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Federal law restricts the use of this device to a physician or a licensed practitioner.

The most recent version of this user guide and additional information are available on Moria website: http://www.moria-surgical.com

I. EQUIPMENT LIST

The equipment supplied with the standard system is the following:

<table>
<thead>
<tr>
<th>Designation</th>
<th>MORIA Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVOLUTIONje Console</td>
<td>19380</td>
</tr>
<tr>
<td>EVOLUTIONje Footswitch</td>
<td>19381</td>
</tr>
<tr>
<td>EVOLUTIONje Cord</td>
<td>19363</td>
</tr>
<tr>
<td>Carrying case</td>
<td>19511</td>
</tr>
<tr>
<td>Instruction manual</td>
<td>65051</td>
</tr>
</tbody>
</table>
II. DESCRIPTION OF THE CONTROL UNIT

A. Front panel

- Vacuum Level Indicator
- Low Vacuum Indicator
- Low Vacuum Switch
- "TEST" Switch
- Motor indicator: - One Use-Plus - M2 - Epi-K™
- Main Power Supply Indicator
- Battery Level Indicators
- Vacuum Tubing Connector
- EPI-K™ Connector
- M2 Connector
- One Use-Plus Connector
- Keratome Selector Switch
- Speed 1 / Speed 2 Switch (Only for M2 and One Use-Plus keratomes)
B. Rear panel

- Footswitch Connector
- Main OFF/ON Switch
- Serial Number and Product Code
- Fuse Housing and 115V – 230V Selector
- Main Power Supply Connector
C. Specifications

### Dimensions
- 430x240x190 mm

### Weight
- 13.4 kg

1. Power Supply

<table>
<thead>
<tr>
<th>Voltage / Cycles</th>
<th>115 V / 50-60Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>External Fuse</td>
<td>500 mA high switching power</td>
</tr>
</tbody>
</table>

⚠️ Only Moria can replace this fuse.

2. Electrical characteristics

⚠️ NEVER OPERATE WITHOUT MAIN POWER SUPPLY.

<table>
<thead>
<tr>
<th>Battery capacity and type</th>
<th>12 V - 7 Ah (Pb)</th>
</tr>
</thead>
</table>

⚠️ Only Moria can replace this battery. Never open the metallic cover of the unit.

<table>
<thead>
<tr>
<th>Fuse (inside the control unit)</th>
<th>3.15 AT and 500 mAT</th>
</tr>
</thead>
</table>

⚠️ Only Moria can replace this fuse. Never open the metallic cover of the unit.
III. INSTALLATION AND CONNECTION

A. Electrical checking

⚠️

Before using Evolution³E, check if power selected (115 or 230V) is appropriate for your country (see also III.B).

⚠️

NEVER OPERATE WITHOUT MAIN POWER SUPPLY.

⚠️

NEVER START OPERATING ONLY ON BATTERY.

The EVOLUTION³E runs on wall current (115 or 230V, 50-60Hz) and is equipped with a rechargeable battery as a back-up system. The battery is charged continuously by the main power supply and its charge level is indicated by two LEDs.

Battery level indicator
- **RED** = Warning: low charge or discharged battery. Charge immediately.
- **GREEN** = Battery charged.

Main Supply indicator :
- Light On (Green) = Connected to the main power supply
- Light Off = Running on battery
B. How to change the main supply (230 V or 115V)

Switch off the control unit and remove the cord.

Open gently the door with a screwdriver.

Remove the selector (A) and select the right voltage (here 115V).

Replace the selector and close the door.
C. Footswitch connection

Using the screw connector, plug in the footswitch connector to the rear panel of the console (finger tight only).

1. **M2, M2SU, ONE USE-PLUS microkeratomes**

<table>
<thead>
<tr>
<th></th>
<th>“Backward” footswitch</th>
<th>“Forward” footswitch</th>
<th>“Vacuum” footswitch</th>
</tr>
</thead>
<tbody>
<tr>
<td>The microkeratome moves backward (even if Vacuum is off or Low vac is On)</td>
<td></td>
<td>Blade Oscillation</td>
<td>VACUUM (ON / OFF)</td>
</tr>
<tr>
<td>Blade Oscillation off</td>
<td></td>
<td>Forward motion of the microkeratome</td>
<td></td>
</tr>
</tbody>
</table>

**Note:**
1. If Vacuum is not activated, the forward footswitch will not operate.
2. If Vacuum is Off or if Low Vac is On, the activation of the backward footswitch moves the Epi-K™ backward.
2. **EPI-K™**

<table>
<thead>
<tr>
<th></th>
<th>“Backward” footswitch</th>
<th>“Forward” footswitch</th>
<th>“Vacuum” footswitch</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td>Backward motion</td>
<td>Slow forward speed</td>
<td>VACUUM (ON / OFF)</td>
</tr>
<tr>
<td></td>
<td>(even if Vacuum is</td>
<td>Medium forward speed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>off or Low vac is On)</td>
<td>Fast forward speed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blade Oscillation off</td>
<td>Oscillation on</td>
<td></td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td></td>
<td>Oscillation on</td>
<td></td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td></td>
<td>Oscillation on</td>
<td></td>
</tr>
</tbody>
</table>

**Steps with forward footswitch**

**Note:**
3. If Vacuum is not activated, the forward footswitch does not operate.
4. If Vacuum is Off or if Low Vac is On, the activation of the backward footswitch moves the Epi-K™ backward.
D. Selecting Mode

The console must be switched ON. Turn the keratome selector switch to either Epi-K™, M2 or One Use – Plus depending on the device to be used.

Example: EPI-K™ Mode
E. Electrical motor connection

Step 1 – Switch ON the console.

Step 2 – Select the appropriate motor ("M2", “OUP” or “EPI-K™”); “OP” must appear on the display panel.

Step 3 – Plug the motor system to the corresponding connector.

Step 4 – Select the appropriate speed (Speed 1 or Speed 2).

Note: “speed 1” is on average 10% slower than “speed 2”. Speed 1 is recommended for steep corneas or when a slower forward speed is required (a lower forward speed increases flap thickness). The oscillation speed rate is not modified.

The speed option is only available for M2 and One Use-Plus keratomes.
F. **Vacuum system connection vacuum tubing to the console**

The vacuum tubing consists of a tubing and a drip chamber designed to protect the vacuum circuit inside the console from leakage of liquid.

**Step 1** – Hold the chamber at the top (Pict.1).

**Step 2** – Slide it down as shown in Pict.2.

- Never place the chamber bottom up (as shown in Pict.3).
- If liquid appears in the chamber, replace the tubing immediately (Pict.4).
- Check for kinks and obstruction (as shown in Pict.5).
- Use only original parts supplied by the manufacturer.
Step 3 – Connect the tubing end “C” to the vacuum connector of the console.

Step 4 – Connect the luer lock “B” to the appropriate suction ring.
G. Test procedure

The unit has a self checking function operated by pressing the “TEST” key on the front panel. This will check the efficiency of the pumps. The unit can only be operated if the test is passed.

Blinking and audible tones will indicate a test that has not been passed.

The test should be made:
- daily and prior to surgery.
- whenever tubing is changed.
- whenever a red indicator light is illuminated

---

**Test function steps**

1 - Clamp the aspiration tubing,
2 - Press the “TEST” key,

The unit will check each pump: “P1”, then “P2”.

The display indicates the pressure obtained by each pump during the test.

The test is passed if the green LED “A” turns ON. The display indicates the atmospheric pressure of the day (approximative 760 mmHg at sea level).

If LED A is green and LED B is red, one of the two pumps has not passed the test. Check that the tubing has been clamped and make another test.

If both LEDs are red, neither the two pumps have passed the test. Check that the tubing has been clamped and make another test. If the problem still occurs, do not use the console and contact your local distributor for a complete evaluation of the unit.
Testing of the tubing

This test must be done whenever new sterile tubing is connected to the console.

1. Connect the sterile, single use aspiration tubing to the unit.
2. Start the pump test with the tubing clamped just after its connection to the console; the test is passed when the green LED is displayed on the console.
3. Unclamp the tubing, press the vacuum pedal, and read the displayed vacuum level. It must be slightly below the value displayed when vacuum is not activated (approximately 690 mmHg on display panel).
4. Clamp the tubing just before the connection with the ring; the new displayed value must be below 250 mmHg.
5. If the test is not passed, proceed as follows:
   - Visually check that the tubing is free of folds both before and after set up. Partial or total obstruction of the tubing may occur as a result of inappropriate folding, crushing in the packaging, or torsion during set up. Aspiration through a partially blocked tube may increase the degree of obstruction and may result in a loss of vacuum during surgery.
   - Poorly connected tubing, either on the console or on the ring, may also cause insufficient aspiration. It is very important to check the integrity of all connections.
   - Moria strongly advises against the re-use of aspiration tubing.
     Re-use of tubing may:
     - Damage connector, resulting in vacuum loss.
     - Damage the vacuum pumps.
   - Only use Moria tubing
   - Check that internal air ducts of the ring are not obstructed by surgical residues. This obstruction, resulting from insufficient or inappropriate cleaning, would create pseudo-aspiration and risk the loss of vacuum.
   - The vacuum is generated by electric pumps, which are protected against external liquid by a collecting chamber placed on the tubing. Penetration of liquid may damage the pumps and reduce aspiration. In such cases, the pumps must be changed by the manufacturer, and the tubing should be discarded.
H. Vacuum level and atmospheric pressure

The system displays the actual vacuum value in mmHg. The higher the vacuum power, the smaller the value displayed. When the ring is fixated on the eye, the vacuum value displayed must be less than 250 mmHg. If the value displayed is above 250 mmHg, the unit must be immediately turned off and sent back to MORIA for an evaluation.

**WARNING**

The vacuum level provided by the console depends on the local atmospheric pressure, and thus, on the elevation. The higher the elevation, the less efficient the suction will be.

The atmospheric pressure decreases with elevation (approx: 8 mmHg/100 m)
The suction capacity of the ring is proportional to the difference in pressure between the vacuum limit level of the pump and the local atmospheric pressure.

The surgery must be performed according to the IOP achieved.
a) Low Vacuum Function

The low vacuum function is activated by pressing the Low Vacuum key on the front panel (left bottom side). When it is activated, the LED “A” turns ON.

For safety reasons, when the low vacuum function is activated, the electrical motor can only be activated for a backward pass.

The “Low Vacuum” allows for low level of vacuum of the suction ring on the eye. This option can be useful to maintain suction on the eye while the patient undergoes laser ablation (nervous patient, eye tracker shut down, etc.).

IV. ALARMS & SAFETY

A. Loss of vacuum

In case of a loss of vacuum during surgery:

1. If a loss of vacuum has been detected on the main pump (over 250 mmHg):
   ⇝ An audible tone informs the surgeon,
   ⇝ The 2nd pump automatically and instantaneously takes over to provide vacuum power. The display is as shown.

2. If a loss of vacuum has been detected during surgery on the safety pump:
   ⇝ An audible tone informs the surgeon,
   ⇝ As the system had previously detected that the first pump was probably defective, the 2nd pump still runs and the red LED is on.

It is recommended to run a test once the surgery is done in order to check pumps.
B. Loss of battery power

If power is not coming from the main supply, the system will run automatically on the backup battery.
- An audible tone informs the surgeon
- The Main power Supply LED turns Off.

If battery is not adequately charged:
- An audible tone informs the surgeon
- The battery red LED turns ON,
- At the end of the surgery during which the alarm has occurred, connect the main power supply and recharge the battery immediately.

V. CLEANING AND MAINTENANCE

- No specific maintenance is required for the control unit.
- To clean the control unit, use isopropyl alcohol on a cloth.
- Do not use solvents or abrasives.

⚠️ WARNING!
Do not pour liquids or solutions on the control unit.

⚠️ WARNING!
If the unit has not been operated for two weeks or more, the battery level should be verified and recharged prior to further use.

⚠️ WARNING!
In case of unusual vibrations or noises, do not use the unit and contact your distributor.
VI. WARRANTY

The EVOLUTION³E system will function optimally provided that the recommendations for cleaning and maintenance are followed carefully. If however you experience a decrease in performance (irregular movement or slowing down for instance…), it is strongly recommended to have your system thoroughly checked by MORIA.

1. Moria warrants the following items exclusively

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVOLUTION³E console (except battery)</td>
<td>19380</td>
</tr>
<tr>
<td>EVOLUTION³E footswitch</td>
<td>19381</td>
</tr>
</tbody>
</table>

- If the above items are found to be defective within the period specified in paragraph 3, MORIA will repair, or at its option, replace the defective parts at no charge. The units must be returned in their original packaging.

- An authorized representative of MORIA must do servicing and replacement of parts.

- In case of malfunction of the equipment, an authorized MORIA technician will do the repairs at the purchaser’s request.

- The servicing of the unit will take place during MORIA’s normal working hours.

- Any defective part exchanged during the period of warranty will become the property of MORIA.

- Batteries and disposable items, such as blades, single-use heads & rings, and tubing, are not covered by the warranty.
2. The warranty does not apply in the following cases:

- When defects or malfunctions occur after the period specified in paragraph 3.
- When the equipment is not properly installed, properly maintained, or used for the intended purposes.
- When the unit is connected to an inappropriate power source.
- If the service is performed by non-authorized MORIA personnel.
- The use of non-Moria components or disposables will void the warranty.
- The manufacturer’s warranty is void if the seal is broken or removed.

3. Warranty Period

The equipment is under warranty for a period of twelve months starting from the date of the shipment.

4. Warranty and Liabilities

1. The use of non-Moria tubing will immediately void the warranty.

2. MORIA’s liability is limited to the service above mentioned in paragraph 1.
   In no case will MORIA be held liable for loss of revenue resulting from the equipment not being in operation.
Please complete and fax this questionnaire to become a Member of the MORIA USERS’ CLUB and have access to our USERS’ CLUB Heading (MORIA website: http://www.moria-surgical.com) and to many other advantages.

Please send or continue sending me MORIA News ☐ YES ☐ NO
Without cost or obligation on my part

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

☐ MD ☐ PhD ☐ Pr. ☐ Associate Pr.
☐ Dr. ☐ Mr. ☐ Ms.

Last name : ..........................................................
First name : ..........................................................
Second name : .......................................................
Date of birth : .......................................................
Function : ...........................................................
Hospital / Institution : ...........................................
Department : ..........................................................
Address : .............................................................
Street Name: ..........................................................
P.O. Box Nr Postal Code: .........................................
City: .................................................................
State: ................................................................
Country : ............................................................
Phone : (................)(.................................)
Fax : (................)(.................................)
E-mail Nr : ..........................................................

From time to time, MORIA may use your name and address to send information on related products and services which may be of interest to you. If you do not wish to receive this information, please tick this box ☐

Your Function:
☐ Hospital Administrator / Director
☐ Medical Department Head
☐ Medical Practitioner
☐ Central Services Staff
☐ Non Hospital Function (E.G. Distributor, Turnkey Contractor)
☐ Other (please specify) :

Type of institution:
☐ Hospital / University Hospital
☐ Clinic
☐ Outpatient clinic / Medical Centre
☐ Nursing Home / Extended Care
☐ Government Authority / Health Agency
☐ Refractive Centre

Type of equipment :

<table>
<thead>
<tr>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Microkeratome One ☐ One Use ☐ CB, CBSU ☐ M2, M2SU ☐ One Use-Plus</td>
</tr>
<tr>
<td>☐ Epikeratome Epi-KTM</td>
</tr>
<tr>
<td>☐ Control Unit Classic ☐ Classic II ☐ Evolution ☐ Evolution II ☐ Evolution 3E ☐ Evolution 3E</td>
</tr>
</tbody>
</table>

☐ Are you using other microkeratomes or epikeratomes ?
☐ Yes ☐ No

☐ If yes, which ones ?

☐ When did you start performing LASIK or Epi-Lasik with MORIA ?

☐ How many LASIK or Epi-Lasik procedures do you perform monthly ?
☐ 0 to 20 ☐ 20 to 50 ☐ 50 to 100 ☐ 100 to 150 ☐ 150 to 200 ☐ 200 and +

☐ Do you know other refractive surgeons who would be interested in joining MORIA’s USERS Club ?
☐ Yes ☐ No

☐ If so, please indicate their names and professional data :

Name : ..................................................................
...........................................................................
Address : ..................................................................
...........................................................................
Phone / Fax : ..................................................................
...........................................................................
E-Mail : ..................................................................
...........................................................................

Please, fax this form back to +33.1.46.74.46.70