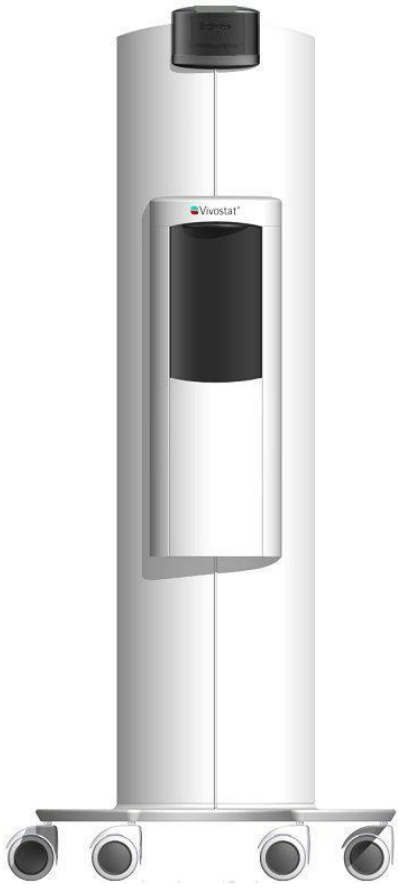
Vivostat®

SEALING | HEALING | REGENERATION

USER MANUAL

Processor Unit PRO 800
Processor Unit PRO 800 – Compact*



CE
0477

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* Processor Unit PRO 800 &
Processor Unit PRO 800 – Compact
are collectively referred to as PRO 800 Series

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Vivostat A/S reserves the right to revise the publication and to make changes from time to time in the contents hereof without obligation to notify any person of such revision or changes, unless otherwise required by law.

Record the serial number of the Processor Unit and retain for future reference (number next to SN symbol, found at the rear of the unit).

SN _____

CONTENTS

1. INTRODUCTION

This **User manual** contains a detailed description of the Processor Unit, instructions for use and other information relevant to the Vivostat® System. The safe and effective use of the system requires understanding of and compliance with all instructions, warnings and cautions included in this manual.

The Vivostat® System comprises four main components:

- a **Processor Unit,**
- a **disposable Preparation Kit, for preparation of an autologous fibrin sealant or autologous platelet rich fibrin matrix*,**
- an **Applicator Unit** and
- a **disposable Application Kit**, used to apply the sealant or matrix.

It is necessary that the user reads this User manual in conjunction with the product specific Instruction for Use (IFU) before using the Vivostat® System.

The Vivostat® System PRO 800 Series is CE marked in accordance with the Medical Device Directive (EU) 93/42/EEC.

CE 0477

The system complies with the requirements of the following international standards:

- IEC 60601-1,
- IEC 60601-1-2
- IEC 61010-2-20 (applicable clauses)

2. INTENDED PURPOSE AND POPULATION

The Vivostat® System is a medical device used for the preparation and application of:

- an autologous fibrin sealant from a whole blood or plasma source, or
- an autologous platelet rich fibrin matrix from a whole blood source.

All autologous products prepared using the PRO 800 Series are indicated for application to a surgical site requiring haemostasis, tissue sealing and/or tissue repair, for patients undergoing surgical interventions and/or tissue repair. The sealant or matrix is to be prepared and applied by health care professionals or personnel supervised by a health care professional.

For medical indications, clinical benefits and performance characteristics, please refer to the IFU for the specific product.

3. SYMBOL DEFINITIONS

CE 0477	The Vivostat® System is CE marked in accordance with the provision of the EC Medical Device Directive 93/42/EEC
MD	Medical Device
	Refer to instruction manual
	Consult instructions for use (IFU)
	Caution
	Manufacturer
	Power “ON”, connected to the mains
	Power “OFF”, disconnected from the mains
REF	Catalogue number
	Date of manufacture
SN	Serial number
	Don’t push with wheels blocked
	Potential equalization
	Warning: for continued protection against risk of fire, replace only with same type and rating fuse
	Disposal as per WEEE directive
	Attention: observe precautions for handling electrostatic dischage sensitive devices
	Hot surface (halogen bulb): Touching this surface could result in bodily injury. Let it cool down before touching it
	Connection for Vivostat® Foot Switch

* sealant = Vivostat® Fibrin
matrix = Vivostat® PRF, Obsidian® ASG, Obsidian® RFT or ArthroZheal®

4. CAUTIONS, WARNINGS AND SAFETY INFORMATION

The following is a list of cautions, warnings, and safety information relating to the system as a whole and its individual components.

4.1. INSTALLATION

When installing or moving the **Processor Unit** please note the following:

1. The **Processor Unit** shall be located in an area with restricted access to prevent non-skilled personnel contact with blood products.
2. The **Processor Unit** must be placed on a level surface.
3. The **Processor Unit** does not need a clearance envelope outside its base plate.
4. Connection to power mains shall follow local law and regulations.
5. The **Processor Unit** can only be connected to grounded mains.
6. Use only approved power cords (see requirements in section 10).
7. To avoid any electromagnetic or other interference problems do not place the **Processor Unit** near sensitive or vital equipment.

4.2. GENERAL CAUTIONS AND WARNINGS

1. The **Processor Unit** is designed for use by medical professionals. The **Processor Unit** shall only be operated by properly trained personnel. Please read and follow all instructions, cautions and warnings included in this **User manual**.
2. Safeguard for personnel.
    - Do not lean on the **Processor Unit**.
    - Keep the wheels locked at all times during operation.
    - Observe not to trip over mains cable.
    - Do not touch the halogen lamp: hot surface immediately after heating. Let cool before touching.
    - Do not look into the halogen lamp during operation without the protection provided by the coloured **Safety shield**.
    - Always follow the procedures stated in this **User manual**.
    - Do not try to override or disengage any of the safety features on the **Processor Unit**.

4.3. BLOOD HANDLING AND INFECTION RISK

Universal precautions for blood handling should always be observed in the operation of the products.

The **Processor Unit** and the disposable kits do not ensure full protection against microbiological contaminants in the event of blood spillage or **Preparation Unit** leakage.

In case that a **Preparation Unit** is leaking during processing, the leak sensors installed inside the **Centrifuge area** will detect and halt the process and issue error message.

Note: if hazardous material is spilt, the user is responsible for carrying out appropriate decontamination.

4.4. DISPOSAL OF USED KITS

Dispose of all accessories that may contain biohazard materials, such as body fluids, according to universal blood handling precautions.

4.5. CONTRAINDICATIONS

See **IFU** delivered with the **Preparation Kits** and **Application Kits**.

4.6. INTERACTIONS

See **IFU** delivered with the **Preparation Kits** and **Application Kits**.

4.7. HARDWARE AND ELECTRICAL INFORMATION

1. The **Processor Unit** is designed and produced according to:
    - IEC 60601-1, Medical electrical equipment - Part 1 General requirements for basic safety and essential performance
    - IEC 60601-1-2, Medical electrical equipment - Part 1-2 General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbances – Requirements and tests
    - and applicable clauses of IEC 61010-2-020 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020 Particular requirements for laboratory centrifuges.
2. Whilst care and attention has been devoted to minimizing all residual risks relating to the **Processor Unit**, please note that it is the user's responsibility to use the **Processor Unit** only in accordance with this **User manual**. It is the user facility's responsibility to ensure that the **Processor Unit** is operated only by staff trained and qualified in accordance with the facility's approved procedures.
3. During the site installation and setup, performance to specification is verified by Vivostat A/S or an authorised distributor. Once the installation has been completed the user only has to clean the system (see section 7), verify the general electrical safety and general mechanical integrity of the equipment, i.e. verify that the **Processor Unit** has not been tampered with or damaged in any way.

Regular electrical safety checks are not required. When electrical components have been exchanged or repaired a new electrical safety check must be performed and documented by Vivostat A/S or an authorised distributor.

Plug the power cord into a properly grounded main supply outlet whose voltage and frequency characteristics are compatible with those listed on the **Processor Unit** or in this User manual. Do not use plug adapters or extension cords; such devices defeat the safety grounds and could cause injury. Do not excessively kink or bend the power cord.

4. All maintenance must be carried out by Vivostat A/S or an authorised distributor in accordance with approved procedures. Find further information in section 8 “Maintenance and service”.

5. The user must not access internal parts via the service panels. To replace blown fuses, access can be gained from the rear of the unit via the power entry module (see section 8.1).

6. Attempting to access internal parts other than the fuse module would constitute use not in accordance with these instructions and might result in the introduction of electrical or mechanical hazards.

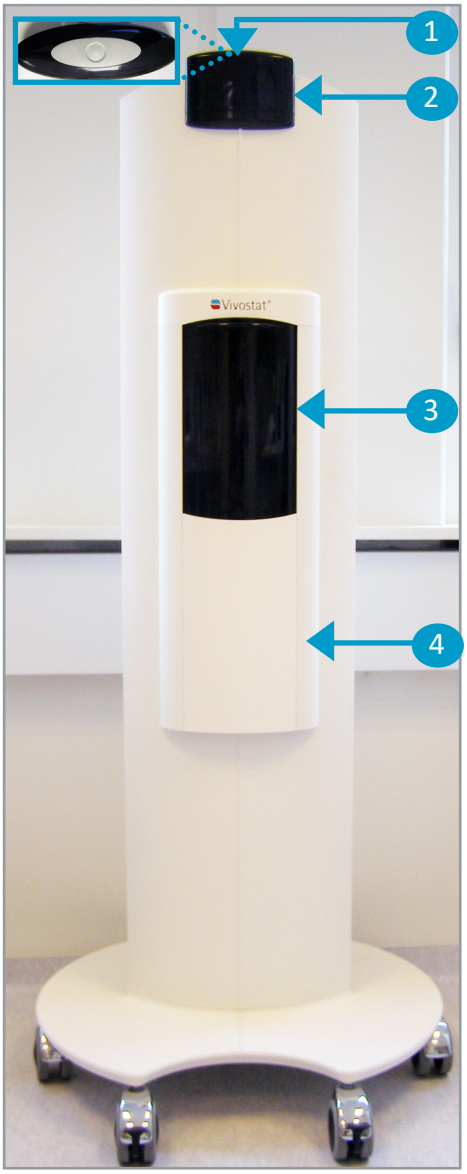
7. Vivostat A/S does not accept responsibility for unauthorised alterations to hardware or software.

5. PROCESSOR UNIT DESCRIPTION

This is an automated electromechanical device for processing whole blood/plasma to prepare sealant or matrix using a **Preparation Kit**.

The **Processor Unit** is sent in a wooden box with the **Base plate** in a separate cardboard box. To assemble it, lift and place the **Processor Unit** on the foam for mounting the **Base plate**. Mount it with the 6 nuts and washers.

Front:



1. **User button:** (open/confirm/start)
   This button is used to open the **Safety shield** and start the preparation process.

2. **Front display:** displays operational status and any error code.

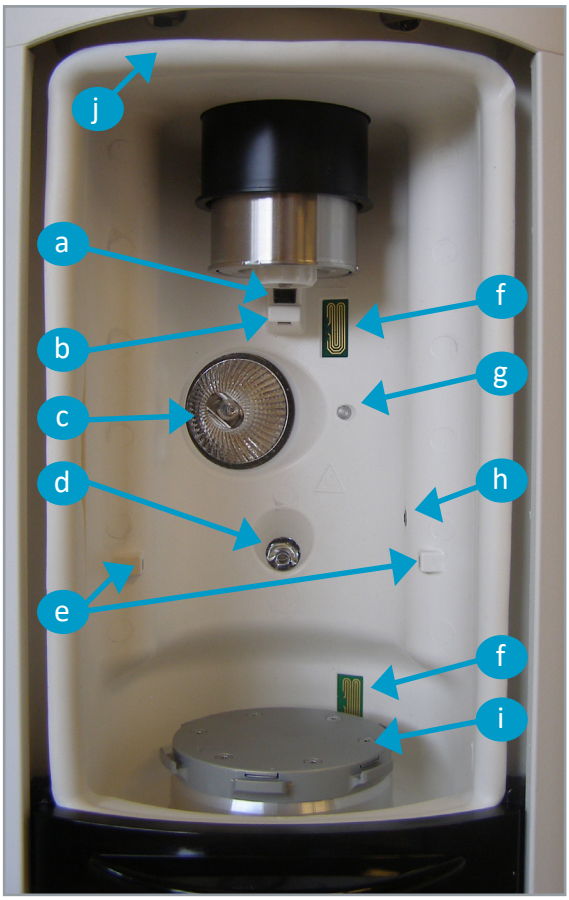
3. **Safety shield:** gives access to the **Centrifuge area** of the **Processor Unit.** Opens automatically and is closed manually. The **Safety shield** is removable for cleaning.

4. **Bottom cover:** removable cover giving access to removal of **Safety shield** for cleaning.

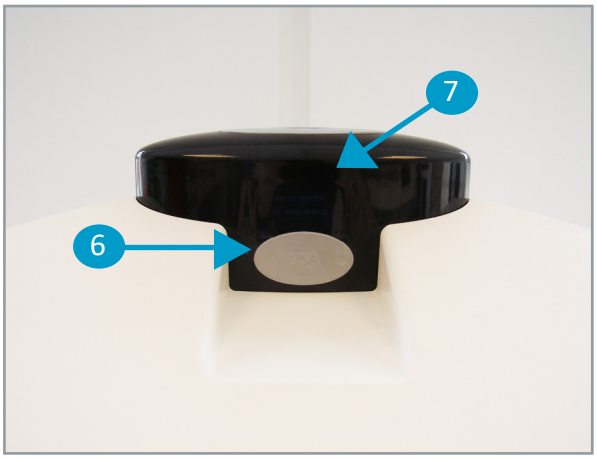
5. **Centrifuge area:**

   a. **Preparation Unit** ID sensor
   b. RBC sensor
   c. Heater lamp
   d. Illumination unit
   e. Fibrin sensor
   f. Leakage sensors
   g. Air temp. sensor
   h. IR temp. sensor
   i. Flywheel
   j. Seal

Centrifuge area:



Rear:

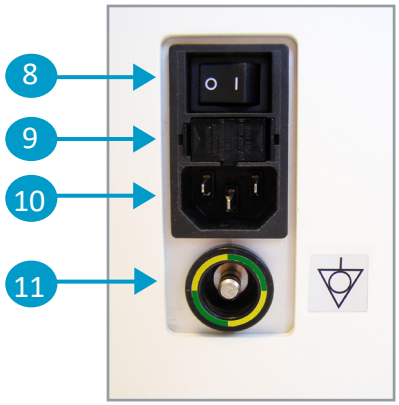


6. **Data port:** dust cap and USB port for connection to PC for download of program updates and for export of logged run data/system diagnostics.

   Only to be used by Vivostat A/S or an authorised distributor.

7. **Rear display:** indicates remaining process time.

8. **Mains power switch:** switches unit ON and OFF.

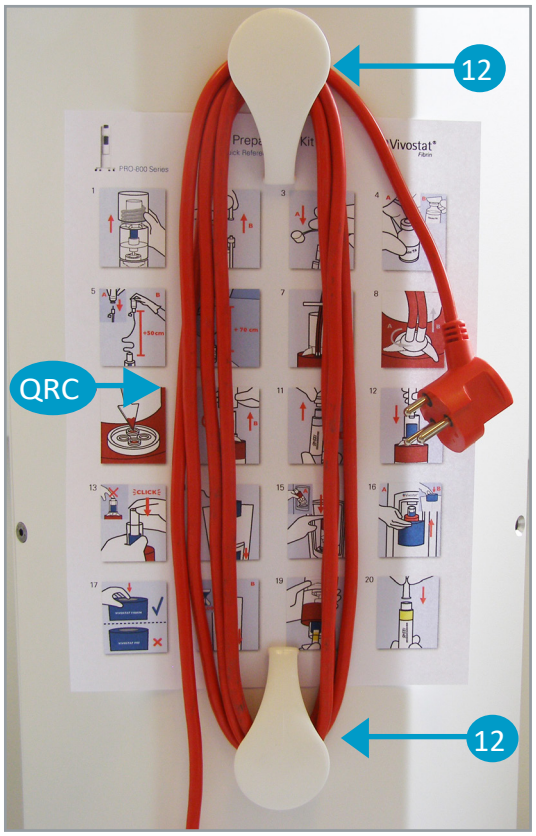


9. **Fuse drawer:** this module houses the replaceable main control fuses.

10. **Main power socket** w. earth contact: connects to a grounded wall outlet by the power cord.

11. **Potential equalization connection:** plug connector (POAG ID6) for connecting to other equipment via standard POAG socket if potential equipotential grounding with other equipment is desired.

12. **Power cord hangers (Processor Unit PRO 800) :** on the rear side the **Processer Unit** is equipped with hangers for holding the power cord when not in use. The hangers further serve as a clip to hold the **Quick Reference Card (QRC):**



6. PREPARATION OF SEALANT/MATRIX

To be used only with a Vivostat® **Preparation Unit.**

6.1. PROCESSOR UNIT SET UP

Read the **QRC** and the **IFU** supplied with the disposable **Preparation Kit** for a complete description of the preparation set up.

Press the **Mains power switch** on the back of the **Processor Unit** and the start-up process will initiate.

During the start-up procedure the **Processor Unit** will perform a self-diagnostic test, and the software version and CRC values will be shown. This will be followed by the display message:

PLEASE WAIT

If the **Safety shield** is open, the display will read:

CLOSE SHIELD

Close the **Safety shield** by pushing it upwards to its locked position until the lock clicks.

6.2. PROCESSING

When the **Processor Unit** is ready to use the display will say:

PRESS BUTTON
TO OPEN SHIELD

The **Safety shield** opens and the display instructs:

INSERT PREP UNIT
CLOSE SHIELD
PRESS BUTTON

Place the **Preparation Unit** on the flywheel. Push down and make sure that it is correctly aligned and home on the flywheel.

Close the **Safety shield** by sliding it up to its engaged and in a locked position.

When the **Safety shield** is closed the **Preparation Unit ID sensor** in the **Processor Unit** will automatically detect the type of **Preparation Unit** inserted and display:

CHECKING PREP UNIT
PLEASE WAIT

and hereafter one of the following:

FIBRIN
PROCESS INITIATING

PRF
PROCESS INITIATING

OBSIDIAN
PROCESS INITIATING

ARTHROZHEAL
PROCESS INITIATING

If, the **Processor Unit** is not able to detect the **Preparation Unit** it will start to toggle between possible processes. Press the **User button** when the right type of product is shown in the display.

If, the **Processor Unit** by mistake selects a wrong type of product, press the **Mains power switch** on the back and try and restart the Processor Unit.

If this does not help, contact your local distributor or Vivostat A/S.

Once the process has initiated the heater lamp will turn on and begin heating the blood to 36°C and the display will indicate:

HEATING: 36°C
XX.X°C

Once heated the process will continue and count down to the end of the process. The time will be recalculated throughout the process as the transfer of plasma may vary from patient to patient.

READY IN
MIN:SEC

When the process is complete, the display will indicate:

COMPLETE
REMOVE PREP UNIT

The **Safety shield** will automatically open, and the **Processor Unit** will emit a warning beep every 7 seconds to remind the user to remove the **Preparation Unit**.

N.B. Do not turn OFF the **Processor Unit** before the display says "**COMPLETE**" and the **Safety shield** is fully open.

Remove the **Preparation Unit** immediately. Do not let the **Preparation Unit** stay inside the **Centrifuge area** for a longer period, as cooling of the **Preparation Unit** is essential to ensure the high quality of the autologous product.

Close the **Safety shield** once the **Preparation Unit** has been removed.

6.3. ERROR HANDLING

The **Processor Unit** is equipped with a control system, which constantly monitors the status of the system and the process via various sensors and control procedures. In case of a detected problem the process will be interrupted, and the display will show an error message. See section 9.

7. CLEANING

This section contains information for basic cleaning/ decontamination of the **Processor Unit**. We recommend cleaning the **Processor Unit** after each process.

Warning: the heater lamp area may still be hot!

Warning: the Processor Unit may contain biohazardous materials, such as body fluids. Perform cleaning according to universal blood handling precautions.

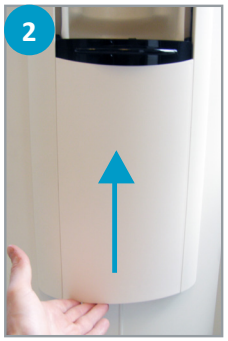
Note: If hazardous material is spilt, the user is responsible for carrying out appropriate decontamination.

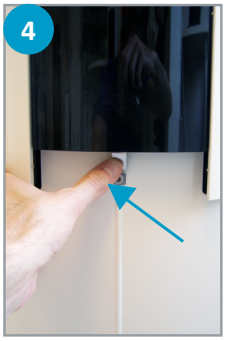
7.1. DISMANTLE BOTTOM COVER AND SAFETY SHIELD

With the **Processor Unit** turned on, press the **User button** to open the **Safety shield**. When the **Safety shield** is fully open, turn the power OFF at the **Mains power switch**.

Push the **Bottom cover** upwards to release and remove it. Then:

- for the **Processor Unit PRO 800:** press the **Shield spring** and slide the **Safety shield** downwards and out of the guides (image 1+2+4+7).
- for the **Processor Unit PRO 800 – Compact:** open the slid at the **Base plate** then press the **Shield spring** and slide the **Safety shield** downwards. Now, tip the **Processor Unit** slightly backwards, so the **Safety shield** slides out of the guides (image 1-7).





7.2. CLEANING THE BOTTOM COVER AND SAFETY SHIELD

Clean the **Safety shield** and the **Bottom cover** with suitable cleaning and disinfectant agent (see section 7.6) and dry with a soft cloth.

7.3. CLEANING THE INTERIOR CENTRIFUGE AREA

Thoroughly wipe the entire **Centrifuge area** using a soft cloth pre-moistened with disinfectant. Allow to dry.

DO NOT USE SPRAY CLEANERS as they may damage sensitive internal electronics.

The internal surfaces houses sensors, which are very delicate and require great caution in the cleaning process. Use a very gentle rubbing action until all residual disinfectants are removed from the sensor area. Use Isopropyl or one of the other approved disinfectants (see section 7.6) to completely remove all streaks and residue from sensor windows / light guides.

Inspect sensor area to ensure it is clean and dry and no lint or fibres remain on sensor surfaces.

7.4. INSPECT THE SAFETY SHIELD AND SEAL AND REMOUNT PARTS

Inspect the **Safety shield** for cracks or other damage. Observe that the aluminium tape is firmly placed on the upper left side of the **Safety shield**.

Then verify that the **Seal** is intact and in place. If both are intact, re-install the **Safety shield** by sliding it into the guides. The **Safety shield** is correctly mounted when the spring “clicks”.

> If cracks or damages are found,
> contact your local distributor or Vivostat A/S

Finally remount the **Bottom cover** by fitting it between the guides and pushing downwards.

When finished cleaning, close the **Safety shield**.

7.5. CLEANING EXTERNAL SURFACES

Wipe the outer surface of the cabinet with a soft cloth, pre-moistened with cleaning agent / disinfectant.

Observe not to scratch the **Display housing** on top of the **Processor Unit**.

7.6. CLEANING AGENTS AND DISINFECTANTS

The **Processor Unit** has been tested to withstand the following cleaning agents and disinfectants:

- ASP Cidex®
- EcoLab Indicin® Liquid
- Dr. Schumacher Optisept®
- Isopropyl alcohol
- Peroxides

Please note that you can **not** use alcohol (ethanol) > 96% when cleaning the **Processor Unit**

Further it withstands spilling of:

- Saline
- Iodine 2.5% solution in 70-80% ethanol

Always follow the instructions provided by the manufacturer of the agents.

Before using any cleaning or decontamination methods except those above, please check with the local distributor or Vivostat A/S to avoid damaging the equipment.

8. MAINTENANCE AND SERVICE

The **Processor Unit** requires only minimal maintenance.

Calibration of the **Processor Unit** is done before initial site installation and acceptance procedure. Further calibration is under normal circumstances not required.

The **Processor Unit** is equipped with a control system, which constantly monitors the status of the system and the process via various sensors and control procedures. Essential data from each run are logged in a data file in the **Processor Unit** memory, and a comprehensive data log file is saved from the last 30 runs for later analysis during possible service or in case of problems.

Should non-recoverable errors (see section 9) or other problems arise, contact your local distributor or Vivostat A/S for service.

8.1. FUSE REPLACEMENT

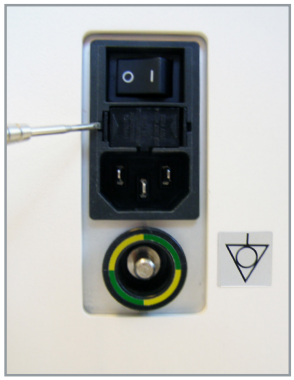
The **Mains fuse** module is situated in the drawer within the **Mains powers switch**.

In the event of a blown fuse, a new one can be installed quickly and easily.

Fuse type: T 2.0A, 250 V.

Note: There are 2 fuses in the drawer (medical 2-pole protection).

1. Turn the **Mains power switch** OFF and unplug from the power source.



2. Insert a small screwdriver or similar device into the slots on the left and the right sides of the fuse module.

3. Pry gently until the fuse module is completely removed.

4. Replace both fuses at the same time using only designated fuses as stated on the rear panel of the **Processor Unit.**

5. Place the fuse module back in the power entry module and press to lock into place.

There are no replaceable fuses inside the **Processor Unit**. Therefore, if replacing the **Mains fuse** does not solve the problem **DO NOT TRY TO OPEN** the **Processor Unit**. Contact Vivostat A/S or the local distributor.

8.2. BATTERIES

There are no replaceable batteries inside the **Processor Unit**.

In order to ensure program settings, data log files etc. are maintained, the **Main control board** is battery supported by a build-in battery having a 10- 12 years lifetime.

8.3. TRANSPORT

Note: If the **Processor Unit** needs to be sent or transported horizontally, the **Safety shield** must be closed and proper protection provided. Please contact Vivostat A/S for instruction.

9. USER PROMPTS / TROUBLESHOOTING

9.1. PRIOR TO INSERTION OF THE PREPARATION UNIT

DISPLAY	EXPLANATION	CORRECTIVE ACTION
XXX	During startup the PRO 800 series makes a self test of all electronic boards, sensors, ect. If an error occurs please follow the instructions in the display.	Note the error code before pressing the User Button or turning of the power. Turn the Mains Power Switch off and on at rear of the unit. If the error persists, contact your local supplier or Vivostat A/S for technical support.
ERROR 121 **DO NOT USE THE UNIT** **UNIT UNCALIBRATED** **SEE USER MANUAL**	The SIB board has lost it's calibration data and has been reset to default, which will result in poor fibrin concentration.	Contact your local supplier or Vivostat A/S for technical support.
REMOVE PREP UNIT **KEEP PRO 800 EMPTY** **CLOSE SHIELD** **PRESS BUTTON**	If for some reason a prep-unit is present in the PRO 800 series, the sensors will not be able to read the right values.	When the shield is open, remove the prep unit, close the shield and press the User Button and the unit will restart. If the error persists, contact your local supplier or Vivostat A/S for technical support.
TEMPERATURE COMPARE ERROR **PLEASE WAIT** **FOR THE UNIT** **TO STABELIZE**	Too high difference between the IR sensor and the AIR sensor.	Wait for 10 sec and when the display indicates: CLOSE SHIELD Close the shield and the unit will be ready for use.
TEMP SENSOR ERROR **NOTE ERROR MESSAGE** **PLEASE CONTACT** **YOUR LOCAL SUPPLIER** **OR VIVOSTAT A/S**	Either the IR sensor or the Air sensor is defect.	If the error persists, contact your local supplier or Vivostat A/S. One of the sensors are defect and your unit needs service.
ERROR 55 **CLAMP SENSOR** **ERROR** **SEE USER MANUAL**	The clamp sensor is defect.	Recycle power. If the problem persist, your unit needs service. Note the error code and contact your local supplier or Vivostat A/S.

9.2. AFTER INSERTION OF THE PREPARATION UNIT, BUT BEFORE PLASMA TRANSFERS TO THE REACTION CHAMBER (SEE ILLUSTRATION PAGE 16).

DISPLAY	EXPLANATION	CORRECTIVE ACTION
REMOVE PREP UNIT IF PRESENT OR CLEAN SENSORS WHEN READY CLOSE SHIELD PRESS BUTTON	The RBC or the colour sensor did not detect the right values, either because there is a prep unit present or they are dirty and needs cleaning.	Remove the prep unit if present or clean the sensors with a cloth moistend in disinfectants. If the error persists, contact your local supplier or Vivostat A/S.
CLAMP ERROR SEE USER MANUAL	The prep unit is not seated correctly on the flywheel or the clamp sensor is defect.	Recycle power and follow the instructions in the display. If the error persists, contact your local supplier or Vivostat A/S.
ERROR 16 SPEED ERROR SEE USER MANUAL PRESS BUTTON	The rotation sensor is defect or the prep unit is not connected correctly.	Follow the instructions in the display and check if the piston on the prep unit is in the right position. If the piston is in the right position your unit needs service. Contact your local supplier or Vivostat A/S.
LEAK DETECTED PRESS BUTTON TO OPEN SHIELD **(AFTER BUTTON IS ACTIVATED) **PLEASE WAIT FIND CAUSE CLEAN LEAKSENSORS	The prep unit is leaking.	The most probably cause is that there are some blood remaining in the valve. Clean it and follow the instructions in the display. **Do not insert the prep unit until showed in the display!!!!**
FIBRINSENSOR FAILED PRESS BUTTON REMOVE PREP UNIT CLEAN FIBRINSENSOR	The fibrin sensor needs cleaning.	Clean the sensor and follow the instructions in the display. If the error persists, contact your local supplier or Vivostat A/S.
MISPOSITIONED PISTON PRESS BUTTON TO OPEN SHIELD SEE USER MANUAL	The top rotation sensor did not detect any rotation.	The prep unit piston is not in the right position. Place the prep unit on a flat surface and remove the pH4 syringe, then pull carefully the piston up in the right position, without transferring blood to transfer channels or the reaction chamber. Follow the instructions in the display. If the error persists, contact your local supplier or Vivostat A/S.

9.3. AFTER THE TRANSFER OF PLASMA TO THE REACTION CHAMBER.

DISPLAY	EXPLANATION	CORRECTIVE ACTION
XXX	All errors after transfer of plasma to the reaction chamber are nonrecoverable.	Note the error code and follow the instructions in the display. Try to restart the unit by turning the Mains Power Switch off and on at rear of the unit. If the error persists, contact your local supplier or Vivostat A/S.
LEAK DETECTED **PRESS BUTTON** **TO CONTINUE** **DISPOSE PREP UNIT**	Leak detected after transfer. This error is nonrecoverable.	After removing the leaking prep unit, it should be disposed. Clean the centrifuge area, sensor windows and the lamp very carefully. Follow the instructions in the display and turn the Mains Power Switch off and on at rear of the unit.
ERROR 98 **WRONG CONCENTRATION** **PRESS BUTTON** **TO CONTINUE**	The calculation for making the right concentration of fibrin went wrong.	Press the User Button to open the shield and dispose the prep unit. The PRO 800 series will be ready to use again after this error.
ERROR 99 **NO FIBRIN DETECTED** **PRESS BUTTON** **TO CONTINUE**	No fibrin detected in the reaction chamber.	Press the User Button to open the shield and dispose the prep unit. The PRO 800 series will be ready to use again after this error.

9.4. ANY ERROR OCCURRING AFTER PROCESSING IS COMPLETE

DISPLAY	EXPLANATION	CORRECTIVE ACTION
XXX	These errors are nonrecoverable.	Note the error code before pressing any buttons. Contact your local supplier or Vivostat A/S for technical support. NOTE: In case of fibrin in the syringe, this can be used as usual.

Never leave the **Processor Unit** turned OFF with the **Safety shield** open for a longer period.

In case of non-recoverable errors, please contact Vivostat A/S and store the **Preparation Unit** and the complete kit for later investigations.

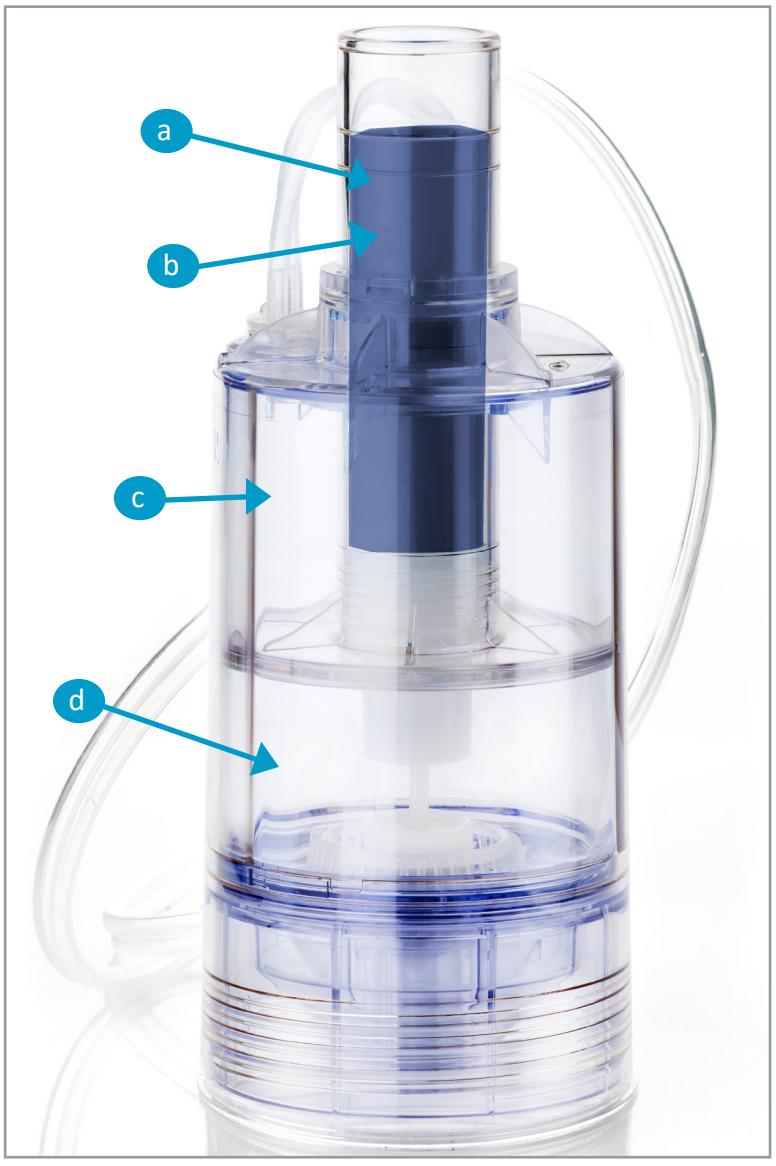
It is also very important to get all information about the incident, to be able to analyse what happened. The most important information is serial number of the unit, error message/code, sealant/matrix product process and what the user experienced.

NOTE: you can never use the Preparation Unit again after an error or in case of lost power if there has been blood or plasma in the reaction chamber.

9.5. PREPARATION UNIT ILLUSTRATION

a. Color coding
   - Dark blue: Vivostat® Fibrin
   - Teal: Vivostat® PRF
   - Light blue: ArthroZheal®
   - White: Obsidian® ASG, Obsidian® RFT

b. Piston
c. Collection chamber
d. Reaction chamber



10.TECHNICAL SPECIFICATIONS

I.E.C. equipment classification:	Class 1, continuous operation (IEC 529, IPXO rated)	
Typical operating requirements:	Input voltage:	100-240 VAC
	Frequency:	50/60 Hz
	Power consumption:	200 VA
	Fuse:	2 pcs. T 2.0 A, 250 V
Potential equalization terminal:	Plug connector:	POAG ID/6 (DIN 42801)
Line frequency leakage:	Earth leakage current:	<500 µA
Weight/dimensions:		
Processor Unit PRO 800:	Weight:	38.5 kg inc. baseplate
	Height:	1,267 mm
	Baseplate diameter:	Ø 584 mm
Processor Unit PRO 800 – Compact:	Weight:	35.6 kg inc. baseplate
	Height:	987 mm
	Baseplate diameter:	Ø 484 mm
Centrifuge rotational speed:	Max 9000 rpm	

10.1. ENVIRONMENTAL

Operation:	Ambient temperature:	+15°C - +30°C
	Relative humidity:	25% - 90%
	Atmospheric pressure:	700 hPa - 1100 hPa
Transport and storage:	Ambient temperature:	-40°C - +70°C
	Relative humidity:	10% - 100% non-condensing
	Atmospheric pressure:	700 hPa - 1100 hPa

10.2. POWER CORD REQUIREMENTS

100/120 volt:

Only use a listed (UL, CSA) detachable power cord manufactured to the following specifications:

Plug end:	NEMA 5-15P hospital grade, 15 A, 125 V
Receptacle end:	IEC 320/CEE-22, 6 A, 250 V / 15 A, 125 V
Cord:	UL style SJT, 18 AWG, 3 conductors

220/240 volt:

Plug end:	Molded straight PVC plug with double grounding system: - DIN 49441, CEE 7/U11, 10/16 A, 250 V - CEBEC, DEMCO, KEMA, NEMKO, OVE, SEMKO, VDE, UTE, FEMKO
Receptacle end:	Molded straight PVC plug: - DIN 49457, CEE 22/V, 10 A, 250 V - VDE, D, N, S, SEV, OVE, KEMA
Cord:	PVC, 7.2 mm diameter - 10 A, 250 V - Conductors: 3 x 1 mm^2 - Conductor colors – brown, blue, green/yellow stripe

11.DISPOSAL

The Vivostat® **Processor Unit** is manufactured from RoHS compatible components and materials. Parts are assembled for easy disassembly into electronic boards and single-sort items. Metal and plastic parts are manufactured from recyclable materials, and all injection molded plastic parts are made from certified materials according to EU RoHS and WEEE directives. Where needed, only halogen free (bromine and chlorine free) flame retardants are used. All injection molded plastic parts are marked with generic material grade identification acc. to ISO 1043/1-4, ISO 11469 and ISO 18064.

Dispose of the Processor Unit in accordance with local laws and regulations.

12.ORDERING INFORMATION

You can find reference numbers for ordering on the product label or online on the Vivostat® website.

Processor Unit and Applicator Units:

https://vivostat.com/the-vivostat-system/#order-codes

Disposables:

ArthroZheal® product codes: https://vivostat.com/arthrozheal-for-orthopaedic-surgery/#order-codes

Obsidian® ASG product codes: https://vivostat.com/obsidian-asg-anastomoses-safeguard/#order-codes

Obsidian® RFT product codes: https://vivostat.com/obsidian-rft-regenerative-fistula-treatment/#order-codes

Vivostat® Fibrin product codes: https://vivostat.com/vivostat-fibrin/#order-codes

Vivostat® PRF product codes: https://vivostat.com/vivostat-prf/#order-codes

Application devices product codes: https://vivostat.com/vivostat-application-devices/#order-codes

Vivostat® Co-Delivery product codes: https://vivostat.com/vivostat-co-delivery/#order-codes

13.FURTHER INFORMATION

For general information, questions, and technical questions, please contact your local distributor or:

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