

# TECHNICAL SHEET

## T4930ST

### TISSUE FILLING EASY

COD. 4930

**MANUFACTURER** : KALTEK SRL  
**IVD CLASS** : A  
**EMDN** : W02029099  
**GIVD (EDMA)** : 29.01.10.01



#### DESCRIPTION

Metal structure in steel sheet treated with antacid epoxy paint, which can be sanitized and disinfected. Designed for the automatic filling of containers for the transport of biological samples with formaldehyde, TISSUE FILLING EASY satisfies the needs of those operating rooms that want an automatic system for filling histological containers with formaldehyde in total safety. With TISSUE FILLING EASY it is possible to fill the six type of containers available, without the operator being subjected to exhalations or contact with the fixative; simply place the container inside the correct location and push the slide drawer into the internal aspirated compartment. The system uses standard tanks available on the market or closed-circuit politainer (optional) with a maximum capacity of 20 liters.

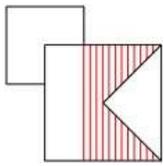
#### FEATURES

- Automatic container identification;
- Automatic dosage of formalin;
- It is possible to view the contents of the individual containers in which the sample is preserved;
- The instrument is able to continuously manage the filling of the samples without interruptions between one sample and another, due to changing the tank or reconditioning the machine;
- The system allows to standardize the fixation of the samples and to guarantee their perfect preservation;
- The instrument is equipped with a balance which is capable of accurately weighting the sample and the quantity of formalin dispensed;
- Closing of the hole through a special label created by a printer which shows the cycle data filling (date, time, sample type and weight, formaldehyde weight), patient identification data (name, surname and barcode) and Operating unit concerned;
- The label fields are customizable;
- During the phase of closing of the containers, the aspiration is always active and this guarantees the maximum level of safety for the user, who will never be able to breathe formaldehyde vapours;
- Ethernet port and USB port;
- Dispenser compartment (illuminated) and formalin tank housing compartment, aspirated;
- Carbon filter for aldehydes and pre-filter supplied, optional HEPA filter;
- Aspiration during all phases of use of the instrument;
- Automatic air cleaning system during the standby phases;
- Swivel wheels with locking system and antistatic;
- Provided with bayonet coupling with dip tube for standard tank or, alternatively, for Politainer closed circuit tank in order to guarantee maximum safety during the tank change;
- Trolley for tank transport (optional);
- Tank holder compartment aspirated and on wheels to facilitate the introduction and removal of the Formaldehyde tank;
- In the rare and accidental case of formalin leakage, there are sensors both in the area where the container is filled and where there is the coupling of the tank, which detect the minimum leakage and activate an audible and visible alarm, blocking the filling phase for ensure maximum user safety (significant reduction in exposure);
- In the event of an accidental spill of Formalin, any formaldehyde that has escaped remains in the special collection tank which reduces it to a minimum operator intervention;



#### SOFTWARE FEATURES

- The software is extremely intuitive and easy to use in order to facilitate operations for the user;
- 10.1" touch-screen display for viewing all working parameters;
- Manual accessible directly from the display;
- It is possible to choose the sample weight / formalin quantity ratio according to the user's needs;
- Possibility of saving data relating to the traceability of the different fillings and of the different operators via USB or via connection to the LIS via FTP;
- The software provides all the information necessary for the correct filling of the containers, as well as the data on the traceability of the fillings and of users;
- The traceability of the samples is guaranteed from the moment they are taken in the operating room, thanks to the input of the sample data via Barcode or manually.
- Traceability of the operator in 2 different ways: registered operator, unregistered operator.



**TISSUE FILLING EASY** does not require any connection to an external duct as the pre-filter, the F2 filter for formaldehyde, the HEPA filter (optional) and the electro-aspirator with which it is equipped, guarantee an aerodispersion value much lower than the acceptance limits established by current legislation (see certificates analysis of attachments). It is also possible to connect any external duct to place outside the vapors.



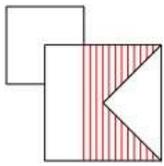
**TECHNICAL DATA**

Height	1760 mm
Nominal height of the work surface (HPL)	920 mm
Width	530 mm (780 with printer holder support)
Depth	620 mm
Smoke exhaust manifold	Ø 150 mm
Weight	80 Kg
Installed electrical power (nominal)	1 kW
Maximum current draw	5 A
Power supply	220 Vac – 50 Hz ±10%
Auxiliary circuits voltage	24 Vdc
Protection cases	I
IP Degree	IPX0
Air flow	100 NL/min
Noise produced	79 dB (A)
Filters	n. 1 prefilter n. 1 F2 filter for formaldehyde n. 1 HEPA filter (optional)
Working environment temperature	+15°C < T < +35°C
Relative humidity of the environment	5% < UR% < 90%
Formaldehyde tank capacity	max 20 liters

**CONTAINERS FOR TISSUE FILLING EASY**

(to be ordered separately)

- Cod. 3184 250 ml container
- Cod. 3173 500 ml container
- Cod. 3174 1.000 ml container
- Cod. 3178 3.000 ml container
- Cod. 3180 5.000 ml container
- Cod. 3570 11.000 ml container



**kalttek srl**

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Codice Fiscale e P. IVA 02405040284

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**STANDARD FORMALDEHYDE TANK FOR TISSUE FILLING EASY**

(to be ordered separately)

Cod. 1614      lt. 5 tank  
Cod. 1617      lt. 10 tank  
Cod. 1616      lt. 20 tank

**CLOSED CIRCUIT FORMALDEHYDE TANK FOR TISSUE FILLING EASY**

(to be ordered separately)

Cod. 1618      lt. 10 tank  
Cod. 1619      lt. 20 tank



**TROLLEY FOR TRANSPORT OF FORMALIN TANKS**

(to be ordered separately)

Code 3838      Trolley for Tissue Filling  
Dim. 73 x 47 cm - Capacity 150 kg

**CLOSURE LABELS FOR CONTAINERS**

(to be ordered separately)

Code 4829      Dim. 50 x 50 – see 500 pcs.

**PRINTER RIBBON**

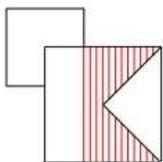
(to be ordered separately)

Code 4841      Pkg. 1 pcs (to print about 1000 labels)

**COMPLIANCE WITH DIRECTIVE AND HARMONIZED STANDARDS**

- 2017/746 EU Regulation
- UNI EN ISO 9001
- UNI EN ISO 13485
- UNI CEI EN ISO 14971
- Directive 2014/35/UE (Low voltage)
- Directive 2014/30/UE (Electromagnetic compatibility)
- Directive 2011/65/UE (Rohs)
- EN 61326-2-6:2013
- EN 61010-1:2010
- EN 61010-2-101:2002
- EN 50581:2012

Attached: n. 2 certificated LECHER ricerche e analisi srl



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ricerche e analisi s.r.l.  
analisi chimiche, microbiologiche e ambientali - consulenze



LAB N° 0141

VIA ROMA, 145 - 30030 SALZANO (VENEZIA) ITALY - TEL. 041 5745699 - FAX 041 5745525 - [www.lecher.it](http://www.lecher.it) - E-mail: [info@lecher.it](mailto:info@lecher.it) - [lecher@pec.lecher.it](mailto:lecher@pec.lecher.it)  
Capitale Sociale € 46.800,00i.v. - P.IVA IT 02560930279 - Cod. fisc. e iscrizione al Registro Imprese Venezia n° 02560930279 - R.E.A. n°VE - 225237

Rapporto di prova n°: **20163460-002**

Descrizione: **POSTAZIONE D'AREA FRONTE USCITA SCARICO ARIA  
FILTRATA  
MACCHINA DOSAGGIO - TISSUE FILLING SYSTEM**

Data Prelievo: **05-ago-16**

Data Arrivo Camp.: **05-ago-16** Data Inizio Prova: **05-ago-16**

Data Rapp. Prova: **24-ago-16** Data Fine Prova: **10-ago-16**

Luogo Prelievo: **KALTEK S.R.L. - VIA DEL PROGRESSO, 2 - 35127 PADOVA (PD)**

Prelevatore: **LECHER RICERCHE E ANALISI SRL**

Prova	U.M.	Metodo	Risultato	LIM. 1	LIM. 2	LIM. 3	LIM. 4
ALDEIDI							
Formaldeide	mg/m <sup>3</sup>	NIOSH 2016 2003	0,12				0,37

#### Riferimenti di Legge Parametri

LIM. 1	Decreto legislativo 9 aprile 2008 n. 81 e s.m.i., titolo IX - Allegato XXXVIII - Valore limite di esposizione professionale 8 ore (TLV-TWA)
LIM. 2	Decreto legislativo 9 aprile 2008 n. 81 e s.m.i., titolo IX - Allegato XXXVIII - Valore limite di esposizione professionale a breve termine (STEL)
LIM. 3	ACGIH 2014 - Valore soglia di esposizione a lungo termine (TLV TWA)
LIM. 4	ACGIH 2014 - Valore soglia di esposizione a breve termine (STEL)

FASE DI PRELIEVO: DURANTE NORMALE TURNO DI LAVORO.

CAMPIONAMENTO: Qv = 0.65 L/min

TEMPO DI PRELIEVO: 30 minuti

Il Responsabile del Laboratorio  
(o suo delegato)

Dr.ZANETTE MAURO

Ordine dei Chimici della Prov. Di Venezia  
Numero di iscrizione: 000460

(\*) = Prova non accreditata da ACCREDIA

I Risultati contenuti nel presente Rapporto si riferiscono esclusivamente al Campione prelevato.  
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Documento firmato digitalmente ai sensi della normativa vigente.

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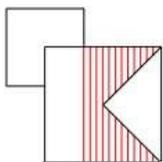
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Preparato  
A.Q.

App./Em.  
D.G.

"Kalttek Srl"  
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# kalttek srl

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analisi chimiche, microbiologiche e ambientali - consulenze



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Rapporto di prova n°: **20163460-001**

Descrizione: **POSTAZIONE PERSONALE - ADDETTO AL RIEMPIMENTO**

Data Prelievo: **05-ago-16**

Data Arrivo Camp.: **05-ago-16** Data Inizio Prvca: **05-ago-16**

Data Rapp. Prova: **24-ago-16** Data Fine Prova: **10-ago-16**

Luogo Prelievo: **KALTEK S.R.L. - VIA DEL PROGRESSO, 2 - 35127 PADOVA (PD)**

Prelevatore: **LECHER RICERCHE E ANALISI SRL**

Prova	U.M.	Metodo	Risultato	LIM. 1	LIM. 2	LIM. 3	LIM. 4
ALDEIDI							
Formaldeide	mg/m <sup>3</sup>	NIOSH 2016 2003	0,095				0,37

#### Riferimenti di Legge Parametri

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FASE DI PRELIEVO: DURANTE NORMALE TURNO DI LAVORO.

CAMPIONAMENTO: Qv = 0.66 L/min

TEMPO DI PRELIEVO: 30 minuti

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