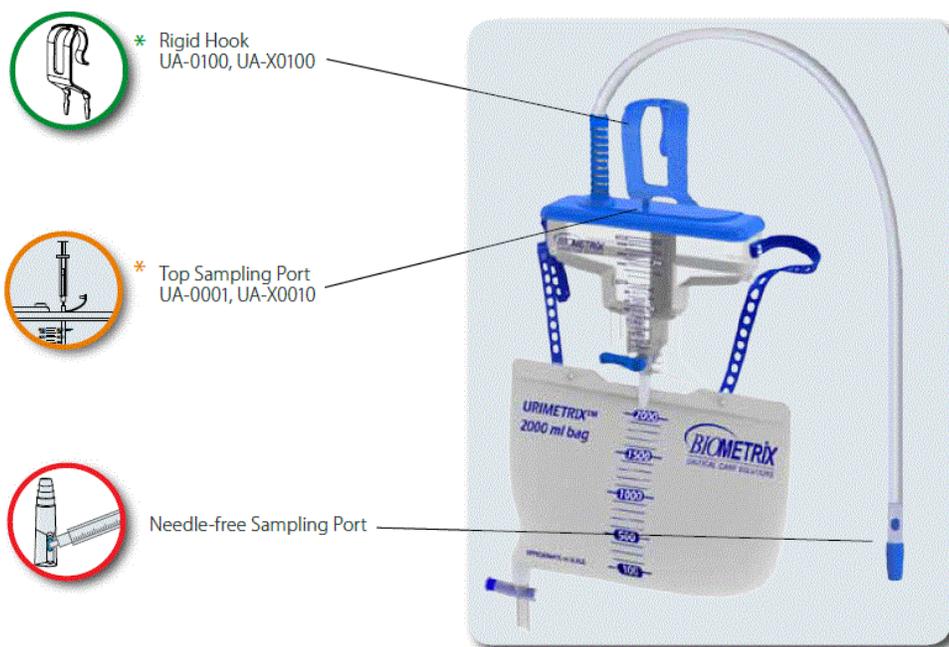


Urimetrix™ – Single Use Urine-Meters

Code	Description
UA-0001*	500cc System with Needleless Sampling Port, Extra Top Sampling Port, 150cm Connecting Tube
UA-0100*	500cc Urimetrix with Needleless Sampling Port, 150 cm Connecting Tube and Rigid Hook
UA-X0010	500cc System with Needleless Sampling Port, Extra Top Sampling Port, 115cm Connecting Tube
UA-X0100	500cc Urimetrix with Needleless Sampling Port, 115cm Connecting Tube and Rigid Hook



Intent of Use: collection, monitoring and management of urine output for critically ill or injured patients

INSPECTION:

1. Incoming Inspection:

Sampling per Mil. Sts 105 E AQL 0.25 Level II, Inspection of Supplier documents of compliance and special attention to integrity of raw materials.

2. Final Inspection:

Sampling per Mil. Sts. 105E AQL 0.25 Level II, functional tests, integrity, pull-out tests and very detailed visual inspection of damages in the product.

A. Product Stability.

The products have been tested with satisfying results for 5 years shelf life when stored in an atmosphere of 22 ± 2 C° temp with 30-60% relative humidity.

No significant light source is recommended/ allowed.

B. Compatibility.

Products are compatible with the Pharmaceutical products with which they are in contact in a day to day use, based on engineering testing and 10 years of experience of use in hospitals.

Biological evaluation of the product is per ISO-10993-1 –Biological evaluation of medical devices, Part 1: Guidance on selection of tests.

C. Sterilization:

By Ethylene Oxide sterilization process. Validation and routine control of the sterilization is complying with ISO 11135-1:2007 requirements.

D. Conformance

Conformance with ISO 13485:2003, ISO 9001:2008 and the Medical Devices Directive 93/42/EEC ANNEX II as amended per 2007/47/EC.