EDC

Endoscope Drying Cabinet

CANTEL

MAXIMISE INFECTION PREVENTION

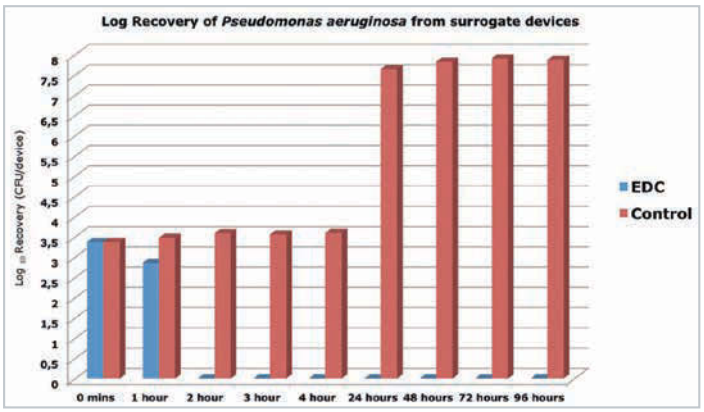
BY CONTROLLING THE ENVIRONMENT WHERE ENDOSCOPES ARE STORED

EDC DELIVERS UNRIVALLED PERFORMANCE, RELIABILITY AND EFFICIENCY FOR YOUR FACILITY

- Full compliance with relevant parts of BS EN 16442
- Dual filtered air maintains positive cabinet pressure
- Clear toughened glass doors allow easy scope recognition
- Secure mounting for scope control section and lightguide plug
- Advanced fully Independent Monitoring System (IMS)
- HEPA filtered and dehumidified air delivered to each scope channel
- Guaranteed dry scopes within 3 hours
- Temperature and humidity monitoring within the cabinet
- Offers full traceability
- Extended storage time (up to 31 days) to cover holiday periods
- Available for up to 10 full size endoscopes

Ease of endoscope placement

EDC RESIDUAL CONTAMINATION RESULTS*



*Data on file.

Large touchscreen for endoscope cycles at a glance

THE COMPLETE CIRCLE OF PROTECTION

As the global vanguard in infection prevention, **only Cantel delivers the Complete Circle of Protection,** a full-value, proactive partnership dedicated to helping you remove risk, streamline operational efficiencies and optimise your success.

ENDOSCOPE DRYING CABINET

Convenient touch screen operation

RFID technology for endoscope and operator identification

Locking doors protect endoscope inventory

Quick identification of endoscope storage time

Document cycle verification

Endoscope hangers available for management and separation of long scopes

Continuous circulation of HEPA filtered air to all endoscope channels

DRY & STORE Bacteria pose significant risk to endoscopes during transport and storage. Cantel's transport, drying and storage solutions are designed to protect valuable inventory, reduce cross contamination touchpoints, eliminate moisture in the endoscope channels and control humidity. Humidity or moisture in endoscope channels is known to aid bacterial growth.

Specifications

Model	EDC10T2
Scope capacity	10 scopes
Independent storage time validated	31 days
Power requirements	230v 50/60Hz
Power consumption data	Normal 2.7A, Max rating 4A
Filter condition monitoring	Yes (filter blockage)
Airflow monitoring	Airflow to each lumen in every endoscope stored monitored
Air changes in cabinet	95% recirculated
Air cleanliness in cabinet	≤ ISO Class 7
Alarms	Door open alarm
Lighting	1 x low energy 30 watt lamp
Noise Level	< 58 dBA
Weight	310kg

EDC Endoscope Drying Cabinet ordering information

MODEL	DESCRIPTION	UNITS PER BOX
LA-EDC10T2	Endoscope Drying Cabinet	1
750002	Dri Mats	20
LA-ESCHA	Colonoscope Hanger	1
70201	Main Override Key	1
275016	Manifold Connector	1
795732	Printer Paper	20
LA-ASIST1	Scope Tags	10
LA-ASGNT3	Operator Tags	10
775018	Validation Kit	1
LA-ASGSO	Silicone Oil	2

www.cantelmedical.co.uk

TO PLACE AN ORDER

p: 01702 291878 | **e:** orders@cantelmedical.co.uk

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 1 din 11.06.2023

Solicitantul **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

CANTEL MEDICAL (ITALY) S.R.L

Product: Endoscope Drying Cabinet - EDC
Model: FG-LA-EDC10T2

Se anexează următoarele acte:

1. Declarație de Conformitate CE
2. Actul prin care producătorul își desemnează reprezentantul
3. Declarație pe propria răspundere.

Data **11.06.2023** Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. ”DataControl” S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscînd prevederile art. **352[1]** , Codul Penal al republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

CANTEL MEDICAL (ITALY) S.R.L

Product: Endoscope Drying Cabinet - EDC
Model: FG-LA-EDC10T2

Sunt autentice și corespund realității

Alexandru Grabazei, director Semnătura _____
Data: **11.06.2023**

Maastricht, November 28th 2022

AUTHORIZATION LETTER

We, Medivators Inc., a STERIS Corp. company, with manufacturing facility at 3155 Pollok Drive, Conroe TX 77303, USA who are the producer of endoscopic accessories EndoGator, EndoSmartCap, EndoSmartCap Hybrid, connectors and disposables herewith appoint F.C.P.C. "DataControl" S.R.L., 20, Melestiu street, MD-2001, Chișinau, Republic of Moldova, to be official representative for registration, renewal, amendments in registration, at the responsible authorities of the Republic of Moldova.

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The Letter will remain valid until 31st of December 2023, unless not revoked by us.

Sincerely yours,
For Medivators Inc
Mr. Andre Kenik
Sales Director, Europe

Kenik Andre

Steris Netherlands BV,
155 Pollok Drive,
Conroe TX 77303, USA
Andre.kenik@cantel.com
www.cantelmedical.eu | www.medivators.com

EU- Declaration of Conformity

Issued under the sole responsibility of the manufacturer listed below:

Manufacturer's Name	*CANTEL MEDICAL (ITALY) S.R.L.*
Manufacturer's address/ SRN	*Via Laurentina, 169 – 00071 Pomezia (Roma) - Italy / IT-MF-000007606*
Quality System Cert No.	*UNI EN ISO 9001 (n.1249.2019) – UNI CEI EN ISO 13485(n.1250.2019)*
Notified Body No./Name	*IMQ S.p.A. (ISO 9001 - ISO 13485)*

As the manufacturer listed above, we declare that the devices listed:

Product(s):	*Endoscope Drying Cabinet - EDC*
REF:	*FG-LA-EDC10T2*
Basic UDI-DI:	*8011517TDF000118D*
Intended Purpose:	*Endoscope Drying Cabinet*

meets all conformity requirements of the safety and performance requirements of the Medical Devices Regulation (MDR, Regulation (EU) 2017/745 as amended).

*Product classification according to the requirements described in **Annex VIII** of the Medical Devices Regulation, the medical device is assigned to risk **Class I** (conformity assessment per **Annex IX**).*

Applied standards:

UNI CEI EN ISO 14971:2012
UNI CEI EN ISO 15223-1:2017
BS EN 16442:2015
IEC 61010-1:2010
IEC 61326-1:2012
BS EN 62366-1:2015
EN 62304:2006

DocuSigned by:
Valentina Castagnola
FD34D942E1274B1...

Signature: Valentina Castagnola
Title: Regulatory Affairs Manager
Place of Issue: Pomezia
Date of Issue: 21/06/2021