FIZE KUO™

Operator's Manual

V- 007

Legal Notice

Disclaimer

FIZE Medical provides this Operator's Manual in its commitment to help reduce patient risk and injury. However, this manual is not intended in any way to replace or substitute duty of care to a patient, professional responsibility, or professional judgment, nor is it intended to provide any warranty, promise, guarantee, assumption of risk or duty, release, or indemnity. Physicians and nurses shall at all times maintain responsibility for patient treatment and outcomes, and FIZE Medical further assumes no liability for patient treatment or outcome or for physician's negligence, breach of duty of care, or malpractice.

The FIZE kUO operator is solely responsible for selecting the appropriate level and method of patient monitoring.

FIZE Medical disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this with other products, whether supplied by FIZE Medical or by other manufacturers, unless such a combination has been specifically endorsed by FIZE Medical. Product modification or misuse can be dangerous.

The design of FIZE kUO, the Operator's and Service Manuals, and the labeling on the device and the disposable kit, take into consideration that the purchase and use of the equipment is restricted to trained professionals, and that certain inherent characteristics of the product are known to the operator. Instructions, warnings, and caution statements are therefore limited to the specifics of the FIZE kUO.

Federal law (US) restricts this device to sale by or on the order of a physician.

This Operator's Manual excludes references to various hazards which are obvious to medical professionals and operators of this equipment, to the consequences of product misuse, and to potential adverse effects in patients with abnormal conditions.

The FIZE kUO is a restricted medical device designed for use by properly trained and qualified personnel under the direction of a physician and in accordance with applicable federal and state laws and regulations.

FIZE kUO operators must recognize their responsibility for implementing safety monitoring mechanisms which supply appropriate information on equipment performance and patient condition. Patient safety may be achieved through a

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wide variety of means, such as electronic surveillance of equipment performance and patient condition. However, equipment surveillance should not replace direct observation of clinical signs.

The liability of FIZE Medical is subject to and limited to the exclusive terms and conditions as set forth herein. Said liability is limited whether arising out of, or related to, the manufacture and sale of goods, their installation, demonstration, sales representation, use, performance, or otherwise. Any liability based upon product warranty is limited regardless of any fault attributable to FIZE Medical and the nature of the action (including breach of warranty, negligence, and strict liability).

The written warranties are in lieu of all other warranties, expressed or implied, including, without limitation, warranties of merchantability, fitness for any purpose, or non-infringement.

FIZE Medical shall not be liable for any special incidental or consequential damages incurred by the buyer to a third party. The buyer shall not be entitled to make liability recoveries from FIZE Medical due to such situations.

Warranty

The FIZE kUO warranty does not apply for/ in case of:

Defects caused by misuse, mishandling, tampering, dropping, or by modifications not authorized by FIZE Medical or its representatives.

Rubber and plastic components and materials, which are guaranteed to be free of defects at time of delivery.

Any product which proves during the warranty period to be defective in workmanship or material, will be replaced, credited, or repaired. FIZE Medical retains the discretion to select the most suitable of these options. FIZE Medical is not responsible for deterioration, wear, or abuse. In all cases, FIZE Medical will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

FIZE Medical or its authorized representatives must be promptly notified upon detection of the defective material or equipment.

Defective material or equipment must be returned to FIZE Medical or its authorized representative.

Examination by FIZE Medical or its authorized representatives must confirm that the defect is covered by the terms of this warranty.

The above is the sole warranty provided by FIZE Medical. No other warranty, expressed or implied, is intended. Representatives of FIZE Medical are not authorized to modify the terms of this warranty.

In no way does this or any of FIZE Medical's policies, training materials, guidelines, or instructions create an obligation for FIZE Medical to perform any services.

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1 Introduction

The FIZE kUO™ is a digital, automatic urine output monitoring device. The FIZE kUO is comprised of two main parts:

- The FIZE kUO Console
    - The console performs the urine output measurement, displays the information on its screen, and transfers data to other hospital systems, such as EMR.
    - The console is connected by the supplied wire to the FIZE kUO Power Supply Box and has a back-up battery for use when transferring patients to procedures or other departments.
- The FIZE kUO Disposable Kit
    - A proprietary, disposable tubing set which includes a urine sample port, the FIZE kUO Smart Sensor, cassette, and a urine-collection bag.
    - The set may be provided as one of the following options:
        - FIZE kUO Full Standard Kit Preconnected to a Foley catheter and provided with all necessary equipment for catheter insertion
        - FIZE kUO Disposable Kit – Can be attached to any Foley catheter 6 Fr. and above.

Figure 1 - The FIZE kUO Device

1.1 Intended Use

The FIZE kUO by FIZE Medical continuously and automatically measures urine output, providing medical staff with accurate, real-time information regarding patient urine production. With FIZE kUO, there is no need to use a manual urine meter.

FIZE kUO may be used on any patient with a Foley catheter, from 6 Fr and above.

FIZE kUO's data can be automatically transferred to the hospital medical records and can also be connected to a local monitoring system.

1.2 Symbols

Symbol	Description
Front Panel	
 START	Initiate/Resume Monitoring
 EJECT	Cassette release button
Rear Panel	
	On/Off button
	Refer to instruction manual
	Caution; consult accompanying documents
	Type BF applied part
	Temperature limitation
	Humidity limitation

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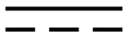
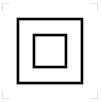
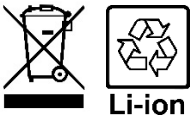
	Atmospheric pressure limitation
	DC – Direct Current
	Class II
	USB – Universal Serial Bus Type C
	Fragile, Handle with care
	Do not use if package is Damaged
	Non-Sterile
	Waste and Li-ion battery inside
	Serial Number
	Lot Number
	Catalog Number
	RX only
	MR Unsafe
	MR Conditional

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	Do not Reuse
	Do not Re-sterilize
	Sterilized using Ethylene Oxide
	Use by date
	Date of Manufacture
	Manufacturer
IP54	Protection against solid particle Protection against ingress of liquid

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2 Safety Instructions

At all times, strictly follow this manual. The safe use of the FIZE kUO requires full understanding of its operation, and adherence to the manual's instructions. The equipment is only to be used for the purpose specified in Section 1.1. Observe all the WARNINGS and CAUTIONS posted in this manual, the console, and associated accessories.

2.1 General Warning

External power connection: To maintain grounding integrity when using AC power, only connect to hospital grade receptacles. Always disconnect the external power supply prior to servicing.

All settings and adjustments must be made in accordance with a physician's prescribed therapy. Regular attention by qualified medical personnel is required whenever a patient's urine is measured with the FIZE kUO.

Do not use any kit other than the FIZE kUO Disposable kit.

Always use a sterile FIZE kUO Disposable kit

If a fault is detected, discontinue use immediately and replace the device/use an alternative method of measurement until the fault has been resolved. Contact your provider or FIZE Medical Technical Support if needed.

Failure to address device alarms may result in patient injury.

As Li-Ion batteries are charged and discharged over time, their ability to hold a charge is decreased with use. This shortens the length of time the FIZE kUO can function while on battery power. If needed, contact FIZE Medical Technical Support for assistance.

When the FIZE kUO is used for in-hospital transport, ensure that the internal batteries are fully charged prior to transit and that the FIZE kUO is secured.

When the Low Battery alarm sounds, only a limited amount of battery power remains, and an alternate power source should be found immediately.

Always plug the FIZE kUO into an AC power supply source when not in use, to ensure best battery performance.

To perform Continuous Bladder Irrigation (CBI), disconnect the FIZE kUO from the patient and perform CBI according to standard of care.

The FIZE kUO device is intended to operate in a closed tubing system only. Air leakage into the tubing may prevent accurate measurement and monitoring. Make sure all tubing is intact and properly secured to patient

2.2 Cautions

Do not place liquid containers in the immediate vicinity or on top of the FIZE kUO. Liquids that get into the FIZE kUO can cause equipment malfunction and damage.

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 CAUTION	All service or repairs performed on the FIZE kUO must be performed by an authorized FIZE Medical technician
 CAUTION	Batteries contain Li-Ion. Do not discard them in an incinerator or force them open. Batteries should not be disposed of with normal waste

3 FIZE kUO Device Description

3.1 Console

3.1.1 Front Panel Features

The front panel contains the control buttons, display screen, and the disposable kit insertion space.

Figure 2 – Front Panel

Label	Name	Description
1	Touch Screen	Touch Screen for operation and monitoring.
2	Start/Pause Button	To Start or Pause monitoring
3	Eject Button	To eject the cassette or replace the disposable kit)

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3.1.2 Back Panel

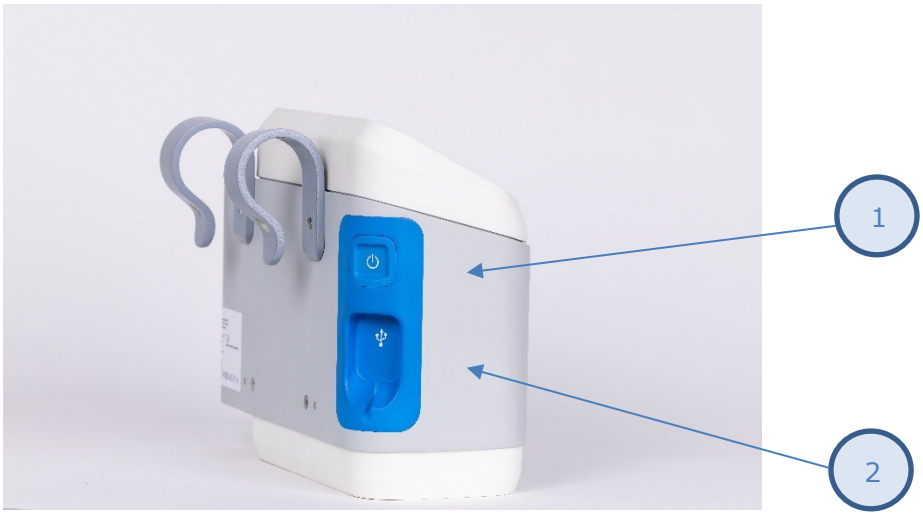

Figure 3 – Back Panel

Features

Label	Name	Description
1	On/Off Button	Power on/off the device
2	Power Supply Connector	Connecting the Power Supply to the device using the provided cable

3.1.3 LCD Screen

The LCD screen of the FIZE kUO is divided into two sections:

- Patient Monitoring Section
- Settings Section

3.1.3.1 Patient Monitoring Section

In the Patient Monitoring Section, real-time urine output measurements are displayed. Patient urine output can be viewed in bar chart display (Figure 4A) or trendline display (Figure 4B).

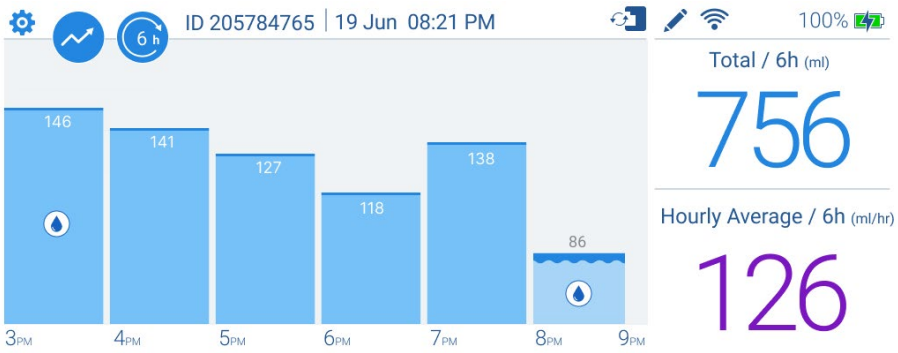

Figure 4A – Monitoring Display – Bar Chart

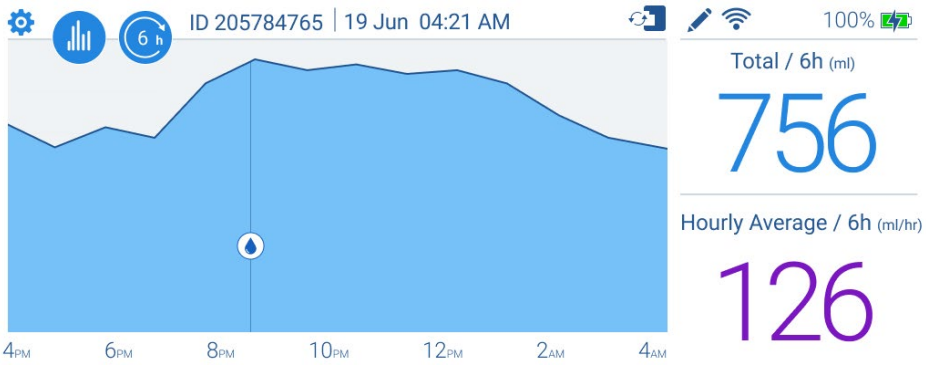

Figure 4B – Monitoring Screen – Trendline Display

3.1.3.2 Settings Section

3.1.3.2.1 Patient Settings Screen

In the Patient Settings screen, user can define patient ID, weight and set personalized alerts.

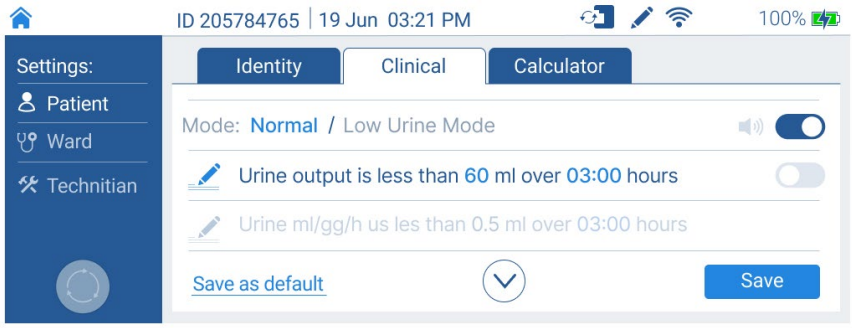

Figure 5 – Patient Settings Screen

3.1.3.2.2 Ward Settings Screen

In the Ward Control Screen, user can define general ward parameters and set the Ward alerts. Note that the Ward alert settings serve as the default settings for every new patient.

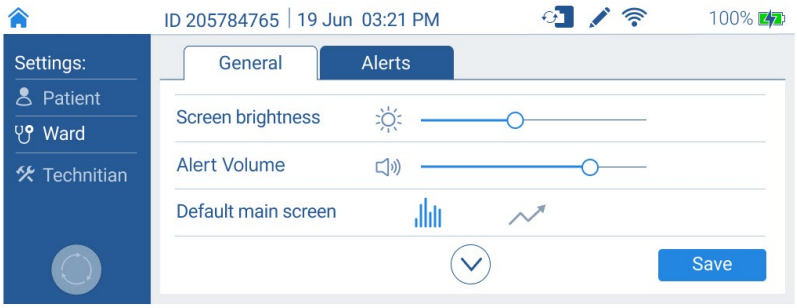

Figure 6 – Ward Settings

3.1.3.2.3 Technical Settings Screen

The 'Technician' section includes connectivity and IT parameters. The Technician section is password protected and should be entered only by a FIZE Medical authorized technician.

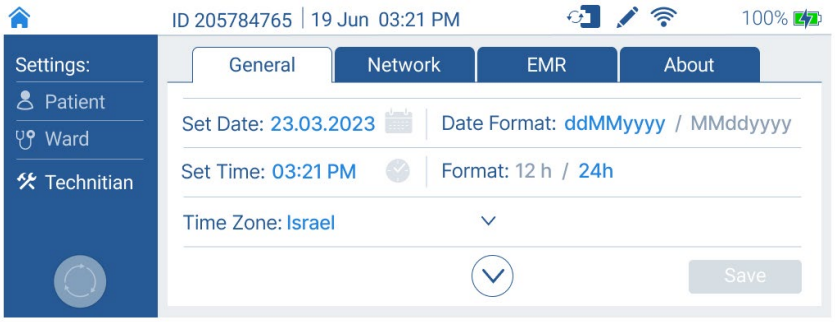

Figure 7 - Technician Settings Screen

3.2 The Disposable kit

The Disposable kit is comprised of a tubing set, urine-sample port, a proprietary sensor, and a urine collection bag. The disposable kit may be provided as one of the two options:

- FIZE kUO Full Standard Kit - Preconnected to a Foley catheter and provided with all necessary equipment for catheter insertion
- FIZE kUO Disposable Kit – Can be attached to any Foley catheter 6 Fr. And above

The disposable kit is inserted into the console as seen in Figure 8. The kit can be easily clipped in/out of the device for ease of handling.

Figure 8 – The FIZE kUO Disposable Kit

3.5 Wireless Radio-Frequency Identification (RFID) System

The FIZE kUO device incorporates a wireless Radio Frequency Identification (RFID) system between the kit and the device. The system consists of two main elements: tags and readers. RFID tags have the capability to store data, which the reader identifies through a wireless connection. In the FIZE kUO device, the kit includes an RFID tag, while the console contains the reader. The tag securely stores patient information such as the patient's identifier number, weight, the last 12 hours of monitoring data, kit usage metrics, and more.

4 Once a new patient is saved unto a kit, his details are stored to the RFID tag. This allows easy tranfer of patient data between different consoles, as well as track kit usage and alert on its upcoming expiry.

4 Installation

4.1 Introduction

Familiarize yourself with the instructions in this section prior to installing the FIZE kUO. Following all the listed steps is essential for ensuring the safest possible operation of the device. Use the information in this section in conjunction with established hospital protocols.

Only properly trained personnel should install the FIZE kUO.

4.2 Unboxing the FIZE kUO

Before installing the FIZE kUO, familiarize yourself with the various components. Remove all the items from the package and inspect each part and component and verify that there is no damage.

The complete assembly consists of the following parts:

- FIZE kUO Console
- FIZE kUO Power Supply Box
- FIZE kUO Instructions for Use
- AC Power Cord
- USB Type C cable (to connect the FIZE kUO Console to the Power Supply)
- Custom hangers (may be provided separately)

4.3 Mounting the FIZE kUO

Mount the FIZE kUO Console to the bed railing using the provided, custom hangers.

The console can be placed up to 20 cm above or below patient level.

Firmly secure the console to bed railing

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4.4 Connecting the FIZE kUO to Power Source

1. Plug the AC power cord into the Power Supply Box entry connector.
2. Connect the USB Type C cable to the Power Supply Box and to the FIZE kUO console.
3. Plug the FIZE kUO's AC power cord into a properly grounded outlet. The white led light in the Power Supply Box USB type-C entry connector indicates that the device is properly connected to the power source.

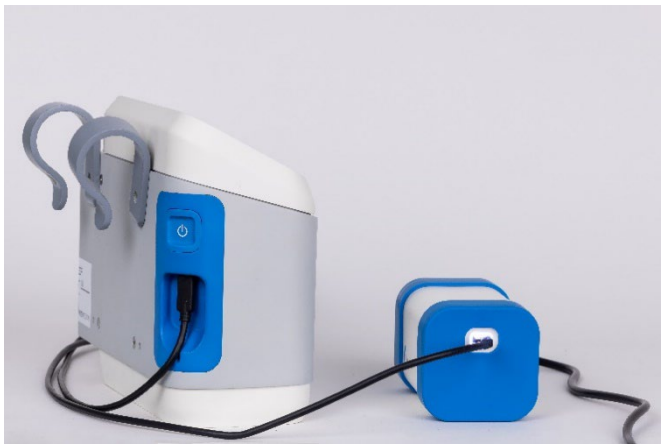

Figure 9 – FIZE kUO Power Supply

4.5 Initial Setup

1. Press the power button (see Figure 3) and wait for the device to turn on, click on the settings icon.
2. Make sure device regional settings and measurement units are correct. If necessary, follow the screens to the Technician Settings Screen (see Figure 7) and configure settings with a FIZE Medical authorized technician.

5 Operating the FIZE kUO

5.1 Basic Operation

5.1.1 Powering on the FIZE kUO

To turn on the FIZE kUO, press the On/Off button in the back panel (see Figure 3).

5.1.2 Connecting the Disposable Kit

FIZE kUO Full Standard Kit:

1. Open the FIZE kUO Full Standard Kit sterile bag.
2. Close the clamp under the catheter.
3. Perform catheter insertion according to hospital guidelines and the FIZE kUO Disposable Kit Instructions for Use.
4. Insert cassette into the console (see Figure 10)
5. Open the clamp
6. Make sure tubing is properly secured to patient and secure the urine collection bag to the bed below patient level.

FIZE kUO Disposable Kit:

1. Open the FIZE kUO Kit sterile bag
2. Close the clamp under the catheter.
3. Remove the cap from the kit and connect the kit to the catheter as instructed in the FIZE kUO Disposable Kit Instructions for Use.
4. Insert the Disposable Kit cassette into the console (see Figure 10)
5. Open the clamp
6. Make sure tubing is properly secured to patient and secure the urine collection bag to the bed below patient level.

Figure 10 – FIZE kUO Disposable Kit insertion to console

5.1.3 Patient Definition

Following cassette insertion, the system will prompt the Patient Details Screen (Figure 12). Insert patient identification number and weight and press Save.

If the console contains previous patient data, the system will first prompt the Patient Definition screen (see Figure 11)

1. For continuing with previous patient - click "Continue with previous patient."
2. For defining a new patient - Click "Discard and start new patient". The system will prompt the Patient Details (Figure 12) Screen. Insert patient identification number and weight and press Save.

Note that when a New Patient option is selected, previous patient's data history is deleted.

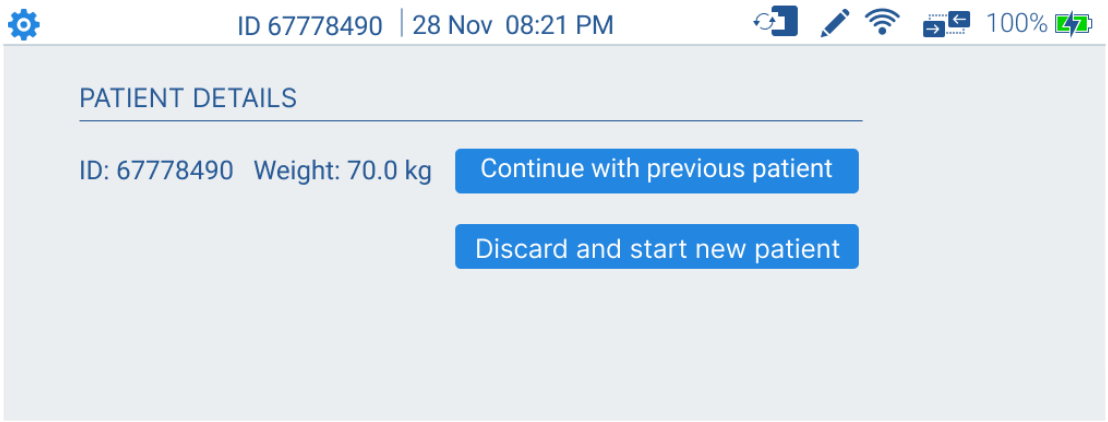

Figure 11 – Patient Definition screen

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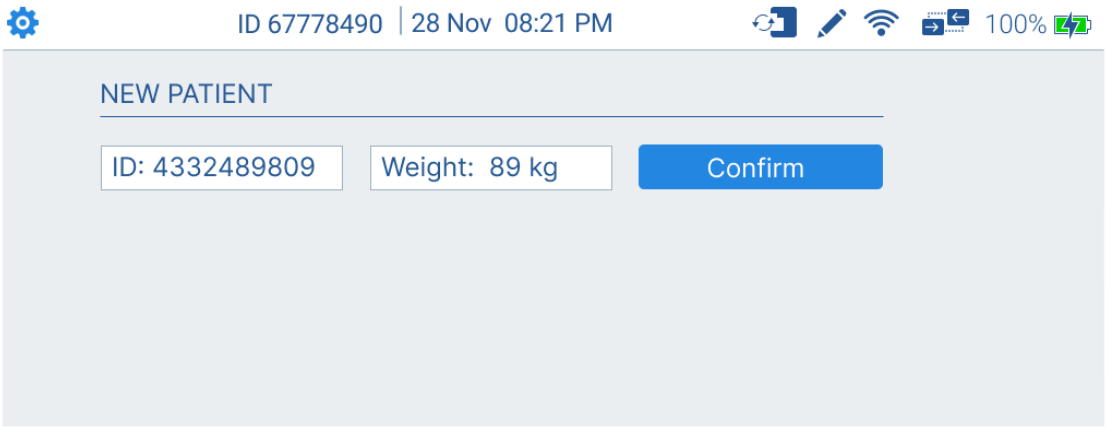

Figure 12 – Patient Details screen

5.1.4 Initialization

Once a patient is defined, the Measurement Initialization Screen will be displayed (See Figure 13). Press the blue button on the screen to start monitoring.

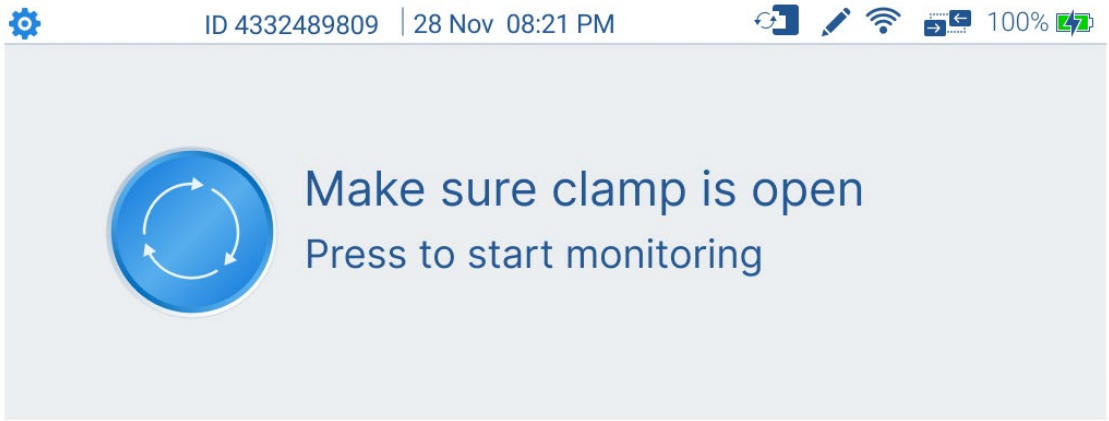

Figure 13 – Measurement Initialization Screen

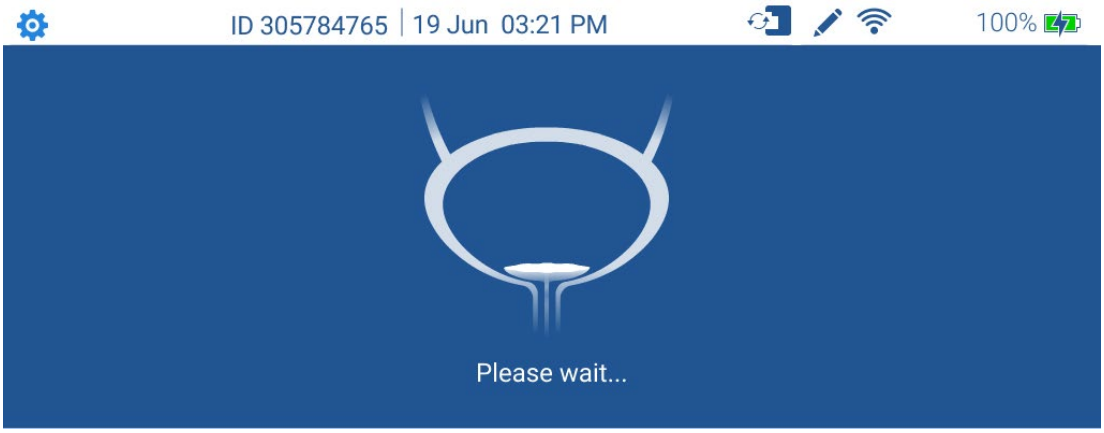

Figure 14 – Initialization in Progress Screen

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During initialization (Figure 14), residual urine in the bladder will be emptied. The volume emptied will be displayed at the end of the animation and can also be viewed in the monitoring display when pressing the drop icon (Figure 15). This amount will be included in the hourly total.

5.1.5 Patient Monitoring

Once initialization is complete, the system will prompt the Patient Monitoring Screen and urine output data will appear.

The bar chart display (Figure 15) presents the total urine output per hour (ML). The trendline display presents minute-by-minute urine flow rate (ML/HR) (see Figure 16).

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.

The function of each icon on the screen can be viewed in Table 1.

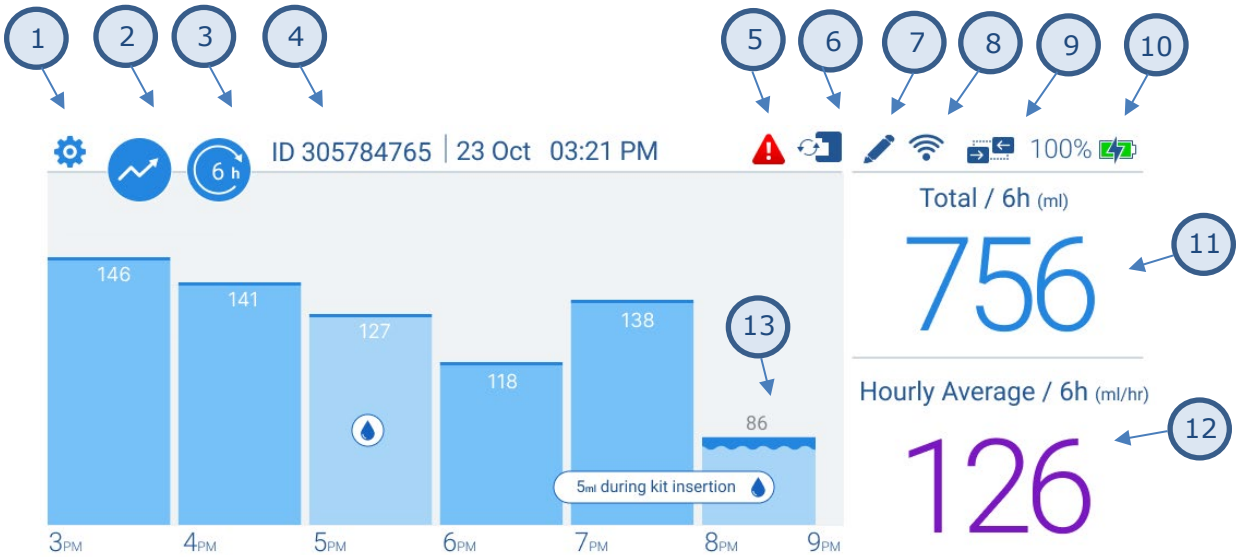

Figure 15 – Patient Monitoring Screen – bar chart display

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Label	Name	Description
1	Settings icon	Press to enter Settings section
2	Graphic display	Display mode – press to switch from bar chart to trendline
3	Time window	Select preferred timeframe
4	Patient ID	Patient ID
5	Active alerts	Active alerts - Press to open
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	Appears when device is connected to the hospital EMR system
10	Battery status	Battery status
11	Total Urine Output	Total urine output in the selected time window
12	Average Urine Output and Weight-Adjusted Average Urine Output	Hourly average in ML/HR or ML/KG/HR for the selected time window.
13	Drop Icon	Press to see residual urine or manual edits added to bar volume.

Table 1 – Patient Monitoring Screen Icons

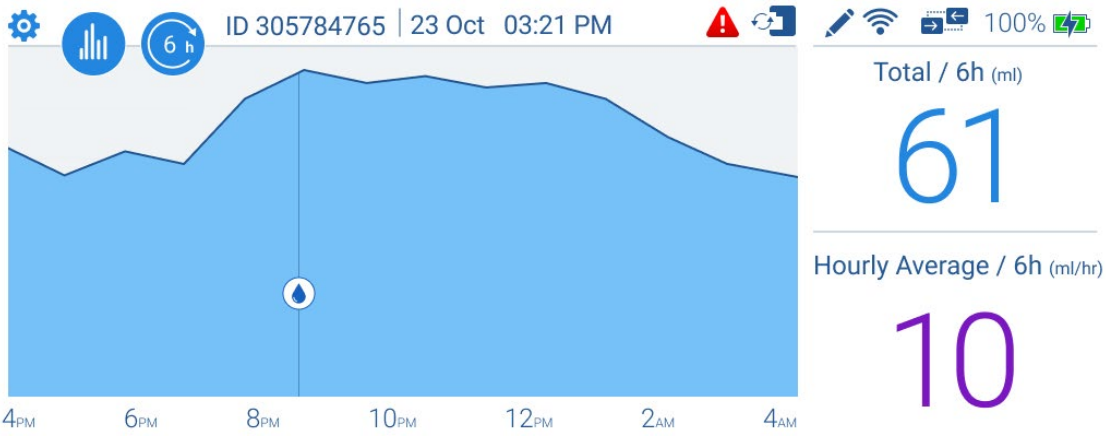

Figure 16 – Patient Monitoring Screen – trendline display

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5.1.6 Inserting an Intervention

To monitor patient response to different interventions such as fluid boluses, diuretics, vasopressors, or inotropes, press the pencil icon in the upper toolbar (See Figure 15 label 11). In the pop-up window, insert intervention time and type and press Save (Figure 17). Intervention will be marked on the trendline (Figure 18).

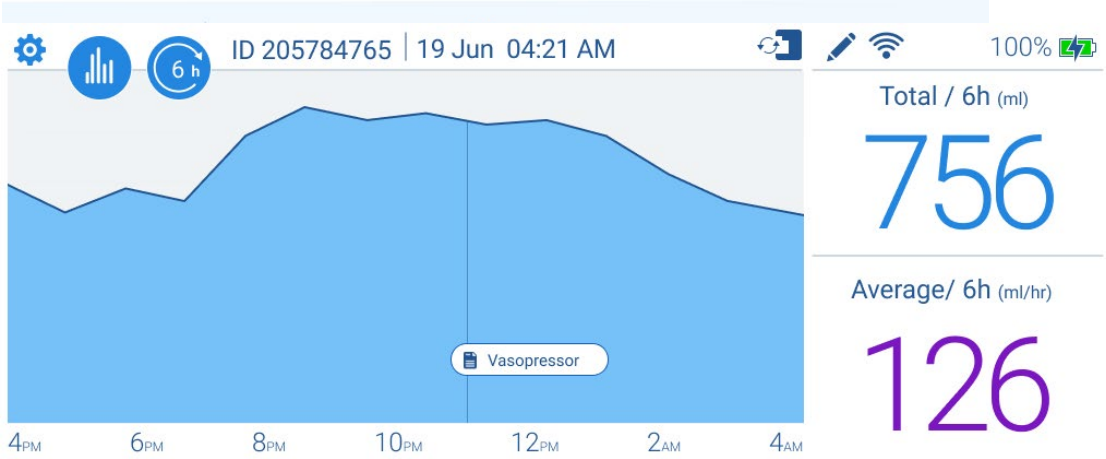


Figure 18 – Intervention display on Trendline

5.2 Urine Sampling

Urine sample may be collected while monitoring through the dedicated urine-sample port, using a compatible, needle-less syringe. Take caution not to damage the port, as air may leak into the tubing system.

Figure 19 – Disposable Kit Urine-Sample Port

5.3 Catheter Irrigation

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

1. Washout directly through catheter

a. Pause monitoring by pressing the Pause button (Figure 2).
b. Disconnect disposable kit from catheter.
c. Perform washout according to hospital standard of care.
d. Reconnect disposable kit to catheter – make sure kit is firmly connected to catheter.
e. Press Start (Figure 2) to resume monitoring

2. Washout through the urine-sample port:
   a. Close clamp tubing between sample port and sensor
   b. Insert washout fluid through port according to hospital standard of care.
   c. Open the clamp
   d. If necessary, deduct the inserted washout fluid using the Edit Feature (see Section 5.7 – Editing Urine Output Volume)

5.4 Patient Transportation

1. If you wish to keep tracking urine output during in-hospital transport, you may keep patient connected to the device. Disconnect the console from the power cable and transport bed with the device. The console may operate on its battery power for up to 4 hours.

2. If you wish to temporarily disconnect the patient from the console, press the "Eject" button (see Figure 2). Cassette will be released, and the disposable kit will serve as a regular urine drainage tubing and bag. To resume measurement – insert cassette back into the FIZE kUO console. Select "Continue with previous patient' and resume monitoring.

3. If you wish to transfer a patient between two different consoles, eject the cassette by pressing the "Eject" button (see Figure 2) and insert the cassette into the new console. The console will identify the cassette and prompt the Start Monitoring screen (see Figure 13). Once the cassette is inserted, patient data such as identifier number, weight, alert preferences, and the last 12 hours of measurement will be transferred to the new console. Previous patient data saved onto the console will be deleted.

5.5 Editing Urine Output Volume

Editing urine output volume may be relevant under two cases:

1. Removing fluid inserted into the tubing through the urine sample port during a bladder washout.

2. Adding missing urine volume that was not measured due to a cassette ejection.

Urine output editing is possible in the In Progress bar. Data from closed hours already sent to the patient EMR cannot be edited retroactively through the console.

To edit urine output:

1. Long press the In Progress bar
2. Fill in the volume you would like to add or remove in the pop-up window (Figure 20)
3. Press Save

Once manually edited, the bar will appear green (Figure 21). The volume edited can be viewed by pressing the drop icon.

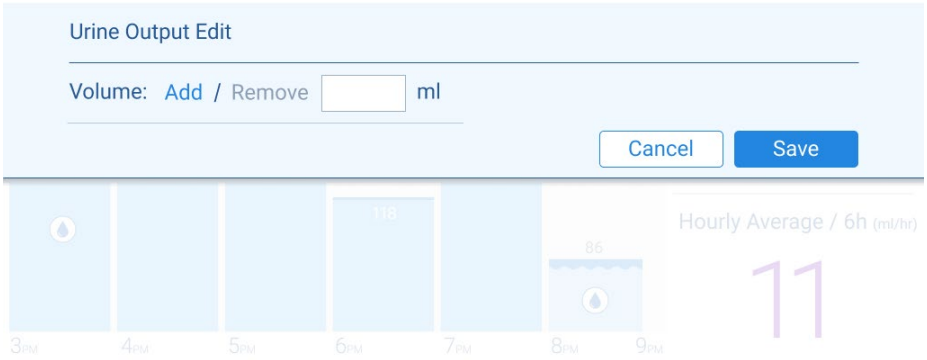


Figure 20 – Urine Output Edit Pop-Up Screen

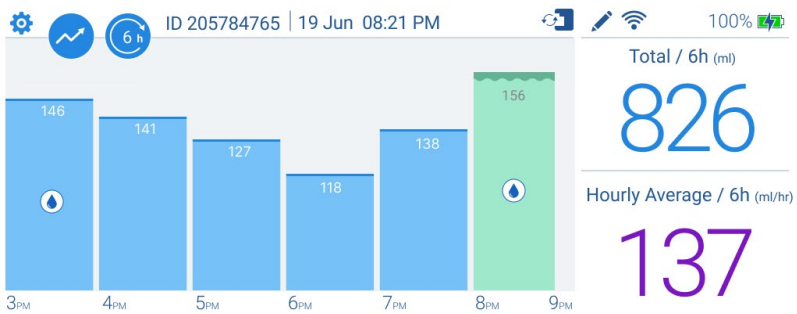


Figure 21 – Manually Edited Bar

5.6 Calculator

To calculate the total and average urine output for a specific time window, enter the Settings section, Patient tab, under the 'Calculator' section (see Figure 22a). Select the Start and End time of your time window and press Calculate.

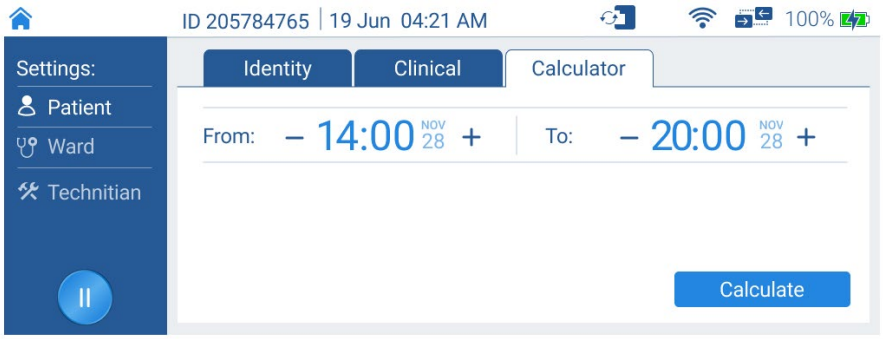


Figure 22a – Calculator Tab

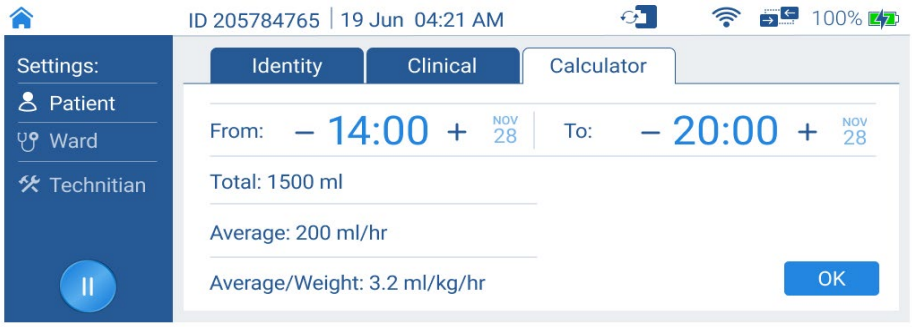


Figure 22b – Calculator Tab

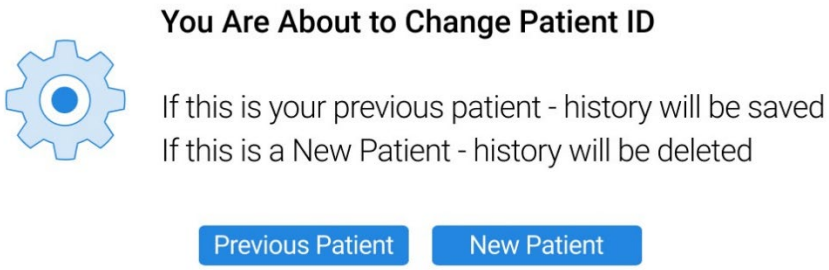
5.7 Editing Patient Identifier

Editing a patient identifier may be relevant in two cases:

1. A new kit was inserted, but the wrong patient identifier was inserted and saved
2. A new kit was inserted, and 'Continue with Previous Patient' was accidentally pressed instead of 'New Patient'.

In case patient identifier must be edited, eject the cassette, re-insert it, and go to Settings->Patient->Identity. Press the ID field and edit it as needed.

Once you press Save, a warning alert will appear on the screen.



1. In case the wrong identifier was inserted, press the 'Previous Patient' button, such that the patients' data history will be saved

2. In case of an accidental assignment of previous patient data to a new patient, press the "New Patient" button and previous patient's data history will be deleted.

5.8 Kit Expiry

All types of the FIZE kUO Disposable kit expire following 14 days of use or following or after reaching their maximal drainage capacity. To replace disposable kit:

1. Press the "Eject" button (see Figure 2)
2. Remove disposable kit from patient as outlined in the FIZE kUO Disposable Kit Instructions for Use.
3. Safely dispose of disposable kit
4. Connect a new disposable kit as described in Section 5.1.2 – Connecting the Disposable Kit.

Once kit expiry is about to be reached, an alert will be prompted on the screen. In addition, you may monitor kit status by pressing the cassette icon in the screen's upper toolbar (see image 15 label 6)

5.9 Patient Discharge

For final disconnection from the device:

1. Press the "Eject" button (see Figure 2)
2. Remove disposable kit from patient as outlined in the FIZE kUO Disposable Kit Instructions for Use.
3. Safely dispose of disposable kit

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4. Sanitize console according to Section 9 – Cleaning and Maintenance

5.10 Shutting Down the FIZE kUO

To shut down the FIZE kUO:

1. Press the On/Off button in the back panel (Figure 3)
2. A pop-up message will appear to confirm shut down. Press 'Approve' to continue with shut down.

6 Alerts

6.1 Alert Types

Table 2 provides a list of the FIZE kUO alerts and their respective solutions.

No.	Displayed Massage	Description	Sound Alarm Option	Solution
1	Low Urine Volume	The system has identified urine output (ML) below the defined threshold	Yes	Check patient clinical status. If no action is needed, close alert. if needed, change the defined alert thresholds (See Section 6.3 – Alert Configuration)
2	Low Urine Volume	The system has identified urine output (ML/KG/HR) below the defined threshold	Yes	Check patient clinical status. If no action is needed, close alert. if needed, change the defined alert thresholds (See Section 6.3 – Alert Configuration)
3	High Urine Volume	The system has identified urine output (ML) above the defined threshold	Yes	Check patient clinical status. If no action is needed, close alert. if needed, change the defined alert thresholds (See Section 6.3 – Alert Configuration)
4	High Urine Volume	The system has identified urine output (ML/KG/HR) above the defined threshold	Yes	Check patient clinical status. If no action is needed, close alert. if needed, change the defined alert thresholds (See Section 6.3 – Alert Configuration)
5	No Urine Detected	Close to no urine was detected by the system due to catheter clog or patient clinical status. Cassette will be ejected in 60 minutes.	Yes	Check if the catheter is clogged and perform irrigation if necessary. If low urine is expected, you may switch to 'Low Urine Mode' (See Section 7 – Low Urine Mode)
6	Monitoring Paused	Monitoring paused by the user. Cassette will be ejected in 60 minutes.	Yes – 5 minutes before cassette ejection	Press "Resume" to continue monitoring
7	Define Patient	Cassette was inserted but patient was not defined. Cassette will be ejected in 17 minutes.	No	Define patient in Patient Definition Screen (see Figure 11-12)

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8	Start Monitoring	Patient was defined but monitoring was not started. Cassette will be ejected in 15 minutes	No	Press Start Monitoring (see Figure 14)
9	Battery Low	Console battery status is at 30%	Yes	Connect console to power supply using the provided cable
10	Battery Very Low	Console battery status is at 20%. Cassette is ejected	Yes	Connect console to power supply using the provided cable. Re-insert cassette and resume monitoring
11	Battery Dead	Battery depleted. Device will shut down in 1 minute	No	Connect console to power supply using the provided cable. Turn device on, re-insert cassette and continue monitoring.
12	Battery Failure	Battery malfunction prevents device operation on battery alone.	No	Keep device connected to power supply and notify FIZE Medical Technical Support
13	Battery Overheated	The system has identified battery overheating	No	Restart device, re-insert cassette and resume monitoring. If the issue is not resolved, replace console and notify FIZE Medical Technical Support
14	Battery Too Cold	The system has identified battery overcooling	No	Restart device, re-insert cassette and resume monitoring. If the issue is not resolved, replace console and notify FIZE Medical Technical Support
15	Very High Urine Flow	The system identified very high urine flow rate. Monitoring was paused due to a suspected air leak in tubing. Cassette will be ejected in 60 minutes.	Yes	Make sure kit is not disconnected from the catheter and press Resume.
16	Cassette Ejected	Cassette was ejected by the system due to an unaddressed alert (low battery, suspected catheter clog, etc.)	Yes	Check cause for cassette ejection and address accordingly. After eliminating the cause of the alert, re-insert cassette and resume monitoring.
17	Disposable Kit Connection Failed	A problem was detected during kit insertion. Cassette is ejected.	Yes	Try inserting the cassette again. Make sure you follow cassette insertion instructions as detailed in section 5.1.4. If the problem repeats, replace kit.

18	Cassette Release Failed	Cassette failed to properly release from console when ejected	Voice alert always on	Pull out the cassette manually. Insert cassette and eject it again to make sure cassette release mechanism is in order. If no issues arise – insert the cassette back in and resume monitoring. If the problem repeats - replace kit.
19	Kit Failure	Kit malfunction occurred while monitoring. Cassette will be ejected in 60 minutes.	Yes	Replace kit
20	Kit About to Expire	Kit is about to expire	Yes	Replace kit when possible
21	Kit Expired	Kit has reached its expiry. Cassette will be released in 60 minutes	Yes	Replace kit and continue patient monitoring
22	Initialization Failed	Measurement initialization could not be completed.	Yes	Initialization may fail due to a kit malfunction, or if it did not complete due to a very high volume of residual urine. Try Initializing again. If initialization fails, replace kit.
23	System Overheated	System overheating prevents proper device function. Cassette will be ejected in 60 minutes.	Yes – 5 minutes before cassette ejection	Restart device, re-insert cassette if necessary and resume monitoring. If the issue is not resolved, replace console and notify FIZE Medical Technical Support
24	Hardware Failure	System detected a hardware failure while monitoring. Cassette will be ejected in 60 minutes.	Yes	Restart device by pressing the 'Restart' button in the alert. If the issue is not resolved –shut down device and contact FIZE Medical Technical Service

Table 2 – Device alerts

6.2 Alert Configuration

Alerts can be configured in the Settings Screen.

6.2.1 Ward Default Alerts

Alert defaults for all patients in the unit are defined in the Settings screen under the Ward tab, alerts section (see Figure 23). Alert configuration is available for clinical alerts, critical alerts and cassette ejection alerts.

6.2.1.1 Clinical alerts

Define thresholds for Low Urine Volume and High Urine Volume alerts by pressing the pencil icon.

Enable or disable alerts by pressing the knob icon.

Enable or disable alert sound by pressing the speaker icon.

6.2.1.2 Critical alerts

Critical alerts include alerts which may lead to a cassette ejection. This alert category includes:

1. Low Battery alert
2. No Urine Detected alert
3. Initialization Failed alert
4. Very High Urine Flow
5. Hardware Failure alert
6. Kit Failure alert

To enable or disable the alert sound, press the speaker icon.

To keep a small alert on the screen as long as alert is active, press the thumbtack icon.

6.2.1.3 Cassette Ejection alerts

Cassette ejection alerts include any cassette ejection by the system.

To enable or disable the alert sound, press the speaker icon. Once the alert sound is activated, the alarm will begin 5 minutes prior to cassette ejection and will continue while cassette is released.

To keep a small alert on the screen as long as alert is active, press the thumbtack icon.

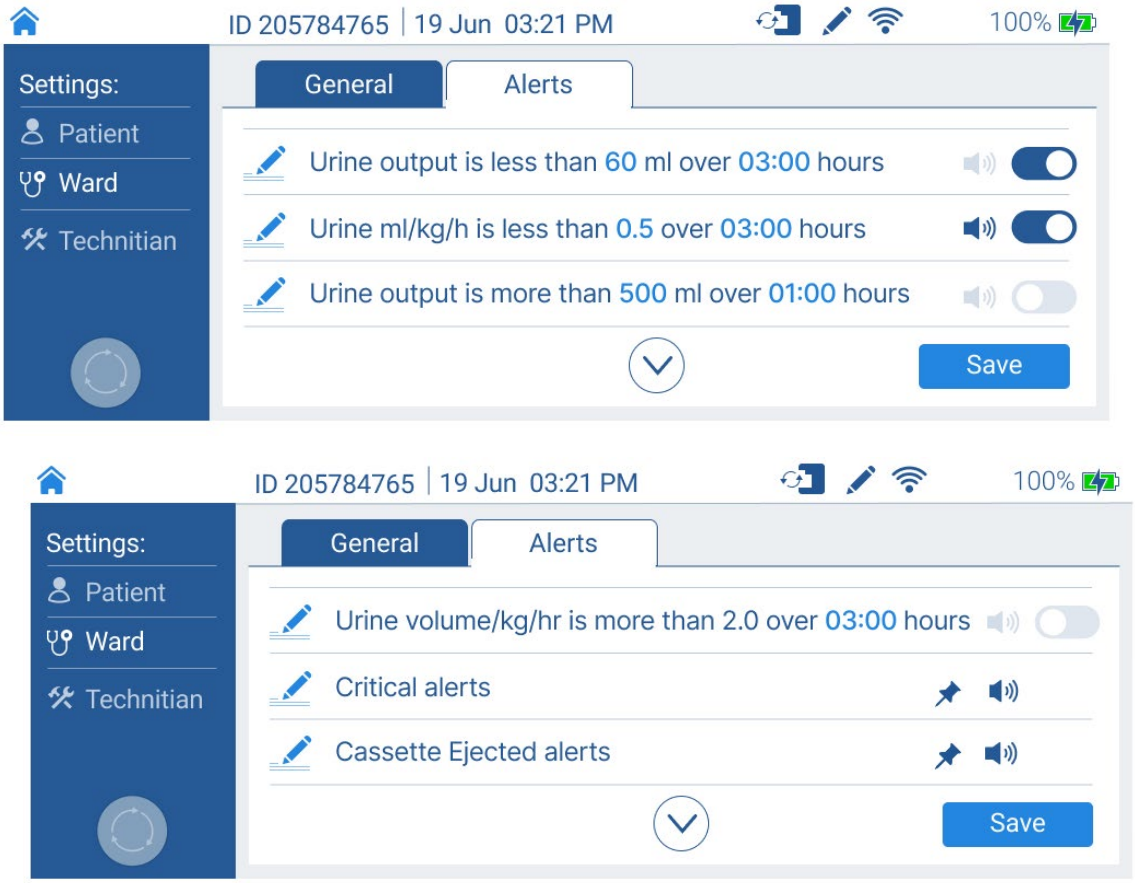

Figure 23 – Ward Alert Settings

6.2.2 Patient-Specific Alerts

Patient-specific alerts can be defined in the Settings Screen, Patient tab, under the 'Clinical' section (see Figure 24). Patient-specific alerts overrule Ward defaults. Once patient data is removed and a new patient is defined in the system, patient-specific alerts are deleted, and the device returns to default settings defined in the ward section.

To enable/disable alert press the switch icon.

To enable/disable sound press the speaker icon.

To edit urine output thresholds of clinical alerts, press the pencil icon. Insert the required threshold and press Save.

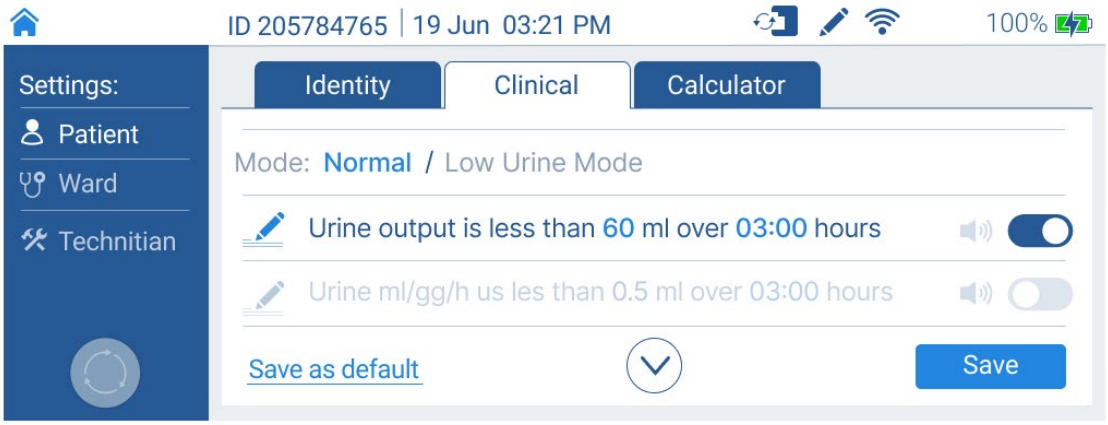

Figure 24 – Patient Alert Settings

6.3 Cassette Ejection Safety Mechanism

The Cassette Ejection Mechanism is a safety measure aimed to prevent potential urine flow obstruction.

In specific alerts, a timeout is initiated in which the user must address the alert.

If an alert is not approved by the user in the set time, the cassette will be ejected, and urine will flow to collection bag without being measured.

The Cassette Ejection Mechanism applies under the following conditions:

Alert Type	**Time to approve**
No Urine Detected	60 minutes
Very High Urine Flow	60 minutes
Monitoring Paused	60 minutes
Define Patient	17 minutes
Start Monitoring	15 minutes
System Overheated	60 minutes
Hardware Error	60 minutes
Kit Failure	60 minutes
Battery Very Low	Cassette immediately ejected

7 Low Urine Mode

Low Urine Mode refers to a state of the program which enables monitoring of patients with extremely low urine output. Low urine mode enables monitoring at a higher visual resolution, without 'Low Urine Volume' and 'No Urine Detected' alerts.

CAUTION

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

During monitoring, if close to 0 ml were detected by the system over approximately one hour, a 'No Urine Detected' alert will be prompted (see Figure 25). If a catheter clog was excluded and low urine is expected in your patient, you may switch to 'Low Urine Mode':

1. Press the 'Low Urine Mode' button in the alert (Figure 25)
2. Press OK in the verification message (Figure 26)

'Low Urine Mode' will automatically terminate if patient urine output increases.

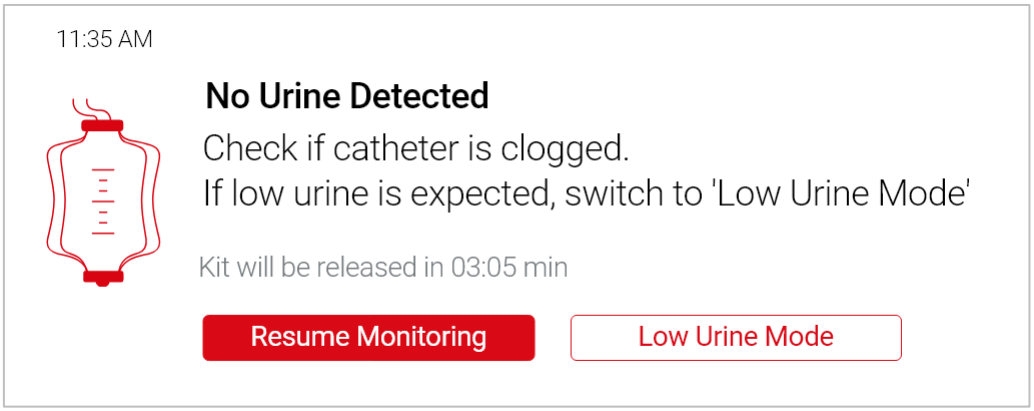

Figure 25 – No Urine Detected Alert

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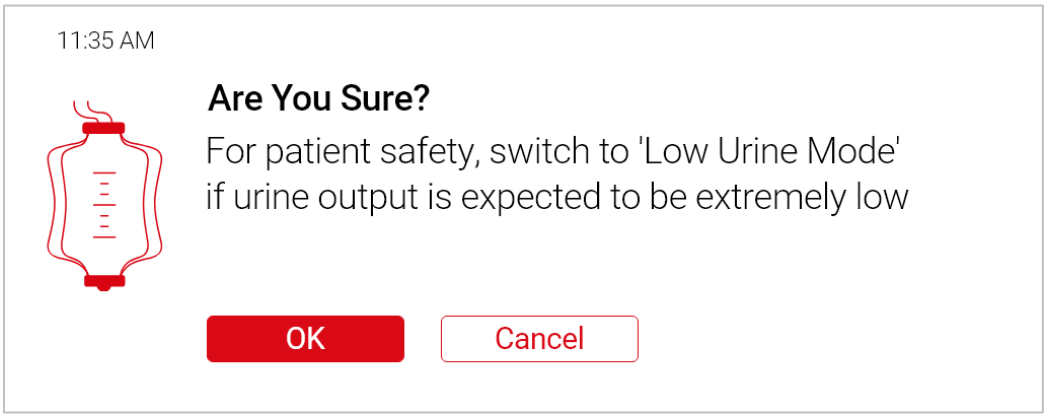

Figure 26 – Low Urine Verification Message

To enable or disable Low Urine Mode through the Settings menu:

1. Go to Patient Settings Screen and press the Clinical tab (Figure 18)
2. Select 'Low Urine Mode'
3. Press 'Ok'

8 Pediatrics Mode

The Pediatrics mode enables urine output monitoring of pediatric patients. The mode is designed to suit a wide range of urine output volumes and catheter sizes, from 6 Fr and above.

FIZE kUO consoles intended for pediatric patient monitoring will be provided pre-programmed with the Pediatrics Mode. To enable Pediatrics Mode in your device, contact the FIZE Medical Technical Support.

The Pediatrics Mode functionality and user interface includes the following modifications:

8.1 Patient Definition

In the Pediatrics Mode, patient weight data is essential for system functionality and calculation of weight-adjusted urine output. Therefore, in the Patient Setup screen, the Weight field is obligatory. Patient weight must be inserted to confirm patient and initiate monitoring.

8.2 Patient Monitoring

The bar chart display presents urine output in ML by default (Figure 27). To see bar chart in ML/KG units, press the 'Hourly Average' value to switch to Weight-Adjusted Hourly Average (Figure 27 label 9). Once pressed, the bar units will transition from ML to ML/KG (Figure 28). The display will switch back to default after a few seconds.
The function of each icon on the screen can be viewed in Table 3.

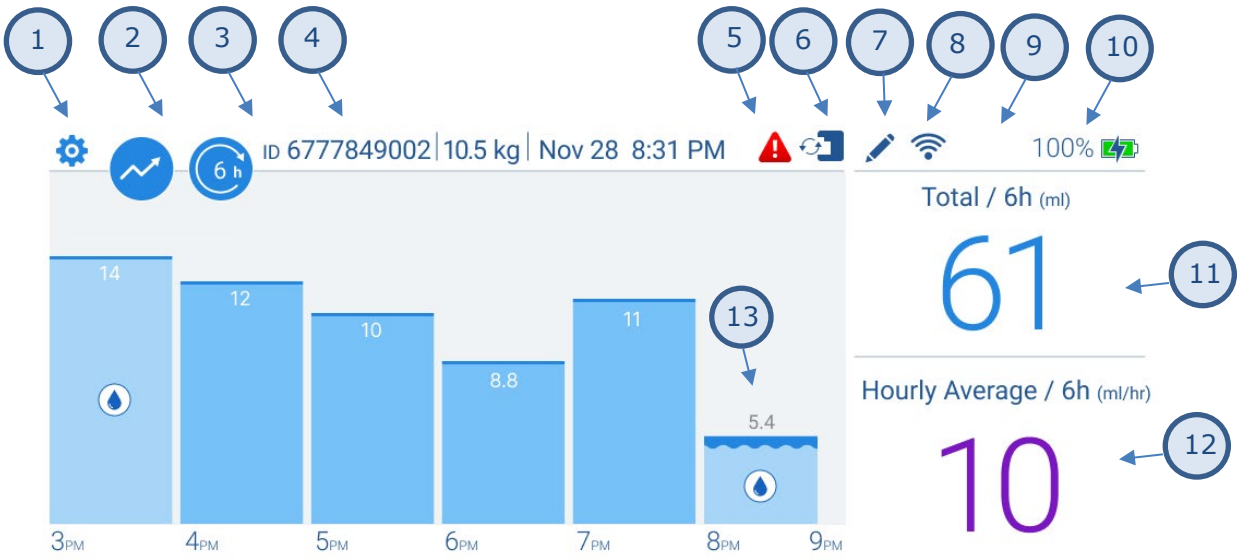

Figure 27 – Patient Monitoring Screen – bar chart display (ml)

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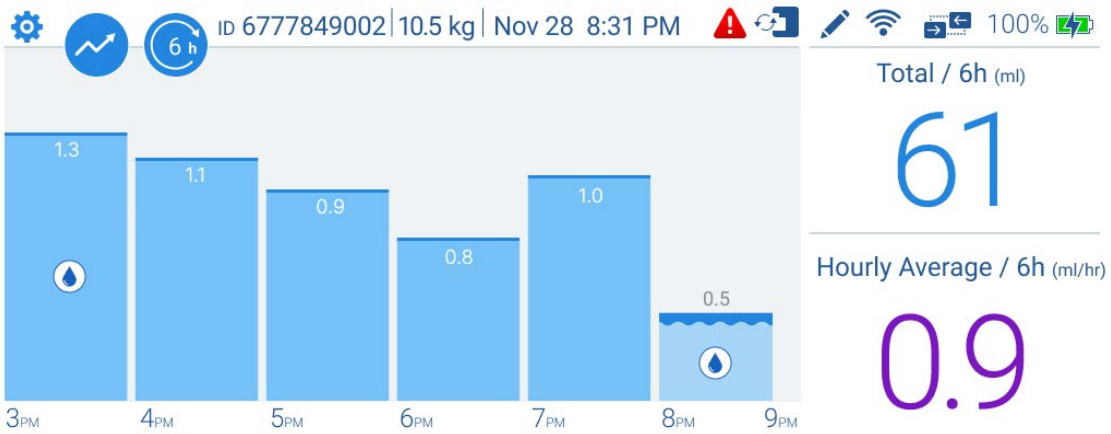

Figure 28 – Patient Monitoring Screen – bar chart display (ml/kg)

Label	Name	Description
1	Settings icon	Press to enter Settings section
2	Graphic display	Display mode – press to switch from bar chart to trendline
3	Time window	Select preferred timeframe
4	Patient ID	Patient ID
5	Active alerts	Active alerts - Press to open
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	Appears when device is connected to the hospital EMR system
10	Battery status	Battery status
11	Total Urine Output	Total urine output in the selected time window
12	Average Urine Output and Weight-Adjusted Average Urine Output	Hourly average in ML/HR or ML/KG/HR for the selected time window. Press to change bar units from ML to ML/KG
13	Drop Icon	Press to see residual urine or manual edits added to bar volume.

Table 3 – Patient Monitoring Screen Icons -Pediatrics

8.3 Pediatric Low Urine Mode

The Pediatric Low Urine Mode operates similarly to the Adult Low Urine Mode and is intended for patients with extremely low urine. The Pediatric Low Urine Mode enables monitoring without 'Low Urine Volume' and "no Urine Detected' alerts.

In monitoring of pediatric patients, if less than 3 ml is detected by the system for over 120 minutes, a 'No Urine Detected' alert will be prompted (see Figure 20). If a catheter clog was excluded and low urine is expected in your patient, you may switch to 'Low Urine Mode':

1. Press the 'Low Urine Mode' button in the alert (Figure 25)
2. Press OK in the verification message (Figure 26)

To enter Pediatric Low Urine Mode through the Settings menu:

Go to Patient Settings Screen and press the Clinical tab (Figure 24)

Select 'Low Urine Mode'

Press 'Ok'

9 Cleaning and Maintenance

9.1 Cleaning and Disinfecting

The FIZE kUO Console and FIZE kUO Power Supply Box are shipped clean but are not in sterile condition.

Use the information in this section in conjunction with hospital policy.

9.1.1 FIZE kUO Console

Sanitize the FIZE kUO Console between patients, and once a week while in use. To clean the FIZE kUO Console and Power Supply Box:

1. Wipe the exterior of the console and all parts not in direct contact with patients using a cloth or wipes dampened with either of the following:
    a. NaDCC medical cleaning solution
    b. chlorine-based medical cleaning solution
    c. Ammonium chloride medical cleaning solution
    d. Quaternary ammonium medical cleaning solution
    e. Alcohol-based medical cleaning solution
2. Following cleaning, the screen may be wiped dry with a paper towel or a lint cloth.
3. Air dry.

Refrain from applying cleaning solutions, solvents, or liquids directly onto the type C cable tip. Such substances may damage internal components or compromise the device electrical connections.

9.1.2 FIZE kUO Disposable Kit

The FIZE kUO Disposable Kit is delivered sterile and should not be reused or cleaned under any circumstance.

9.2 Periodic On-Site Maintenance

it is recommended that the following maintenance tasks be performed once a year:

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1. Perform a calibration verification using the designated calibration kit.
2. Clean peristaltic pump rollers thoroughly using the specified cleaning detergents mentioned in section 9.1.1.
3. Visually inspect device integrity, including the screen, bed-handles, and USB type-C connector attached to the console. Check for any signs of corrosion in the cassette insertion site.
4. For optimal battery maintenance, it is recommended to allow the battery to deplete to its minimum, then recharge to its maximum capacity.

9.3 General Warnings

1. Repairs and service may only be performed by FIZE MEDICAL authorized technician. trained or factory-authorized personnel.
2. Always follow accepted hospital procedures or physician instructions for handling equipment contaminated with body fluids.

9.4 Contact Information

Address further questions or problems to one of the FIZE Medical Technical Support.

FIZE Medical Ltd.
Address: Hashdera Hamerkazit 15, Modi'in, Israel

Email: Service@FizeMedical.com

Or call the Service number on the FIZE kUO Console.

10 Technical Specifications

10.1 Physical Specifications

Physical Characteristics	Specification
Weight	2.6 KG
Dimensions(mm)	265 x 215 x 111
FIZE kUO kit	1.80 meters
Urine Volume Measurement	Range: 0 to 2000 ml Accuracy: 3%

10.2 Electrical Specifications

Voltage	Frequency	Current Consumption
100 – 240 VAC	50 – 60 Hz	0.9 Amp MAX

10.3 Internal Battery Specifications

Battery Characteristic	Specification
Integral Battery	
Battery Type	Li-Ion
Nominal Voltage	VDC 10.8
Nominal Pack Capacity	AH 5.2
Average operating time for the battery: When new and fully charged, the batteries supply power for up to 4 hours of operation.	

10.4 Safety and Particular Standard Specifications

Safety	IEC60601-1 Medical electrical equipment general requirements for basic safety and essential performance.
	IEC60601-1-2 General requirements for basic safety and essential performance; Collateral standard: electromagnetic compatibility.

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IEC 60601-1-8 (2003) 1st edition Medical electrical equipment – Parts 1-8: general requirements for safety; Collateral standard: general requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.

10.5 MRI Safety Information

The FIZE kUO console is MR unsafe.
Do not take the console into an MRI unit.

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

Static magnetic field	1.5T	3.0T
Resonance frequency	63.675 MHz	123.259 MHz
Gradient amplitude per axis	40-45 mT/m	80 mT/m
Gradient slew rate per axis	200 T/m/s	200 T/m/s
Maximum effective gradient amplitude	72 mT/m	139 mT/m
Maximum effective gradient slew rate	346 T/m/s	346 T/m/s
Maximum spatial gradient	11 T/m	7 T/m
Maximum spatial product (B_0*Gradient)	17 T_2/m	17 T_2/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 located between the patient legs and the urine bag should be located at the end of the bed (the far side from the MRI scanner)..

10.6 Environmental Specifications

Condition	Range
Operating Temperature	-18 ^{O}C to 50 ^{O}C / -.4 ^{O}F to 122 ^{O}F
Storage Temperature	-20 ^{O}C to 60 ^{O}C / -5.8 ^{O}F to 160 ^{O}F
Operating Pressure (Altitude)	70 KpA to 110 KpA
Humidity	15% to 95% RH at 31 ^{O}C
Water Resistance: Power Box	IP54 IEC 60529

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11 Patient Risks

Per FDA Guidance, general urological catheters for short-tern (<30 days) are considered non-significant risk (NSR) devices. The device is not intended as an implant, nor is it purported or represented to be for use supporting or sustaining human life, nor is it of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health.

The FIZE kUO Disposable Kit is single use only. It has not been tested or designed for cleaning and re-sterilization.

The potential risks associated with using or re-using the FIZE kUO disposable kit are:

- urinary tract infection
- systemic infection
- peritonitis
- urinary retention
- bladder perforation/tear/rupture/injury
- urethral perforation/tear/rupture/injury
- renal dysfunction
- skin infection
- skin irritation
- hypothermia
- hyperthermia
- elevated ıntra-abdominal pressure
- dehydration
- fluid overload
- allergic reaction
- prostatic injury
- intestinal injury
- pressure ulcer

12 Guidance on Manufacturer's Declaration

Electromagnetic Emission

This device in intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emission Test	**Compliance**	**Electromagnetic Environment- Guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishment and those directly connected to the public low-voltage power supply network that supplies building used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Immunity test	**IEC60601 Test level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electromagnetic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 5 %
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply main ±1 kV for input/output lines	Main power quality should be that of a typical home or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Main power quality should be that of a

	±2 kV common mode	±2 kV common mode	typical home or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in $U_{T)}$ for 5 cycles. 70% U_T (30% dip in U_T) fir 25 cycles. <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in $U_{T)}$ for 5 cycles. 70% U_T (30% dip in U_T) fir 25 cycles. <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical home or hospital environment. if the user of the device requires continued operation during power main interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical home or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Immunity test	**IEC60601 Test level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the

Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz Outside ISM bands1 10 Vrms 150 kHz to 80 MHz in ISM bands2 10 V/m 80 MHz to 2.5 GHz	3V 10V 10 V/m 26 MHz to 2.5 GHz	frequency of the transmitter. Recommended separation distance: d= 1.2 $\sqrt{p}$ d= 1.2 $\sqrt{p}$ d= 1.2 $\sqrt{p}$ 80 MHz to 800 MHz d= 2.3 $\sqrt{p}$ 800 MHz to 2.5 GHz where p is the maximum output power rating of the transmitted in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meter (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey1, should be less than the compliance level in each frequency range2.

			Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE A: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE B: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, object, and people.

[1] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceed the applicable RF compliance level above, the device should be observed to verify normal operation. If an abnormal performance is observed, additional measure may be necessary, such as re-orienting or relocating the device.

[2] over the frequency range 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended separation distance between portable Mobile RF communications Equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz **$d = 1.2\sqrt{P}$**	**80 MHz to 800 MHz** **$d = 1.2\sqrt{P}$**	**800 MHz to 2.5GHz** **$d = 2.3\sqrt{P}$**
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.