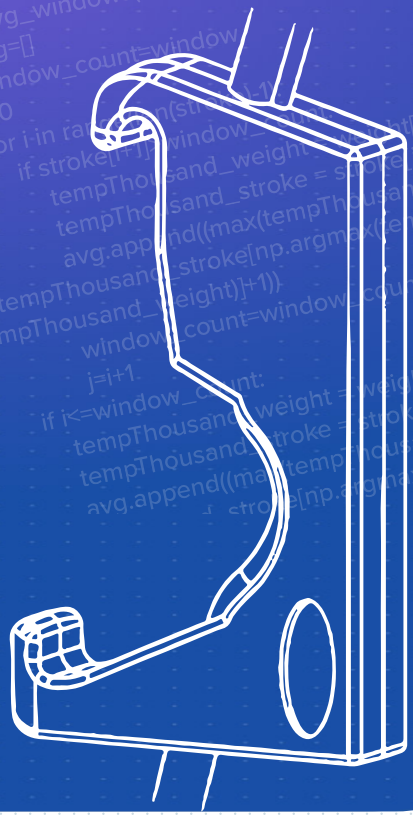
FIZEMEDICAL

FIZE KUO®
Disposable Kit
Instructions for Use



- Note: for indication, intended use, technical specification, and additional information – see the FIZE kUO® Instructions for Use.
- Before use, make sure to read carefully the FIZE kUO® Instruction for Use and this FIZE kUO® Disposable Kit Instructions for Use.
- The FIZE kUO® Disposable Kit should only be used with the FIZE kUO® console.

Instructions for Use

1. Wash hands, don clean gloves and follow the applicable hospital procedures.
2. Remove the FIZE kUO® Disposable Kit from the sterile bag.
3. Close clamp positioned between the urine sample port and sensor.
4. Connect the kit to the catheter. Note that the standard disposable kit may be connected to a catheter size of 6 Fr and above.
5. Insert the blue cassette into the device (see image 1)
6. The device will detect the cassette and lock it in automatically. No need to apply force.
7. **Open clamp**
8. Secure the urine collection bag to the bed below patient level and make sure tubing is not kinked.

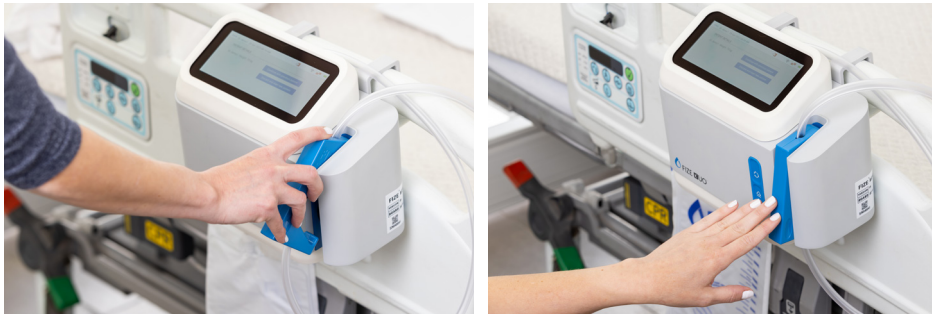


Image 1 – FIZE kUO™ Disposable Kit insertion

FIZE KUO™ Needle-less Sampling Port

Urine sample may be collected through the FIZE kUO® Needle-less Sampling Port (indicated by the blue stem in the port) using a compatible, needle-free syringe such as Luer Lock or slip tip syringes.

1. Swab surface of FIZE kUO® Needle-less Sampling Port with antiseptic
2. wipe. Using aseptic technique, position the needle-free syringe in the center of the sampling port. Press the syringe and twist gently to access the sampling port.
3. Slowly aspirate urine sample into syringe.
4. Once the needed amount was aspirated, remove the syringe from sampling port.
5. Transfer urine specimen into specimen cup or follow hospital protocol.
6. Discard syringe according to hospital protocol.
7. Follow established hospital protocol for specimen labeling and transport to lab.

Catheter Irrigation

Catheter irrigation can be performed through the sample port or directly through the catheter. Make sure to perform irrigation according to hospital guidelines.

To washout directly through catheter:

1. Pause monitoring by pressing the Start/Pause button.
2. Disconnect disposable kit from catheter and perform washout according to hospital standard of care.
3. Let washout fluid exit the catheter.
4. Reconnect disposable kit to the catheter. Make sure kit is firmly connected.
5. Resume monitoring

To Washout through urine-sample port:

1. Pause monitoring by pressing the Start/Pause button.
2. Close clamp between sensor and urine-sample port
3. Insert washout fluid through port according to hospital guidelines.
4. Open clamp
5. Resume monitoring

MR Safety Information

MR Safety Information

The FIZE kUO disposable kit has been found to be MR conditional. A catheterized patient can remain connected to the FIZE kUO Disposable kit and safely scanned in MR systems meeting the following conditions:

Static Magnetic Field	1.5T	3.0T
Resonance frequency	MHz 63.675	123.259 MHz
Gradient amplitude per axis	mT/m 40-45	80 mT/m
Gradient slew rate per axis	T/m/s 200	200 T/m/s
Maximum effective gradient amplitude	mT/m 72	139 mT/m
Maximum effective gradient slew rate	T/m/s 346	346 T/m/s
Maximum spatial gradient	**T/m (1100 gauss/ 11 (cm**	**7 T/m (700 gauss/cm)**
Maximum spatial product (B0*Gradient)	T2/m 17	17 T2/m
Note: Maximum spatial field gradient and force product for common 1.5 and 3.0 scanners available in 2021 are 20 and 17 T/m, and 41 and 48 T^2/m respectively		
Specific absorption rate (SAR): Whole Body average SAR limit of 2W/kg (Normal Operating (Mode		
Magnetic field orientation: Each Principal axis of the test device oriented parallel to the MR system's static magnetic field. (Angles: 0,45,90,135,180,225,270,315,360)		

Note: the disposable kit should be placed between the patient's legs. Urine collection bag should be located at the end of the bed (the far side from the MRI scanner).

Failure to follow the mentioned MRI conditions and instructions may result in injury to the patient.

General Warnings

- Federal (U.S.A) law restricts this device to sale by or on the order of a physician.
- Sterilized using ethylene oxide. Do not re-use and do not re-sterilize.
- Examine the package before use. If it is damaged or open – do not use.
- Check kit expiration date – if expired, do not use
- Kit should be used for a period of up to 14 days only.
- The kit is intended for single use only.
- For urological use only

After use, this product may be a potential biohazard. Handle and dispose in accordance with accepted medical practices and applicable local, state, and federal laws and regulations.
Visually inspect the product for any imperfections or surface deterioration prior to use. If package is opened or if any imperfection or surface deterioration is observed, do not use the product.
Please consult product label and insert for any indication, contraindications, hazards, warnings, cautions and directions for use.

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For further questions contact FIZE Medical Technical Support.

FIZE Medical Ltd.

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Email: Service@FizeMedical.com

Or call the service number on the FIZE kUO® console.

Manufacturer

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www.fizemedical.com