EICKEMEYER® PHACOVET 2.0

USER MANUAL



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1 Preface

1.1 Description of the user

The instructions for use are intended for the following types of users:

- A) trained ophthalmic veterinary surgeons
- B) trained surgical assistants who will prep or operate the device before and/or during the surgery (e.g. surgical nurse)

WARNING! The PhacoVET device is for VETERINARY USE only. Non-compliance can lead to hazards with a level of risks which, if not avoided, could result in death or serious injury.

1.2 Conventions used in the instructions for use

The following style conventions are used in this document:

Bold

Names of product elements, commands, options, programs, processes, services, and utilities Names of interface elements (such windows, dialog boxes, buttons, fields, and menus)

[Bold with Square Brackets]

Interface elements the user selects, clicks, presses, or types

Italic

Publication titles referenced in text Emphasis (for example a new term) Variables

Courier

System output, such as an error message or script URLs, complete paths, filenames, prompts, and syntax

User input variables

- < Angle brackets surround user-supplied values</p>
- [] Square brackets surround optional items
- Vertical bar indicates alternate selections the bar means "or"

1.3 Explanation of safety warnings

DANGER! Danger indicates a hazard with a high level of risk which, if not avoided, will result in death or serious injury

WARNING! Warning indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury.

CAUTION! Caution indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury.

NOTICE Indicates information considered important, but not hazard-related.

1.4 Retaining instructions

Read and understand this manual and its safety instructions before using this product. Failure to do so can result in serious injury or death.

Follow all the instructions. This will avoid fire, explosions, electric shocks or other hazards that may result in damage to property and/or severe or fatal injuries.

Keep all safety information and instructions for future reference and pass them on to subsequent users of the product.

1.5 Obtaining documentation and information

1.5.1 Internet

The latest version of the documentation can be requested by contacting: info@medicalvet.ch

1.5.2 Ordering documentation & additional information

Documentation, user instructions, and technical information can be ordered by reaching out to:

Medical VET AG

Hafnerwisenstrasse 2 9442 Berneck Switzerland

Phone: +41 (0)76 589 08 07 Email: <u>info@medicalvet.ch</u>

1.5.3 Documentation feedback

If you are reading Medical VET AG product documentation on the internet, any comments can be submitted via the contact section of our website. Comments can also be sent to info@medicalvet.ch.

We appreciate your comments.

2 Description of the product

2.1 Purpose of the product

PhacoVET is a simple, robust, and compact system for phaco and vitrectomy surgeries in veterinary medicine.

Reduced to the essential core functions, PhacoVET is simple and reliable to operate. Its high performance meets the requirements of veterinary medicine. The system is ready for use in a very short time and, thanks to its compact design, can be used both as a mobile solution and as a stationary system in your clinic. All functions can be operated precisely using the specially developed pedal, while the relatively high weight prevents the pedal from slipping. With the wide range of instruments, operations can be performed on horses or large animals as well as on small animals.

2.2 Technical data

Parameter	Unit		
Power	110 VA (Voltampere)		
Voltage	100 - 240 V		
Frequency	50 – 60 Hz		
Fuses	2x 2AT		
Weight	3.1 kg (main device) + 7.0 kg (foot pedal)		
IP class	IP20 Class II		
Operating temperature	10 to 35 °C (50 to 95 °F)		
Humidity range	10 to 90 % relative humidity (RH)		
Software version	see within device software under 'setup' (displayed in bottom bar)		
Manufacturing date	see back of PhacoVET device		

Table 1 Technical data

2.3 Product Compliance

This product complies to:

- Directive (EU) 2024/2853 on liability for defective products
- IEC 60601-1 Medical electrical equipment: General requirements for basic safety and essential performance

2.4 Product elements

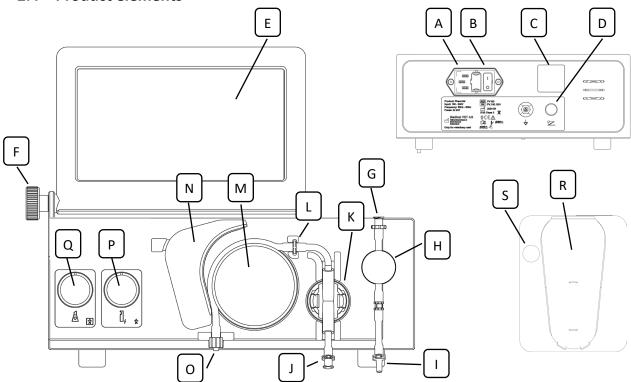


Fig. 1 Product illustration (schematic) with main elements highlighted (with rear view in upper right area and foot pedal on bottom right area of illustration)

- A. Socket for power cord
- B. Power switch (ON/OFF)
- C. LAN port (only to be used by service technician)
- D. Port for foot pedal
- E. Touchscreen
- F. Rotary knob to adjust touchscreen angle
- G. Luer connector of irrigation cannula tube system to connect to infusion bottle
- H. Black valve for blocking/unblocking flow through irrigation cannula
- I. Luer connector of irrigation cannula to connect to medical accessory (e.g. coaxial or bimanual irrigation handpiece or phaco handpiece)
- J. Luer connector of aspiration cannula to connect to medical accessory (e.g. coaxial or bimanual aspiration handpiece or phaco or vitrectomy handpiece)
- K. Sensor for pressure / vacuum level
- L. Notch for correct cannula routing
- M. Peristaltic pump
- N. Manual clamp for peristaltic pump
- O. Luer connector of aspiration cannula to connect to aspiration bag
- P. Port for vitrectomy handpiece
- Q. Port for phaco handpiece
- R. Foot pedal
- S. Foot pedal button to activate/deactivate continuous irrigation

Please note: Accessories such as handpieces, the cannula tube system, infusion bottle and aspiration bag are not included in scope of delivery and have to be purchased separately. The cannula tube system is shown here for illustration and explanatory purposes.

3 Safety instructions

3.1 How to use the product safely

3.1.1 Personal safety

- 1. Before plugging in the device and switching it on, make sure the device is clean, dry, and has no visible damage.
- 2. Make sure to transport, store, and operate the device only in temperatures and conditions as specified in **Section 2.2 Technical Data**.
- 3. Make sure to position the device on a non-slipping, even, and secure surface. If using an operating trolley, make sure to fix its position by locking the wheels properly.
- 4. Do NOT block the device's ventilation openings (e.g. by putting other items directly in front of it).
- 5. Make sure to NOT use the device in case the device seems damaged, open, or seems to operate in an unusual way (e.g. limited responsiveness to changes in settings, unusual sounds, etc.). Turn the device off and stop using it immediately if that is the case. Hazardous voltage inside. Can shock, burn, or cause death if used when severely damaged.
- 6. The device may only be operated by trained professional veterinary surgeons who have received a device onboarding.
- 7. Do NOT make changes to the device and do NOT open it. Hazardous voltage inside. Can shock, burn, or cause death. Keep out.
- 8. Make sure to only connect and use accessories (e.g. irrigation / aspiration / phaco / vitrectomy handpieces, cannula tube systems, etc.) that are recommended by Medical VET. Using non-recommended accessories may result in severe injuries or death of the patient and/or the operating personnel (e.g. due to high voltage).

3.1.2 Work area and electrical safety

- 1. The PhacoVET is an electromechanical device. Do NOT use the device in hazardous places and make sure to transport, store and operate the device only in temperatures and conditions as specified in **Section 2.2 Technical Data**.
- 2. Do NOT use PhacoVET in case of fluctuating power.
- 3. Ensure that the device will not get wet, in particular while operating it.
- 4. Ensure that the device will not get exposed to inflammatory gases, high voltages or other safety hazards.

WARNING! The PhacoVET device is for VETERINARY USE only. Non-compliance can lead to hazards with a level of risks which, if not avoided, could result in death or serious injury.

4 Preparation

4.1 How to transport, handle, and store the product

The PhacoVET is a complex ophthalmo-surgical device and therefore has to be handled and transported with care.

4.1.1 Lifting, handling, and transporting the product

To lift, transport and store the product safely:

- 1. Make sure the device is turned off and no cables, cannulas or handpieces are attached to it.
- 2. Make sure the device is wiped clean (e.g. using disinfectant spray) and dry.
- 3. The product CANNOT be sterilized.
- 4. Use the rotary knob on the side to unfasten the locked position of the monitor. Then turn the monitor from its upright operating position down into the transport position (flat on the device). Secure the new position using the rotary knob.
- For transport and storage, make sure to use the transport trolleys recommended by Medical VET and specifically designed to transport and store the device, including its foot pedal.

4.1.2 Handling the product

To handle the product safely:

- 1. Make sure the device is clean and dry (see above).
- 2. Make sure to transport, store, and operate the device only in temperatures and conditions as specified in **Section 2.2 Technical Data**.
- Make sure to position the device on a non-slipping, even, and secure surface. If
 using an operating trolley, make sure to fix its position by locking the wheels
 properly.
- 4. Do NOT block the device's ventilation openings (e.g. by putting other items directly in front of it).
- 5. Make sure to NOT use the device in case the device seems damaged, open, or seems to operate in an unusual way (e.g. limited responsiveness to changes in settings, unusual sounds, etc.) Turn it off and stop using it immediately if that is the case.
- 6. The device may only be operated by trained professional veterinary surgeons who have received a device onboarding.
- 7. Do NOT make changes to the device and do NOT open it.
- 8. Adhere to **Section 3 Safety Instructions**.
- Make sure to only connect and use accessories (e.g. irrigation / aspiration / phaco / vitrectomy handpieces, cannula tube systems, etc.) that are recommended by Medical VET.

5 Operation/Use

5.1 Operational environment

Make sure to adhere to **Section 3 Safety Instructions** and **Section 4 Preparation**. Only use the device in temperatures and conditions as specified in **Section 2.2 Technical Data**.

5.2 Setup of PhacoVET device

Follow the instructions mentioned above. Then attach all accessories and cannula tube system as shown in the illustration and explained in the instructions below.

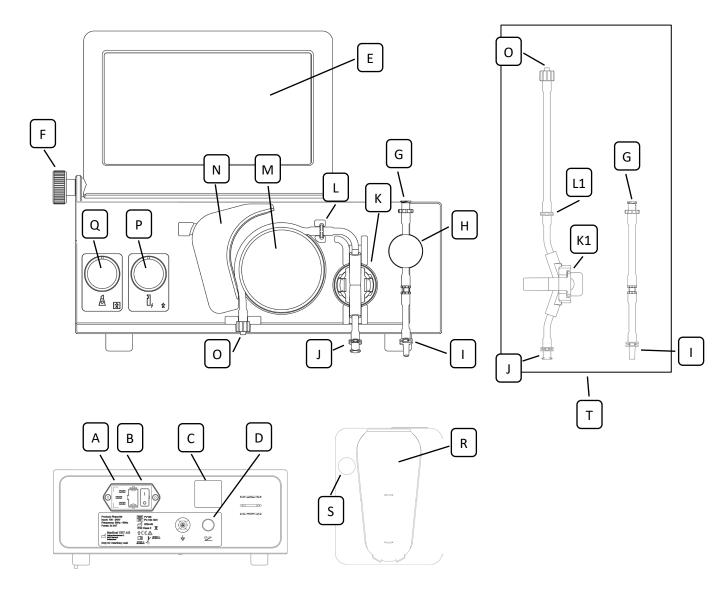


Fig. 2 Product illustration (schematic) with tube system illustrated on the right, with rear view and foot pedal shown on the bottom

- 1. Familiarize yourself with Section 2.4 Product elements.
- 2. Plug the power cord into the device (A) and into your operating room's power outlet.

- 3. Connect the foot pedal's cable to the PhacoVET device by pushing it gently into the port (C). The arrow on the end shows which way is up while inserting the cable.
- 4. Use the rotary knob (F) to adjust the angle of the touchscreen (E).
- 5. Unpack the cannula tube system (T), as shown on the right side of Fig. 2.
- 6. Pick up the tube with the Luer connectors (G) and (I), then press on the black valve (H) to open it to be able to position the tube as seen in Fig. 2.
- 7. Connect the Luer connector (G) to the tube of your infusion / irrigation bottle.
- 8. Connect the Luer connector (I) to the tube of your irrigation handpiece or to the irrigation tube of your phaco handpiece. (See more in **section 5.3 Setup of handpieces/instruments**.)
- 9. Pick up the tube with the integrated (K1) element and lock it into place in front of the pressure sensor (K). To lock it into place correctly, make sure to squeeze gently on both clamps of (K1), position it on sensor (K) and let go of the clamps. It should then be fixed as seen in Fig. 2.
- 10. Guide the rest of the tube around the peristaltic pump (M).
- 11. Make sure to use the notch (L) to fix the connector (L1) as seen in Fig. 2.
- 12. Gently pull on the tube until the Luer connector (O) reaches the fixed position at the bottom of the device as seen on Fig. 2.
- 13. Connect the Luer connector (O) to the tube of your aspiration bag.
- 14. Connect the Luer connector (J) to the tube of your aspiration handpiece, or to the aspiration tube of your vitrectomy / phaco handpiece. (See more in **section 5.3 Setup of handpieces/instruments**.)
- 15. Use the knob on the manual clamp (N) to move the clamp into the shut position. It should then encase the tube which is routed around the peristaltic pump (see step 10).
- 16. Connect the cord of your vitrectomy handpiece to the vitrectomy port (P) by gently pushing it into the port. The arrow on the cord's end shows which way is up while inserting the cord.
- 17. Connect the cord of your phaco handpiece to the phaco port (P) by gently pushing it into the port. The arrow on the cord's end shows which way is up while inserting the cord.
- 18. Open the flow of your infusion bottle.
- 19. Use the power switch (B) to turn on the PhacoVET device. You can then continue with the steps described in **section 5.4 Operating the product**.

Please note: Accessories such as handpieces, the cannula tube system, infusion bottle and aspiration bag are not included in scope of delivery and have to be purchased separately.

WARNING! Failure to adhere to the Setup, Preparation and Safety Instructions of sections 3, 4 and 5 may lead to hazards with a level of risk which, if not avoided, could result in death or serious injury.

5.3 Setup of handpieces/instruments

Make sure to only use connect and use accessories (e.g. irrigation / aspiration / phaco / vitrectomy handpieces, cannula tube systems, etc.) that are recommended by Medical VET.

5.3.1 Setup of I/A instruments/systems

Make sure to sterilize, connect, and use I/A systems only as described in the instructions for use of the respective product.

Make sure to connect the irrigation tube and the aspiration tube to the correct connectors. Do not alter or cut off the LUER connectors to make it fit. If a tube does not fit, if it is damaged, the wrong tube, and/or the product is not part of our recommended list of accessories, we strongly advise NOT to use it.

In the following, an example of a bimanual I/A set is shown:

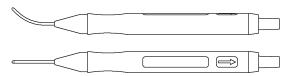


Fig. 3 Product illustration (schematic) of bimanual aspiration handpiece

In the illustration above, an aspiration handpiece is shown from the side and from above.

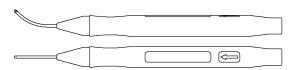


Fig. 4 Product illustration (schematic) of bimanual irrigation handpiece

In the illustration above, an irrigation handpiece is shown from the side and from above.

The arrow shows the direction of the flow. The arrow of the aspiration handpiece is pointing away from the handpiece tip. The arrow of the irrigation handpiece is pointing towards the handpiece tip.

When using coaxial handpieces, the irrigation and aspiration are in one handpiece. All of our recommended coaxial handpieces feature arrows that help guide where to place the irrigation and aspiration tubes.

WARNING!

Insufficient flow conditions can cause an imbalance of the fluidics. It is strongly recommended to observe the pressure conditions and, if necessary, to adjust them. It is very important to prevent any collapse of the anterior chamber. Medical VET AG disclaims any liability for any inappropriate and incorrect handling of I/A instruments.

CHECK BEFORE USE

Following inspection are necessary before use:

- Visual inspection of obstruction, deformation and no cracks
- Filling of irrigation and aspiration system with NaCl 0.9% solution to ensure the functionality
- Adhering to all instructions enclosed with the product intended to use

WARNING!

- Many I/A instruments/systems are designed for single use; any re-sterilization or re-use is strongly forbidden and can lead to dangerous postoperative infections of the eye.
- Don't use the I/A instruments/system after expiry date or if the packaging is damaged.
- Prior to use, inspect the tips of the I/A system. Don't use the product, if the tips are damaged.
- The instruments/handpieces are only to be used by qualified professionals.
- The manufacturer shall not be liable for any injury or damage suffered by the animal due to the use of the product.
- Please note: Maintaining the balance of flow and vacuum are of essential
 importance to not damage the animal's eye (e.g. causing any form of collapse of
 the eye). Keep the pressure conditions in permanent observation and, if
 necessary, adjust. In addition, make sure to adhere to all instructions enclosed
 with the product you are intending to use.

Non-compliance to any of the above instructions could lead to hazards with a level of risk which, if not avoided, could result in death or serious injury.

5.3.2 Setup of phaco handpiece

Make sure to sterilize, connect, and use phaco systems/handpieces only as described in the instructions for use of the respective product.

Make sure to connect the irrigation tube and the aspiration tube to the correct connectors. Do not alter or cut off the LUER connectors to make it fit. If a tube does not fit, if it is damaged, the wrong tube, and/or the product is not part of our recommended list of accessories, we strongly advise NOT to use it.

Make sure to connect the phaco cord correctly to the PhacoVET port (see component **Q** in section **2.4 Product elements**).

In the following, an example of a phaco set is shown, including the handpiece, a tip, a silicone sleeve and a wrench:



Fig. 5 Exemplary product illustration of assembling tip onto phaco handpiece

In most phaco sets, you will find a key/wrench (W) to screw and tighten the tip (V) tightly onto the phaco handpiece (U), see exemplary picture above.

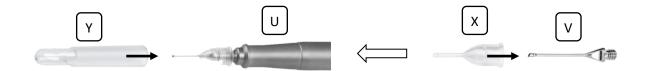


Fig. 6 Exemplary product illustration of putting sleeve and test chamber onto phaco tip

Gently push the silicone sleeve (X) over the tip (V). Make sure to place the sleeve correctly, with the tip of the sleeve ending shortly below the end of the tip and the irrigation ports placed in the wanted direction (e.g. sideways, perpendicular to the angle of the angled tip). Then carefully place the test chamber (Y) over the tip (V) and sleeve (X). Make sure the test chamber is filled before testing the phaco functionality.

WARNING!

- Make sure to test the phaco tip thoroughly before using it in surgery.
- Make sure not to touch any other instruments etc. with the tip. It might break or parts might detach.
- Make sure not to use the phaco tip outside a wet environment such as the filled test chamber, the eye, water, BSS, etc.

In addition, make sure to adhere to all instructions enclosed with the product you are intending to use.

WARNING!

Insufficient flow conditions can cause an imbalance of the fluidics. It is strongly recommended to observe the pressure conditions and, if necessary, to adjust them. It is very important to prevent any collapse of the anterior chamber. Medical VET AG disclaims any liability for any inappropriate and incorrect handling of phaco sets and additional instruments.

CHECK BEFORE USE

Following inspection are necessary before use:

- Visual inspection of obstruction, deformation and no cracks
- Using the phaco set with a filled test chamber with NaCl 0.9% solution to ensure the functionality
- Adhering to all instructions enclosed with the product intended to use

WARNING!

- Parts of reusable phaco sets (e.g. tips, sleeves, test chambers) are designed for single use; any re-sterilization or re-use is strongly forbidden and can lead to dangerous postoperative infections of the eye.
- Don't use the phaco sets after expiry date or if the packaging is damaged.
- Prior to use, inspect the tips of the phaco set. Don't use the product, if the tips are damaged.
- The instruments/handpieces are only to be used by qualified professionals.
- The manufacturer shall not be liable for any injury or damage suffered by the animal due to the use of the product.
- Please note: Maintaining the balance of flow and vacuum are of essential
 importance to not damage the animal's eye (e.g. causing any form of collapse of
 the eye). Keep the pressure conditions in permanent observation and, if
 necessary, adjust. Make sure to adhere to all instructions enclosed with the
 product you are intending to use.

Non-compliance to any of the above instructions could lead to hazards with a level of risk which, if not avoided, could result in death or serious injury.

5.3.3 Setup of vitrectomy handpiece

Make sure to sterilize, connect, and use phaco systems/handpieces only as described in the instructions for use of the respective product.

Make sure to connect the aspiration tube to the correct connector. Do not alter or cut off the LUER connectors to make it fit. If a tube does not fit, if it is damaged, the wrong tube, and/or the product is not part of our recommended list of accessories, we strongly advise NOT to use it.

Make sure to connect the vitrector cord correctly to the PhacoVET port (see component **P** in section **2.4 Product elements**).

In the following, an example of a vitrector is shown:



Fig. 7 Exemplary product illustration of a reusable vitrector

If you are using a re-usable vitrectomy handpiece, make sure it is properly sterilized and adhere to all instructions enclosed with the product you are intending to use. Make sure to follow the instructions for assembling the tip carefully.

WARNING!

- Make sure to test the vitrector tip thoroughly before using it in surgery.
- Make sure not to touch any other instruments etc. with the tip. It might break or parts might detach.
- Make sure not to use the vitrector tip outside a wet environment such as the eye, water, BSS, etc.

In addition, make sure to adhere to all instructions enclosed with the product you are intending to use.

WARNING!

As the vitrector only offers aspiration while using the vitrectomy functionality, usage of a suitable extra (e.g. bimanual) irrigation instrument is needed to ensure the pressure in the eye remaining constant. Insufficient flow conditions can cause an imbalance of the fluidics. It is strongly recommended to observe the pressure conditions and, if necessary, to adjust them. It is very important to prevent any collapse of the anterior chamber. Medical VET AG disclaims any liability for any inappropriate and incorrect handling of phaco sets and additional instruments.

CHECK BEFORE USE

Following inspection are necessary before use:

- Visual inspection of obstruction, deformation and no cracks
- Using the vitrectomy set with NaCl 0.9% solution to ensure the functionality
- Adhering to all instructions enclosed with the product intended to use

WARNING!

- Parts of reusable vitrectomy sets (e.g. tips) are designed for single use; any resterilization or re-use is strongly forbidden and can lead to dangerous postoperative infections of the eye.
- Don't use the vitrectomy sets after expiry date or if the packaging is damaged.
- Prior to use, inspect the tips of the vitrectomy set. Don't use the product, if the tips are damaged.
- The instruments/handpieces are only to be used by qualified professionals.
- The manufacturer shall not be liable for any injury or damage suffered by the animal due to the use of the product.
- Please note: Maintaining the balance of flow and vacuum are of essential
 importance to not damage the animal's eye (e.g. causing any form of collapse of
 the eye). Keep the pressure conditions in permanent observation and, if
 necessary, adjust. Make sure to adhere to all instructions enclosed with the
 product you are intending to use.

Non-compliance to any of the above instructions could lead to hazards with a level of risk which, if not avoided, could result in death or serious injury.

5.4 Operating the product

5.4.1 DEVICE CHECK

After fulfilling all steps described in the previous section, you'll see the following screen:

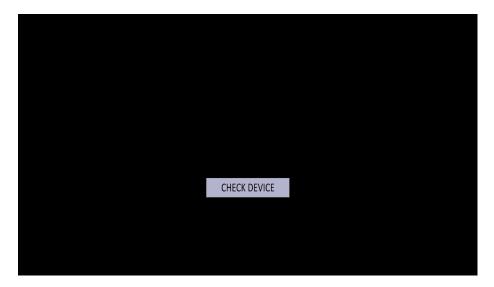


Fig. 8 CHECK DEVICE screen (default)

1. Click [CHECK DEVICE].

The device will then check all systems. If everything is working correctly, the following screen is displayed:

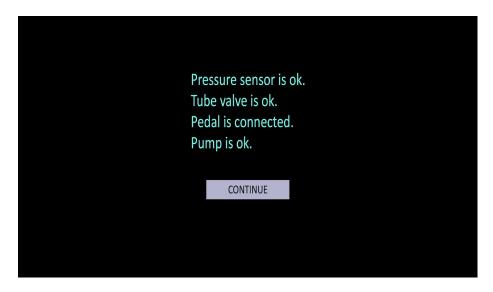


Fig. 9 CHECK DEVICE screen (check successful)

- 1. Check and redo all steps described in sections 3, 4, and 5.2 in case of errors or red warning messages.
- 2. If the check was successful as seen in Fig. 4, click **[CONTINUE]**. The PRE-OP screen will then be displayed.

5.4.2 PRE-OP mode

After fulfilling the steps of **5.4.1 Device check**, the device will go into PRE-OP mode, see screen below:

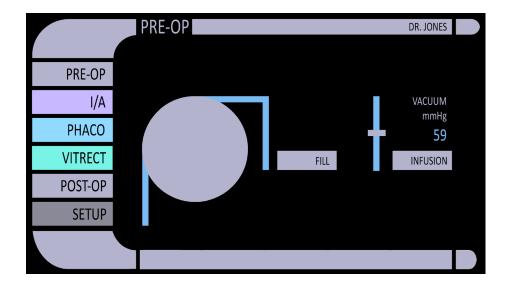


Fig. 10 PRE-OP screen

1. Click [FILL].

- A counter appears which indicates the time remaining in seconds. Wait for the counter to count to 0 and disappear. The tubes are then filled.
- 2. You can check the pressure by the numbers indicated on the right side of the screen under **[VACUUM]**. Make sure to set up the height of your infusion bottle appropriately in relation to the operating table and the phaco device to ensure your gravity-based vacuum is suitable for the surgery.
- 3. If you are using the device for the first time, click on **[SETUP]** to calibrate your foot pedal, to set up your user profiles and preferences (e.g. screen brightness, sound volume, presets, etc.).
- 4. If you are experienced using this device and all settings are already correctly adjusted, you can click on [I/A], [PHACO], or [VITRECT] to go into the respective mode and start your surgery.

5.4.3 SETUP mode

When you click on **[SETUP]**, you'll see the following screen:

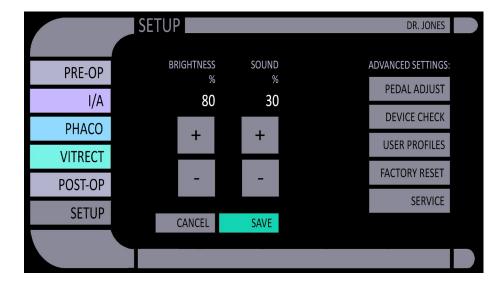


Fig. 11 SETUP screen

- You can directly adjust the screen [BRIGHTNESS] and the volume of the [SOUND] by clicking on their adjacent [+] and [-] buttons below. To keep the changes, click [SAVE].
- On the right side of the screen, you will also find [ADVANCED SETTINGS]. Such as
 [PEDAL ADJUST], [DEVICE CHECK], applying and renaming of [USER PROFILES]
 (including renaming of each user's [USER PRESETS]. You can also click on [FACTORY RESET] in case you want to delete all customized settings and revert your PhacoVET device back to its default settings.
- 3. In case a service technician does a maintenance check or repairs or a software update for your device, he/she will use the [SERVICE] button and enter their SERVICE CODE to be able to access further settings. Please do not enter this area if you are not a trained employee from Medical VET and assigned to do so.

5.4.4 SETUP – ADVANCED SETTINGS: FOOT PEDAL ADJUST

If you are in [SETUP], and then click on [PEDAL ADJUST], you'll see the following screen:

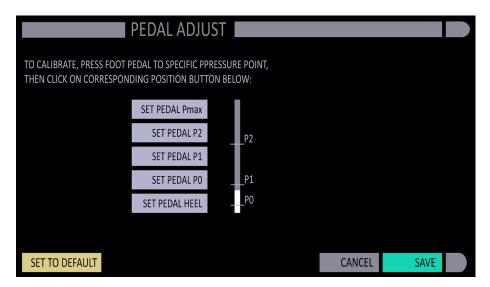


Fig. 12 PEDAL ADJUST screen

- 1. On the vertical bar in the middle of the screen, you can see in real-time how far you are pressing down the foot pedal. To calibrate the pressure points and positions of the foot pedal, first do not touch the foot pedal, then click on [SET PEDAL PO] to calibrate this neutral position PO.
- 2. For a maximum of accuracy, please remove your shoes and follow the next steps barefoot or with socks only.
- 3. Gently press the foot pedal down (towards its cable) until you feel the first pressure point. Hold it there and click on [SET PEDAL P1] to calibrate this first pressure point P1.
- 4. Then gently press the foot pedal further down (towards its cable) until you feel the second pressure point. Hold it there and click on [SET PEDAL P2] to calibrate this second pressure point P2.
- 5. Then press the foot pedal down all the way (towards its cable). Hold it there and click on [SET PEDAL Pmax] to calibrate this maximally tilted position Pmax.
- 6. As a last step, press the foot pedal all the way down in the other direction (NOT towards its cable) using your foot's heel. Hold it there and click on [SET PEDAL HEEL] to calibrate this maximally tilted pedal heel position.
- 7. To keep the changes, click [SAVE].
- 8. To start fresh or to calibrate a new foot pedal, repeat steps 1 to 7.

5.4.5 SETUP – ADVANCED SETTINGS: DEVICE CHECK

If you are in **[SETUP]**, and then click on **[DEVICE CHECK]**, you'll go into the Device Check as shown and described already in section **5.4.1 DEVICE CHECK**.

5.4.6 SETUP – ADVANCED SETTINGS: USER PROFILES & USER PRESETS

5.4.6.1 USER PROFILES

If you are in [SETUP], and then click on [USER PROFILES], you'll see the following screen:

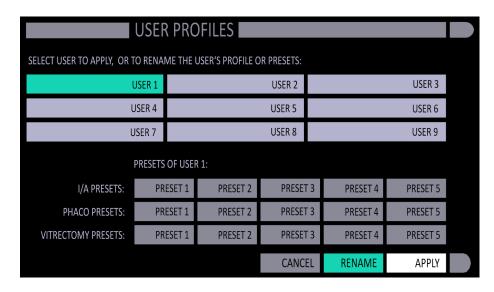


Fig. 13 USER PROFILES & USER PRESETS screen (with [USER 1] selected)

Selecting and using a USER PROFILE:

- 1. Click on one of the nine **USER PROFILES** to select it. You can then see the individual **USER PRESETS** of the selected **USER PROFILE** in the lower part of the screen.
- 2. Click on **[CANCEL]** to de-select everything and get back to the **[SETUP MENU]**. Alternatively, you can also simply click on another **USER PROFILE** to select it instead.
- 3. Click on [APPLY] to use the selected USER PROFILE while operating with PhacoVET.
- 4. From now on, you'll see your user profile name (e.g. <DR. JONES>, see renaming instructions below) in the upper right corner of your main setup screen and in the I/A, PHACO and VITRECT mode. You'll also see your user profile's individual presets at the bottom of these screens.
- After switching off the device: The next time the device is switched on, the same USER PROFILE will be applied as when the device had been switched off the last time.

Renaming a USER PROFILE:

1. Go to [SETUP], and then click on [USER PROFILES].

- 2. Click on one of the ten **USER PROFILES** to select it. You can then see the individual **USER PRESETS** of the selected **USER PROFILE** in the lower part of the screen.
- 3. Click on **[CANCEL]** to de-select everything and get back to the **SETUP MENU**. Alternatively, you can also simply click on another **USER PROFILE** to select it instead.
- 4. Click on [RENAME] to rename the selected USER PROFILE.

You'll then see the following screen:



Fig. 14 EDIT USER NAME screen (default)

- 1. Click on the light-grey horizontal bar in which you'll enter the new name.
- 2. Type in the new name as you wish, using the keyboard on the screen. Only numbers or English capital letters are available and no special characters other than blank spaces, <,> and <.>.
- 3. The entered user name (e.g. <DR. JONES>) can be no longer than 18 characters.
- To remove a typing error, use the [←] to remove the last characters or use the [CLEAR] button to delete all that was typed in.
- 5. If you click on [SET TO DEFAULT], the user profile name will revert back to its default state, e.g. USER 1.
- 6. If you don't want to save your changes, click [CANCEL].
- 7. To keep the changes, click [SAVE].

5.4.6.2 USER PRESETS

If you are in [SETUP], and then click on [USER PROFILES], you'll see the following screen:

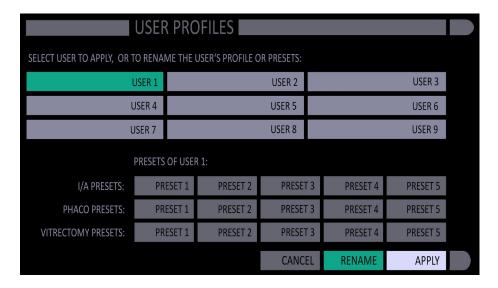


Fig. 15 USER PROFILES & USER PRESETS screen (with [USER 1] selected)

Renaming a USER PROFILE:

- 1. Click on one of the nine **USER PROFILES** to select it. You can then see the individual **USER PRESETS** of the selected **USER PROFILE** in the lower part of the screen.
- Click on [CANCEL] to de-select everything and get back to the SETUP MENU.
 Alternatively, you can also simply click on another USER PROFILE to select it instead.
- 3. Then click on the individual **PRESET** (e.g. **PRESET 1** of **PHACO PRESETS**) that you wish to rename.
- 4. Click on [RENAME] to rename the selected PRESET.

You'll then see the following screen:

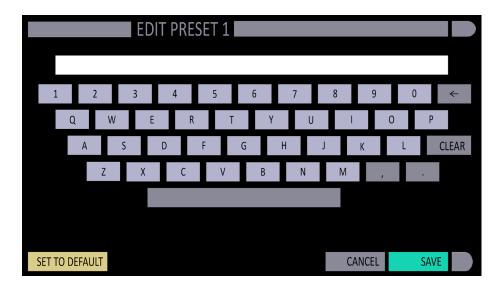


Fig. 16 EDIT USER PRESET screen (with [PRESET 1] selected)

- 1. Click on the light-grey horizontal bar in which you'll enter the new preset name.
- 2. Type in the new name as you wish, using the keyboard on the screen. Only numbers or English capital letters are available and no special characters other than blank spaces, <,> and <.>.
- 3. The entered preset name (e.g. <EQUINE>, <ANT.VITR>) can be no longer than 8 characters.
- To remove a typing error, use the [←] to remove the last characters or use the [CLEAR] button to delete all that was typed in.
- 5. If you click on **[SET TO DEFAULT]**, the user preset name will revert back to its default state, e.g. **PRESET 1**.
- 6. If you don't want to save your changes, click [CANCEL].
- 7. To keep the changes, click [SAVE].

5.4.7 SETUP – ADVANCED SETTINGS: FACTORY RESET

If you are in [SETUP], and then click on [FACTORY RESET], you'll be asked if you really want to proceed and do a FACTORY RESET.

Click [YES] if you wish to proceed. Click [CANCEL] if not.

CAUTION!

A **FACTORY RESET** means that the device will revert back to all of its default settings. All **USER PROFILES**, all **USER PRESETS**, **PEDAL ADJUST** (calibration), etc. will be lost.

5.4.8 SETUP – ADVANCED SETTINGS: SERVICE

If you are in [SETUP], and then click on [SERVICE], you'll be asked to enter a SERVICE CODE.

Only trained service & support personnel of Medical VET AG is permitted to enter this section.

When it is used: In case a service technician does a maintenance check or repairs or a software update for your device, he/she will use the **[SERVICE]** button and enter their **SERVICE CODE** to be able to access further settings. Please do not enter this area if you are not a trained employee from Medical VET and assigned to do so.

WARNING!

Non-compliance can lead to altered or non-functioning software and settings which could pose a level of risk which, if not avoided, could result in death or serious injury.

5.4.9 I/A mode

When you click on [I/A], you'll see the following screen:

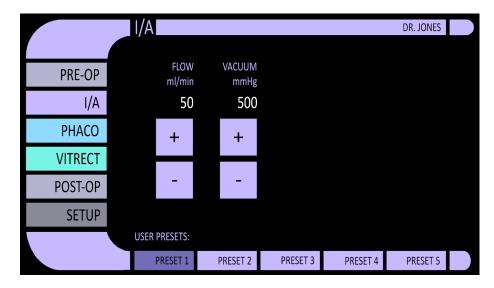


Fig. 17 I/A screen (with user profile DR. JONES and PRESET 1 applied)

- 1. You can directly adjust the maximum **FLOW** and the maximum **VACUUM** by clicking on their adjacent [+] and [-] buttons below.
- On the upper right corner of the screen, you can see which USER PROFILE is currently active. In the illustration above, it is the user profile named <DR. JONES>.
 To switch to another user's USER PROFILE or to rename it, see section 5.4.6.1 USER PROFILES.
- 3. On the bottom of the screen, you can see the current user's five **USER PRESETS** for I/A mode. You can click on one to apply it. When applied, it will be displayed in a darker tone (see illustration above, where **[PRESET 1]** is applied).
- 4. After using the [+] and [-] buttons to adjust your maximum **FLOW** and maximum **VACUUM**, you can turn these current settings into one of your presets by simply pressing long (approx. 3 seconds) onto the **PRESET** button you wish to overwrite.
- 5. You can then use the single-linear foot pedal to regulate the irrigation and aspiration.
- 6. For a maximum of accuracy, please remove your shoes and follow the next steps barefoot or with socks only.
- 7. For irrigation only, you can press on the foot pedal button (S) (see section 2.4 Product elements) to activate/deactivate continuous irrigation.
- 8. Alternatively, you can gently press the foot pedal down (towards its cable), but not further than the first pressure point P1. (See section **5.4.4 Foot pedal adjust** for more details on pressure points.) This functionality is not linear. The amount of irrigation once you press the foot pedal down is fixed and gravity-based. The higher the height of the infusion bottle and the bigger the smallest inner diameter of your instrument's cannula, the more irrigation you'll have.
- 9. For irrigation plus aspiration, gently press the foot pedal further down than pressure point P1. This functionality is linear. The more you press the foot down, the more

- aspiration you'll have until the maximum of flow and vacuum is reached of what you set on the touchscreen.
- 10. To use the reflux functionality, press on the heel instead of the tip of the foot pedal (i.e. pressing the foot pedal all the way down in the other direction (NOT towards its cable) using your foot's heel.

CAUTION! Always test the handpiece's correct functionality before using it on the animal.

In addition, please note: Maintaining the balance of flow and vacuum are of essential importance to not damage the animal's eye (e.g. causing any form of collapse of the eye). Test the pressure conditions and balance beforehand and keep the pressure conditions in permanent observation. If necessary, adjust.

5.4.10 PHACO mode

When you click on [PHACO], you'll see the following screen:

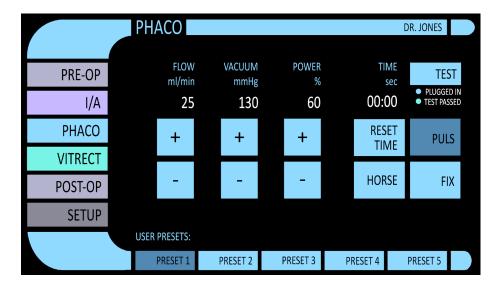


Fig. 18 PHACO screen (with user profile DR. JONES, PRESET 1, and PULS applied)

- To start, make sure your PHACO handpiece is properly assembled and connected (see also section 5.3.2 Setup of phaco handpiece). Then press on [TEST] and wait. The notifications PLUGGED IN and TEST PASSED will be displayed if the test was successful. In case the TEST FAILED or other issues, please check your accessories, the proper connection and retry. You can also turn off the PhacoVET and turn it back on before trying again.
- 2. You can directly adjust the maximum **FLOW**, the maximum **VACUUM**, and the maximum **POWER** by clicking on their adjacent [+] and [-] buttons below.
- 3. Underneath the title **TIME**, you can see a timer that displays how long you have used the phaco functionality since the successful test of your phaco handpiece. You can reset the counter to **00:00** by clicking on **[RESET TIME]**.
- 4. On the upper right corner of the screen, you can see which USER PROFILE is currently active. In the illustration above, it is the user profile named <DR. JONES>. To switch to another user's USER PROFILE or to rename it, see section 5.1.3.6.1 USER PROFILES.
- 5. On the bottom of the screen, you can see the current user's five **USER PRESETS** for PHACO mode. You can click on one to apply it. When applied, it will be displayed in a darker tone (see illustration above, where **[PRESET 1]** is applied).
- 6. After using the [+] and [-] buttons to adjust your maximum FLOW, maximum VACUUM, maximum POWER and switching on/off [PULS], [FIX], or [HORSE], you can turn these current settings into one of your presets by simply pressing long (approx. 3 seconds) onto the PRESET button you wish to overwrite.
- 7. You can then use the single-linear foot pedal to regulate the irrigation, aspiration, and phaco functionality.
- 8. For a maximum of accuracy, please remove your shoes and follow the next steps barefoot or with socks only.

- For irrigation only, you can press on the foot pedal button (S) (see section 2.4 Product elements) to activate/deactivate continuous irrigation.
- 11. Alternatively, you can gently press the foot pedal down (towards its cable), but not further than the first pressure point **P1**. (See section **5.4.4 Foot pedal adjust** for more details on pressure points.) This functionality is not linear. The amount of irrigation once you press the foot pedal down is fixed and gravity-based. The higher the height of the infusion bottle and the bigger the smallest inner diameter of your instrument's cannula, the more irrigation you'll have.
- 10. For irrigation plus aspiration, gently press the foot pedal further down than pressure point **P1** (but not further than pressure point **P2**). This functionality is linear. The more you press the foot down, the more aspiration you'll have until the maximum of flow and vacuum is reached of what you set on the touchscreen.
- 11. For irrigation plus aspiration plus phaco, gently press the foot pedal further down than pressure point **P2**. Per default, this functionality is also linear right until the maximum of phaco power is reached of what you set on the touchscreen. Make sure to use phaco only for the shortest amount of time and with as little power as possible to minimize potential harm to the patient.
- 12. To use the reflux functionality, press on the heel instead of the tip of the foot pedal (i.e. pressing the foot pedal all the way down in the other direction (NOT towards its cable) using your foot's heel.
- 13. As an additional option, you can switch from linear (default mode) to the mode [FIX] by clicking on it. When applied, it will be displayed in a darker tone (see illustration above, where [FIX] is applied). Then when pressing down the pedal further than pressure point P2, the maximum phaco **POWER** will be applied right away.
- 14. As another option, you can also apply [PULS] mode.
- 15. In case of an equine surgery, select **[HORSE]** mode. This is needed as the handpieces for equine phaco surgery is operating at another kHz frequency than the small animal phaco handpieces.

CAUTION! Always test the handpiece's correct functionality before using it on the animal.

In addition, please note: Maintaining the balance of flow and vacuum are of essential importance to not damage the animal's eye (e.g. causing any form of collapse of the eye). Test the pressure conditions and balance beforehand and keep the pressure conditions in permanent observation. If necessary, adjust.

5.4.11 VITRECT mode

When you click on [VITRECT], you'll see the following screen:

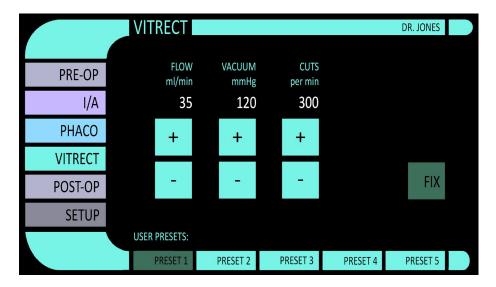


Fig. 19 VITRECT screen (with user profile DR. JONES, PRESET 1, and FIX applied)

- 1. To start, make sure your VITRECTOMY handpiece is properly assembled and connected (see also section **5.3.3 Setup of vitrectomy handpiece**).
- 2. You can directly adjust the maximum **FLOW**, the maximum **VACUUM**, and the maximum **CUTS PER MINUTE** by clicking on their adjacent [+] and [-] buttons below.
- On the upper right corner of the screen, you can see which USER PROFILE is currently active. In the illustration above, it is the user profile named <DR. JONES>.
 To switch to another user's USER PROFILE or to rename it, see section 5.1.3.6.1 USER PROFILES.
- 4. On the bottom of the screen, you can see the current user's five **USER PRESETS** for VITRECT mode. You can click on one to apply it. When applied, it will be displayed in a darker tone (see illustration above, where **[PRESET 1]** is applied).
- 5. After using the [+] and [-] buttons to adjust your maximum FLOW, maximum VACUUM, maximum CUTS PER MINUTE and switching on/off [FIX], you can turn these current settings into one of your presets by simply pressing long (approx. 3 seconds) onto the PRESET button you wish to overwrite.
- 6. You can then use the single-linear foot pedal to regulate the irrigation, aspiration, and vitrectomy functionality.
- 7. For a maximum of accuracy, please remove your shoes and follow the next steps barefoot or with socks only.
- 8. For irrigation only, you can press on the foot pedal button (S) (see section 2.4 Product elements) to activate/deactivate continuous irrigation.
- 12. Alternatively, you can gently press the foot pedal down (towards its cable), but not further than the first pressure point **P1**. (See section **5.4.4 Foot pedal adjust** for more details on pressure points.) This functionality is not linear. The amount of irrigation once you press the foot pedal down is fixed and gravity-based. The higher

- the height of the infusion bottle and the bigger the smallest inner diameter of your instrument's cannula, the more irrigation you'll have.
- 9. For irrigation plus aspiration, gently press the foot pedal further down than pressure point **P1** (but not further than pressure point **P2**). This functionality is linear. The more you press the foot down, the more aspiration you'll have until the maximum of flow and vacuum is reached of what you set on the touchscreen.
- 10. For irrigation plus aspiration plus vitrectomy, gently press the foot pedal further down than pressure point **P2**. Per default, this functionality is also linear right until the maximum of CUTS per minute is reached of what you set on the touchscreen. Make sure to use vitrectomy only for the shortest amount of time and with a suitable cut rate to minimize potential harm to the patient.
- 11. To use the reflux functionality, press on the heel instead of the tip of the foot pedal (i.e. pressing the foot pedal all the way down in the other direction (NOT towards its cable) using your foot's heel.
- 12. As an additional option, you can switch from linear (default mode) to the mode **[FIX]** by clicking on it. When applied, it will be displayed in a darker tone (see illustration above, where **[FIX]** is applied). Then when pressing down the pedal further than pressure point P2, the maximum **CUTS per minute** will be applied right away.

CAUTION! Always test the handpiece's correct functionality before using it on the animal.

In addition, please note: Maintaining the balance of flow and vacuum are of essential importance to not damage the animal's eye (e.g. causing any form of collapse of the eye). Test the pressure conditions and balance beforehand and keep the pressure conditions in permanent observation. If necessary, adjust.

5.4.12 POST-OP mode

When you click on **[POST-OP]**, you'll see the following screen:

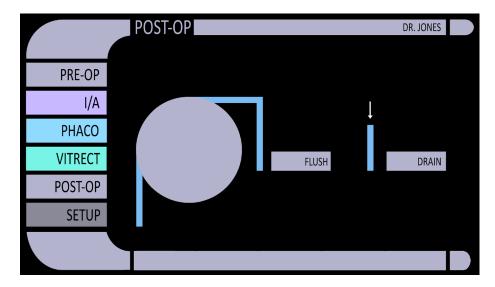


Fig. 20 POST-OP screen

- Before plugging off a handpiece (e.g. reusable I/A, phaco or vitrectomy handpiece), you can flush it in POST-OP mode by clicking on the [FLUSH] button.
 After clicking on [FLUSH], a counter appears which indicates the time remaining in seconds. Wait for the counter to count to 0 and disappear.
- 2. If you want the tubes to NOT be filled when you disconnect them from the system (e.g. after your surgery), you can close the valve of the irrigation bottle and disconnect it from the tube system.
- 3. Then, click on **[DRAIN]**. A counter appears which indicates the time remaining in seconds. Wait for the counter to count to **0** and disappear.
- 4. The tube system will not be completely dry, but it will be more comfortable when you disconnect the tubing and dispose of the hazardous waste material and put the reusable accessories away for being sterilized.
- 5. Do steps 1-4 after each surgery (or each surgical step where applicable).
- 6. You can then switch off the device using the power switch on the back of the device (see component **B** in section **2.4 Product elements**).
- On the upper right corner of the screen, you can see which USER PROFILE is currently active. In the illustration above, it is the user profile named <DR. JONES>.
 To switch to another user's USER PROFILE or to rename it, see section 5.4.6.1 USER PROFILES.
- 8. The next time the device is switched on, the same **USER PROFILE** will be applied as when the device had been switched off the last time.

6 What to do in emergency and exceptional situations

WARNING!

Make sure to NOT use the device in case the device seems damaged, open, or seems to operate in an unusual way (e.g. limited responsiveness to changes in settings, unusual sounds, etc.).

Turn the device off and stop using it immediately if that is the case.

Hazardous voltage inside. Can shock, burn, or cause death if used when severely damaged.

WARNING!

Do NOT make changes to the device and do NOT open it. Hazardous voltage inside. Can shock, burn, or cause death. Keep out.

Contact your seller or Medical VET AG for product support, repairs, and maintenance.

Contact data:

Medical VET AG

Hafnerwisenstrasse 2 9442 Berneck Switzerland

Phone: +41 (0)76 589 08 07 Email: <u>info@medicalvet.ch</u>

Do NOT attempt repairs if you are not a trained employee from Medical VET and assigned to do so.

Make sure to adhere to all safety instructions given in section 3 Safety instructions.

7 Maintenance and cleaning

7.1 Maintenance overview

Maintenance tasks shall be done according to the following plan:

Task	Recommended Frequency
General maintenance check	Every 12 months
Software update	Every 12 months or as needed
Cleaning with suitable cleansing agents	After every use

Table 2 Maintenance Overview

7.2 Cleaning

Clean your PhacoVET device with suitable cleansing agents after every use (e.g. by using 'Dr.Weigert neodisher MediClean forte'). Make sure to never apply the cleansing agent directly to the PhacoVET. Instead, apply cleansing agent to a suitable cleansing cloth / microfibre cloth and then use the cloth to clean the PhacoVET device.

In addition, make sure to use sterile accessories only. Adhere to all safety instructions given in **section 3 Safety instructions**.

7.3 General maintenance check and software updates

Contact your seller or Medical VET AG for **general maintenance checks** as well as **software updates**.

Contact data:

Medical VET AG

Hafnerwisenstrasse 2 9442 Berneck Switzerland

Phone: +41 (0)76 589 08 07 Email: <u>info@medicalvet.ch</u>

Do NOT attempt repairs, technical maintenance or software updates if you are not a trained employee from Medical VET and assigned to do so.

8 Repair

WARNING!

Make sure to NOT use the device in case the device seems damaged, open, or seems to operate in an unusual way (e.g. limited responsiveness to changes in settings, unusual sounds, etc.).

Turn the device off and stop using it immediately if that is the case.

WARNING!

Do NOT make changes to the device and do NOT open it. Hazardous voltage inside. Can shock, burn, or cause death. Keep out.

Contact your seller or Medical VET AG for product support, repairs, and maintenance.

Contact data:

Medical VET AG

Hafnerwisenstrasse 2 9442 Berneck Switzerland

Phone: +41 (0)76 589 08 07 Email: info@medicalvet.ch

Do NOT attempt repairs if you are not a trained employee from Medical VET and assigned to do so.

Make sure to adhere to all safety instructions given in **section 3 Safety instructions**.

9 Disposal

WARNING!

Do NOT make changes to the device and do NOT open it. Hazardous voltage inside. Can shock, burn, or cause death. Keep out.

After usage, all accessories, instruments, as well as the PhacoVET device must be handled as contaminated items.

In case you need to dispose of the PhacoVET device, the following applies:

The devices must be disposed according to local regulations. For information, contact your local environmental or public office and appropriate waste disposal companies. In this regard, waste is to be recycled or disposed of:

- without danger to human health
- without using procedures or methods harmful to the environment, particularly to the water, air, soil, flora and fauna
- without creating noise or smell

If in doubt, contact your seller or Medical VET AG for disposal of your PhacoVET device.

Contact data:

Medical VET AG

Hafnerwisenstrasse 2 9442 Berneck Switzerland

Phone: +41 (0)76 589 08 07 Email: <u>info@medicalvet.ch</u>

In addition, make sure to adhere to all safety instructions given in **section 3 Safety instructions**.

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NOTES				



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