

AUTOMATIC PROCESSOR

B-PRO450



CODE	DESCRIPTION	EMDN
40-100-200	Automatic processor for histological samples	W0202059010



In vitro diagnostics – medical device
Basic UDI: 080341202W0202059010M2
UDI-DI: 08034120278584
IVD in Class A, Reg. EU 2017/746



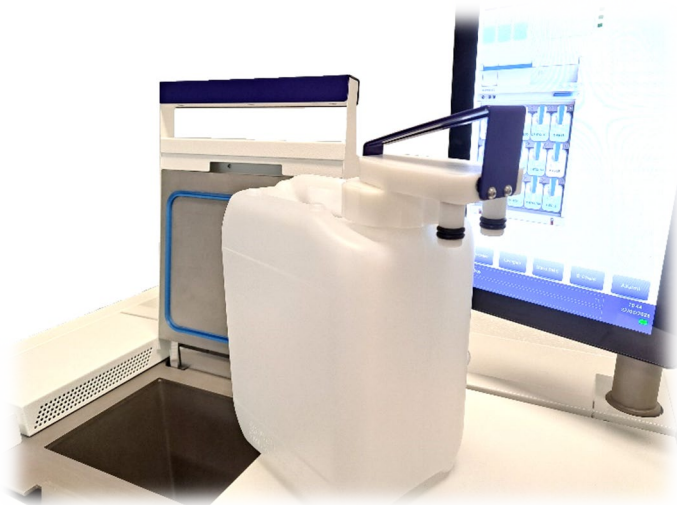
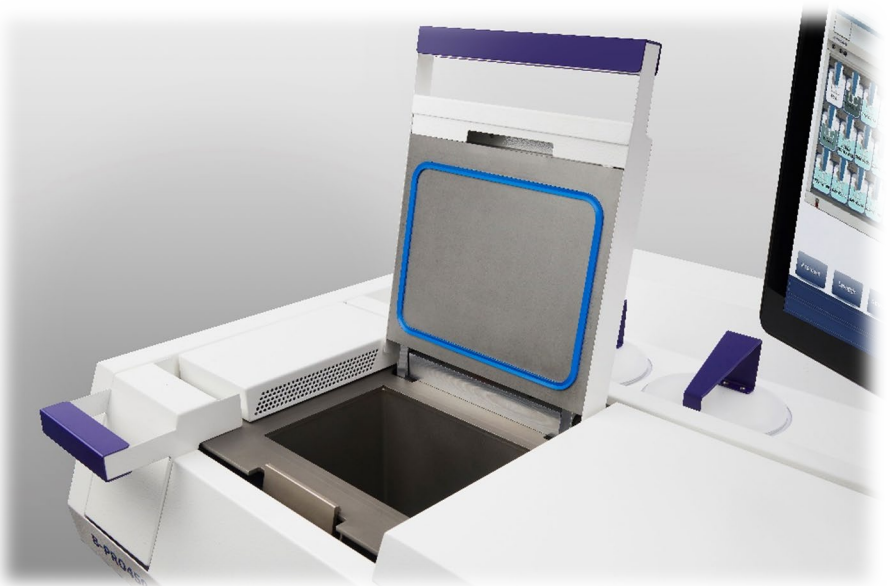
Manufacturer: Bio-Optica Milano S.p.A.

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The new B-PRO450 is a fully programmable, closed-loop, automatic histology processor suitable for processing histological samples. Designed with advanced technology and equipped with unique features, it guarantees maximum operator safety and a new level of sample standardization. The processing system is capable of both standard and rapid processing.

B-PRO450 PROCESSOR FEATURES

- Stainless steel processing chamber with integrated **extraction system**, capable of holding up to **450 histological samples**;
- **Reagent pre-heating by means of Enhanced Heat Exchanger (EHE) technology**: enables safe and even pre-heating of the reagent prior to its actual use within the processing chamber. This allows small biopsies (up to 1 mm) to be processed in less than one hour;
- 4 work modes can be set: Immediate, Overnight, Weekend, Customized;
- **Reagent management and quality control system, RMS (Reagent Management System)**. Reagent and paraffin wear control system. To ensure a high standard of processing quality, the processor performs a reagent and paraffin wear check using a special algorithm;



- **Preliminary self-diagnostics system**: before starting processing, it automatically checks the status of the processor; it processes a checkup of the instrument and warns in the event of a fault.
- **Software and graphic interface**: user-friendly system with a simple and intuitive graphic interface for immediate handling of main functions; rapid display of system and reagent status.

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- **RFID:** for maximum safety, traceability and easy reagent exchange. Facilitates identification of reagent tanks, avoiding errors during reagent replacement;
- **Safe reagent load management system in processing chamber** consisting of 4 level sensors of which:
 - o **3 optical sensors** inside processing chamber to manage partial load of reagents
 - o **1 optical sensor** inside chamber with safety function for processing chamber “overflow”;
- **Paraffin draining** in 2 modes, selectable by the user: **PWD** (Protect Wax Dumping), into empty tank pre-installed inside the processor, or **EWD** (External Wax Dumping) through external pipe;
- **Activated carbon filters with “plug and play” mode:** avoids the need for technical intervention that stops operation, leaving the replacement of both filters to the operator. There is a dual filter system on the instrument:
 - rear tank removable by user, without the need for intervention from technical assistance
- front filter for processing chamber extraction for filtering vapors from reagents
- **System equipped with manifold for connection to centralized laboratory extraction system** (optional accessory)
- **REVERSED protocol:** option to run a reverse protocol for each step (de-processing)

Reagent tank identification

RFID system for tank identification:

- The software guides the reagent replacement procedure;
- Avoids cases of incorrect reagent replacement
- Traceability of reagent type, lot number

The B-PRO450 processor only recognizes reagents in RFID-equipped Bio-Optica tanks.

Capacity and productivity:

The B-PRO450 guarantees high productivity with an extremely small footprint:

- Stainless steel rack with screen-printed barcode with a maximum capacity of 450 standard cassettes, on three levels of 150 cassettes each
- 3 paraffin pre-melting elements of 5 (max) and 4.4 (min) liters each
- 15 positions for reagent tanks
- Adjustable processing chamber temperature
- Reagent status always available on main screen



Process safety system

Self-diagnostic system of sensitive parts of instrument. Prevents unexpected blockages during overnight processing. The procedure is performed automatically before each processing, performing an automatic check on the sensitive mechanical parts of the processor. In the event of an emergency, the system is able to guarantee the safety of the processing by recruiting an equivalent reagent from among those in use in the processing protocol. This reagent will keep the samples safe until the arrival of laboratory personnel.

Processing chamber

Solvent- and heat-resistant processing chamber in stainless steel:

- Three-layer stainless steel rack, approx. 450 samples (150 per level)
- 3 level sensors plus 1 safety sensor for overflow detection.
- For each protocol step, the user can adjust the incubation time, pressure/vacuum cycles, temperature and reagent mixing.



Remote support

To ensure extremely short turnaround times, Bio-Optica provides full remote support for every instrument installed around the world via an Internet-connected remote support service for both technical and specialist support.

For connection, we strongly recommend using the router, available as an optional accessory, in SIM or Wi-Fi mode.

Mixing

Innovative stirring technology for the reagent in the processing chamber during the various steps of the protocol. From the protocol creation screen, the mixing mode (steps every 15 minutes) can be selected for each processing step during the reagent incubation phase in the processing chamber.

“Plug and play” activated carbon filters

Activated carbon filter suitable for filtering vapors from reagents and the processing chamber extraction system.

Filter system using a tank removable by the user without the need for intervention from technical assistance:

special tank to avoid direct contact with the filter.

The instrument has an extraction point above the processing chamber.



EHE (Enhanced Heat Exchanger)

Protocol option for activating the reagent pre-heating procedure prior to its actual use within the processing chamber.

- Option to pre-heat the reagent before loading into the processing chamber;
- Procedure allowing processing of small biopsies (1 mm thickness maximum) in less than one hour.
- The user can activate this function during protocol creation.



RMS (Reagent Management System)

The RMS monitors and reports reagent and paraffin wear. The processor performs a wear check, using a special algorithm, indicating the progressive reduction of the processing capacity of each individual reagent. The number of possible processings for each reagent is determined according to the number of samples processed.

Processor consumables

CODE	DESCRIPTION	PACKAGING
450001	Tank of 10% neutral buffered formalin, red cap	5 liters
450002	Tank of Unyhol, yellow cap	5 liters
450003	Tank of distilled water, blue cap	5 liters
450004	Tank of Dehyol 70, white cap	5 liters
450005	Tank of Dehyol 95, white cap	5 liters
450006	Tank of absolute Dehyol, yellow cap	5 liters
450007	Tank of X-Free, green cap	5 liters
450008	Tank of Isopar Ultra, green cap	5 liters
450009	Tank of Xylene, green cap	5 liters
450010	Empty tank for draining paraffin, 1 pc.	1 pc
450011	Activated carbon filter kit	1 pc
450012	BioWax paraffin	3 x 3,8 kg
65-CT1	Key for opening tanks	1 pc

Color-coded identification system for pre-filled reagent tanks

With the color-coded identification system, the correct reagent tank can be identified immediately and quickly. Reagent storage can also be managed easily and optimized. Distilled water can be identified by the color blue, while alcohol reagents (Dehyol and Unyhol) can be identified by the color codes white and yellow respectively. Formalin is color-coded red while X-Free is identified by the color green.

Visual identification alone, however, will not be the only verification that will be carried out; in fact, using the RFID, selection will be confirmed with extreme safety and no possibility of error.



Accessories

CODE	DESCRIPTION
65-SL3000	UPS uninterruptible power supply
40-500-061	Manifold for external vapor discharge, diameter 100 mm
40-500-067	Container for transporting baskets

Technical specifications of system B-PRO450

Dimensions and weight	Dimensions (W x D x H)	850 x 750 x 1650 mm
	Clearance	1,000 x 900 x 1800 mm
	Weight	250 kg
Electrical data	Voltage	230 V
	Frequency	50 ÷ 60 Hz
	Reagent vapor treatment	Special carbon filter with forced ventilation, also in SPC; provision for external extraction
	Absorption	1.8 kW
Protocol features	Number of storable protocols	20 programs (4 IVDR certified, 2 washing and 1 reverse)
	Maximum time per step	9 hours 59 minutes
	End of processing time	Modifiable for each process
	Process start	User selectable
Reagents	Reagent tanks	15 (13 for reagents, 1 for discharge and 2 for washing reagents), capacity 5 liters
	Paraffin tanks	3 cylinders, 4.4 – 5 liters each
	Paraffin melting time	Approx. 5.5 hours
	Reagent heating temperature	Ambient +65°C
	Paraffin heating temperature	52 – 65°C
	Mixing	Step every 15 minutes
	Level sensor for differentiated loading	no. 3 level sensors for detecting correct filling, plus no. 1 sensor for detecting overflow
	Management system	RMS: complete control over reagents, paraffins, washes and filters
Hardware and software	Monitor	Color touch screen, 15" LCD-TFT
	USB ports	2
	Network	1 LAN network port 10/110 Mb
	Operating system	Linux
Warnings and precautions	Product classification	The product is intended for professional laboratory use by healthcare professionals.
	Recommendations	We recommend in case of a serious accident to inform Bio-Optica Milano S.p.A. and the competent authorities immediately

REVIEW	REASON	DATE
00	First issue	23/02/2023
01	Accessories update	27/12/2023
02	Paraffin code 3.8 kg added	06/06/2024

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