

DETERGENT - DISINFECTANT  
MEDICAL DEVICE  
CLASS IIa



# UMONIUM<sup>38</sup> PROBES



✓ FORMULA FREE FROM

- CMR\*\* COMPONENT
- ENDOCRINE DISRUPTOR

“ Disinfection of probes  
and their environment ”

SPORICIDE



UMONIUM<sup>38</sup> 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*





# UMONIUM<sup>38</sup> PROBES

One 20 x 20cm wipe treats an area of 3 m<sup>2</sup>.



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## 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<sup>38</sup>: 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<sub>50</sub> (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 )

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

## PROCEDURE FOR USE



### STEP 1: CLEANING/PRE-DISINFECTION



Take out a wet wipe

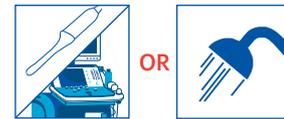
Wet wipe to eliminate all dirt

### STEP 2: 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 <i>S. aureus, E. hirae, P. aeruginosa</i>	30 sec.	1	
		30 sec.	-	
	EN 13697	BACTERIA <i>S. aureus, E. hirae, E. coli, P. aeruginosa</i>	5	15
			1	1
EN 16615	BACTERIA <i>S. aureus, E. hirae, P. aeruginosa</i>	10	30	
EN 14561	BACTERIA <i>S. aureus, E. hirae, P. aeruginosa</i>	5	5	
EN 13624	MUSH./FUNGI <i>C. albicans</i>	10	15	
EN 13697		30 sec.	30 sec.	
EN 16615		10	10	
EN 14562	MUSH./FUNGI <i>C. albicans, A. niger</i>	10	10	
EN 14476	VIRUSES Norovirus, Adenovirus, Poliovirus Human coronavirus, Vaccinia virus	10	10	
EN 16777		5	-	
EN 17111		-	30	
EN 17111		60	-	
EN 16615***		5	-	
EN 14348	MYCOBACT. <i>M. avium, M. terrae</i>	10	10	
EN 14563		10	10	