VIASURE

Kituri de detectare Real Time PCR

by CerTest BIOTEC

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CSQ MED

Medical–Biological
Research & Technologies

Attn: To whom it may concern

LETTER OF AUTHORIZATION No. P138/2020

We, **BIOSAN SIA** (registration number: 40003072462), who are established and reputable manufacturers of Laboratory Equipment, having factories at Latvia, Riga, Ratsupites str. 7, build. 2, LV-1067, hereby certify that

Dealer: **AMS 2000 Trading Impex SRL**
Address Str. Turturelelor nr 62, Decebal Tower
Sector 3, Bucharest, Romania
Contact person: **Alina Anghelache**
Tel: +4021 324 70 50

is a distributor authorized to:

- participate in the public tender: Anunt de participare simplificat: [SCN1065672] - Achiziționare Sistem PCR de detectie Cov-2 cu accesoriile si consumabilele aferente acestuia organized by Spital Clinic Judetean de Urgenta Arad, Romania using Biosan products.
- provide after-sales support and service for Biosan devices.

Territory of distribution and service is **Romania.**

This Letter of Authorization shall be valid for the tender term only. Upon the respective written from Biosan this Letter of Authorization automatically becomes null and void.

Biosan SIA shall have no obligation or responsibility regarding any actions of distributor whatsoever.

Monday, 30/03/2020

Riga

Aleksey Konstantinov
Sales Director
SIA Biosan

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SIA
biosan
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for documents
LATVIJA

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SC "Citadele bank"
Republikas laukums 2A, Riga, LV-1010
SWIFT: PARXLV22 • LV66PARX0012666440001

4. Getting started

4.1. **Unpacking**. Remove packing materials carefully and retain them for future shipment or storage of the unit. Examine the unit carefully for any damage incurred during transit. The warranty does not cover in-transit damage. Warranty covers only the units transported in the original package.

⚠ **Caution!** Due to the unit's weight its unpacking and installing is to be carried out by two persons.

4.2. **Complete set**. Package contents:

4.2.1. Standard set

- DNA/RNA UV Cleaner box ..... 1 pce
- Spare dust filters ..... 2 pcs
- Spare fuse for control block* ..... 1 pce
- Spare fuse for built-in power outlet** ..... 1 pce
- Power cable ..... 1 pce
- Operating manual, declaration of conformity ..... 1 copy

4.2.2. Optional accessories

- T-4 / T-4L moving table for UV Cleaner box ..... on request

T-4 T-4L

4.3. Setup:

- If the moving table is used, unpack it carefully and assemble according to the enclosed assembling scheme.
- Place the unit upon stable surface. Ensure that the unit is placed on a solid, level surface not less than 720x550 mm (1290x600 mm for UVT-S-AR model), which is able to support its weight and the weight of equipment and materials inside, for instance on the T-4 / T-4L table.
- Plug the power cable into the socket on the rear and position the unit for easy access to the power switches and the power plug.

* For information on fuses, see table on page 12

** Only for models with outlets, see table on page 11

5. Operation

5.1. Connect the power plug to a grounded power socket.

5.2. UV exposition of the working place.

Caution! The open UV lamp inside the unit (fig. 3/3) operates only when the front protective screen is fully lowered. Any operations under direct UV radiation is forbidden!

5.2.1. Turn ON the switch **2** (fig. 2/2) on the control panel (fig. 3/1). This switches on the UV recirculator inside the unit (fig. 3/2) and the open UV lamp exposition time controller. The UV recirculator will operate all the time until the switch **2** is turned OFF.

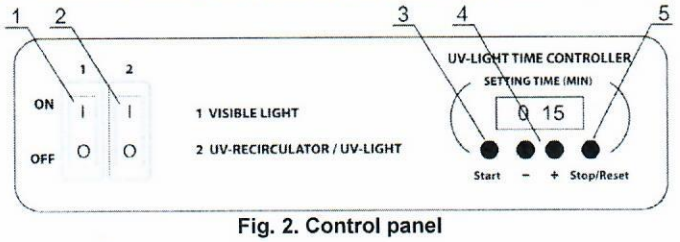


Fig. 2. Control panel

Note. Open UV lamp operation can be checked with the visible light lamp switched off (switch **1** is OFF). Use the indicator in the centre of recirculator cover (fig. 1/3) to check operation of UV lamp inside the recirculator. If indicator lights from inside while switch **2** is ON, then the UV lamp is functioning.

5.2.2. Use the timer **+** and **-** keys (fig. 2/4) to increase and decrease the time (UV-LIGHT TIME CONTROLLER) of direct UV light exposition of the working place, with 1 min increment. Pressing down and holding the button for more than 2 seconds increases the increment.

Recommended time of exposition is 15-20 min.

5.2.3. Press the **Start** key (fig. 2/3), the UV lamp will be turned on automatically and the timer will start counting the exposition time. Timer indicator shows actual time: until 1 hour - in minutes and seconds (mm:ss), after 1 hour - in hours and minutes (hh:mm).

After reaching the set time the timer will automatically turn off the open UV lamp.

5.2.4. The open UV lamp can be switched off by pressing the **Stop/Reset** key (fig. 2/5). The set time of exposition will be saved in the memory. The set time will not be saved after the complete turning off the unit.

5.2.5. If the set time of open UV light exposition is 0:00, pressing the **Start** key will make the unit operate continuously during 24 hrs or until the **Stop/Reset** key is pressed.

5.3. The box is ready for operations. Work in the box.

Note. Opening the front protective screen will switch off the open UV lamp automatically, but the timer will continue counting the exposition time.

5.3.1. Turn ON switch **1** (fig. 2/1) for lighting of the working place. This turns ON the luminescent (visible light) lamp inside the cabinet (fig. 3/3).

5.3.2. Lift the front protective screen (fig. 3/5) up for work in the cabinet. The opening height is up to 180 mm (fig. 3/9).

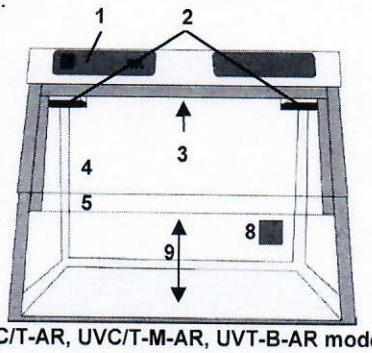
Note. Do not block recirculator openings (fig. 3/2).

5.3.3. To use electric devices inside the cabinet, pull their power cable through the inlet and close the flap (fig. 3/7 and 3/8, models with cable inlet) or connect the power cable to a built-in mains socket (fig. 3/6 and 3/8, models with mains socket).

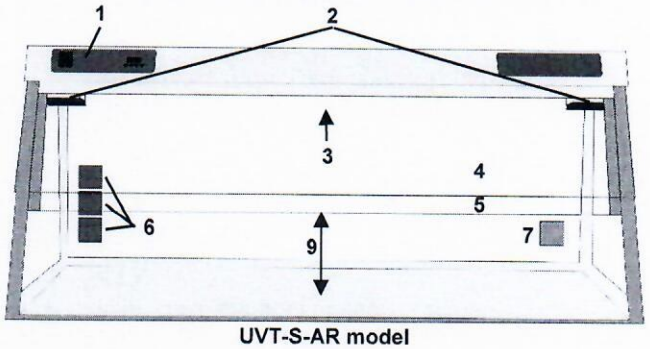
Caution! Overall consumed power of devices connected through internal mains sockets should not exceed 1000 W for 230V, or 600 W for 100 V, 120 V.

5.3.4. After the task is done, close the front protective screen.

5.4. After finishing the operation turn OFF switch **2** and switch **1**. Disconnect the power cable from the mains.



UVC/T-AR, UVC/T-M-AR, UVT-B-AR models



UVT-S-AR model

Fig. 3. DNA/RNA UV box, frontal view:
1. Control panel. 2. Recirculator openings. 3. Daylight lamp and open UV lamp. 4. Upper front panel. 5. Movable front protective screen. 6. Power outlets. 7. Cable inlet. 8. Power outlet OR cable inlet. 9. Opening height.

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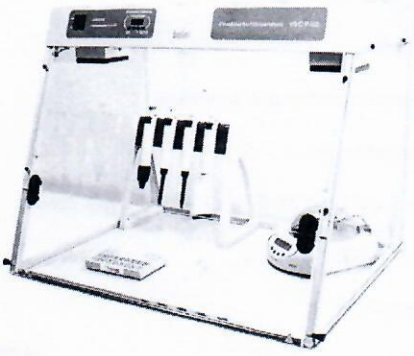
Medical Biological Research & Technologies

UVC/T-AR, DNA/RNA UV-cleaner box

Basic Plus

DESCRIPTION



DNA/RNA UV-cleaner box**UVC/T-AR** is designed for clean operations with DNA samples. UV-cleaner box provide protection against contamination.

Model is a bench-top type, made of metal framework, plexiglas walls and working surface painted with powder enamel.

UV-cleaner boxes are equipped with an open UV lamp installed in the upper hood. UV-radiation from the open lamps disinfects the working area inactivating DNA/RNA fragments during 15–30 min of exposure. A digital timer controls duration of the direct UV irradiation. A daylight lamp provides proper illumination of the working surface.

UV-cleaner boxes are equipped with a flow-type bactericidal UV cleaner–recirculator AR, which provides constant decontamination inside the box during operation. They are recommended for operations with DNA/RNA amplicons.

UV cleaner–recirculator AR consists of a UV lamp, a fan and dust filters organized in a special body so that a user working with a UV-cleaner box is protected against UV light. Recirculator increases the maximum density of UV light making it sufficiently effective for DNA/RNA inactivation. The UV–recirculator processes 100 UV-cleaner box volumes per hour, creating permanent aseptic conditions of operation inside the UV-cleaner box.

Specially assigned moving tables **T-4** (with wheel locks) with a drawer are available on request.

Advantages of Biosan UV-cleaner boxes:

- Ozone free high density UV decontamination
- Long living UV lamps (9,000 hours average)
- Automatic switch off of UV-lamps when the protective screen is opened
- Bactericidal flow-type recirculator providing permanent decontamination inside UV-cleaner box during operation
- Low noise, low energy consumption
- Tables for installation of UV-cleaner boxes
- UV-cleaner boxes with the bactericidal UV cleaner–recirculator AR is the patented Biosan solution

CAT. NUMBER

BS-040102-AAA	100-240VAC 50/60Hz Euro plug
BS-040102-AAB	100-240VAC 50/60Hz UK plug
BS-040102-AAC	100-240VAC 50/60Hz US plug
BS-040102-AA3	100-240VAC 50/60Hz AU plug
BS-040102-AK	IQ OQ document
BS-040102-BK	PQ document

SPECIFICATIONS

Walls material	Plexiglas: Polymethyl methacrylate ALTUGLAS EX
Working surface material	Steel with chemicals resistant powder coating
Open UV-lamp	1 x 25W built-in bactericidal, TUV25WG13 UV-C
UV radiation level	15 mW / cm2 / sec
Radiation type	UV (λ = 253.7 nm), ozone-free
Digital time setting of direct UV exposure	1 min–24 hrs / non–stop (increment 1 min)
UV-recirculator	1x25W (efficiency >99% per 1 hour)
Daylight lamp (for working area illumination)	1 x TLD-15W
Thickness of side panels	4 mm
Thickness of upper front panel	8 mm
Thickness of screen	8 mm
Optical transmission	92%
UV protection	>99.90% Polymethyl methacrylate ALTUGLAS EX
Working area	650 × 475 mm
Opening dimensions (fully raised protective screen)	645 × 170 mm
Safety features	Automatic open UV-lamp switch off when screen is open
Power outlets inside the unit	Inlet for power cords
Overall dimensions (W×D×H)	690 × 535 × 555 mm
Weight (net / gross)	23 / 33 kg
Power consumption	67 W
Nominal operating voltage	100-240 V, 50/60Hz
Optional table	T-4 (800 × 600 × 750 mm)

ACCESSORIES

T-4
BS-040101-BK
Table

New modular design of laboratory furniture provides flexibility and ease of use.

LF-1
BS-050101-BK
Drawer unit

New modular design of laboratory furniture provides flexibility and ease of use.

PDS-250
BS-040107-DK
DNA/RNA Decontamination Solution

Contamination is especially problematic in the highly sensitive PCR technique. Originating from aerosolized fragments, contaminant DNA can lead to cross contamination thus resulting in inaccurate data

and as a result misinterpreted analysis.

PDS-250 is ready-to-use solution for eliminating DNA, RNA, DNases and RNases from surface prior PCR reaction preparation. DNA/RNA is removed within seconds after use. The solution contains a surfactant and a non-alkaline and non-carcinogenic agent. PDS-250 is intended for use at PCR cabinets and laminars (e.g. **UVT-S-AR**), lab devices - **Biomagpure 12**, **TS-100**, pipettors - **Assist series piettes**, etc.

Benefits - Highly effective
PDS-250 is effective against amplicon, plasmid, or genomic DNA and RNA from most surfaces with the exception of light or non-ferrous metals (e.g. aluminium, copper, lead, nickel, tin, titanium, zinc etc.).

PDS-250 is ready-to-use for eliminating DNA and RNA from suitable surfaces. Fast and easy decontamination; The use of PDS-250 both before and after PCR analysis is fast, easy and ideal to maintain a clean work area and thereby saves time and expenses.

PDS-250 is heat resistant and stable for several years

Recommended Use: Applicable in research and industry only. Not recommended for clinical applications. Use as directed. PDS-250 should be applied on glass, ceramic, plastic, rubber, steel and precious metal. PDS-250 cannot be used for the cleaning of light or non-ferrous metals. To avoid damage or discoloration, it is recommended to spot test sensitive surfaces prior to use.

BIOSAFETY EQUIPMENT

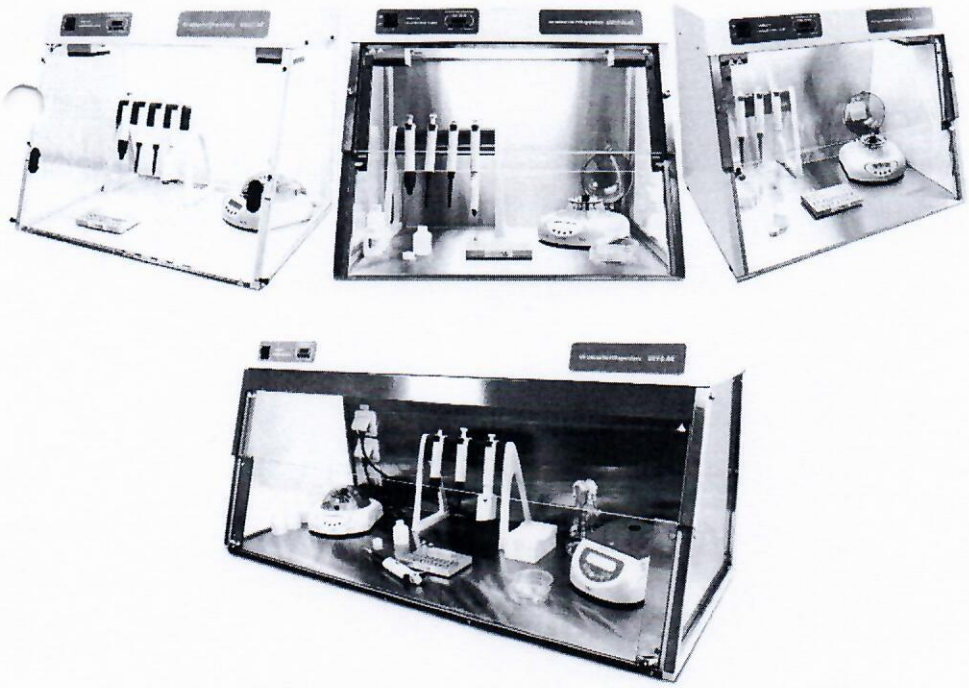
UV cabinet

biosan

Medical–Biological
Research & Technologies

UVC/T-AR, UVC/T-M-AR, UVT-B-AR, UVT-S-AR

DNA/RNA UV-cleaner box



Operating manual

Contents

1. About this edition of the operating manual

The manual applies to following models and versions of DNA/RNA UV cleaner boxes:

- UVC/T-AR version V.3AD
- UVC/T-M-AR versions V.4AD, V.4A02, V.4A03, V.4A04 and V.4A12
- UVT-B-AR versions V.3AA, V.3AB, V.3AD, V.3AE and V.3A12
- UVT-S-AR versions V.4AA, V.4AB, V.4A7 and V.4A04

2. Safety precautions

The following symbols mean:

Caution: Make sure you have fully read and understood the present Manual before using the equipment. Please pay special attention to sections marked by this symbol.

Caution: Do not work in the cabinet or open the front protective screen while the open UV lamp is switched ON. Otherwise, it can expose the operator to a dangerous level of UV emission.

Caution! Exposure to UV light is harmful and can cause damage to unprotected eyes and skin. The UV Cleaner box contains a powerful source of UV radiation, therefore, before operating the unit, ensure all personnel working with the UV Cleaner box are properly protected.

The operator should wear a closed-front lab coat (fully buttoned), UV certified safety glasses and gloves, which should overlap the lab coat or surgical gown cuffs.

GENERAL SAFETY

- Use only as specified in the operating manual provided.
- Do not use the unit if dropped or damaged.
- Store and transport the unit at ambient temperatures between -20°C and +60°C and maximum relative humidity of 80%.
- After transport or storage in humid conditions and before connecting to electric circuit, keep the unit under room temperature for 2-3 hrs.
- Before using any cleaning or decontamination methods except those recommended by the manufacturer, check with the manufacturer that the proposed method will not damage the equipment.
- Do not make modifications to the design of the unit.

ELECTRICAL SAFETY

- Connect only to the mains with voltage corresponding to that on the serial number label.
- Ensure that the switches and plug are easily accessible during use.
- Do not plug the unit into an ungrounded power socket, and do not use an ungrounded extension lead.

- Disconnect the unit from the mains before moving.
- If liquid penetrates into the unit, disconnect it from the electric circuit and have it checked by a repair and maintenance technician.
- Do not operate the unit in premises where condensation can form. Operating conditions of the unit are defined in the Specifications section.

DURING OPERATION

- Do not operate the unit in environments with aggressive or explosive chemical mixtures. Please contact manufacturer for possible operation of the unit in specific atmospheres.
- Do not operate the unit without dust filters installed.
- Do not operate the unit if it is faulty or has been installed incorrectly.
- Do not use outside laboratory rooms.
- Do not work in the box while the open UV lamp is switched ON.

BIOLOGICAL SAFETY

- It is the user's responsibility to carry out appropriate decontamination if hazardous material is spilt on or penetrates into the equipment.

WASTE DISPOSAL

- Daylight and UV lamps used in the unit must be disposed of according to national standards and Waste Electrical and Electronic Equipment (WEEE) Directive guidelines.

3. General information

DNA/RNA UV Cleaner boxes – **UVC/T-AR**, **UVC/T-M-AR**, **UVT-B-AR** and **UVT-S-AR** – are designed for clean operations with DNA/RNA samples. They provide protection against contamination.

All models are bench-top type, with metal framework, glass or acrylic walls and working surface painted with powder enamel or made of stainless steel. Box is equipped with inlet for power cables or built-in power outlets for units inside the box. For availability of the required characteristics, please clarify for each model separately (see Table 2 on page 11).

UV Cleaner boxes are equipped with an open UV lamp installed in the upper hood. UV radiation from the open lamps disinfects the working area inactivating DNA/RNA fragments during 15-30 min of exposure. A digital timer controls duration of the direct UV irradiation. A daylight lamp provides proper illumination of the working surface.

UV Cleaner box is equipped with a flowing bactericidal UV cleaner-recirculator AR, which provides constant decontamination inside the box during operation. It is recommended for operations with DNA/RNA amplicons.

UV recirculator consists of an UV lamp (fig. 1/1), a fan and dust filters (fig. 1/2) organized in a plastic case. Operator working in a UV Cleaner box with a switched on UV recirculator is not exposed to UV radiation. It allows continuous treatment of the airflow with UV light without interrupting working process. Air circulation at a short distance from the UV lamp combined with reflective surfaces in the air duct results in increased density of UV rays leading to higher efficiency of disinfection. UV recirculator generates 100 volumes of PCR cabinet per one hour of airflow exchange ensuring maximally aseptic conditions inside the cabinet. Cabinet UV lamps do not produce ozone.

Box for clean operations with DNA/RNA samples with built-in recirculator is a patented solution (patent LV13115 from 20/05/2004, Dr. biol. V. Bankovsky).

Microbiological studies at the R&D Department of Biosan led by Dr. biol. V. Bankovsky demonstrated a high level of biosafety and efficacy of UV-cleaner box (maximal level of contamination is 1-3 cfu per 100 litres of air)*.

UV Cleaner box is designed to biologically protect the product, but not the operator, therefore, it is not recommended to use the UV Cleaner box for working with pathogenic microorganisms of biosafety level BSL-II and higher, without specialized protection.

Advantages:

- UV-recirculator;
- Ozone free high density UV decontamination;
- Open UV lamp is switched off automatically in case of opening the front screen;
- Long life UV lamps (9000 h);
- Low noise level and energy consumption;
- Compact tabletop model for personal laboratories;
- Table with drawer T-4 / T-4L (on request).

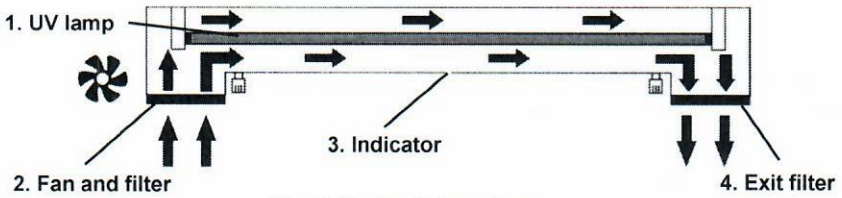


Fig. 1. Recirculator scheme.

* http://biosan.lv/efficiency_eng

4. Getting started

4.1. **Unpacking**. Remove packing materials carefully and retain them for future shipment or storage of the unit. Examine the unit carefully for any damage incurred during transit. The warranty does not cover in-transit damage. Warranty covers only the units transported in the original package.

⚠ **Caution!** Due to the unit's weight its unpacking and installing is to be carried out by two persons.

4.2. **Complete set**. Package contents:

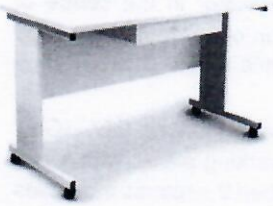
4.2.1. Standard set

- DNA/RNA UV Cleaner box ..... 1 pce
- Spare dust filters ..... 2 pcs
- Spare fuse for control block* ..... 1 pce
- Spare fuse for built-in power outlet** ..... 1 pce
- Power cable ..... 1 pce
- Operating manual, declaration of conformity ..... 1 copy

4.2.2. Optional accessories

- T-4 / T-4L moving table for UV Cleaner box ..... on request

T-4



T-4L

4.3. Setup:

- If the moving table is used, unpack it carefully and assemble according to the enclosed assembling scheme.
- Place the unit upon stable surface. Ensure that the unit is placed on a solid, level surface not less than 720x550 mm (1290x600 mm for UVT-S-AR model), which is able to support its weight and the weight of equipment and materials inside, for instance on the T-4 / T-4L table.
- Plug the power cable into the socket on the rear and position the unit for easy access to the power switches and the power plug.

* For information on fuses, see table on page 12

** Only for models with outlets, see table on page 11

5. Operation

5.1. Connect the power plug to a grounded power socket.

5.2. UV exposition of the working place.

Caution! The open UV lamp inside the unit (fig. 3/3) operates only when the front protective screen is fully lowered. Any operations under direct UV radiation is forbidden!

5.2.1. Turn ON the switch **2** (fig. 2/2) on the control panel (fig. 3/1). This switches on the UV recirculator inside the unit (fig. 3/2) and the open UV lamp exposition time controller. The UV recirculator will operate all the time until the switch **2** is turned OFF.

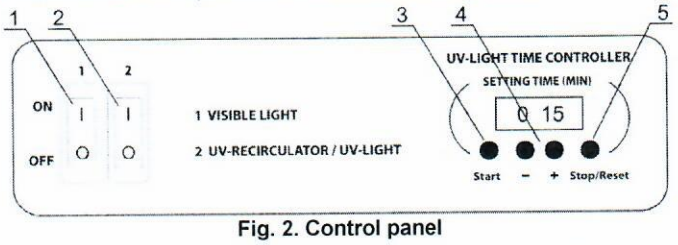


Fig. 2. Control panel

Note. Open UV lamp operation can be checked with the visible light lamp switched off (switch **1** is OFF). Use the indicator in the centre of recirculator cover (fig. 1/3) to check operation of UV lamp inside the recirculator. If indicator lights from inside while switch **2** is ON, then the UV lamp is functioning.

5.2.2. Use the timer **+** and **-** keys (fig. 2/4) to increase and decrease the time (UV-LIGHT TIME CONTROLLER) of direct UV light exposition of the working place, with 1 min increment. Pressing down and holding the button for more than 2 seconds increases the increment.

Recommended time of exposition is 15-20 min.

5.2.3. Press the **Start** key (fig. 2/3), the UV lamp will be turned on automatically and the timer will start counting the exposition time. Timer indicator shows actual time: until 1 hour - in minutes and seconds (mm:ss), after 1 hour - in hours and minutes (hh:mm).

After reaching the set time the timer will automatically turn off the open UV lamp.

5.2.4. The open UV lamp can be switched off by pressing the **Stop/Reset** key (fig. 2/5). The set time of exposition will be saved in the memory. The set time will not be saved after the complete turning off the unit.

5.2.5. If the set time of open UV light exposition is 0:00, pressing the **Start** key will make the unit operate continuously during 24 hrs or until the **Stop/Reset** key is pressed.

5.3. The box is ready for operations. Work in the box.

Note. Opening the front protective screen will switch off the open UV lamp automatically, but the timer will continue counting the exposition time.

5.3.1. Turn ON switch **1** (fig. 2/1) for lighting of the working place. This turns ON the luminescent (visible light) lamp inside the cabinet (fig. 3/3).

5.3.2. Lift the front protective screen (fig. 3/5) up for work in the cabinet. The opening height is up to 180 mm (fig. 3/9).

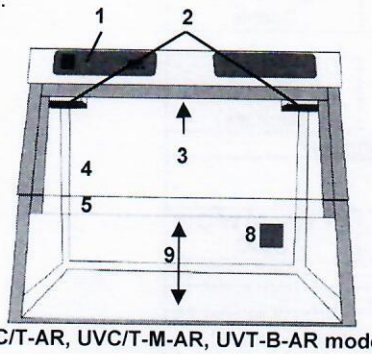
Note. Do not block recirculator openings (fig. 3/2).

5.3.3. To use electric devices inside the cabinet, pull their power cable through the inlet and close the flap (fig. 3/7 and 3/8, models with cable inlet) or connect the power cable to a built-in mains socket (fig. 3/6 and 3/8, models with mains socket).

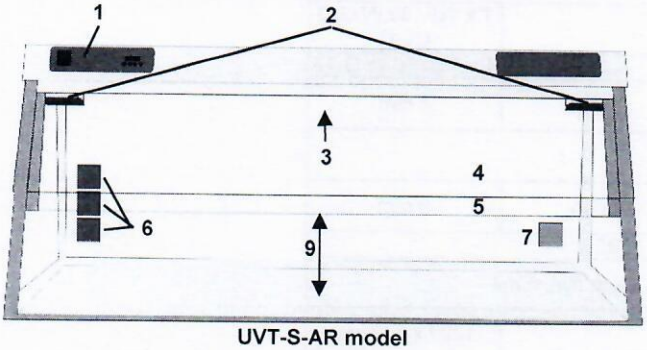
Caution! Overall consumed power of devices connected through internal mains sockets should not exceed 1000 W for 230V, or 600 W for 100 V, 120 V.

5.3.4. After the task is done, close the front protective screen.

5.4. After finishing the operation turn OFF switch **2** and switch **1**. Disconnect the power cable from the mains.



UVC/T-AR, UVC/T-M-AR, UVT-B-AR models



UVT-S-AR model

Fig. 3. DNA/RNA UV box, frontal view:

1. Control panel. 2. Recirculator openings. 3. Daylight lamp and open UV lamp. 4. Upper front panel. 5. Movable front protective screen. 6. Power outlets. 7. Cable inlet. 8. Power outlet OR cable inlet. 9. Opening height.

6. Specifications

The unit is designed for operation in cold rooms and closed laboratory rooms at ambient temperature from +4°C to +40°C in a non-condensing atmosphere and maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C.

Biosan is committed to a continuous program of improvement and reserves the right to alter design and specifications of the equipment without additional notice.

Model	**UVC/T-AR** Compact	**UVC/T-M-AR** Compact	**UVT-B-AR** Compact	**UVT-S-AR** Double
Back panel	Acrylic glass (ALTUGLAS EX)	Stainless steel		
Side panels		Glass (EUROGLASS, Germany)	Powder coated steel	Glass (EUROGLASS, Germany)
Front panel and screen		Glass (EUROGLASS, Germany)		
Working surface	Powder coated steel	Stainless steel		
Open UV lamp	1 x TUV 25 W G13 UV-C			2 x TUV 30 W G13 UV-C
UV intensity	15 mW/cm^2/s			
Radiation type	Ultraviolet light (λ=253.7 nm), no ozone			
Digital timing setting of direct UV exposure	1 minute - 24 hours / non-stop (increment 1 minute)			
UV recirculator	1 x TUV 25 W G13 UV-C			1 x TUV 30 W G13 UV-C
Visible light lamp	1 x TLD 15 W G-13			1 x TLD 30 W G-13
Thickness of side panels	4 mm	4 mm	2 mm	4 mm
Thickness of upper front panel	8 mm			
Thickness of protective screen	8 mm	4 mm	4 mm	5 mm
Optical transparency	92%	95%		
UV protection	> 99.90% PMMA ALTUGLAS EX	>96% Clear film, 4 mil		
Working surface dimensions (WxD)	650 x 475 mm			1200 x 520 mm
Opening size (WxH, fully raised protective screen)	630 x 180 mm			1180 x 180 mm
Power inside the box (see Table 1)	Power cable inlet	Power cable inlet or 1 power socket*		Power cable inlet and 3 power sockets*
Operating current	100 - 240 V, 50/60 Hz			
Power consumption	67 W			135 W
Dimensions	690 x 535 x 555 mm		690 x 585 x 555 mm	1245 x 585 x 585 mm
Weight (net/gross)**	23 / 33 kg	28.8 / 39 kg	31.2 / 42 kg	58 / 68.5 kg
Laboratory table	T-4			T-4L

* **Caution!** Consumed power of devices connected to internal mains outlets must not exceed 1000 W for 230V models or 600 W for 100-120V models.

** Accurate within ± 10%.

Table 1. DNA/RNA UV cleaner box models and built-in mains outlets.

Model	Catalogue number	Version	Power inside the cabinet	
			Power cable inlet	Power sockets
UVC/T-AR	BS-040102-AAA	V.3AD	1	-
UVC/T-M-AR	BS-040104-AAA	V.4AD	1	-
	BS-040104-A06	V.4A02	-	1 x Euro
		V.4A03	-	1 x UK
		V.4A04	-	1 x US
		V.4A12	-	1 x AU
UVT-B-AR	BS-040109-A05	V.3AA	1	-
	BS-040109-AAA	V.3AD	-	1 x Euro
		V.3AE	-	1 x UK
		V.3AB	-	1 x US
		V.3A12	-	1 x AU
UVT-S-AR	BS-040107-AAA	V.4AA	1	3 x Euro
		V.4AB	1	3 x UK
		V.4A7	1	3 x US
		V.4A04	1	3 x AU

⚠ **Caution!** Consumed power of devices connected to internal mains outlets must not exceed 1000 W for 230V models or 600 W for 100-120V models

Optional accessories	Description	Catalogue number
T-4	Movable table with a drawer and wheel locks, dimensions 800x600x745 mm	BS-040101-BK
T-4L	Movable table with a drawer and wheel locks, dimensions 1290x600x770 mm	BS-040107-BK

7. Maintenance

7.1. If the unit requires maintenance, disconnect the unit from the electric circuit and contact Biosan or your local Biosan representative.

7.2. All maintenance and repair operations (excluding mentioned below) must be performed only by qualified and specially trained personnel.

7.3. **Fuse replacement**.

7.3.1. Fuse for the control box. Disconnect the unit from electric circuit. Remove power cable from its socket on the rear side of the unit. Open the fuse holder by pulling out the holder (fig. 4/**A**, compact models) or by screwing off the holder lid marked FU2 (fig. 4/**C**, model UVT-S-AR). Check the fuse and replace if necessary, **M** 3.15 A (type **M** - time lag: **M**edium).

7.3.2. Fuse for the mains outlets (for models with built-in mains outlets). Disconnect the unit from electric circuit. Open the fuse holder by screwing off the holder lid (fig. 4/**B** or 4/**C**, FU1). Check the fuse and replace if necessary, **M** 5.0 A (type **M** - time lag: **M**edium).

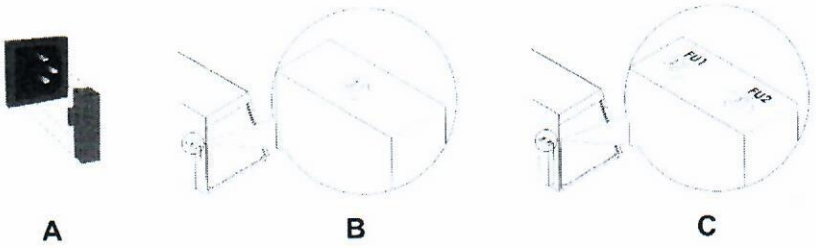


Fig. 4. Fuse replacement

7.4. **UV lamp replacement**. Average lifetime of UV lamps supplied is 9000 hrs. Replacement is necessary after lamp stops functioning or at the end of manufacturer specified lifetime.

Only persons who have completed special training are allowed to perform lamp replacement.

Open UV lamp operation can be checked with the visible light off (switch 1 is OFF). Use the indicator in the centre of recirculator cover (fig. 1/3) to check operation of UV lamp inside the recirculator. If indicator lights from inside while switch 2 is ON, then the UV lamp is functioning.

7.5. **Dust filter replacement**. The dust filters (fig. 3/2) on either end of the UV recirculator with the hidden UV lamp should be checked monthly and cleaned or replaced when they become clogged. To check, replace or clean the filters, simply unclip the covers, if it is necessary fit a new or rinse in water, dry and set up existing filters. Clip covers back in place.

7.6. **Cleaning and decontamination**. Disconnect the unit from the mains before cleaning.

⚠ **Caution!** Do not let liquid get into the control box.

7.6.1. Model UVC/T-AR, inner and outer cleaning. Front panel, front protecting screen and side panels are made of acrylic glass (polymethylmethacrylate ALTUGLAS EX) and are prone to scratches and optical transmission capacity decrease if improperly cleaned. Use mild soap and water with a soft cloth or sponge for cleaning the panels. Wipe excess water from inside and outside the unit with an absorbent soft cloth or sponge.

For decontamination, it is recommended to use a special DNA/RNA removing solution (e.g. DNA-Exitus Plus™, RNase-Exitus Plus™). After washing the inside parts of the box it is necessary to rub them dry.

⚠ **Caution!** Never use organic based compounds, pure alcohol, alcohol-containing cleaners (more than 15%) or ammonia containing cleaners for acrylic glass. Do not use abrasives. The table below shows the interaction of acrylic glass with ethyl alcohol and other solutions.

Solution	Interaction with acrylic glass
DNA-Exitus Plus™	No reaction
RNase-Exitus Plus™	No reaction
H_2O_2 (6%)	No reaction
Ethanol (10–15%)	No reaction
Ethanol (30%)	Limited reaction
Ethanol (98–99%)	Full reaction, do not use!

⚠ **Note.** Crazing is a normal process for acrylic glass panels exposed to open UV light. Crazing will occur over time. Crazing may occur within the warranty period and is regarded as normal wear and not covered by the warranty. Acrylic glass panels can be replaced.

7.6.2. Models UVC/T-M-AR, UVT-B-AR and UVT-S-AR, external cleaning. Glass panels on the outside are coated in 4 mil clear film for UV protection. Film manufacturer recommends using a soft sponge or cloth with common washing solution for glass, removing excess and wiping dry. Do not use ethanol or other organic solvents.

7.6.3. Models UVC/T-M-AR, UVT-B-AR and UVT-S-AR, internal cleaning and decontamination. The following substances are recommend to use for decontamination: 75% ethanol, sodium hypochlorite solution, DNA/RNA removing solution (e.g. DNA-Exitus Plus™, RNase-Exitus Plus™). After washing the inside parts of the box it is necessary to rub them dry.

8. Warranty and Claims. Registration

8.1. The manufacturer guarantees the compliance of unit with the requirements of specifications, if the customer follows the operation, storage and transportation instructions.

8.2. The warranted service life of unit from date of delivery to the customer is 24 months. For extended warranty, see p. **8.5**.

8.3. Warranty covers only the units transported in the original package.

8.4. If any manufacturing defects are discovered by the Customer, an unsatisfactory equipment report shall be compiled, certified and sent to the local distributor address. To obtain the claim form, visit section Technical support on our website at link below.

8.5. Extended warranty.

- For **UVC/T-M-AR** and **UVT-S-AR**, the *Premium* class models, one year of extended warranty is available free of charge after registration, during 6 months from the date of sale. Online registration form can be found in section **Warranty registration** on our website at the link below.
- For **UVC/T-AR** and **UVT-B-AR**, the *Basic Plus* class models, extended warranty is a paid service. Contact your local Biosan representative or our service department through the **Technical support** section on our website at the link below.

8.6. Description of the classes of our products is available in the **Product class description** section on our website at the link below.

Technical support

biosan.lv/en/support

Warranty registration

biosan.lv/register-en

Product class description

biosan.lv/classes-en

8.7. The following information will be required in the event that warranty or post-warranty service comes necessary. Complete the table below and retain for your records.

Model	UVC/T-AR / UVC/T-M-AR / UVT-B-AR / UVT-S-AR DNA/RNA UV cleaner box
Serial number	
Date of sale	

9. EU Declaration of conformity

EU Declaration of Conformity

Unit type	DNA/RNA UV cleaner boxes
Models	**UVC/T-AR, UVC/T-M-AR, UVT-B-AR, UVT-S-AR**
Serial number	14 digits styled XXXXXXYYMMZZZZ, where XXXXXX is model code, YY and MM – year and month of production, ZZZZ – unit number.
Manufacturer	SIA BIOSAN Latvia, LV-1067, Riga, Ratsupites str. 7/2
Applicable Directives	EMC Directive 2014/30/EU LVD Directive 2014/35/EU RoHS2 2011/65/EU WEEE 2012/19/EU
Applicable Standards	LVS EN 61326-1: 2013 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements. LVS EN 61010-1: 2011 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.

We declare that this product conforms to the requirements of the above Directives

Signature

Svetlana Bankovska
Managing director

19.07.2016
Date

Signature

Aleksandr Shevchik
Engineer of R&D

19.07.2016
Date

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http://www.biosan.lv

Edition 3.-4.01 – January 2017

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Managing director

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Signature

Aleksandr Shevchik
Engineer of R&D

19.07.2016
Date

Development and evaluation of DNA amplicon quantification

Case study: UV–Cabinet with UV Air Recirculator UVC/T-M-AR and Class II Biological Safety Cabinets

Authors

Biotechnomica:

Marina Tarvida, Julija Isakova, Vasily Bankovsky

Biosan:

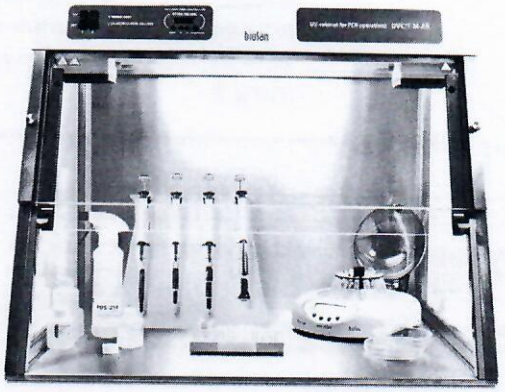
Arturs Kigitovics, Vadim Gimelfarb

Introduction

Personal and product safety during clinical and laboratory studies have stimulated the development of sterile cabinets and special laboratory safety techniques, to protect the environment, operator, and product. Monitoring DNA/RNA amplicon concentration in laboratory air in sterile cabinets has become topical as PCR and isothermal amplification technologies have developed along with wide spread mass analyses.

Development of methods for repeatable DNA/RNA amplicon detection in air samples is now a reality. Recent research "Behaviour of aerosol particles in fibrous structures" (Igor Agranovsky's PhD thesis, 2008, Novosibirsk, Russia) describes the development of samplers and monitoring of DNA/RNA amplicon concentration in the air from sterile cabinets, microbial quantitative analyses.

UVC/T-M-AR, UV–Cabinet for PCR operations



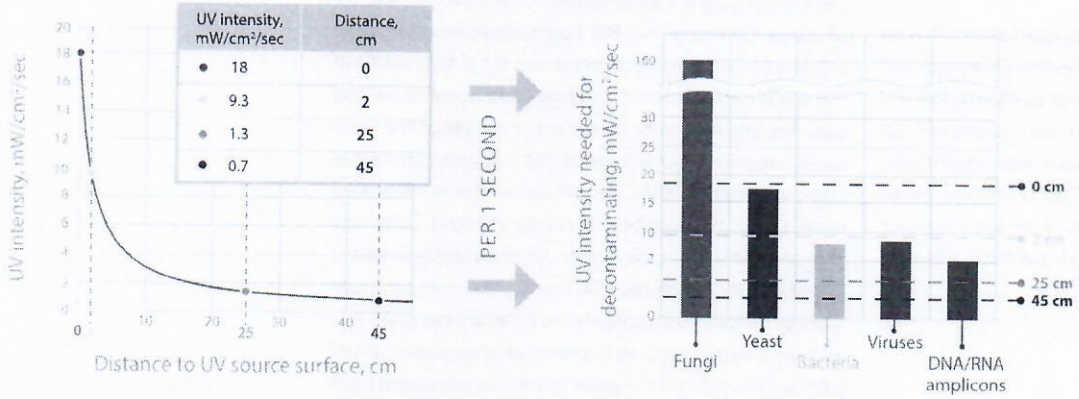


Fig. 1, Germicidal, shortwave (254 nm) ultraviolet energy is used for complete destruction of various biological agents

Aim of the study

The aim of this study is to evaluate the of efficiency of UV cabinets produced by BioSan (Latvia) in comparison to Class II BioSafety cabinets.

UV air treatment

More than a century has passed since the germicidal effect of UV light was recognized by Niels Ryberg Finsen — a Nobel Prize winner in physiology or medicine in 1903 [5], and many researches have been performed on UV induced destruction of DNA and microorganisms.

Low pressure germicidal UV lamps characteristically emit monochromatic low intensity radiation principally at 253.7 nm, within the germicidal wavelength range as defined by the DNA absorbance spectrum. The germicidal UV dose LP-UV lamps is calculated as the product of the volume averaged incident irradiance (E, mW/cm^2) and the time of exposure (t, seconds) resulting in units of mJ/cm^2 for UV dose [1] *(Fig. 1)*.

Air flow organization through HEPA filter

HEPA is an acronym for "high efficiency particulate absorbing" or "high efficiency particulate arrestance" or, as officially defined by the Department of Energy (DOE) "high efficiency particulate air".

The first HEPA filters were developed in the 1940's by the USA Atomic Energy Commission to fulfil a an efficient, effective way to filter radioactive particulate contaminants. HEPA filter technology was declassified after World War 2 and then allowed for commercial and residential use [6].

This type of air filter can theoretically remove at least 99.97% of dust, pollen, mold, bacteria and any airborne particles with a size of 0.3 µm at 85 litres per minute (l/min). In some cases, HEPA filters can even remove or reduce viral contamination. The diameter specification of 0.3 responds to the most penetrating particle size (MPPS). Particles that are smaller or larger are trapped with even higher efficiency [7] *(Fig. 2)*.

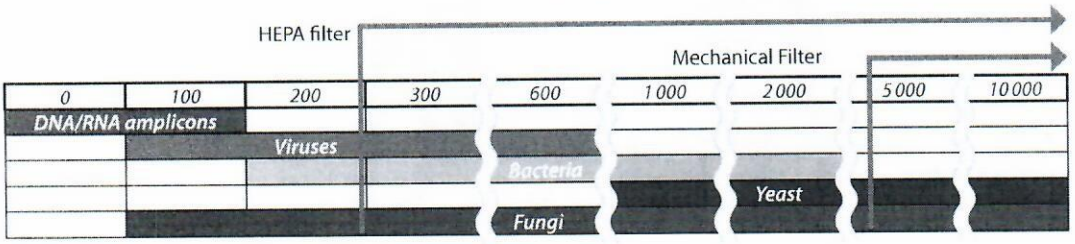


Fig. 2. Biological agent sizes and filters effectivity range, nm

Biological agent sizes, nm

Colony forming units (CFU) test

Media

LBA media was prepared using Standard Methods Agar (Tryptone Glucose Yeast Extract; Becton, Dickinson and Company) and dissolved in 1 litre of purified water. 7.5 grams of Yeast Extract (Biolife S.r.l.) and 5 grams of Tryptone (Difco laboratories) were added to enrich the media. The media was autoclaved at 121°C for 15 minutes. Media control samples were taken to check for presence/absence of colony forming units in media itself and the results were negative (0 CFU per 3 plates).

Experimental setup:

Impaction aerobiocollector airIDEAL 3P (bioMérieuxSA, France) was used to take air samples to test for the presence of colony forming units (CFU). Each sample was exposed to 500 litres of air. Aerobiocollector was set in the middle of the sterile cabinets for test samples and negative control samples, and in specific places in the middle of the laboratory room for positive control. The negative control was taken in Microflow ABS Cabinet Class II. This was repeated three times, the number of colony forming units was counted manually on each plate. Reading tables provided in airIDEAL 3P (bioMérieuxSA, France) The most probable number (MPN) of microorganisms collected per plate was estimated with respect to the number of agglomerates of colonies counted on the plate. (MPN was calculated from the CFU count using FELLER's law). Subsequently results were converted to CFU per m^3.

Mechanical contamination test

Instrument:

Laser particle counter (produced by Met One, USA) was used to determine mechanical contamination in the sterile cabinets and laboratory air as positive control.

Method:

Average amount of particles per litre of air were measured in sterile cabinet/laboratory air. Measurements were performed 9 times and the average value presented in the results as number of particles per m3 of air.

Two channels were used to measure amount of particles of different size: 5 µm and 0.3 µm. Mechanical filter stops particles larger than 5 µm while HEPA filter larger then 0.3 µm.

DNA Amplicon test

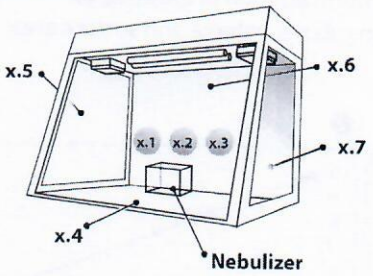
Instruments:

- Nebulizer, BioSan
- Shaker OS-20, BioSan
- Mini–Centrifuge/Vortex FV-2400, BioSan
- Centrifuge Pico 17, Thermo Electron Corp.
- Centrifuge-Vortex MSC-6000, BioSan
- Real–Time PCR cycler Rotor Gene 3000, Corbett Research

Reagents:

- Lambda DNA, Thermo Fisher Fermentas
- GeneJet Plasmid Miniprep Kit, Thermo Fisher Fermentas
- Real Time PCR reagents, Central Research Institute of Epidemiology

Fig. 3, Air and surface samples and surface sample taking path



Samples taken from:

x.1, x.2, x.3	: **Air** (Syringes)
x.4	: **Working surface** (Swab)
x.5, x.7	: **Side walls** (Swabs)
x.6	: **Back wall** (Swab)

Experiment setup:

- Sampling was performed as shown *on Fig. 3*
- Extraction and analyses were performed as shown *on Fig. 4*
- Quantitative PCR (Polymerase Chain Reaction):

  DNA amplicon quantification in sterile cabinets was performed by qPCR. Controls and standards were set in each experiment:

  » 4 standards of Lambda DNA of different concentration prepared in 10 fold dilution: starting concentration 0.6 ng/µl or ≈1,000,000 copies/µl

  » 2 NTC (no template control- sterile H_2O), experiment was considered successful only if control was negative.

After samples were taken and extracted as mentioned above, qPCR reaction master mix was prepared by adding the following components for each 25 µl of reaction mix to a tube at room temperature:

PCR mix:

2-FL : **7 µl**; dNTP's : **2.5 µl**; Forward Primer : **1 µl**;
Reverse Primer : **1 µl**; DNA probe : **1 µl**; Template DNA : **10 µl**;
Water, nuclease-free to : **25 µl**; Total volume : **25 µl**

Sample taking path

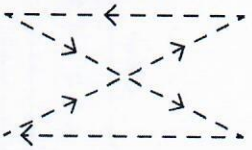


Table 1, Cycling protocol

Three-step cycling protocol steps	Temperature, °C	Time	Number of cycles
Initial denaturation	95	5 min	1
Denaturation	95	5 sec	42
Annealing	60	20 sec	42
Extension	72	15 sec	42

Detection Channel: FAM

Ⓐ Air / Ⓑ Surface samples

DNA extraction:

Ⓐ From Air Samples :

- Incubation on Shaker OS-20 (BioSan) 180 rpm 15'
- Spin columned (GeneJet Plasmid Miniprep Kit, Thermo Fisher Fermentas)

Ⓑ From Surface Samples:

- Vortex 2-3"
- Centrifuge at 13,300 rpm for 2'

Isolated DNA:

❶ Real time PCR amplification *(Fig. 7)*
❷ Detection of Ct values and normalization of data *(Fig. 8)*
❸ Copy number estimation on cabinet volume and surface area

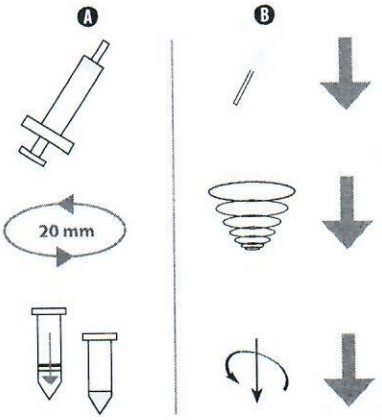
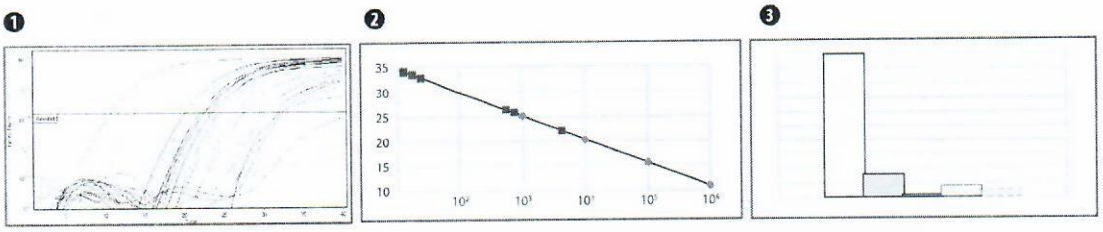


Fig. 4, DNA extraction, samples analyses and result detection



Results:

Mechanical contamination

Results of mechanical air contamination in cabinets of two types: PCR cabinet (UVC/T-M-AR, BioSan) and laminar flow cabinets (BioSafety class II cabinet prototype by BioSan and BSC II cabinet ABS Cabinet Class II by Microflow) as the positive control laboratory air samples were taken *(Fig. 5)*.

Microbial contamination

Microbial contamination in laboratory air and sterile cabinets. Quantitative results of microbial air contamination in cabinets of two types: PCR cabinet (UVC/T-M-AR, BioSan) and laminar flow cabinets (BioSafety class II cabinet prototype by BioSan and BSC II cabinet ABS Cabinet Class II by Microflow) as the positive control laboratory air samples were taken *(Fig. 6)*.

Fig. 5, Mechanical contamination, 0.3 µm particles

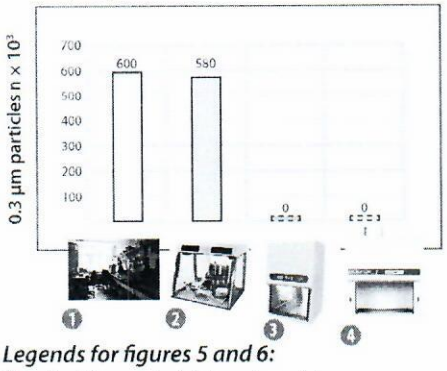
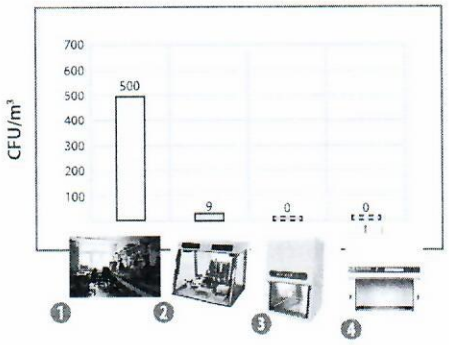


Fig. 6, Microbial contamination



Legends for figures 5 and 6:

❶ Positive control (laboratory air)
❷ UV Cabinet (UVC-T-M-AR, Biosan, Latvia)
❸ Laminar flow cabinet (HEPA BSC II Cabinet prototype, Biosan, Latvia)
❹ BSC II Cabinet (ABS Cabinet Class II, Microflow, UK)

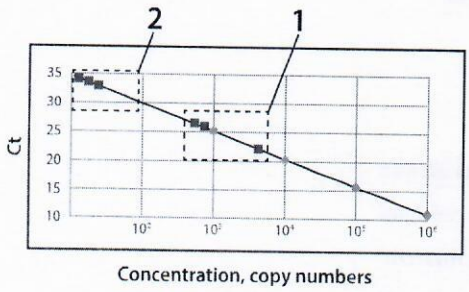
Amplicon contamination-inactivation efficiency:

Results analysis:

Real time PCR ensures product quantification using four standards of different Lambda phage DNA concentration and comparing Ct/Cq values of samples to those of concentration standards, based on standard curve *(Fig. 8)* (see Corbett Research Rotor Gene 3000 manual for more information) Following the amplification Lambda DNA copy number values were estimated for cabinet volume and surface area, results presented in *(Fig. 9)*.

Inactivation efficiency was calculated as ratio of DNA amplicons before and after treatment: direct and indirect UV treatment for 15 and 30 minutes, presented in percents in *table 2*.

Fig. 8, Standard curve, influence of direct and indirect UV irradiation on lambda phage DNA copy number



1 — *Samples after Lambda Phage spraying, no UV irradiation (positive control)*

2 — *Samples after 30 min UV inactivation*

● — *Concentration standards*

■ — *Samples*

Fig. 7, Effect of UV irradiation on Ct/Cq values (raw results)

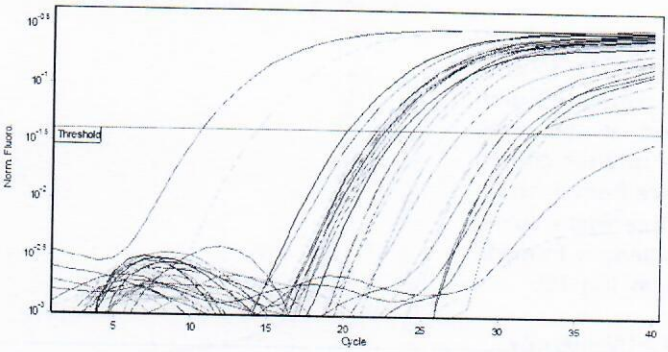
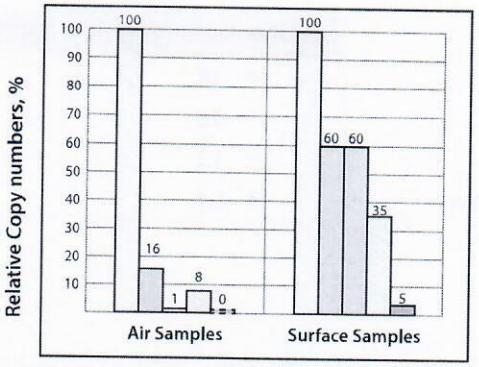


Fig. 9, Effect of direct and indirect UV irradiation on the amplicon concentration inside PCR cabinet UVC/T-M-AR, Biosan, Latvia



After Lambda phage DNA spraying

UV Air Recirculator for 15 min (Closed UV light irradiation, 25 W)

UV Air Recirculator for 30 min (Closed UV light irradiation, 25 W)

Open UV light (25 W) irradiation for 15 min

Open UV light (25 W) irradiation for 30 min

The horizontal axis show: air or surface samples, along with the relative copy number presented on vertical axis. Four series represent inactivation techniques and time of treatment, open UV light and UV air recirculator treatment kinetics are presented in the graph.

Table 2. DNA amplicon inactivation efficiency in PCR cabinet UVC/T-M-AR, Biosan, Latvia

Sample	Inactivation method efficiency			
	15 min of UV Air Rec.	30 min of UV Air Rec.	15 min of Open UV + UV Air Rec.	30 min of Open UV + UV Air Rec.
Air Samples	84%	99%	92%	100%
Surface Samples	40%	40%	65%	95%

Calculation of UV dose for each treatment

Direct UV Irradiation

Cabinet's air treatment

BioSan's cabinet features a single open UV lamp 25 Watt, germicidal UV irradiation (253.7 nm) measurements have been performed and UV intensity were recorded at the level from 18 mW/sec/cm² to 0.7 mW/sec/cm² at distance to UV source surface from 0 cm to 45 cm respectively. [2] In PCR cabinet volume following UV intensity gradient is formed: from 0.7 mW/cm² to 18 mW/cm² *(Fig. 10)*.

UV dosage during treatment = UV intensity at specific distance (mW/cm²/sec) × time of irradiation (sec)

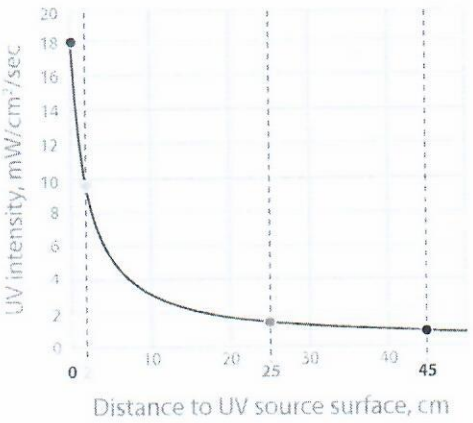
UV dosage during 15 min: gradient from 570-15,700 mW/cm²

UV dosage during 30 min: gradient from 1,140-31,400 mW/cm²

Cabinet's Surface treatment:

Distance to UV source ranges between surfaces and consequently the UV intensity *(table 3)*:

Fig. 10, UV intensity dependence on distance to UV tube (measured by radiometer VLX 254, Vilber Lourmat, France)



UV intensity, mW/cm²/sec	Distance, cm
18	0
9.3	2
1.3	25
0.7	45

Table 3. Average dosage for different surfaces

Surface	Dosage after 15 min	Dosage after 30 min
Working surface (40-50 cm)	570-680 mW/cm²	1,140-1,360 mW/cm²
Side walls (10-50 cm)	570-2,500 mW/cm²	1,140-5,000 mW/cm²
Front window (10-50 cm)	570-2,500 mW/cm²	1,140-5,000 mW/cm²

UV air recirculation:

Cabinet's Air treatment

BioSan PCR cabinets feature UV air recirculator. Recirculator consists of a fan, dust filters and closed UV-lamp (25 W) installed in a special aluminium casing, which is located in the upper hood. Fan's air flow speed is 14 m³/hour, which processes 1.3 cabinet volumes per minute. Distance from closed UV lamp to recirculator's walls is less than 2 cm at which UV intensity level is 9.3-18 mW/sec/cm² *(Fig. 10)*.

UV air recirculators are designed for constant air decontamination during operations.

Resulting in following UV dosage for cabinet's volume:

- During 15 min recirculation: 180 mW/cm²
- During 30 min recirculation: 360 mW/cm²

Cabinet's Surface treatment:

UV Air recirculator does not provide cabinet surface irradiation.

For deactivation of microorganisms and amplicons on the cabinet's surface additional open UV treatment is needed for protection against contamination

Conclusions

Air sampling methods developed by BioSan has been proven to be compatible with real time PCR detection of product. This method enables monitoring of laboratory air and sterile cabinet for presence of target DNA amplicons.

The research was designed to evaluate BioSan PCR cabinets' efficiency in comparison to Class II BioSafety cabinets. Based on the experiment results PCR cabinets prevent microbial contamination with inactivation efficiency up to 96%, but in comparison to Class II BioSafety cabinets do not provide protection against mechanical contamination.

UV air treatment in BioSan PCR cabinets for 30 min provides DNA amplicon deactivation efficiency:

- Combined UV treatment (Open UV and UV air recirculation) provides 100% efficiency
- UV air recirculation provides 99% efficiency
- Open UV irradiation provides 100% efficiency

Based on classification of BioSafety cabinets from European standard EN 12469 *[3]* and experiment results: BioSan PCR Cabinets and Class I, II, III BioSafety Cabinets were compared on product protection ability in *table 4*.

Further studies will be focused on:

- Development of high speed monitoring technology of RNA amplicon concentration in the laboratory air and in sterile cabinets.
- Investigation of Class II BioSafety cabinets efficiency against DNA amplicon contamination. Based on preliminary experiment results: DNA amplicon particles which are not stopped by HEPA filters *(Fig. 2)* can result in constant contamination of cabinets volume.

Table 4. Classification of sterile cabinets, based on protection against contamination

BioSafety cabinets	Protection against contamination forming units		
	Microorganisms	Viruses	DNA/RNA Amplicons
Class I	+	–	–
Class II (A1, A2, B1, B2)	+	–	–
Class III	+	–	–
BioSan PCR Cabinets	+/–	+	+

Table 5. Relation of risk groups to biosafety levels, practices and equipment (source: Laboratory biosafety manual, Third edition)

Risk Group	Biosafety Level	Laboratory Type	Laboratory Practices	Safety Equipment
1	Basic — Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Basic — Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	Containment — Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum Containment — Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air

BSC, biological safety cabinet; GMT, good microbiological techniques

Table 6. Summary of biosafety level requirements (source: Laboratory biosafety manual, Third edition)

	Biosafety Level			
	1	2	3	4
Isolation [a] of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
— Inward airflow	No	Desirable	Yes	Yes
— Controlled ventilating system	No	Desirable	Yes	Yes
— HEPA-filtered air exhaust	No	No	Yes/No [b]	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	—
Anteroom with shower	No	No	Yes/No [c]	No
Effluent treatment	No	No	Yes/No [c]	Yes
Autoclave:				
— On site	No	Desirable	Yes	Yes
— In laboratory room	No	No	Desirable	Yes
— Double-ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability [d]	No	No	Desirable	Yes

[a] Environmental and functional isolation from general traffic.
[b] Dependent on location of exhaust (see Chapter 4 of Laboratory Biosafety Manual).
[c] Dependent on agent(s) used in the laboratory.
[d] For example, window, closed-circuit television, two-way communication.

Acknowledgement

We acknowledge BioSan for financial support and technical assistance, Anete Dudele for work done in the beginning of the research on microbial contamination in PCR cabinets.

We acknowledge Central Researcha Institute of Epidemiology (Moscow, Russia) and M. Markelov, G. Pokrovsky, and V. Dedkov in particular, for development and provision reagents for lambda DNA quantitative analysis using Real–Time PCR method.

We acknowledge Paul Pergande for donating his time and expertise by reviewing this article.

References

1. K Linden, A Mofidi. 2004. Disinfection Efficiency and Dose Measurement of Polychromatic UV Light (1-6)
2. BioSan UV-air flow Cleaner-Recirculators test report (http://www.biosan.lv/eng/uploads/images/uvrm%20uvrmi%20article%20eng.pdf)
3. European Committee for Standardization (2000) European standard EN 12469: Biotechnology-Performance criteria for microbiological safety cabinets.
4. Web source: http://nobelprize.org
5. Web source: http://www.aircleaners.com/hepahistory.phtml
6. Web source: http://www.filt-air.com/Resources/Articles/hepa/hepa_filters.aspx#Characteristics
7. Web source: http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf
8. Laboratory biosafety manual, Third edition

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Centrifugues and laboratory products

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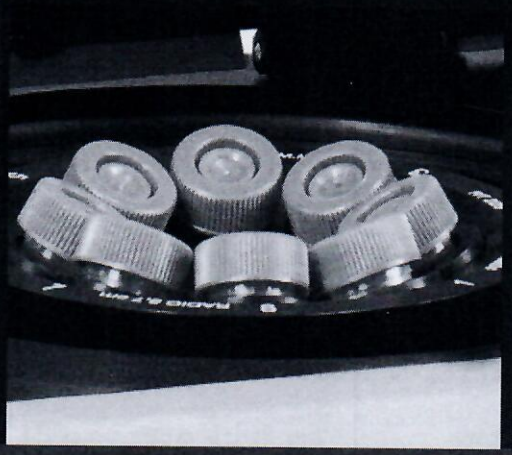

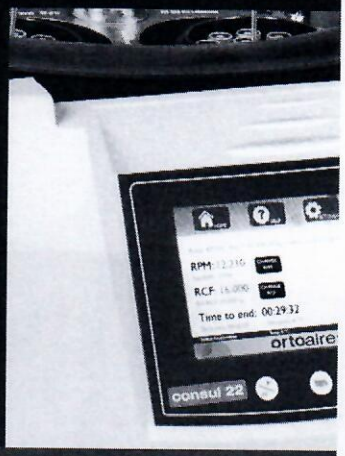

General

DIGICEN 21R

LCD

PC BS

CE IVD

Max. capacity: 4 x 100 ml.
Max. volume: 480 ml.

Max. speed: 26.480 xg / 16.500 RPM

Versatility fused with effectiveness. The centrifuge Digicen 21 R has a wide range of angle fixed rotors, both for low revolutions, with capacity up to 32 tubes of 15 ml./15 ml. conical, and for microtubes, cryotubes and high speed tubes. For the swing out versions, it has rotors for 4 tubes of 100 ml. and up to 28 positions for 15 ml. tubes. The wide range of reducers that accompany each of these rotors give the great versatility that defines the universal centrifuges. Its powerful refrigeration system enables it to maintain the minimum temperature of the chamber below 4 °C regardless of the type of rotor and the speed selected.

This particularity, joined to the control of the process of each of the stages and the parameters that control them, gives the user confidence in traceability during the centrifugation cycle.

Features

LCD screen:

- Shows RPM and RCF, time, temperature and acceleration/deceleration (PCBS).
- Speed programming in 10 RPM/ 10 xg steps.
- Timer countdown/up from "0" or at "set RPM/ RCF" for reproducible tests.
- Timer from 1 to 99 min. programmable in 5 sec. steps and hold position.
- PCBS: Progressive controlled acceleration and braking system up to 175 selectable ramps that prevents sample homogenization after separation.
- 16 programmable memories.
- Several acoustic and visual messages warning the user the device situation.

Easy to use

- Microprocessor controlled.
- Induction motor maintenance free (brushless).
- Rotors list on memory.
- Noise level: below 56 dB.
- Start, stop, open lid and short spin with adjustable speed buttons.
- Option of free/locked adjustment of RPM/ RCF along the run.
- Low height for easy access.
- Last values remain in memory.
- Automatic rotor recognition. Over-speed protection.

Safety

- Lid provided with security systems:
  - Automatic lid lock system, motorized with doubl
  - Emergency lid-lock release.
  - Locking and protection against opening along th
  - Lid dropping protection.
  - Port in the lid for calibration and operation chec
- Unbalance detection and switch off.
- Protection safety ring between the centrifugation
- Chamber of centrifugation in stainless steel (easy
- Rotors can be removed with the lid closed. Herme
- Rotors and adapters autoclavable, easy to install t
- Automatic disconnection for energy saving up to 8

Refrigeration

- Remains the refrigeration after centrifugation pro
- Precooling program with rotor spinning and tempe
- Guarantee 4 °C at maximum RPM.
- Temperature range from -20 °C (-4 °F) to 40 °C (10
- Temperature sensor inside the chamber.
- Gas R 449A HFO (CFC free).

EU Directives: 2011/65/EU, 2012/19/EU, 2014/30/E
Regulation n°: (EC) 1005/2009, (EU) 517/2014.
Standards: EN 61010-1, EN 61010-2-101, EN 6101C

Versions

	Dimensions (mm)(w x d x h)			Net weight (Kg)	Voltage (V)	Fr
CE 113	590	620	320	65	220-230	
CE 119	590	620	320	65	110-120	

Accessories

Centrifuges series Digicen 21

		RT 267		RT 143		RT 138		RT 150		MICROT RT 183	
						 (1)		 (2)			
ROTOR		SWING OUT		SWING OUT		SWING OUT		SWING OUT		ANGLE FIXED 45°	
Max. capacity		28 x 15 ml.		4 x 50 ml.		4 x 100 ml.		6/4/2 microtiter		32 x 0,2 ml.	
RPM Max.		5.000		5.300		5.000		4.000		16.500	
Radius (mm)		147		145		147		122 (3)		55 (3)	
RCF Max. (xg)		4.108		4.554		4.109		2.182		16.741	
Min. temp. at max. speed (°C)		-6		-7		-7		-9		-6	
SAMPLE VOLUME	**Dim (mm) approx.**	**ADAPTERS** Tubes	Ref.	**ADAPTERS** Tubes	Ref.	**ADAPTERS** Tubes	Ref.	**ADAPTERS** Tubes	Ref.	**ADAPTERS** Tubes	Ref.
100 ml.	ø48 x 100	-	-	-	-	4	RE 446	-	-	-	-
85 ml. (hs) / 80 ml. (hs)	ø38 x 112	-	-	-	-	4	RE 380	-	-	-	-
80 ml.	ø44 x 100	-	-	-	-	4	RE 338	-	-	-	-
50 ml. (hs)	ø29 x 108	-	-	4	RE 342	4	RE 341	-	-	-	-
50 ml.	ø34 x 100	-	-	4	RE 445	4	RE 335	-	-	-	-
50 ml. conical	ø29 x 117	-	-	4	RE 342	4	RE 341	-	-	-	-
30 ml. / 30 ml. (hs)	ø25 x 98	-	-	4	RE 333	4	RE 332	-	-	-	-
15 ml.	ø16 x 100	28	-	4	RE 329	16	RE 316	-	-	-	-
15 ml. conical	ø17 x 122	4	-	4	RE 329	4/8	RE 339/579	-	-	-	-
10 ml. (hs)	ø16 x 80	28	-	4	RE 329	16	RE 316	-	-	-	-
10 ml.	ø13 x 100	28	RE 516	12	RE 313	20	RE 320	-	-	-	-
10 ml. blood sample	ø16 x 107	28	-	4	RE 329	16	RE 316	-	-	-	-
7/10 ml. blood sample	ø13 x 107	28	RE 516	4	RE 337	20	RE 320	-	-	-	-
5 ml.	ø13 x 75	28	RE 512	12	RE 313	20	RE 320	-	-	-	-
5 ml. conical / screw cap	ø17 x 60/ 68	-	-	-	-	-	-	-	-	-	-
5 ml. blood sample	ø13 x 82	28	RE 512	4	RE 337	20	RE 320	-	-	-	-
Microtubes 1,5-2 ml.	ø11 x 42	28	RE 578	12	RE 463	20	RE 408	72	RE 401	-	-
Microtubes 0,5-0,6 ml.	ø8 x 30	28	RE 582	12	RE 531	20	RE 519	72	RE 580	-	-
Microtubes 0,2-0,4 ml.	ø6 x 45	28	RE 583	12	RE 532	20	RE 473	72	RE 581	32 x 0,2	-
Microtiter plates	128x86x15/21/45	-	-	-	-	-	-	6/4/2	-	-	-
Cell culture	128x86x22	-	-	-	-	-	-	4	-	-	-

(1) This rotor includes hermetic lids.
(2) Allows different configurations depending of the microplates height.
(3) Medium radius.
(4) Available adapters for cryotubes.
(5) Please check tubes features.
(6) Fitting these tubes the rotor can not be

		RT 110		RT 108		RT 266		RT 121		RT 152		HI
								 (5)		 (5)		
ROTOR		ANGLE FIXED 35°		ANGLE FIXED 35°		ANGLE FIXED 35°		ANGLE FIXED 45°		ANGLE FIXED 30°		ANG
Max. capacity		24 x 5 ml.		24 x 15 ml.		32 x 15 ml.		6 x 50 ml.		12 x 10ml. Hermet		8 x
RPM Max.		6.500		5.000		4.200		6.000		15.000		
Radius (mm)		113		132/114		149/130		132		78		
RCF Max. (xg)		5.338		3.689/3.186		2.938/2.563		5.313		19.621		
Min. temp. at max. speed (°C)		-4		-6		-5		-4		-5		
SAMPLE VOLUME	Dim (mm) approx.	ADAPTERS Tubes	Ref.	ADAPTERS Tubes	Ref.	ADAPTERS Tubes	Ref.	ADAPTERS Tubes	Ref.	ADAPTERS Tubes	Ref.	A Tube
100 ml.	ø48 x 100	-	-	-	-	-	-	-	-	-	-	-
85 ml. (hs) / 80 ml. (hs)	ø38 x 112	-	-	-	-	-	-	-	-	-	-	-
80 ml.	ø44 x 100	-	-	-	-	-	-	-	-	-	-	-
50 ml. (hs)	ø29 x 108	-	-	-	-	-	-	6	RE 365	-	-	-
50 ml.	ø34 x 100	-	-	-	-	-	-	6	RE 447	-	-	-
50 ml. conical	ø29 x 117	-	-	-	-	-	-	6	RE 365	-	-	-
30 ml. / 30 ml. (hs)	ø25 x 98	-	-	-	-	-	-	6	RE 387	-	-	8
15 ml.	ø16 x 100	-	-	24	-	32	-	6	RE 361	-	-	8
15 ml. conical	ø17 x 122	-	-	12	-	32	-	6	RE 361	-	-	-
10 ml. (hs)	ø16 x 80	-	-	24	RE 384	32	RE 529	6	RE 361	12	-	8
10 ml.	ø13 x 100	-	-	24	RE 385	32	RE 518	18	RE 360	-	-	8
10 ml. blood sample	ø16 x 107	-	-	24	-	32	-	6	RE 361	-	-	-
7/10 ml. blood sample	ø13 x 107	-	-	24	RE 385	32	RE 518	6	RE 364	-	-	-
5 ml.	ø13 x 75	24	-	24	RE 306	32	RE 517	18	RE 360	12	RE 389	8
5 ml. conical / screw cap	ø17 x 60/68	-	-	-	-	-	-	-	-	-	-	-
5 ml. blood sample	ø13 x 82	24	-	24	RE 306	32	RE 517	6	RE 364	12	RE 389	8
Microtubes 1,5-2 ml.	ø11 x 42	-	-	-	-	-	-	18	RE 464	-	-	-
Microtubes 0,5-0,6 ml.	ø8 x 30	-	-	-	-	-	-	18	RE 533	-	-	-
Microtubes 0,2-0,4 ml.	ø6 x 45	-	-	-	-	-	-	18	RE 534	-	-	-
Microtiter plates	128x86x15/21/45	-	-	-	-	-	-	-	-	-	-	-
Cell culture	128x86x22	-	-	-	-	-	-	-	-	-	-	-

RT 128: Available rotor for capillaries (includes microhaematocrit reader card).

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About centrifugation

Álvarez Redondo S.A.
Edition: January 2019.
Subject to modifications.

Made in Spain (UE)

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SGS SGS

CERTIFICATE

of the service personnel training

We hereby certify, that

Ing. Eugen Dragomirescu and Ing. Bebi Cretu

Company:

AMS 2000 Trading Impex SRL - Romania

Attended a professional training for the following devices:

Centrifugues for general applications: Minicen; Microcen 24; Biocen 22; Biocen 22 R; Bioprocen 22 R; Unicen 21; Digicen 21; Digicen 21 R; Consul 22; Consul 22 R; Digtor 22; Digtor 22 R; Dilitcen 22 R; Magnus 22; Magnus 22 R

Centrifugues for special applications: Lacter 21; Digtor 22 C-U; Digtor 22 C-8; Digtor 22 C; Vetcen; Plasma 22; Cytocentrifuge; Digtor 22 Col

On 21th – 25th January 2019

And acquired practical and theoretical knowledge in servicing of the above units. They are therefore authorized to provide installation, service, training, guarantee and consulting.

Date: 25.1.2019

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About centrifugation

J.A. ALVAREZ GONZALEZ
Gerente/Manager

3.3.9. Forced ventilation

Reduce the temperature increasing inside the chamber of centrifugation. It is not available in refrigerated centrifuges.

3.3.10. Automatic rotor recognition

Limit the maximum values allowed by the equipment configuration.

4. Installation

In this chapter you may find all instructions for a right centrifuge installation on your working place.

Pay attention about the guidelines for unpacking as section 9.4 - Unpacking

4.1. Inspection

Once the centrifuge and accessories unpacked, check the packing list. Plug the device to the power supply, open manually the cover pressing the button on the keypad and take out the packing and accessories. If you miss any part, please contact with your dealer.

Be careful carrying the centrifuge, as it has a high weight a wrong handling during the moving could result in a physical damage to the person performing it and/or damage to the centrifuge.

4.2. Location

The table or bench top where the centrifuge is going to be placed on must be solid enough to avoid vibrations. You must keep a security distance at the sides and back of 30 cm. Within this security distance there must not be any device, wall, panels or any other object or obstacle in order to maintain both the operator's security and good air ventilation. The bench top which the centrifuge is placed on must be levelled and must have a power supply available within 1m maximum distance, with the features required by the centrifuge.

The equipment can work at an installation altitude of up to 2,000m.

Do not locate the centrifuge on a way which does not allow the user the main switch handling.

Do not locate any precision instrument in surrounding area.

CAUTION

The use of this equipment in a stacked or adjacent configuration must be avoided because it may result in an operational malfunction. If such a placement is necessary, this equipment must be supervised to verify that they are operating normally.

4.3. Network connection

At the right side, it is the network connector, the main switch and fuse register are integrated in it. Before connecting the network cable to the centrifuge, check if the network values (voltage, frequency, etc...) are the right ones. These values can be obtained from the plate next to the network connector or at the section 5.3 of this manual.

The grounding pole must be connected, as the network must have grounding and the centrifuge connected to it.

CAUTION

Check the centrifuge network needs so that the device is not connected to an unsuitable power source.

4.4. Installation

Once the centrifuge has been unpacked, and placed at its work location, make sure that the security distances are the suitable ones according to section 3.2.1, and that the centrifuge is levelled and with perfect stability.

Connect the centrifuge making sure that the power supply is the specified in section 4.3.

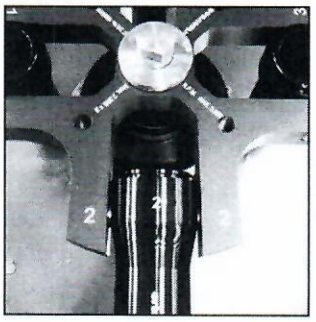
With these performances, your centrifuge is ready to use.
Open according to 6.1 and place the buckets, adapters and other fitting on its suitable position, according their numeration.
Check that the main switch, located at the network connector, is at the position "0" (switched off).
Once it has been installed, please remain the unit at least 5 hours before to switch it ton, in order the oil of refrigeration unit should be placed at the bottom of the compressor (Only Digicen 21R).

4.5. Rotor installation

CAUTION

Do not remove rotor screws.

Rotor coupling:
- Place the head in the central axis, with two hands, being careful to house the fastener in its low slot.
- Turn the nut in the opposite clockwise.
- When you find resistance, tight slightly with a No. 13/ Allen No. 8 wrench the central nut, in the same sense.
-If the rotor to be installed has buckets, make sure that each bucket is in the number indicated (bucket number match with the position to be located) and that the number is oriented towards the outside of the rotor.



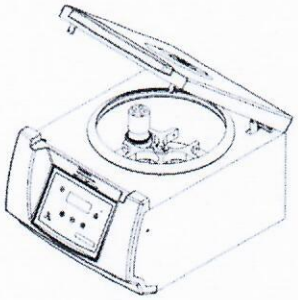
Rotor removing:
- First take out the buckets, adapters and cushions.
- Hold the bottom part of the rotor in one hand.
- Lose the nut, with the no. 13 /Allen No. 8 wrench clockwise.
- Turn around the nut, with the no. 13 /Allen No. 8 wrench clockwise.
- A first resistance is overcome, but after a half turning, the nut becomes tight again, so you must overcome a new resistance point.

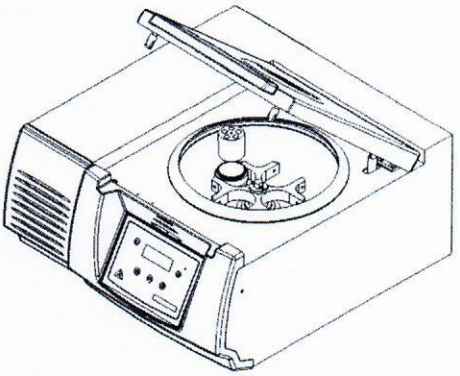
- With your left hand pull upwards while you keep on turning the nut clockwise, until you can take out the rotor.

CAUTION

Make sure the rotor has been properly installed: all its corresponding accessories (caps, head, nuts, etc.) coupled in place and adjusted to the shaft for proper operation.

5. Description:





5.1. General Description:

The centrifuges Digicen 21 and Digicen 21 R are proper for all kind of works in clinical lab, because of its versatility it should run vacuum tubes, on industrial lab because of the wide range of rotors, as well as on research, because of the rotors tailor made are available for our customers.

The centrifuge housing is made in steel covered by epoxy treatment and front made in ABS plastic, so it is highly resistant to corrosion. Its chamber of centrifugation is made in stainless steel AISI 304, easy to clean and resistant.

Rotors are made in light alloys and high precision machining, for high speed and safety use.

The keyboard is formed by two sections, a display pad and two lines of displays. The control of all systems and peripherals is controlled by microprocessor. Parameters to control are:

- Speed: in RPM o RCF.
- Centrifugation time.
- Acceleration selectable on two steps: soft and fast, and deceleration for 5 to 180 seconds rotor dependent.
- Up to 16 memories.
- Temperature (just Digicen 21 R)
- Saving energy system: after 15 minutes of rest, the keypad will be switched off. This value should be selectable.
- Open lid selectable manual or automatic after centrifugation finished (Only Digicen 21R)

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About centrifugation

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DECLARACIÓN CE DE CONFORMIDAD

EC DECLARATION OF CONFORMITY

CE

El siguiente equipo cumple con todos los requisitos esenciales para la salud y seguridad de las Directivas Europeas.
The following machinery complies with all the essential health and safety requirements of the European Directives

Descripción - Description of device	**CENTRÍFUGA DE LABORATORIO /CENTRIFUGE FOR LABORATORY**
Marca - Trade Mark:	**ORTOALRESA**
Modelo - Model:	**DIGICEN 21/ DIGICEN 21R**
Clasificación 98/79/CE - Classification 98/79/EC:	**No clasificado en Anexo II o autodiagnóstico/ Non classified in Annex II or autodiagnostic**

Directivas Europeas. European Directives:

Directiva relativa a las máquinas 2006/42/CE.
Directive on machinery 2006/42/EC.

Directiva sobre productos sanitarios para diagnostico in vitro (IVD) 98/79/CE.
Directive on in vitro diagnostic medical devices (IVD) 98/79/EC.

Directiva de comercialización de material eléctrico destinado a utilizarse con determinados límites de tensión 2014/35/UE.
Directive on the market of electrical equipment designed for use within certain voltage limits 2014/35/EU.

Directiva de compatibilidad electromagnética 2014/30/UE.
Directive to electromagnetic compatibility 2014/30/EU.

Directiva sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos (RoHS) 2011/65/UE.
Directive related to the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) 2011/65/EU.

Directiva sobre residuos aparatos eléctricos y electrónicos (RAEE) 2012/19/UE.
Directive on waste electrical and electronic equipment (WEEE) 2012/19/EU.

Normas armonizadas aplicadas. Applied harmonized standards

EN 61010-1 **EN 61010-2-101** **EN 61326-2-6**

EN 61010-2-020 **EN 61326-1**

Los ensayos de las normas están certificados por laboratorio acreditado.
The tests of the norms are certified for accreditation laboratory.

A 08 de septiembre de 2016

orto alresa
About centrifugation

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Gerente/Manager

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CIF/VAT: ESA 78757903

Manufacturer's Authorization Letter

Dated: 30/03/2020

Anunt de participare simplificat: [SCN1065672] - Achiziționare Sistem PCR de detectie Cov-2 cu accesoriile si consumabilele aferente acestuia.

To
Spital Clinic Judetean de Urgenta Arad

Whereas we Álvarez Redondo S.A. (under Ortoalresa brand), who are official manufacturers of centrifuges, having our factory at Los Frailes 121, Pol. Ind. Los Frailes, 28814 Daganzo-Madrid-SPAIN, do hereby

Authorize AMS 2000 Trading Impex SRL, str. Turturelelor nr 62, Decebal Tower, Sector 3, Bucharest, Romania, to supply the following goods manufactured by us, refrigerated centrifuges, for the above referred tender.

We hereby extend our full guarantee and warranty as stated under General Conditions of Contract (GCC), with respect to the goods offered for the above tender.

Penélope Álvarez
Export Manager
Ortoalresa

Medical–Biological
Research & Technologies

Attn: To whom it may concern

LETTER OF AUTHORIZATION No. P138/2020

We, **BIOSAN SIA** (registration number: 40003072462), who are established and reputable manufacturers of Laboratory Equipment, having factories at Latvia, Riga, Ratsupites str. 7, build. 2, LV-1067, hereby certify that

Dealer: **AMS 2000 Trading Impex SRL**
Address Str. Turturelelor nr 62, Decebal Tower
Sector 3, Bucharest, Romania
Contact person: **Alina Anghelache**
Tel: +4021 324 70 50

is a distributor authorized to:

- participate in the public tender: Anunt de participare simplificat: [SCN1065672] - Achiziţionare Sistem PCR de detectie Cov-2 cu accesoriile si consumabilele aferente acestuia organized by Spital Clinic Judetean de Urgenta Arad, Romania using Biosan products.
- provide after-sales support and service for Biosan devices.

Territory of distribution and service is **Romania.**

This Letter of Authorization shall be valid for the tender term only. Upon the respective written from Biosan this Letter of Authorization automatically becomes null and void.

Biosan SIA shall have no obligation or responsibility regarding any actions of distributor whatsoever.

Monday, 30/03/2020

Riga

Aleksey Konstantinov
Sales Director
SIA Biosan

SABIEDRIBA AR IEROBEŽOTU ATBILDIBU
SIA
biosan
dokumentiem
for documents
LATVIJA

Address:
Biosan SIA, Ratsupites str. 7/2, Riga, LV-1067
Reg. No: 40003072462
VAT No: LV40003072462

Contacts:
Tel.: +371 67 426 137, Fax: +371 67 428 101
E-mail: info@biosan.lv, www.biosan.lv

Bank details:
AS "Swedbank"
Balasta dambis 15, Riga, LV-1047
SWIFT: HABALV22 • LV97HABA0551013587195

SC "Citadele bank"
Republikas laukums 2A, Riga, LV-1010
SWIFT: PARXLV22 • LV66PARX0012666440001

4. Getting started

4.1. **Unpacking.** Remove packing materials carefully and retain them for future shipment or storage of the unit. Examine the unit carefully for any damage incurred during transit. The warranty does not cover in-transit damage. Warranty covers only the units transported in the original package.

4.2. **Complete set.** Package contents:

4.2.1. **V-1 plus**:

- V-1 plus, personal vortex ..... 1 pce.
- External power supply ..... 1 pce.
- Operating manual, declaration of conformity ..... 1 copy

4.2.2. **V-32**:

- V-32, multi-vortex ..... 1 pce.
- External power supply ..... 1 pce.
- PV-32, universal platform (..... 1 pce.
- PL-1, single tube vortexing head (..... 1 pce.
- Operating manual, declaration of conformity ..... 1 copy
- PV-6/10, platform (.....on request
- PV-48, platform for strips (.....on request

PV-32 **PL-1** **PV-6/10** **PV-48**

4.3. **Setup**.

- Place the unit upon even horizontal stable non-flammable surface 30 cm away from any flammable materials, and clear 20 cm around the device on all sides for ventilation.
- Connect the external power supply unit into the socket at the rear side of the unit and position the unit for an easy access to the external power supply and the power switch.
- Connect the power cable to the external power supply.

4.4. Platform replacement (model V-32):

- Using a flat screwdriver, unscrew black screw at the middle of the platform (fig. 2/1) and remove it together with the washer.
- Using a Phillips screwdriver, loosen two fixing screws (fig. 2/3) on the rotor under the platform.
- Remove and replace the platform (fig. 2/2), fix the platform in place in opposite order.

5. Operation

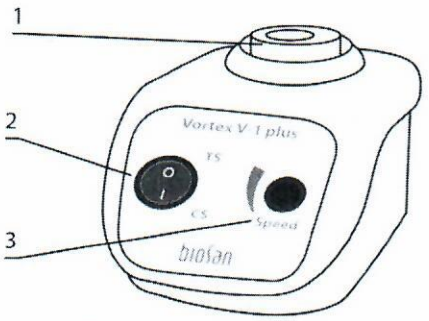


Figure 1. V-1 plus, front view

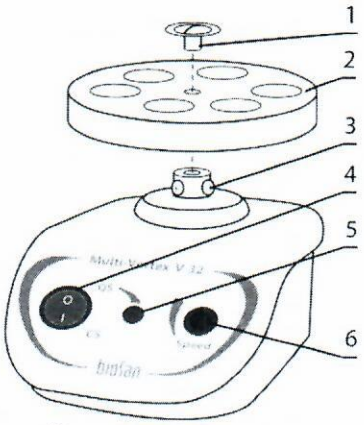


Figure 2. V-32, front view

5.1. Working with model **V-1 plus**.

5.1.1. Connect the external power supply to the mains.

5.1.2. Gently holding a tube by its upper part, press the lower part to the vortex head (fig. 1/1). During rotation of the rotor, control the intensity of shaking by varying applied pressure.

⚠ **Caution!** To achieve effective vortexing, do not fill the tubes for more than 50% of volume.

5.1.3. Continuous shaking mode – **CS**

5.1.3.1 Turn the **TS/CS** switch (fig. 1/2) to position **CS**.

5.1.3.2 Set the required speed by turning the **Speed** knob (fig. 1/3).

5.1.3.3 After finishing the operation, turn the switch into position **TS**.

5.1.4. Impulse shaking mode – **TS**.

5.1.4.1 Turn the **TS/CS** switch (fig. 1/2) to position **TS**.

5.1.4.2 Set the required speed by turning the **Speed** knob (fig. 1/3).

5.1.4.3 Push the tube on the vortex head (fig. 1/1) and hold for vortexing. Rotor stops when the tube is raised.

5.1.5. Disconnect the external power supply from the mains outlet.

5.2. Working with model **V-32**.

5.2.1. Connect the external power supply to the mains.

5.2.2. When shaking several tubes, place the tubes on the platform.

5.2.3. When shaking single tube (PL-1 head), gently holding a tube by its upper part, press the lower part to the vortex head. During rotation of the rotor, control the intensity of shaking by varying applied pressure.

⚠ **Caution!** To achieve effective vortexing, do not fill the tubes for more than 50% of volume.

5.2.4. Continuous shaking mode – **CS**

5.2.4.1 Turn the **QS/CS** switch (fig. 1/4) to position **CS**.

5.2.4.2 Set the required speed by turning the **Speed** knob (fig. 1/6).

5.2.4.3 After finishing the operation, turn the switch into position **TS**.

5.2.5. Quick shaking mode – **QS**.

5.2.5.1 Turn the **QS/CS** switch (fig. 1/4) to position **QS**.

5.2.5.2 Set the required speed by turning the **Speed** knob (fig. 1/6).

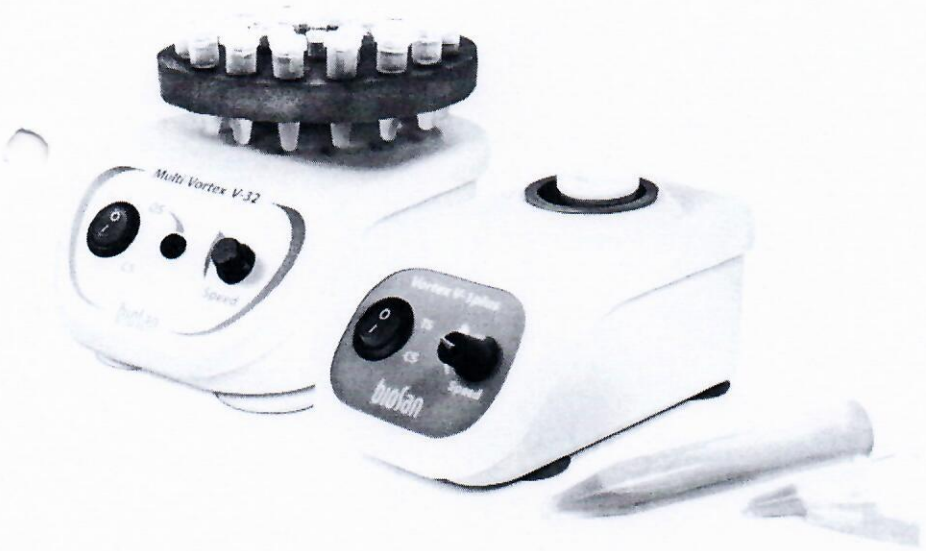
5.2.5.3 Position the tube on the vortex head, press and hold **QS** button (fig. 1/5) for vortexing. Rotor stops when the button is released.

5.2.6. Disconnect the external power supply from the mains outlet.

biosan

Medical–Biological
Research & Technologies

V-1 plus & V-32
Vortex for tubes



User instructions

Contents

1. About this edition of user instructions

The manual applies to following models and versions of personal vortexes for tubes and microtubes:

- **V-1 plus** ..... version V.4AW
- **V-32** ..... version V.2AW

2. Safety precautions

⚠ **Caution!** Make sure you have fully read and understood the present Manual before using the equipment. Please pay special attention to sections marked by this symbol.

GENERAL SAFETY

- The protection provided can be ineffective if the operation of the appliance does not comply with the manufacturer's requirements.
- Save the unit from shocks and falling.
- Store and transport the unit in a horizontal position (see package label) at ambient temperatures between -20°C and +60°C and maximum relative humidity of 80%.
- After transportation or storage and before connecting it to the electric circuit, keep the unit under room temperature for 2-3 hrs.
- Before using any cleaning or decontamination methods except those recommended by the manufacturer, check with the manufacturer that the proposed method will not damage the equipment.
- Do not make modifications in design of the unit.

ELECTRICAL SAFETY

- Connect only to the mains with voltage corresponding to that on the serial number label.
- Use only the external power supply provided with this product.
- Ensure that the power plug is easily accessible during use.
- Do not plug the unit into an ungrounded power socket, and do not use an ungrounded extension lead.
- Disconnect the unit from the mains before moving.
- If liquid penetrates into the unit, disconnect it from the mains and have it checked by a repair and maintenance technician.
- Do not operate the unit in premises where condensation can form. Operating conditions of the unit are defined in the **Specifications** section.

DURING OPERATION

- Do not impede the platform motion.
- Do not operate the unit in environments with aggressive or explosive chemical mixtures. Please contact manufacturer for possible operation of the unit in specific atmospheres.
- Do not operate the unit if it is faulty or has been installed incorrectly.
- Do not use outside laboratory rooms.
- Do not place a load exceeding the maximum load value mentioned in the **Specifications** section of this manual.

BIOLOGICAL SAFETY

- The user is responsible to carry out appropriate decontamination if hazardous material spills on or penetrates into the equipment.

3. General information

V-1 plus / V-32 vortex is intended for intensive mixing of samples in tubes using an eccentric mechanism. Vortex is applicable in all the fields of laboratory research in biotechnology, microbiology and medicine:

- Mixing tissue samples;
- Suspending cell samples;
- Mixing chemical samples;
- Mixing bacterial and yeast cells when washing from the culture medium
- Extracting metabolites and enzymes from cells and cell cultures, etc.
- Vortexing during various operations with DNA/RNA.

Vortex has two operation modes:

- continuous operation;
- impulse operation.

Model V-1 plus is a personal vortex with fluoroplastic head for single tube (0.2 – 50 ml) vortexing.

Model V-32 is a universal vortex multipurpose device with different accessories. It is supplied with a 32-socket universal platform PV-32 for Eppendorf type tubes up to 15 ml (1.5/0.5/0.2 ml - 16/8/8 sockets) and a PL-1 head for vortexing a single tube up to 50 ml. An optional 6-socket platform PV-6/10 for 10 ml tubes (maximum tube diameter 15 mm) or a platform PV-48 for 6 strips of 8x0.2 ml microtubes can be supplied on request.

4. Getting started

4.1. **Unpacking.** Remove packing materials carefully and retain them for future shipment or storage of the unit. Examine the unit carefully for any damage incurred during transit. The warranty does not cover in-transit damage. Warranty covers only the units transported in the original package.

4.2. **Complete set.** Package contents:

4.2.1. **V-1 plus**:

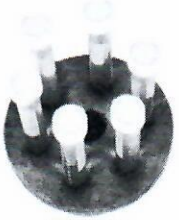
- V-1 plus, personal vortex ..... 1 pce.
- External power supply ..... 1 pce.
- Operating manual, declaration of conformity ..... 1 copy

4.2.2. **V-32**:

- V-32, multi-vortex ..... 1 pce.
- External power supply ..... 1 pce.
- PV-32, universal platform (..... 1 pce.
- PL-1, single tube vortexing head (..... 1 pce.
- Operating manual, declaration of conformity ..... 1 copy
- PV-6/10, platform (..... on request
- PV-48, platform for strips (..... on request

PV-32

PL-1



PV-6/10

PV-48

4.3. **Setup**.

- Place the unit upon even horizontal stable non-flammable surface 30 cm away from any flammable materials, and clear 20 cm around the device on all sides for ventilation.
- Connect the external power supply unit into the socket at the rear side of the unit and position the unit for an easy access to the external power supply and the power switch.
- Connect the power cable to the external power supply.

4.4. Platform replacement (model V-32):

- Using a flat screwdriver, unscrew black screw at the middle of the platform (fig. 2/1) and remove it together with the washer.
- Using a Phillips screwdriver, loosen two fixing screws (fig. 2/3) on the rotor under the platform.
- Remove and replace the platform (fig. 2/2), fix the platform in place in opposite order.

5. Operation

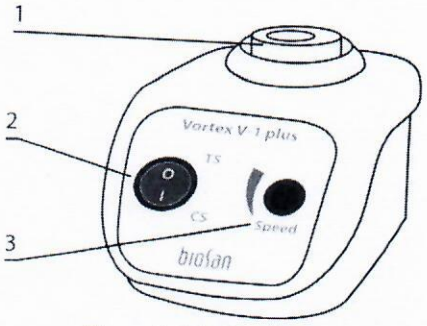


Figure 1. V-1 plus, front view

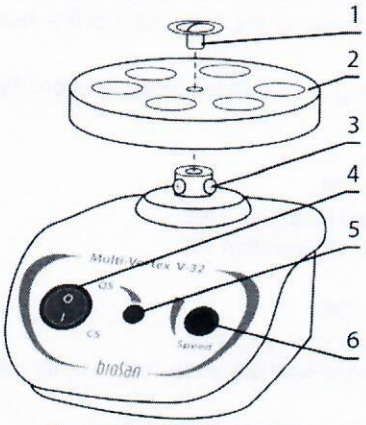


Figure 2. V-32, front view

5.1. Working with model **V-1 plus**.

5.1.1. Connect the external power supply to the mains.

5.1.2. Gently holding a tube by its upper part, press the lower part to the vortex head (fig. 1/1). During rotation of the rotor, control the intensity of shaking by varying applied pressure.

Caution! To achieve effective vortexing, do not fill the tubes for more than 50% of volume.

5.1.3. Continuous shaking mode – **CS**

5.1.3.1 Turn the **TS/CS** switch (fig. 1/2) to position **CS**.

5.1.3.2 Set the required speed by turning the **Speed** knob (fig. 1/3).

5.1.3.3 After finishing the operation, turn the switch into position **TS**.

5.1.4. Impulse shaking mode – **TS**.

5.1.4.1 Turn the **TS/CS** switch (fig. 1/2) to position **TS**.

5.1.4.2 Set the required speed by turning the **Speed** knob (fig. 1/3).

5.1.4.3 Push the tube on the vortex head (fig. 1/1) and hold for vortexing. Rotor stops when the tube is raised.

5.1.5. Disconnect the external power supply from the mains outlet.

5.2. Working with model **V-32**.

5.2.1. Connect the external power supply to the mains.

5.2.2. When shaking several tubes, place the tubes on the platform.

5.2.3. When shaking single tube (PL-1 head), gently holding a tube by its upper part, press the lower part to the vortex head. During rotation of the rotor, control the intensity of shaking by varying applied pressure.

⚠ **Caution!** To achieve effective vortexing, do not fill the tubes for more than 50% of volume.

5.2.4. Continuous shaking mode – **CS**

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5.2.5.1 Turn the **QS/CS** switch (fig. 1/4) to position **QS**.

5.2.5.2 Set the required speed by turning the **Speed** knob (fig. 1/6).

5.2.5.3 Position the tube on the vortex head, press and hold **QS** button (fig. 1/5) for vortexing. Rotor stops when the button is released.

5.2.6. Disconnect the external power supply from the mains outlet.

6. Specifications

The unit is designed for operation in cold rooms, incubators (except CO_2 incubators) and closed laboratory rooms at ambient temperature from +4°C to +40°C in a non-condensing atmosphere and maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C.

Biosan is committed to a continuous programme of improvement and reserves the right to alter design and specifications of the equipment without additional notice.

	V-1 plus	V-32
Speed control range	500-3000 rpm	
Acceleration time	2 s	3 s
Maximum continuous operation time[1]	24 h	
Tube volume	0.2 – 50 ml	
Maximum load	30 g	70 g
Orbit	4 mm	2 mm
Dimensions	90x150x80 mm	120x180x100 mm
Working current / Power consumption	12 V, 320 mA / 3.8 W	
External power supply	in AC 100-240 V, 50/60 Hz, out DC 12 V	
Weight[2]	0.8 kg	1.5 kg

Optional accessories	Description	Catalogue number
PV-6/10 for V-32	6-socket platform for 10 ml tubes, maximum ø 15 mm	BS-010207-BK
PV-48 for V-32	6 strip platform, 8x0.2 ml each or for 48 microtubes 0.2 ml each	BS-010207-GK

Replacement parts	Description	Catalogue number
PV-32 for V-32	32-socket platform for Eppendorf type microtubes, 1.5/0.5/0.2 ml - 16/8/8 sockets	BS-010207-CK
PL-1 for V-32	Platform for single tube vortexing, 0.2 - 50 ml in volume	BS-010207-GK

7. Care and maintenance

7.1. If the unit requires maintenance, disconnect the unit from the mains and contact Biosan or your local Biosan representative.

7.2. All maintenance and repair operations must be performed only by qualified and specially trained personnel.

7.3. Standard ethanol (75%) or other cleaning agents recommended for cleaning of laboratory equipment can be used for cleaning and decontamination of the unit.

[1] Maintain at least 1 hour long pause between prolonged continuous operations

[2] Accurate within ± 10%

8. Warranty

8.1. The Manufacturer guarantees the compliance of the unit with the requirements of Specifications, provided the Customer follows the operation, storage and transportation instructions.

8.2. The warranted service life of the unit from the date of its delivery to the Customer is 24 months. For extended warranty, see **8.5**.

8.3. Warranty covers only the units transported in the original package.

8.4. If any manufacturing defects are discovered by the Customer, an unsatisfactory equipment report shall be compiled, certified and sent to the local distributor address. To obtain the claim form, visit section **Technical support** on our website at link below.

8.5. Extended warranty. For **V-1 plus & V-32**, the *Basic Plus* class models, extended warranty is a paid service. Contact your local Biosan representative or our service department through the **Technical support** section on our website at the link below.

8.6. Description of the classes of our products is available in the **Product class description** section on our website at the link below.

Technical support

biosan.lv/en/support

Product class description

biosan.lv/classes-en

8.7. The following information will be required in the event that warranty or post-warranty service comes necessary. Complete the table below and retain for your records.

Model	**V-1 plus** personal vortex **V-32** multi-vortex
Serial number	
Date of sale	

9. EU Declaration of conformity

EU Declaration of Conformity

Unit type	Rockers, shakers, rotators, vortexes
Models	**MR-1, MR-12;** **3D, Multi Bio 3D, PSU-10i, PSU-20i, OS-20, MPS-1, PSU-2T;** **Bio RS-24, Multi Bio RS-24, Multi RS-60;** **V-1 plus, V-32, MSV-3500**
Serial number	14 digits styled XXXXXXYYMMZZZZ, where XXXXXX is model code, YY and MM – year and month of production, ZZZZ – unit number.
Manufacturer	SIA BIOSAN Latvia, LV-1067, Riga, Ratsupites str. 7/2
Applicable Directives	EMC Directive 2014/30/EU LVD Directive 2014/35/EU RoHS2 2011/65/EU WEEE 2012/19/EU
Applicable Standards	LVS EN 61326-1: 2013 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements. LVS EN 61010-1: 2011 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements. LVS EN 61010-2-051: 2015 Particular requirements for laboratory equipment for mixing and stirring.

We declare that this product conforms to the requirements of the above Directives

Signature

Svetlana Bankovska
Managing director

19.07.2016
Date

Signature

Aleksandr Shevchik
Engineer of R&D

19.07.2016
Date

HOW TO CHOOSE
A PROPER SHAKER, ROCKER, VORTEX

biosan
Medical-Biological Research & Technologies

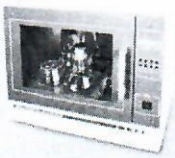
Sample volume 10^3 ... 10^2 ml
Erlenmeyer flasks and Cultivation flasks

Sample volume 10^1 ml
Petri dishes, vacutainers and tubes up to 50 ml

Sample volume 10^0 ... 10^{-3} ml
PCR plates, microtest plates and Eppendorf type tubes

PSU-20i, Orbital Shaker

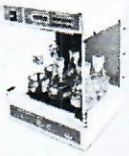
ES-20/60, Orbital Shaker-Incubator



Applications:
Microbiology
Extraction
Cell cultivation

PSU-10i, Orbital Shaker

ES-20, Orbital Shaker-Incubator



MR-12, Rocker-Shaker

Multi RS-60, Programmable rotator

Multi Bio RS-24, Programmable rotator

Applications:
Microbiology
Extraction
Cell cultivation
Hematology

Bio RS-24, Mini-Rotator

V-1 plus, Vortex

NEW

RTS-1 and RTS-1C, Personal bioreactors

MSV-3500, Multi Speed Vortex

MR-1, Mini Rocker-Shaker

Applications:
Nucleic acid Analysis
Molecular Analysis
Protein Analysis
Genomic Analysis

Applications:
Agglutination
Gel staining/ destaining

Multi Bio 3D, Mini Shaker

Applications:
Agglutination
Extraction
Blot hybridisation
Gel staining/destaining

PST-60HL-4, Thermo-Shaker

PST-100HL, Thermo-Shaker

TS-DW, Thermo-Shaker for deep well plates

PST-60HL, Thermo-Shaker

NEW

Applications:
ELISA Analysis
Genomic Analysis
Hybridization
Immunology

MPS-1, Multi Plate Shaker

PSU-2T, Mini-Shaker

NEW

CVP-2, Centrifuge vortex for PCR plates

TS-100, TS-100C, Thermo-Shakers

V-32, Multi-Vortex

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+371 67426137, fax: +371 67428101
marketing@biosan.lv http://www.biosan.lv

EU Declaration of Conformity

Unit type	Rockers, shakers, rotators, vortexes
Models	**MR-1, MR-12;** **3D, Multi Bio 3D, PSU-10i, PSU-20i, MPS-1, PSU-2T;** **Bio RS-24, Multi Bio RS-24, Multi RS-60;** **V-1 plus, V-32, MSV-3500**
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Svetlana Bankovska
Managing director

19.07.2016
Date

Signature

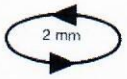
Aleksandr Shevchik
Engineer of R&D

19.07.2016
Date

V-32 multi vortex mixer

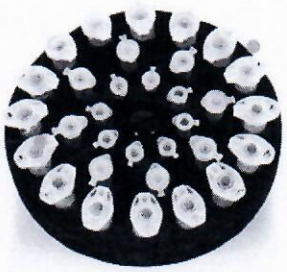
Versatile multi vortex mixer for vigorous re-suspension of cell or chemical pellets in tubes up to 1.5 ml, with the facility to mix individual tubes up to 15 ml.

- **Adjustable speed control: 500 to 3000 rpm**
- **'Continuous' or 'quick' operation**
- **Handles up to 32 tubes in three different sizes/combinations or a larger tube with the single platform head**

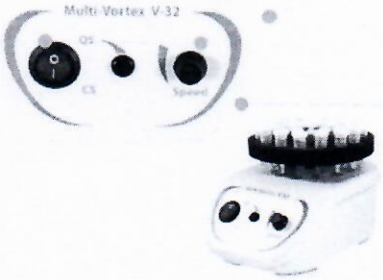


Orbit

Compact rugged design plus powerful motor delivering consistent performance and quiet operation - fits neatly and unobtrusively into the workspace



Easy operation – select 'continuous' or 'touch' operation and dial to control speed from 500 rpm to 3000 rpm



The 32-socket universal platform PV-32 and single tube platform PL-1 included as standard

PV-32 for three tubes sizes (16 x 1.5 ml, 8 x 0.5 ml, 8 x 0.2 ml)

PL-1 for mixing individual tubes up to 15 ml provides maximum flexibility

Optional 6 x 10 ml platform available

Low voltage cord easily fits through door gaskets, allowing use in incubators, refrigerators and workstations

Rubber suction pads hold tight to the work surface and prevent the unit from 'walking' – they also absorb vibration and prevent its transmission to the workbench

Applications:

- Life-sciences - performing various DNA operations – deproteinisation of DNA/protein complexes, mixing of immunostained human cells, purification of low-molecular DNA/RNA fragments in PCR-diagnostic
- Industrial - de-airing adhesive
- General - mixing and dispersion of particle suspensions
- Biopharm - solubilising powders

Vortex mixers – models and specifications

● = standard

		Personal vortex mixer	Multi vortex mixer
		PV-1	V-32
		 80 mm 150 mm 90 mm 1.1kg	 100 mm 180 mm 120 mm 1.5 kg
Speed	rpm	750 to 3000	500 to 3000
Acceleration time to maximum speed	sec	–	3
Orbit	mm	4	2
Maximum tube diameter	mm	28.5*	16
Capacity		1 up to 50 ml tube	16 x 1.5 ml, 8 x 0.5 ml and 8 x 0.2 ml tubes
Input voltage	V dc	12	
Input current	A	0.32	0.32
Ambient temperature range	°C	+4 to 40	

Accessories

PV6-10
Universal 6-socket platform for 10 ml tubes (maximum tube diameter 15 mm)

– ●

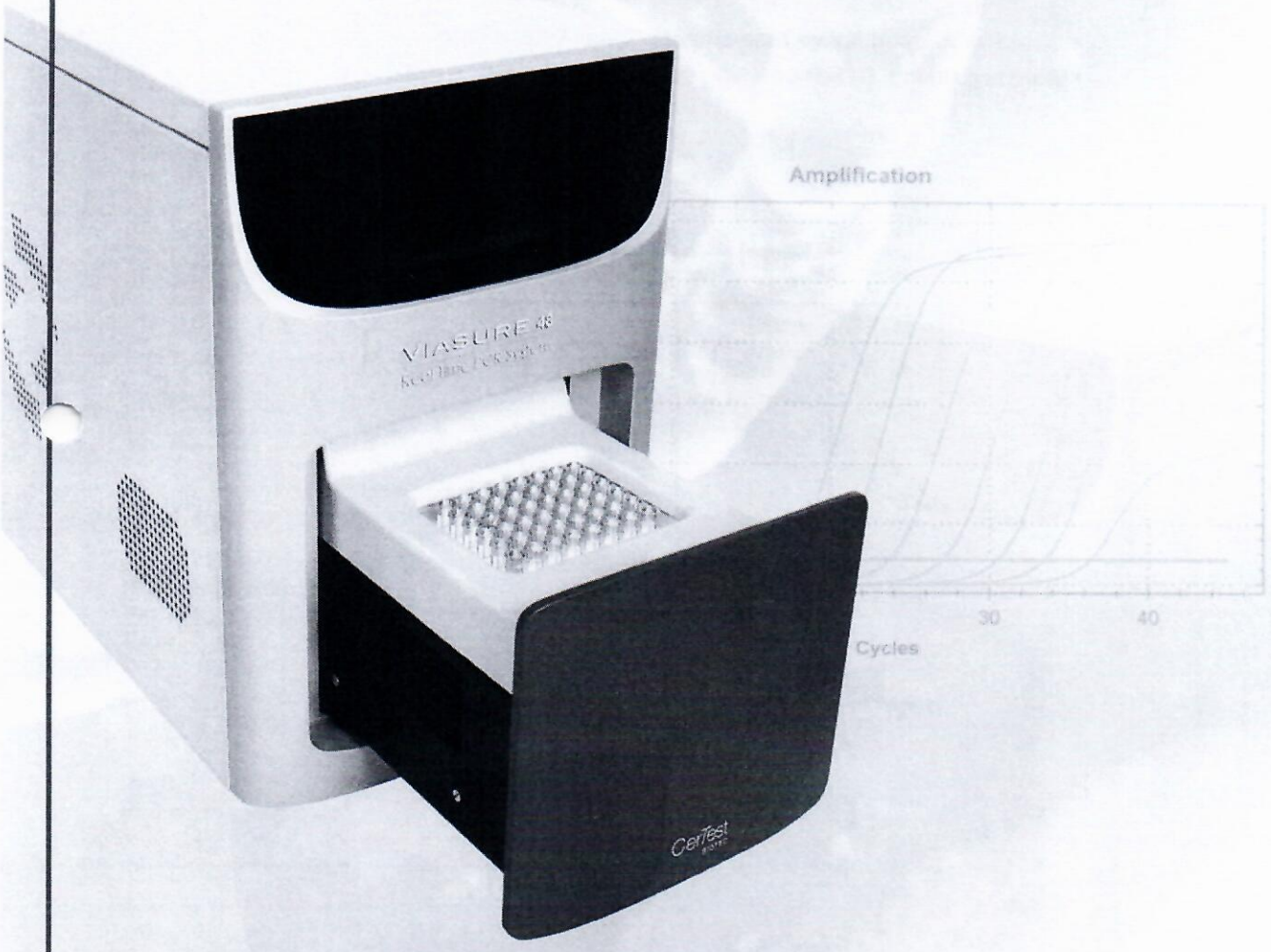
PV-32 replacement platform (16 x 1.5 ml, 8 x 0.5 ml, 8 x 0.2 ml)

– ●

* The PV-1 takes conical tubes up to 50 ml

VIASURE 48

Real Time PCR System



Introduction & Features

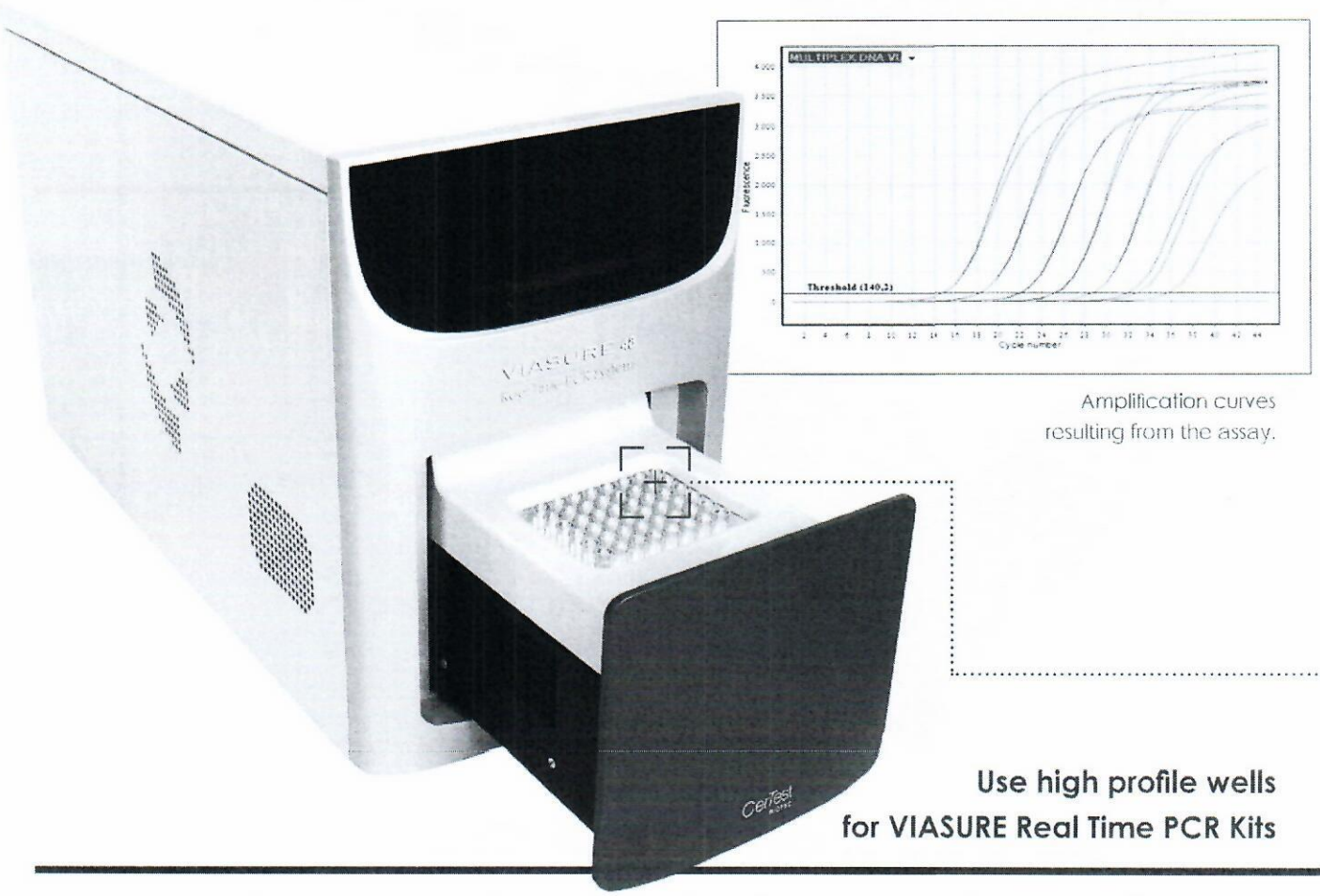
Advanced Real Time PCR System with 48-well block for scalling up research and high sample throughput in diagnostic lab applications

The detecting thermocycler permits to conduct qualitative and quantitative PCR-analysis dropping out the stage of electrophoresis of PCR products in agarose gel when using test-systems based on the fluorescent detection principle.

Measurement of the quantity of the accumulated product of PCR amplification takes place right in the course of reaction temperature cycles (Real Time PCR). The qualitative analysis, carried out with a relevant mathematical tool, is based on evaluation of kinetics of PCR visible part.

The use of fluorescent detection of PCR products has a number of substantial advantages:

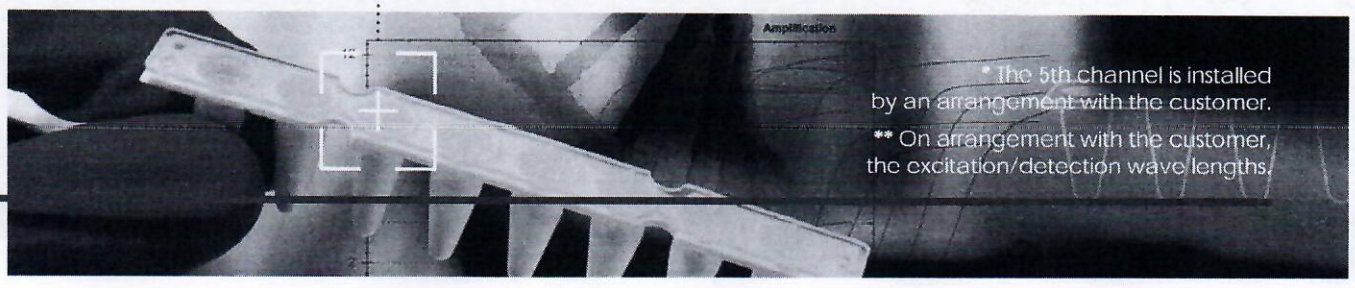
- High **specificity o**f detection (applying oligonucleotide probes allows detecting only amplicons in question);
- High **efficiency**;
- **Reduced time** of research;
- **Carrying out detection in a closed test tube**, which practically rules out contamination of further experiments;
- Possibility of **quantitative assessment** of initial DNA-matrix;
- **Data registering** and accounting in electronic format.



Amplification curves resulting from the assay.

Use high profile wells for VIASURE Real Time PCR Kits

Characteristics	Value
Thermal block format	48 test tubes of 0.2 ml (8x6)
Test tube type	0.2-ml test tubes for PCR (individual, in strips, 8 pieces each)
Range of thermal block temperature control	0 °C...100°C
Resolution of temperature setting	0.1°C
Absolute accuracy of temperature maintenance, not worse than	±0.2°C
Non uniformity of thermal block temperature, not more than	±0.3 °C
Average heating rate of the thermal block within temperature range of 4...99 °C	5.0 °C /s
Maximum heating rate of the thermal block within temperature range of 4...99 °C	5.0 °C/s
Average cooling rate of the thermal block within temperature range of 99....55 °C	2.5. °C /s
Maximum cooling rate of the thermal block within temperature range of 99....55 °C	4.0 °C /s
"Hot cover" temperature	105°C ±1°C
Actuating device of the thermal block	Peltier elements
Excitation source	Light-emitting diode
Detector	CCD (charge coupled device) - matrix
Number of the fluorescence measurement channels	5*
Excitation/detection wave length	470/525, 532/570, 585/633, 633/670, 690/750 ** FAM, HEX, ROX, Cy5, Cy5.5
Threshold sensitivity of each of the channels for solutions of standard fluorophors	0.05x10E-12M
Computer interface	USB 2.0 High-speed
Power consumption	Not over 550 W
Overall dimensions, WxDxH	210x480x310 mm
Preparation time after switching-on	Not over 5 minutes
Weight	17 kg



* The 5th channel is installed by an arrangement with the customer.

** On arrangement with the customer, the excitation/detection wave lengths.

Benefits & Advantages

- Compatible with all **VIASURE** Real Time PCR Detection Kits
- Robust & Reliable equipment
- **Qualitative & Quantitative** data analysis
- System for assay with high and low wells
- Automatic **interpretation** and **analysis** of results

VIASURE

Real Time PCR Detection Kits

by CerTest BIOTEC

CerTest Biotec, S.L.
Pol. Industrial Rio Gállego II · Calle J, Nº1
50840, San Mateo de Gállego, Zaragoza (Spain)
www.certest.es

CE IVD CSQ MED ISO 13485

VIASURE/VIASURE48-1017EN

CSQ

MED

www.imq.it

CISQ is a member of

IQNet

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATE N. 9124.CRTB
CERTIFICADO N.

WE HEREBY CERTIFY THAT THE MANAGEMENT SYSTEM OPERATED BY
CERTIFICAMOS QUE EL SISTEMA DE GESTIÓN DE

CERTEST BIOTEC, S.L.

CALLE J N° 1 POL. IND. RÍO GÁLLEGO II - 50840 SAN MATEO DE GÁLLEGO (ZARAGOZA)
SPAIN

OPERATIVE UNITS / INSTALACIÓN DE

CALLE J N° 1 POL. IND. RÍO GÁLLEGO II - 50840 SAN MATEO DE GÁLLEGO (ZARAGOZA)
SPAIN

IS IN COMPLIANCE WITH THE STANDARD / REÚNE LOS REQUISITOS DE LA NORMA

EN ISO 13485:2012

FOR THE FOLLOWING ACTIVITIES / PARA LAS SIGUIENTES ACTIVIDADES

Diseño, desarrollo, fabricación y distribución de productos sanitarios para diagnóstico in Vitro
Design, development, manufacture and distribution of in vitro diagnostic products

Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization
Cualquier aclaración adicional relativa a la aplicación de la norma EN ISO 13485:2012, puede obtenerse consultando a la organización

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS
EL PRESENTE CERTIFICADO ESTÁ SUJETO AL RESPETO DEL REGLAMENTO PARA LA CERTIFICACIÓN DE LOS SISTEMAS DE GESTIÓN

DATES:	FIRST CERTIFICATION *PRIMERA CERTIFICACIÓN*	CURRENT ISSUE *EMISION ACTUAL*	EXPIRY *VÁLIDO HASTA*
	2011-09-21	2017-07-26	2020-08-29

The Organization shall obtain the certification according to EN ISO 13485:2016 within 2019/02/28;
otherwise the validity of this certificate will expire
La Empresa deberá obtener la certificación de acuerdo con la norma EN ISO 13485:2016 antes del 28/02/2019;
de lo contrario, expirará la validez de este certificado

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.

CISQ is the Italian Federation of management system Certification Bodies.

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N°005A, SGA N°006D, SCR N°005F,
SSI N°003G, FSM N°007I, SGE N°006M,
EMAS N°003P, PRD N°005B, PRS N°080C
ISP N°063E, LAB N°0121, LAT N°021
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years
La validez del certificado está sujeta a auditorias anuales y a la recercertificación completa del Sistema de Gestión con una periocidad trienal

AMS 2000
Analytical & Medical Solutions For All Laboratories

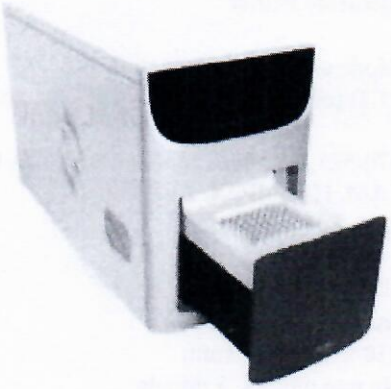
27.03.2020

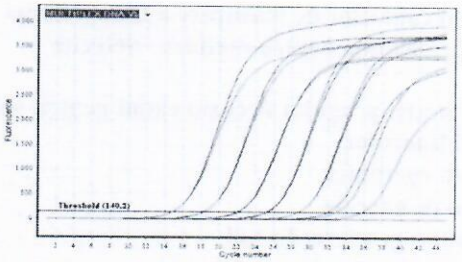
Catre: Spital Clinic Judetean de Urgenta Arad

Oferta de pret

Ca urmare a publicarii a **Anuntului de participare simplificat: [SCN1065672]** - Achiziționare Sistem PCR de detectie Cov-2 cu accesoriile si consumabilele aferente acestuia, cu specificatiile tehnice primite si in urma analizei acestora coroborata cu produsele pe care le avem in portofoliu nostru, va rugam sa regasiti detaliata in cele ce urmeaza propunerea tehnica pentru urmatorul **SISTEM DE DETECTIE SI AMPLIFICARE REAL TIME PCR PT 48 TESTE**:

VIASURE 48 Real Time PCR System (CerTest) / DTlite 4S1 (DNA-Technology)





Amplification curves resulting from the assay

Un sistem Real-Time PCR avansat cu bloc de 48 de godeuri.
Permite analiza calitativa si cantitativa de tip PCR abandonand electroforeza produsilor de PCR in gel de agaroza prin utilizarea sistemelor de testare bazate pe detectie de fluorescenta.

Determinarea cantitatii produsilor acumulati prin amplificare PCR se desfasoara in cursul ciclurilor de reactie (Real Time PCR). Analiza calitativa, efectuata prin intrumente matematice relevante, este bazata pe evaluarea cineticii partii vizibile a PCR.
Utilizarea detectiei de fluorescenta a produsilor PCR are un numar mare de avantaje:
Specificitatea mare a detectiei;
Eficienta mare;
Timp redus;
Detectia se realizeaza in tub inchis, eliminand astfel riscul de contaminare;

Posibilitatea de evaluare cantitativa a matrix-ului ADN initial;
Inregistrarea si cuantificarea datelor in format electronic.

Caracteristici	Valori
Format Termobloc	48 tuburi de testat cu volum de 0.2 mL (8 x 6)
Tipul tubului de testat	Tuburi de 0.2 mL pentru PCR (individuale, in stripuri, cate 8 bucati fiecare)
Intervalul controlului intervalului de temperatura	0°C … 100°C
Rezolutia setarii temperaturii	0.1°C
Acuratetea absoluta a mentinerii temperaturii, nu mai mica de	±0.2°C
Neuniformitatea temperaturii termoblocului, nu mai mica de	±0.3°C
Rata medie de incalzire a termoblocului in intervalul de temperatura de 4 … 99°C	5°C / s
Rata maxima de incalzire a termoblocului in intervalul de temperatura de 4 … 99°C	5°C / s
Rata medie de racire a termoblocului in intervalul de temperatura de 99 … 55°C	2.5°C /s
Rata maxima de racire a termoblocului in intervalul de temperatura de 99 … 55°C	4°C /s
Temperatura "Capac incins"	105±1°C
Dispozitiv de actionare a termoblocului	Elemente Peltier
Sursa de excitare	Diode emitatoare de lumina
Detector	CCD (charge coupled device) - matrix
Numarul canalelor de masurare a fluorescentei	4
Lungime de unda pentru excitare / detectie	470/525, 532/570, 585/633, 633/670, 690/750 **
	FAM, HEX, ROX, Cy5, Cy5.5
Sensibilitatea pragului fiecarui canal pentru solutii ale fiecarui fluorofor	0.05x10E-12M
Interfata computer	USB 2.0 High-speed
Consum de energie	Nu mai mult de 550 W
Dimensiuni grosiere, LxAxI	210 x 480 x 310 mm
Timp de pregatire dupa pornire	Nu mai mult de 5 minute
Greutate	17 kg

Perioada de garantie: 24 de luni de la data achizitiei
Produsul ofertat este nou, fara defecte ca urmare a proiectului, materialelor sau manoperei ori oricarei alte actiuni sau omisiuni ale producatorului, si corespunde caracteristicilor mentionate din propunerea tehnica si a cerintelor din caietul de sarcini aferent Anuntului de participare simplificat: [SCN1065672]
Termenul de livrare: maxim 10 zile de la data transmiterii comenzii ferme

Conditii de amplasare: verificati manualul de utilizare (limba romana) transmis, paginile 16 – 17 – capitol 3.2 Instalarea și conectarea dispozitivului:

3.1 Instalarea și conectarea dispozitivului

Atenție! Atunci când alegeți un loc pentru instalarea dispozitivului, luați în considerare faptul că trebuie să existe o distanță de cel puțin 14 cm de la panoul frontal al dispozitivului până la marginea mesei, fără alte

obiecte. În caz contrar, placa frontală a unității termice poate fi deteriorată din cauza obiectelor străine care sunt plasate sau apar în zona sa de mișcare.

Dispozitivul trebuie instalat într-un loc convenabil pentru utilizare, cu o ventilație suficientă, eliminând condensul și asigurând accesul liber la unitatea termică și la comutatorul de alimentare. Pentru funcționare normală, trebuie să existe un spațiu liber de cel puțin 12 cm în partea dreaptă, stângă și în spatele dispozitivului.
Dispozitivul este pornit cu ajutorul unui întrerupător de alimentare situat pe panoul din spate al dispozitivului.

Pentru a deconecta complet dispozitivul, este necesar accesul la panoul din spate al dispozitivului și la priza de alimentare pentru a deconecta cablul și cablul de comunicare USB 2.0 de la calculator.

Puterea rețelei, consumată de dispozitiv, în timpul funcționării, nu depășește 550 W.

Dispozitivul nu are nevoie de echipamente suplimentare care stabilizează tensiunea rețelei. Dacă este necesar să conectați dispozitivul la surse de alimentare neîntrerupte, trebuie menționat că acesta din urmă trebuie să furnizeze o putere de ieșire de cel puțin 550 W pentru a alimenta dispozitivul în plus față de alte sarcini.

Înainte de a conecta dispozitivul la rețea, asigurați o împământare de protecție disponibilă la priza la care va fi conectat dispozitivul. Mai întâi conectați cablul de alimentare furnizat la dispozitiv. Apoi, după ce vă asigurați că întrerupătorul este în poziția „O" (Oprit), introduceți mufa de alimentare în priză.

Conectați dispozitivul la calculator utilizând cablul de comunicație USB HighSpeed AB USB 2.0 furnizat.

Atenție! Este importantă conectarea fiabilă la prizele la care este conectat dispozitivul și calculatorul de control. Dacă această condiție nu este respectată, pot apărea defecțiuni ale dispozitivului.

Atenție! Pentru a utiliza dispozitivul DTprime, trebuie să folosiți calculatoare care acceptă o interfață mai mare de 2.0 la USB de mare viteză.

Atenție! Dacă dispozitivul a rămas la rece mult timp, mențineți dispozitivul 4 ore la temperatura camerei (+18 - 25°C) înainte de pornire.

Cu deosebita consideratie,

Adina Iancu
Product Manager
Tel.: 0747.219.451
e-mail: adina.iancu@ams.ro

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

"DNA-Technology, Research&Production", LLC
Address:142281, Moscow region, Protvino, Zheleznodorozhnaya street, 20
Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

List of Products

No	Code No.	Name
1	O-DTPRIME4M1-EU O-DTPRIME4X1-EU O-DTPRIME4M3-EU O-DTPRIME4M6-EU O-DTPRIME5M1-EU O-DTPRIME5X1-EU O-DTPRIME5M3-EU O-DTPRIME5M6-EU	DTprime
2	O-DTLITE4S1-EU O-DTLITE4S2-EU O-DTLITE4L1-EU O-DTLITE5S1-EU O-DTLITE5S2-EU O-DTLITE5L1-EU	DTlite
3	O-GENE4-EU	Gene-4
4	R1-P801-S3/6EU R1-P802-S3/5EU R1-P803-S3/4EU	FEMOFLOR

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).

- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- ISO 9001:2015;
- ISO 13485:2016.

Corporate Contact Information

"DNA-Technology, Research&Production", LLC
Address:142281, Moscow region, Protvino, Zheleznodorozhnaya street, 20
Country: Russia
Phone: +7(495)640-17-71; +7(4967) 31-07-64;
Fax: +7(4967) 31-06-70; +7(495)640-17-71
E-mail: info@dna-technology.com, protvino@dna-technology.ru
Mr. Vladimir Dmitrovskiy
Position: General Director

Signature:

Date: 27 July 2019

Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

CERTIFICATE

No. 71271

LL-C Certification

This is to certify the Quality Management System of

ДНК-ТЕХНОЛОГИЯ

«DNA-Technology Research&Production», LLC
Zheleznodorozhnaya street, 20
142281 Protvino, Moscow region
Russia

Site 1: "DNA-Technology" LLC, Russia, 117587, Moscow, Varshavskoye shosse, 125Zh, block 6, floor 5, office 14
Site 2: "DNA-Technology R&D", LLC, Russia, 109388, Moscow, Gurianova street, 83, bld.1
Site 3: "DNA-Technology TS", LLC, Russia, 117246, Moscow, Nauchnyi proyezd, 20,bld.4.
Site 4: "DNA-Technology, Research&Production", LLC, Russia, 142281, Moscow region, Protvino, Zheleznodorozhnaya street, 3

has been assessed and found to be in compliance with the Standard

ISO 9001:2015

applicable to

Design, manufacturing, sales, marketing and distribution of in-vitro diagnostic reagents and devices for molecular-genetic diagnostics and other laboratory use.

The certificate has been issued under No. **71271** for the registration period from 14 December 2019 to 13 December 2022.
The first certificate date of issue is 16 December 2013.

Approved by

Printed by

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

S 3137

SAFETY · SECURITY · ENVIRONMENT · QUALITY LL-C

validity code **923E863C-2F3**
Check the validity of this certificate using this code at **www.ll-c.info**

CERTIFICATE

No. 71271

LL-C Certification

This is to certify the Quality Management System of Medical Devices of

ДНК-ТЕХНОЛОГИЯ

«DNA-Technology Research&Production», LLC
Zheleznodorozhnaya street, 20
142281 Protvino, Moscow region
Russia

Site 1: "DNA-Technology" LLC, Russia, 117587, Moscow, Varshavskoye shosse, 125Zh, block 6, floor 5, office 14
Site 2: "DNA-Technology R&D", LLC, Russia, 109388, Moscow, Gurianova street, 83, bld.1
Site 3: "DNA-Technology TS", LLC, Russia, 117246, Moscow, Nauchnyi proyezd, 20,bld.4.
Site 4: "DNA-Technology, Research&Production", LLC, Russia, 142281, Moscow region, Protvino, Zheleznodorozhnaya street, 3

has been assessed and found to be in compliance with the Standard

EN ISO 13485:2016

applicable to

Design, manufacturing and distribution of in-vitro diagnostic reagents and devices for medical molecular-genetic diagnostics.

The certificate has been issued under No. **71271** for the registration period from 14 December 2019 to 13 December 2022.
The first certificate date of issue is 16 December 2013.

Approved by

Printed by

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

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validity code **1B497190-2A0**
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AMS 2000

FORMULAR DE OFERTA

Catre : Spital Clinic Judetean de Urgenta Arad

Domnilor,

1. Examinand documentatia de atribuire, subsemnatii, reprezentanti ai ofertantului **AMS 2000 TRADING IMPEX SRL** , ne oferim ca, in conformitate cu prevederile si cerintele cuprinse in documentatia mai sus mentionata, sa furnizam **Sistem PCR de detectie Cov-2 cu accesoriile si consumabilele aferente acestuia pentru suma de 189834.00 lei** platibila dupa receptia produselor, in conditiile specificate in documentatia de atribuire, la care se adauga taxa pe valoarea adaugata **36068.46 lei.**

Nr Crt	Descriere produs	UM	Cantitate	Pret unitar fara TVA (RON)
1	VIASURE 48 Real Time PCR System (5 canale)	buc	1	80500.00
2	Hota PCR - UVC/T-AR, DNA/RNA UV Cleaner Box	buc	1	9797.00
3	Centrifuga Digicen 21R+RT150+RE401+RT151	buc	1	35308.00
4	V-32 Multivortex	buc	1	2804.00
5	Pipete automate cu volum variabil (0,5-10 µl, 2-20 µl, 10-100 µL, 20-200 µl si 100-1000 µl)	Set 5 pipete automate	1	2425.00
6	Ultracongelator U401 (-80 grade C) - fara accesorii	buc	1	59000.00
Valoare totala LEI fara TVA				**189834.00**
TVA				**36068.46**
Valoare totala LEI cu TVA				**225902.46**

2. Ne angajam ca, in cazul in care oferta noastra este stabilita castigatoare, sa furnizam produsele in graficul de timp anexat.

3. Ne angajam sa mentinem aceasta oferta valabila pana la data de **30.08.2020** si ea va ramane obligatorie pentru noi si poate fi acceptata oricand inainte de expirarea perioadei de valabilitate.

4. Pana la incheierea si semnarea contractului de achizitie publica aceasta oferta, impreuna cu comunicarea transmisa de dumneavoastra, prin care oferta noastra este stabilita castigatoare, vor constitui un contract angajant intre noi.

5. Precizam ca:

|x| nu depunem oferta alternativa.

6. Am inteles si consimtim ca, in cazul in care oferta noastra este stabilita ca fiind castigatoare, sa constituim garantia de buna executie in conformitate cu prevederile din documentatia de atribuire.

7. Intelegem ca nu sunteti obligati sa acceptati oferta cu cel mai scazut pret sau orice alta oferta pe care o puteti primi.

Data completării 27.03.2020
Radion Crijanovschi
Administrator