Cool-Cut

Sample Cooler (for use with rotary microtomes)

Operator Guide

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epredia

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CE IVD

These instruments conform to the essential requirements of:

- In Vitro Diagnostic Regulation (IVDR) EU 2017/746

Symbols

The following symbols and conventions may be used throughout this document and on the instrument:

This symbol is used on the instrument, or in a document, to indicate that instructions must be followed for safe and correct operation. If this symbol appears on the instrument, always refer to the operator guide.

This symbol is used on the instrument, or in a document, to indicate that irritants or potentially harmful chemicals are present. Refer to the Material Safety Data Sheets for the products, and always use Good Laboratory Practice.

Separate taking back of electrical and electronic instruments in the countries of the European Union: This is to be applied in the countries of the European Union and other European countries with a separate collecting system within the waste management. This product, being an electro and/or electronic instrument, must be treated separately within the waste management process (WEEE).

This symbol is used on the instrument, or in a document, to indicate that there are potential biological risks associated with the instrument and / or instrument use. Always use Good Laboratory Practice.

Manufacturer

Cold surface, if necessary, use gloves

Cutting hazard, sharp edges, watch your fingers

Consult Instructions for Use

A warning is given in the documentation if there is a potential risk of injury, equipment failure or poor tissue sample processing outcome.

Note

Notes give additional information about a job or instruction, but do not form part of the instruction.

Contents

Safety Information

Introduction

Epredia instruments are designed for convenient and reliable service; however, improper use or handling by a user may damage the instrument or cause a hazard to health. The instrument must not be used in a manner not specified by Epredia. Correct maintenance procedures are essential for consistent performance. It is recommended that users secure a maintenance contract with our service department.

Any problems and queries should be referred to your Epredia service department.

The following sections contain important information for the safe setup and use of the instrument and should be read and understood by the user before using the instrument.

General Safety

This instrument, as supplied, conforms to IEC 61010-1 and IEC 61010-2-101. Good Laboratory Practice must be employed, and consideration must be given to the potential for hazard when dealing with these chemicals.

Do not use the instrument in close proximity to strong electromagnetic radiation, as these may interfere with the proper operation. The electromagnetic environment should be evaluated prior to operation of the device.

Good Laboratory Practice must be used when handling tissue samples to prevent cross contamination and infection. The user should complete a risk assessment to determine any potential hazards related to tissue handling.

Related to the potential hazards of the specimens to be processed personal protection measures shall be considered:

- protection gloves
- surgical mask
- decontamination activities

- Do not remove any panels or access covers, unless specifically instructed to do so. The instrument does not have any user serviceable parts. Potentially lethal voltages are present inside the instrument.
- The device may only be used with the original power supply or an original replacement. Only power supply type FW8030M/08 should be used.
- Use only factory approved accessories or replacement parts within the instrument.
- Only use cleaning reagents recommended in the operator guide.

Chemical Safety

The introduction of chemicals creates potential hazards. Epredia has adopted the following position with regard to the subject of volatile chemicals used in laboratories:

- Customers using non-specified chemicals in the instrument, do so at their own risk.
- All chemicals recommended by Epredia have auto-ignition temperatures considerably above any surface temperatures that can be reached during a single fault failure on the instrument.
- The instrument contains no source of ignition in any areas of the instrument where chemicals are stored, or likely to leak into, in a single fault condition.
- The operator is fully aware of the contents of the specification documents detailing the properties of the chemicals they are using.
- The operator has carried out any legally required assessment of chemicals used and is using Good Laboratory Practice.

Environment

This instrument complies with the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU. It is marked with the following symbol:

Epredia has contracts with one or more recycling / disposal companies in each EU Member State, and this product and packaging should be disposed of or recycled through them. For further information contact your Epredia service representative.

Warranty Statement

Epredia are proud of their quality, reliability and of our after-sales service. We continuously strive to improve our service to our customers.

Please ask your distributor or Epredia representative about service contracts which can help maintain your instrument in an optimal operating condition.

Warranty provisions necessarily vary to comply with differences in national and regional legislation. Specific details can be found in the delivery documentation or from your dealer or representative.

Please note that your warranty may be invalidated if:

- This instrument is modified in any way, or not used as intended by Epredia.
- Accessories and reagents which have not been approved by Epredia are used.
- The instrument is not operated or maintained in accordance with instructions.
- The installation of the instrument was not conducted by a certified Epredia representative.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established

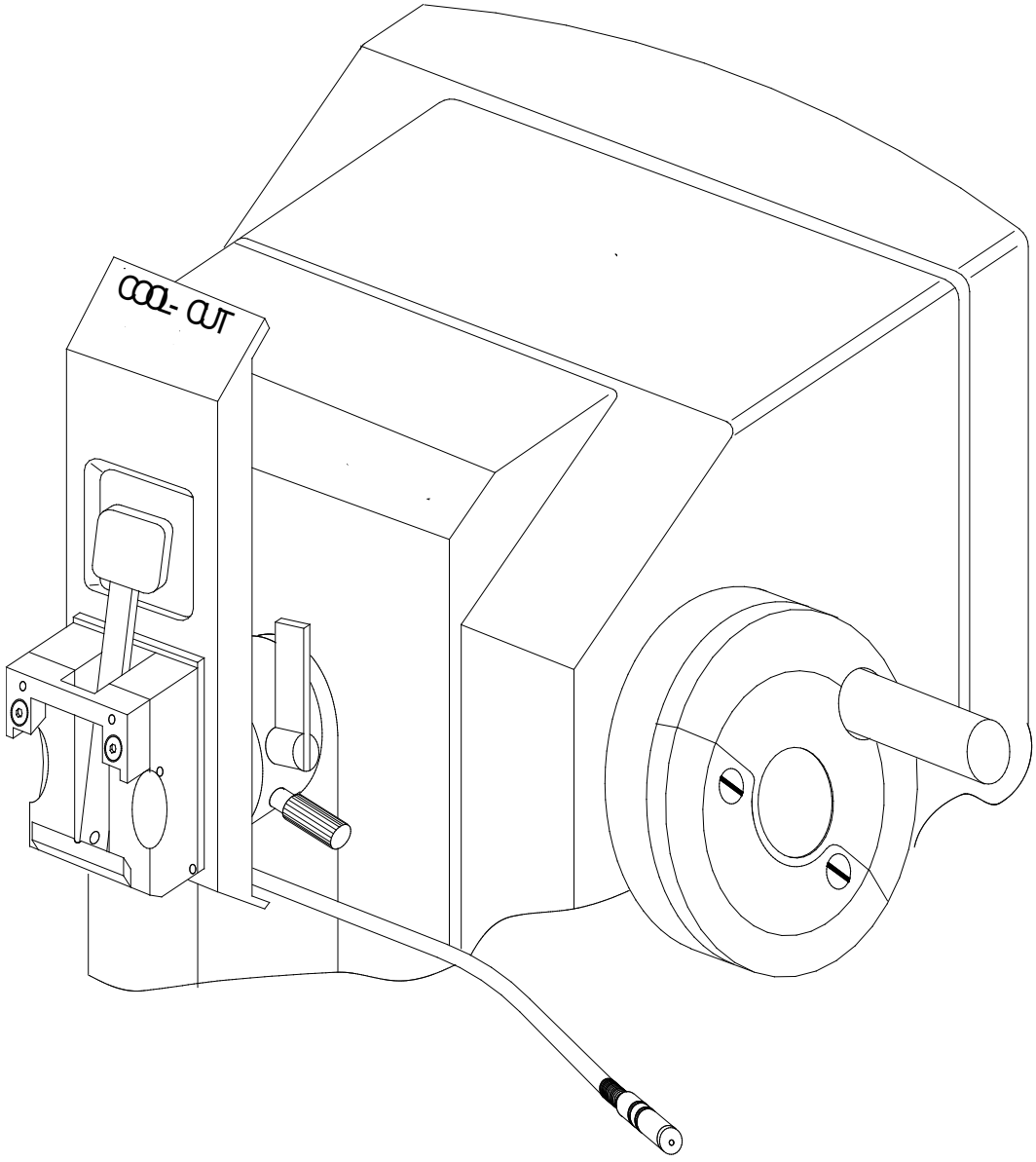


Fig 1

Chapter 1 – Introduction

IVD

IVDR Intended Purpose

The Epredia Cool-Cut is an in vitro diagnostic device intended to be used alongside the rotary microtomes. It is designed to cool samples for taking precision sections of tissue specimens including the sectioning of paraffin embedded samples in medical, pharmaceutical laboratories as necessary preparation for their diagnostic examination. Only qualified and trained laboratory personnel may operate the Cool-Cut.

Description cooling device Cool-Cut

The cooling device Cool-Cut includes an actively cooled specimen clamp (fig. 2.1), an external power supply (fig. 2.2) as well as a counterweight consisting of pieces (fig. 2.3, 2.4 and 2.5).

Biological and human tissue specimens which are embedded in paraffin can be cooled with the Cool-Cut.

The Cool-Cut is available in two different versions. One version includes a standard specimen clamp (fig. 3.1) for paraffin blocks. The other version is equipped with a universal specimen clamp (fig. 3.2) for all commercially available standard embedding cassettes.

The device can exclusively be adapted to all rotary microtomes from Epredia.

Each current Epredia rotary microtome can easily be equipped with a Cool-Cut

Technical Data

Clamp temperature		16°C below ambient temperature
Specimen orientation:	x - and y - axes	universal 8°
	z - axis	up to 360°
Transport and Storage conditions	-25°C to +55°C (at max. 60% rel. humidity)	
Operating conditions:	+5°C up to +35°C (at a max. rel. humidity of 60%)	
	altitude up to 2000 m M.S.L.	
	for indoor use only	
Power requirements:	100-240 V / 0.6 A +/-10%/50...60 Hz 7.5V DC/3.3A	
Pollution degree:	2	
Protection Class	Power Supply Class II	Device Cool-Cut Class III
Overvoltage category:	II	
Acoustic pressure:	20 dB(A)	
Dimensions:	180 x 60 x 95 mm (long x wide x deep)	
Weight:	700 g	

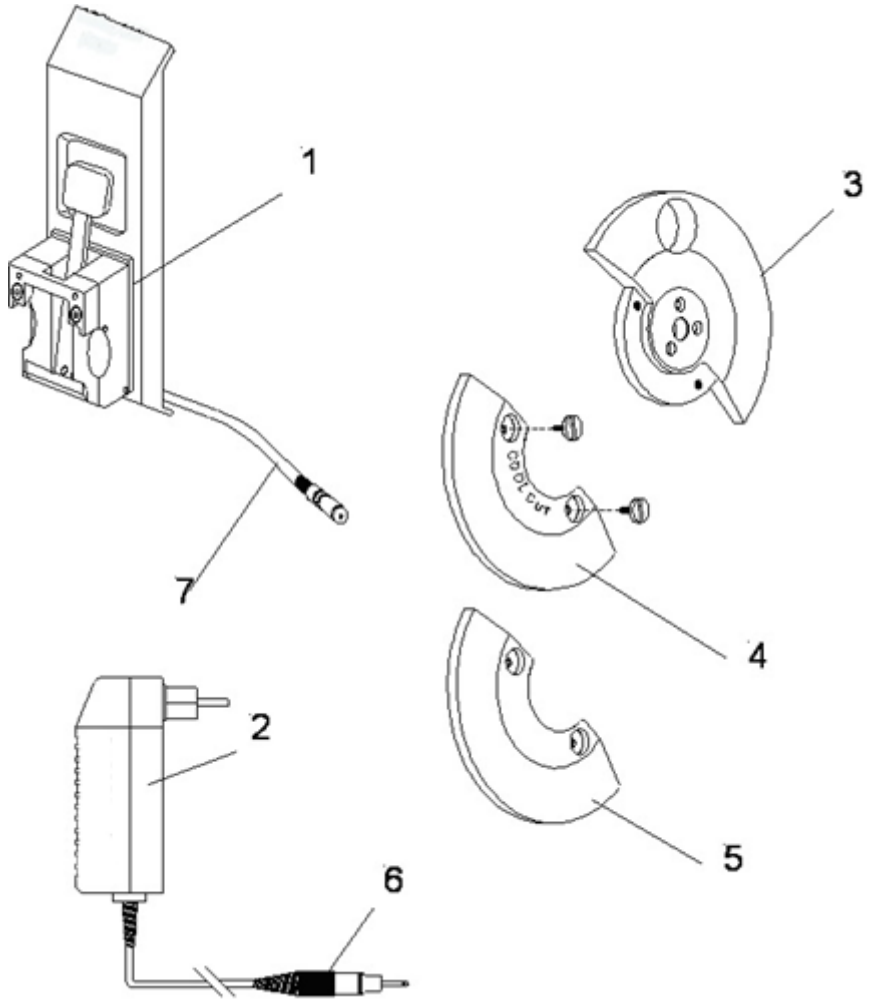


Fig. 2

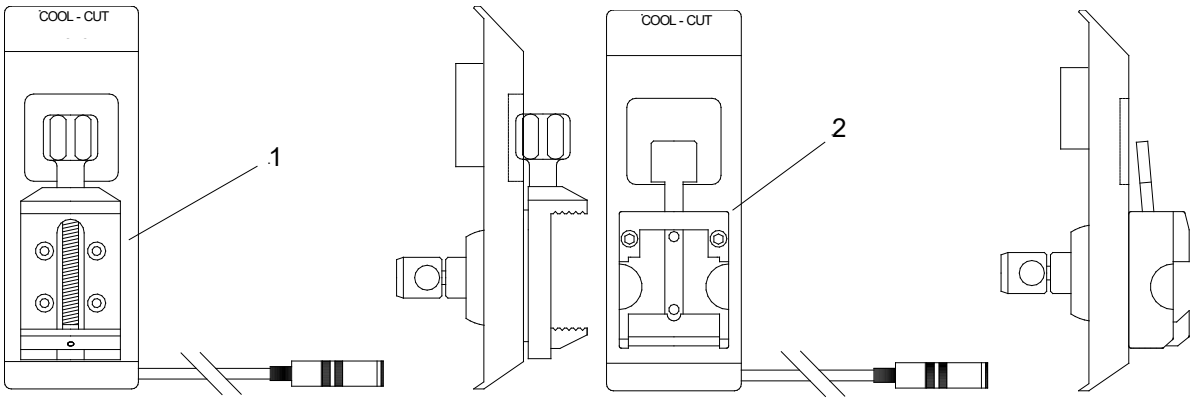


Fig 3

Chapter 2 – Operating Instructions

Initial turn-On

The Cool-Cut can be adapted to all current rotary microtomes from Epredia.

Due to different designs of the various microtome models, the corresponding installation varies slightly.

The installation of the Cool-Cut on the different microtome models is described in the following parts.

Note

Before the initial turn-on of the Cool-Cut, the type of the respective rotary microtome must be determined.

Installing the Cool-Cut on the Rotary Microtomes HM 310, HM 315, HM 325 and HM 340 E

The sequence of the below-described steps must strictly be adhered to. Otherwise, there is the danger to get injured.

The Cool-Cut is heavier than a specimen clamp without cooling device. For this reason, a downward movement of the specimen head must be anticipated after having inserted the Cool-Cut.

- Bring the rotary microtome into its working position. This means, the instrument must show with its specimen holding device towards the user.
- Lock the hand wheel brake of the respective rotary microtome.
- Remove the knife carrier from the dovetail guide.
- If the specimen clamp is still installed, remove it. For this, loosen the clamping lever and remove the clamp from the microtome.
- Remove the cover plate (fig. 4.8) which is placed on the hand wheel (fig. 4.6) by using a small screwdriver.
- Remove the hand wheel handle (fig. 4.5) using the attached Allen key (size 5).
- Loosen the centre screw (fig. 4.7) of the hand wheel using the attached Allen key (size 5) and remove the screw.
- One part of the counterweight, the carrier plate (fig. 4.1), is fastened together with the hand wheel on its centre screw (fig. 4.4) via the extended countersunk screw M8-55.

Note

The carrier plate always has four holes for fastening it on the hand wheels of each current Epredia rotary microtomes.

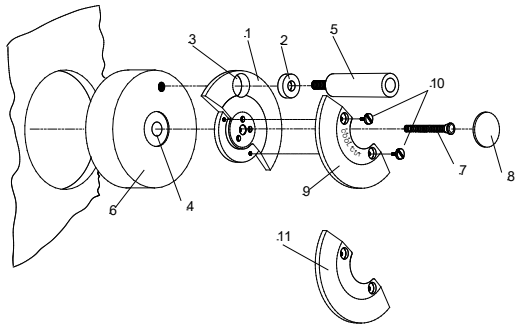


Fig 4

Now insert the hand wheel handle together with the respective distance ring (fig. 4.2) into the intended hole (fig. 4.3). Tighten them again on the hand wheel via the remove screw using the attached Allen key (size 5).

- Cover the centre screw of the hand wheel via the self-adhesive replacement cover plate (fig. 4.8).
- Place the hand wheel counterweight (fig. 4.9) against the carrier plate and tighten the screws (fig. 4.10).

The hand wheel counterweight bears the expression "Cool-Cut". The compensating plate (fig. 4.11) which is similar in design has no inscription. Its function is described in part "2-3 Changing to conventional specimen clamps".

- Now fit the Cool-Cut to the orienting adapter on the microtome using the clamping lever on the microtome.

Note

If needed, readjust the Cool-Cut on the adapter. For this, please see part "Readjusting of specimen clamps" in the instruction manuals of the respective rotary microtomes

Before turning on the instrument for the first time, please check if the power requirements indicated on the type plate correspond to the power supply voltage being used.

- Connect the power supply unit (fig. 2.2) of the Cool-Cut with the socket.

Note

Two adapters for plugs are attached to the power supply unit (power requirements from 100 up to 240 V, see fig. 7).

- Place the cable of the power supply beside the microtome.
- Insert the plug (7,5 V) of the power supply unit (fig 2.6) into the socket of the Cool-Cuts (fig. 2.7).
- The specimen clamp of the Cool-Cut is now being cooled down.
- During operation a fan is activated, and a diode lights up behind the clamping handle.

Note

During operation, the cooling plate heats up. On its rear side, a fan is placed for heat elimination. This fan must move freely and must not be touched or stopped.

- Fix the knife carrier on the dovetail guide.

Installing the Cool-Cut on the Rotary Microtome HM 335 E

The sequence of the below-described steps must strictly be adhered to. Otherwise, there is the danger to get injured.

The Cool-Cut is heavier than a specimen clamp without cooling device. For this reason, a downward movement of the specimen head must be anticipated after having inserted the Cool-Cut.

- Bring the rotary microtome into its working position. This means, the instrument must show with its specimen holding device towards the user.
- Lock the hand wheel brake of the respective rotary microtome.
- Remove the knife carrier from the dovetail guide.
- If the specimen clamp is still installed, remove it. For this, loosen the clamping lever and remove the clamp from the microtome.
- Remove the cover plate (fig. 5.8) which is placed on the hand wheel (fig. 5.6) by using a small screwdriver.
- Remove the hand wheel handle (fig. 5.5) using the attached Allen key (size 5).
- Loosen the three decentral screws (fig. 5.7) of the hand wheel by using the attached Allen key (size 4) and remove the screws.
- One part of the counterweight, the carrier plate (fig. 5.1), is fastened together with the hand wheel on its centre screw (fig. 5.4) via the three extended screws (fig. 5.7) using the attached Allen key (size 4).

Note

The carrier plate always has four holes for fastening it on the hand wheels of each current Epredia rotary microtomes.

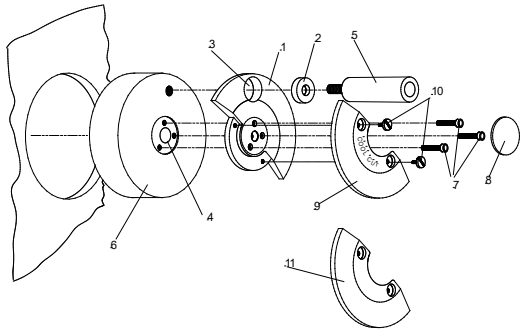


Fig 5

Now insert the hand wheel handle together with the respective distance ring (fig. 5.2) into the intended hole (fig. 5.3). Tighten them again on the hand wheel via the remove screw using the attached Allen key (size 5).

- Cover the centre screw of the hand wheel via the self-adhesive replacement cover plate (fig. 5.8).
- Place the hand wheel counterweight (fig. 5.9) against the carrier plate and tighten the screws (fig. 5.10).

The hand wheel counterweight bears the expression "Cool-Cut". The compensating plate (fig. 5.11) which is similar in design has no inscription. Its function is described in part "2-3 Changing to conventional specimen clamps".

- Now fit the Cool-Cut to the orienting adapter on the microtome using the clamping lever on the microtome.

Note

If needed, readjust the Cool-Cut on the adapter. For this, please see part "Readjusting of specimen clamps" in the instruction manuals of the respective rotary microtomes.

Before turning on the instrument for the first time, please check if the power requirements indicated on the type plate correspond to the power supply voltage being used.

- Connect the power supply cord (fig. 2.2) of the Cool-Cut with the socket.

Note

Two adapters for plugs are attached to the power supply unit (power requirements from 100 up to 240 V, see fig. 7).

- Place the cable of the power supply beside the microtome.
- Insert the plug (7,5 V) of the power supply unit (fig 2.6) into the socket of the Cool-Cuts (fig. 2.7).
- The specimen clamp of the Cool-Cut is now being cooled down.
- During operation a fan is activated, and a diode lights up behind the clamping handle.

Note

During operation, the cooling plate heats up. On its rear side, a fan is placed for heat elimination. This fan must move freely and must not be touched or stopped.

- Fix the knife carrier on the dovetail guide.

Installing the Cool-Cut on the Rotary Microtomes HM 355, HM 355 S and HM 360

The sequence of the below-described steps must strictly be adhered to. Otherwise, there is the danger to get injured.

The Cool-Cut is heavier than a specimen clamp without cooling device. For this reason, a downward movement of the specimen head must be anticipated after having inserted the Cool-Cut.

- Bring the rotary microtome into its working position. This means, the instrument must show with its specimen holding device towards the user.
- Lock the hand wheel brake of the respective rotary microtome.

Note

Rotary microtomes with motorized cutting drive must be turned on for this, as they are equipped with an electro-magnetic brake. For this, please see part "Initial turn-on" in the instruction manual of the respective rotary microtomes.

- Remove the knife carrier from the dovetail guide.
- If the specimen clamp is still installed, remove it. For this, loosen the clamping lever and remove the clamp from the microtome.
- Remove the cover plate (fig. 6.8) which is placed on the hand wheel (fig. 6.6) by using a small screwdriver.
- Loosen the three decentral screws (fig. 6.7) of the hand wheel by using the attached Allen key (size 4) and remove the screws.
- One part of the counterweight, the carrier plate (fig. 6.1), is fastened together with the hand wheel on its centre screw (fig. 6.4) via the three extended screws (fig. 6.7) using the attached Allen key (size 4). The hole of the carrier plate (fig. 6.3) is pushed over the hand wheel handle (fig. 6.5)

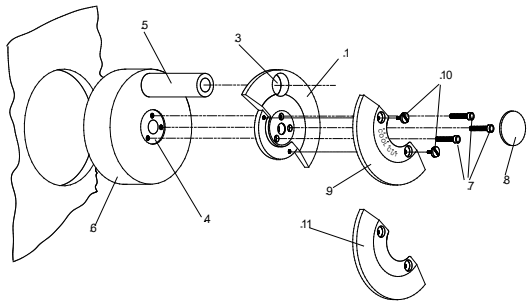


Fig 6

Note

The carrier plate always has four holes for fastening it on the hand wheels of each current Epredia rotary microtomes.

- Cover the centre screw of the hand wheel via the self-adhesive replacement cover plate (fig.6.8).
- Place the hand wheel counterweight (fig. 6.9) against the carrier plate and tighten the screws (fig. 6.10).

The hand wheel counterweight bears the expression "Cool-Cut". The compensating plate (fig. 6.11) which is similar in design has no inscription. Its function is described in part "2-3 Changing to conventional specimen clamps".

- Now fit the Cool-Cut to the orienting adapter on the microtome using the clamping lever on the microtome.

Note

If needed, readjust the Cool-Cut on the adapter. For this, please see part "Readjusting of specimen clamps" in the instruction manuals of the respective rotary microtomes.

Before turning on the instrument for the first time, please check if the power requirements indicated on the type plate correspond to the power supply voltage being used.

- Connect the power supply unit (fig. 2.2) of the Cool-Cut with the socket.

Note

Two adapters for plugs are attached to the power supply unit (power requirements from 100 up to 240 V, see fig. 7).

- Place the cable of the power supply beside the microtome.
- Insert the plug (7,5 V) of the power supply unit (fig 2.6) into the socket of the Cool-Cuts (fig. 2.7).
- The specimen clamp of the Cool-Cut is now being cooled down.
- During operation a fan is activated, and a diode lights up behind the clamping handle.

Note

During operation, the cooling plate heats up. On its rear side, a fan is placed for heat elimination. This fan must move freely and must not be touched or stopped.

- Fix the knife carrier on the dovetail guide.

Installing the Cool-Cut on the Rotary Microtomes HM 350 and/or HM 350 SV

The sequence of the below-described steps must strictly be adhered to. Otherwise, there is the danger to get injured.

The Cool-Cut is heavier than a specimen clamp without cooling device. For this reason, the standard equipment includes a (hand wheel) counterweight. However, the HM 350 S/SV is not equipped with a hand wheel and does not need this counterweight.

- Bring the rotary microtome into its working position. This means, the instrument must show with its specimen holding device towards the user.
- Lock the hand wheel brake of the respective rotary microtome.

Note

Rotary microtomes with motorized cutting drive must be turned on for this, as they are equipped with an electro-magnetic brake. For this, please see part "Initial turn-on" in the instruction manual of the respective rotary microtomes.

- Remove the knife carrier from the dovetail guide.
- If the specimen clamp is still installed, remove it. For this, loosen the clamping lever and remove the clamp from the microtome.
- Now fit the Cool-Cut to the orienting adapter on the microtome using the clamping lever on the microtome.

Note

If needed, readjust the Cool-Cut on the adapter. For this, please see part "Readjusting of specimen clamps" in the instruction manuals of the respective rotary microtomes.

Before turning on the instrument for the first time, please check if the power requirements indicated on the type plate correspond to the power supply voltage being used.

- Connect the power supply unit (fig. 2.2) of the Cool-Cut with the socket.

Note

Two adapters for plugs are attached to the power supply unit (power requirements from 100 up to 240 V, see fig. 7).

- Place the cable of the power supply beside the microtome.
- Insert the plug (7,5 V) of the power supply unit (fig 2.6) into the socket of the Cool-Cuts (fig. 2.7).
- The specimen clamp of the Cool-Cut is now being cooled down.
- During operation a fan is activated, and a diode lights up behind the clamping handle.

Note

During operation, the cooling plate heats up. On its rear side, a fan is placed for heat elimination. This fan must move freely and must not be touched or stopped.

- Fix the knife carrier on the dovetail guide.

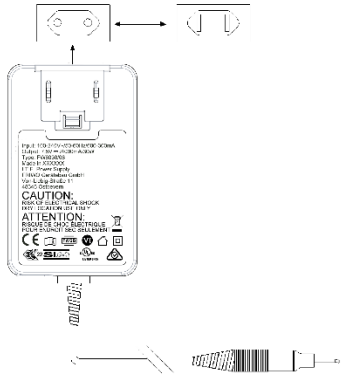


Fig 7

Sectioning of Specimens

Especially at high ambient temperatures, the lower specimen temperature generated by the Cool-Cut has very positive effects on the sectioning results.

The active cooling of a paraffin specimen clamped in the specimen clamp allows thin sections of excellent quality without re-cooling the specimen.

Best sectioning results are achieved at constant section thicknesses.

Note

We recommend a pre-cooling of specimens on a cooling plate down to at least -2°C.

Sectioning with the Cool-Cut in Routine and Research

- Compared with the ambient temperature, the metal surface of the specimen clamp shows a temperature which is approx. 16 Kelvin less.
- Under these conditions, the surface temperature of a cassette or a paraffin block clamped into a Cool-Cut, starting with a surface temperature of -2 to -3°C, will warm up to 10°C only after approx. 5 min.

Sectioning Serial Sections

- Depending on the ambient temperature, specimen clamp as well as the size of the specimen, the paraffin surface of the specimen reaches a constant end-temperature after approx. 15 min. This temperature is between 10°C and 16°C. The paraffin does not expand anymore.
- Sectioning at these constant temperature guarantees an optimal section thickness consistency for producing serial sections.

Orienting the Cool-Cut on a Rotary Microtome

For orienting the specimen, the Cool-Cut is equipped with an identical adapter as a conventional specimen clamp. Please see under "Adapters for specimen clamping" in the instruction manual of the respective rotary microtome.

Changing to Conventional Specimen Clamps

As an average, the Cool-Cut is 400 g heavier than a conventional specimen clamp.

The counterweight increases the weight on the hand wheel accordingly. Resulting in a smooth run of the rotary microtome during the sectioning process with the Cool-Cut. This additional weight is solely compensated by the hand wheel counterweight (fig. 8.2).

For this reason, changing the counterweight for conventional specimens is very easy:

- The standard equipment of the Cool-Cut includes one carrier plate (fig. 8.1) and two hand wheel weights. The heavier hand wheel weight (the actual counterweight) consists of brass and is marked with the expression "Cool-Cut" (fig. 8.2). The lighter one is made of aluminium and does not have an inscription. It is used as a compensating plate (fig. 8.3).

Note

*The heavier counterweight (fig. 8.2) with the expression "**Cool-Cut**" must be used together with the Cool-Cut.*

- As described in part "Initial turn-on", put the respective hand wheel counterweight against the carrier plate and tighten it by the screws.
- The lighter compensating plate (without inscription) is then tightened on the carrier plate, in case conventional (un-cooled) specimen clamps are used.

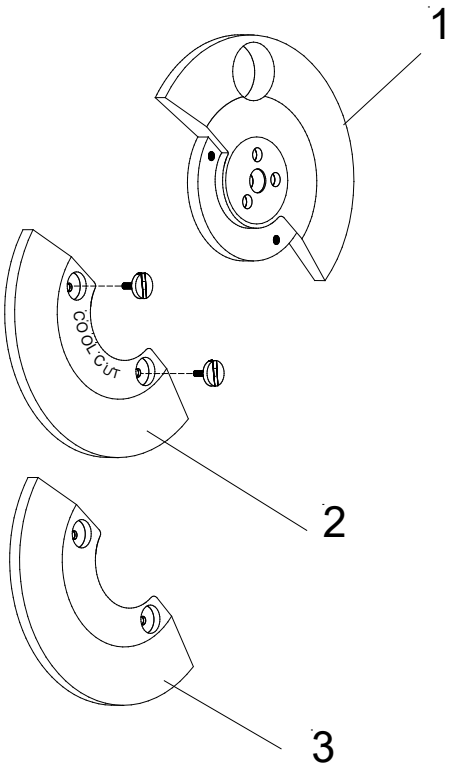


Fig 8

Standard Equipment

The Cool-Cut is supplied with the following accessories:

Cool-Cut complete with standard specimen clamp (cat. no. 771120)

- 2 screws
- 1 distance ring
- 1 carrier plate
- 1 counterweight (brass)
- 1 compensating plate (aluminium)
- 1 cover disk
- 3 fillister head screws M5x65
- 1 countersunk screws M8x55
- 3 spring disks
- 1 serrated lock washer
- 1 Allen key SW 5
- 1 cable
- 1 power supply unit
- 1 Euro adapter
- 1 US adapter

Cool-Cut complete with universal cassette clamp (cat. no. 771110)

- 2 screws
- 1 distance ring
- 1 carrier plate
- 1 counterweight (brass)
- 1 compensating plate (aluminium)
- 1 cover plate
- 3 fillister head screws M5x65
- 1 countersunk screw M8x55
- 3 spring disks
- 1 serrated lock washer
- 1 Allen key SW 5
- 1 cable
- 1 power supply unit
- 1 Euro adapter
- 1 US adapter

Chapter 3 – Theory of Operation

Cooling of the Specimen Clamp

The Cool-Cut is an additional equipment for cooling specimens embedded in paraffin. As the consistency of the specimen and consequently the sectioning results depend on the temperature, a pre-cooling on a cooling plate is recommended.

However, the specimen will warm up depending on the ambient temperature and the site of installation of the rotary microtome. As a consequence, sectioning results tend to get worse.

When working with the Cool-Cut, the paraffin embedded specimens must also be pre-cooled in a conventional way. In the Cool-Cut the paraffin warms up slower. Even, after having reached the end temperature after 10 min., good sectioning results at a constant section thickness can be achieved.

The function of the Cool-Cut is realized via cooling the specimen clamps by means of a Peltier element.

The cooling plate on the rear side of the specimen clamp warms up during operation with the Cool-Cut. In its upper area, a fan is place for eliminating the heat

Chapter 4 – Working with the Cool-Cut

How to avoid malfunctions

Always use a cassette with a paraffin block which has been pre-cooled on a cooling plate. Un-cooled paraffin, due to its slight heat conductivity, would need approx. 10 min. to achieve an optimal temperature in the Cool-Cut.

When placing the cable of the power supply unit, please note that the cable is able to follow the cutting movement of the Cool-Cut. Otherwise, the cable might be ripped out of the socket on the Cool-Cut, or the socket or the cable might be damaged.

How to Proceed in Error Cases

Note

In case of an error, the Cool-Cut must only be checked or repaired by trained skilled service personnel.

Note

In case components or assemblies must be replaced, only original spare parts must be used.

Chapter 5 – Cleaning and Care

Cleaning

Cleaning of the cooling unit and the counterweight depends on how often the Cool-Cut is used and on the degree of debris.

To clean the control unit, use commercially available cleaning agents.

The cooling element and the control unit of the Cool-Cut must not be immersed in a Xylene bath

A cleaning agent in which paraffin is soluble is recommended (for example Xylene).

Do not use Acetone!

To clean the specimen clamp of the Cool-Cut from paraffin, use a cloth soaked with solvent.

Alternatively, still sticking paraffin can be removed in an oven with max. 70°C for a maximum of three hours.

Note

Before using the instrument, use commercially available paraffin repellent.

The possibility that paraffin adheres to the individual parts of the Cool-Cut is considerably reduced.

Transportation of instrument

Any shipping of the instrument requires original packaging materials! Damages caused by shipping with non-conform packaging are not covered by the manufacturer warranty! Any damage repairs resulting in non-conforming package are fully charged to the sending party. We reserve the right depending on seriousness of damage NOT to repair.

To order original packaging materials, please contact Epredia or your local, by Epredia authorized, dealer.

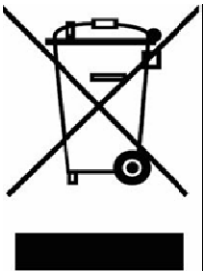
The user must care for a clean and safe condition of the instrument when returning it to an appropriate service provider.

Note

If the original packaging is no longer available, please contact your local Epredia representation.

Disposal of Instrument after final shutdown

After the final shutdown of the instrument, we recommend contacting a local recycling company for the disposal according to the national applicable regulations.



To be applied in the countries of the European Union and other European countries with a separate collecting system within the waste management

To be applied in the countries of the European Union and other European countries with a separate collecting system within the waste management.

The marking of the product and/or the respective literature indicates that, after its final shutdown, it must not be disposed of together with ordinary domestic waste.

- Please dispose of your instrument separately from other waste to not harm our environment and/or human health by uncontrolled waste disposal.
- Recycle your instrument to support the sustainable recycling of material resources.
- Industrial users should contact their suppliers and observe the conditions of the contract. This product must not be disposed of together with other commercial waste.
- Please contact your supplier!!

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Revision Control for this Document

Date	Revision number	Changes made
February 2022	18	IVDR compliance requirements added, including this revision record table.

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