

Cook Australia

William A Cook Australia Pty Ltd ACN 005 526 723

K-FTH-1012

TEST TUBE HEATER

USER INSTRUCTIONS

Please familiarise yourself with the safety instructions before using the device. Accessories and devices may be used only by physicians and medical assistants with the appropriate technical qualification.



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EXPLANATION OF PICTOGRAMS



Before connection, read operation manual



Direct current



Type B equipment



Test Tube Heater

IP RATING 64

Protection against dust and water sprayed from all directions.

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GENERAL INFORMATION

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WARNING

- Any adjustment, modification or repairs to the equipment should be carried out by persons authorised to perform them.
- The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements.

Some of the parts and equipment referred to in this manual bear registered trademarks but are not identified as such. It should therefore not be assumed that the absence of the trademark indicates that any given designation is not subject to trademark protection.

Users of WILLIAM A. COOK AUSTRALIA PTY LTD products should not hesitate to point out to us any errors or ambiguities in this manual.

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Document No. MNM30013
Version No. 2
Date: November 2001

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HOW TO USE THIS MANUAL

Read this manual

Please familiarise yourself with the contents of the manual before using the device. Failure to follow these instructions may result in injuries to both the patient and the user. Medical accessories and devices may be used only by physicians or medical assistants under the direction of a physician with the appropriate technical qualification.

Please read this manual completely and follow its instructions carefully. The words **WARNING**, **CAUTION** and **NOTE** carry special meanings and they should be read carefully.

WARNING!

The personal safety of the patient may be involved. Disregarding this information could result in injury to the patients.

CAUTION!

These instructions point out special service procedures or precautions that you must follow to avoid damaging the device.

NOTE!

This provides special information that facilitates maintenance or clarifies important instructions.

Please pay particular attention to the chapters **Safety Instructions** and **Purpose of the Device**.

Who should use the manual

The manual is addressed to physicians or medical assistants with an appropriate qualification. These persons are authorised to operate this device.

The structure of the manual

The big titles in the header help you to find the chapters quickly. With the help of the smaller titles on the left side of each page, you can skip from chapter to chapter.

The numbers in parentheses correspond to the numbering in the accompanying illustration.

There is a list of error messages and warning indications at the end of the manual that should help you to troubleshoot problems.

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1. SAFETY INSTRUCTIONS

Please familiarise yourself with the safety instructions before using device!

Federal law

Federal Law (U.S.A.) restricts this device to use by or on the order of a physician.

Warranty

The manufacturer warrants that the device and the accessories will be free from manufacturing and material defects for one year from date of purchase. This warranty is limited to the terms and conditions described herein, and there are no other warranties, expressed or implied.

No liability

The manufacturer is not liable for direct or resulting damage and the warranty becomes void if:

- the device or the accessories are improperly used
- the instructions and rules in the manual are not adhered to
- the device or the accessories are improperly prepared or maintained
- non-authorised persons perform repairs, adjustments or alterations on the device or accessories
- the prescribed maintenance schedule is not adhered to

If the manufacturer provides you with technical documentation, this does not authorise you to perform repairs, adjustments or alterations on the device or accessories.

Care and maintenance

To guarantee safe operation, it is absolutely necessary to carry out proper care and maintenance of the device and accessories. For the protection of the patient and the operating team, check that the device is complete and functional before each use.

Brand new products as well as repaired products must be prepared and tested according to the manual instructions before you use them for the first time.

Service technician

The manufacturer has the exclusive right to train and certify authorised service technicians.

Contamination

All devices or accessory parts that are sent in to be repaired must be prepared for transportation as described in the manual, for the protection of the service personnel and for safety during transportation. If this is not possible, the contaminated product must be clearly marked with a contamination warning and should be doubly sealed in safety foil.

The manufacturer has the right to refuse to carry out repairs if the products it receives are contaminated.

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1.1 Warnings

Reading the manual	<p>This manual describes the operation and the intended use of the device and the accessories.</p> <p>It is essential to use this manual to familiarise yourself with the functions and the operation of the device before using it in the operating room.</p> <p>Not following the manual instructions can result in serious injury to the patient or the operating team and can lead to damage or breakdown of the device and accessories.</p>
Professional qualification	<p>This manual does not provide a detailed description of operation technologies, nor is it suitable for introducing a beginner to this operating technique. Medical accessories and devices may be used only by physicians and medical assistants under the direction of a physician with the appropriate technical qualification.</p>
Replacement device and accessories	<p>In case the device fails during an operation, a replacement device and replacement accessories should be kept within reach so that the operation may be completed.</p>
Specific device warnings	<p>Read the warnings specific to this device under Section 2, Purpose of the Device.</p> <p>The manufacturer has the right to refuse to carry out repairs if the products it receives are contaminated.</p>
Available voltage	<p>Determine if the available voltage corresponds to your device. Working with the wrong voltage will cause malfunction or destruction of the device.</p>
Not explosion proof	<p>Electrical components are not explosion proof. Do not use in an area where flammable gases are present.</p>
Risk of electrical shock	<p>To reduce the risk of electrical shock, do not remove cover (or back). Refer servicing to qualified service personnel.</p>
Replacing fuse	<p>For continued protection against fire hazards, replace the fuse only with a fuse of the same type and rating.</p>
Internal temperature setting	<p>The operating temperature of the device is factory pre-set to a user specified value, prior to delivery. The set temperature may not be that required by a doctor during an operation, for which the doctor is responsible.</p>
Cleaning the device	<p>Do not sterilise the device.</p>

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2. PURPOSE OF THE DEVICE

The K-FTH-1012 Test Tube Heater is an electronically controlled heating unit that accepts collection test tubes and their contents during oocyte recovery. The unit is designed to accept up to six Falcon® 2001 Series 10 ml Test Tubes.

2.1 Warnings

Power Supply

Electrical shock hazard present. Do not use in the presence of flammable anaesthetics. No attempt should be made to open the unit casing. Should any electrical or mechanical fault occur while using the K-FTH-1012, please contact your nearest authorised service technician or COOK® Distributor.

2.2 Cautions

Device Deficiency

If a device is suspected or confirmed of being deficient, stop using the device until it has been checked by authorised service personnel.

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3. INITIAL USE OF THE DEVICE

Initial inspection

Check the device and all accessories immediately upon receipt to make sure the contents are complete and that nothing is damaged. The manufacturer will only honour claims for compensation which are forwarded immediately to the sales representative or the authorised service company.

Returning the device

If it becomes necessary to return the device, use of the original packaging is required. The manufacturer does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging. Please enclose the following information with the device:

- owner's name
- owner's address
- model type
- serial number of the equipment (see identification plate)
- description of the damage

Setting up the device

Place the device on a level surface in a dry place. The recommended ambient temperature should be between +15-+30 °C (+59-+85°F), and the relative air humidity should be between 10-90%.

Power supply connection

The K-FTH-1012 is powered from either the rear outlet socket on the K-MAR-5100 or the K-APS-200 (220-240 Vac) or K-APS-100 (100-120 Vac) power supply.

CAUTION!

Determine if the available voltage corresponds to your device. Working with the wrong voltage will cause the device to malfunction or may permanently damage the device.

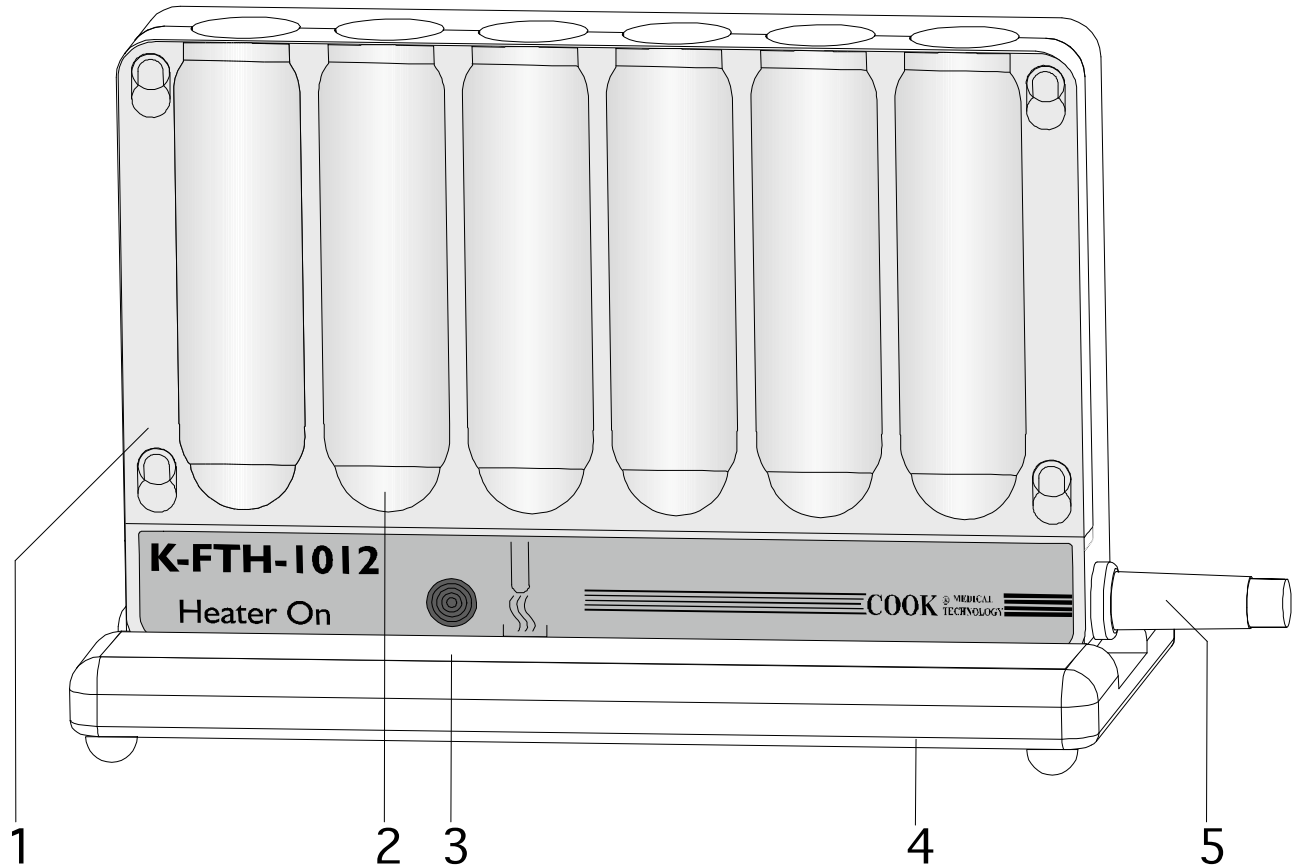
The electrical components are not explosion proof. Do not use in an area where flammable gases are present.

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4. OPERATION OF THE DEVICE

4.1 Front of the Device



1. Removable acrylic cover (re-order code K-FTH-1012-CP)
2. Test Tube heating compartments
3. Heater On indicator light
4. Removable acrylic K-FTH-1012 stand (re-order code K-FTH-1012-AS)
5. Power cable entry

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4.2 Rear of the Device



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4.3 Turning the Unit On

Connect the power cable of the unit to the socket outlet on the rear of the K-MAR-5100 vacuum pump.

The amber indicator light (3) will glow and a short single tone will sound when the power supply is turned on.

4.4 Initial Heating of the Unit

1. When the power supply has been turned on, the amber indicator light (3) will glow continuously, if the unit is not already heated to the operating temperature.

Note: *If beginning at ambient room temperature the unit takes approximately five minutes to heat up to the optimal operating temperature. During this time the amber indicator light (3) will glow continuously.*

2. When the unit has reached the set operating temperature the amber indicator light (3) will begin to flash slowly. The unit is now ready to be used.
3. Throughout the use of the unit the operating temperature will be thermostatically maintained.
4. If the power supply is less than approximately 10 V DC an audible tone will sound indicating not enough heat is generated to maintain the set temperature.
5. The temperature of the K-FTH-1012 is factory pre-set to 36.9°C at room temperature. Alternatively different temperatures may be nominated and set prior to delivery.

4.5 Placement of Test Tubes

1. The K-FTH-1012 has been designed to accept Falcon® 2001 Series Test Tubes. Any number, up to six can be used at the same time.
2. All test tubes should be placed in the test tube heating compartments (2) through the openings in the top of the unit. The test tube should fit snug in the appropriate test tube heating compartment (2) without using excessive force.
3. No lubricant should be used on the outside of the test tube or in the heating compartment (2).

4.6 Turning the Unit off

1. When the power supply to the K-FTH-1012 is disconnected, the amber indicator light (3) will turn off. A single audible tone will also sound to alert the user to power disconnection.

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5. ALARM CONDITIONS

The K-FTH-1012 uses both audible and visual indicators for a variety of conditions.

5.1 Unit Insufficiently Heated

When the unit is "ON" but not at the operating temperature the amber indicator light (3) will glow continuously. The unit should not be used when in this condition.

5.2 Unit at Operating Temperature

When the unit has reached its operating temperature (within approx. 1°C) the amber indicator light (3) will begin to flash slowly. The unit should only be used when in this condition.

5.3 Overheating Alarm

If the temperature of the unit exceeds the preset temperature a secondary safety circuit will be activated preventing overheating of the test tube contents. In this alarm condition:

- the amber indicator light will turn off and no further heating of the unit will occur.
- a continuous audible tone will sound until the temperature drops to preset temperature.

***Note:** If the ambient temperature of the environment is high, the overheating alarm may activate. The unit will not commence heating until the ambient temperature falls below the preset temperature. The overheating alarm will activate again when the temperature of the unit exceeds the preset temperature. This cycle will be repeated as long as the ambient temperature remains high.*

5.4 Disconnection Alarm

Each time the power supply to the unit is disconnected or turned off a single audible tone will sound to alert the user.

5.5 Insufficient Power Alarm

If the power supply drops below approximately 10V DC the audible tone will sound.

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6. SERVICE AND MAINTENANCE

To preserve the device and ensure its proper functioning, proper service, maintenance and storage must be provided for. To protect the patient from infections, all accessory items that come into contact with human tissue (example test tubes and tubing) must be sterile. Accessory items must be discarded after each patient use.

6.1 Cleaning the Device

After each use, remove the power cable from the connection at the rear of the unit.

Use a hydrous disinfecting solution or a 70% isopropyl alcohol solution to clean the exterior of the device. Follow instructions provided by the disinfectant manufacturer to determine the correct fluid concentration. Moisten a cloth with the disinfectant solution and wipe the surface of the device. The front acrylic panel may be removed in order to facilitate cleaning. Do not submerge the unit in the disinfectant solution.

CAUTION! Do not sterilise the device!

6.2 Biannual Inspection

IEC 601-1 Regulation

The IEC 601-1 stipulates that the user or a hospital technician must regularly test the device to assess its functionality and technical safety. These tests must be performed on a biannual basis.

Regular inspections will assist in early detection of possible malfunctions. This helps preserve the device and maintains its safety.

6.3 Inspection by the Authorised Service Technician

Inspections at least once a year

To guarantee the operational safety of the device, the device must be maintained at regular intervals by an authorised service technician. Depending on the duration and frequency of use, the device should be maintained at least once a year. Failure to adhere to this maintenance schedule will result in the manufacturer refusing liability for the operational safety of the device.

Authorised service technicians

All services such as alterations, repairs, calibrations etc., may only be performed by the manufacturer or by service technicians who are authorised by the manufacturer.

Unauthorised service technicians

If an unauthorised service technician performs inspections or any other service, the manufacturer will not accept liability for the operational safety of the device.

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Liability	The manufacturer is free from all liability for the operational safety of the device if the device has been wilfully opened and unauthorised persons have performed repairs or alterations on it.
Certification	The device owner should receive a certificate from the service technician for all inspections or repairs. This certificate states the type and scope of the services rendered, the service date and the name of the service company. The certificate should be signed.
Technical documentation	If the manufacturer provides you with technical documentation, this does not authorise the user to perform repairs, adjustments or alterations to the device or accessories.

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7. TECHNICAL DATA

Power Supply	12V DC ($\pm 15\%$)
Power consumption (max)	18W
Max. current	1.5A
Protection class	Type B
Dimensions	Width x Height x Depth 150 x 100 x 28mm 6 x 4 x 1 inch
Weight	0.7kg (1.5 lbs.)
Recommended Operational Environment	+15 to +30°C (+ 59 to +85°F) 10-90% relative air humidity
Accuracy	Set temperature to $\pm 1.0^\circ\text{C}$ over recommended operational range.
Storage and Transportation Directions	-40 to +70°C/-40 to +159°F 10-100% RH
Manufactured and Tested to following standards	AS3200.1/IEC 601-1 IEC601-1-2
	Directive 93/42/EEC
Cord Length	1.5m

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8. TROUBLESHOOTING INSTRUCTIONS

Error and Alarm Indicator	Source of Error	Elimination of Error
Indicator light does not illuminate	Power supply is not connected Incorrect voltage	Check the power supply connection Check the output of power supply if not connected to the K-MAR-5100 unit
Indicator light does not illuminate and a single continuous tone sounds	Factors in the environment may have warmed the unit above the preset temperature	Check the ambient temperature and remove the unit to cooler environment. Allow the unit to cool for 10 minutes and then turn on. If the unit heats up but then sounds the overheating alarm again, contact your nearest service centre.
A continuous audible tone sounds	Power supply inadequate	Check that the power supply lead is connected firmly into the outlet socket at the rear of the K-MAR-5100 unit. If using an external power supply check that it is rated to output 12V/1.5A

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9 LIMITED WARRANTY

COOK AUSTRALIA warrants to the purchasers of this device that at time of manufacture, the product was prepared and tested in accordance with good manufacturing practices and guidelines specified by the Australian Therapeutic Goods Administration or relevant competent authority.

In the event of product failure under normal use, due to defects in material or workmanship, within a period of one (1) year from the date of purchase, the product will be repaired, or at Cook's option, replaced, at no charge. This limited warranty does not apply to products subjected to abnormal use or damaged by accident, misuse, improper line voltage or to products altered or serviced by anyone other than Cook Australia or its authorised agent.

The foregoing limited warranty is exclusive and in lieu of all other warranties whether written, oral, expressed or implied. In particular, Cook Australia does not warrant that the product is suitable for the needs of the purchaser and there are no warranties given as to merchantability or fitness for a particular purpose. Cook Australia's representations concerning fitness for purpose or suitability for use by any purchaser does not extend beyond those representations set out in the Cook Australia literature that accompanies the product. Cook Australia assumes that the purchaser is experienced in the use of this device and is able to judge from his/her own expertise the suitability or otherwise of the product for the intended use. Cook Australia conducts a technical advisory service which can be consulted by a purchaser or intended purchaser on an advisory basis.

After one (1) year from the date of purchase, this device will be repaired for a repair charge equal to the cost of parts, labour and transport.

Before returning a product for any reason, please contact your nearest Cook distributor for assistance and instructions.

Because Cook Australia has no control or influence over the conditions under which this device is used, over its method of use or administration, or on handling of the product after it leaves its possession, Cook Australia takes no responsibility for the results, use and/or performance of the product. Cook Australia expects that use of the product will be confined to trained and expert users.

In no event will Cook Australia be liable for any direct or indirect damages including incidental, consequential or special damages, arising out of or in connection with the use or performance of the product.

Cook Australia reserves the right to change or discontinue this product without notice.

No representative of Cook Australia and no vendor or lessor of the product is authorised to change any of the foregoing terms and conditions, and the purchaser accepts the product subject to all terms and conditions herein, subject always to any contrary provisions which are necessarily implied by statute or law notwithstanding the within terms and conditions.

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