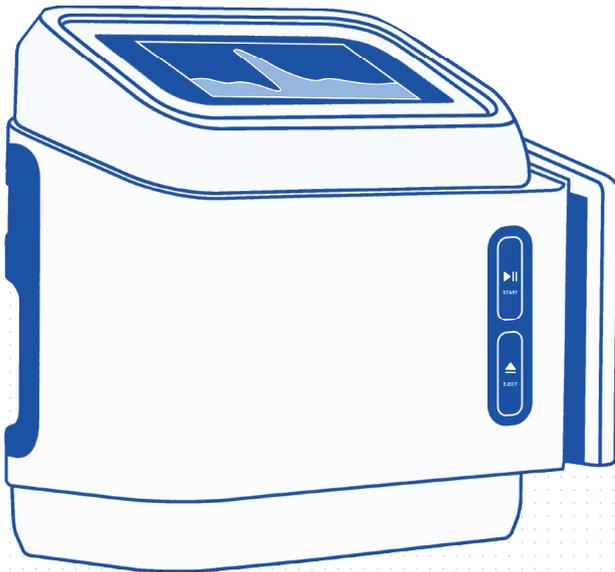


FIZE kUO[®]

Monitoring System

Quick Guide



More detailed instructions are available in FIZE kUO Instructions for Use.
For service-related issues, contact us at service@fizemedical.com
(833) 307 4002

Power On/Off

- 1 Mount the FIZE kUO Console to the bed railing using the attached hooks.
- 2 Firmly secure the console to bed railing. You may use the provided cable ties.
- 3 Connect console to power supply using the provided cable and Power Box or the FIZE power supply (Image 1B)
- 4 Turn device on by pressing the On/Off button (Image 1A)

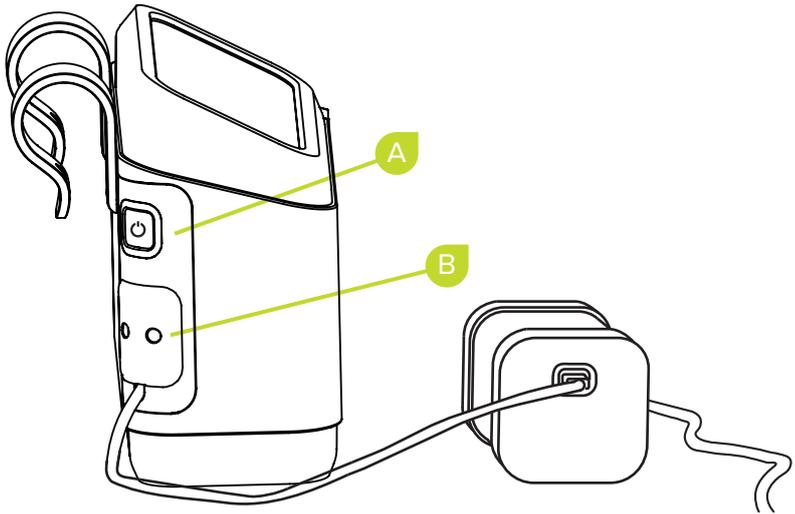


Image 1: Turning device on/off

Power On

Disposable Kit

To connect the FIZE kUO disposable kit:

- 1 Open the FIZE kUO Kit sterile package.
- 2 Remove the cap from the kit and attach the FIZE kUO disposable kit to the catheter according to facility standard practices for connecting urine collection systems to indwelling catheters.

Note:

When the disposable kit is connected to the Foley catheter but not yet inserted into the console, urine flows freely through the tubing without being captured. If capturing this initially drained urine is critical, close the clamp prior to connecting the kit to the catheter and open the clamp after the disposable kit is inserted into the console.

- 3 Insert the disposable kit cassette into the console (see Figure 5-1).
- 4 Ensure the tubing is adequately secured to the patient, and hang the urine collection bag off the bed below the patient's level.

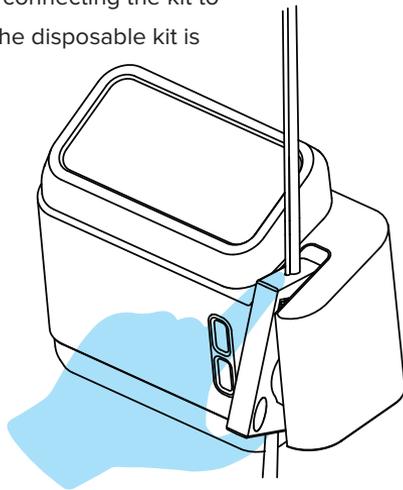


Image 2: Cassette Insertion

Define Patient

- 1 To define a new patient, select 'Discard and Start New Patient' (Image 3) and enter patient details (Image 4). **Note that previous patient's data will be deleted.**
- 2 To continue with previous patient, press 'Continue with Previous Patient'.
- 3 Once a new patient is saved, data such as patient identifier, weight, monitoring history, kit usage metrics and more are saved to the kit.

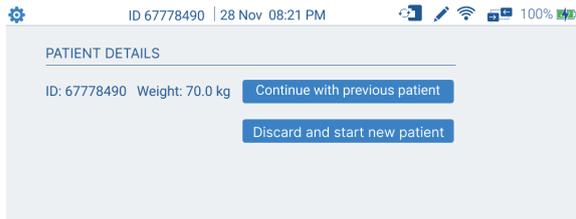


Image 3: Selection between Previous Patient and New Patient



Image 4: New Patient details

- 4 Click 'Start Monitoring' (Image 5).

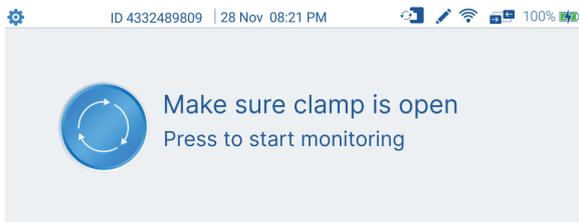


Image 5: Click start monitoring

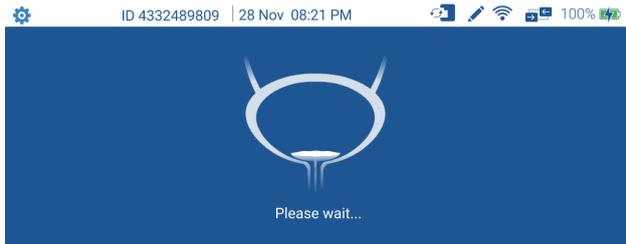


Image 6: Initialization animation

During initialization (Image 6), excess urine volume is emptied according to individualized patient-appropriate levels, as determined by FIZE kUO algorithms. The emptied volume is displayed at the end of the animation and can also be viewed in the monitoring display by pressing the drop icon in the trendline display. This amount is included in the hourly total.

Monitoring Display



Image 7 – Patient Monitoring Screen – bar chart display
Complete legend in next page

In the bar chart display, each column represents a measurement from a single hour in ml units.

The light blue column represents a measurement from a partial hour, for example:

- A measurement still in progress
- A measurement from an incomplete hour

Once a measurement from a full hour is complete, the light blue column will turn dark blue.

To edit urine output volume:

1. Long press the In Progress bar.
2. Fill in the volume you would like to add or remove in the pop-up window (Image 8).
3. Press Save

Once manually edited, the bar will appear green (Image 9). The volume edited can be viewed by pressing the drop icon.

Volume editing can be relevant in two cases:

1. Subtracting volume added to the tubing during a catheter-flushing.
2. Adding missing urine volume produced while the cassette was released from the console.



Image 8 - Urine Output Edit feature



Image 9 - Manually edited bar

Monitoring Display

Label	Name	Description
1	Settings icon	Enter settings screen
2	Graphic display	Switch display from bar chart to trendline
3	Time window	Select the preferred timeframe
4	Patient ID	View patient ID
5	Active alerts	Open active alerts
6	Cassette Status	See the number of days cassette is in use
7	Edit Intervention	Insert an intervention (diuretic, fluid bolus, etc.) Intervention event can be viewed in the trendline view
8	WIFI Status	Appears when device is connected to WIFI
9	EMR connectivity	EMR connection active
10	Battery status	View battery status
11	General metrics	Total urine output and average urine output in the selected time window
12	Weight-adjusted average urine output	Weight-adjusted average urine output

Table 1 – Patient Monitoring Screen Icons

Alerts

Clinical alerts

Appears when urine output is above or below the defined threshold (Image 10)



Image 10: Clinical alert example

The alerts can be adjust according to preference through the Settings menu, under the Patient-> Clinical Tab (Image 11)

To enable/disable alert press the Toggle icon

To turn on/o sound alert press the speaker icon

To edit urine output thresholds press the pencil icon

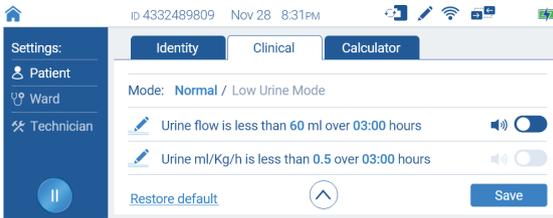


Image 11: Clinical alert Editing

'No Urine Detected' alert

Appears when the system detects close to zero urine output (Image 12).

If very low urine is expected, you may switch to 'Low Urine Mode' (Image 12).

In Low Urine Mode, 'Low Urine Volume' and 'No Urine Detected' alerts will be disabled.

If you wish to keep the normal monitoring mode, Press 'Resume Monitoring'.

Low Urine Mode may also be enabled and disabled through the Settings menu, under the Patient- > Clinical tab (Image 11)''

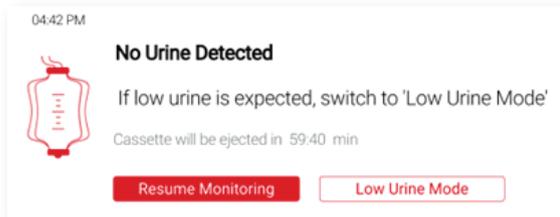


Image 12: No Urine Detected alert

Alerts

'Catheter Clogged' alert

Check if catheter is clogged and if necessary, perform catheter flushing or positional changes according to hospital protocols. Then Press 'Resume Monitoring.'" (Image 13)

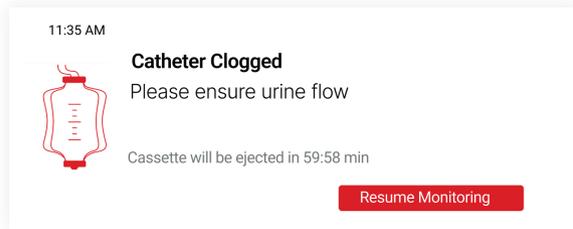


Image 13: Catheter Clogged alert

Kit Expiration alert

The disposable kit is considered expired after 14 days or after reaching its maximal drainage capacity. Replace the kit as described in the Patient Care section. Kit status can be viewed at any time by pressing the cassette icon in the upper toolbar (see Image 7 label 6).

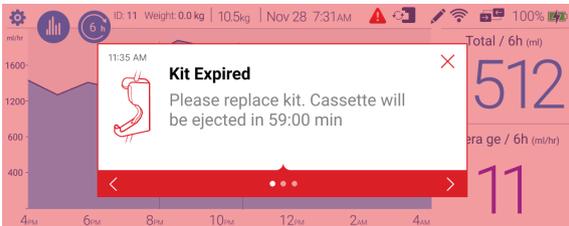


Image 14: Kit Expiry alert

Patient Care

Kit Replacement

- 1 Eject cassette by pressing the Eject button (Image 15B).
- 2 Disconnect kit from catheter and attach a new disposable kit as described in the 'Disposable Kit' section

The device will track and alert when a kit needs replacement as shown in the 'Alerts' section.

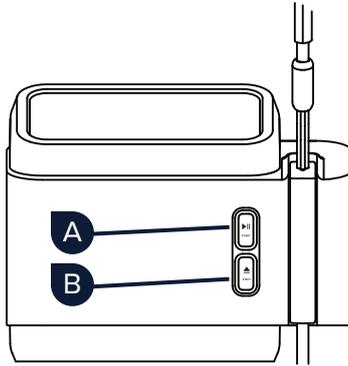


Image 15: Buttons on console

Urine Sampling

Urine sample may be collected while monitoring through the dedicated urine-sampling port, using a compatible, needle-free syringe. Avoid using needles, thus introducing air into the system.

Catheter Irrigation

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

To flush through urine-sampling port:

- 1 Close clamp below the catheter.
- 2 Lock needleless syringe into designated port and steadily introduce flushing fluid.
- 3 If necessary, deduct the inserted volume using the Urine Output Edit feature (see Monitoring Display section).

To flush directly through catheter:

- 1 Pause monitoring by pressing the Start/Pause button (Image 15A).
- 2 Disconnect disposable kit from catheter.
- 3 Perform catheter flushing according to hospital standard of care.
- 4 Reconnect disposable kit to catheter – make sure kit is firmly connected to catheter.
- 5 Resume monitoring

Patient Transfer

To transfer a patient with the console, disconnect the console from the power supply (Image 1B). The device may run on its battery for up to 4 hours. If you wish to temporarily disconnect the patient from the console, press the Eject button (Image 14A). Kit will be released and urine will flow into the collection bag without being measured.

To transfer the kit between two consoles, eject the cassette (Image 15A). Insert the cassette into the new console. The console will identify the cassette and prompt the Start Monitoring screen (Image 5). Once the cassette is inserted, patient data such as identifier, weight, alert preferences, and the last 12 hours of monitoring will be transferred automatically to the new console.

MR Safety

The FIZE kUO Disposable Kit is MR Conditional, thus it can remain connected to the patient during an MRI scan. The exact MRI conditions are defined in the Instructions for Use. Please review the information to make sure your MRI is included.

Note: Note: The disposable kit should be located between the patient legs and the urine bag should be located at the end of the bed (on the far side from the MRI scanner). The FIZE kUO console is MR unsafe.

Training video & more

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