DETERGENT- DISINFECTANT
MEDICAL DEVICE
CLASS IIa

Lab Dynamics
For Scientists by Scientists

UMONIUM 38®
PROBES

ECO FRIENDLY

✓ FORMULA FREE FROM
- ➜ CMR** COMPONENT
- ➜ ENDOCRINE DISRUPTOR

“ Disinfection of probes and their environment ”

SPORICIDE





UMONIUM 38® **PROBES** wipes are specifically developed for the disinfection of ultrasound scanners, surface and endocavity probes. Validated as safe for use even in embryonic environments, they are perfectly suitable for gynaecological examinations. With no toxic fumes, they kill germs as quickly as 5 seconds and do not dry out in the box.

** Carcinogenic, Mutagenic or Reprotoxic

laboratoire HUCKERT'S INTERNATIONAL
mastered disinfection

MADE IN BELGIUM

www.huckerts.net

UMONIUM[38]® PROBES

One 20 x 20cm wipe treats an area of 3 m².



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VALIDATION MOUSE EMBRYO ASSAY

VALIDATION HUMAN SPERM SURVIVAL ASSAY

INDICATIONS
Cleaning and disinfection of non-invasive medical devices.

COMPOSITION
White non-woven wipes (20cm x 20cm) made of 50% wood pulp and 50% polyester and soaked in a solution of UMONIUM[38®]: N-benzyl-N-dodecyl-N,N-dimethyl-ammonium chloride/N-benzyl-N, N-dimethyl-N-tetradecyl-ammonium chloride. 11.9g/L.

The impregnation solution is classified as a class IIb medical device.

REGULATORY STANDARDS
- The bactericidal, fungicidal and sporicidal activity of the soaked wipe has been validated according to standards ASTM 2967-15 and EN 16615
- The bactericidal, fungicidal, levoricidal, mycobactericidal and virucidal activity of the impregnation solution has been validated according to EN 13727, EN 14561, EN 13624, EN 14562, EN 14348, EN 14563 and EN 14476
- Compliant with ED 93/42/EEC relating to medical devices. (Appendix II, excl.§4)
- Quality and traceability guaranteed by ISO 9001:2015 and EN ISO 13485:2016
- MEA (Mouse Embryo Assay) validation
- HSSA (Human Sperm Survival Assay) validation
- CE marking 1639

INSTRUCTIONS FOR USE
Cleaning/Pre-disinfection: Take out a wet wipe. Wet wipe to eliminate all dirt. **Disinfection**: Take out a new wet wipe. Wipe the clean devices for at least 5 seconds. Leave to dry or rinse with water* (or with a cloth dampened with water*) if necessary. Make sure to fully close the cover after use.

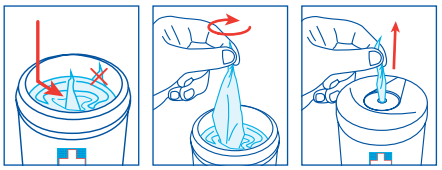
PROPERTIES
- Class IIa medical device
- Detergent- disinfectant wipe with a broad spectrum of activity
- Non-toxic, no dangerous vapours
- LD_{50} (rat): > 5840 mg/kg
- Non-corrosive: pH-neutral
- Ready-to-use product, non-irritating for the skin (no transdermal toxicity)
- Free from aldehyde, peroxide and biguanide, and other carcinogenic, mutagenic, or reprotoxic components
- Non-coagulant
- Non-flammable
- Bactericide, fungicide and sporicide activities
- 100% compatible on fibre optic, rubber, polycarbonate, acrylic compound, glass, Pyrex, PU, PVC, HDPE, PET, neoprene, latex, silicone, paints and stainless steel 410
- Effective, fast-acting and efficient (dissolves blood)
- Effective in the presence of organic materials
- Effective against Covid-19
- active within 5 seconds
- Residual on non-rinsed surfaces (bacteriostatic film)
- No residue after rinsing
- Stability: 36 months date of manufacture
- Colourless, fragrance-free product
- Safety validated up to the embryonic environment
- Biodegradable impregnating solution

VALIDATION
- ESAOTE
- FUJIFILM healthcare/ HITACHI diagnostic imaging
- GE healthcare
- SAMSUNG Medison

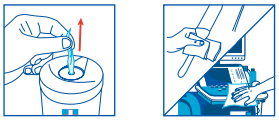


ITEM No.	NAME	BOX
PF 10800	Box of 100 wipes (20 x 20cm)	6 x 100
PF 10810	Box of 500 individual packs	500 x 1
PF 12800	Dispenser box	(2 x 50 items)

PROCEDURE FOR USE



STEP ❶: CLEANING/PRE-DISINFECTION



Take out a wet wipe

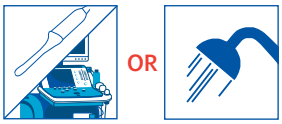
Wet wipe to eliminate all dirt

STEP ❷: DISINFECTION



Take out a new wet wipe

Wipe the clean devices for at least 5 seconds



Leave to dry OR rinse with water* (or with a cloth dampened with water*) if necessary

TECHNICAL DETAILS

Standards	Target organisms		Contact time (min.)	
			Clean condition	Dirty condition
EN 13727	BACTERIA	*S. aureus, E. hirae, P. aeruginosa*	30 sec.	1
		E. faecalis (vancomycin-resistant), E. coli (carbapenem-resistant), K. pneumoniae (carbapenem-resistant), S. aureus (methicillin-resistant)	30 sec.	-
EN 13697	BACTERIA	*S. aureus, E. hirae, E. coli, P. aeruginosa*	5	15
EN 16615	BACTERIA	*S. aureus, E. hirae, P. aeruginosa*	1	1
EN 14561	BACTERIA	*S. aureus, E. hirae, P. aeruginosa*	10	30
EN 13624	MUSH./FUNGI	*C. albicans*	5	5
EN 13697	MUSH./FUNGI	*C. albicans*	10	15
EN 16615	MUSH./FUNGI	*C. albicans*	30 sec.	30 sec.
EN 14562	MUSH./FUNGI	*C. albicans, A. niger*	10	10
EN 14476	VIRUSES	Norovirus, Adenovirus, Poliovirus	10	10
	VIRUSES	Human coronavirus, *Vaccinia virus*	5	-
EN 16777	VIRUSES	*Vaccinia virus*	-	30
EN 17111	VIRUSES	*Vaccinia virus*	60	-
EN 16615***	VIRUSES	*Vaccinia virus*	5	-
EN 14348	MYCOBACT.	*M. avium, M. terrae*	10	10
EN 14563	MYCOBACT.	*M. avium, M. terrae*	10	10

* Clean drinking water at room temperature
** Carcinogenic, Mutagenic or Reprotoxic
*** Modified

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