

# Amadeus Microkeratome Operator Manual



## Description

The **AMADEUS** Microkeratome is a medical instrument exclusively designed for use in ophthalmic surgery.

This Operators' Manual provides important information regarding the use of the **AMADEUS** Microkeratome. Physicians using the **AMADEUS** Microkeratome should read the manual thoroughly prior to operating the device. Additional information can be obtained at your local SIS representative.

### Unique features of the **AMADEUS** Microkeratome

- Elegant and simple to use touch screen Control Unit
- Single-handed operation
- Visual contact while creating the flap
- Integrated blade loading system
- Vacuum level displayed on LCD display
- Fully enclosed gearless drive eliminates risk of gear jams
- Advanced design to eliminate on-eye assembling of dovetails or gears
- One-way assembly to reduce the risk of pre-operative error
- Multiple safety checks to ensure consistently smooth, high quality keratectomies

### Indications for Use

The **AMADEUS** Microkeratome is a precision manufactured instrument specifically designed for cutting a precise corneal disc of preselected thickness and diameter. This device is intended for use in performing lamellar corneal resections.

### Site Preparation, Unpacking and Installation

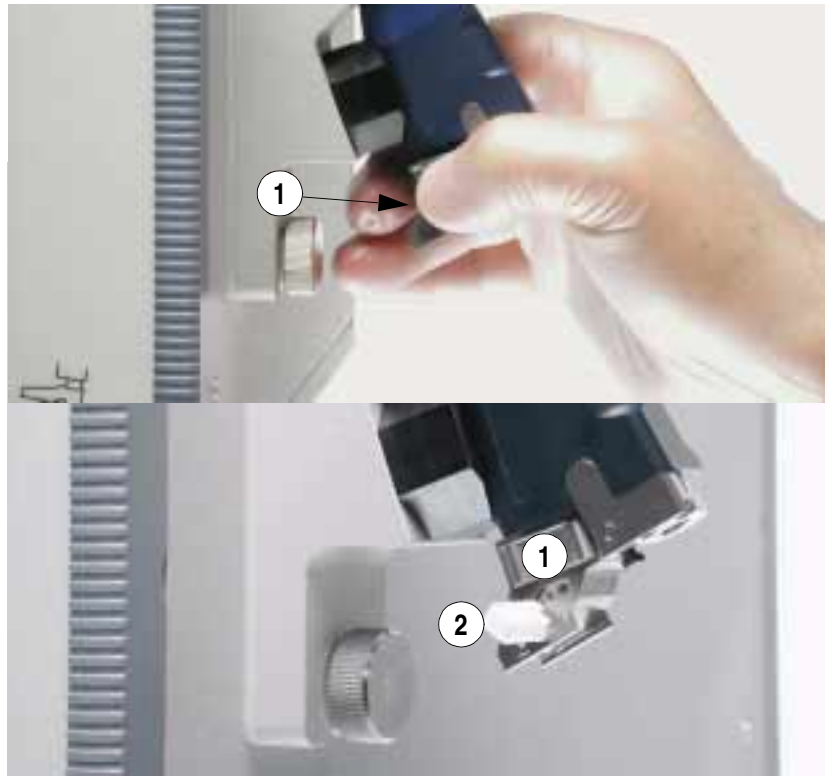
Unpacking and installation should be done only after reading this manual thoroughly. Please check all items relating to the device against the packing list (see *Components list* on page 69 for details). Each item should be inspected and any damage noted and reported within 30 days of reception to the local SIS representative

## Handpiece assembly

### Fasten Blade Holder to Motor Unit

Fig. 21:  
Fasten Blade Holder to Motor Unit:

- 1 Spring loaded buttons at the Blade Holder
- 2 Blade Handle (longer piece)



- 1 Attach the Blade Holder to the Motor Unit:
  - Squeeze from both sides the two spring loaded buttons (1) with two fingers.
  - Snap the Blade Holder to the motor shaft.
  - If the Blade is not centered correctly, the Blade Holder can not snap into place. In this case move the Blade with the long handle (2) a little bit to center it again. You may also use the Blade removal tool for this pupose.
- 2 As soon as the Blade Holder has clicked into position, remove the Blade handle (2) by pulling it. The Blade Holder is absolutely immobile and sits firmly on the Motor Unit.

## Apply the Suction Unit

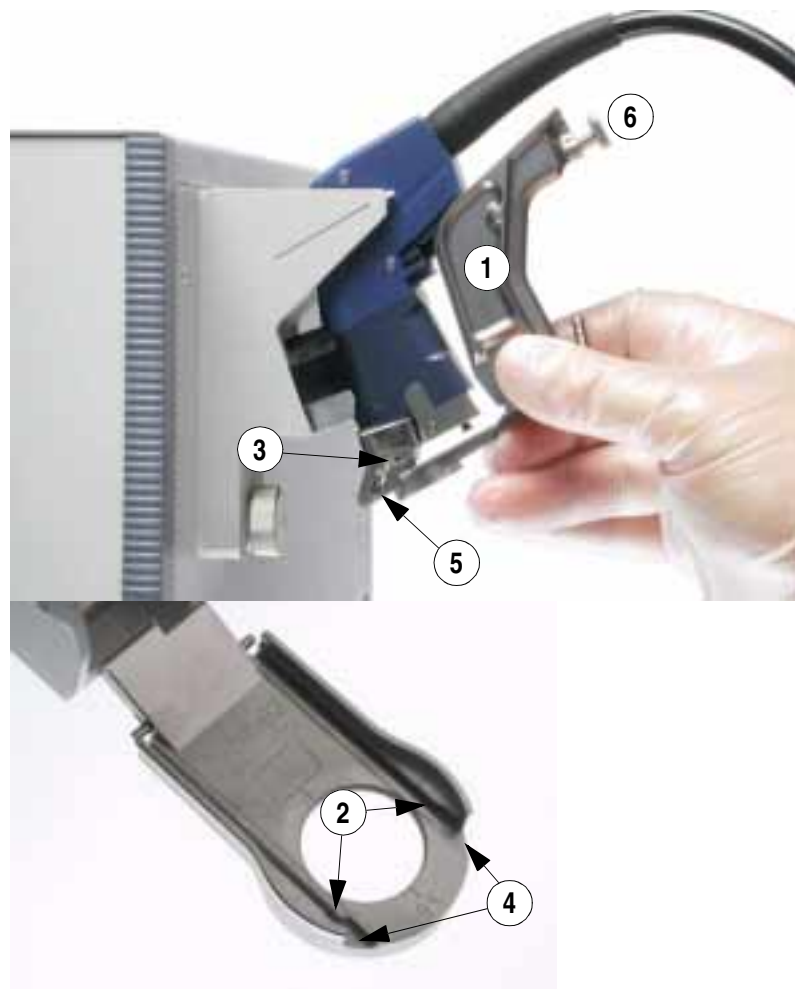
### General Information

When inserting the Suction Unit, consider the following general information:

- The Motor Unit with fastened Blade Holder remains in the mount. Check that the vacuum tube is connected to the Suction Unit and to the Control Unit.
- Gently hold the Suction Unit at the bottom with two fingers. Support your hand at the wrist.

Fig. 22:  
Add Suction Unit to Blade Holder

- 1 Suction unit
- 2 Guiding tracks on Suction Unit
- 3 Blade Holder
- 4 Guiding surface
- 5 Small railings at the Blade Holder
- 6 Tappet



### Apply the Suction Unit

- 1 Assure the Tappet of the Suction Unit is pulled out.
- 2 Put some eye drops into the guiding tracks (2) of the suction unit and the small railings (5) of the Blade Holder for lubrication.



---

**Warning**

*Do not use BSS or other saline solutions for lubrication. This may glue the pieces rather than lubricate.*

---

- 3 At the front of the Suction Unit near to the Suction Ring where the guiding tracks begin, there are small surfaces (4) which enable safe initial positioning.
- 4 First, place these surfaces on either side of the corner points of the small railings of the Blade Holder. Then align the Suction Unit guiding tracks (2) with the small railings of the Blade Holder.
- 5 Carefully slide the guiding tracks (2) into the small railing (5) of the Blade Holder - never use force! If correctly positioned the suction unit glides diagonally downwards with minimal force.
- 6 Slide the Suction Unit towards the Motor Unit.
- 7 Lock the Suction Unit to the Motor Unit by pushing the Tappet (6) as far as it will go. This procedure allows the advance motor to move the advance mechanism into 'park' position.



---

**Caution**

*Never lock the Handpiece with the Tappet if the Handpiece is not connected to the Control Unit. This risks damaging the internal electronics.*

---

## Connect the vacuum tube



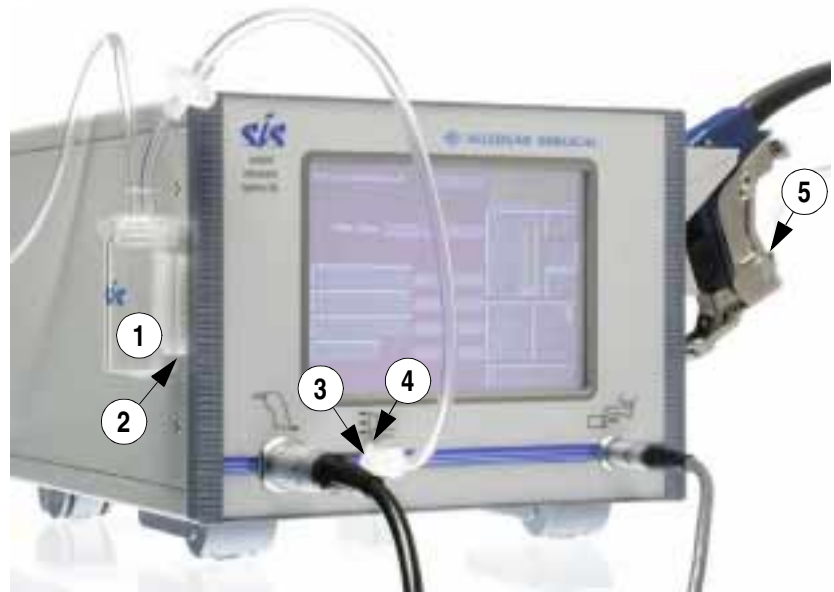
### *Exchange of vacuum tubing*

*Once the reservoir becomes 1/2 full, it must be replaced with a new SIS single-use tubing.*

- 1 Remove the sterile vacuum tube from the packaging and attach the reservoir container to the Velcro pad located on the left-hand side of the Control Unit.

Fig. 23:  
Vacuum tubing

- 1 Reservoir container
- 2 Velcro pad
- 3 Vacuum connector
- 4 Lid at outlet
- 5 Vacuum fitting at Suction Unit



- 2 Mount the reservoir (1) on the left side of the Control Unit by means of the velcro (2). The tubing must be on top!
- 3 Press the small lid at the outlet (4) downwards.
- 4 Insert the tube connector (3) until a positive lock is achieved.
- 5 Release the lid (4).
- 6 Connect the other side of the tube (no special connector) to the Handpiece (5).

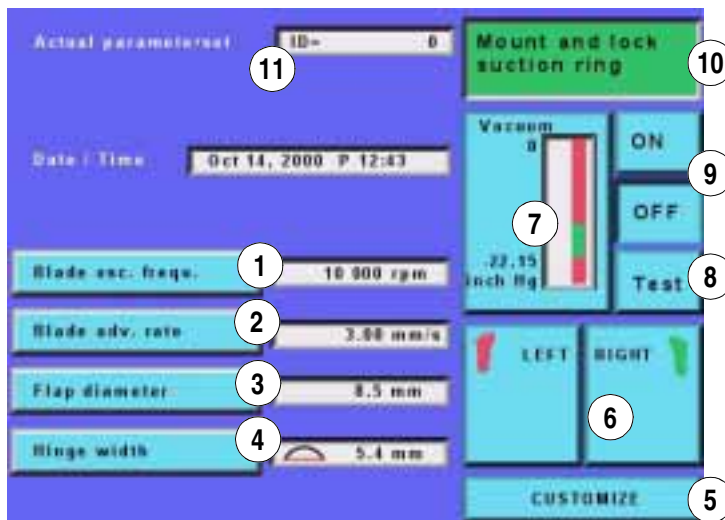
# Surgery

Surgery is guided by the main display at the touch screen.

For detailed instructions how to change the parameters see *Operator-machine interface* on page 37.



Fig. 24:  
Display for surgery

- 1 Blade oscillation frequency
- 2 Blade advance rate
- 3 Flap diameter
- 4 Hinge width
- 5 Display the Customize window
- 6 Left/right button
- 7 Vacuum setting
- 8 Vacuum test
- 9 Vacuum on/off
- 10 Status window
- 11 Actual parameter



Change value of parameters 1 to 4

To change values of items 1 to 4, simply touch the button panel on the left of each display:

Parameter	minimum	maximum	unit
Blade oscillation frequency	4000	20 000	rpm
Blade advance rate	1	4	mm/s
Flap diameter	8.5 or 9.5		mm
Hinge width 	3.6	8	mm
Hinge width 	0.4	2	mm



### Free cap

The instrument can **not** be customized to make free cap cuts without first requesting an access modification code from SIS.

Vacuum monitor

To change the vacuum value to be reached, touch the button (7). This opens an on-screen numeric keypad to define a new (negative) value for the vacuum.

## Check operation parameters

Check the unit settings and cut parameters and adapt if necessary. Recommended cut parameters are (1 mil = 1/1000 inch):

Blade oscillation frequency	10000 rpm.  To change the blade oscillation frequency, touch the button of the oscillation frequency.
Blade advance. speed	2.5 mm/sec. (1/10 inch/sec.).  To change the blade advancement rate touch the button of the advancement rate.
Vacuum	830 mbar (24.5 inch Hg).  To change vacuum level touch the button of the vacuum level.
Hinge	0.9 mm (1/28 inch) <sup>1</sup>  To change hinge width touch the button of the hinge width.
Flap diameter	8.5 mm (1/3 inch) or 9.5 mm (3/8 inch).  To select the flap diameter touch the button of the flap diameter.



### **Illegal values**

*The selection of illegal values is suppressed and the corresponding message appears. After confirming by touching the 'Clear' button on the display, the control program sets the value closest to the one selected.*

*Touching the Pedal icons activates the same procedure as if the Pedals themselves were depressed. As soon as a Pedal is depressed (or icon selected) the subsequent command is carried out.*

---

1. The nomogramm is still missing - what does it display?



---

# Care and maintenance

See *Control Unit description* on page 37 for detailed instructions on how to change parameters and enter values.

## Master reset

A master reset resets all individual control parameters to their default value. The default values are set by the manufacturer.

To perform a master reset:

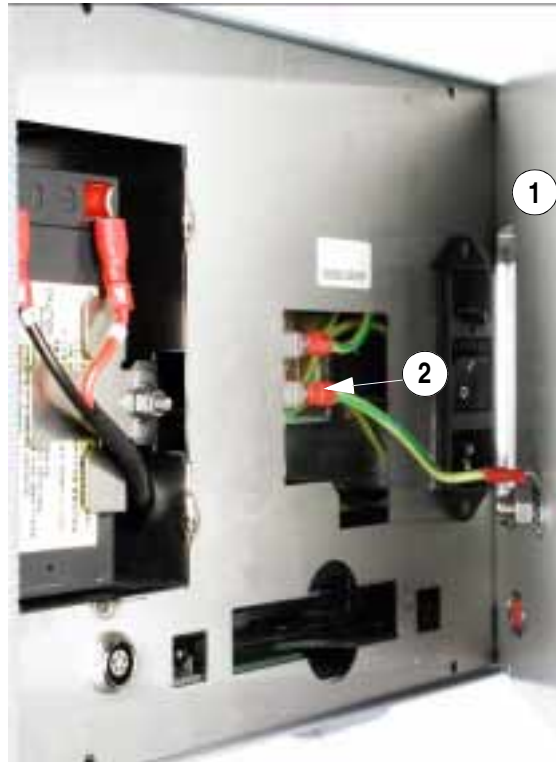
- 1 Switch on the Control Unit.
- 2 Press button **Customize**.
- 3 Press button **Master Reset**.
- 4 Switch off the Control Unit and wait until the display is off.
- 5 Switch on the Control Unit again.

## Remove and restore back plate

The back plate must be removed to exchange the battery and to change the PC card with the software.

Fig.34:  
Remove the back plate

- 1 Back plate
- 2 Grounding plug



### Remove the back plate

- 1 Unplug the Control Unit from mains
- 2 Unplug the Pedals and the Handpiece
- 3 Remove the 4 Phillips screws at the back
- 4 Lift the back plane gently on the side of the Pedal connector (3) and unplug the flat earthing plug (1) (yellow/green wire).

### Restore the back plate

- 1 Hold the back plate with one hand open and connect the grounding wire (2).
- 2 Insert the back plate into back side of the Control Unit. Watch the grounding wire!
- 3 Insert the four Phillips screws and fasten them firmly.

## Maintain the battery

The performance of the battery is permanently checked by the Control Unit. If the Control Unit diagnoses a weak battery before its estimated life time it may be sufficient to re-initialize the battery.

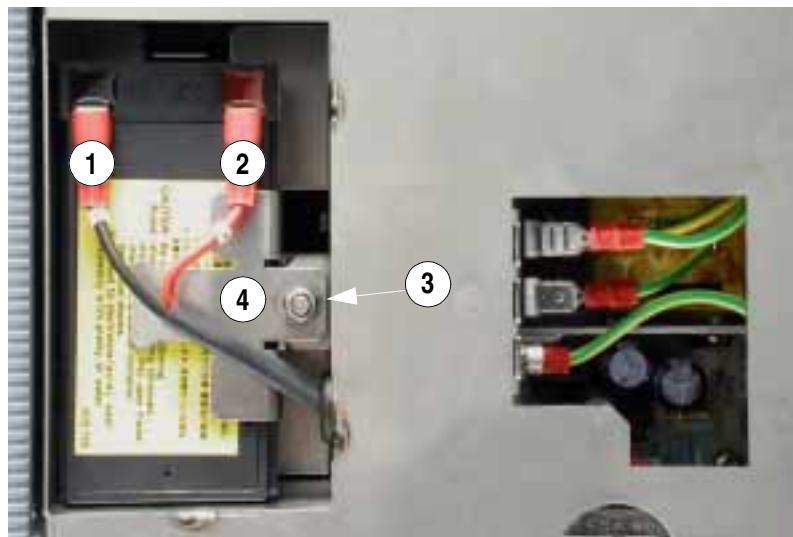
The end of the life time of the battery is estimated with the installation date of the battery + 3 years. The installation date of the battery must be entered when it is replaced.

The battery must be replaced

- at the end of the life time regardless its assumed performance
- when the battery is reported to be weak and re-initialization does not correct the report.

Fig.35:  
Replace battery

- 1 - plug (black)
- 2 + plug (red)
- 3 Hexagon nut
- 4 Battery clamp



### Replace battery

- 1 Remove the back plate (see *Remove the back plate* on page 48)
- 2 Remove the black (1) and red(2) wires from the battery
- 3 Open the fastening nut (3) at the battery clamp (4) with a 7 mm wrench and remove the clamp.
- 4 Lift the Control Unit housing gently at the front side until the battery slits out.
- 5 Insert new battery
- 6 Apply the battery clamp (4) and fasten the nut (2).

- 7 Apply the red wire (2) to the + pole and the black wire (1) to the - pole of the battery.
- 8 Restore the back plate (see *Restore the back plate* on page 48)
- 9 Set the installation date (see *Define battery installation date* on page 51)
- 10 *Initialize battery* on page 50

### Initialize battery

- 1 Switch on the Control Unit
- 2 Press button **Customize**
- 3 Press button **Battery charge initialization**
- 4 Press **Yes** in the window **Operator Decision**
- 5 Enter 6398.45 in the field **Enter Code**
- 6 Switch off the Control Unit




---

#### **Caution**

*Although the Control Unit is switched off now, it drains the battery. Do not switch on before the red window is displayed!*

---

- 7 Wait until the Control Unit displays a red window with Battery initialization in the middle of the display. After that it really switches off itself.
- 8 Switch on the Control Unit. The following message must appear: "Battery is being initialized!" Leave power on until message "complete" appears.
- 9 If the before mentioned message does not appear, restart the procedure at point 2.
- 10 Clear the message "Battery is being initialized".
- 11 Leave the Control Unit switched on until the message "Initial charge of battery successfully completed" is displayed.
- 12 If one of the following messages appears, restart the procedure at point 2.
  - "Initial charge of battery failed"
  - "Constant current cycle too short, initialization aborted"
  - Constant volt cycle too short, initialization aborted