FIZEMEDICAL

FIZE kUO®

Operator's Manual

FIZE Medical Ltd.

15 HaShdera Hamerkazit st.

Modi'in-Maccabim-Re'ut, 7173002

Israel

Email: Service@FizeMedical.com

Web: www.fizemedical.com

Legal Notice

Disclaimer

FIZE Medical Ltd. ("FIZE Medical") provides this Operator's Manual in its commitment to help reduce patient risk and injury. However, the FIZE kUO and this manual are not intended in any way to replace or substitute duty of care to a patient, professional responsibility, or professional judgment, nor are intended to provide any warranty, undertaking, statement, promise, guarantee, assumption of risk or duty, release, or indemnity.

Physicians and nurses shall maintain responsibility for patient treatment and outcomes at all times. FIZE Medical assumes no liability for patient treatment or outcome or physician's negligence, breach of duty of care, or malpractice.

The responsibility for determining appropriate parameters for patient monitoring lies solely with the FIZE kUO operator.

Product modification or misuse can be dangerous.

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.

The design of FIZE kUO, the Operator's Manual, and the labeling on the device and the disposable kit take into consideration that the purchase and use of the equipment are restricted to trained professionals that have expertise and knowledge in the intended use, 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.

Caution

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 that are obvious to medical professionals and operators of this equipment, to the consequences of product misuse, and potential adverse effects in patients with abnormal conditions.

The FIZE kUO is a restricted medical device designed to be operated by properly trained and qualified healthcare 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 safe monitoring procedures that supply appropriate information on equipment performance and patient condition. Patient safety may be achieved through various 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 of the Limited Warranty as set forth below. 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).

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

All purchases from FIZE Medical and the use of the FIZE kUO are subject to FIZE General Terms and Conditions of Sale, as amended from time to time (the "**GTC**"). In case of any discrepancy between the provisions of this Operator's Manual and the provisions of the GTC, the provisions of the GTC shall prevail.

Limited Warranty

FIZE Medical warrants that the FIZE kUO shall be free from material defects in workmanship or materials and conform in all material respects to its specifications, which are available upon request, for a period agreed with the customer, from the original date of shipment from FIZE Medical (the "**Warranty Period**"). This warranty does not cover any rubber and plastic components and materials or any disposables provided with the FIZE kUO, which are guaranteed to be free of defects at time of delivery solely.

All warranty claims must be submitted in writing to FIZE Medical within the Warranty Period and all non-conforming products must be returned to FIZE Medical, at purchaser's cost and expense, before FIZE Medical replaces the same or refunds the purchase price to the Purchaser as set forth below. No products shall be returned to FIZE Medical without obtaining a Return Material Authorization (RMA) number first which must be clearly marked on the outside of the shipping container. The warranty for products repaired after the expiration date of the new products warranty, as stated above, is limited to the repaired portion and is valid for ninety (90) days from the date of reshipment.

FIZE Medical's liability for breach of warranty shall be limited to, in FIZE Medical' sole discretion, (i) repairing or replacing products that FIZE Medical determines do not conform to the foregoing warranty, or (ii) refunding the sales price received by FIZE Medical in respect of the non-conforming products. This remedy shall be the Purchaser's sole and exclusive remedy for any defect or nonconformity in the product. This warranty extends only to the immediate purchaser from FIZE Medical and does not extend, expressly or impliedly, to any other party.

In no event shall FIZE Medical incur any obligation to repair or replace Products which are determined by FIZE Medical, at its sole discretion, to be defective due to (i) installation, maintenance, operation, modification, alteration, accident, neglect or use in any way other than in strict compliance with FIZE Medical's published specifications for the product, (ii) the failure to maintain appropriate

environmental conditions, as communicated by FIZE Medical, (iii) as the result of the use of unauthorized parts or repairs, or unauthorized modifications (iv) any repair work on the product that is performed by the Purchaser or any third party on behalf of the Purchaser (other than FIZE Medical), or (v) modification or alteration of the products such that FIZE Medical is unable to verify the defect with its standard test equipment.

EXCEPT FOR THE EXPRESS LIMITED WARRANTY STATED HEREIN, THE PRODUCTS SUPPLIED BY FIZE MEDICAL ARE SUPPLIED ON AN "AS IS" BASIS AND PURCHASER'S USE OF THE PRODUCTS IS AT PURCHASER'S RISK. FIZE MEDICAL DOES NOT MAKE AND HEREBY DISCLAIMS ALL OTHER EXPRESS AND/OR IMPLIED WARRANTIES WITH RESPECT TO THE PRODUCTS, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE OR ANY WARRANTIES ARISING FROM A COURSE OF DEALING OR USAGE OF TRADE AND ANY WARRANTIES OF NONINFRINGEMENT AND TITLE.

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.

About this Manual

This operator's manual introduces the FIZE KUO® system and provides instructions on how to use it.

Please read this user guide carefully before starting to use the FIZE KUO™ device. If any part of this guide is unclear, please contact FIZE Medical support for assistance at Service@FizeMedical.com.

We recommend that you always keep this guide for quick reference.

Conventions

The following symbols have been inserted on the left-hand side of this guide for a more comprehensive user experience:

Symbol	Description
	**Caution:** cautions are used to warn you of a potentially hazardous situation which, if not avoided, may result in loss of data or may cause minor personal injury equipment/property damage. Do not proceed beyond a CAUTION message until you fully understand and observe the indicated conditions.
	**Warning:** warning messages indicate a potential hazard or unsafe practice which, if not avoided, could result in misdiagnosis, mistreatment, equipment damage, death, or severe injury. Do not proceed beyond a WARNING message until you fully understand the conditions and have taken the appropriate preventive action.

Table of Contents

List of Figures

List of Tables

1 Introduction

FIZE kUO® is a digital, automatic urine output monitoring device, which is comprised of two main parts:

- The FIZE kUO Console
  - The console performs the urine output measurement, displays the information on its screen, and obtains functionality for data transfer to other hospital systems, such as EMR.
  - The system is designed for integration into the hospital's network and securely transmits patient data to the Electronic Health Record (EHR) system. It supports secure connectivity protocols, including EAP-TLS and EAP-TTLS, ensuring encrypted communication and compliance with hospital network security requirements.
  - The console connects to the FIZE kUO Power Supply Box with the supplied cable or directly to an AC plug with a power adapter. It also has a backup battery that can be used when transferring patients to procedures or other departments.
- The FIZE kUO Disposable Kit
  - A proprietary disposable tubing set that includes the FIZE Smart Sensor™, a urine sampling port, a cassette, and a urine collection bag.

    The FIZE kUO Disposable Kits can be attached to any two-lumen Foley catheter 6-24 Fr. and is suitable for any urine volume enabling use in a broad range of patient populations.

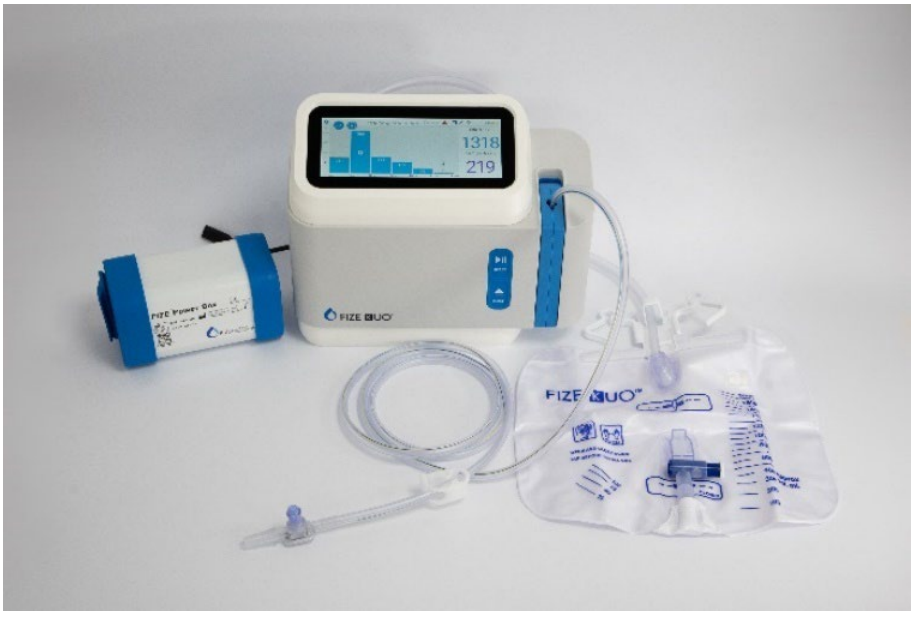

Figure 1-1. The FIZE kUO Device

1.1 Product Description

1.1.1 Intended Use

The FIZE kUO system is intended for urine output measurement. It is intended for use in hospitals and healthcare facilities by healthcare professionals.

The FIZE kUO disposable kit is a single-use sterile device for short-term use.

1.1.2 Intended Patient Population

The FIZE kUO may be used on any patient with an indwelling Foley catheter from 6-24 Fr with a standard connector, with the exception of those listed below.

1.1.2.1 Contraindications

FIZE kUO should not be used in any cases where the bladder is possibly not intact, such as:

- Patients with reconstructed bladder or urinary diversion.
- Patients with congenital malformations of a genito-urinary system involving bladder or urethra.
- Patients with a significant burden of blood clots or calculi in the bladder.

FIZE kUO is not intended for Continuous Bladder Irrigation (CBI). If required, disconnect the FIZE kUO from the patient and perform CBI according to the standard of care.

1.1.3 Intended Users

Warning

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 laws and regulations.

1.1.4 Clinical benefit

Clinical benefits with clinical outcome parameters and source of substantiation are listed in Table 1 below:

Table 1: FIZE kUO® Clinical benefits and outcome parameters

	Clinical benefit	Clinical outcome parameters
	Accurate and continuous Urine Output (UO) Measurement (indirect benefit) *	Accurate automated urine output measurement (measured by urine flow and urine volume).
		Ability to perform minute-by-minute, real-time, and continuous digital urine output measurement in microliter resolution

* The main ability of the subject device is the ability to automatically measure urine output. Even though this measurement itself does not represent direct clinical benefit to the patient, it serves as the critical diagnostic and management tool of different clinical conditions, such as hemodynamic management and renal function management (direct clinical benefits).

1.2 Labels and Symbols

Table 2. Labels and Symbols

Label/ Symbol	Definition	Explanation
	Consult instructions for use	Indicates to consult hardcopy or electronic instructions for use (eIFU).
	"Manufacturer" and "Manufacturer date" (combined symbol)	Indicates the medical device manufacturer and the date when the medical device was manufactured (combined symbols).
	Type BF applied part (IEC60601-1)	Part of medical device equipment, which in normal use necessarily comes into physical contact with the patient to perform its function.
	Class II equipment	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	Direct current (DC)	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
	Prescription use only (lower case)	Caution: Federal law (USA) restricts the sale of this device by or on the order of a licensed healthcare practitioner.
	Medical Device	Indicates the item is a medical device.
	Catalog Number	Indicates the manufacturer's catalog number to identify the medical device.
	Serial Number	Indicates the manufacturer's serial number to identify a specific medical device.
	Use by date	Indicates the date after which the medical device is not to be used.
	Quantity	The net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination thereof, or other terms that accurately reflect the package contents.
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed. • For the external box, it indicates the temperature limits for transportation. • For the internal box and device, it indicates the temperature limits for operation and storage.
	Keep dry Keep away from rain	Indicates a medical device that needs protection from moisture.

Label/ Symbol	Definition	Explanation
	Do not use it if the package is damaged	Indicates the packaged item should not be used if the package is damaged.
	Collect separately. Requirements for Li-ion batteries inside	Do not dispose of batteries in municipal waste. The symbol indicates that a separate collection of batteries is required.
	Requirements for Waste of Electrical and Electronic Equipment (WEEE) directive	Indicates separate waste collection of electrical and electronic equipment.
	Initiate/Resume Monitoring	Indicates that the button or feature represented by this symbol will either start or resume an action or process.
	Cassette release button	Indicates a function to safely eject a removable media, such as a disk, USB drive, or other device, from a machine or system (in Fize's case, the cassette).
	On/Off button	Indicates a button that is used to turn a device on or off.
	Caution; consult accompanying documents	Indicates that caution is necessary when operating the device or control close to where the symbol is placed or that the current situation needs operator awareness or action to avoid undesirable consequences.
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed. • For the external box, it indicates the humidity limits for transportation. • For the internal box and device, it indicates the humidity limits for operation and storage.
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed during transportation and storage.
	Fragile, Handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Lot Number	Indicates the manufacturer's batch code to identify the batch or lot.
	MR Unsafe	Indicate that the medical device is MR Unsafe and should remain outside the MRI scanner room.
	MR Conditional	Indicate that the medical device can safely be taken into any MR environment.

Label/ Symbol	Definition	Explanation
	Do not Reuse	Indicates a medical device that is intended for one single use only.
	Sterilized using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.
IP22	Ingress Protection (IP) rating	Protected against solid objects over 12.5mm (e.g., a finger) and protected against falling drops of water if the case is disposed at any angle up to 15 degrees from vertical.
IP54	Ingress Protection (IP) rating	The product is protected against dust that could interfere with its normal operation but is not fully dust tight. The product is completely protected against solid objects. It is also protected against water splashing from any angle.
	Do not Resterilize	Indicates a medical device that is not to be resterilized.
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.
	Unique Device Identifier QR code	Indicates a unique device identifier carrier of the product (console or disposable kit accordingly)
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside.
	Single sterile barrier system	Indicates a single sterile barrier system.
	Does not contain a natural rubber latex	Indicates that there is no presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device which may cause allergic reactions.
 **2797**	CE mark and notified body number	BSI British Standards Institution (Class IIa Medical Device)
	Authorized representative in the European Community / European Union	Indicates the authorized representative in the European Community/European Union. This symbol shall be accompanied by the name and address of the authorized representative, adjacent to the symbol

Label/ Symbol	Definition	Explanation
UKRP	UK Responsible Person	Name and address, with UKRP written in English adjacent to the text "UK Responsible Person"
UK CA 0086	UKCA marking	BSI British Standards Institution (Class IIa Medical Device)

2 Safety Instructions

Strictly follow this manual at all times. Safe use of the FIZE kUO requires a complete understanding of its operation and adherence to the manual's instructions. The equipment shall only be used for the purpose specified in section 1.1. Observe all the WARNINGS and CAUTIONS posted in this manual, as well as the console and associated accessories.

2.1 General Warnings


Warning

1. All device settings must be made following a physician's instructions.


Warning

2. Regular attention by qualified medical personnel is required whenever a patient's urine is measured with the FIZE kUO.


Warning

3. Do not use any kit other than the FIZE kUO Disposable kit, the FIZE kUO Full Standard Disposable Kit, or other FIZE-approved kits.


Warning

4. Ensure the integrity of the disposable kit package before use. Discard disposable kit if sterile packaging seems tampered with, damaged, or compromised.


Warning

5. Always follow accepted hospital procedures or physician instructions for handling equipment contaminated with body fluids.


Warning

6. Failure to address device alerts may result in patient injury.


Warning

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


Warning

8. Ensure that the FIZE kUO console is firmly secured to a patient bed or a stable pole at all times, including during in-hospital transport.


Warning

9. FIZE kUO system shall only be used with the accessories provided by FIZE medical, including but not limited to power supplies, power cords, and disposable kits.


Warning

10. The FIZE kUO device is intended to operate only with a closed tubing system. Air leakage into the tubing may prevent accurate measurement and monitoring. Ensure all tubing is intact and properly secured to the patient and the catheter and that the catheter is properly placed within the bladder.


Warning

11. Repairs and service may only be performed by FIZE MEDICAL authorized technicians, trained or factory-authorized personnel.


Warning

12. Issues that originate from using Foley catheters (e.g., catheter clogging or other type of positional obstruction) may remain when using FIZE kUO, which may result in urine accumulation in the bladder without being drained.

2.2 Cautions


Caution

1. 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.


Caution

2. Batteries contain Li-Ion. Do not discard them in an incinerator or force them open. Batteries should not be disposed of with normal waste.


Caution

3. Only limited battery power remains when the Low Battery alert sounds, and an alternate power source should be found immediately.


Caution

4. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2.3 Complications and side effects

The potential complications associated with using or re-using the FIZE kUO® disposable kit are listed below. These complications are general for any use of a catheter and are not specific for FIZE system:

- 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 intra-abdominal pressure
- dehydration

3 FIZE kUO Device Description

3.1 Console

3.1.1 Front Panel Features

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

Figure 3-1. Front Panel

Label	Name	Description
1.	Touch screen	Touch screen for operation and monitoring.
2.	Disposable kit slot	The disposable kit insertion space
3.	Start/Pause button	To Start or Pause monitoring.
4.	Eject button	To eject the cassette or replace the disposable kit.

3.1.2 Back Panel Features

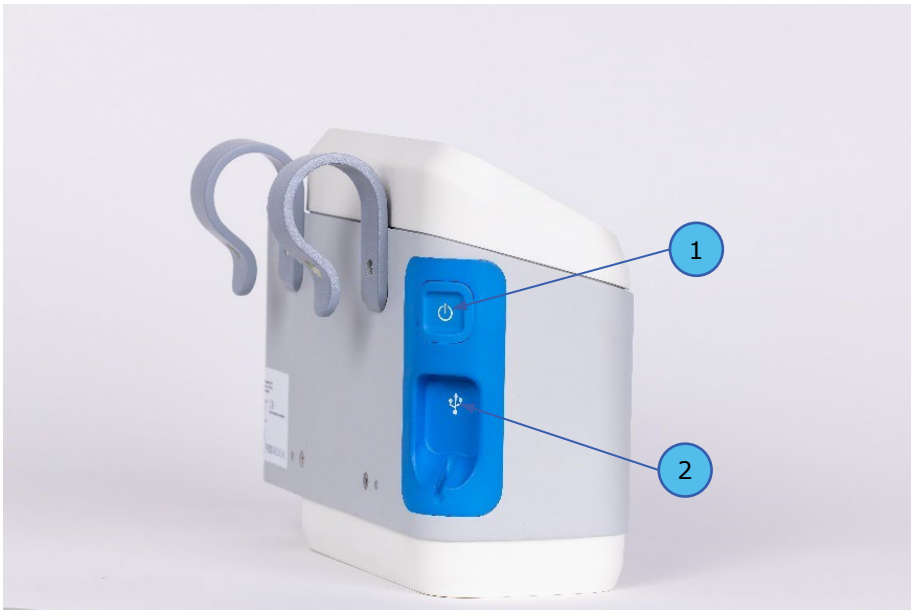

Figure 3-2. Back Panel

Label	Name	Description
1.	On/Off button	Powers the device on/off.
2.	Power Supply connector	For connecting the Power Supply to the device using the provided cable,

3.1.3 LCD Screen

The interactive LCD screen of the FIZE kUO enables users to navigate to the following two sections:

- **Patient Monitoring** section (see section 5.3)

  Real-time urine output measurements can be viewed in a bar chart display (Figure 5-9) or a trendline display (Figure 5-10).

- **Settings** section (see section 5.3)

3.2 Disposable Kit

The Disposable kit comprises a tubing set, a proprietary sensor, a urine-port sample, and a urine collection bag.

The Disposable kit includes the parts shown in Figure 3-3.

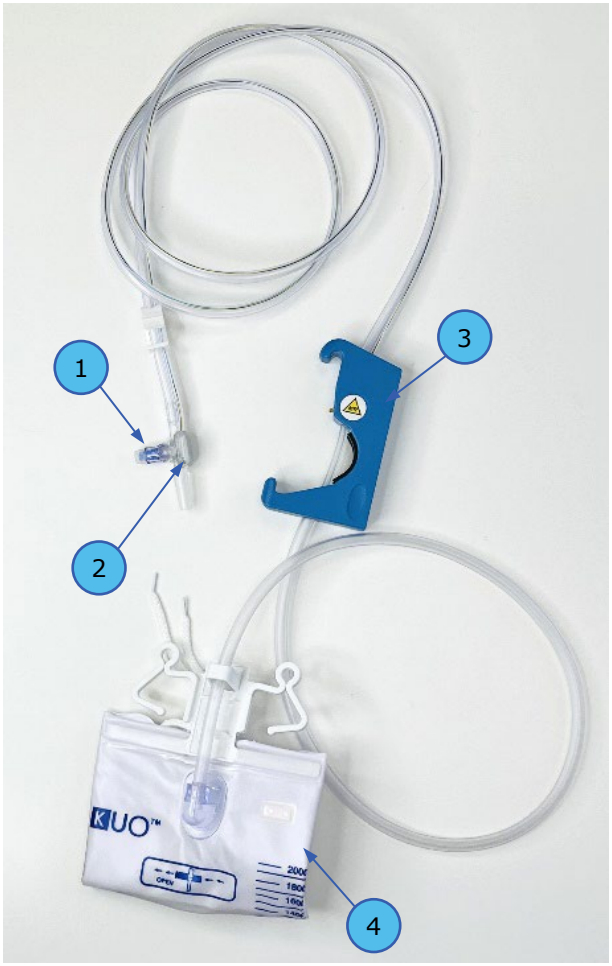

Figure 3-3. Disposable Kit Parts

Label	Name	Description
1.	Needleless port	For urine sampling and irrigation when using a needless syringe.
2.	FIZE Smart Sensor™	For detecting minute pressure changes in the bladder and signaling the device to drain and measure the urine (FIZE Adaptive Drainage System™)
3.	Cassette	To connect the disposable kit to the console.
4.	Urine collection bag	For collecting the accumulated urine. **Note:** The volume markings are for illustration only

The disposable kit can be attached to any two-way Foley catheter of 6 to 24 Fr. diameter with a compatible standard connector.

The disposable kit is inserted into the console, as seen in Figure 3-4., and can be easily clipped in/out of the device for ease of handling.

Figure 3-4. The FIZE kUO Disposable Kit

3.3 Disposable Kit Expiry

3.3.1 Sterility Shelf-Life

FIZE kUO Disposable is provided in a sterile form and intended for use with a single patient only.

Warning

Discard disposables after use, and do not resterilize them. Do not use past the sterilization date as detailed on its sterile package label.

3.3.2 Usage expiry

All FIZE kUO Disposable kit types expire after 14 days of use or 32 liters, whichever comes first.

An alert is displayed on the screen 8 hours before the kit expires. In addition, you may monitor the kit status by pressing the cassette icon in the screen's toolbar (label 6 in Figure 5-9).

Warning

Do not use the disposable kit past its usage expiration date.

To replace a disposable kit:

1. Press the "**Eject**" button (see Figure 3-1).
2. Detach the disposable kit from the Foley catheter as is practiced when swapping manual urimeters/urine collection systems and per hospital protocols.
3. Safely dispose of the disposable kit according to hospital guidelines.
4. Connect a new disposable kit, as described in section 5.1 – Connecting Disposable Kits.

Note: More frequent drainage line replacement is subject to hospital policy and is at the hospital's sole discretion, according to its standard operating procedures.

3.4 Kit Data Capture

The FIZE kUO Disposable kit has proprietary data capture capabilities, enabling streamlined interoperability with connected consoles. The technology stores the last 12 hours of measurement data in the cassette memory, allowing seamless data transfer between consoles.

Data is accessible only when plugged into the FIZE kUO console.

4 System Setup

4.1 Introduction

Following all the steps listed below is essential for ensuring the safest operation of the device. Use the information in this section in conjunction with established hospital protocols.

4.2 Unboxing the FIZE kUO

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

Warning

Ensure the integrity of the Console package before use. Do not use the console if its packaging seems tampered with, damaged, or compromised.

The complete FIZE kUO system consists of the following parts:

- FIZE kUO Console.
- Power Supply Box or charger.
- AC Power Cord if using Power Box.
- USB Type C cable (to connect the FIZE kUO Console to the Power Supply if using a Power Box).
- Instructions for Use (printed version or QR code for digital version).
- Hanging Hooks.
- Allen wrench for hook assembly.

4.3 Mounting the FIZE kUO

Using the supplied Allen wrenches, always attach both hanging hooks to the back panel of the device in the designated screw holes. This action should be performed by FIZE or hospital-authorized technicians.

Mount the FIZE kUO Console to the bed railing using both provided custom hooks. Firmly secure the console to the bed railing by ensuring proper hook positioning and grip.

The console can be placed up to 20 cm above the patient's bladder or 1 m below the patient's level.

4.4 Connecting the FIZE kUO to the Power Source

4.4.1 Connection to Power and Communication Supply Box

1. Plug the AC power cord into the Power Supply Box entry connector or the power adapter.
2. Connect the USB Type C cable to the Power Supply Box and the FIZE kUO console.

Warning

Use only the FIZE kUO USB power supplies. Do not use any other USB power sources.

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 the device is correctly connected to the power source.

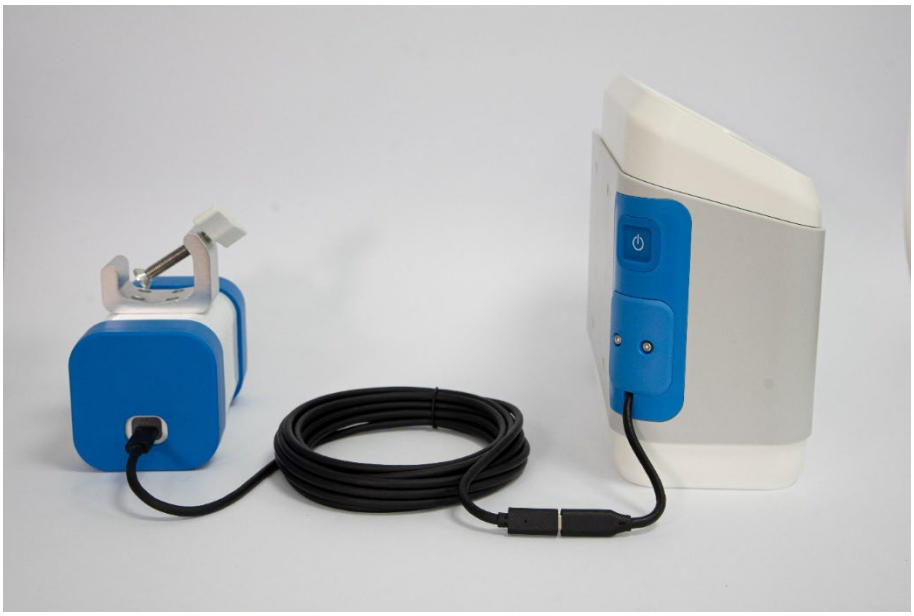

Figure 4-1. FIZE kUO Power Box

4.4.2 Connection to Power Adaptor

1. Plug the power adaptor into an AC outlet.

Figure 4-2. FIZE kUO Power Supply

2. Connect the power cord's USB-C connector to the console.

Warning	Avoid ingress of liquids into the power supply and make sure the enclosure is intact to prevent damage or malfunction. If liquid exposure occurs, immediately stop using the power source and switch to backup batteries.
Caution	Ensure the power cord is securely stored and not left on the floor. Keep the cord away from walkways to prevent tripping hazards.

4.5 Initial Setup

1. Press the power button (see Figure 3-2) and wait for the device to power on.

Figure 4-3. Introduction screen

An introduction screen is displayed for a few seconds, followed by the Patient Details screen.

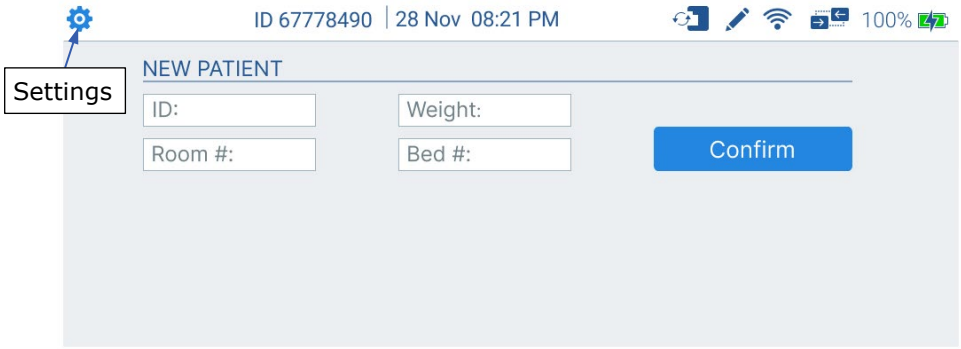

Figure 4-4. Patient Details screen

2. Press the **Settings** icon in the upper left corner (see Figure 4-4) and select the **Technician** page (Figure 4-6).

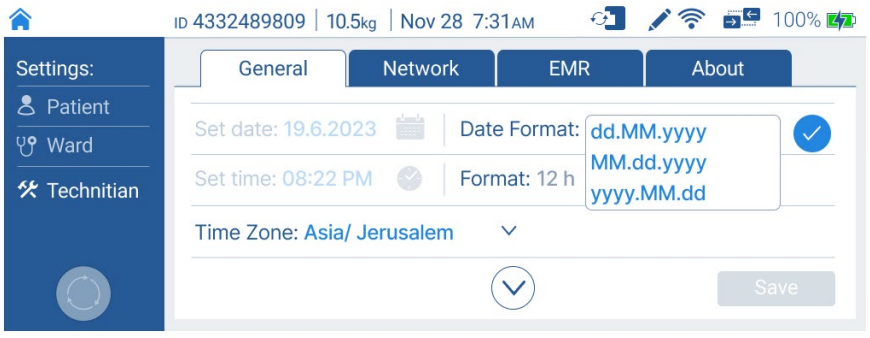

Figure 4-5. Technician Settings page (1 of 3)

3. Press the page down arrow to review the following settings pages (see Figure 4-6).

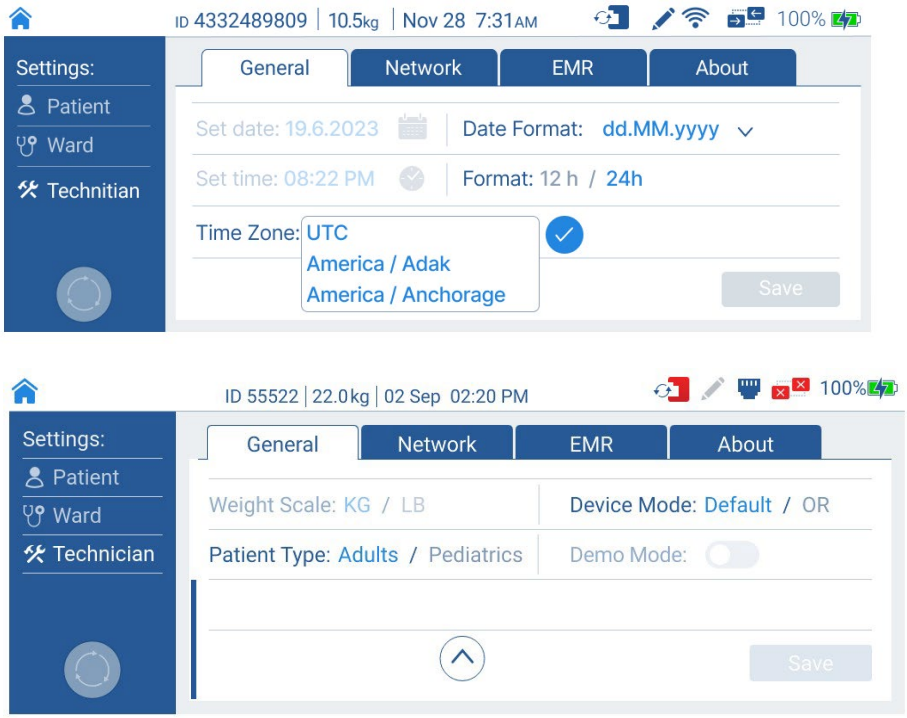

Figure 4-6. Technician Settings page (2 and 3 of 3)

4. Make sure the device's regional settings and measurement units are correct. If necessary, contact a FIZE Medical authorized technician.

5 Operating the FIZE kUO

5.1 Connecting Disposable Kits

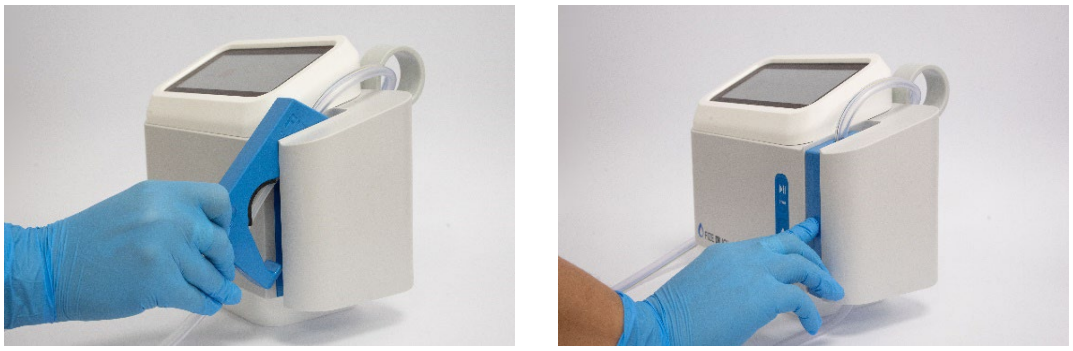

Figure 5-1. FIZE kUO Disposable Kit insertion to console

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.

Warning

The urine collection bag must be positioned below the patient's bladder height.

Caution

Once the cassette is inserted, the patient setup must be completed, and monitoring must begin within a limited time. If the defined time is reached, the cassette is ejected.

5.2 Patient Setup

If the console contains previous patient data, following cassette insertion, the system displays the Patient Details screen (Figure 5-3).

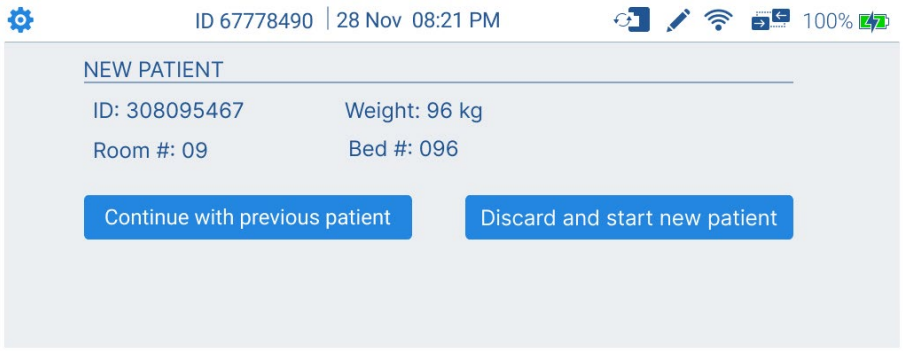

Figure 5-2. Patient Details screen

Select how to proceed:

- Press **Continue with the previous patient** to continue with a previous patient.
- Press **Discard and start a new patient** for defining a new patient.

Note

When a New Patient option is selected, the previous patient's data history is deleted.

The system displays the Patient Details screen (see Figure 5-3).

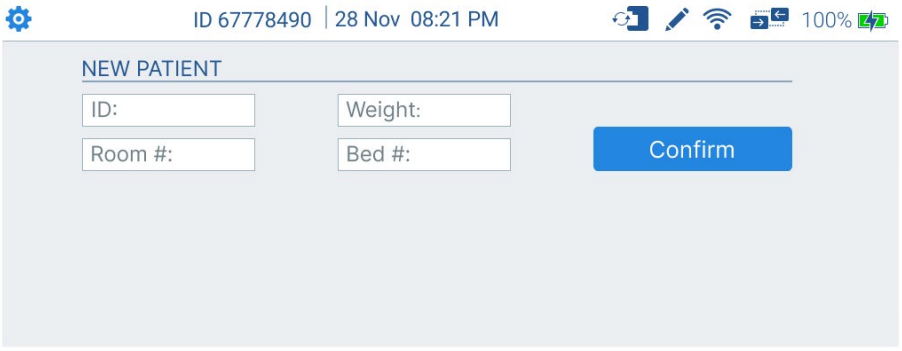

Figure 5-3. New Patient screen

Insert the patient's identification number (**ID**), **Weight**, and bed/room number. Then, press **Confirm**.

Note: Verify the accuracy of details prior to continuing to the next steps.

5.2.1 System Initialization

Once a patient is defined, the Measurement Initialization screen is displayed (see Figure 5-4).

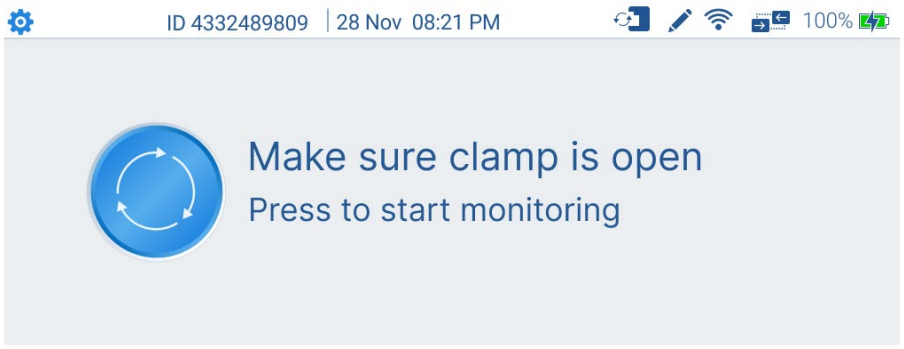

Figure 5-4. Start/Resume Monitoring screen

Press the blue button on the screen to start monitoring.

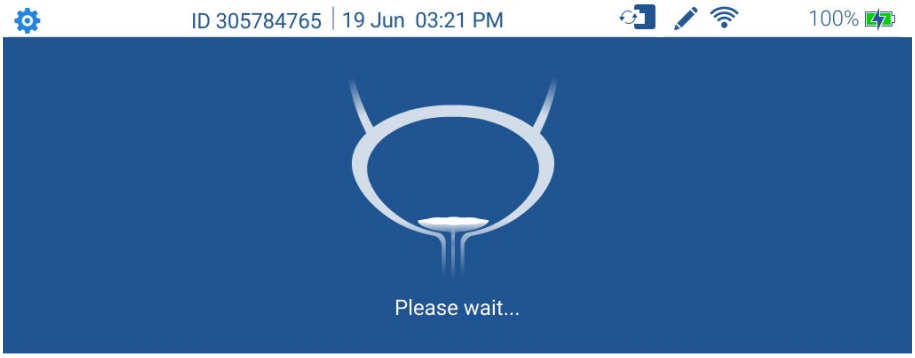

Figure 5-5. Initialization in Progress screen

During initialization (see Figure 5-5), 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 (see 5-10.). This amount is included in the hourly total.

5.3 Settings Section

The Settings section can be accessed by pressing the gear icon in the upper left corner of the top toolbar (see Figure 5-9 in section 5.3).

5.3.1 Patient Settings Screen

In the Patient Settings page, the user can define the patient ID and Weight and set personalized alerts.

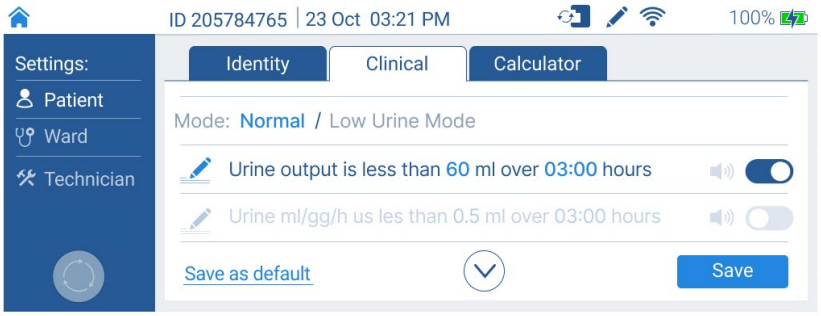

Figure 5-6. Patient Settings screen

5.3.2 Ward Settings Screen

In the Ward Settings page, the 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.

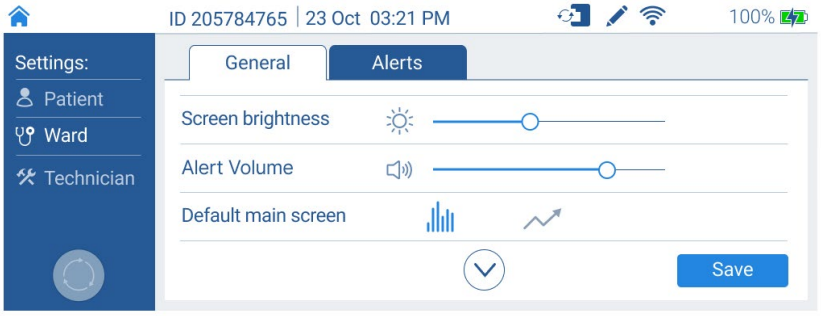

Figure 5-7. Ward Settings screen

5.3.3 Technical Settings Screen

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

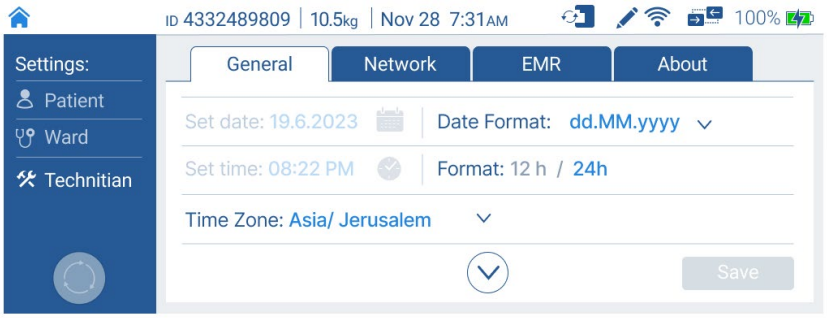

Figure 5-8. Technician Settings screen

5.4 Patient Monitoring

Following initialization, the main screen is displayed (Figure 5-9).

Figure 5-9. Patient Monitoring screen – bar chart display

The bar chart displays the total urine output per hour (ml), and the light blue column represents a measurement from a partial hour (i.e., a measurement still in progress or a measurement from an incomplete hour (<51 min)).

Once a measurement from a full hour is complete, the light blue column turns to a dark blue.

Table 3 describes the function of each icon on the screen.

Table 3. Patient Monitoring Screen Icons

Label	Name	Description
1.	Settings icon	Enter the 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 the cassette is in use.
7.	Edit Intervention	Insert an intervention (diuretic, fluid bolus, etc.) Intervention events can be viewed in the trendline view.
8.	Wi-Fi Status	Appears when the device is connected to Wi-Fi.

Label	Name	Description
9.	EMR Connectivity	Appears red when there is no connection to a server. Appears blue or purple when connected to a server, depending on the connection type.
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	ml/Kg/hr for the selected time window.

The trendline display (Figure 5-10) presents a minute-by-minute urine flow rate (ml/hr). The drop icon indicates emptying of residual urine. To view residual urine volume, press the drop icon.

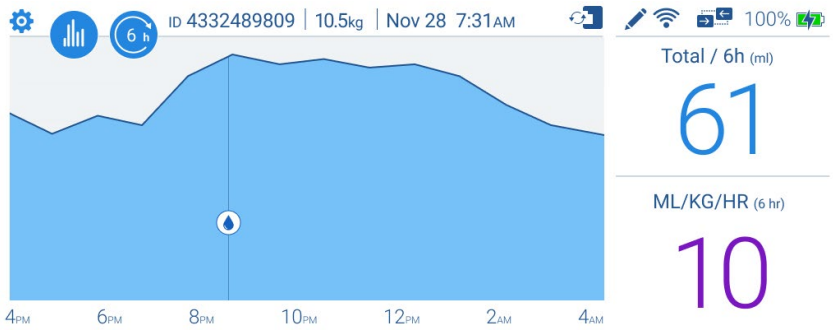

Figure 5-10. Monitoring screen – Trending display

5.4.1 Recording an Intervention

To monitor patient response to different interventions, such as fluid boluses, diuretics, vasopressors, or inotropes:

1. Press the pencil (✎) icon in the top toolbar (label 7 in Figure 5-9).
2. In the pop-up window, insert the intervention Time, Type, and Method (see Figure 5-11.)
3. Press **Save**.

The Intervention is marked on the trendline, as shown in Figure 5-12.

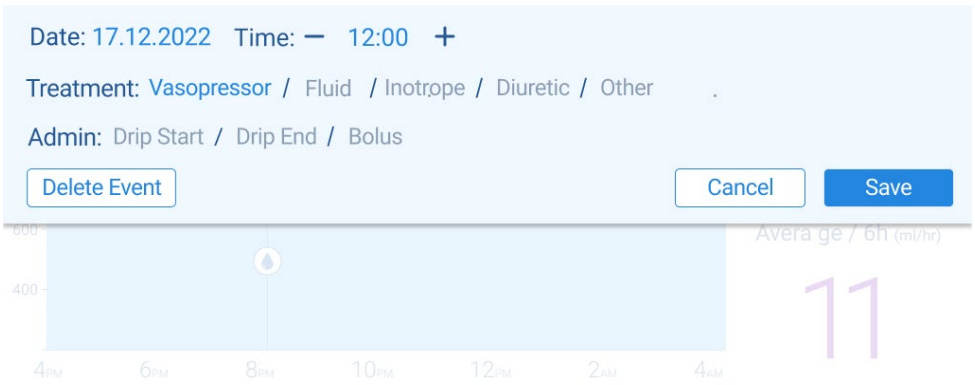

Figure 5-11. Insert Intervention pop-up window

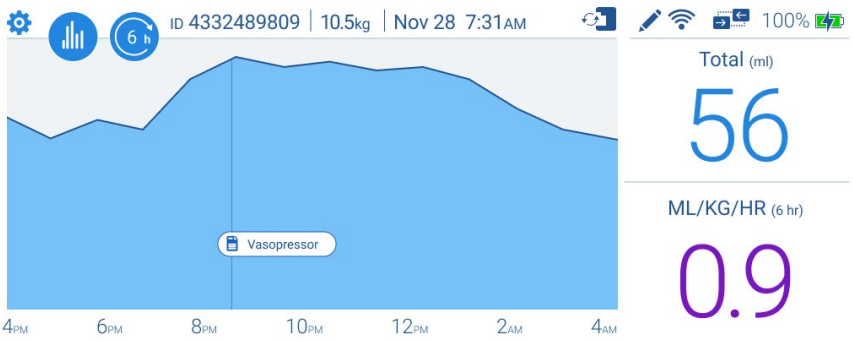

Figure 5-12. Intervention display on the trendline

6 Additional Actions

6.1 Editing Patient Identifier

Editing a patient identifier may be relevant in two cases:

- When starting monitoring for a **new** patient but **Continue with existing patient** was accidentally pressed.
- When it is required to edit information for an existing patient.

In either case, follow these steps:

1. Go to **Settings->Patient>Identity**.
2. Press the **ID** field and edit it as needed.
3. Press **Save**; a warning alert appears on the screen.

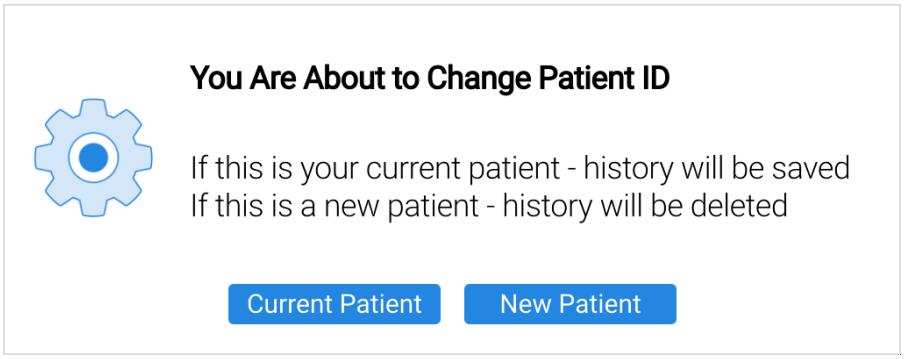

Figure 6-1. Change Patient ID alert

- In case of an accidental assignment of a previous patient's data to a new patient, press the **New Patient** button. The previous patient's data history is deleted, and a new memory log for the new patient is started.
- If you want to edit identifiers for an existing patient, press the **Existing Patient** button, edit the identifier fields as desired, and press **Save**.

6.2 Calculating the Average Urine Output

To calculate the total and average urine output for a specific time window, do the following:

1. Enter the **Settings** section, navigate to the **Patient** page, and press the **Calculator** tab (see Figure 6-2).
2. Select the Start and End time of the desired time frame and press **Calculate** (see Figure 6-2 and Figure 6-3).

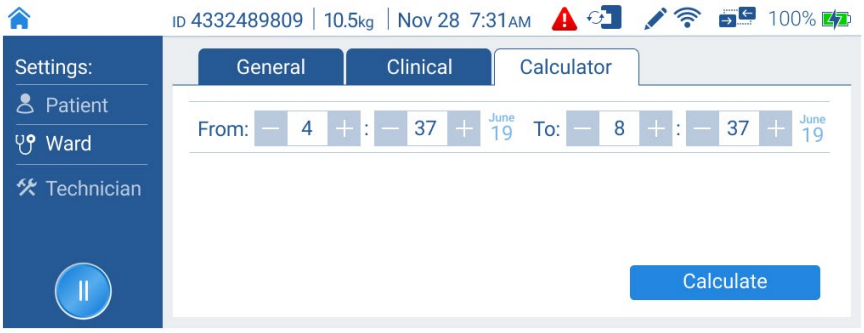

Figure 6-2. Calculator tab

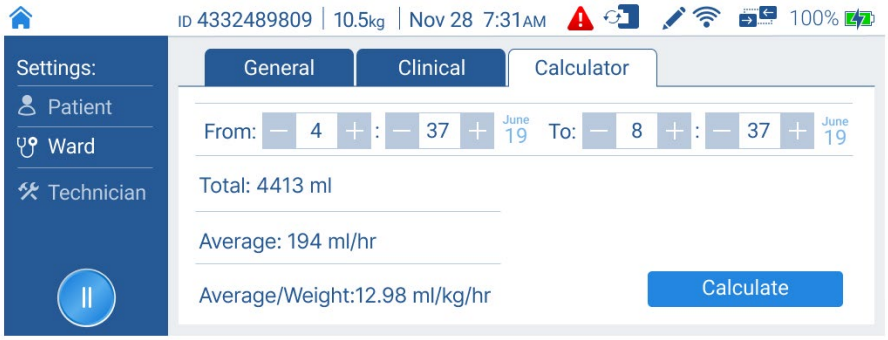

Figure 6-3. Calculator tab – example of results

6.3 Urine Sampling

Urine samples may be collected while monitoring using a compatible needleless syringe through the dedicated urine-sampling Luer lock port.

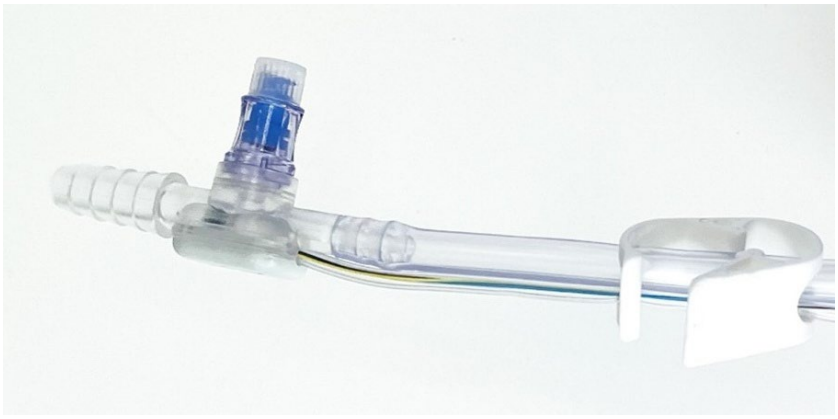

Figure 6-4. Disposable Sampling Port Kit

Warning

The sampling port is intended for use only with a Luer-lock-type syringe. Do not use a syringe with a needle, as it may compromise the kit sealing, allow air to leak into the tubing, and disrupt monitoring accuracy.

6.4 Catheter Irrigation

Catheter flushing can be performed through the sampling port (with a luer lock syringe only) or directly through the catheter.

Make sure to perform irrigation according to hospital guidelines.

To flush through the urine-sampling port:

1. Close the clamp below the catheter.
2. Lock the needleless syringe into the designated port and steadily introduce flushing fluid.
3. If necessary, deduct the inserted volume using the Urine Output Edit feature (see details in section 6.5).

To flush directly through the catheter:

1. Pause monitoring by pressing the **Start/Pause** button (see Figure 6-5).

Figure 6-5. Start/Pause button

2. Disconnect the disposable kit from the catheter.

Warning

Always pause the FIZE kUO console or eject the disposable kit from the console prior to disconnecting the catheter from the disposable kit or removing the catheter from the patient.

3. Perform catheter flushing according to the hospital standard of care.
4. Reconnect the disposable kit to the catheter. Make sure the kit is firmly connected to the catheter.
5. Resume monitoring.

Warning

Always resume monitoring after the FIZE kUO console is paused or after reinserting an ejected cassette.

6.5 Editing Urine Output Volume

Manually editing the urine output volume may be relevant in two cases:

- Subtracting volume that was introduced during catheter irrigation by the user.
- When adding missing urine volume not measured by the FIZE kUO system while the disposable kit was disconnected from the console.

In both cases, the user shall estimate urine volume using external measurement tools such as a syringe or graduated cylinder.

Urine output can be manually edited only for the **In Progress** bar.

Note

Data from previous hours already sent to the patient's EMR cannot be edited retroactively through the console.

To edit urine output:

1. Press and hold the **In Progress** bar.
2. Fill in the volume to add or subtract in the pop-up window (see Figure 6-6).
3. Press **Save**.

   When manually edited, the bar color turns green (Figure 6-7). The edited volume can be viewed by pressing the drop icon.

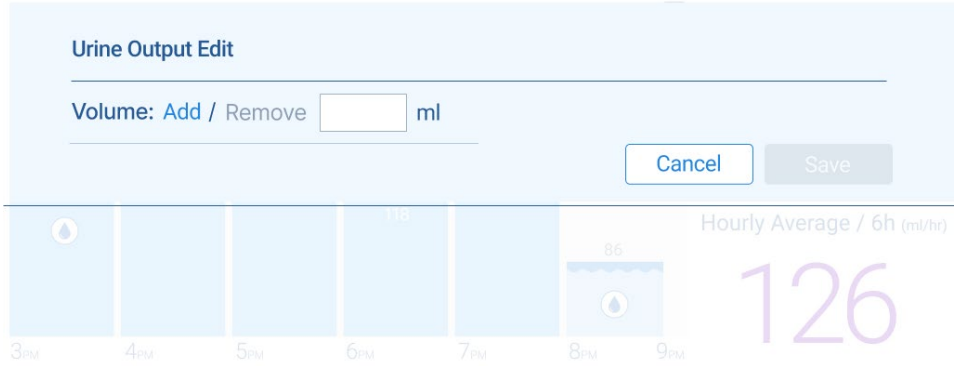

Figure 6-6. Urine Output Edit pop-up screen

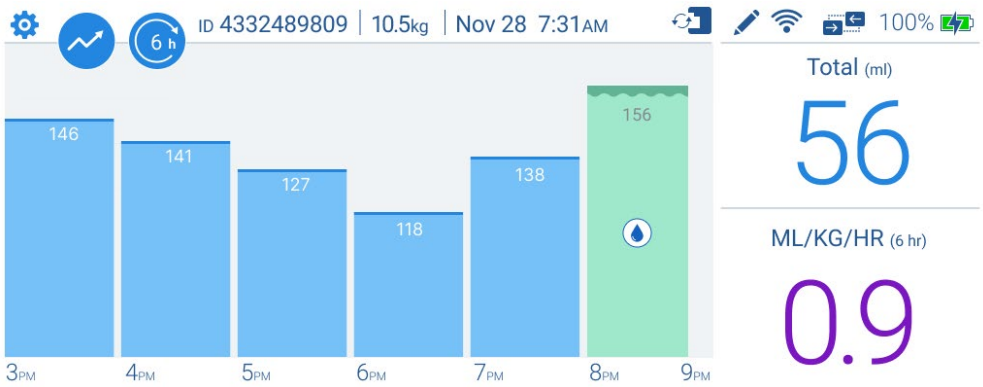

Figure 6-7. Manually edited bar

6.6 Patient Transportation

6.6.1 In-Hospital Transport

To keep tracking urine output during in-hospital transport and keep the patient connected to the device, disconnect the console from the power cable and transport the bed with the device.

The console can operate on its battery power for up to 4 hours.

Note

Prior to in-hospital transport, ensure that the battery charging level is sufficient for the transport duration.

Note

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

6.6.2 Temporary Disconnecting the Console

To temporarily disconnect the patient from the console, do one of the following:

- Press **Eject** to release the cassette so that the disposable kit serves as a regular urine drainage tubing and bag to allow free urine flow during ambulation over conserving data.

  To resume measurement, insert the cassette back into the FIZE kUO console and press **Start monitoring**.

- Utilize the clamp to halt urine flow for ambulating while disconnected from the console, thus preserving the volume in the bladder until returning to the console for measuring.

  This choice should be made solely at the users' discretion, using medical considerations and abiding by best practices as determined by the facility. FIZE Medical holds no clinical responsibility over what the user deems an "acceptable" amount of time to halt urine clearance.

  While the clamp is closed, urine accumulates in the bladder until the system is reconnected to the console and unclamped. At this point, the initialization algorithms drain the bladder, drain accumulated urine, and recover data for measurement continuity.

  To perform ambulation using this method, securely close the clamp, press the **Eject** button (see Figure 3-1), and proceed with ambulation. When returned/arrived at the destination console, reattach the cassette, unclamp, and press **Resume**.

6.6.3 Transfer Patient Between Two Different Consoles

Press the **Eject** button (see Figure 3-1) to eject the cassette and insert the cassette into the new console.

The console identifies the cassette and displays the Start Monitoring screen (Figure 5-4). Once the cassette is inserted, patient data such as identifier number (ID), weight, alert preferences, and the last 12 hours of measurement are automatically transferred to the new console. Previous patient data saved onto the console is deleted.

6.7 Patient Discharge

To disconnect the device from the patient:

1. Press the **Eject** button (see Figure 3-1).
2. Remove the disposable kit from the patient as practiced for manual urinometers/urine collection systems according to hospital protocols.
3. Safely dispose of disposable kit, as per hospital guidelines.
4. Sanitize the console as described in section 9, Cleaning and Maintenance.

6.8 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 appears requesting confirmation of shutdown.
2. Press **Approve** to continue with the shutdown.

7 Special Operation Modes

7.1 Low Urine Mode

Low Urine Mode is a program feature that enables specifically adapted monitoring for patients with extremely low urine output.

While the device usually displays alerts when low urine output is detected, **Low Urine Mode** enables monitoring at a higher visual resolution, adjusting the algorithm to the expected low urine output volume.

During monitoring, if the system detects less than 5 ml over one hour, a **No Urine Detected** alert appears (see Figure 7-1).

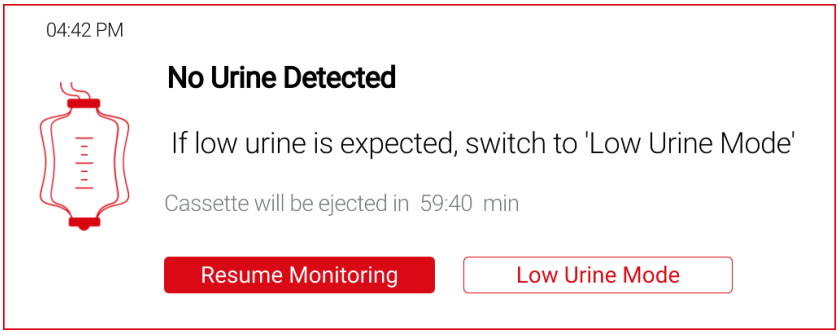

Figure 7-1. No Urine Detected alert

If low urine is expected for this patient, it is advised to switch to **Low Urine Mode**:

1. Press the **Low Urine Mode** button on the alert window (Figure 7-1).
2. Press **OK** in the verification message (Figure 7-2).

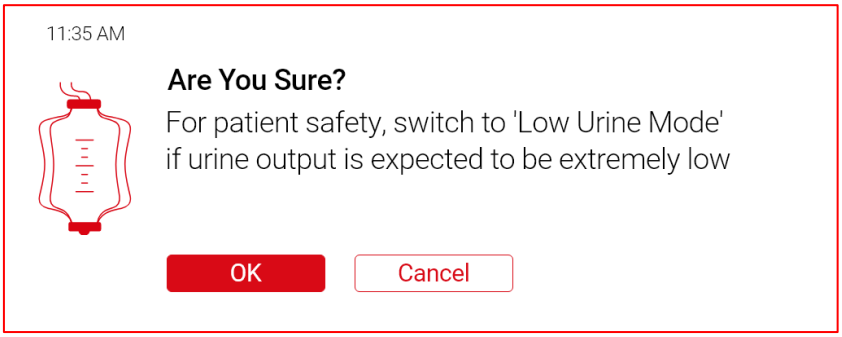

Figure 7-2. Low Urine Verification message

If the patient's urine output increases, the kUO automatically reverts to normal monitoring mode.

To turn Low Urine Mode on or off through the Settings menu:

1. Go to the **Patient Settings** screen, press the **Clinical** tab, and select **Low Urine Mode** (see Figure 8-2).
2. Press "**OK**".

7.2 Pediatrics Mode

The Pediatrics mode enables monitoring pediatric patients' urine output and is designed to suit a wide range of urine output volumes and catheter sizes, from 6 to 24 Fr.

FIZE kUO consoles intended for pediatric patient monitoring are provided pre-programmed with the **Pediatrics Mode** (to enable Pediatrics Mode in a device that has not been pre-configured to Pediatrics Mode, contact FIZE Medical Technical Support). The Pediatrics Mode can be used only with the corresponding FIZE kUO Pediatric Disposable Kit

Pediatrics mode will be indicated in the upper toolbar of the Settings screen (see Figure 7-3.)

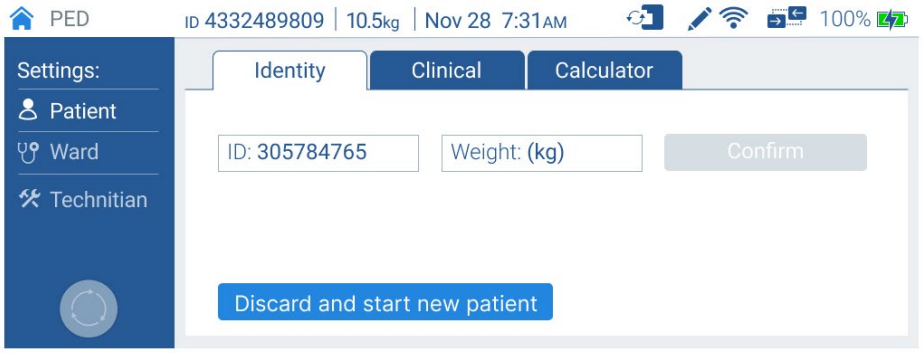

Figure 7-3. Settings Screen – Pediatrics Mode

7.2.1 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.

When monitoring pediatric patients, a **No Urine Detected** alert appears if the system detects less than 3 ml for over 1 hour (see Figure 6-6). If low urine is expected for this patient, it is advised to switch to **Low Urine Mode**:

1. Press the **Low Urine Mode** button on the alert window (Figure 7-1).
2. Press **OK** in the verification message (Figure 7-2).

To set Patient Low Urine Mode through the Settings menu:

1. Go to the **Patient Settings** screen, press the **Clinical** tab, and select **Low Urine Mode** (see Figure 8-2).
2. Press **OK**.

7.3 Operating Room (OR) Mode

The OR mode is intended to adjust device display and functionality to better suit urine output monitoring during surgeries.

FIZE kUO consoles intended for operating rooms are provided pre-programmed with the **OR Mode.** To enable OR Mode in a device that has not been pre-configured, contact FIZE Medical Technical Support or FIZE Medical authorized personnel.

The OR Mode functionality and user interface include the following modifications.

7.3.1 Patient Monitoring Screen

The monitoring screen includes the following modifications:

7.3.1.1 Mark Event feature

The 'Mark Event' feature in the bottom part of the right panel (see figure 7-5.) allows you to track urine output over a specific period. To use this feature, press the 'Start' button on the right panel of the monitoring screen when you wish to begin tracking. The device will then sum the urine output from that moment until you press 'Stop.'

The tracked period will be highlighted as a purple slice in the trendline view for easy reference. This feature is especially useful for monitoring urine output during specific interventions or procedures.

General metrics such as total urine output, hourly average or ml/kg/hr for the selected time window can be viewed in the upper part of the right panel. To switch between them, press the upper right panel.

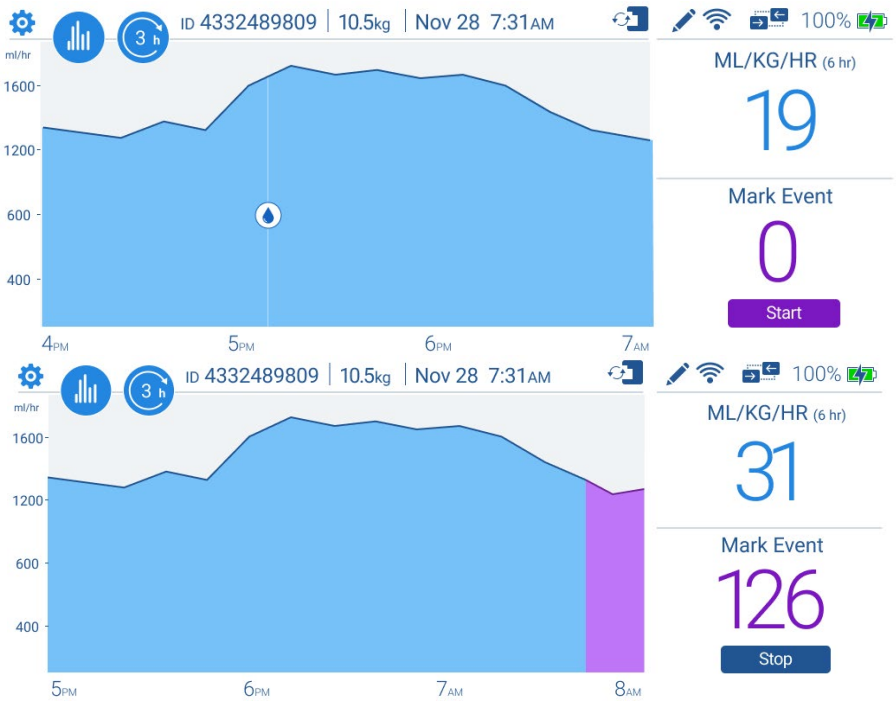

Figure 7-4. OR Mode - Mark Event feature

7.3.1.2 Automatic timeframe adjustment

In OR mode, the monitoring screen automatically adjusts the time frame based on the duration of the surgery. Initially, it starts with a 3-hour view. If the surgery extends beyond 3 hours, the time frame automatically adjusts to 6 hours, and then to 12 hours as needed. If a specific timeframe is manually selected, the automatic adjustment will stop, and the selected view will be maintained.

7.3.2 Alerts

In OR mode, No Urine Detected alerts are disabled since surgeries often contains periods where urine output is low for reasons unrelated to anuria

8 Alerts and Safety

8.1 Alert Types

Pay attention to the alerts listed below to improve product usage and patient treatment.

Table 4 lists the FIZE kUO alerts and respective solutions.

Table 4. Device Alerts

No.	Displayed Message	Description	Alert sound	Solution
1.	Low Urine Volume	The system has identified urine output (ml) below the defined threshold.	Optional	Check patient clinical status. If no action is needed, close the alert. If needed, change the defined alert thresholds (see section 8.2 – Alert Configuration).
2.	Low Urine Volume	The system has identified urine output (ml/Kg/hr) below the defined threshold.	Optional	Check patient clinical status. If no action is needed, close the alert. If needed, change the defined alert thresholds (see section 8.2 – Alert Configuration).
3.	High Urine Volume	The system has identified urine output (ml) above the defined threshold.	Optional	Check patient clinical status. If no action is needed, close the alert. If needed, change the defined alert thresholds (see section 8.2 – Alert Configuration).
4.	High Urine Volume	The system has identified urine output (ml/Kg/hr) above the defined threshold.	Optional	Check patient clinical status. If no action is needed, close the alert. If needed, change the defined alert thresholds (see section 8.2 – Alert Configuration).
5.	No Urine Detected	Close to no urine was detected by the system due to patient clinical status. The cassette is ejected after 60 minutes.	Optional	If low urine is expected, switch to 'Low Urine Mode' (See section 7.1 – Low Urine Mode).
6.	Catheter clogged	The system has detected a potential catheter clog.	Optional	Check if the catheter is clogged, and if necessary, perform irrigation.

No.	Displayed Message	Description	Alert sound	Solution
7.	Monitoring Paused	Monitoring paused by the user. The cassette is ejected after 60 minutes.	Optional– if enabled, alert sounds 5 minutes before cassette ejection.	Press "Resume" to continue monitoring.
8.	Define Patient	Cassette was inserted, but a patient was not defined. The cassette is ejected in 17 minutes.	None	Define the patient on the Patient Definition screen (see section 5.2).
9.	Start Monitoring	Patient was defined, but monitoring was not started. The cassette is ejected in 15 minutes.	None	Press Start Monitoring (see Figure 5-4).
10.	Battery Low	Console battery status is at 30%.	Optional	Connect the console to a power supply using the provided cable.
11.	Battery Very Low	Console battery status is at 20%. The cassette is ejected.	Optional	Connect the console to a power supply using the provided cable. Reinsert the cassette and resume monitoring.
12.	Battery Dead	Battery depleted. Device shuts down within 1 minute.	None	Connect the console to a power supply using the provided cable. Turn the device on, reinsert the cassette, and continue monitoring.
13.	Battery Failure	Battery malfunction prevents device operation on battery alone.	None	Keep the device connected to a power supply and notify FIZE Medical Technical Support.
14.	Battery Overheated	The system has identified battery overheating.	None	Restart the device, reinsert the cassette, and resume monitoring. If the issue is not resolved, replace the console and notify FIZE Medical Technical Support.

No.	Displayed Message	Description	Alert sound	Solution
15.	Battery Too Cold	The system has identified battery overcooling.	None	Restart the device, reinsert the cassette, and resume monitoring. If the issue is not resolved, replace the console and notify FIZE Medical Technical Support.
16.	Cassette Ejected	Cassette was ejected by the system due to an unaddressed alert (low battery, suspected catheter clog, etc.).	Optional	Check the cause of cassette ejection and address it accordingly. After eliminating the cause of the alert, reinsert the cassette and resume monitoring.
17.	Disposable Kit Connection Failed	A problem was detected during kit insertion. The cassette is ejected.	Optional	Try inserting the cassette again. Make sure to follow cassette insertion instructions as detailed in section 5.15.1. If the problem repeats, replace the kit.
18.	Cassette Release Failed	Cassette failed to be released from the console when ejected.	Voice alert is always on	Pull out the cassette manually. Insert and eject the cassette again to ensure the cassette release mechanism is in order. If no issues arise, insert the cassette back in and resume monitoring. If the problem repeats - replace the kit.
19.	Kit Failure	Kit malfunction occurred while monitoring. The cassette is ejected in 60 minutes.	Optional	Replace kit.
20.	Kit About to Expire	Kit is about to expire.	None	Replace the kit when possible.
21.	Kit Expired	Kit has reached its expiry. The cassette is released in 60 minutes.	Optional	Replace the kit and continue patient monitoring.
22.	Disposable kit incompatible	Disposable kit authenticity and sterility cannot be verified.	Optional	Replace kit.

No.	Displayed Message	Description	Alert sound	Solution
23.	Disposable kit incompatible – Please replace with pediatric kit	Disposable kit is incompatible with the device's operating mode	Optional	If you are monitoring in Pediatric Mode, replace the kit with a Pediatric Disposable Kit.
24.	Disposable kit shelf life expired	Disposable kit is no longer sterile.	Optional	Replace kit.
25.	RFID not accessible	Kit shelf life and expiry information cannot be accessed by the system.	Optional	Replace kit.
26.	Initialization Failed	Measurement initialization could not be completed due to a kit malfunction or a very high volume of residual urine.	Optional	Try Initializing again. If initialization fails, replace the kit.
27.	System Overheated	System overheating prevents proper device function. The cassette is ejected in 60 minutes.	Optional– if enabled, an alert sounds 5 minutes before cassette ejection	Restart the device, reinsert the cassette if necessary, and resume monitoring. If the issue is unresolved, replace the console and notify FIZE Medical Technical Support.
28.	Hardware Failure	System detected a hardware failure while monitoring. The cassette is ejected in 60 minutes.	Optional	Restart the device by pressing the 'Restart' button in the alert. If the issue is unresolved, shut down the device and contact FIZE Medical Technical Service.
29.	Tubing Obstruction	System detected an obstruction in the tubing. This could be caused for example by a closed clamp	Optional	Make sure tubing is unclamped, free of kinks. and properly secured to the catheter. If the issue persists, replace kit

8.2 Notification and Alert Configuration

Notifications and alerts can be configured in the **Settings** Screen.

8.2.1 Ward Alerts

Notification defaults for all patients in the unit are defined in the **Settings** screen **Ward** page, under the **Alerts** tab (see Figure 8-1).

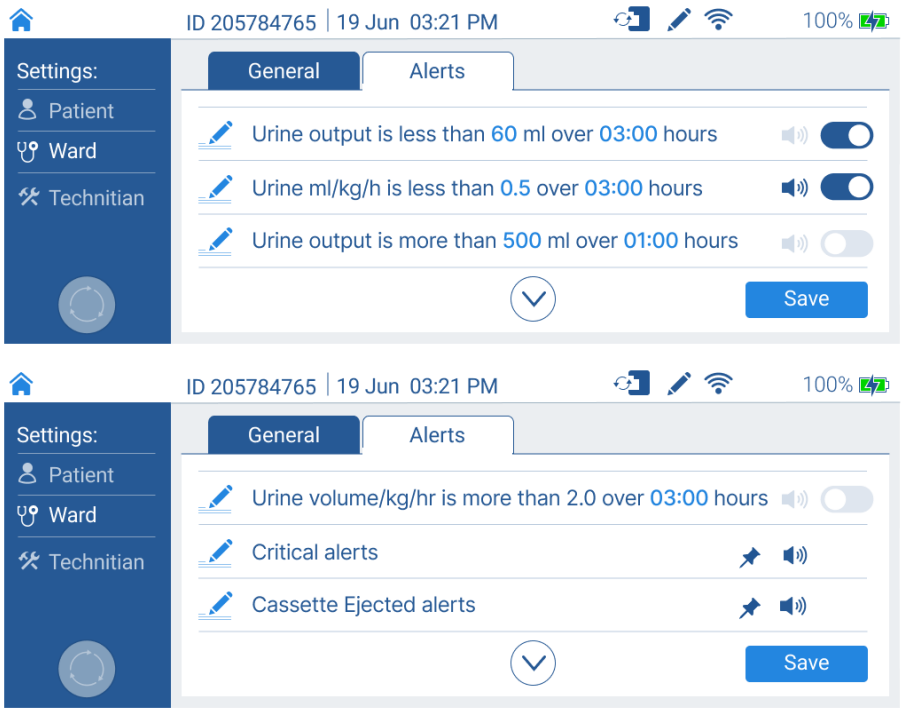

Figure 8-1. Ward Alerts settings

Notifications and alert configurations are available for clinical alerts, critical alerts, and cassette ejection alerts.

- Turn alerts on or off by pressing the toggle icon.
- To turn the alert sound on or off, press the speaker icon.
- Press the thumbtack icon to keep an alert banner on the screen as long as the alert is active.

8.2.1.1 Clinical Alerts

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

8.2.1.2 Critical Alerts

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

- Low Battery alert.
- No Urine Detected alert
- Catheter Clogged alert
- Initialization Failed alert

8.2.1.3 Cassette Ejection Alerts

Cassette ejection alerts are displayed on the screen for any cassette ejection by the system after the cassette is ejected from the console.

Press the speaker icon to turn the alert sound for cassette ejection on or off.

When the cassette alert sound is activated, the sound notification begins 5 minutes before any system-generated cassette ejection and continues while the cassette is released until the alert is addressed.

Press the thumbtack icon to keep an alert banner on the screen as long as the alert is active.

8.2.2 Patient-Specific Alerts

Patient-specific alerts can be defined in the **Settings** Screen **Patient** page under the **Clinical** tab (see Figure 8-2).

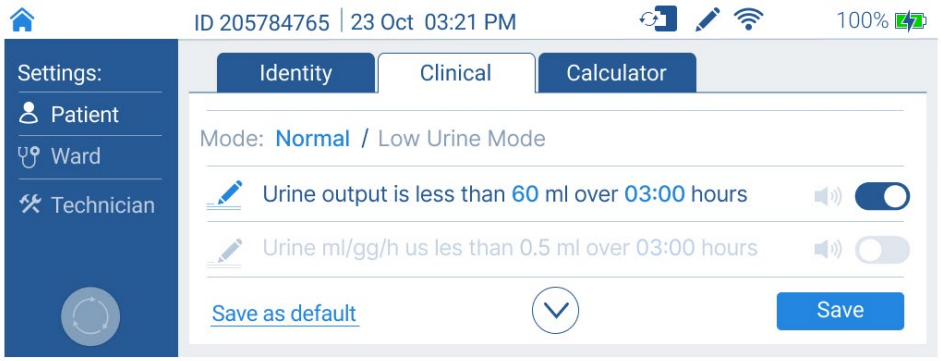

Figure 8-2. Patient Alerts settings

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 reverts to default ward settings.

- To turn alerts on/off, press the toggle icon.
- To turn sounds on/off, press the speaker icon.
- To edit urine output **thresholds** of clinical alerts, press the pencil icon, insert the desired threshold, and press **Save**.

8.3 Cassette Ejection Safety Mechanism

The Cassette Ejection Mechanism is a safety measure for ensuring continuous urine flow.

A countdown timer is initiated and displayed onscreen for specific alerts, which must be addressed before the timer runs out.

If an alert is not addressed on time, the cassette is ejected, making the disposable kit a regular urine drainage bag. In this situation, urine flows to the collection bag without being measured.

The Cassette Ejection Mechanism applies under the following conditions:

Alert Type	Time to address
No Urine Detected	60 minutes
Monitoring Paused	60 minutes
Start Monitoring	22 minutes
System Overheated	60 minutes
Hardware Error	60 minutes
Kit Failure	60 minutes
Battery Very Low	Cassette immediately ejected

9 Cleaning and Maintenance

9.1 Cleaning and Disinfecting

The FIZE kUO Console and Power Supply Box are shipped clean but are not sterile. Use the information in this section and hospital policy to properly clean and disinfect FIZE equipment.

9.1.1 FIZE kUO Console

Sanitize the FIZE kUO Console between patients.

Caution

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

To clean the FIZE kUO Console and Power Supply Box:

1. Wipe the console exterior and all parts not in direct contact with patients using FDA-approved single-use wipes, such as CaviWipes or CaviCide, or using a sterile cloth sprayed with 70% isopropyl alcohol or equivalent, such as ethanol.
2. Pay attention to wiping the cassette cavity area properly.
3. Following cleaning, the screen may be wiped dry with a paper towel or a lint-free cloth.
4. Air dry.

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 Maintenance

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

1. Visually inspect the 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.
2. Utilize the FIZE kUO calibration verification kit to ensure the device is within its defined accuracy.

9.3 Service and Support

Please read this user manual thoroughly. If you have questions, you may contact 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 × 215 × 111
FIZE kUO disposable length	2.80 meters
Urine Volume Measurement	Range: 0 to 1500 ml/hr Accuracy: ±5%

10.2 Electrical Specifications

Characteristic	Specification
Voltage	100 – 240 VAC
Frequency	50 – 60 Hz
Current Consumption	4 Amp (max)

10.3 Wireless Network Specifications

Specification	Standard
Network Standard	IEEE 802.11ac, 802.11n, 802.11a and 802.11b IEEE 802.11g, 802.11d, 802.11h and 802.11i
Frequency Band	2412-2484 MHz, 5170-5825 MHz
Data Rates Supported	1, 2, 5.5, 11, 6, 9, 12, 18, 24, 36, 48, 54 Mbps, MCS0-MCS9
Wireless Medium	Direct Sequence Spread Spectrum (DSSS) Orthogonal Frequency Division Multiplexing (OFDM) HT20, HT40 and VHT80 at 5GHz only
Roaming	IEEE 802.11a, 802.11b, 802.11g, 802.11n compliant
Authentication	PSK EAP-TLS EAP-TTLS EAP-PEAP

Encryption	WEP-64bit WEP-128bit WPA-TKIP WPA2 AES-CCMP

10.4 Internal Battery Specifications

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

10.5 Environmental Specifications

Transportation Conditions	Range
Temperature	-30 °C to 60 °C / -22 °F to 140 °F
Humidity	15% to 90% RH at 31 °C

Storage Conditions	Range
Temperature	15 °C to 30 °C / 59 °F to 86 °F
Humidity	15% to 90% RH at 31 °C

Operating Conditions	Range
Temperature	15 °C to 30 °C / 59 °F to 86 °F
Operating Pressure (Altitude)	70 KpA to 110 KpA
Humidity	15% to 90% RH at 31 °C
Power Box IP rating	IP54 IEC 60529
Console IP rating	IP22 IEC 60529

10.6 Safety and Particular Standard Specifications

Caution	The disposable kit should be placed between the patient's legs and the urine bag at the end of the bed (the far side from the MRI scanner).

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.

10.7 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 is MR conditional. A catheterized patient can remain connected to the Fize kUO and be safely scanned in MR systems, meeting the following conditions.

MRI Safety Information A person may be safely scanned while connected to FIZE Disposable Kit under the following conditions. Failure to follow these conditions may result in injury	
Device Name	Fize kUO
Static Magnetic Field Strength (B0)	1.5T, 3.T
Maximum Spatial Field Gradient	37.49 T/m (3749 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Receive Coil Type	Any
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)

11 Guidance on Manufacturer's Declaration

11.1 Electromagnetic Emission

This device is 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 establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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 contact	±8 kV air ±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 ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Main power quality should be that of a typical home or hospital environment.

Immunity test	IEC60601 Test level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) fir 25 cycles. <5% UT (>95% dip in UT) for 5 seconds	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) fir 25 cycles. <5% UT (>95% dip in UT) 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: UT 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 frequency of the transmitter.
	3 Vrms 150 kHz to 80 MHz Outside ISM bands1	3V	Recommended separation distance:

Immunity test	IEC60601 Test level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3	10 Vrms 150 kHz to 80 MHz in ISM bands2 10 V/m 80 MHz to 2.5 GHz	10V 10 V/m 26 MHz to 2.5 GHz	d= 1.2 √p d= 1.2 √p d= 1.2 √p 80 MHz to 800 MHz d= 2.3 √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: 

Immunity test	IEC60601 Test level	Compliance Level	Electromagnetic Environment Guidance
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√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5GHz d = 2.3√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.