioned in this IFU may contain chemicals including Urethane, which is known to the State of California to cause cancer, birth defects, or other reproductive harm. For more information go to, www.p65warnings.ca.gov

⚠ WARNING

Risk of Radio Interference

- If the System is used in close proximity to or stacked with other equipment, the user should periodically observe the device to verify it operates normally in that environment.
- Simultaneous use with medical products sensitive to radio interference (e.g. cardiac pacemakers, patient monitors, etc.) can lead to malfunctions. Therefore, careful monitoring of the System and patient is required.
- The cables or accessories other than those specified by the manufacturer of the System may cause increased electromagnetic interference or reduced electromagnetic immunity and result in incorrect operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12in) to any part of the ThermAffyx System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The System has been tested and is compliant with applicable electromagnetic interference standards for the intended environment (refer to section 17). Unforeseeable electromagnetic disturbances could occur that affect the heating performance of the device.
- The System 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 realignment, a new configuration of the System or shielding.

⚠ WARNING

Risk of Injury - Infection

- The Pad is for single patient use only. Do not reuse or reprocess the Pad. Reuse or reprocessing of the Pad may lead to biocontamination, cross-infection, failure or injury.
- After use, dispose of the Pad in accordance with hospital procedures.
- Clean and disinfect the Controller and the Extension Cable after every use and before you return the Controller for repairs. See **section 8.8 Clean and Disinfect**.
- Always use aseptic procedures.

⚠ WARNING

Risk of Injury - Skin Injury

- Follow hospital procedures to minimize the risk of skin injury.
- In the case of arterial occlusion, the ThermAffyx™ Pad must not be used distal to this area. Be aware that overheating of ischemic extremities can occur with the use of the Pad.

⚠ WARNING

Risk of Injury - Electric Shock

- To avoid the risk of electric shock, this equipment must only be connected to an appropriate facility electrical outlet.
- Do not use power adapters that interrupt the grounding conductor.
- Do not open the Controller housing.
- If the Controller is connected with multiple devices in one multiple socket-outlet, the sum of the leakage current may not exceed the permissible limit (please see the respective national regulations).
- All electrical installations must conform to the applicable electrical standards and the specifications defined by the manufacturer.
- To fully disconnect the Controller from the power source, the Power Cable must be removed from the facility electrical outlet.

⚠ WARNING

Risk of Misinterpretation

Although the majority of the Pad is radiolucent in radio images (e.g., CT, X-ray), internal cables and sensors will appear as artifacts if they are located in the image area. The images should be assessed by clinical experts to determine the quality and diagnostic suitability of the image.

3.2 Cautions

⚠ CAUTION

Risk of Injury - General

- Always read and follow all instructions, labels, and documentation provided with the System. Operate and inspect the system only as directed, in accordance with hospital protocols and guidelines. Failure to do so may result in user or patient injury, device damage, and the manufacturer will not be held liable.
- Before every use, check that the Controller, Power Supply Cable, and Extension Cable are undamaged (e.g. any signs of damage, including worn or damaged cables, plugs, or sockets; damaged or loose housing or control panel; and missing or illegible labels, safety signs, or warnings).
- Do not use the System if no visual or audible alarm or display activated after switching on via the Standby button.
- Do not use the Pad after expiration date.
- The OR table and OR mattress must be prepared according to hospital procedures and guidelines.
- Ensure that the Pad is secured flat to the table and is not folded underneath the patient.
- Never insert pointed or sharp objects into the Pad or damage the surface of the parts in any other way.
- Damage to the Pad may result in overheating. For this reason, avoid mechanical stress, e.g. kinking, clamping, pinching, cutting.
- Be aware when using transdermal drug applications (patches) that the additional heat can increase the uptake of the drugs and result in injury to the patient.

⚠ CAUTION

Risk of Injury - Unintentional Patient Movement

To ensure patient anti-slip positioning, take measures to maximize static friction between the patient and Pad and Pad and table mattress such as the following:

- Avoid placing any materials/objects between the table mattress and the Pad.
- Be aware that placing any objects between the Pad and the patient can reduce the anti-slip performance.
- Ensure the Pad remains flat under the patient.
- Avoid using lubricants, oils, or powders on the patient's skin in contact with the Pad. If necessary, clean skin before use.
- Ensure maximum direct contact between the Pad and uncovered patient skin.
- Ensure the Pad and the patient are secured correctly before tilting the operating table.

⚠ CAUTION

Risk of Injury - Hypothermia

- Be aware that whenever an alarm is triggered (except the low temperature alarm), the System automatically switches off the heating function.
- The patient's body temperature must be monitored at regular intervals when the System is used.
- The temperature displayed on the control panel is the temperature of the Pad and NOT the patient's body temperature. Use suitable devices to determine/monitor the patient's temperature.
- Use additional warming methods as necessary if the patient's temperature becomes too low.
- When this product is used in combination with other warming devices (e.g. forced air warming) monitor the patient's temperature frequently.

3.3 Notices

NOTICE

The specified IPX2 ingress protection rating for the Pad is only ensured when the Pad connecting cable is connected to the approved Extension Cable listed in **section 16 Ordering Information and Accessories**.

- Actions to avoid damaging the System:
  - *Do not immerse the Controller, the Pad or the plugs of the Extension Cables in liquid.*
  - *Only clean and disinfect the device using the agents and procedures in* **section** *8.8 Clean and Disinfect.*
- The customer is responsible for the proper packaging and labelling of returns.

4. Intended Use

The ThermAffyx™ Patient Safety System is intended to maintain normothermia, treat hypothermia and provide anti-slip positioning securement for patients.

4.1 Indications For Use

The ThermAffyx™ Patient Safety System is intended to maintain normothermia, treat hypothermia and provide anti-slip positioning securement for patients. The system is intended to be used by trained healthcare professionals in all areas of professional healthcare facilities. It is indicated for use on adult patients.

4.2 Possible Adverse Effects

With proper use, no side effects are expected from the System.

4.3 Contraindications

The use of the ThermAffyx™ Pad is contraindicated in patients who may be sensitive to polyurethane foam.

4.4 Clinical Benefit

To aid hospital facilities in providing a safe and effective warming method and anti-slip positioning for patients in the Trendelenburg position.

4.5 Intended Patient Group

The System is intended for use on adult patients requiring patient warming. The System may not be appropriate for use with patients above 135 kg/297 lbs or taller than 187 cm/74 in.

4.6 Intended Body Parts

The Pad is intended for use underneath the patient's upper body (buttocks, torso, arms and head).
The Pad is intended to have direct contact with intact skin.
The ThermAffyx™ Controller and Extension Cable are not designed for direct patient contact.

4.7 Intended User Profile

The System is intended to be used by trained healthcare professionals in all areas of professional healthcare facilities.

4.8 Intended Environment of Use/Operation

The System is intended to be used in all areas of professional healthcare facilities (including when RF surgical devices are in use).

- The System is not designed for use in a magnetic resonance imaging (MRI) environment.
- The System may not be used in a potentially explosive environment or in the presence of flammable anesthetics.

5. Symbols

5.1 Symbols and Indications on the Control Panel

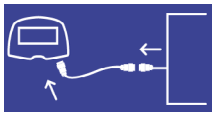
Standby button: Switches between *Standby mode* and *On mode.*

When the blue LED is off, ThermAffyx™ is in the *Unpowered mode* (disconnected from mains).

When the blue LED is lit, ThermAffyx™ is in *Standby mode.*

Alarm condition when the yellow LED is flashing.

5.2 Symbols and Indications on the Display



The ThermAffyx™ Pad is not connected to the Controller.

The actual Pad temperature is still below the Pad set temperature and is currently increasing.

The actual Pad temperature is higher than the Pad set temperature and is currently decreasing.

Pad set temperature select button

Pad set temperature 40°C (unselected)

Pad set temperature 40°C (selected)

Pad set temperature 37°C (unselected)

Pad set temperature 37°C (selected)

Pad set temperature 34°C (unselected)

Pad set temperature 34°C (selected)

Indicates that the Pad's temperature is outside of the intended temperature range (L ≤ 20°C, H ≥ 45°C)

Indicates that the selected or actual temperature is the temperature of the Pad (not the patient temperature)

Indicates an over-temperature condition (heating is automatically shut off)

Indicates a low temperature condition

Code for alarm/fault condition. See **Section 11 Alarms, Error Codes and Troubleshooting**

Stop use, indicates that the device has a failure and service is required

5.3 Other Symbols

Where applicable, these symbols appear at the appropriate location on the ThermAffyx™ System, on the packaging, on the device label or in the accompanying documentation.

	Defibrillation protected applied part type BF in accordance with IEC 60601-1
IPX2	Protected against dripping water in accordance with IEC 60529
	Follow the instructions for use
	Consult the instructions for use
	Caution: Federal US law restricts this device to sale by or on order of a Licensed Healthcare Practitioner
	Electronic instructions for use are available at https://gentherm.com/en/medical
	General warning symbols
	Do not reuse
	Do not use if the package is damaged
	Use-by date. Indicates the date after which the medical device is not to be used
UDI	UDI (Unique Device Identifier) carrier
REF	Reference (catalog) number
SN	Serial number
LOT	Batch designation
MD	Medical device
	Date of manufacture
	Manufacturer
	Symbol on plug connector for potential equalization in accordance with IEC 60601-1
	Symbol used to identify terminals of protective earth
	Additional information

	Electrical devices 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 transport
	Symbol for the permitted humidity range for transport
	Symbol for the permitted atmospheric pressure range for transport
	Transport upright with the arrows pointing up
	Keep dry
	Fragile, protect against impacts
CE 0124	The notified body, DEKRA Certification GmbH (identification number 0124), monitors the manufacturer's quality management system
 75JA	MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH standards IEC 60601-1:2005/AMD2:2020, AAMI ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:14/AMD2:2022. Control No. 75JA
	Acoustic alarm signal
	No acoustic alarm signal
	Prohibited: Never pierce the ThermAffyx™ Pad with pointed or sharp objects - risk of damage and possible overheating!
	Prohibited: Keep the ThermAffyx™ System outside the MRI area!
	Non-ionizing electromagnetic radiation

6. Product description

6.1 Technical Description

The ThermAffyx™ Controller has one output (connecting socket) to connect to the ThermAffyx™ Pad. The Controller heats up the Pad to a desired Pad set temperature. The Pad set temperature can be selected within 3 Pad set temperatures (34°C, 37°C, 40°C) on the control panel of the Controller. The selected Pad set temperature and the actual temperature of the Pad are displayed on the control panel.

The temperature control of the Pad is performed with integrated temperature sensors. The Controller does not regulate or display the patient's actual body temperature. The display only shows the Pad surface temperature.

Heat is generated on the principle of resistance heating by passing current through a carbon fiber mesh with a defined electrical resistance. The current to the heater is supplied by the Controller with low voltage (< 48 V).

The patient will only be actively warmed within the heating zone marked by four (4) small tabs along the edge of the Pad, as shown in Figure 2.

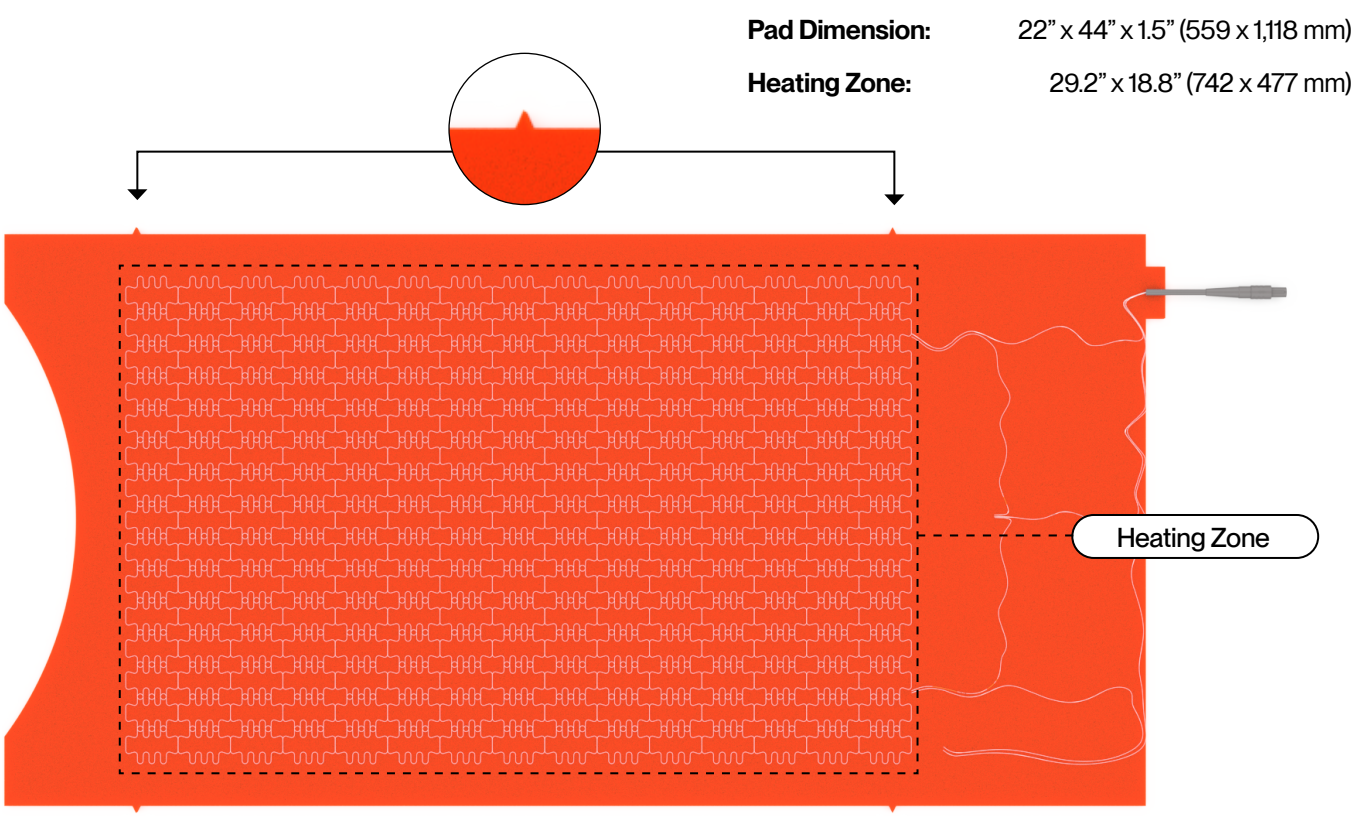


Fig. 2 Heated zone of the ThermAffyx™ Pad

The Polyurethane (PU) foam offers anti-slip properties and patient support to ensure the patient remains positioned throughout the surgical procedure.

The Controller and Pad are individual medical products, and when used together with the Power Supply Cable and Extension Cable, achieve the intended use of the System.

Safety of the System is ensured by the following measures:

- Several temperature sensors for the Pad
- Redundant independent temperature monitoring
- Sensor (resistance) monitoring
- Heater (resistance) monitoring
- Visual and acoustic alarm signals
- Overheating and low-temperature alarms if the contact surface temperature deviates from the temperature Controller setting

6.2 The ThermAffyx™ Patient Safety System

Fig. 3 ThermAffyx™ Patient Safety System

Table 1: Parts of the ThermAffyx™ Safety System

No.	Designation	Description
1	ThermAffyx™ Controller	The Controller supplies power, controls and displays the temperature of the Pad
2	ThermAffyx™ Power Supply Cable	The Power Supply Cable connects the Controller to the facility electrical outlet The device is only completely deenergized when the Power Supply Cable is disconnected from the facility electrical outlet
3	ThermAffyx™ Extension Cable	The Extension Cable connects the Pad to the Controller
4	ThermAffyx™ Pad	The Pad warms the patient and secures them against slipping on the table
5	Table Rail Straps	The table rail straps (4x) secure the Pad on the table
6	Pad Connecting Cable	The Pad connecting cable connects the Pad to the Extension Cable
7	Draw Sheet	Optional draw sheet
8	Body Straps	Additional securement straps (2x)

6.3 Components of the ThermAffyx™ Controller

Fig. 4 ThermAffyx™ Controller

Table 2: Controller Components and Functional Elements

No.	Designation	Description
1	Control Panel	Display & buttons for operation and temperature selection
2	Recessed Handle	For securely carrying the ThermAffyx™ Controller
3	Attachment Device	For the secure attachment of the Controller on an infusion stand, IV pole or medical rail
4	Controller Extension Cable Socket	Plug-in connection to connect the Extension Cable to the ThermAffyx™ Pad
5	Connection for Potential Equalization	Equalizes electrical potential differences of various metal parts which can be touched at the same time. Reduces electrical potential differences that can arise in the application between the body, medical electrical equipment and foreign conductive parts The connection is made via green-yellow insulated cables (min. 4 mm²) on standardized connection bolts and connection sockets When connecting/combining medical electrical devices to form an medical electrical system, the requirements of IEC 60601-1 must be observed
6	Device Connector for Detachable Power Supply Cable	Power Supply Cable connection to the Controller

6.4 Control Panel

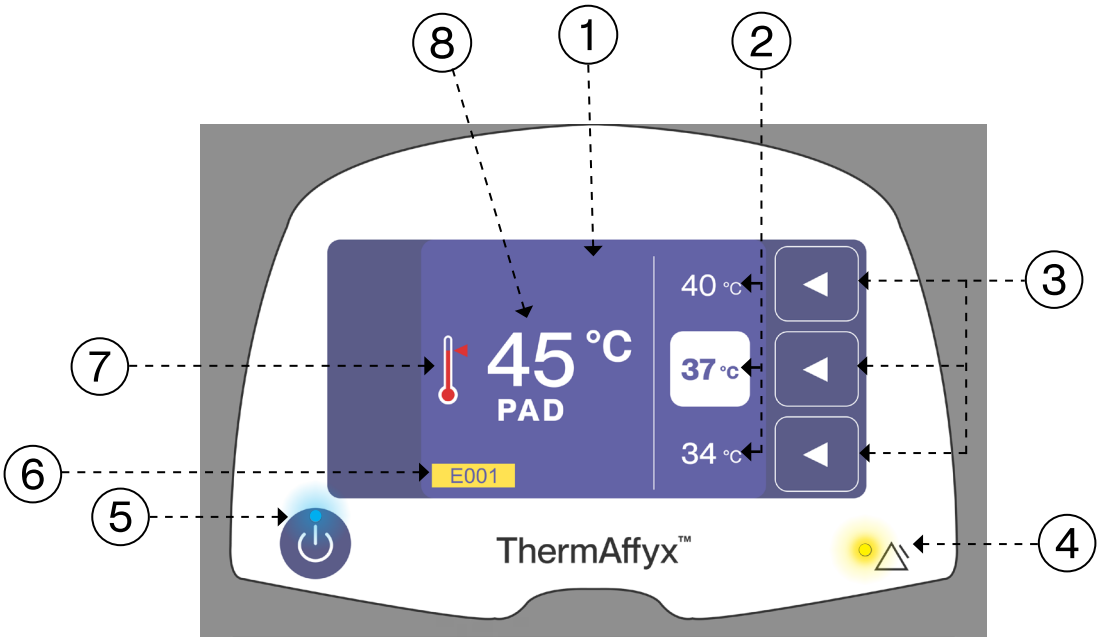
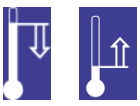
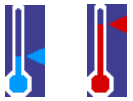


Fig. 5 Control Panel

Table 3: Control Panel Elements

No.	Designation	Description
1	Display	Provides information about the device state, temperatures and alarm/error conditions.
2	Pad Set Temperature	Displays the three Pad set temperatures of the Pad (34°C, 37°C, 40°C).
3	Select Buttons	Enables the user to choose one of the Pad set temperatures (②).
4	Alarm LED (yellow)	LED flashes and the acoustic alarm signal sounds when the device is in an alarm/error state.
5	Standby Button Standby LED (blue)	The Standby button switches between *Standby mode* and *On mode.*
6	Alarm Indicator	Displays the corresponding alarm/error code in an alarm/ error state. Refer to **section 11 Alarms, Error Codes and Troubleshooting**.
7	Status Indicator 	Pad's temperature is decreasing/increasing
		Low temperature or over temperature condition of the Pad
		System/device failure
8	Actual Temperature	Displays the actual contact surface temperature of the Pad.

7. Installation

7.1 Initial Start-Up

Prior to first use, perform the following inspections:

- Visual inspection. See **section 13.6 Annual Maintenance**.
- Check the facility supply voltage (compare the details on the device label on the backside of the Controller with the available facility supply voltage). An incorrect facility supply voltage may damage 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 13.6 Annual Maintenance**.

7.2 Installing the Thermaffyx™ Controller

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

7.2.1 Attaching to IV Poles, Infusion Stand/Round Pipe (14 - 40 mm/1/2" - 1.5"" Dia.)

1. Turn the handwheel counterclockwise to open the attachment device.
2. Select a maximum height of 165 cm on the IV pole or infusion stand and place the opened clamping area of the attachment device on the IV pole or infusion stand.
3. Turn the handwheel clockwise to tighten the attachment device to the IV pole or infusion stand.
4. Check that the Controller is securely fastened.

Fig. 6 Attaching to IV pole, infusion stand/round pipe

7.2.2 Attaching to Standard Medical Rail (25 X 10 mm/1" X 0.4")

1. Hang the Controller perpendicular to the standard rail using the attachment device.
2. Fix the Controller by tightening the hand wheel to the standard rail.
3. Check that the Controller is securely fastened.

Fig. 7 Attaching to infusion stand/round pipe

For attachment to the medical rail it may be necessary to move the attachment device into another position. To do this, release the fixing screws. Once the position is changed, the screws must be screwed in again according to the positioning of the attachment device.

7.3 Setting Up the Controller for Use

- The user should be positioned in front of the Controller so they are able to easily see the display and operate the device.
- For optimum pre-warming, start the heating process upon set up, before placing a patient on the Pad.
- Do not position the Controller and Power Supply Cable so that it is difficult to operate the power plug.

1. Inspect the Controller, Power Supply Cable and Extension Cable for visible signs of damage. Do not use if visible signs of damage are found.
2. Connect the Power Supply Cable to the Controller power cable socket.
3. Connect the Power Supply Cable to the appropriate facility electrical outlet.
4. Align the pins on the Extension Cable with the socket then, insert the Extension Cable into the Controller Extension Cable socket
5. Secure the connection by rotating the collar of the Extension Cable twist lock connector to the right.

8. Getting started

8.1 Preparation for Use

- Clean and disinfect the ThermAffyx™ Controller and Extension Cable according to the instructions **section 8.8 Clean and Disinfect**.
- Install the Controller according to **section 7.2 Installing the Controller**.

8.2 Unpack the ThermAffyx™ Pad

1. Check the expiration date of the Pad.
2. Use scissors to cut open the plastic bag containing the Pad. Be careful not to cut any part of the Pad (foam, table rail straps or connection cable).
3. Remove the Pad from the plastic bag. The optional draw sheet and body strap are included for your convenience. Set aside for later.
4. Inspect the Pad for visible signs of damage. If visible signs of damage are found, discard it and use a new Pad. Visible signs of damage could include cuts or missing material from the foam or table rail straps, detached table rail straps, damage to the Connection Cable or detached Connection Cable.

8.3 Position and Secure the Pad

1. Before using the Pad, ensure that the operating table mattress is clean, dry, and securely attached to the operating table.
2. Ensure that there is nothing between the operating table mattress and the Pad. Place the Pad on the operating table with the adhered table rail straps on the underneath side of the pad, closest to the OR table mattress. Align the Pad and OR table mattress perineal cutouts.
3. Secure the Pad to the table by sliding the table rail straps downwards between the rail and the OR table. Pull the table rail straps back up and around the outside of the rail. Affix the strap back upon itself securely with the hook-and-loop fastener patch.
4. Repeat this step for the remaining 3 straps.
5. Ensure the Pad lies flat and without wrinkles on the OR table mattress.

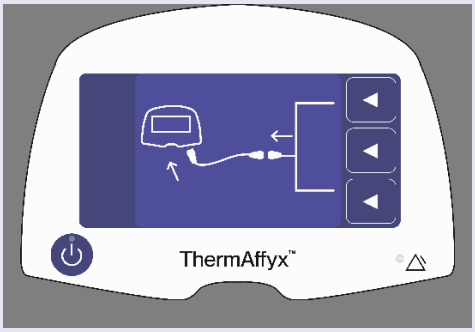
8.4 Connect the Pad to the Controller and Pre-Warm

1. Connect the Extension Cable to the Pad.
2. Switch on the Controller with the Standby button .
3. The self-test is automatically activated (display illuminates, the Alarm LED will lights up briefly and the acoustic alarm sounds once). Once complete, the System is ready for use.

⚠WARNING Risk of Injury - Do not use the ThermAffyx™ System if no visual or acoustic alarm or display is activated when it is switched on via the Standby button (self-test failure).

4. Press one of the Pad set temperature buttons ◄ to start the heating process (set to 34, 37 or 40°C).
5. To Pre-Warm: Connect the Pad to the Extension Cable which should be connected to the Controller. Switch the Controller into Heat mode according to **section 8.4 Connect the Pad to the Controller and Pre-Warm or 9.6 Heat Mode**.

If the Pad is not properly connected to the Controller the display shows:



8.5 Position and Secure the Patient on the Pad

1. Position the patient according to the surgical procedure. It is important that the pad has as much contact with the patient as possible to achieve optimal clinical effectiveness.
2. If the draw sheet is used, minimize the width to maximize patient contact with the Pad.
3. Ensure that the patient's sacrum, upper body, and shoulders are in direct contact with the Pad.
4. Ensure that the Pad is flat underneath the patient and that the Pad will not fold.
5. A body strap is included in the Pad Kit. To use, secure each piece on either sides of the OR table rails so they are aligned next to the patient's upper arms. Fasten straps across the patient's body using the fasteners applied to the straps.

Secure the patient to the table according to your facility's protocol for the surgical procedure. If a head positioner is used, ensure that the patient's shoulders are in contact with the Pad and not with the head positioner.

8.6 Change the Pad Set Temperature

1. Press and hold the select button ◄ for 1.5 seconds to choose a new Pad set temperature (set to 34, 37 or 40°C).

When changing the Pad set temperature, the select button needs to be pressed for 1.5 seconds. This is a protection against unintentional temperature change.

8.7 Switch off the Controller

1. Press the Standby button of the Controller for 1.5 seconds to switch off (all displays are turned off, the Standby LED illuminates).
2. Disconnect the Controller from the Pad.

When switching off the Controller, the Standby button needs to be pressed for 1.5 seconds. This is a protection against unintentionally switching the device off.

8.8 Clean and Disinfect

During use, the Controller, Extension Cable and Power Supply Cable may get contaminated with organic contaminants (such as blood or body fluids) or microorganisms. Therefore, after each use, the following cleaning and disinfecting procedures shall be followed. Visually inspect all surfaces (all sides) of the Controller and the cables for wear and tear, cuts, holes, cracks, and other unacceptable deterioration.

While cleaning and disinfecting, wear gloves with chemical resistance.

Reminder, the Pad, Draw Sheet and Straps are single-use and must not be cleaned or disinfected.

NOTICE Cleaning and disinfection are only possible if no damage is present. Damaged components cannot be used, cleaned or disinfected!

8.8.1 Cleaning Procedure

- Always work from top to bottom and from clean to dirty areas.
- Work methodically to clean each area of the device or component.
- Use an adequate number of wipes. A minimum of 3 wipes should be used per surface.
- Wipe the device or component for a minimum of two (2) minutes.
- Dispose of used wipes according to the instructions of your facility.
- Visually inspect the device or component for the presence of soil.
  - *Repeat cleaning steps if visible soil is present.*
- Let air dry.

8.8.2 Disinfection Procedure

- Always work from top to bottom areas.
- Work methodically to disinfect each area of the device or component.
- Ensure all surfaces remain wetted with disinfectant for a minimum of 2 minutes. (See Table 4 for the validated wipe manufacturer's specifications). If another type of disinfection wipe is used be sure to follow the manufacturer's instructions as specified on the label to ensure adequate disinfection.
  - *Use new disinfectant wipes as necessary to maintain wetted surfaces.*
- Dispose of used wipes according to the instructions of your facility.
- Let air dry.

8.8.3 Recommended Cleaning and Disinfection Agent

For routine disinfection use an EPA*-registered intermediate level disinfectant that is labelled as tuberculocidal.

Table 4: Validated Disinfectant

Product name:	Super Sani-Cloth® Germicidal Disposable Wipes
Manufacturer:	Professional Disposables International, Inc.
EPA* Reg. No.:	9480-4
Disinfection Level:	EPA-registered intermediate level disinfectant
Formulation:	Quaternary ammonium and isopropyl alcohol (IPA)
Active Ingredients:	– n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides: 0.25% – n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides: 0.25% – Isopropyl Alcohol: 55.00%
Efficacy:	Bactericidal, Tuberculocidal, Virucidal (Hepatitis B and C, HIV), Fungicidal, effective against SARS-CoV-2
Overall Contact Time:	2 minutes

EPA = U.S. Environmental Protection Agency*

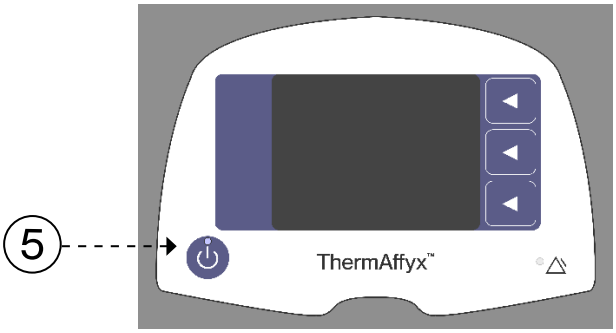
8.8.4 Other Cleaning and Disinfection Agents

The only disinfection agent validated to disinfect this device is stated in Table 4. EPA-registered intermediate level disinfection agents with a similar chemical composition and efficacy may also be used for routine disinfection but have not been validated.

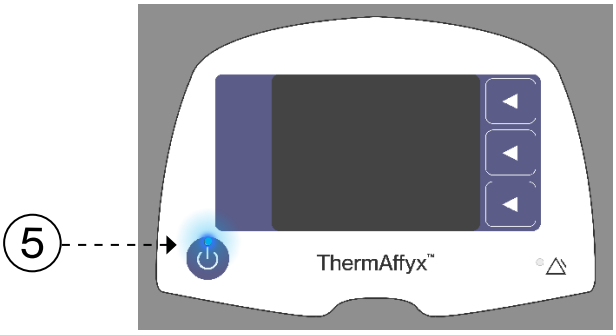
The use of disinfectants with other chemical compositions may cause chemical stress to the product. It is possible that the use of such disinfectants may reduce the expected service life, depending on the frequency of use and the age of the product. Follow all chemical manufacturers' guidelines for all disinfectants.

9. Operating States

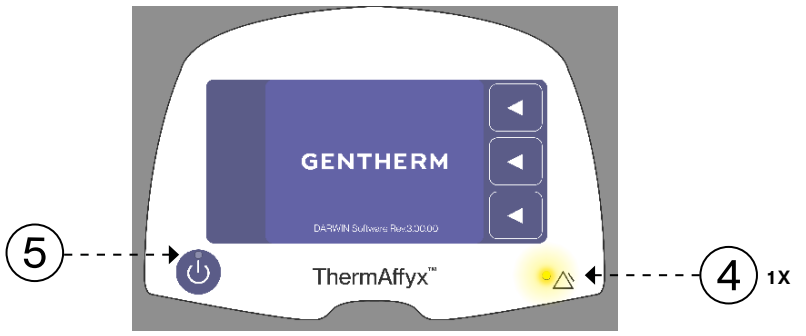
9.1 Unpowered Mode (device not connected to the power supply)

Control Panel	
Status/Condition	Before connecting the Power Cable to the electrical outlet, the controller is in *Unpowered mode.*
Device Response	The Standby LED (⑤) is not lit.
ⓘ	– In Unpowered mode the device will not respond to any user action. – In Unpowered mode the device is disconnected from facility electrical outlet.

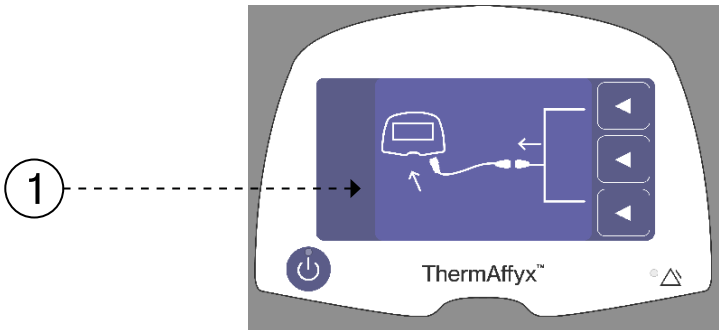
9.2 Standby Mode

Control Panel	
Status/Condition	After connecting the Power Cable to the electrical outlet, the Controller is in Standby mode.
Device Response	The Standby LED (⑤) lights up.
ⓘ	– Press the Standby button (⑤) to switch the Controller from any mode to Standby mode. – In Standby mode only the electronics and the Pad are disconnected from the power supply. The Controller remains connected to the power supply. – After a power failure, the device automatically switches to Standby mode (a power failure is indicated by an audible alarm lasting for 10 minutes).

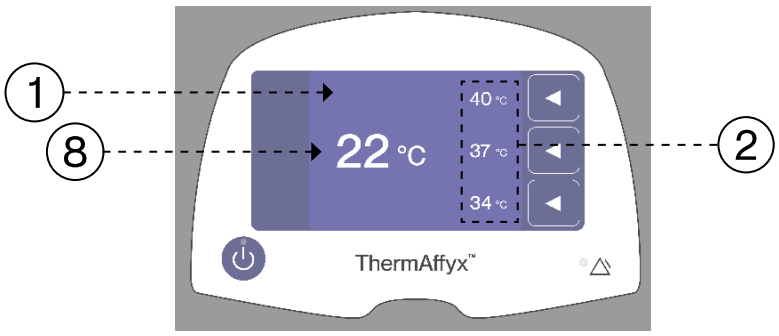
9.3 Self-test Mode

Control Panel	
User Action	Press the Standby button (⑤) to switch the Controller from Standby mode to Self test mode.
Device Response	– The Standby LED (⑤) turns off. – Display shows the Gentherm logo and the software version – The device performs a self-test. – After successful self-test, the yellow Alarm LED (④) lights up briefly and the audible alarm signal sounds once, to confirm that the Controller is working properly.
ⓘ	– If the self-test fails, the device shows an alarm/error code. Refer to alarm/error overview in **section 11 Alarms, Error Codes and Troubleshooting**. – If a Pad is not connected to the Controller, it displays the No Pad symbol. Refer to **section 9.4 No Pad Mode**.

9.4 No Pad Mode (The Pad is not connected to the Controller)

Control Panel	
Status/Condition	The Pad is not connected to the Controller.
Device Response	The Display (①) shows the animation 'Connect Pad'.
ⓘ	– The animation remains until a Pad is connected to the Controller. – After connecting a Pad properly to the Controller, the device switches into the On mode.

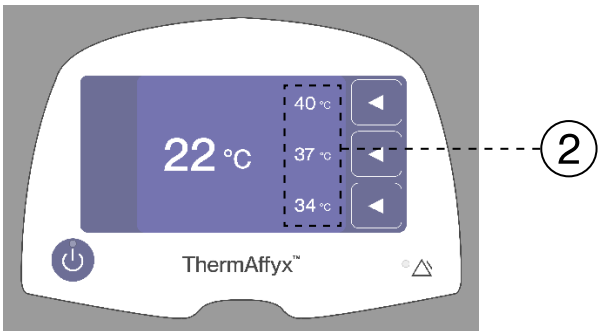
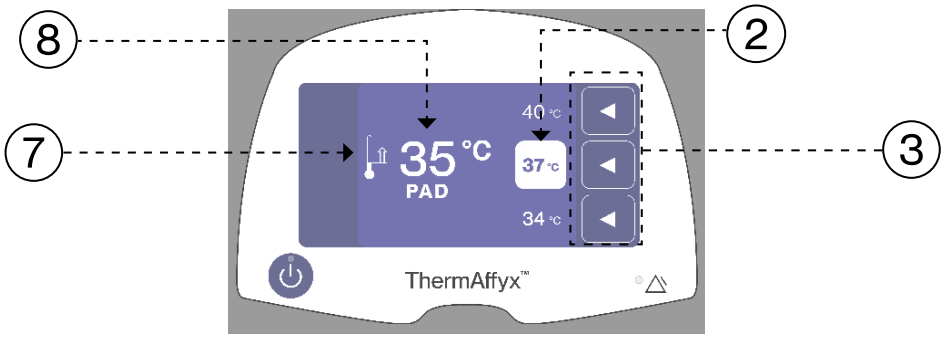
9.5 On Mode (The Pad connected to the Controller)

Control Panel	
Status/Condition	The self-test (9.3) has been carried out successfully and The Pad is connected to the Controller.
Device Response	The display (①) shows the actual temperature (⑧) of the Pad and the three Pad set temperatures (②).

- Ensure that a Pad is properly connected to the Controller.
- Pressing one of the select buttons will start the heating process to the selected Pad set temperature. See **section 9.6 Heat Mode**.

9.6 Heat Mode

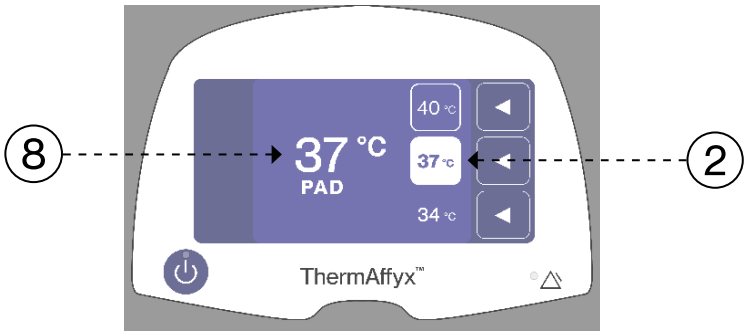
9.6.1 Heat Mode - Select Temperature

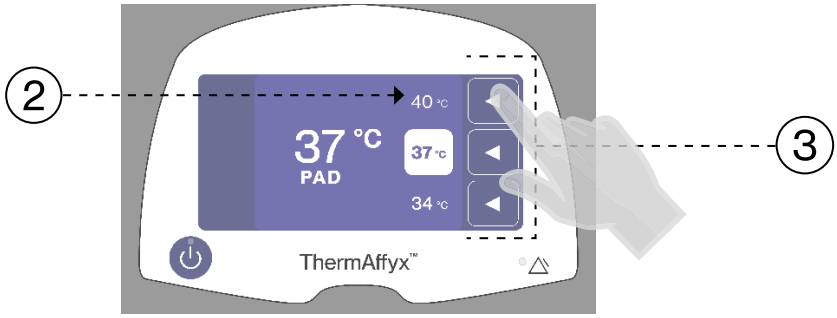
Control Panel	
Status/Condition	Controller is in On mode, the display shows the three Pad set temperatures (②).
User Action	Press the 34, 37 or 40°C select button (③) to start the heating process to the selected Pad set temperature.
Device Response	

1. The selected Pad set temperature (②) is highlighted to confirm the selection (37°C in this example).
2. Heating will start, as indicated by:
   - *the symbol ( ), which indicates that the Pad temperature is increasing, and*
   - *the actual temperature of the Pad ( ) will increase as the Pad temperature rises to the selected Pad set temperature.*

- Coming from On mode, the heating starts immediately after pressing the button.
- After the device has been turned on and a Pad set temperature has been set, the select buttons must be pressed and held for at least 1.5 seconds to change the Pad temperature and protect against unintentional temperature changes.

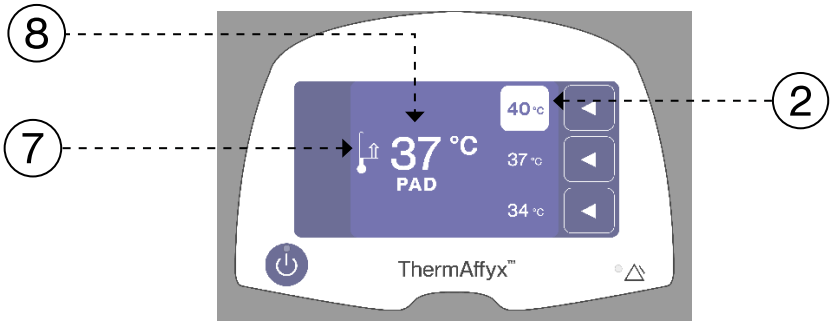
9.6.2 Heat Mode - Change (increase) Temperature

Control Panel	
Status/Condition	Controller is in Heat mode, Pad set temperature (②) and actual temperature (⑧) of the Pad are equal (37°C in this example).
User Action	Press the select button (③) for the new Pad set temperature for 1.5 seconds to change the Pads temperature.



Device Response

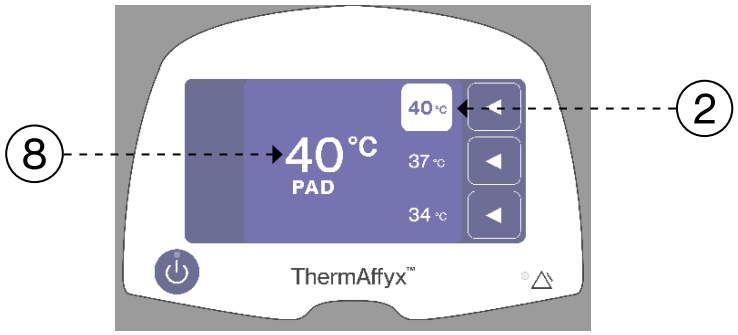
1. A frame is displayed around the new selected temperature (②) (40°C in the example below).

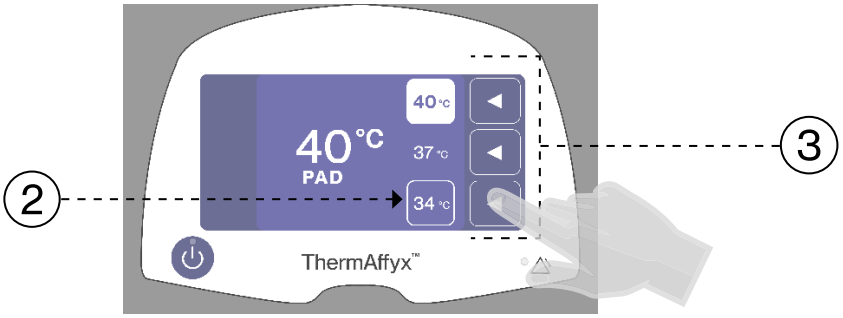


2. After holding the button for 1.5 seconds, the selected Pad set temperature (②) is highlighted as confirmation of the new setting (40°C in this example).
3. Heating will start, as indicated by:
   - *the symbol ( ), which indicates that the Pad temperature is increasing, and*
   - *the actual temperature ( ) of the Pad will increase as the Pad temperature rises to the new Pad set temperature.*

Being in Heat mode, the temperature change starts after pressing the button for 1.5 seconds.

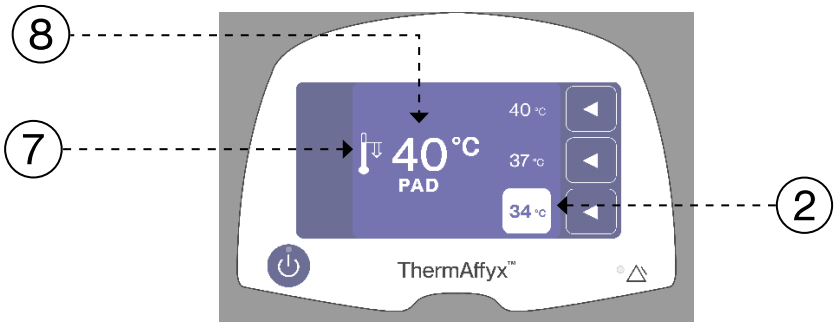
9.6.3 Heat Mode - Change (decrease) Temperature

Control Panel	
Status/Condition	Controller is in Heat mode, display shows Pad set temperature (②) and actual temperature (⑧) of the Pad (40°C in this example).
User Action	Press one select button (③) for the new Pad set temperature for at least 1.5 seconds to change the Pad temperature.



Device Response

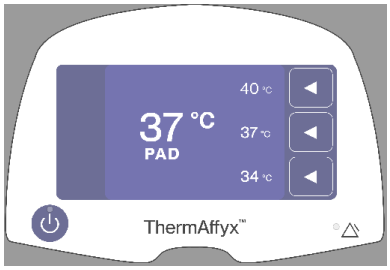
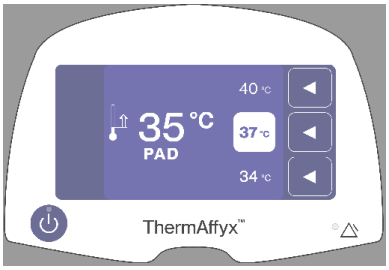
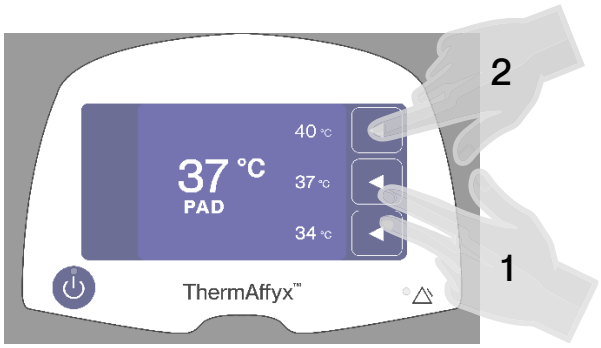
1. A frame is displayed around the new selected Pad set temperature (②) (34°C in this example).



2. After holding the button for 1.5 seconds, the selected Pad set temperature (②) is highlighted as confirmation of the new setting (34°C in this example).
3. Heating will pause (to allow the Pad to cool to the lower Pad set temperature), as indicated by:
   - *the symbol ( ), which indicates that the Pad temperature is decreasing, and*
   - *the actual temperature of the Pad ( ) will decrease as the Pad temperature lowers to the new Pad set temperature.*

Being in the Heat mode, the temperature change starts after pressing the button for at least 1.5 seconds.

9.7 Brightness Mode

Control Panel	 or 
Status/Condition	The brightness of the display can only be changed in On mode or in Heat mode.
User Action	

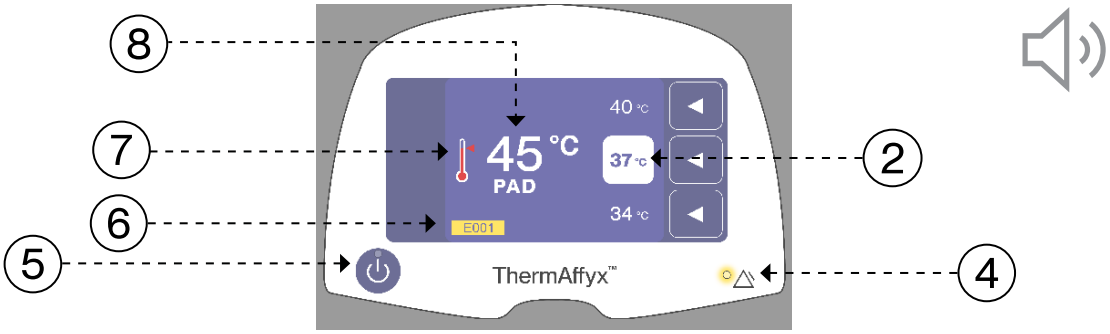
1. Press both 34°C and 37°C select buttons simultaneously for a minimum of 1.5 seconds and continue to hold them to switch the device into Brightness mode.
2. While continuing to hold the 34°C and 37°C select buttons, press the 40°C select button to change the brightness within 3 levels.
3. Release the 34°C and 37°C select buttons to store the current brightness level and to return to the previous mode.

The selected brightness level is saved and remains unchanged even after the Controller is switched off.

10. Alarm Modes

The generated alarms are 'medium priority' alarms and the acoustic and visual signals are defined by the medical device standard IEC 60601-1-8.

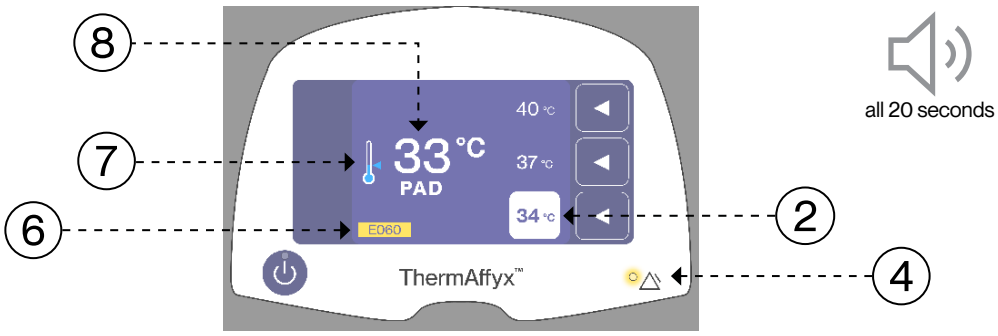
10.1 Alarm Condition – Over Temperature

Control Panel	
Status/Condition	An overheating condition can occur if the device thermal regulating system fails or if an external heat source (e.g., heater, radiator, etc.) applies additional heat to the Pad.
Device Response	– The display shows the 'over temperature' symbol (⑦). – The display shows the actual temperature (⑧) of the Pad. – The display states an alarm code within a blinking yellow bar (⑥). – The yellow alarm condition LED (④) is blinking. – The device will issue an acoustic alarm. – The last selected set temperate (②) is framed. – The device will automatically shut off the heating function.
User Action	1. Switch the device off, using the Standby button (⑤). 2. Identify and eliminate the cause of the alarm, if possible. 3. If the cause of the alarm cannot be eliminated, consider warming the patient with a new ThermAffyx™ System or alternative methods. Contact the manufacturer or authorized service representative for Service.

A list of all possible alarm codes and conditions can be found in **section 11 Alarms, Error Codes and Troubleshooting**.

To silence the alarm, press the Standby button to switch into Standby mode.

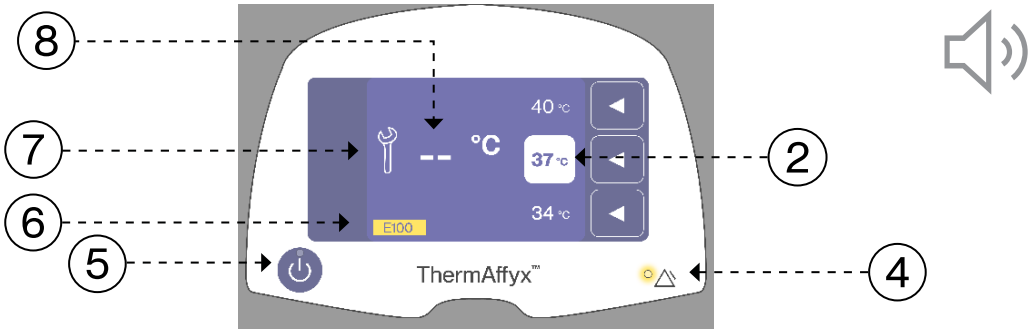
10.2 Alarm Condition – Low Temperature

Control Panel	
Status/Condition	A low temperature alarm may occur if the Pad is operated in an environment outside of its specifications. See **section 14 Technical Data for specifications**.
Device Response	– The display shows the 'low temperature' symbol (⑦). – The display shows the actual temperature (⑧) of the Pad. – The display states an alarm code within a blinking yellow bar (⑥). – The yellow alarm condition LED (④) is blinking. – The device will issue an acoustic alarm (every 20 seconds). – The selected Pad set temperature (②) is highlighted white.
User Action	1. Identify and eliminate the cause of the alarm, if possible. 2. If the cause of the alarm cannot be eliminated, consider warming the patient with a new ThermAffyx™ System or alternative methods. Contact the manufacturer or authorized service representative for Service.

A list of all possible alarm codes and conditions can be found in **section 11 Alarms, Error Codes and Troubleshooting**.

To silence the alarm, press the Standby button to switch into Standby mode.

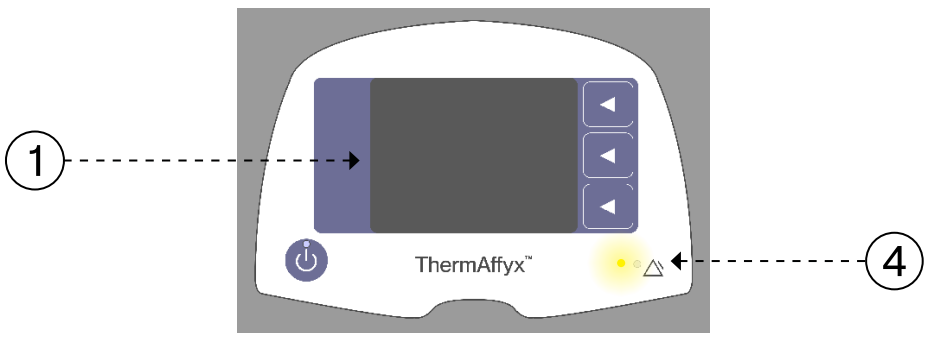
10.3 Alarm Condition – Device Failure

Control Panel	
Status/Condition	A device failure can occur if one of the internal components fails due to damage, aging, misuse or if the internal self-test fails. A device failure can be caused by the Controller, the Pad or the Extension Cable.
Device Response	– The display shows the 'service required' symbol (⑦). – The temperature display (⑧) of the Pad is replaced by 2 dashes. – The display states an alarm code within a blinking yellow bar (⑥). – The yellow alarm condition LED (④) is blinking. – The Controller will issue an acoustic alarm. – The last selected set temperate (②) is highlighted white. – The Controller will automatically shut off the heating function.
User Action	1. Switch the Controller off, using the Standby button (⑤). 2. Identify and eliminate the cause of the alarm, if possible. 3. If the cause of the alarm cannot be eliminated, consider warming the patient with a new ThermAffyx™ System or alternative methods. Contact the manufacturer or authorized service representative for Service.

A list of all possible alarm codes and conditions can be found in **section 11 Alarms, Error Codes and Troubleshooting**.

To silence the alarm, press the Standby button to switch into Standby mode.

10.4 Alarm Condition – Power Interruption

Control Panel	
Status/Condition	The power supply has failed/been interrupted, or the power plug has been disconnected while in No Pad mode, On mode or Heat mode.
Device Response	– The display (①) is completely off. – The yellow alarm condition LED (④) is blinking. – The Controller will issue an acoustic alarm.
User Action	1. Switch the Controller off, using the Standby button (⑤). 2. Identify and eliminate the cause of the power interruption, if possible. 3. If power cannot be restored, consider warming the patient with alternative methods.
ⓘ	The maximum duration of the alarm is 10 minutes. To avoid unwanted alarms, always switch off the device using the Standby button before disconnecting the power plug. To silence the alarm, press the Standby button to switch into Standby mode.

11. Alarms, Error Codes and Troubleshooting

The ThermAffyx™ System does not require continuous supervision by the user but must be inspected at regular intervals (depending on the condition of the patient or as directed by the physician). The intended operating location is directly in front of the control panel of the ThermAffyx™ Controller.

In the event of System failure, patient warming may be delayed and the user should eliminate the failure condition or provide alternative warming to the patient.

The System is equipped with a series of alarms. See **section 15 Conformity with International Standards.**

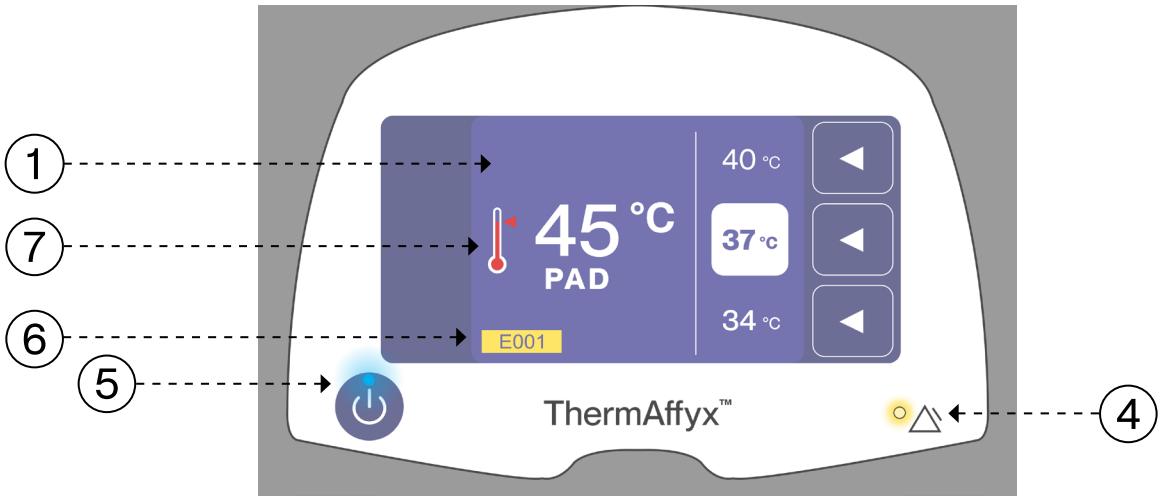
The alarm signal is output visually and acoustically as shown in **section 10 Alarm Modes.**

The following list states all possible alarm codes the Controller can display during a faulty condition. In case of an alarm, please refer to the troubleshooting column to restore to an operational mode:

Alarm / Error Code	Status/ Condition	Description	Troubleshooting
E001	Over-Temperature Condition	Determined Contact surface temperature T_{Pad} > 41°C	Press Standby button to switch the device off – If over temperature is a result of external heat source (e.g. other heating devices) let the device cool down and restart the device with the desired Pad set temperature. – If over temperature is a result of a device fault, discontinue use. Consider other methods or devices to warm the patient. Contact the manufacturer or authorized service representative for Service.

E011 or E012	Sensor Shorted	Short circuit of temperature sensor	Press Standby button to switch the device off – If short circuit is a result of a fault inside the pad, discontinue use. Consider other methods or devices to warm the patient or exchange the pad if possible. – If short circuit is a result of a device fault (Controller or Extension Cable) discontinue use. Consider other methods or devices to warm the patient. Contact the manufacturer or authorized service representative for Service.
E021 or E022	Sensor Open	Open circuit of temperature sensor	Press Standby button to switch the device off – If open circuit is a result of a fault inside the pad discontinue use. Consider other methods or devices to warm the patient or exchange the pad if possible. – If open circuit is a result of a device fault (Controller or Extension Cable) do not use it further. Consider other methods or devices to warm the patient. Contact the manufacturer or authorized service representative for Service.
E030	Thermal Shut-off Condition	Independent Thermal shut-off triggered $T_{Pad} > 46°C$	Press Standby button to switch the device off – If the thermal shut-off is a result of external heat source (e.g.other heating devices) let the pad cool down and restart the device with the desired Pad set temperature. Consider removing the external heat source, if possible. – If the thermal shut-off is a result of a device fault, discontinue use. Consider other methods or devices to warm the patient. Contact the manufacturer or authorized service representative for Service.
E040	Temperature out of range (Over-Temperature condition)	Determined contact surface temperature variation $T_{Pad} > T_{Set} + 1°C$	Press Standby button to switch the device off – If over temperature is a result of external heat source (e.g. other heating devices) let the pad cool down and restart the device with the desired Pad set temperature. Consider removing the external heat source, if possible. – If over temperature is a result of a device fault, discontinue use Consider other methods or devices to warm the patient. Contact the manufacturer or authorized service representative for Service.
E050 or E051	Heating resistance failure	Heating resistance out of range	Press Standby button to switch the device off – If heating resistance failure is a result of a fault inside the pad, discontinue use. Consider other methods or devices to warm the patient or exchange the pad if possible.
E060	Temperature out of range (Low Temperature condition)	Determined contact surface temperature variation $T_{Pad} < T_{Set} - 1°C$	Consider alternative/additional heating methods to warm the patient – If low temperature is a result of extreme environmental conditions (e.g. air conditioning, other cooling devices), try to warm the environment, if possible. – If low temperature is a result of a device fault, discontinue use. Consider other methods or devices to warm the patient. Contact the manufacturer or authorized service representative for Service.
E070	Temperature not reached	T_{Set} not reached within 60 minutes	Consider alternative/additional heating methods to warm the patient – If 'temperature not reached' is a result of extreme environmental conditions (e.g. air conditioning, other cooling devices) try to warm the environment, if possible. – If 'temperature not reached' is a result of a device fault, discontinue use. Consider other methods or devices to warm the patient. Contact the manufacturer or authorized service representative for Service.
E100 through E200	Hardware failure	Various	Press Standby button to switch the device off – This is a Controller failure. Discontinue use. Consider other methods or devices to warm the patient or exchange the Controller if possible. Contact the manufacturer or authorized service representative for Service.
106 (not displayed during alarm)	Mains Power interruption	Mains Power Supply interruption (Alarm LED and Speaker active only, Display inactive)	Check the power supply – Power Supply Cable (inlet Controller & mains plug) – Mains wall outlet – Circuit breaker

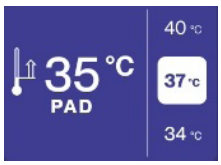
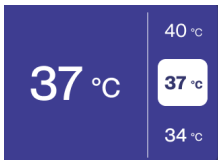
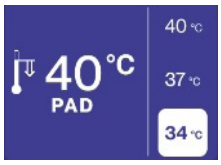
12. Brief Overview of Operating States and Alarms



12.1 Overview of Operating States

Legend: ○ = LED Off ● =LED On ☀ = LED Flashing

Operating State	Display ①	Alarm LED ④ yellow	Standby LED ⑤ blue	Acoustic Alarm Signal	Comment
Unpowered Mode		○	○		Controller not connected to mains
Standby Mode		○	●		Controller is switched off
Self-test Mode	GENTHERM	☀ 1x	○	1x	Controller's start screen shows Gentherm logo and software version
No Pad Mode		○	○		Check and connect Pad to the Controller
On Mode	22 °C / 40 °C / 37 °C / 34 °C	○	○		Display shows Pad's actual temperature (left). User can select one of three Pad set temper¬atures (right).

Heat Mode - Heating Up		○	○		Display shows selected temperature (e.g. 37°C highlighted, right), Pad's actual temperature (middle) and that Pad's temperature is increasing (symbol, left).
Heat Mode - Teamperature Reached		○	○		Display shows selected temperature (e.g. 37°C highlighted, right), Pad's actual temperature (middle).
Heat Mode - Cooling		○	○		Display shows selected temperature (e.g. 37°C highlighted, right), Pad's actual temperature (middle).

12.2 Overview of Alarms

Legend: ○ = LED Off ☀ = LED Flashing

	Display		Alarm LED		
	(7)	(6)	(4)		
Operating State	**Status Indicator**	**Alarm Indicator**	**yellow**	**Acoustic Alarm Signal**	**Comment**
Over-Temperature Alarm		**E001** **E030** **E040**	☀		Actual temperature > 41°C Independent thermal cut-out has triggered at a temperature > 46°C Actual temperature is 1°C or higher than Pad set temperature
Low Temperature Alarm		**E060** **E070**	☀		Actual temperature is at least 1°C lower than the Pad set temper¬ature for at least 10 minutes. Pad set temperature not reached within 60 minutes
Sensor Failure		**E011 or E012** **E021 or E022**	☀		Shortage of Pad's temperature sensor Breakage of Pad's temperature sensor
Heater Failure		**E050 or E051**	☀		Heating resistance of Pad out of range
Hardware Failure		**E100 → E200**	☀		Internal unit of the Controller is defective
Power Failure		-	☀		Controller is no longer supplied with mains voltage

13. Service

13.1 Service and Repairs

Service and repairs may only be carried out by the manufacturer or authorized service representatives.

13.2 Disposal of the Equipment

Please follow regulations and your facility's procedures for the disposal of used or contaminated medical products.

13.3 Return of a Used Product

Contact the manufacturer to initiate a return. A description 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.

⚠WARNING Risk of Infection - Clean and disinfect the equipment before you return the equipment for repairs. See **section 8.8 Clean and Disinfect**.

13.4 Service Information

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

North American & South American Customers:

Gentherm Medical
12011 Mosteller Rd.
Cincinnati, OH 45241-1528
USA

Tel. 1-513-772-8810
Fax. 1-513-772-9119
www.gentherm.com/medical
Medtechsupport@Gentherm.com
medicalorders@gentherm.com

All Other Customers:

STIHLER ELECTRONIC
GmbH Gaussstrasse 4
70771 Leinfelden-
Echterdingen GERMANY

Tel. +49 (0) 711-720670
Fax +49 (0) 711-7206757
www.gentherm.com/medical
service@gentherm.com
complaint@gentherm.com
info.ste@gentherm.com

13.5 Incident Reporting

Report any serious incident in relation to the device to the manufacturer and to the correct local authority.

13.6 Annual Maintenance

An Annual Maintenance Test of the ThermAffyx™ Controller must be performed at least every 12 months by qualified Service Staff.

For this test, you must purchase the required test equipment and instructions from the manufacturer.

Observe all other applicable regulations (e.g. IEC 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 ThermAffyx™ System Testing Instructions:

- Testing instructions ThermAffyx™ System, English (Order no. 25.0000.44)

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

- Test Plug for ThermAffyx™ Controller (Order no. 25.0000.46)

The Test Instructions and Test Plug are included in the scope of delivery of the ThermAffyx™ Test Plug Kit (REF 368).

14. Technical Data

ThermAffyx™ Controller, REF 360			
Type of use	Reusable (after reprocessing)		
Electrical connection	100 – 240 VAC, 50 – 60 Hz		
Rated current	100 V = 1.5 A, 240 V = 0.7 A		
Primary fuses	2 x T3.15 A/250 V, 1500A breaking capacity, 5 x 20 mm (not removable by user)		
Power consumption	155 W < 0.5 W (Standby)		
Classification (IEC 60529)	IPX2		
Classification (IEC 60601-1)	Protection Class I, defibrillation-protected applied part type BF		
Recovery time after defibrillation	0 seconds		
Regulatory class as per FDA	II		
Classification (MDD 93/42/EEC) (MDR (EU) 2017/745)	Class IIb		
Code EMDN	Z12040208		
Code GMDN	37329		
Dimensions *Height* *Width* *Depth*	max. 300 mm / 11.8 in 155 mm / 6.1 in 130 mm / 5.1 in		
Weight	1.7 kg / 3.75 lb		
Operating mode	Continuous operation		
Permissible environmental conditions	**Humidity**	**Temperature**	**Atmospheric Pressure**
In operation/long time storage	20% to 80% non-condensing	+15°C to +25°C	70 kPa to 106 kPa
In transport/short time storage		-20°C to + 60°C	
Essential performance (critical functions that must work correctly)	Maintaining/regulating the Pad set temperature with a tolerance of ± 1.0°C		
Display precision of the contact surface temperature	± 0.7°C		
Over temperature alarm	T_{Set} + 1°C (± 0.5°C)		
Over temperature shut-off	41.0°C (± 0.5°C)		
Independent thermal cut-out	≥ 46°C (± 0.5°C)		
Low temperature alarm	T_{Set} - 1°C (± 0.5°C)		
Acoustic alarm volume level (Distance = 1 m)	approx. 58 dB(A)		
Expected Service Life	The expected service life is 3 years from the date of manufacture, providing the product is not subject to misuse, negligence, damage or inappropriate use and the equipment is used and serviced properly and as intended.		

ThermAffyx™ Pad, REF 363			
Type of use	Single use/single patient		
Electrical connection	24 VDC		
Power consumption (W)	150 W		
Classification (IEC 60529)	IPX2		
Code EMDN	Z12040208		
Code GMDN	37329		
Dimensions *Height* *Width* *Depth*	max. 1118 mm / 44 in 559 mm / 22 in 38 mm / 1.5 in		
Weight	1.9 kg / 4.2 lb		
Material	Polyurethane foam with embedded Carbotex® heating element		
Permissible environmental conditions	Humidity	Temperature	Atmospheric Pressure
In operation/long time storage	20% to 80% non-condensing	+15°C to +25°C	70 kPa to 106 kPa
In transport/short time storage		-20°C to +60°C	
Heating-up period from 23.0°C to 37.0°C	Approx. 2 minutes		
Expected Service Life	The expected shelf life is 12 months from the date of production, providing the product has been stored under the recommended conditions and was not exposed to sunlight.		

ThermAffyx™ Extension Cable, REF 362			
Length	2 m / 6.56 ft		
Weight	0.2 kg / 0.44 lb		
Permissible environmental conditions	Humidity	Temperature	Atmospheric Pressure
In operation/long time storage	20% to 80% non-condensing	+15°C to +25°C	70 kPa to 106 kPa
In transport/short time storage		-20°C to + 60°C	
Expected Service Life	The expected service life is 3 years from the date of manufacture, providing the product is subject to misuse, negligence, damage or inappropriate use and the equipment is used and serviced properly and as intended.		

15. Conformity with International Standards

Standard	Title
IEC 60601-1 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 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 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 60601-2-35	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 60601-1-6 IEC 62366-1	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - collateral standard: Usability.

According to IEC 60601-2-35, cl. 201.3.219, the ThermAffyx™ Heated Securement Pad is defined as "under-blanket" (Blanket designed to be used under a patient).

16. Ordering Information and Accessories

Cat #	Order #	Variant	Description
364	90364	XX	ThermAffyx™ Controller Kit (Controller, Extension Cable, Power Supply Cable)
XX=	– EU: With Power Supply Cable with Schuko (CEE 7/3) plug – AU: With Power Supply Cable with Australia plug – CN: With Power Supply Cable with China plug – CH: With Power Supply Cable with Switzerland plug – DK: With Power Supply Cable with Denmark plug – GB: With Power Supply Cable with Great Britain plug – NA: With Power Supply Cable with US Hospital Grade plug		

Cat #	Order #	Description
365	90365	4x ThermAffyx™ Heated Securement Pad Kit (Pad, Disposable Draw Sheet, Single Body Strap Set)
362	80362	ThermAffyx™ Extension Cable, 2 m [78.7”]
361	1830.4000	Power Supply Cable with Schuko (CEE 7/3) plug
	1830.4060	Power Supply Cable with Australia plug
	1830.4030	Power Supply Cable with China plug
	1830.4040	Power Supply Cable with Switzerland plug
	1830.4050	Power Supply Cable with Denmark plug
	1830.4010	Power Supply Cable with Great Britain plug
	80361	Power Supply Cable with US Hospital Grade plug

Cat #	Order #	Description
368	25.0000.45	Test Plug Kit (Test Plug, Testing Instructions)

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

17. EMC Warnings, Guidelines and Manufacturer's Declaration

Guidelines and Manufacturer's Declaration - Electromagnetic Emissions

ThermAffyx™ is intended for use in the electromagnetic environment specified below. The customer or user of ThermAffyx™ 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	ThermAffyx™ 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	NOTE: 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 components in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations and flicker in accordance with IEC 61000-3-3	Complies	

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity

ThermAffyx™ is intended for use in the electromagnetic environment specified below. The customer or user of ThermAffyx™ 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 ± 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 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 ± 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 % UT; ½ cycle At 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % UT; 1 cycle and 70 % UT; 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 % UT; 250/300 cycles	Complies	
Magnetic fields with energy rated frequencies according to IEC 61000-4-8	30 A/m 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

ThermAffyx™ is intended for use in the electromagnetic environment specified below. The customer or user of ThermAffyx™ 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 61000-4-6	3 V_{eff} 0.15 MHz to 80 MHz 6 V_{eff} in ISM frequency bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Complies	$d = 1{,}2\sqrt{P}$
Radiated RF disturbances IEC 61000-4-3	3 V/m/10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Complies	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2.7 GHz
RF Communications Equipment (incl. 5G FR1 bands) IEC 61000-4-3	385 MHz - 6 GHz 9 V/m to 54 V/m depending on frequency	Complies	$d = \frac{6\sqrt{P}}{E}$
Proximity Magnetic Fields and Wireless Power Transfer (WPT) IEC 61000-4-39	9 kHz - 26 MHz 7.5 A/m, 65 A/m	Complies	$d = 0.3\ \mathrm{m}$
RFID Readers (AIM 7351731)	LF RFID (125 kHz) HF RFID (13.56 MHz) UHF RFID (860–960 MHz)	Complies	$d = \frac{6\sqrt{P}}{E}$
IEC 60601-2-2	Ad-hoc Testing according to Annex BB.4	Complies	No separation required, when used with max. 300 W (Pure) 200 W (Blend) 150 W (ACE) 120 W (Coag, Spray)

Portable and mobile RF communication equipment should not be used at a distance from ThermAffyx™ (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 ThermAffyx™ is used exceeds the compliance level specified above, the ThermAffyx™ 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 ThermAffyx™.

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 ThermAffyx™

ThermAffyx™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of ThermAffyx™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and ThermAffyx™ 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 $d = 1{,}2\sqrt{P}$	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 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.

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STIHLER ELECTRONIC GmbH

Gaussstrasse 4
70771 Leinfelden-Echterdingen
GERMANY

Tel. +49 (0) 711-720670
Fax +49 (0) 711-7206757
https://gentherm.com/en/medical
E-mail: info.ste@gentherm.com