

UnoMeter™ Safeti Plus

Hourly Diuresis Monitoring System



Protect your patients

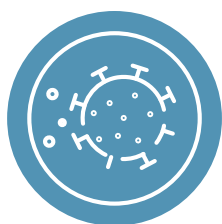
Demonstrated effectiveness against retrograde infections^{*,1,2,3}

Protect your patients

Demonstrated effectiveness against retrograde infections ^{*}, 1, 2, 3

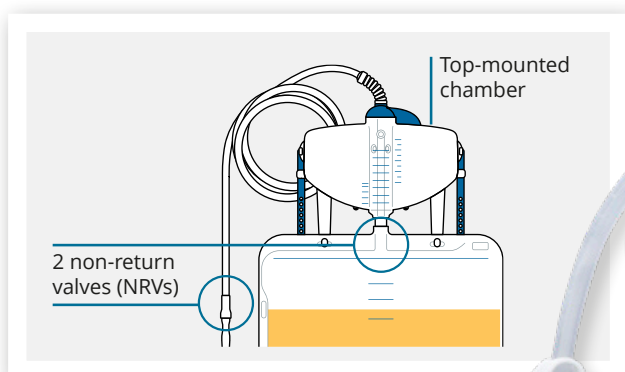
The UnoMeter™ Safeti Plus Hourly Diuresis Monitoring System helps to prevent retrograde urinary tract infections.^{*}, 1, 2 In vitro study results have demonstrated that the system helps to prevent retrograde infection more effectively than traditional competitor devices with a front-mounted chamber.²

In addition, the UnoMeter™ Safeti Plus has been designed to save nursing time and provide accurate urine measurement for all patients, even for low volumes, for various bed types and the measurement is protected during transportation.



Infection Prevention

In vitro study results have demonstrated that the UnoMeter™ Safeti Plus contains contamination and does not allow bacterial migration to the measuring chamber or catheter.^{*}, 1, 2



The design of UnoMeter™ Safeti Plus with the top-mounted chamber and 2 non-return valves (NRVs) helps to minimize the risk of retrograde infection.¹

Double lumen tube designed to reduce urine stasis

Non-return-valve in connector helps to eliminate the risk of urine back flow into the catheter

Non-return-valve in collection bag supports prevention of urine backflow to the chamber

Anti-kink spiral helps to reduce urine stasis

Hydrophobic and oleophobic filter to support flow, also in wet conditions



Hydrophobic and oleophobic filter to support flow, also in wet conditions



Optimized Nursing

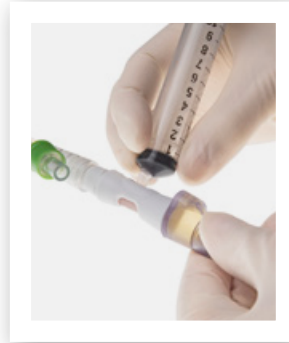
UnoMeter™ Safeti Plus has been developed to save nursing time and provide caregivers with the confidence of reliable urine measurement. The system has been designed with features to help optimize nurses' experience so they can focus on their patients.



Intuitive open/close handle allows for emptying the chamber with one hand.



Detailed graduation with large digits on chamber for fast, easy and accurate measurement.



The unique KombiKon™ sample port with transparent window is needle-free and allow for observation of urine build up before sample taking. A non-return valve ensures that only fresh urine is sampled⁴. With its unique design it furthermore helps to reduce the contamination risk to the drainage system and thus the risk of retrograde infection².

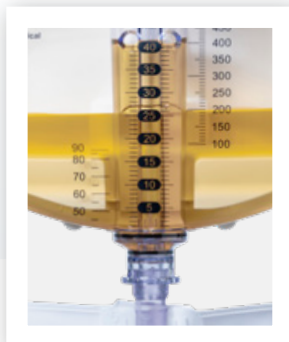


For All Patients

The UnoMeter™ Safeti Plus is designed to provide accurate urine measurement for all patients, even during transportation, and is compatible with a large variety of bed types. Its measuring chamber allows for accurate measurements⁶, also for patients with low urine output, such as patients with oliguria, and paediatric patients.



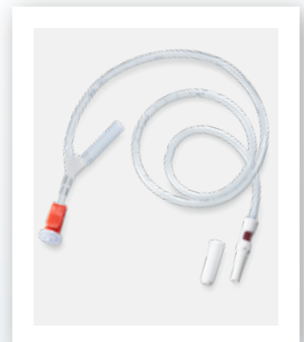
The UnoMeter™ Safeti Plus does not lose the measurement in the chamber during transportation.



Low volume inner chamber allows for accurate measurement also for small volumes.⁶



Multiple hanging options (straps, cord or hook) enable quick attachment for use on all bed types.



The UnoMeter™ Abdo-Pressure™ can be connected to the UnoMeter™ Safeti Plus and allows for monitoring of intra-abdominal pressure (IAP) and hourly diuresis at the same time.

The UnoMeter™ Safeti Plus Difference

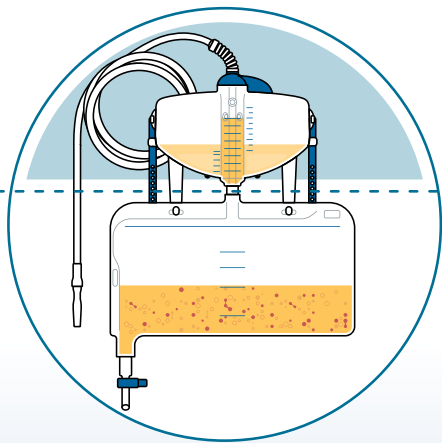
The UnoMeter™ Safeti Plus helps to prevent retrograde infection more effectively than traditional urine measuring devices with a front-mounted chamber. ^{*, 1, 2, 3}

An in vitro study compared the UnoMeter™ Safeti Plus and two front-mounted devices in preventing bacterial migration from the collection bag to the measuring chamber²

Percentage of Samples with Bacteria Growth

	After 2 days	After 4 days	After 7 days
Urine meter 1	75%	100%	100%
Urine meter 2	100%	100%	100%
UnoMeter™ Safeti Plus	0%	0%	0%

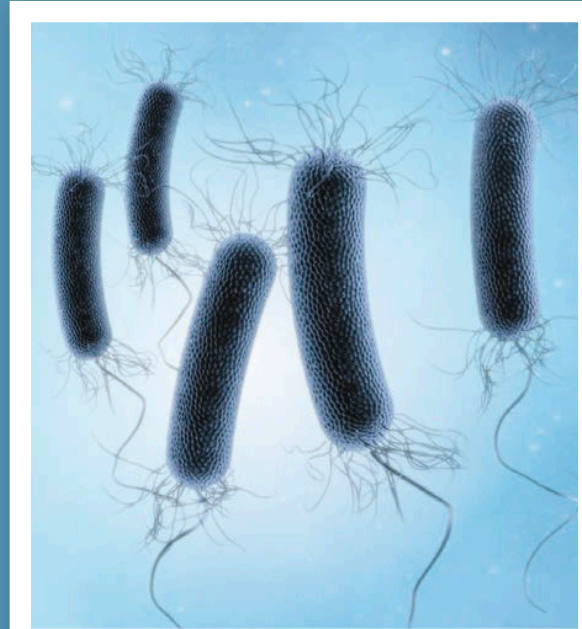
In vitro study: Four samples were tested for each device and taken at set time intervals to show whether there was bacteria growth (n=4)



Summary of study results ^{*, 2:}

The UnoMeter™ Safeti Plus demonstrated better infection control compared to the front-mounted systems

- In both front-mounted devices, contamination progressed into the measuring chamber after 2 days. The UnoMeter™ Safeti Plus showed no progression of bacteria after 7 days
- The study results demonstrated that the UnoMeter™ Safeti Plus contains contamination within the collection bag and does not allow bacterial migration to the measuring chamber or catheter



The risk of Catheter Associated Urinary Tract Infections (CAUTI)

Monitoring hourly diuresis is more than just a measurement. It is essential for detecting impaired fluid balance, renal insufficiency, or possible infections of critically ill patients.

While important to perform, catheterbased urine measurement can lead to CAUTI and additional treatment complications.

The prevalence of CAUTI

CAUTIs are the most common nosocomial infections in hospitals, accounting for >40% of all institutionally acquired infections.⁵

CAUTIs result in

- Increased morbidity and mortality
- Increased length of hospital stay by 2-4 days
- Excess health care cost of \$400 to 500 million per year in the US

Product range

UnoMeter™ Safeti Plus – with KombiKon™ sample port
Hourly Diuresis Monitoring System

REF No	Description	Chamber volume	Bag volume	Sample Port	Double lumen tube	NRV in bag	NRV in inlet tube	Bottom Outlet (free flow)	Round Hook	Straps	Cords	Exchangeable bag	Sliding clamp
1710086	2.0L Exchangeable bag, straps and round hook, 110cm tube, Free flow bottom outlet, sterile	500 ml	2000 ml	KombiKon™ Needle-free sample port with inspection window	●	●	●	●	●	●		●	●
1710085	2.0L Exchangeable bag, straps and round hook, 150cm tube, Free flow bottom outlet, sterile	500 ml	2000 ml	KombiKon™ Needle-free sample port with inspection window	●	●	●	●	●	●		●	●
1710088	2.0L Exchangeable bag, straps and cord, 110cm tube, Free flow bottom outlet, sterile	500 ml	2000 ml	KombiKon™ Needle-free sample port with inspection window	●	●	●	●		●	●	●	●
1710087	2.0L Exchangeable bag, straps and cord, 150cm tube, Free flow bottom outlet, sterile	500 ml	2000 ml	KombiKon™ Needle-free sample port with inspection window	●	●	●	●		●	●	●	●
1710089	2.0L Exchangeable bag, straps and round hook, 120cm tube, Free flow bottom outlet, sterile	500 ml	2000 ml	KombiKon™ Needle-free sample port with inspection window	●	●	●	●	●	●		●	●
1710090	2.0L Exchangeable bag, straps and round hook, 200cm tube, Free flow bottom outlet, sterile	500 ml	2000 ml	KombiKon™ Needle-free sample port with inspection window	●	●	●	●	●	●		●	●

Material specifications:

Component	Materials
Contains latex or DEHP?	No
KombiKon™ connector and cap	PVC – Phthalate free, TPE, PP, PE
Tube, Clamp and anti-kink spring	PVC – Phthalate free, PP, PE, TPU
Rigid chamber incl. strap, Hanger, lid and inner cylinder	SAN, ABS, ePTFE membrane, PE, SBC, PA, PVC – Phthalate free, NBR
Bag incl. bottom outlet	PVC – Phthalate free, ePTFE membrane, PE, ABS
Packaging materials	PE/PET, PE, corrugated cardboard

Sterilization:

Sterile?	Yes
Sterilized by	Ethylene oxide
Shelf life	3 years

Certifications:

CE-marking?	Yes
Product classification	Class Is, Im (EU)
Quality system certified to	ISO 13485
Global Medical Device Nomenclature (GMDN)	32072
EMDN Code	A06030302

Storage and handling

Instructions for use included.



Packaging specifications:

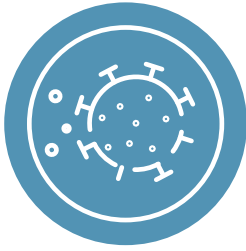
REF No	Shipping Carton				
	Quantity (pcs)	Dimensions (mm) L x W x H	Gross Weight (kg)	Piece identifier GTIN - UDI	Inner carton identifier GTIN - UDI
1710085	14	580x380x280	6,8	07350057674253	07350057674260
1710086	14	580x380x280	6,5	07350057674284	07350057674291
1710087	14	580x380x280	6,6	07350057674314	07350057674321
1710088	14	580x380x280	6,3	07350057674345	07350057674352
1710089	14	580x380x280	6,6	07350057674376	07350057674383
1710090	14	580x380x280	7,0	07350057674406	07350057674413



Free of Phthalates and Latex

Protect your patients

Demonstrated effectiveness against retrograde infections ^{*, 1, 2, 3}



Infection Prevention

Protecting patients at risk by reducing the risk of retrograde infection. In vitro proven effectiveness against retrograde urinary tract infection.^{1, 2}



Optimized Nursing

Intuitive product design with features that help to save nursing time and provide caregivers with the confidence of reliable urine measurement.⁶



For All Patients

Designed to provide accurate urine measurement for all patients, even for low volumes⁵, during transportation and for various bed types at different wards.

The UnoMeter™ family consist of:



UnoMeter™ 500



UnoMeter™ Abdo-Pressure™

* As demonstrated in vitro

References

1. Frimodt-Møller N, Corneliussen L. In vitro test of different urine-meters in an experimental bladder-drainage model: prevention of ascending contamination depends on construction of the urine meter. *British J of Infect Control* 2005;6(5):14-17
2. Ashman P, SMTL Closed System Study Test Report, 2009, Data on file, Observe Medical.
3. Frimodt-Møller N, Corneliussen L. In vitro test of ascending contamination in different urine meter systems. Test Report: December 2011, data on file, Observe Medical.
4. Performance of Kombikon needle free sample port. July 2004 Data on file
5. Maki DG, Tambyah PA; Engineering out the risk of Infection with Urinary Catheters. *Emerging Infectious Diseases*: Vol. 7, no. 2, March-April 2001.
6. Price, L., UnoMeter Safeti Plus measuring accuracy testing (WHRI3693 TA263), Test Report, October 29, 2012, Data on file, Observe Medical.

Observe Medical AB • Krokslätts Parkgata 4, 431 68 Mölndal
010-641 02 02 • order@observemedical.com • www.observemedical.com

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