Flexi-therm

Instructions for Use

Vitl

LIFE SCIENCE SOLUTIONS

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1 Symbols Used in this Instruction Manual

The following advisory symbols are used in this manual.

Table 1: Advisory Symbol Meanings	
 **DANGER**	Indicates a Risk of Electric Shock which could, if not avoided, result in severe injury or death.
 **DANGER**	Indicates a Burn Hazard which could, if not avoided, result in severe injury or death.
 **DANGER**	Indicates a Risk of Explosion which could, if not avoided, result in severe injury or death.
 **WARNING**	Indicates a hazardous situation which could, if not avoided, result in severe injury or death; or severely damage the unit.
 **CAUTION**	Indicates a hazardous situation which could, if not avoided, result in minor or moderate injury; or degrade or impair the functionality of the unit.
 **CAUTION**	Indicates an Electrostatic-Sensitive Device for which care should be taken not to touch the exposed electrical contacts as this could degrade or impair the functionality of the unit.
	Advisory note or other useful information.
⇨ ***NN***	Refer to “section NN” for more details.

2 Safety Precautions and Limitations of Use

It is essential that all users of this equipment have fully read and understood the following safety precautions and limitations of use before installing or operating the Flexi-therm unit.

IMPORTANT	
 **WARNING**	The protection provided by this equipment may be impaired if it is not used in a manner described in this manual.
 **WARNING**	It is essential that the user of this equipment is aware of the potential hazards associated with the unit and its accessories. All operators should be familiar with the safety precautions and warnings given in these instructions before attempting to operate the unit. Improper use of this unit or its accessories may impair their functionality and invalidate the manufacturer's warranty.

Unit Handling Precautions	
 **CAUTION**	Care should be taken not to drop the unit or subject it to rough physical handling, both during normal use and during transportation and storage. Do not use the unit if it shows any signs of damage or wear.
 **WARNING**	The unit should be held and supported in both hands when lifting or moving. Do not lift the unit by the Heated Module.
 **CAUTION**	Care should be taken not to knock the LED display. Do not use excessive force when pressing the control buttons.

Unit Installation and Operating Environment	
 **DANGER**  **WARNING**	The Flexi-therm unit is designed for indoor laboratory use only. The acceptable operating temperature range is 10ºC to 38ºC, with a relative humidity of 20% to 85% non-condensing, at a maximum altitude of 2000m above sea level. If the unit is stored in conditions outside of these ranges, it must be left to stand unpowered until it has acclimatised to within these environmental limits before being powered.
 **DANGER**	Use only the AC mains power cord provided with the unit or as specified in section 9 of this manual. The unit must be connected to a suitably earthed mains supply, with appropriate earth-leakage and over-current protection.
 **WARNING**	Always ensure that the mains power connector is securely inserted into the rear of the unit and that any excess power cord does not pose a potential trip or pull hazard.
 **DANGER**	Do not operate the unit in any area which is, or has been, or is thought to have been exposed to explosive or flammable gases, vapours or liquids.
 **WARNING**	The unit must be installed and operated on a solid, stable and level working surface; ensuring that the ventilation holes on the underside and rear of the unit are not obstructed.

General Operating Precautions	
 **DANGER**	Ensure that the power is switched off at both the AC mains supply outlet and at the back of the unit before inserting or removing the mains power cord. However, if a spillage occurs in or over the unit, always switch the power off and unplug the power cord at the mains supply outlet first, before attempting to deal with the spill.
 **DANGER**	The heaters can reach temperatures of 105ºC and will remain hot for a considerable time after being turned off. Extreme care must be taken not to touch the heated surfaces as they may cause a severe burn injury.
 **DANGER**	The unit is intended for use with aqueous solutions and suspensions only. Never use the unit with any explosive, volatile or highly reactive substances or chemicals.
 **WARNING**	To avoid liquid spills and possible cross-contamination of samples, only use sealed plates and closed tubes. Always follow prescribed laboratory procedures and use appropriate personal protective equipment (PPE, such as gloves, clothing, goggles, etc) when handling samples.
 **CAUTION**	Do not touch the exposed electrical contacts of the unit or associated Heated Modules as an Electrostatic Discharge (ESD) could degrade or impair the functionality of the unit.
 **CAUTION**	For optimum performance and to prevent dirt build-up or ingress, always keep the Heated Module lid closed when not accessing the sample plates or tubes.

Unit Maintenance and Serviceability	
 **DANGER**	There are no user or operator serviceable parts inside the unit. Do not remove the unit casework.
 **WARNING**	Removal of the unit's casework will void the manufacturer's warranty and may expose the user to a Risk of Electric Shock resulting in serious injury or death.
 **DANGER**	The externally accessible unit fuse will only blow under an extreme internal fault condition. This fuse should only be changed after the unit has been thoroughly inspected by a qualified engineer. See section 7.1 for details.
 **DANGER**	Always switch off the unit and disconnect the power cord before performing any cleaning or decontamination procedure. If liquid is spilt into or over the unit, switch off and disconnect the power from the AC mains outlet before attempting to deal with the spillage.
 **DANGER**	Never push any object into the ventilation slots on the underside or rear of the unit. Such actions may damage the unit and expose the user to hazardous voltages resulting in serious injury or death.
 **CAUTION**	Ensure that the heated surfaces have cooled down to room temperature before performing any cleaning operation and before moving or storing the unit.
 **CAUTION**	The use of harsh chemicals and cleaning agents may damage the unit and degrade its performance. Always follow the cleaning and decontamination procedures specified in sections 7.2 and 7.3 of this instruction manual.

3 Regulatory Limitations of Use

Declaration of Conformity

Integrated Technologies Limited (ITL) affirm that this product fulfils the essential requirements of the Low Voltage Directive (LVD) 2006/95/EC and the EMC Directive 2004/108/EC, when installed and operated in accordance with the instructions given in this manual.

ELECTRICAL SAFETY
E113628

The Flexi-therm unit has been type tested by TRaC Global Ltd (UKAS accredited Testing Laboratory No 0026) against the Safety and EMC Requirements listed below, and issued Certificate Nos GB-TRAC 0684 and TRA-025949-38.

Safety and EMC Requirements

SAFETY	• EN 61010-1:2010, EN 61010-2-010:2003 • UL 61010-1:2001 2nd Edition (CAN C22.2 CSA 61010-1)
EMC	• EN 61326:2006, Class B • FCC CFR 47 Parts 15.107 and 15.109, Class B

RoHS and WEEE Directive Compliance

This product complies with the requirements of the RoHS2 Directive 2011/65/EU for Electrical and Electronic Equipment.

Where applicable, the Flexi-therm unit should be disposed of in accordance with the European Union WEEE Directive 2002/96/EC on Waste Electrical and Electronic Equipment.

Do not dispose of this product into unsorted municipal waste or public landfill. Please refer to section 7.5 for details of how to correctly dispose of this product.

The Flexi-therm unit is designed and manufactured under ISO 9001 by:

Integrated Technologies Limited
Viking House, Ellingham Way, Ashford, Kent, TN23 6NF
United Kingdom

4 Unit Description

The Flexi-therm is a compact static sample heater base-station for use with the extensive range of VITL Heated Modules.

The unit has the following external features:

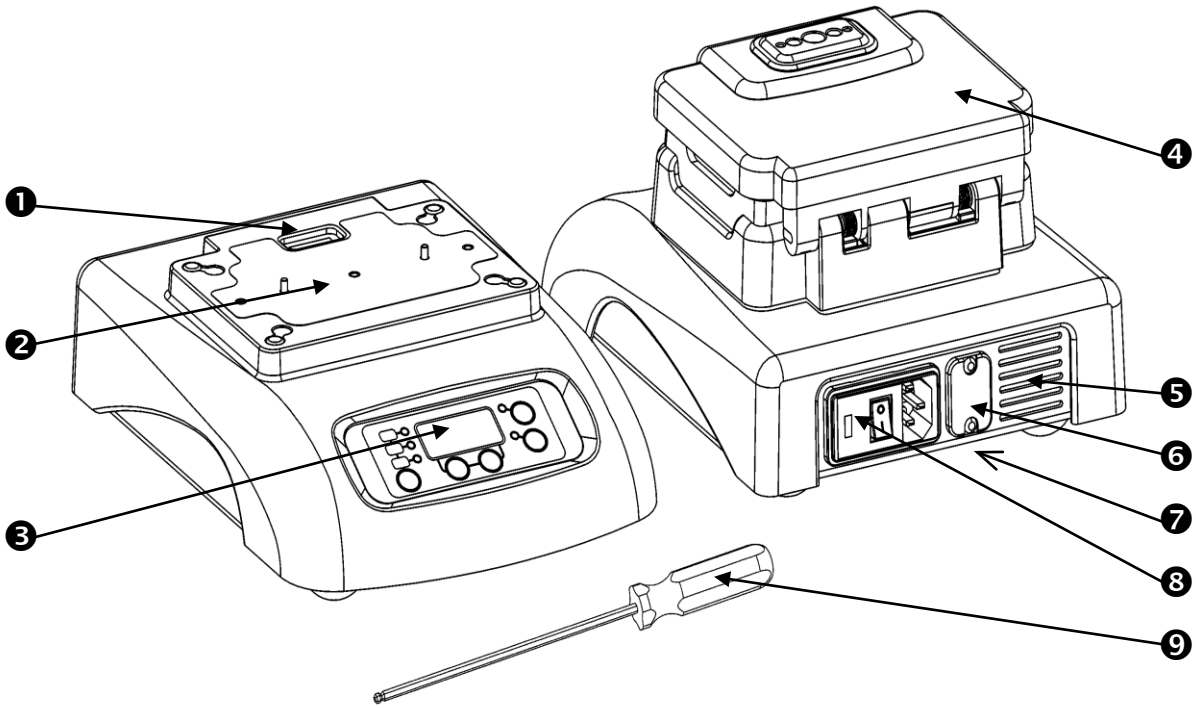
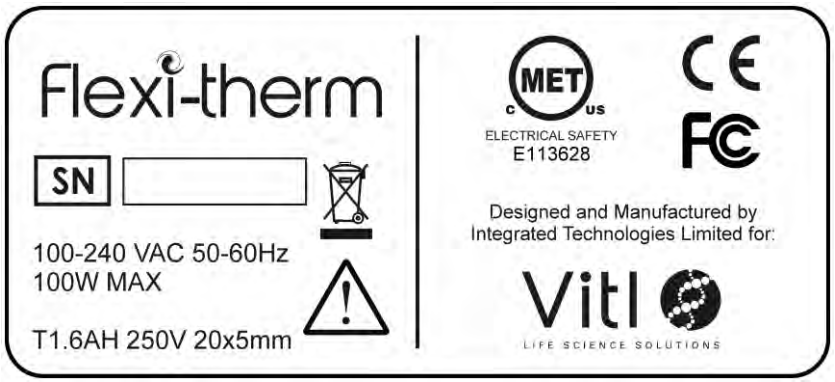


Table 2: Unit Features		
❶	Heated Module Interface Port	⇨ *6.2*
❷	Heated Module Docking Platform	⇨ *6.2*
❸	User Interface Display and Control Buttons	⇨ *6.1*
❹	Heated Module	⇨ *6.2*
❺	Rear Ventilation Holes	⇨ *5*
❻	Communications Port (optional)	
❼	Product Information Label (underside)	⇨ *below*
❽	Power Inlet, On/Off Switch and Fuse Holder	⇨ *5*
❾	3mm Hex-Driver Module Securing Tool	⇨ *6.2*

The Heated Modules are interchangeable sample block heaters specifically designed for particular sample plate and tube types. Please contact your distributor to ensure you have the most appropriate module for your application.

Other optional accessories and specialist Heated Modules may be available on request. Please contact your distributor for details.

The product information label is located on the underside of the unit and provides the unit serial number, voltage and power ratings and fuse rating:



5 Unit Installation

Before installing the Flexi-therm unit, please check that the delivery is complete and that the unit and any accessory parts are intact and free from any signs of transportation damage. Also ensure that all external and internal packaging has been removed from the unit before installation.

Please retain all packaging for future transportation and storage of the unit and its accessories.

The Flexi-therm unit should be installed in a location which meets the following requirements:

- Safe and suitable operating environment (see section 2)
- Solid, stable, level working surface
- At least 10cm clearance around the unit to adjacent objects and walls
- Earthed AC mains power connection (see section 9)

WARNING

Please also observe and abide by the **Unit Installation and Operating Environment** safety precautions and preconditions listed in section 2 of this manual and the associated **Heated Module Instructions for Use**.

Install the Flexi-therm unit using the following procedure:

1) Place the unit on the suitably selected working surface (as specified above), ensuring that the ventilation holes on the underside and rear of the unit are not obstructed.
2) Connect the unit to the AC mains power outlet using the mains power cord supplied or as specified in section 9.
3) Attached the Heated Module, as described in section 6.2.
4) Switch the mains power on at supply outlet first, and then switch the unit on using the power switch located at the rear of the unit.

DANGER

If the unit has been stored in a cool environment, it must be left to stand unplugged until it has acclimatised to the new room temperature before being powered.

6 Unit Operation

WARNING

Please ensure that you have read and fully understood all of the **Safety Precautions and Limitations of Use** listed in section 2 before attempting to operate the Flexi-therm unit.

6.1 User Display and Controls

The unit's user interface consists of a large 3-digit LED display, five control buttons and five status indicator LEDs.

The LED display shows the current temperature or timer set-point (depending on the mode). The button and LED functions are listed in Table 3.

Table 3: User Buttons and Status LEDs

	Display **MODE** select button		**LID** temperature **BLOCK** temperature **TIMER** mode
	UP button (increase temperature or time)		
	DOWN button (decrease temperature or time)		
	Timer **START** button and status LED	**Off** **Flashing** **On**	Timer stopped Timer running Timer complete
	HEATER on/off button and status LED	**Off** **Flashing** **On**	Heaters off Warming up Heaters stable

6.2 Attaching a Heated Module

The Heated Module is a self-contained precision-calibrated sample heater with integral anti-condensation lid. Each module is specifically designed for optimum sample heating within a particular plate or tube type. Please refer to the **Heated Module Instructions for Use** for specific usage details.

CAUTION	Always switch off the Flexi-therm unit before attaching or removing the Heated Module. Do not touch the exposed electrical contacts on the unit or Heated Module as this may impair their functionality.

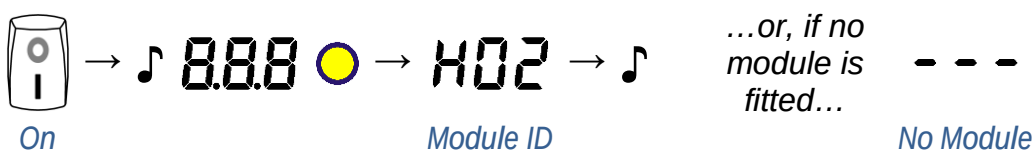
To attach a Heated Module:

1) Switch off the unit and wait for the LED display to go blank.
2) Place the Heated Module on the Docking Platform ensuring that it is sitting flat and correctly positioned on the two location dowels.
3) Using the supplied hex-driver, screw the module to the platform (refer to the **Heated Module Instructions for Use** for full details).
4) For modules with a lid, always keep the lid closed when not accessing the fixing screws or sample plates and tubes.
5) Switch the unit back on, the display should light up (see section 6.3 for the more details).

Each Heated Module will remember its own temperature and time settings. When swopping between modules, the new module's settings are automatically loaded back into the Flexi-therm unit.

6.3 Unit Power-up

When the unit is switched on, the display and all status LEDs will light up for 2 seconds and then go out. If a Heated Module is attached (see section 6.2) the Module ID will then be displayed for 3 seconds. In the example below, H02 denotes Heated Module type HM02:



If no module is fitted, or it is not fully screwed down (see section 6.2), the unit will not display a Module ID and no further actions can be performed until the module is correctly affixed.

If a Heated Module is attached at unit power-up, the heaters will automatically turn on so that warmup starts immediately. If desired, this feature can be disabled - refer to section 6.6 for details.

6.4 Setting the Heater Temperatures

All Heated Modules have a sample block heater, and most also have an independently controllable anti-condensation heated lid.

To set the sample block temperature, use the MODE button to select the BLOCK temperature display mode, and then use the UP and DOWN buttons to set the target temperature.

** Note: The available temperature range may depend on the Heated Module type. Refer to the **Heated Module Instructions for Use** for specific details.*

The temperature settings can only be changed when the BLOCK or LID temperature display mode is selected and the heaters are off (i.e. the HEATER status LED is off).

If the module has a heated lid, its temperature can be independently set by using the MODE button to select the LID temperature display mode, and then the UP and DOWN buttons to set the target temperature.

In Auto mode, the lid automatically adjusts its temperature to be higher than the sample block temperature, thus preventing condensation from forming on the caps of the sample vessels. In Off mode, the lid heater is disabled.

NOTE

The new temperature settings are stored within the Heated Module when the HEATER button is next pressed. These settings stay with the individual Heated Module and are automatically reloaded into the Flexi-therm unit whenever that module is being used.

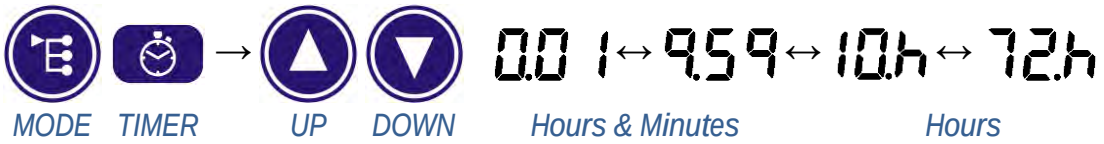
Pressing the HEATER button automatically selects the temperature display mode and turns the heaters on. When the heaters are on, the display shows the current temperature and the HEATER status LED will flash until the target temperature is reached.

** Note: The warmup rate depends on the Heated Module type being used. Refer to the **Heated Module Instructions for Use** for further details.*

When the heaters are on and the temperature is displayed, pressing the UP or DOWN button will display the temperature set-point but will not adjust its value. To change the set-point, the heater must first be turned off via the HEATER button.

6.5 Using the Timer Function

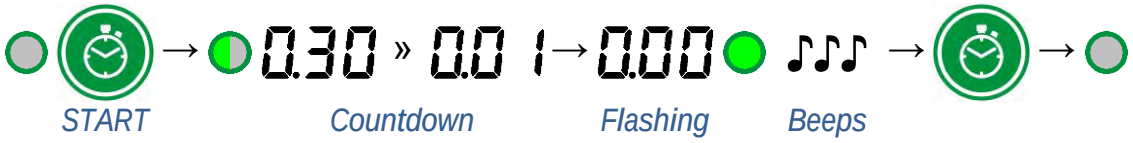
The unit also has a general purpose timer function. This timer can be set between 1 minute and 72 hours by using the MODE button to select the TIMER mode, and then the UP and DOWN buttons to adjust the set value.



NOTE

The timer duration can only be changed when the TIMER display mode is selected and the timer it is not running (i.e. the TIMER status LED is off). The new time setting is stored within the Heated Module when the START button is next pressed.

Pressing the timer START button automatically selects TIMER display mode and starts the timer countdown with the TIMER status LED flashing. When the timer reaches zero the display starts flashing, the unit beeps three times and the TIMER status LED stays on.

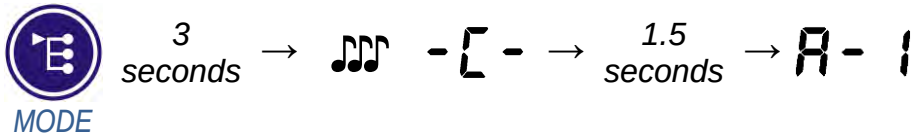


To cancel the timer, press the START button again so that the TIMER status LED turns off. The display will then return to showing the timer set value.

The timer complete alert beeps can be configured to occur once only, or repeat every 30 seconds (until cancelled), or be disabled completely. See section 6.6 for details.

6.6 Changing Unit Configuration Settings

The Flexi-therm unit provides several configuration settings, which are accessed by pressing and holding down the MODE button for 3 seconds until the unit displays -C-, and then continuing to hold down the MODE button for a further 1.5 seconds.



Next use the MODE button to step through the setting options (A, C and H), and the UP and DOWN buttons to change the setting value (0, 1 or 2).

Table 4: Configuration Options and Values

Option	Purpose	Values	
A-0 A- 1 A-2	Timer Alert	**0**	Beep disabled
		1	Beeps three times when timer reaches zero
		2	Beeps three times every 30 seconds until timer cancelled
C-0 C- 1	Button Click	**0**	Keypad Button click disabled
		1	Button click enabled
H-0 H- 1	Heater Power-up	**0**	Heaters disabled at unit power-up. Enable via HEATER button
		1	Heaters automatically enabled at unit power-up

Once all configuration options have been stepped through (using the MODE button) the new values are saved to the Flexi-therm internal memory and the unit restarts from the power-up state.

6.7 Unit Shutdown

Before switching off the unit, it is recommended to turn off the heaters and remove all disposables from the Heated Module. The unit can then be shutdown via the power switch at the rear of the unit.

DANGER

The heaters will remain hot for a considerable time after being turned off. Extreme care must be taken not to touch the heated surfaces as they may cause a severe burn injury.

When the power to the unit is switched off or disconnected, the LED display may remain lit for up to 15 seconds before going blank.

6.8 Troubleshooting

The following table lists some troubleshooting suggestions:

Table 5: Troubleshooting Suggestions

Problem	Possible Causes	Suggestion
Unit does not recognise the Heated Module.	Heated Module not fully screwed down to Flexi-therm unit.	Ensure module securely screwed down before turn unit on (see section 6.2).
Unit keeps resetting or restarting.	Heated Module loose. Room temperature too hot or too cold. Heated Module or contacts damaged.	Ensure module securely screwed down. Ensure correct operating conditions (see section 9).
Heater LED flashes but BLOCK does not get to temperature.	Block temperature set-point too low or too close to ambient room temperature.	Refer to **Heated Module Instructions for Use** for temperature ranges.
Heater LED flashes but LID does not get to temperature.	Lid temperature set too low or below the block heater temperature.	Set temperature higher or use **Auto** mode (see section 6.4).
New settings not stored in Heated Module.	New are settings are only stored when the HEATER or TIMER button is pressed.	See sections 6.4 and 6.5 for details.

If the software detects a problem with the Flexi-therm unit or Heated Module, the unit will show an error code, as listed in Table 6 below.

Table 6: Error Codes

Code	Cause	Suggestion
Er 1	Heated Module interface fault	Turn off unit, remove Heated Module and leave for 5 minutes. Then refit module and screw securely to unit (see section 6.2). Turn unit back on.
Er2	Heated Module block fault	
Er3	Heated Module lid fault	
Er4	Heated Module overheated	Ensure correct operating conditions (see section 9). Turn unit off for 30 minutes then try again.
Er8	Flexi-therm unit internal fault	Turn unit off, remove Heated Module, then turn unit back on and check if the problem still occurs.
Er9		

If the problem persists, please contact your local distributor or ITL at the address on page 2 of this manual.

7 Maintenance and Servicing

Although the Flexi-therm unit does not require any scheduled maintenance or servicing, the operator should regularly clean and inspect the unit for any detects, as described in section 7.2 below.

DANGER

Please observe and comply with all of the **Unit Maintenance and Serviceability** precautions listed in section 2.

Never remove the unit casework. There are no user or operator serviceable parts inside the unit.

WARNING

Always switch off and unplug the unit before performing any cleaning or disinfecting tasks.

CAUTION

Practise anti-static precautions by avoiding direct touching of the exposed electrical contacts or using statically charged cleaning clothes.

For technical and service related enquiries, please contact your distributor or ITL at the address given on page 2 of this manual.

7.1 Replacing the Unit Fuse

The unit fuse should only be replaced by a suitably qualified engineer.

DANGER

The unit fuse will only blow as a result of an internal unit fault. This fuse should only be changed after the unit has been thoroughly inspected by a qualified engineer, and must be replaced with the exact type specified in section 9.

Thoroughly inspect the unit for any signs of damage, loose components or liquid spillage or ingress. If in doubt, please contact ITL on the number given on page 2 of this manual.

DANGER

The fuse holder is removed by disconnecting the mains power cord and then using a flat bladed screwdriver to carefully lever open the fuse access cover and ease out the fuse holder.

After replacing the fuse with an identically rated fuse (see section 9), push the fuse holder firmly back into the inlet module and close the access cover.

The unit must be electrically safety tested for excess leakage current before being repowered from the mains supply.

7.2 Routine Cleaning and Inspection

The unit casework should be cleaned and inspected at regulator intervals, and whenever contamination or spillage occurs, as follows:

1. Switch off the unit and disconnect the power before performing any inspection checks or cleaning.
2. Before cleaning, always inspect the unit casework and Heated Modules for any signs of wear, damage, cracks or other defects.
3. Use a dry linen cloth or cotton bud to remove any dirt build-up on or around the electrical contacts of the Heated Module interface port. Do not wet these contacts as this will cause corrosion and malfunction.
4. Wearing suitable PPE, clean the casework using a damp cloth soaked with a disinfectant solution (such as Virkon).
5. Clean the display and buttons, taking care to avoid over wetting.
6. Check that the ventilation holes on the underside and rear of the unit are clear of dust and fluff build-up.
7. Check and carefully clean the Heated Module (refer to separate **Heated Module Instructions for Use** for details). Do not wet the electrical contacts on the base.

DANGER

After cleaning, ensure that the unit is thoroughly dry, especially around the mains power inlet, before reconnecting the power cord and switching the unit on.

7.3 Decontamination Procedure

The unit and accessories should be decontaminated using the following procedure before being stored or transported.

Certificate of Decontamination

We respect the health and safety of our customers and employees, and request that any products or accessories being returned are decontaminated in accordance with the procedure below.

1. Decontamination Procedure

Thoroughly clean all outside surfaces of the product (including any accessories, power cords, manuals, packaging, etc) with a damp cloth soaked with suitable disinfectant solution (such as Virkon).

Allow to dry fully before packing.

2. Decontamination Declaration

Company Name: _____

Address: _____

Product Code: Flexi-therm

Serial Number: _____

Reason For Return: _____

Where Product Used: _____

Please tick the appropriate option(s) below:

☐ I certify that I have decontaminated the product as per the above procedure.
Decontaminant Used: _____

☐ I certify that the product has not been exposed to any chemical or biological materials.

Title: _____ Name: _____

Signature: _____ Date: _____

Telephone: _____ Email: _____

7.4 Transportation and Storage

The Flexi-therm unit and its accessories should be thoroughly decontaminated using the procedure detailed in section 7.3 before being placed in its original packaging for transportation or storage.

WARNING

Refer to section 9 for the acceptable range of Storage and Transportation environmental conditions.

Always ensure that the unit and accessories are completely dry and free of any condensation before being packed.

7.5 Product Disposal

At end-of-life, this product must be disposed of in accordance with your local authority regulations for the disposal of potentially hazardous waste and electronic equipment.

The unit and its accessories should be decontaminated using the procedure detailed in section 7.3 before disposal or shipping.

Do not dispose of this product into unsorted municipal waste or public landfill.

Please contact your distributor (or ITL at the address on page 2 of this manual) for details of how to correctly dispose of this product.

8 Warranty and Returns

Integrated Technologies Limited (ITL) warrants the Flexi-therm product, when purchased new and installed and operated in accordance with the instructions of this manual, to be free from defects in materials and workmanship, and will repair or replace, at their discretion, any unit or accessory which exhibits such defects.

In no event will ITL be liable for any indirect, incidental or consequential damages resulting from any defect or warranty claim.

NOTE

Unspecified use or unauthorised modification of any part of the Flexi-therm unit or its accessories or the use or attachment of any adaptor or peripheral not supplied, specified or sanctioned by ITL will invalidate this warranty.

This warranty is provided to the original purchaser of the product for one year from the date of purchase.

Under the terms of this warranty, the product must be returned in its original packaging, transportation prepaid by the sender, with a copy of the Proof of Purchase and a detailed description of the problem.

WARNING

The product must be decontaminated using the procedure detailed in section 7.3 and a Certificate of Decontamination supplied with any return. If the product is considered too hazardous to be shipped, please contact ITL on the number given on page 2 of this manual for further instructions.

Please contact your distributor (or ITL on the number given on page 2 of this manual) to receive authorisation to return the product.

9 Technical Specification

Physical Unit Properties

Dimensions (W x D x H)	190 mm x 250 mm x 80 mm
Weight (without Heated Module)	1.7 kg

Mains Supply

Power Cord Rating	IEC C13, 3-Core, 5A min
Inlet Module Type	IEC C14, DPST, Single Fuse
Supply Voltage Range	100 to 240 VAC ±10%
Supply Frequency Range	50 to 60 Hz ±5%
Power Consumption	100 W max
Fuse Rating and Size	T1.6AH 250V 20x5mm

Operating Environment

Temperature Range	+10 to +38 °C
Relative Humidity Range	20% to 85% non-condensing
Maximum Operating Altitude	2000 m above sea-level

Storage and Transportation

Temperature Range	-10 to +50 °C
Relative Humidity Range	20% to 95% non-condensing

Temperature Control

Display Resolution	0.1 °C (0.0 °C to 99.9 °C) 1 °C (100 °C to 105 °C)

Timer Control

Display Resolution	1 minute (0 to 9 hours 59 minutes) 1 hour (10 to 72 hours)

Heated Modules

Operational Parameters	Refer to the **Heated Module Instructions for Use** for detailed specifications

10 Glossary of Terms and Abbreviations

ANSI	American National Standards Institute
Deepwell Plate	Plate with an SBS footprint featuring 48, 96 or 384 wells with a larger volume than microplates
DWP	Deepwell plate
EMC	Electro-Magnetic Compatibility
Microtiter Plate	Plate with an SBS footprint featuring 24, 48, 96 or 384 wells
MTP	Microtiter plate
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
SBS	Society for Bio molecular Screening
Semi-skirted PCR Plate	PCR plate with an outer surrounding half edge
Skirted PCR Plate	PCR plate with an outer surrounding edge
Un-skirted PCR Plate	PCR plate without an outer surrounding edge
Well	A single sample cavity in a Microtiter plate, PCR plate or Deepwell plate

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