



VACUETTE® MultiMixer including Software (Vers. 1.0)

USER'S MANUAL

MAN-127 – Revision 02
Revision date: January, 2019

This user manual follows the directions as prescribed by the CEN/TC 140 recommendations for in-vitro diagnostic instruments:

INSTRUMENT NAME:

VACUETTE® MultiMixer
including Software (Vers. 1.0)
Short cut name: MultiMixer

Device for mixing of blood or other
biological liquids



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**PLEASE READ THIS ENTIRE PRODUCT MANUAL
BEFORE USING THE INSTRUMENT FOR THE FIRST TIME**

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1. INTRODUCTION

1.1 General description

The **VACUETTE® MultiMixer** is a simple and reliable device designed to perform the mixing of blood or other biological liquids. Different styles of tubes can be accommodated by a variety of rack adapters.

The microprocessor of the **VACUETTE® MultiMixer** controls different programs and speeds of mixing to ensure accuracy and reproducibility of results. To ensure proper mixing, the **VACUETTE® MultiMixer** mixes for five minutes. At the end of five minutes, the operator is alerted by an acoustic signal and a flashing display. Samples are now ready for analysis.

In case of interruption of power supply or in case of a fault the equipment will not re-start alone but will go in stand-by.

To restart the equipment, refer to §3 of this manual.

1.2 Proper Use

The **VACUETTE® MultiMixer** must be used accordingly to the following prescriptions:

- 1) The device must be used only in association with its own racks.
- 2) Use different racks only to mix the proper test tubes and vials.
- 3) The device has to be used only by trained personnel for working in laboratory.
- 4) The device must be used by user always in safety conditions wearing gloves, glass, and all the safety tools recommended for laboratory work.
- 5) Use the device following always the instructions contained in this manual.
- 6) Equipment not to be used in hazardous atmosphere and with hazardous materials for which the equipment is not designed.

1.3 Improper Use

Every kind of use or action, not included in proper use, is considered improper use. Moreover, also the following points are considered improper use:

- 1) The voluntary hindrance of racks movement during mixing.
- 2) The use of racks not belonging to the device and not indicated by manufacturer.
- 3) The use of device near centrifuges or on a not flat surface (please follow the instructions written in section INSTALLATION of this manual).

2. Potential Dangers and Safety Precautions

2.1 User Precautions

Before beginning the use of the mixing device, the operator must know the rules for handling potentially infectious materials and for handling Electro-mechanical systems

2.1.1 User Identification

This mixing device is intended for professional use only. The operator must be trained for working in laboratory using hazardous materials and professional equipment. The use of this mixing device by a not trained operator is considered an improper use.

2.2 Electrical equipment

As all electrical equipment, the power supply is a potential source of danger. Please avoid handling electrical parts before disconnecting them from the power supply. Never carry out

maintenance on the instrument when it is under electrical tension. Until the instrument is packaged, as supplied, the operator is protected against electric shock. Pay attention to the power supply. The **VACUETTE® MultiMixer** is powered by low voltage, and it doesn't present the same dangers of the equipment's powered by an electrical line. Even though it has a voltage elevator circuit inside, and it could provoke strong electrical shocks, it is not dangerous for the service assistance personnel. We suggest disconnecting the power supply every time a technical operator make instrument maintenance.

2.3 Mechanical equipment

For the mechanical part of the mixing device we suggest do not open the machine before having disconnected it from the power supply. If the power is on, it is not dangerous for the operator, but instrument would damage if brought into contact with the parts in movement

2.4 Biohazardous material

As with all in vitro diagnostic equipment, patient samples and quality control (QC) products that are assayed on this system, should be treated as potentially bio-hazardous. All materials should be handled according to your facility's biohazard procedure. Always wear the personal protective equipment recommended by your facility when using the mixing device.

2.4.1 Human samples

Always wear gloves and eye protective glasses when handling human samples. Treat all samples as potentially bio-hazardous and infectious. If any sample is spilt on the instrument, utilize the correct personal protective equipment (PPE-gloves, lab coat, etc.), wipe it up immediately and clean the contaminated surface with a disinfectant (e.g. Sodium hypochlorite 0.5%) solution.

2.4.2 Waste solution and solid waste

Avoid direct contact with waste solution and/or solid waste. Both should be handled as potentially bio-hazardous. Dispose of waste solution and/or solid waste according to local governmental regulations.

2.5 Notes on safety measure

Please pay attention to the sample collection. The vacuum test tubes used for this instrument, have been studied to draw the right level of blood. To fill the test tube with a higher volume of blood, could cause a serious infection risk for tube leakage. Furthermore the leakage could damage the inner optical part of the instrument and annul the guarantee.

2.6 Disposal and Recycling

Herewith we declare that this instrument is subject to the European Directive 2011/65/EU (RAEE Directive) and 2011/65/EU). Therefore the instrument must be disposed separately, not as urban waste and delivered to the specific collection centre in accordance with the Directive 2011/65/EU and 2011/65/EU).

The user may request that the supplier collect the instrument for correct disposal, if a new instrument is ordered

2.7 Bio-Hazardous Parts Disposal

All parts which have a direct contact with samples must be disposed as POTENTIALLY

INFECTIOUS. Follow local regulations.

2.8 Additional Precautions

The following symbols are placed on the instrument and/or on the outer box to assure correct usage:



Caution



In vitro diagnostic medical device



Consult instructions for use



Biological risks



See chapter 2.6 'Disposal and recycling'



Electrostatic discharge sensitive device (ESDS)



DC (direct current)



Manufacturer



Date of manufacture



Serial number



Conformité Européenne (European Conformity)



Catalogue number

3. Installation

3.1 Delivery contents

Check contents of carton using this list

- 1x VACUETTE® MultiMixer
- 1x 12-volt power supply
- 1x Power cable with Schuko plug
- 1x Certificate of Quality

Optional – not included in the packaging

836578 Rack for VACUETTE® 20-Pos. MultiMixer for 9 mm VACUETTE® Tubes

836579 Rack for VACUETTE® 20-Pos. MultiMixer for 13 mm VACUETTE® Tubes

3.2 Positioning of the analyzer

The **VACUETTE® MultiMixer** must not be placed near centrifuges, oscillating agitators or other vibrating instruments which might cause movement of the bench. The workbench must be flat and leveled.

Direct light on the instrument and sudden changes in temperature should be avoided.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with proper operation.

This equipment has been designed and tested to CISPR 11 Class A.

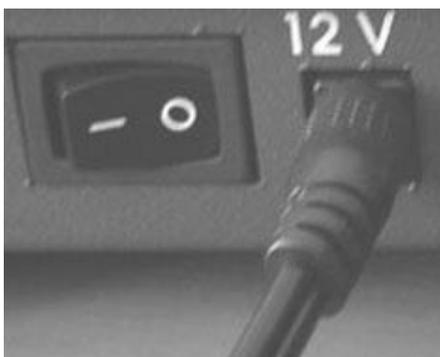
In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Therefore the electromagnetic environment should be evaluated prior to operation of the device.

The instrument is not intended to be integrated into a system.

Do not replace the detachable power cord by an inadequately rated power cord.

Connect the VACUETTE® MultiMixer to the electricity supply by plugging the 12V power supply into the intended power inlet on the VACUETTE® MultiMixer. Only use the power supply provided.



Keep a free area of at least 15 cm around the instrument to allow instrument cooling by the internal back panel fan. Use the mains plug to disconnect the apparatus from the mains supply. The mains plug must be accessible always. Take care to connect the power supply to a socket with ground connection.

3.3 Rack assembly

Racks can be removed or inserted by pressing the button as shown in the picture.

Connect the power supply outlet to the mixer and insert the power supply plug into the electrical socket on the rear of the mixer.

Once connected, the **VACUETTE® MultiMixer** automatically turns on.

Each time the **VACUETTE® MultiMixer** turns on, it carries out an electronic and mechanic initialization and performs an instrument self-test to check for proper operation.

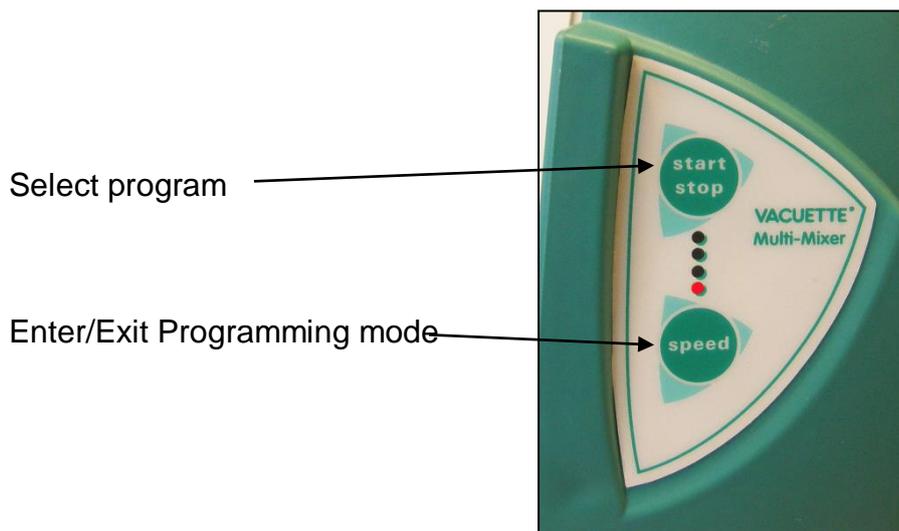


4. FUNCTIONS

4.1 The instrument control panel

The **VACUETTE® MultiMixer** is controlled by two buttons:

- A: START/STOP button
- C: SPEED button
- B: The four LEDs indicate the level of rotation speed



4.2 Selecting rotation functions

When the **VACUETTE® MultiMixer** is in stand-by mode, it is possible to select 4 different programs. To do that, press the SPEED button for 2 seconds. Once in the program mode, the LED will flash. Press the START/STOP button to change program.

F1		Continuous rotation
F2		Continuous rotation of the rack with STOPS in upper and lower vertical position.
F3		Rotation with STOPS under the angles of 150° and 300°.
F4		Loop type of rotation under the angle of $\pm 300^\circ$

Once you selected the desired program, to confirm and exit from the “program mode”

press the SPEED button (C).

Attention: Remember that it is possible to change the program only when the rack is in the home position and not mixing.

4.3 Mixing speed

To select the mixing speed, press the SPEED button (C). The speed will increase from level 1 (1 led on) to level 4 (4 led on).

4.4 Start mixing

To start mixing, press the START button. The **VACUETTE® MultiMixer** will start mixing using the program currently selected. To stop mixing, press the STOP button; the rack will go to the home position.

After five minutes of mixing, the **VACUETTE® MultiMixer** beeps and the indicators start to blink. To stop mixing, press **START/STOP** button.

If the mixer has not been used for 10 minutes, it will switch to a SLEEP mode to save energy. All LED indicators will turn off. To activate the device again, simply press the **START/STOP** button.

4.5 Tubes Mixing

The best program to mix tubes is the Program F3, at second speed level.

Five minutes mixing is enough to assure a complete mixing of blood.

After five minutes of mixing, the **VACUETTE® MultiMixer** beeps and the indicators start to blink. To stop mixing, press **START/STOP** button.

A longer mixing will not damage blood into tubes, on the contrary will assure a better erythrocyte mixing.

5. Maintenance

The **VACUETTE® MultiMixer** should be cleaned, when it is necessary, or after about 40 hours of work. Before cleaning, you should unplug the mixer from the outlet.

5.1 Cleaning and decontamination instructions

Dust can be removed using an ordinary vacuum cleaner. Pay particular attention to the test tube: it must be well closed and the cap should not be never removed. The label must be correctly positioned and well stuck to the test tube surface. Label fragments could stick into the tube position and obstruct a correct holding during mixing.

Although the Instrument only uses closed ESR tubes and therefore the contamination of the Instruments is reducing to an absolute minimum one has to treat any foreign material on any surface of the Instrument as a biohazard for safety. Treated surface should remain in contact with decontamination solution for at least 10 minutes. Perform the following steps that are applicable to the area of the instrument that is being serviced.

1. Remove all samples from the Instrument.

2. Make sure no liquid is dripping into the Instrument.
3. Only use a moistened cloth.
4. Wipe the complete outer surface with one of the Appendix mentioned disinfectants.
5. Wipe the tube positions underneath the transparent tube cover (when applicable).

5.2 Spare parts

SAP	MultiMixer - SPARE PARTS LIST
Code	Description
836250	ESR-Spare part SEM30-001 Fan for SRT 10/II, MultiMixer 12 Vdc; 40x40x10
836256	ESR-Spare part ELE10-029 Power supply (Voltage 12 Vdc) for: - SRT 10 & SRT 10/II - MultiMixer
836578	Rack for VACUETTE® 20-Pos. MultiMixer for 9 mm VACUETTE® Tubes
836579	Rack for VACUETTE® 20-Pos. MultiMixer for 13 mm VACUETTE® Tubes

WARNING: in order to assure the safety and performance of the instrument do not use other spare parts than the ones specified above.

6. Technical Specifications

Area of application:	Biological liquid mixing
Instrument size:	Width 350 mm Depth 170 mm Height 170 mm
Weight:	about 2 kg
Instrument input and output:	12 VDC 1.5 A (external power supply unit)
External power supply unit input:	100 - 240 VAC +/-10%, 1.8A, 50/60 Hz
Operating Conditions:	temperature 15° - 32° C room temperature humidity: 0% - 95% altitude: up to 2.000 m overvoltage: category II pollution: degree 2 for indoor use only sound level <60 dBA
Applicable standards	ISO 9001:2008, EN-ISO 13485:2012 and LV Directive 2014/35/EU and following amendments.
General Directives:	2011/65/EU 2012/19/EU
EMC Standards:	EN 61326-6:2006
Safety Standards:	IEC/EN 61010-1:2010 IEC/EN 61010-2-051:2015 IEC/EN 61010-2-101:2015
Machine Directives:	98/79/EC
Transport and storage:	Do not refrigerate during transport Storage temperature: 4 – 30°C

Appropriate decontamination shall be performed prior to transportation, removal from use and/or disposal. See Decontamination instruction ESR Instrument for details.

Do not throw the packaging away.
The packaging can be used to transport the MultiMixer if you change location or return the instrument in case of a complaint.

7. APPENDIX

Read this document first and keep it for later reference.

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The contents of this instruction can also be changed without prior warning.

Greiner Bio-One cannot be held responsible for any damage resulting from changes made to the instrument after it was supplied. Greiner Bio-One cannot be held responsible for any damage resulting from not complying to the specifications supplied with the instrument.

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Dear Customer,

This document is intended to offer guidance for decontaminating ESR Instruments that have been used to process specimens that may constitute a biological hazard. This procedures can be performed by the operator of the Instrument.

The last page, “Decontamination Certificate of ESR Instruments”, of this document should be filled in and signed by the executor which clarifies that this decontamination procedure has been followed as described in this document. This certificate needs to be returned with the decontaminated Instrument.

We always try to be as complete as possible but we can imagine that questions remain after reading this document. Please feel free to contact us in case of any questions.

Product Management Preanalytics
Greiner Bio-One.
Austria

Safety Requirements and Restrictions.

Personal protections.

When performing this procedure, wear, at a minimum, safety glasses, gloves and disposable lab coat (according Good Laboratory Practice).

Spills of fluid waste prior to decontamination.

Wipe up spills with paper towels.

Clean area with decontamination solution.

Dispose of paper towels in a container designated for biohazard waste or autoclave before putting in general trash.

Unprotected contact with biohazard material.

- ✓ Eye contact – Flush with water.
- ✓ Ingestion – Report to nearest available medical facility.
- ✓ Skin contact – Wash thoroughly with soap and water (use a germicidal soap, if available).
- ✓ Notify your supervision.

Be sure to check that items representing a biohazard or a chemical hazard are removed.

Preparation of Decontamination Solution

One of the following disinfectants can be used

- Cleaning Solution SLNA-5900 as decontamination solution
- A solution of a 1:10 dilution of Clorox® Bleach should be used (one part of bleach plus nine parts of water). This solution should be fresh.
- A solution of 70% alcohol can also be used.
- Other commercial available disinfectant used in the laboratory.

Decontamination Procedure

Although the Instrument only uses closed ESR tubes and therefore the contamination of the Instruments is reducing to an absolute minimum one has to treat any foreign material on any surface of the Instrument as a biohazard for safety. Treated surface should remain in contact with decontamination solution for at least 10 minutes. Perform the following steps that are applicable to the area of the instrument that is being serviced.

6. Remove all samples from the Instrument.
7. Make sure no liquid is dripping into the Instrument.
8. Only use a moistened cloth.
9. Wipe the complete outer surface with one of the above-mentioned disinfectants.
10. Wipe the tube positions underneath the transparent tube cover (when applicable).

The Instrument is now reasonable decontaminated.

Universal precaution is recommended when handling this instrument after it has been decontaminated. Apply the completed certificate to the decontaminated instrument as described in the accompanied instruction of the return kit.

Decontamination Certificate

of

ESR Instruments

Underneath named and signed executor engineer clarifies that concerned Instrument has been decontaminated as described in the document “Decontamination Procedure for ESR Instruments” documented as MAN-100-Rev.00.

For completeness mark the check-box of each separated item if it has been decontaminated and/or disinfected and fill-in the requested information. Mention exceptions as remarks when (partly) not being able by following the decontamination procedure.

Outer surface.....

Tube area.....

Type of instrument:

Serial number of instrument:

Decontamination date (dd/mm/yyyy):

Executor Engineer:

Date (dd/mm/yyyy):

Name:

Signature:

Distributor stamp: