

IVFtech Tube warmer



SERVICE MANUAL

CE

Symbols used in this manual



NOTE: Used to direct attention to a special item



WARNING: Used in case of danger of a serious accident

Each symbol might be followed by several bullets with warnings, notes, or recommendations.



- To avoid unintended or improper installation, service, maintenance, calibration, test, or repair of the IVFtech Tubewarmer, please read this Service Manual and the Tube warmer User Manual before you install or do any work on the Tube warmer. Keep this Service Manual for future reference.
- The proper function and safety of the IVFtech Tube warmer is only secured if installation, calibrations, tests, service, repair, and maintenance is performed in accordance with this Service Manual and the Tubewarmer User Manual.

IVFtech, Klintehøj Vænge 3
DK-3460, Birkerød
Tel: +45 3940 2565
Mail: info@ivftech.dk
Internet: www.ivftech.dk

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1 Introduction and overview of the Tube warmer



- Always read the Tubewarmer User Manual before you do any work on the Tubewarmer. Information, instructions, warnings, and precautions provided in the Tubewarmer User Manual is not repeated in this Service Manual. Therefore, you should always keep a copy of the Tubewarmer User Manual together with this Service Manual.
- Only trained and authorized service personnel are allowed to do any repair or replacements on the IVFtech products. If you need to replace or repair items not described in this Service Manual, you should always obtain further information from the IVFtech Service Support before you start.

1.1 Overview of the Tube warmer

The Tube warmer is designed to provide protections of the samples in the tubes by providing them with a constant and uniform temperature. Where it is meant to be used by professionals trained in using the Tubewarmer and trained in handling IVF samples.

- An example of a Tube warmer design is provided on the next page.

The Tube warmer is available with 3 different aluminum blocks with holes for 4, 12 or 14 tubes.

As an option all models can be equipped with rechargeable batteries that allows the use of the Tube warmer temporarily without any connection to the mains. An on/off switch and a power plug is located at the rear side of the Tube warmer. The display placed on the front is used to control the Tube warmer.

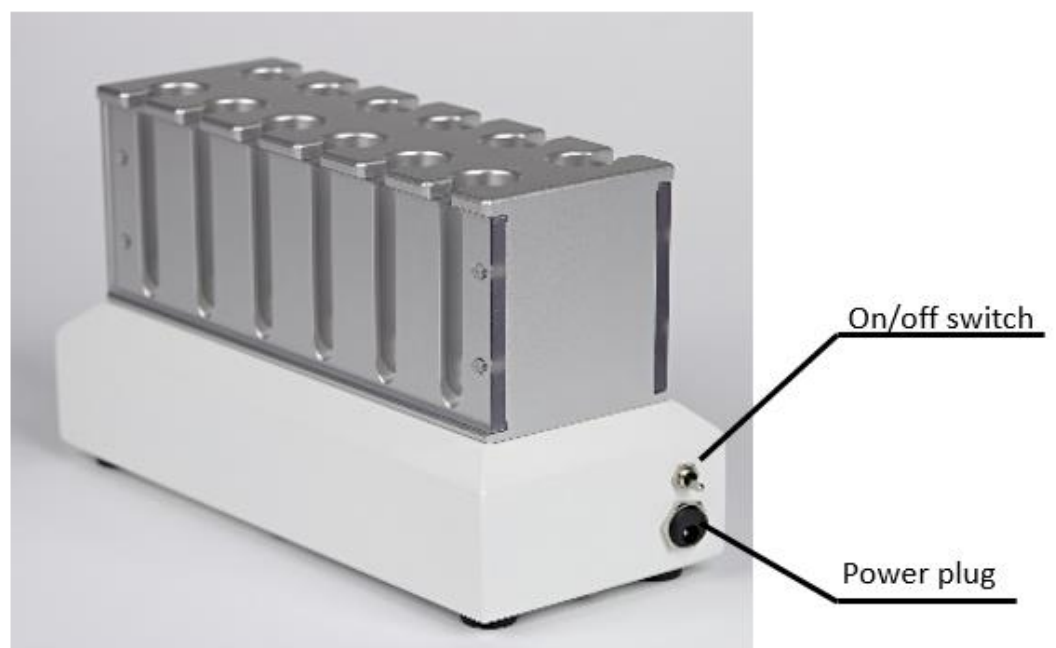
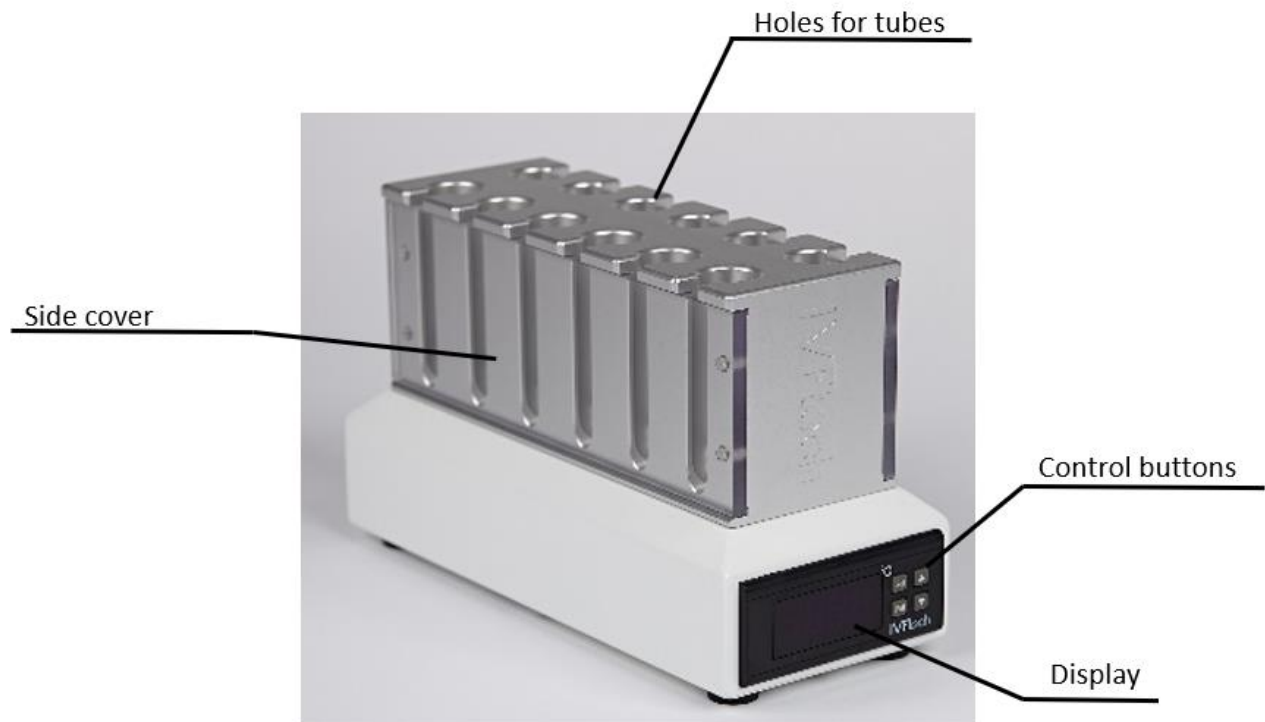
Tube variants of the Tube warmer:

Model	Tube diameter	Tube hole depth	Tubes supported
4 Tubes ¹	29,5 mm	65.5 mm	50 ml
12 Tubes	17 mm	68 mm	14 ml ²
14 Tubes	17 mm	68 mm	14 ml

¹ The 4-tube model is mainly used for animal samples

² 59 7x30.5x24.8 (NUNC) and 17x100 (FALCON)

Illustration of 12-tube Tube warmer:



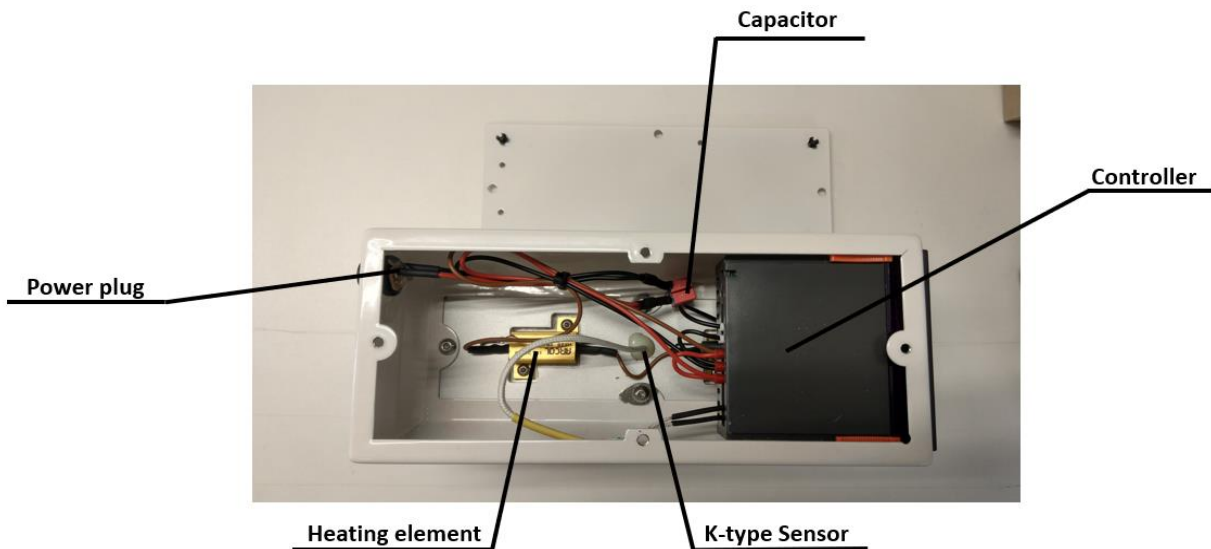
1.2 Overview of the main components



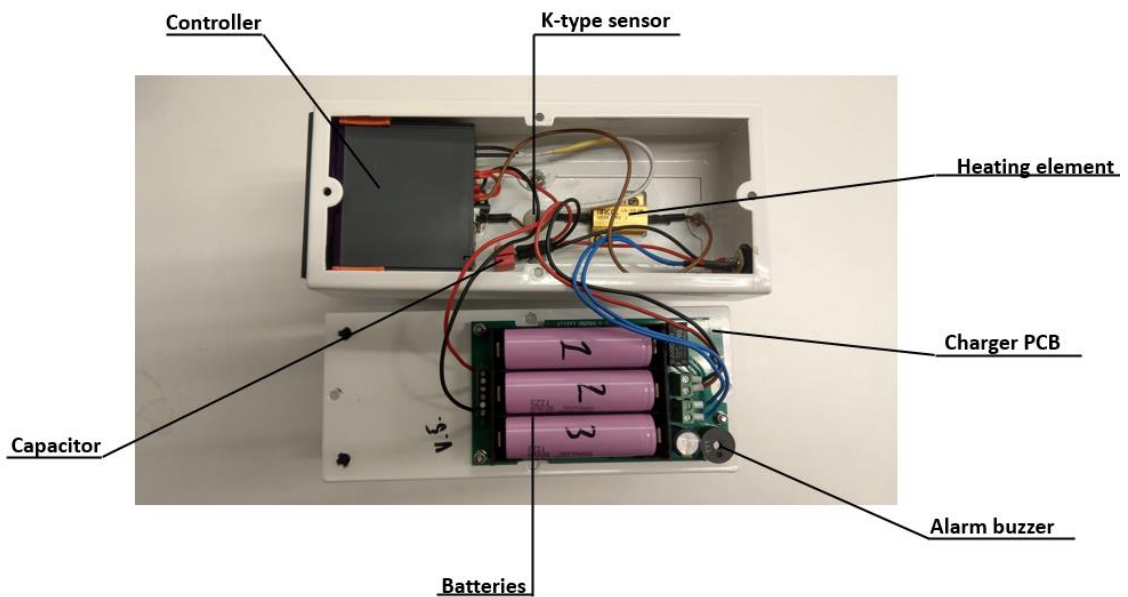
- Always supply the serial number of the Tube warmer when you order spare parts.

The main controller unit placed on the front of the Tube warmer also serves as its display. This is where targeted set point temperatures and off set temperatures can be adjusted. On the bottom of the Tube warmer a cover plate can be removed by using a screwdriver to access the electronics.

Tube warmer without battery:



Tube warmer with battery:



As shown on the illustrations on the previous page, the inside of the Tube warmers with and without battery is similar except from the battery part. Both have the same basic construction with two heating elements, two capacitors and the K-type sensor drilled directly into the aluminum block for best accuracy of measurements.

Both models of the Tubewarmer are using the same controller/display, for temperature control and calibration of the temperature off sets.

The charger PCB of the Tube warmer battery version is mounted on the cover plate and can be unfitted using a screwdriver. The charger PCB has a slot for three batteries and a buzzer for low battery level alarm.

1.2.1 Temperature control unit

The Tube warmer is equipped with an IVFtech temperature controller identical for all Tube warmer variants. This controller acts as a main controller. Via the 4 control buttons the following parameters can be adjusted: Targeted Set Temperature, Offset Temperature, Higher Temperature Limit and Lower Temperature Limit.

Within approximately 40 minutes the Tube warmer will be fully stabilized for the target set temperature.



2 Installation of the Tube warmer



- Proper function of the Tube warmer is only secured if installation, calibration, tests, services, repairs, and maintenance is performed in accordance with the Tube warmer User Manual and this Service Manual. After installation, relocation, maintenance, repair, and before first use, the Tube warmer must be properly cleaned, disinfected, and tested as described in this Service Manual and the Tube warmer User Manual. The test results should be documented in a “Service, Repair, and Maintenance Log-book” for the Tube warmer.

2.1 Transport, relocation, and storage of the Tube warmer

The Tube warmer is small and light enough to be carried around.



- When transporting or relocating the Tube warmer is required, always take precautions to prevent the Tubewarmer from slipping or dropping. This might cause serious damage to the Tube warmer.
- In order to prevent damage, the Tube warmer must always be handles as fragile goods.
- Storage of the Tube warmer must be in an environment with maximum 75% relative humidity and temperatures between 5°C and 50°C.

2.2 Preparations before installation of the Tube warmer

Make sure that you have space planned for the Tube warmer and space planned for charging if the Tube warmer is with batteries.

The Battery is charged to 30% capacity from the factory, so make sure to have charging planned before first use.

2.2.1 Intended environment for the Tube warmer

To ensure safe operation of the Tube warmer, please note the following recommendations regarding the intended use environment.



- The Tube warmer is intended for indoor use only.
- Only use the Tube warmer in a clean environment (operating environment of Pollution Degree 2 or below).
- The Tube warmer may only be operated at temperatures between 20°C and 35°C with a relative humidity between 30 and 75%.
- The Tube warmer should be used away from any heaters, ventilators, coolers, air-conditioning units, and air outlets.

Recommendations for using or placing the Tube warmer near other equipment:



- Use of the Tube warmer adjacent to or stacked with other equipment should be avoided. It could result in improper operation. If such use is necessary, both the Tube warmer and the other equipment must be monitored to verify that they are fully functional.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Tube warmer, including cables specified by the IVFtech. Otherwise, degradation of the performance of the Tubewarmer could result.
- Use of accessories, transducers, and cables other than those specified or provided by your IVFtech distributor could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Tube warmer. This can result in improper operations.

2.3 Unpack the Tube warmer



- It is recommended to unpack the Tube warmer outside the laboratory. This minimizes the introduction of unnecessary particles in the clean air environment.

The Tube warmer is packed inside a cardboard box, where it is protected by a layer of packaging film and furthermore 2 foam pieces in each end of the Tube warmer. When you unpack the Tube warmer, remove the protective film and foam, you will find the following parts in the package:

- Tube warmer
- Power cord
- Power adapter
- User Manual
- Factory Test Report

When you have unpacked the Tube warmer, always make sure that all necessary parts have been delivered. If there are any discrepancies, please contact IVFtech Sales.

2.3.1 Disposal of packaging material

Please dispose the packaging material in accordance with the local regulatory requirements. The shipping materials are comprised of cardboard, foam, and plastics.



2.4 Connect the Tube warmer to the mains

Please note the following warnings when you connect the Tube warmer to the mains.



- Always comply with the safety requirements of the local power supply company.
- The Tube warmer must always be connected to mains using the provided power adapter and power cord.

The power plug is placed on the back of the Tube warmer. Connect the Tube warmer to the mains using the provided power adapter and the provided cord. If your Tube warmer has an on/off switch it is used to turn on the Tube warmer. Otherwise, the Tube warmer is automatically turned on when it is connected to the mains.



2.4.1 Clean and disinfect the Tube warmer

The Tube warmer must be cleaned and disinfected before first use. It is recommended to use “Oosafe disinfectant for CO² incubators and laminar flow hoods” from SparMed (www.Sparmed.dk). The cleaning and disinfection procedures are described in detail in the Tube warmer User Manual.

2.4.2 Test the Tube warmer

After installation, the Tube warmer should be tested before actual use.

It is recommended to conduct the following tests as a part of the installation:

- Temperature test and calibration
- Battery test

The test results should be noted in a “Service, Repair, and Maintenance Log-book” for each Tube warmer.

3 Setting up the Tube warmer

The Tube warmer is as mentioned controlled by the controller/display placed on the front of the Tube warmer. In this controller the user can set up the following key parameters:

- Set Target Temperature
- Set Minimum Temperature Range
- Set Maximum Temperature Range
- Set Target Offset Temperature

Please note the following:



- The default target temperature is adjusted for 37.0°C.
- The Tube warmer does not have a cooling function. Therefore, it is not possible to obtain a temperature that is lower than the surrounding temperature.

3.1 Set the target temperature level

The target temperature is the temperature that the Tube warmer stabilizes towards. The target temperature is the same for all tube holes. To change the target temperature do as follows:

1. Press and release the “SET” button. The “SET” light in the display will flash and the current target temperature will be shown in the display.
2. Use the up/down arrows to adjust the target temperature.
3. Press “Rst” button or wait 10 seconds to store the new target temperature. The display will return from the settings menu and show the currently measured temperature.

In the example below, the target temperature is changed from 37.2°C to 37.0°C. The starting point of each arrow indicate the button that must be pressed to obtain the screen shown at the ending point of the corresponding arrow.



3.2 Set the minimum allowed target setting



- If you change the minimum/maximum allowed target setting, the target temperature level might accidentally be adjusted to an extremely low or extremely high value.

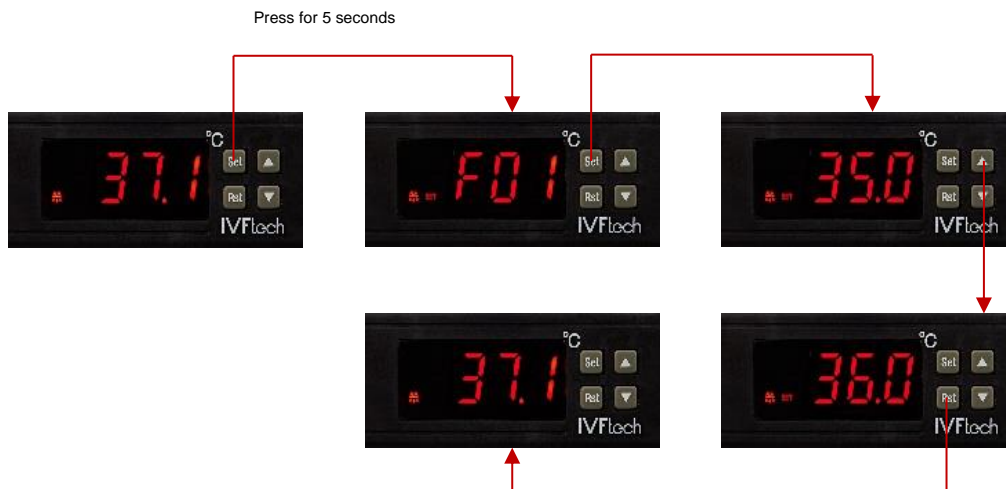
As a safety feature, the default factory setting allows you to set the target temperature between 35°C and 40°C. If you need to set your target temperature outside this range, the minimum and maximum allowed target setting can be adjusted.

To adjust the minimum allowed target setting, do as follow:

1. Press the “Set” button for five seconds until “FO1” appears.
2. Press and release the “Set” button.

The currently minimum allowed target temperature is shown in the display.

3. Use the up/down arrows to change the allowed minimum temperature.
4. Press the “Rst” button or wait 10 seconds to store the new minimum value.

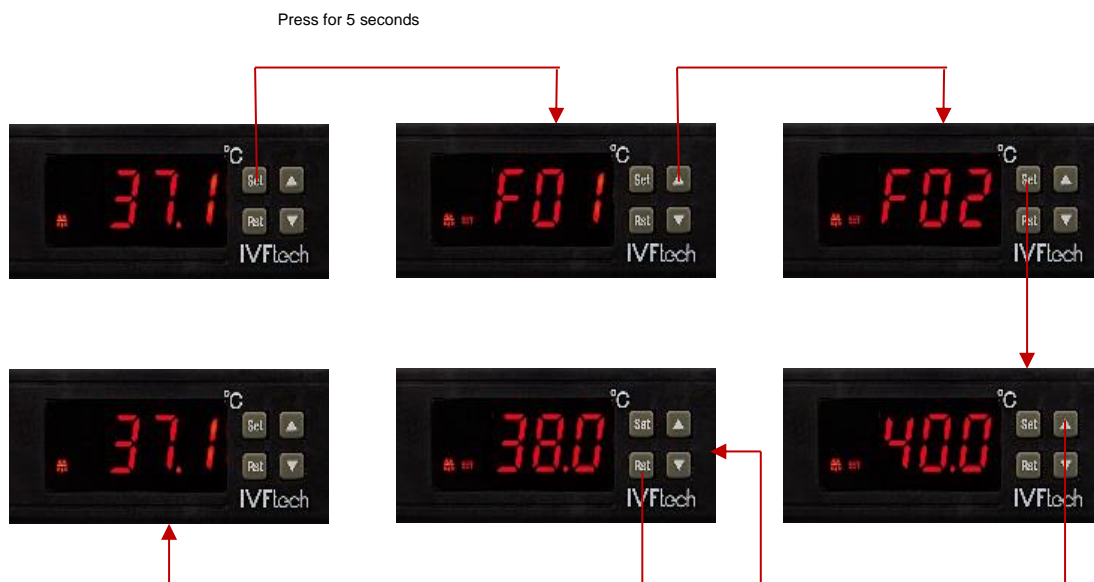


3.3 Set the maximum allowed target setting

1. Press the “Set” button for five seconds until “FO1” appears in the display.
2. Press the up/down arrows until “FO2” appears in the display.
3. Press and release the “Set” button.

The currently maximum allowed target temperature is shown in the display.

4. Use the up/down arrows to change the allowed maximum temperature.
5. Press the “Rst” button or wait 10 seconds to store the new maximum value.



4 Test and calibration of the Tube warmer



- All tests should be documented in a “Service, Repair, and Maintenance Log-book” for each Tubewarmer
- The tests described in this chapter are recommended by IVFtech. Always validate the test procedures with the quality policy of the individual clinic/laboratory and local regulatory requirements.

4.1 Temperature test and calibration

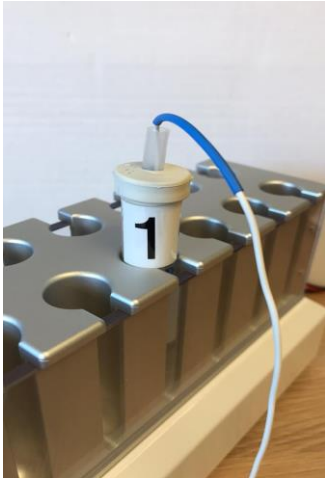

The temperature controller should be tested and calibrated before using the Tube warmer for the first time and after all kind of maintenance and repair. It is also recommended to test and calibrate the temperature controller as a part of the yearly preventive service.




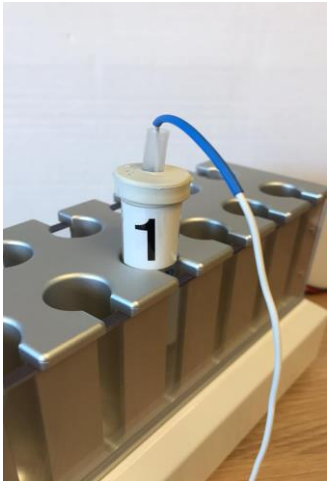
The purpose of this test is to ensure the accuracy of the temperature sensors. The temperature controller needs to be showing the same temperature as a calibrated reference thermometer and sensor.

Recommended test equipment:

- Calibrated reference thermometer

Recommended test procedure:

1		<p>Prepare the Tubewarmer for the test:</p> <p>Start up the Tube warmer and wait until it has stabilized - approximately 30 minutes.</p> <p>Fill purified water or silicone oil into a test tube and put the test tube in one of the Tubewarmer tube holes.</p> <p>Place the calibrated reference probe into the tube.</p>
2		<p>Test the temperature controller:</p> <p>Read the temperature measured by the calibrated reference thermometer and the temperature from the controller display.</p> <p>If the values obtained from the reference thermometer and the controller are different, the controller should be calibrated (go to step 3). If the values are sufficiently similar, no calibration is needed (go to step</p>

3		<p>Calibrate the temperature controller, if necessary:</p> <p>To correct the controller, start with holding in the “SET” button for 5 seconds.</p>
4		<p>Calibrate the temperature controller, if necessary:</p> <p>Thereafter the “FO1” menu will appear. Use the up and down arrows until you find the menu called “FO3”.</p>
5		<p>Calibrate the temperature controller, if necessary:</p> <p>Press the “SET” button to enter the “FO3” menu.</p> <p>You can now use the up and down arrows to set the offset adjustment.</p> <p>Press “Rst” or wait 10 seconds for the controller to return to the main display and save the adjustments.</p>
6		<p>Finish the test and calibration:</p> <p>Allow the system to fully stabilize (approximately 30 minutes). Read the temperature measured by the calibrated reference thermometer and the temperature from the Tube warmer display. If the measurements are sufficiently similar, the test is finalized.</p> <p>Document the test results and any necessary calibration in a “Service, Repair, and Maintenance Log-book” for the individual Tube warmer.</p>

5 Service and preventive maintenance

All maintenance, repairs, replacements, calibrations, tests, and changes must be documented in the “Service, Repair, and Maintenance Log-book” for each Tube warmer. This includes both services performed by an authorized service technician and maintenance performed by the user. The logbook is found as an appendix in the Tube warmer User Manual.



- To ensure safety of the authorized service technician, the Tube warmer must be properly cleaned and disinfected before any kind of service, repair, maintenance, or change of location. The laboratory manager / safety manager must confirm this in writing to the authorized service technician (see appendix A).
- Always turn off the Tube warmer before any replacement, repair, or modifications.

5.1 Service plan overview

The Tube warmer should go through a preventive service check **once every year**. This ensures the continues reliability and compliance of the Tube warmer. This service check must be conducted by an authorized service technician. The service check should be documented in a “Service, Repair, and Maintenance Log-book” together with any replacements, calibrations, and test results. It is the responsibility of the user to arrange the service check with the local IVFtech distributor. An overview of the required replacements for each service check is provided below:

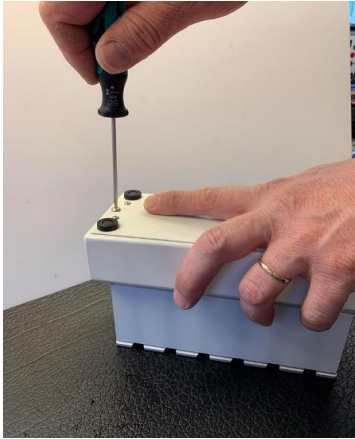
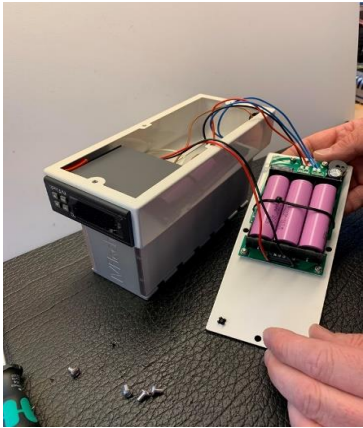
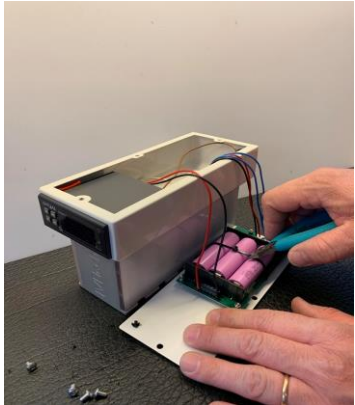
Task	Recommended Frequency	Instructions
Test and calibration of temperature controller	Every year	See section 4.1
Change of batteries (battery model)	Every year	See section 5.2

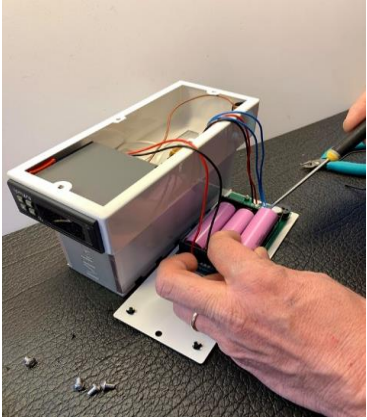


5.2 Change of batteries

This section describes how to change the three 12V rechargeable batteries.

For daily use it is recommended to change the batteries once a year.

Recommended procedure:

<p>1</p>		<p>Gaining access to the batteries:</p> <p>The first step is to unscrew the four screws in the bottom of the Tube warmer.</p>
<p>2</p>		<p>Gaining access to the batteries:</p> <p>Remove the bottom cover and the batteries are now visible.</p> <p>After bottom cover is removed it should look like the picture on the left.</p>
<p>3</p>		<p>Removal of the batteries:</p> <p>The three pink batteries are being held together with a black strip.</p> <p>Cut off this black strip to release them.</p>

<p>4</p>		<p>Dismounting the batteries:</p> <p>Remove the three 12V rechargeable batteries one by one.</p> <p>NOTE:</p> <p>In case of the batteries are difficult to remove by hand, carefully push them up with a screwdriver.</p>
<p>5</p>		<p>Mounting the new batteries:</p> <p>Mount the new three 12V rechargeable batteries in the battery slots.</p>
<p>6</p>		<p>Closing the Tube warmer</p> <p>When all the new rechargeable batteries are inserted, they should be tightened with a plastic strip.</p> <p>Remount the bottom cover.</p> <p>The batteries have now been changed.</p>

6 Troubleshooting



- If this troubleshooting guide, doesn't help to fix the problem, please contact IVFtech Service Support for further guidance.
- Always turn off the power before you perform any replacements on the electrical parts.

What is wrong?	How to fix it....
<p>The display on the Tube warmer does not show the menu</p>	<p>Make sure that the power is turned on (see sections 2.4 and 3.3 in the Tube warmer User Manual).</p> <p>Connect the Tube warmer to the mains (see sections 2.4 and 2.2.3 in the Tube warmer User Manual)</p>
<p>The Tube warmer has an unexpected temperature ref to the setpoint</p>	<p>Make sure that the target temperature has been defined correctly (see section 3.4 in the Tube warmer User Manual)</p> <p>Test the Tube warmer and calibrate the temperature sensor and controller, if necessary (see section 4.1 and 3.5 in the Tube warmer User Manual).</p>
<p>The battery life is lower than specified in the User Manual and Technical Specifications</p>	<p>Note that the battery life is prolonged by connecting the Tube warmer to mains power during the heating up phase.</p> <p>If the battery begins to perform lower than specified, it might be time to replace the batteries. This must be done by an authorized service technician. Contact your local IVFtech distributor to schedule a battery change.</p>

Appendix A: Statement regarding safety for repair/inspection

IVFtech is legally obliged to protect its employees from all dangers.

We therefore kindly ask you to complete this statement before any work is initiated.

Subject: Service report No. _____ Service agreement No. _____

The undersigned hereby declares that the above repair/inspection will not expose the service technician to hazardous biological, chemical, or radioactive agents. Reservations, if any, may be indicated here (e.g. use of gloves, respiratory gear, etc.).

Date	Name in capital letters	Signature