Bio-Optica
Improving Pathology

PATENTED
Data Sheet

CE

KLESSIDRA 90

90 ml

CODE	PACKAGING
05-01V125PK	8 prefilled containers with 90 ml of neutral buffered formalin 10%

IVD

In Vitro Diagnostic – medical device
EMDN: W01030705
IVD in Class A, Reg. UE 2017/746

UDI-DI: 08034120276924
Basic UDI: 080341202W01030705AJ

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

Disposable

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TECHNICAL FEATURES

Code	Packaging	Capacity	Filling volume	Container dimensions (cm)	Box dimensions (cm)
05-01V125PK	8 prefilled containers + 8 empty containers	190 ml 190 ml	90 ml of formalin	Ø 6,8 x h 6,5 Ø 6,8 x h 6,5	30 x 35 x 9,5

PRODUCT DETAILS

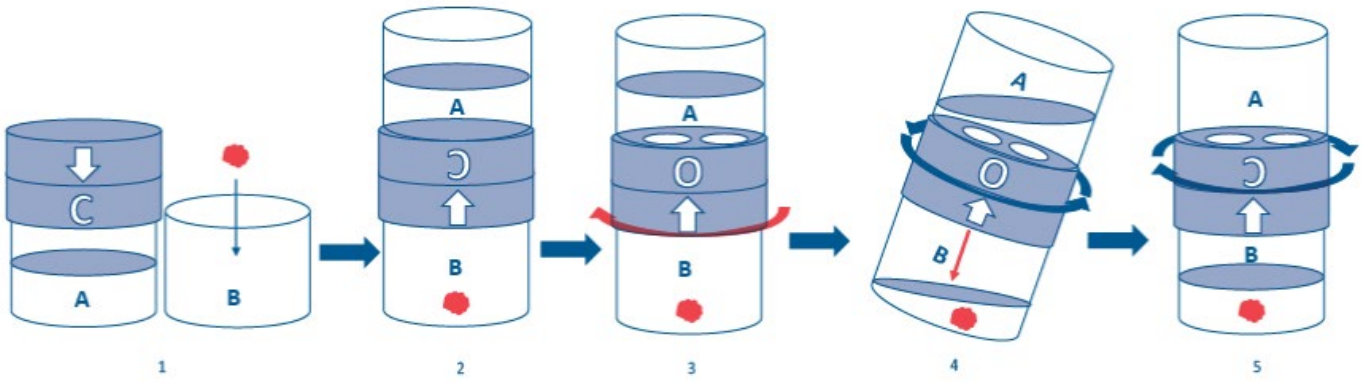
Klessidra 90 is a special closed-circuit system which prevents the contact between formaldehyde and the user **in compliance with the European Regulation 605/2014**. It is ideal for the fixation and the transport of small histologic specimens.
The device consists of two containers in neutral PP:

- one empty, for receiving the specimen
- the second one prefilled with ready to use formalin.

The two containers are connected by a special double screw lid in blue PE.
The formalin flow between the two containers is made possible thanks to two holes on the lid which are aligned after rotating the two parts of the lid.
The seal is guarantee by two silicon spheres for the occlusion of the holes and by the conformity with the standard **UNI EN 14254:2004**.
The device is provided by a mechanism which prevents the reflux of formalin into the previous container in order to avoid ipofixation problems and the loss of the biopsies.
Klessidra 90 could be used in association with the filter of Vabb Brevera Hologic system.
Latex free.

INSTRUCTIONS FOR USE

1) Put the specimen into the empty container (B) with or without biocassette;
2) On a flat surface, connect the containers (solution A on top) and apply slight pressure from above (red arrow) to get the correct alignment.
3) On a flat surface, screw the prefilled formalin container (A) on container (B) which contains the specimen;
4) Rotate the two lids on “open” position (until the arrow is aligned with the “O”) and tilt the device to let the formalin flow in the lower container;
5) Rotate the two lids again on “close” position (until the arrow is aligned with the “C”).



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Technical details

Specifications	Expected aim	Product for the preparation of cyto-histological samples for optical microscopy. Safety fixation and transport with 10% neutral buffered formalin (equivalent to an aqueous solution of 4% formaldehyde).		
	Intended use	Fixative for histology.		
	Principle	Interaction between formaldehyde and functional groups in tissue macromolecules (proteins and nucleic acids) occurs as follow: - The formaldehyde molecule in water gives the following equilibrium $CH_2O + H_2O = CH_2(OH)_2$ with the formation of methylene glycol. - Methylene glycol interacts primarily with functional groups in the side chains of proteins and with acids stabilizing the nuclear structure. - Formaldehyde form crosslinks between the free amino groups present in the side chains of amino acids.		
	Technical specifications	pH	7,2 ± 0,2	
		Density	1,003	
		Buffer molarity	0,05 M	
	Fixation technique	Specimen / fixative ratio	1:20 (volume)	
		Specimen thickness	1 cm	
		Fixation time at room temperature	For specimens up to 5 mm 5 hours For greater thickness 1-2 days	
	Packaging	Primary container: container in neutral PP with blue screw cap in PE, watertight. Secondary container: carton box, white colour. Wear, water, alcohol and solvents resistant PVC label. Scratchproof ink resistant to water and alcohol.		
Components	Formaldehyde 4% p/v	CAS: 50-00-0	CE: 200-001-8	Index: 605-001-00-5
	Methanol 0,1% v/v	CAS: 67-56-1	CE: 200-659-6	Index: 603-001-00-X
	Sodium phosphate monobasic monohydrate 0,15-0,2% p/v	CAS: 7558-80-7	CE: 231-449-2	-
	Sodium phosphate dibasic dihydrate 0,7-0,8% p/v	CAS: 10028-24-7	CE: 231-448-7	-
	Deionized water	-	-	-
Storage	Storage	Store the preparation at 15-25°C. Keep the containers tightly closed.		
	Storage temperature	15-25°C		
	Stability	After opening, it is usable until the expiry date, if correctly stored.		
	Validity	2 years		
Warning	Product classification	The product is intended for professional laboratory use for healthcare professionals. Carefully read the information on the label (danger symbols, risk and safety phrases) and always consult the safety data sheet. Do not use if the primary container is damaged.		

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		In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.
	Disposal	Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.
	Transport	It is not recommended to transport by air

REVISION N°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022
002	Product name update	22/07/2024

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