

EdgeFlow UW20

User Manual



Manufacturer



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Chapter1. Introduction

1. Manual Information

1.1 Intended purpose of this Manual

This manual is provided for EdgeFlow UW20 system users and describes the system and procedure for component connection and system settings. This manual describes the cautions of EdgeFlow UW20 system also. It describes possible hazards that users should be aware of and pay attention to during use. The user should read this entire user manual before using the EdgeFlow UW20 system.

1.2 General Information

The information in this manual is the property of Edgcare Inc. No content of this manual may be reproduced, transmitted, or transcribed without the written permission of the manufacturer and authors of this manual.

Contact Edgcare Inc. or your local service representative if there are any questions about the system.

1.3 Quality Assurance

The information in this manual is subject to change without notice. If the device is not properly set causing it to malfunction or fail, we cannot guarantee any responsibility.

1.4 Revision History

The document number and revision number in this manual are the current version. When there are changes in the technical content of the product, the revision number of manual may change.

1.5 Definitions of different types of Warnings

The various safety and caution are defined as follows in this manual. Read all safety information carefully about using the system.

	PROHIBITION
	Prohibition relates product damage and patient's harm. It means "should not be done."
	WARNING
	Warning indicates that injury, death, or other serious adverse effects may result from use or misuse of the system.
	CAUTION
	Cautions indicate that use or misuse of the device may cause a problem, such as a malfunction, failure, or damage to the product.
	NOTE
	Used for instructions to draw attention to information that is important for the operator to know.

2. Revision History

This document number : **EC-IFU-UW20EN**

Rev.	Release date	Main modifications	Remark
0	2025-Feb-14	Initial release	
1	2025-Dec-30	Change the manufacture address	
2	2026-Jan-18	Apply FDA 510(k) feedback (K252237)	Compatible S/W ver: V1.0.2
3	2026-Mar-26	Modification procedure in Section 1.6 Cleaning & Disinfection of Patch (including Probe) and Section 1.7 Cleaning & Disinfection of Charging station.	
4	2026-April-01	Adding the number of wipes in Section 1.6 Cleaning & Disinfection of Patch (including Probe) and Section 1.7 Cleaning & Disinfection of Charging station.	
5	2026-April-16	Modification of Section 1.3 Intended use and Section 1.4 the Intended patient population	
6	2026-May-28	Adding cybersecurity requirements according to Korea Digital Medical Devices 1) System usage notification messages 2) Password change recommendation feature 3) Backup and restore function 4) Added explanation for initial user password setting	Compatible S/W ver: V1.1.0

3. Safety Information

3.1 General Safety Information

This manual includes directions for general use of EdgeFlow UW20 and checks these directions on each chapter for more information.



EdgeFlow UW20 is MR Unsafe. These components have not been evaluated for safety or compatibility in the MR environment.

Remove the EdgeFlow UW20 Patch from the patient before the patient enters the MRI scanner room or MR environment.

Exposure to the MR environment may result in device malfunction.

3.2 WARNING

	WARNING Users must read and understand the user manual before use and do not use the system except for the intended use.
	WARNING Avoid dropping the equipment and accessories or subjecting them to strong impacts. Doing so may result in electric shock or injury.
	WARNING Do not disassemble or modify this equipment or its components arbitrarily. This may result in serious injury to the operator or damage to the equipment and will void the warranty. For all necessary services, contact Edgcare Inc. or your local dealer.
	WARNING The use of accessories, adapters, and cables other than those specified or provided by Edgcare Inc. may result in increased electromagnetic emissions or decreased electromagnetic immunity of the EdgeFlow UW20, which may cause improper operation. It may also result in inaccurate measurement results.
	WARNING Stop using the equipment if it emits smoke or toxic gases. Failure to do so may result in electrical shock or fire.
	WARNING Please keep in mind the following conditions that can affect ultrasound transmission and measurement accuracy. • Air gaps between the probe and the patient's skin or air bubbles in the ultrasound gel impede ultrasound transmission. • Charge the system sufficiently before starting measurement. • Check the condition of the probe before use, as damage to the probe, foreign matter, etc. can affect ultrasound transmission.
	WARNING Do not connect or disconnect cables when your hands are wet. To avoid the risk of electric shock, make sure your hands are dry before disconnecting the cable.

	WARNING
	This equipment contains lithium-ion batteries, which may cause leakage, explosion, fire, or serious injury. Please take the following precautions when handling. • When EdgeFlow UW20 system is not used for an extended period, turn off the power and store it properly. To prevent complete battery discharge, recharge it periodically during storage. • Battery replacement can only be performed by personnel designated by Edgcare Inc. (service engineers or certified technicians). Please refer to the service manual for details regarding battery replacement. • If a battery-related issue occurs, please contact your local service representative or dealer.
	WARNING
	When charging this device, please note the following. • Make sure that the device is completely powered off before starting charging. • Before charging this device, inspect the adapter and cable for damage. If there is any damage to the adapter or cable, contact Edgcare Inc. or your local dealer. • Place the charging station on a firm and level surface to charge and store the patch. • Do not use a damaged power cord or loose outlet as there is a risk of electric shock or fire. • The power cord of the power adapter is not designed to come into contact with the patient. • Be sure to check the voltage of the power supply (wall power) before connecting the power plug of the adapter, and do not place the product in a place where it is difficult to unplug the power cord. • During charging, B-mode scans and bladder measurement monitoring cannot be performed.
	WARNING
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the EdgeFlow UW20, including any cables specified by Edgcare Inc., as this may result in degraded performance of the equipment.
	WARNING
	To prevent noise from occurring in ultrasound images and ensure normal operation of the EdgeFlow UW20, it is recommended to keep a distance of at least 15 cm from RFID devices that use 13.56 MHz or higher.
	WARNING
	EdgeFlow UW20 should not be used adjacent to or stacked with other equipment, as this may result in improper operation. If such use is necessary, the EdgeFlow UW20 and other equipment should be observed to ensure proper operation.
	WARNING
	EdgeFlow UW20 Patch (including Probe) should be removed from the patient prior to application of a defibrillator.
	WARNING
	Edgcare Inc. is not responsible for any viruses affecting the EdgeFlow UW20 device that may cause data loss.

	WARNING Do not store or use near flammable anesthetics or gases as there is a risk of explosion.
	WARNING Do not use with high-frequency surgical equipment, etc. as there is a risk of electric shock or burns.
	WARNING For safe use, the following are recommendations for cleaning and disinfecting the equipment: • Clean and disinfect the equipment according to the procedures provided in this user manual. • If the device is not properly cleaned, contamination may remain even after the disinfection procedure is completed, so visually check whether cleaning is complete before disinfection.
	WARNING For safe use, the following are recommendations for cleaning and disinfecting the equipment: • Clean and disinfect the equipment according to the procedures provided in this user manual. • If the device is not properly cleaned, contamination may remain even after the disinfection procedure is completed, so visually check whether cleaning is complete before disinfection.
	WARNING Use of devices that transmit radio waves near the system could cause it to malfunction. Before installing or using the system, be aware of the proximity of known radio frequency (RF) sources, such as: • Radio and TV stations • Portable and mobile RF communication devices (cell phones including 5G communications, two-way radios) • Fixed RF communication devices including RFID (Radio-frequency identification), EAS (electronic article surveillance), and Wireless power transfer (WPT) • X-ray, CT, or MRI devices These devices are also possible sources of interference as they may emit higher levels of electromagnetic radiation.

3.3 CAUTION

	CAUTION To avoid damage to cables and accessories, do not excessively twist or bend cables associated with the system.
	CAUTION To avoid injuries from sharp edges or rough surfaces, ensure that the exterior of the equipment is not damaged in any way.
	CAUTION Users should be careful not to drop the system.
	CAUTION Failure to follow these instructions may cause device damage not covered by the warranty. • Do not immerse the device in cleaning/disinfectant solution or other liquids. • Do not subject any part of the device to steam, ethylene oxide, radiation, or similar methods of sterilization or autoclaving. • Do not use metal or abrasive brushes to avoid scratch on the device that can cause permanent device damage.
	CAUTION Medical electrical equipment requires special precautions regarding electromagnetic compatibility and must be installed and operated according to the instructions in this manual. Please refer to the Electromagnetic Compatibility section. This device can radiate radio frequency energy and is very unlikely to cause harmful interference with other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. Evidence of interference may include degradation of performance in this device or other devices when operated simultaneously. To resolve interference, use the following measure. • Turn devices on and off in vicinity to determine the source of interference. • Reorient or relocate this device or other devices. • Increase the separation between the device and the influential environment. • Other medical devices in the vicinity should be complied with the IEC 60601-1-2 standard. • Note that portable and mobile radio frequency communications equipment (cellular phones, etc.) may affect medical electrical equipment; take appropriate precautions during operation.
	CAUTION To dispose of the device or accessories that have reached the end of valid warranty or product life, see Recycling and Disposal section in the Maintenance chapter.

3.4 USER Information

FCC ID: 2BRIC-ESPPICOMINI

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

This device complies with RF exposure requirement

CAUTION

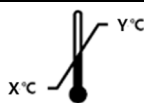
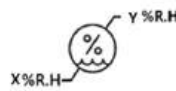
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

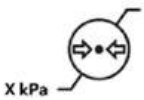
4. Regulatory

Standard	
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard : Usability
IEC 60601-2-37	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	Medical device software – Software life-cycle processes
IEC 62366-1	Medical device – Application of usability engineering to medical devices
ISO 14971	Medical devices – Application of risk management to medical devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ISO 7010	Graphical symbols – Safety colors and safety signs – Registered safety signs

5. Meaning of symbols

The following table describes symbols used in this manual, labels, and packaging provided on the equipment.

Symbols	Description
	Date of manufacture
	Name and address of the manufacturer
	Medical device serial number
	Type BF applied part or connection
	Follow instructions for use.
	Caution
	General warning sign (Safety sign)
	General prohibition sign (Safety sign)
	Alternating current
	Direct current
IPX7	Water resistance of the probe (IPX4)
	Keep dry
	This end up
	Fragile handle with care
	Temperatures limitation (X = lower limit, Y = upper limit)
	Humidity limitation (X = lower limit, Y = upper limit)

	Atmospheric pressure limitation (X = lower limit, Y = upper limit)
	WEEE (Waste Electrical and Electronic Equipment)
	Wireless communications
Rx Only	Federal law restricts this device to sale by or on the order of a physician
	Unique device identification (UDI)
	Don't use when packing damaged
	Direct current
	Alternating current
	Rechargeable battery (Lithium-ion)
	Power On/Off key
	Recycled materials or may be recycled
	EdgeFlow UW20 is MR Unsafe. This symbol indicates that this device is MRI not compatible and should not be used in the Magnetic Resonance Environment.

6. Safety Considerations

6.1 Ultrasonic Safety

EdgeFlow UW20 is a device that uses ultrasound and exposure to be pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, total patient exposure should be maintained as low as reasonably achievable (ALARA). Therefore, EdgeFlow UW20 should be used by healthcare professionals using the lowest possible exposure times necessary to obtain clinically useful information. For more information about acoustic output levels, refer to 6.3 Acoustic Output Tables.

6.2 Acoustic Output

EdgeFlow UW20 provides real-time display features according to IEC 62359. The system displays a thermal index (TI). This index aims to estimate the potential biological effects of ultrasound. The TI value is shown in increments of 0.1, but only when the value exceeds 1.0. Note that the displayed (estimated) TI values are nominal values.

- **Thermal Index (TI)**

TI is defined as a ratio of attenuated output power at a specified point to the attenuated output power required to raise the temperature at that point in a specific tissue model by 1°C. The displayed thermal index is an estimate of temperature increase to help the operator to implement the ALARA (As Low As Reasonably Achievable) principle.

Depending on the examination and type of tissue involved, the TI parameter will be one of three types:

- TIS (Soft tissue Thermal Index) : Used when imaging soft tissue only, it provides an estimate of potential temperature increase in soft tissue.
- TIB (Bone Thermal Index): Used when bone is near the focus of the image as in the third trimester OB examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.
- TIC (Cranial-bone Thermal Index) Used when bone is near the skin surface as in transcranial examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.

- **Mechanical Index (MI)**

MI is a predictor of the likelihood of tissue damage due to cavitation.

- **Controls Affecting Acoustic Output**

EdgeFlow UW20 operates using the following ultrasound imaging modes:

- B-mode (Imaging mode : Harmonic)

6.3 Acoustic Output Tables

EdgeFlow UW20 probe is designed as phased array module.

1) Ultrasound Imaging mode: **Harmonic**

	NOTE
	- MI and TI (TIS, TIB) values are below 1.0 all. - N/A* indicates that there are no corresponding intended use or data reported.

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.58	0.17		0.17		N/A
Index component value				0.17	0.17	0.17	0.17	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.74					
	P	(mW)		N/A		N/A		N/A
	$P_{1 \times 1}$	(mW)		22.00		22.00		
	z_s	(cm)			3.60			
	z_b	(cm)					3.60	
	z_{MI}	(cm)	3.40					
	$z_{pii,\alpha}$	(cm)	3.60					
	f_{awf}	(MHz)	1.63	1.63		1.63		N/A
Other Information	pr_r	(Hz)	1800					
	srr	(Hz)	28.29					
	n_{pps}	-	1.00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm ²)	18.33					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sij,\alpha}$	(mW/cm ²)	124.11					
	$I_{spta,\alpha}$ at z_{pii} or z_{sij}	(mW/cm ²)	189.15					
	p_r at z_{pii}	(MPa)	0.89					
Operating control conditions	Mode		B-mode					N/A
	Focal depth	(cm)	7.50	7.50	7.50	7.50	7.50	N/A
	Working frequency	(MHz)	1.60	1.60	1.60	1.60	1.60	N/A

6.4 Maximum Probe Temperature

EdgeFlow UW20 shall not produce unintended or excessive probe surface temperature.

6.5 Electromagnetic Compatibility (EMC)

EdgeFlow UW20 is designed to follow IEC 60601-1-2, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical facility.

The system complies with the applicable essential performance requirements in IEC 60601-1 and 60601-2-37. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables.

- Electromagnetic Emissions**

EdgeFlow UW20 is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance
Conducted emissions CISPR 11	Group 1	The emissions characteristics of EdgeFlow UW20 make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Radiated emissions CISPR 11	Class A	EdgeFlow UW20 is suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network that supplies buildings used for domestic purposes. However, heed the following warning: EdgeFlow UW20 is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment.
Harmonic emissions IEC 61000-3-2		
Voltage fluctuations / Flicker emissions IEC 61000-3-3	In compliance	

- Electromagnetic Immunity**

EdgeFlow UW20 is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Immunity Tests	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines 100 kHz repetition frequency	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1 kV line(s) to line(s)	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Tests	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
	± 0.5 kV, ± 1 kV, ± 2 kV line(s) to ground		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % Ur: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % Ur: 1 cycle and 70 % Ur: 25/30 cycles Single phase: at 0° 0 % Ur: 25/30 cycle	0 % Ur: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % Ur: 1 cycle 70 % Ur: 25/30 cycles Single phase: at 0° 0 % Ur: 25/30 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EdgeFlow UW20 requires continued operation during power mains interruptions, it is recommended that the EdgeFlow UW20 is powered from an uninterruptible power supplied or a battery.
Power frequency (50/60Hz) Magnetic fields IEC 61000-4-8	30 A/m, 50/60 Hz	30 A/m, 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz immunity IEC 61000-4-39	65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50 kHz	65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50 kHz	Resistance to magnetic fields was tested and applied only to surfaces of enclosures or accessories accessible during intended use.
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 80% Am at 1 kHz	3 Vrms 0.15 MHz to 80 MHz 80% Am at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the EdgeFlow UW20, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF and Proximity fields from Rf wireless communications equipment IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	The interface between the patient physiological signal simulation, if used, and the ME Equipment or ME System shall be located within 0.1 m of the vertical plane of the uniform field area in one orientation of the ME Equipment or ME System.
	385 MHz (18 Hz Pulse Modulation)	27 V/m	
	450 MHz (FM +/- 5 kHz deviation 1 kHz sine or 18 Hz Pulse Modulation)	28 V/m	
	710 MHz to 780 MHz (217 Hz PM)	9 V/m	
	810 MHz to 930 MHz (18 Hz PM)	8.5 V/m	
	1720 MHz to 1970 MHz, 2450 MHz (217 Hz PM)	28 V/m	
	5240 MHz to 5785 MHz (217 Hz PM)	9 V/m	



NOTE

EdgeFlow UW20 is not life-supporting equipment.



NOTE

U_t is the A.C. mains voltage prior to application of the test level.



NOTE

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

- Recommended Separation Distances

The system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system 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 2.7 GHz $d=2.0 \sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

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

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



NOTE

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

Chapter2. System Introduction

1. System Overview

1.1 Product Introduction

EdgeFlow UW20 is a wireless ultrasound bladder volume measurement device that acquires ultrasound images of the bladder using an ultrasound patch integrated with a probe. The ultrasound images acquired from the patch are transmitted wirelessly to a mobile application running on a mobile device.

The bladder volume measurements can be performed periodically at a set time interval set by the user.

1.2 Product Name

EdgeFlow UW20

1.3 Intended Use

The EdgeFlow UW20 is a wearable ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively in adult patients with BMI up to 30. The bladder volume measurements can be performed periodically at a set time interval set by the user. It is intended for use in professional healthcare facilities, such as hospitals and clinics, by qualified and trained healthcare professionals. The EdgeFlow UW20 supports B-mode and harmonic imaging modes.

1.4 Intended Patient Population

- Age: adult (≥ 18 years)
 - Patients with temporary urinary incontinence and cognitive impairment after surgery (stroke)
 - Partially ambulatory or less mobile
- Location: worldwide
- Sex: male and female
- BMI: $\leq 30 \text{ kg/m}^2$

	CAUTION
	Limitations: EdgeFlow UW20 has been clinically evaluated in patients with a Body Mass Index (BMI) of up to 30 kg/m^2. The effectiveness of this device in patients with a BMI exceeding 30 kg/m^2 have not been established. Use of this device in patients outside the evaluated BMI range is not recommended.

- Height: no limitations

	NOTE
	Patients are not considered intended users of the EdgeFlow UW20 and are not involved in the operation, interpretation, or adjustment of the device.

1.5 Intended User

EdgeFlow UW20 is intended for use by qualified and trained healthcare professionals (e.g. doctors, nurses)

	NOTE
	Intended user of EdgeFlow UW20 is task and responsibility; 1. Intended Users and Overall Clinical Workflow The EdgeFlow UW20 system is designed for use only by trained and authorized healthcare professionals (HCPs) in a clinical environment as the intended users. Healthcare professionals are responsible for all clinical tasks associated with use of the

	device, including but not limited to: • Initial placement, attachment, and securement of the device • Verification of proper positioning and adequate acoustic coupling • Review of ultrasound images and bladder volume measurement results • Clinical interpretation of device outputs and all related clinical decision-making Patients are not considered intended users of the EdgeFlow UW20 system and are not involved in device operation, interpretation, or adjustment. Despite the wearable nature of the device, the clinical workflow is designed such that clinical responsibility and decision-making always remain with the healthcare professional. 2. Healthcare Professional Oversight During Monitoring At the initiation of monitoring, the healthcare professional is responsible for verifying that the device is functioning as intended and for reviewing measurement results generated during use. Continuous physical presence of the healthcare professional at the patient's bedside for each measurement event is not required, as the device is designed to perform automated measurements under pre-validated conditions. Nevertheless, professional oversight is maintained through: • Availability of measurement results and ultrasound images for healthcare professional review • Healthcare professional assessment of measurement validity and clinical relevance • Defined procedures for responding to invalid or missing measurements This clinical workflow is consistent with that of other wearable monitoring devices used in clinical practice. 3. Image Accessibility and Measurement Quality Verification The EdgeFlow UW20 system provides healthcare professionals with access to the following information: • Bladder volume measurement results • Ultrasound images used to generate the corresponding measurements Healthcare professionals are responsible for verifying: • That the bladder is adequately visualized within the image • That image quality is sufficient for segmentation • That the calculated bladder volume is clinically reasonable Automated segmentation and measurement results are intended to support clinical decision-making and do not replace the judgment of a healthcare professional. 4. Handling of Failed or Invalid Measurements If a measurement is not successfully performed: • The condition is communicated to the healthcare professional via the application interface Based on clinical judgment, the healthcare professional determines appropriate actions, which may include device repositioning, continuation of monitoring, or discontinuation of use. 5. Notifications, Alerts, and Attribution of Responsibility The EdgeFlow UW20 system does not assign any clinical responsibility to the patient. System notifications or display features are intended solely to inform the healthcare professional of device status or measurement availability. Patients are not required to respond to alerts or make clinical decisions.
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1.6 Use Environment

EdgeFlow UW20 is intended to be used in healthcare environments such as hospitals or medical clinic.

1.7 Contraindications

Use may be restricted for patients with the following conditions.

- Patients with surgery or wounds, sutures, incisions, etc. in the lower abdomen
- Patients with excessive lower abdominal obesity
- Pregnant women
- Under adult (<18 years)

2. System Components

The components of EdgeFlow UW20 are the following.

2.1 EdgeFlow UW20 Patch



The ultrasound bladder scanner is a small patch-type device that can be attached to a patient and has a probe that transmits and receives ultrasound on its lower surface. The patch transmits the acquired ultrasound image data of the bladder to a mobile application via wireless communication. The patch contains a rechargeable lithium-ion battery, which can be charged using a charging station. For more information, see [Section 3. Patch](#).

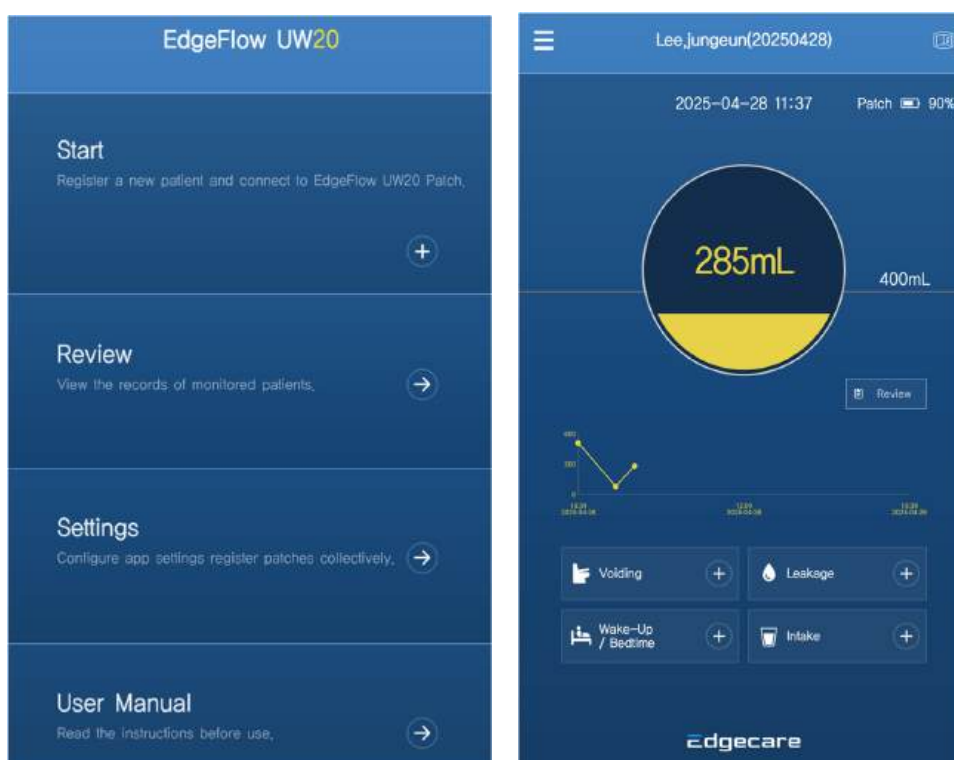
2.2 EdgeFlow UW20 Charging Station



It can charge the battery of patch and store patch and can hold up to 4 UW20 patches. For more details, see [Section 4. Charging Station](#).

2.3 Mobile Application

A software application/app installed on a mobile device (e.g., tablet PC) that measures and records the amount of urine in the bladder using image processing and deep learning of the ultrasound energy transmitted from the UW20 patch.



2.4 Accessories

2.4.1 Power Adapter

The charging station is powered by a power adapter. Connect the charging station to a wall outlet using the cable from the power adapter.



	NOTE					
	The AC plug can be detached and replaced. The provided AC plug varies depending on the country in which you purchase this product.					
	Interchangeable Type of AC plug					
	EU	US	UK	AU	CN	KR

2.4.2 Gel Pad

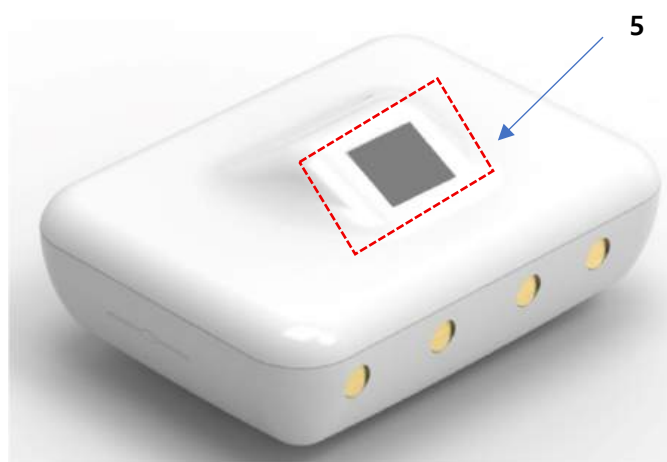
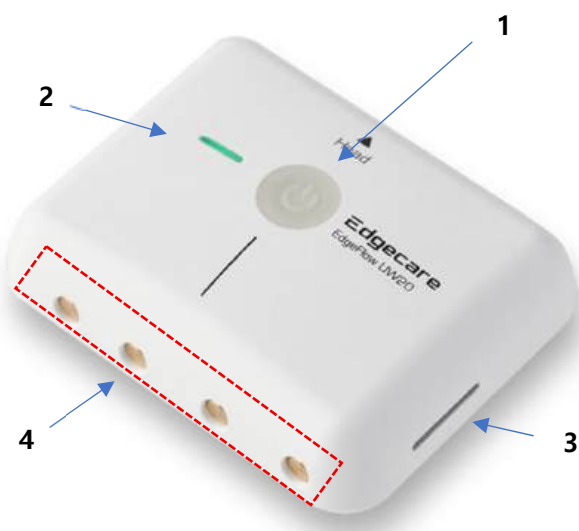
An adhesive, non-sterile, solid medical gel used to enhance energy transfer information from the probe of the EdgeFlow UW20 patch. Refer to detailed information in [EC-IFU-GELPADEN] EdgeFlow GEL PAD Instructions for Use.

	WARNINGS
	- Do not use it for purposes other than medical devices. - Do not use it on wounds or inflamed areas. - Dispose of after use as a disposable medical product. Repeated use may result in decreased performance and efficacy, contamination, yellowing, and other deformations. - Stop using the gel pad if you experience a rash or allergy. - If you have an allergic reaction, hypersensitive skin, or skin disease, be sure to use it under the instructions of a doctor or other specialist. - When attaching the gel pad to the skin, be sure to completely remove moisture from the skin. - Do not use with skin care products such as cosmetics, ointments, and lotions.

	NOTE
	Gel pads are not included in the basic configuration of EdgeFlow UW20. If needed, it must be purchased separately.

3. Patch

3.1 Shape and Structure



[Top view]

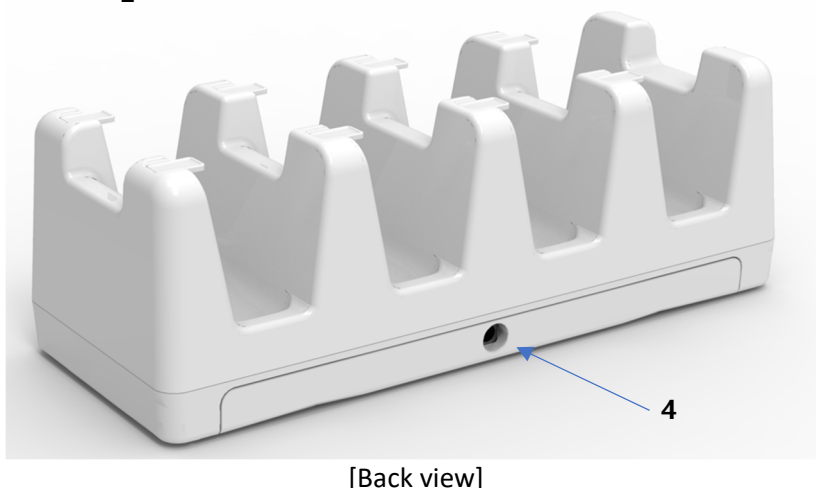
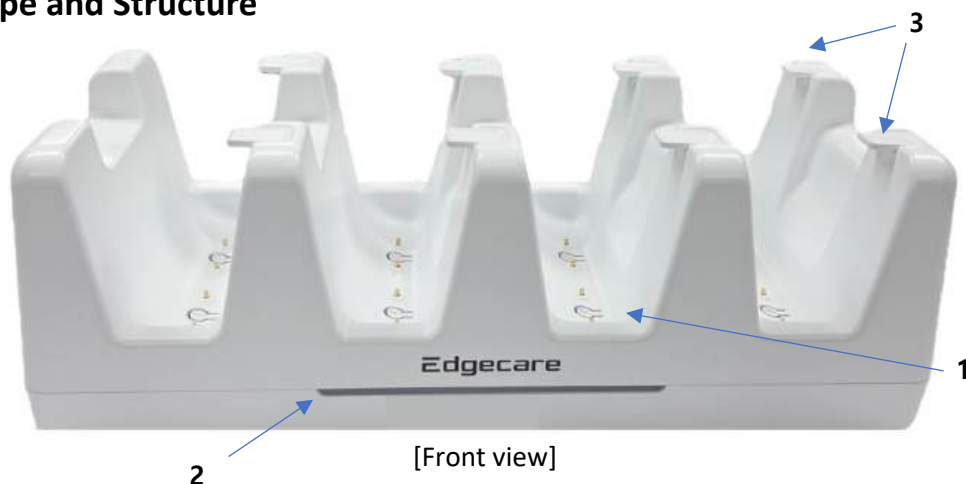
[Lower view]

No.	Name	Description																													
1	Power button	A button to turn the patch on/off. During bladder residual urine monitoring, press the button to manually obtain the bladder residual urine value in addition to the automatic measurement.																													
2	Status LED indicator	LED indicator light that indicates the status of the patch, showing the following information. <table border="1"> <thead> <tr> <th rowspan="2">Status of patch</th><th colspan="2">Status LED indicator</th></tr> <tr> <th>Color</th><th>Blinking</th></tr> </thead> <tbody> <tr> <td>Patch power off</td><td colspan="2">No light</td></tr> <tr> <td>During Patch is powering on</td><td>Green</td><td>Continuing in green</td></tr> <tr> <td>Waiting for application and wireless connection (Bluetooth, Wi-Fi).</td><td>Green</td><td>Blink slowly</td></tr> <tr> <td>Application and wireless connection (Bluetooth, Wi-Fi) are completed</td><td>Green</td><td>Continuing in green</td></tr> <tr> <td>During live B-mode scanning</td><td>Green</td><td>Blink slowly</td></tr> <tr> <td>Sleep mode (During the monitoring of bladder measurement)</td><td colspan="2">No light</td></tr> <tr> <td>Battery level of Patch is low.</td><td>Orange</td><td>Continuing in orange</td></tr> <tr> <td>Patch is in a high-temperature.</td><td>Red</td><td>Continuing in red</td></tr> </tbody> </table>	Status of patch	Status LED indicator		Color	Blinking	Patch power off	No light		During Patch is powering on	Green	Continuing in green	Waiting for application and wireless connection (Bluetooth, Wi-Fi).	Green	Blink slowly	Application and wireless connection (Bluetooth, Wi-Fi) are completed	Green	Continuing in green	During live B-mode scanning	Green	Blink slowly	Sleep mode (During the monitoring of bladder measurement)	No light		Battery level of Patch is low.	Orange	Continuing in orange	Patch is in a high-temperature.	Red	Continuing in red
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3	Charging LED indicator	When a patch is mounted on a charging station, this is an LED indicator to indicate the charging status. The charging LED indicator shows the following information. <table><tr><th>Charging status of patch</th><th>LED color</th></tr><tr><td>The patch has not been created on the charging station.</td><td>No light</td></tr><tr><td>The battery of the patch created on the charging station is charging.</td><td>Orange</td></tr><tr><td>The battery of the patch created on the charging station is fully charged.</td><td>Green</td></tr></table>	Charging status of patch	LED color	The patch has not been created on the charging station.	No light	The battery of the patch created on the charging station is charging.	Orange	The battery of the patch created on the charging station is fully charged.	Green
Charging status of patch	LED color									
The patch has not been created on the charging station.	No light									
The battery of the patch created on the charging station is charging.	Orange									
The battery of the patch created on the charging station is fully charged.	Green									
4	Charger terminals	This is the part that is mounted to charge and store the patch in the charging station.								
5	Probe	The probe is attached to the patient's lower abdomen at the bladder location, transmitting and receiving ultrasound energy. The ultrasound energy received by the probe can be wirelessly transmitted to the app in real time to display images of the bladder.								

4. Charging Station

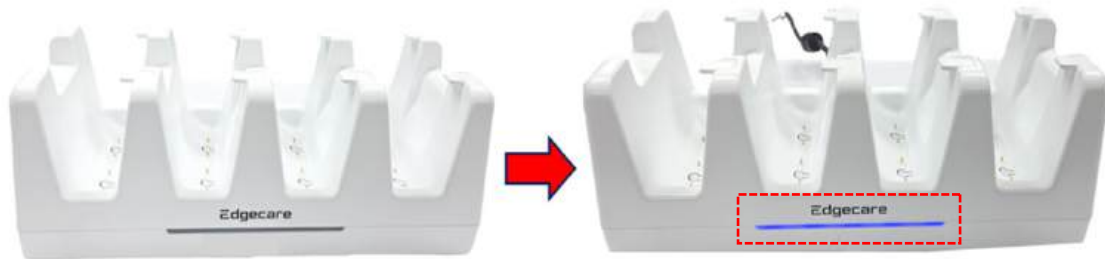
4.1 Shape and Structure



No.	Name	Description						
1	Battery slot	This is the part that is mounted on the charging terminal of the patch. There are a total of 4 battery slots in the charging station, so you can mount up to 4 patches for storage and charging.						
2	Power LED indicator	Indicates whether the charging station is powered on/off.<table><tr><th>LED color</th><th>Status</th></tr><tr><td>No light</td><td>If the power adapter is not connected to the charging station, it will not be powered. The battery in the patch will not be charged and can only be stored.</td></tr><tr><td>Blue</td><td>When the power adapter is connected to the charging station, power is supplied. The patch's battery can be charged.</td></tr></table>	LED color	Status	No light	If the power adapter is not connected to the charging station, it will not be powered. The battery in the patch will not be charged and can only be stored.	Blue	When the power adapter is connected to the charging station, power is supplied. The patch's battery can be charged.
LED color	Status							
No light	If the power adapter is not connected to the charging station, it will not be powered. The battery in the patch will not be charged and can only be stored.							
Blue	When the power adapter is connected to the charging station, power is supplied. The patch's battery can be charged.							
3	Fixing part	To prevent the patch from falling out of the charging station.						
4	Power adapter connection terminal	This is a connection terminal for receiving power from a power adapter.						

4.2 How to charge a patch

1. Connect the power adapter plug to the wall outlet.
2. Connect the power adapter to the terminal of the charging station to turn on the power. (The power LED indicator light on charging station will turn blue.)



3. Plug the patch's battery charging terminal into one of the four battery slots on the charging station.



CAUTION

If the charging terminal of the patch is not properly connected to the battery slot terminal, the battery will not charge.

4. Secure the patch to the fixing part on the charging station so that the patch is fully secured.
5. The charging LED indicator on the patch will turn orange color and charging will begin.



CAUTION

If the patch is not charging properly, the charging LED indicator on the patch will not light up.

6. When the patch's battery is fully charged, the charging LED indicator light on patch will turn green.



NOTE

It takes approximately 2 hours to charge a battery from a completely discharged state to a fully charged state.

7. Remove the patch from the charging station.



CAUTION

- Forcing the patch away from the charging station's fixing part may damage the patch.
- When storing and charging patches in the charging station, place the charging station on a flat surface that minimizes the risk of dropping or exposure to fluid spills.

Chapter3. Instructions for use

1. Instruction

1.1 Preparing for use

When using EdgeFlow UW20, follow these guidelines:

- Check that the patch has been properly cleaned for any obvious physical damage.
- Before use, fully charge the UW20 patch and mobile device.
- Prepare the disposable Gel pad.

1.2 Initial Launch of the Mobile Application



Power on the mobile device and tap the UW20 app icon (EdgeFlow UW20) to run the mobile application. When using UW20 mobile application for the first time, you must set 'location permission' and register passwords for an 'administrator' and 'operator'.

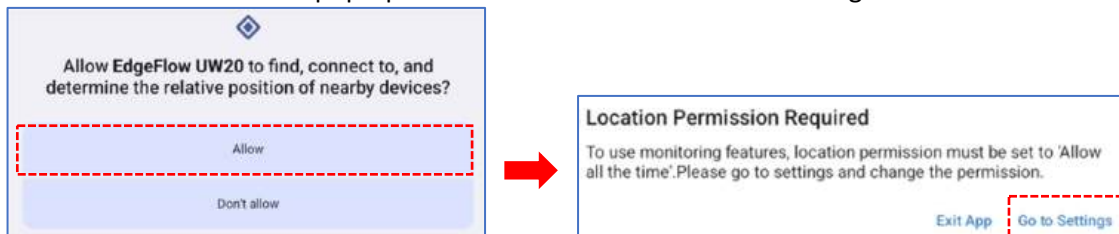
	NOTE Using the UW20 mobile application with a mobile device which does not meet the minimum requirements may result in unexpected results. The UW20 mobile application may not work on all devices.
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	NOTE Data communication between UW20 patch and mobile application are encrypted using WPA/PSK.
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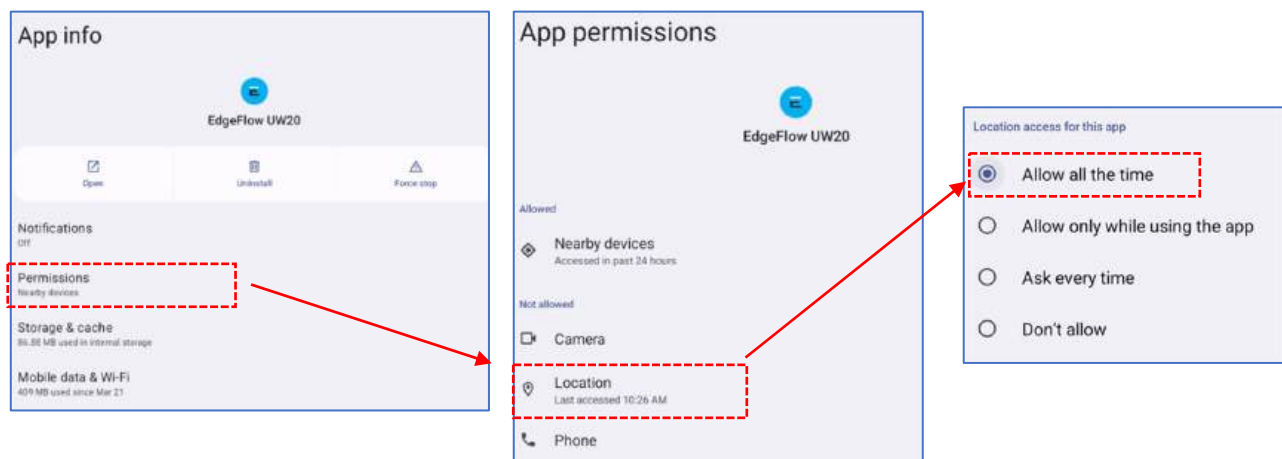
1.2.1 Location permission

When using mobile application for the first time, the location permission must be set as 'Allow all the time'.

1. Select 'Allow' button on the pop-up window and then select 'Go to Settings' button.



2. Select 'Permissions' menu and select Location menu and then select 'Allow all the time'.



1.2.2 Password registration

When using mobile application for the first time, after location permission setting, a pop-up window appears to create passwords for 'administrator' and 'operator'. If you don't set passwords initially, you can't enter the Home screen and use mobile application.

For security in UW20 system, 2 types of users (administrator and operator) are separated access the application.

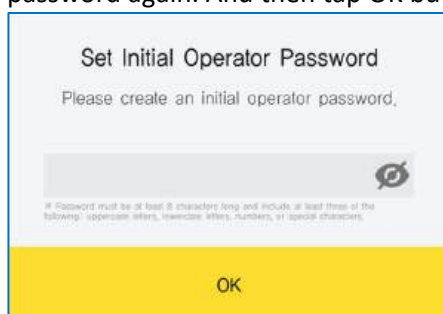
- **Operator:** It is possible to access Start, Review and Setting (except for Administrator Settings menu). This user work to measure the bladder volume or review measurement value.
- **Administrator:** It is possible to access all menus. The administrator may be the data manager for the site, the local service engineer (representative) or local dealer.

1. Enter the password for an administrator as following password rule. And then tap OK button.

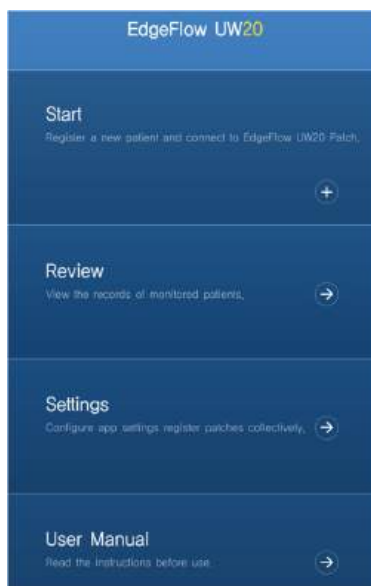


	NOTE
	[Password Rule] The password must be at least 8 characters long and include a combination of at least three of the following: numbers, lowercase letters, uppercase letters, and special characters. All passwords are displayed as the mark (•) instead of text. If you want to show the password you entered, tap the password show button ().

2. Enter the same administrator password again. And then tap OK button.
3. After the administrator password is created, the Initial Operator Password Creation screen appears. Enter the initial operator password in accordance with the password rule, and then tap the Confirm button.
4. Enter the same initial operator password again. And then tap OK button



5. Once the initial user password setup is complete, the Home screen will appear.



6. When accessing the menu for the first time, the user must enter the initial operator password provided by the administrator and then set a new operator password in accordance with the password rule.

Create Operator Password

Please enter password

* Password must be at least 8 characters long and include at least three of the following: uppercase letters, lowercase letters, numbers, or special characters.

OK

	NOTE
	The operator password cannot be set to the same password as the initial operator password.

7. Once the operator password has been created, the “System Notice” window will appear on the screen, and the operator must agree to it.
(To prevent the “System Notice” window from appearing every time, select “Do not show again.”)

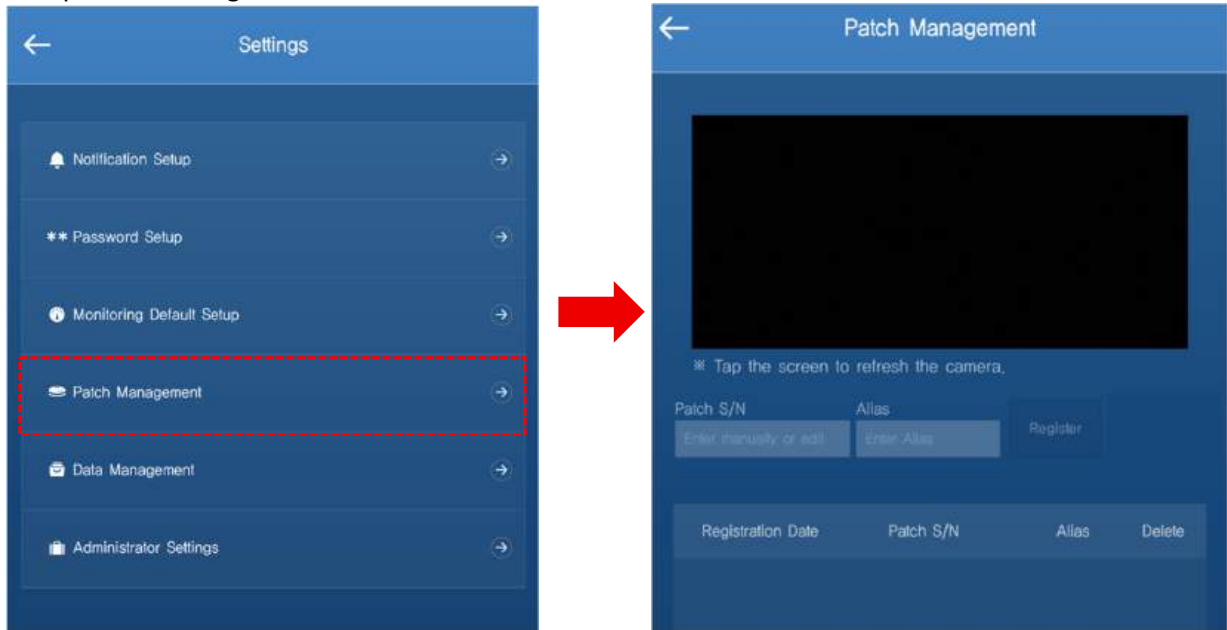
	NOTE
	After the operator sets a password, the application displays a notification recommending periodic password changes (at least every six months) to maintain system security and protect patient data.

1.3 Turn on UW20 Patch

To turn on the patch, press the power button on the patch. The LED indicator on the patch will be light green. When using a new patch for the first time, you must register a new patch in a mobile application.

1.3.1 Patch pre-registration

1. Tap Settings menu on the home screen and then enter the operator or administrator password.
2. Tap Patch Management menu.



[Patch Management screen]

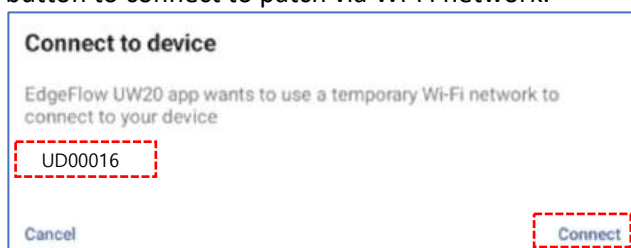
3. Enter the serial number(or alias) of the new patch you want to register and then tap Register button.

	NOTE
	To enter the serial number, there are 2 methods using keypad or camera on mobile device. Make sure that the serial number is located on the system label on the side of the patch. (The form of serial number is UDxxxxx. X is a 5-digit number.)
	 Model: EdgeFlow UW20  Edgecare Inc. (01)0000000000000000 Rated Voltage DC 5 V, 1 A (11)250000 SN (21)UD00000 UDI    [Example-EdgeFlow UW20 system label]
<u>Entering method using camera on the mobile device.</u>	
1. Align the system label on the side of patch within the square screen of the application. 	

	2. The serial number will be automatically recognized and displayed in the Patch S/N field. <u>Or Entering method using keypad on the mobile device,</u> Enter the serial number in the Patch S/N field using keypad directly.
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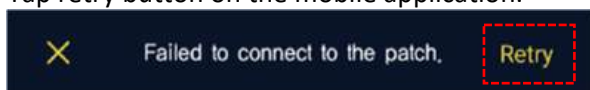
	NOTE
	If you assign an alias for each patch managed by the hospital, users to easily recognize the patch from the list by alias.

- A pop-up window appears including the serial number of the patch as following image. Tap Connect button to connect to patch via Wi-Fi network.



[Example]

- Wait for patch registration.
- If patch registration fails in mobile application, you retry as follows.
 - Tap the power button on the patch again.
 - Tap retry button on the mobile application.

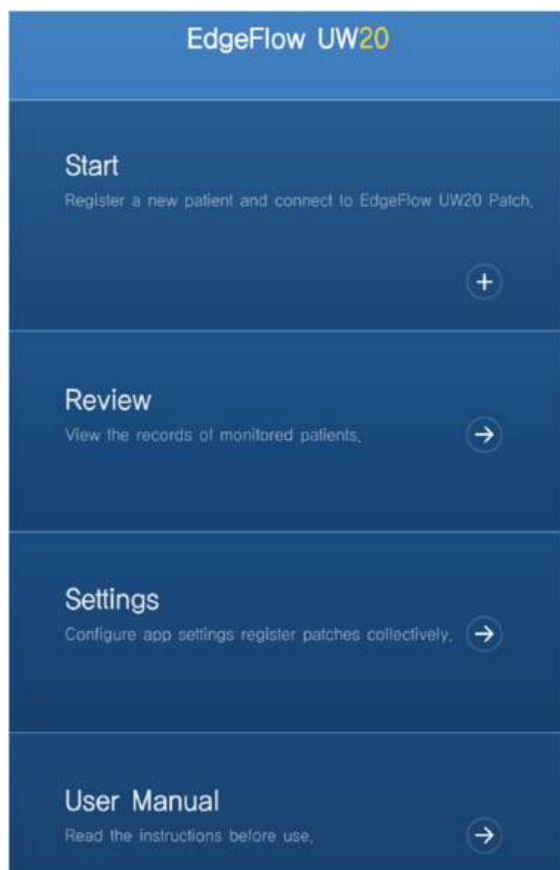


- When patch registration is successful, the message appears. And then the registered patch is displayed in the patch list.



1.4 Home Screen

Home screen consists of menus as shown in the table below, and you tap each menu button to perform a function.



[Home screen]

Items	Description
Start	This menu is to start bladder volume measurement by registering a new patient, connecting (pairing) the UW20 patch with the application, and attaching the patch to the patient.
Review	You can review bladder volume measurement data of previous patients and manage patient data.
Settings	You can set the system for Notifications, Passwords, Patch management and Data management etc.
User Manual	You can view the EdgeFlow UW20 user manual.

NOTE	
	All menus (except for the User Manual menu) can only be accessed by authorized users via entering a password.
	Entering the wrong password multiple times is considered a security risk. If the password is entered incorrectly 5 times in a row, the mobile application will be locked to enhance security.
	During the lock state: 1. Password entry is not possible. In the lockout state, additional password entry attempts are blocked. 2. Waiting time occurs. You must wait for 30 seconds before you can attempt to enter the password again.

NOTE	
	If the application unexpectedly terminates while monitoring a patient, a pop-up window will appear when the application is re-launched, allowing you to resume monitoring the patient whose bladder volume was previously being measured.

1.5 Monitoring Starting

1.5.1 Patient Registration

This is the first screen that appears when you select the 'Start' menu. This is the step to register a patient who wants to measure bladder volume values in the application.

[Patient Registration Screen]

Enter the patient information corresponding to each input field.

Item	Description
Patient ID	Patient ID is a required field and must contain between 1 and 30 characters. The Patient ID can be entered either by using the mobile device's camera (automatic input) or by manually entering it via the keypad. If the entered Patient ID already exists in the system, the patient's saved information (such as Name, Date of Birth, etc.) will be automatically populated once the ID entry is completed.

	Patient ID entry via camera - Tap the barcode icon () in the ID input field. - When you align the patient's ID barcode within the square screen of the application. - It will be automatically captured and the patient's ID will be automatically recognized and displayed in the patient ID field. To refresh the camera, tap the square screen. - The correct patient ID has been entered, tap 'Confirm' button. <table border="1"> <tr> <td data-bbox="395 954 528 1104" rowspan="2"> </td> <td data-bbox="528 954 1418 994" style="text-align: center;">CAUTION</td> </tr> <tr> <td data-bbox="528 994 1418 1104"> If there is foreign matter on the camera lens of your mobile device or damage to the label on the patient's barcode, the application may have difficulty recognizing the code. </td> </tr> </table> Patient ID entry via keypad - Tap the ID entry field and a keypad will appear. - Manually enter the patient ID by using keypad.		CAUTION	If there is foreign matter on the camera lens of your mobile device or damage to the label on the patient's barcode, the application may have difficulty recognizing the code.
	CAUTION			
	If there is foreign matter on the camera lens of your mobile device or damage to the label on the patient's barcode, the application may have difficulty recognizing the code.			
Name	Patient name is a required mandatory field and can be 1 and 70 characters long When taping the patient input field, a keypad will appear. Enter the patient's name using the keypad.			
Date of Birth	Enter the patient's date of birth via the keypad. Alos tap calendar icon () will bring up a calendar pop-up. You can select the patient's date of birth from the calendar.			
Gender	Select the patient's gender (Male/Female/Other).			
Height (cm)	Enter the patient's height			
Weight (kg)	Enter the patient's weight			
Patient's Location	Enter the current patient's location in the order of building-ward-room.			
Measurement Frequency	Depending on the set measurement frequency (10 minutes, 20 minutes, 30 minutes and 1 hour), the application automatically measures the bladder volume value periodically from the current time. If you select 'Hourly Measurement' function, the measurement frequency is automatically adjusted from the current time so that the measurement time matches the hour. (For example, When selecting the measurement frequency as '10 minutes' with 'Hourly Measurement',			

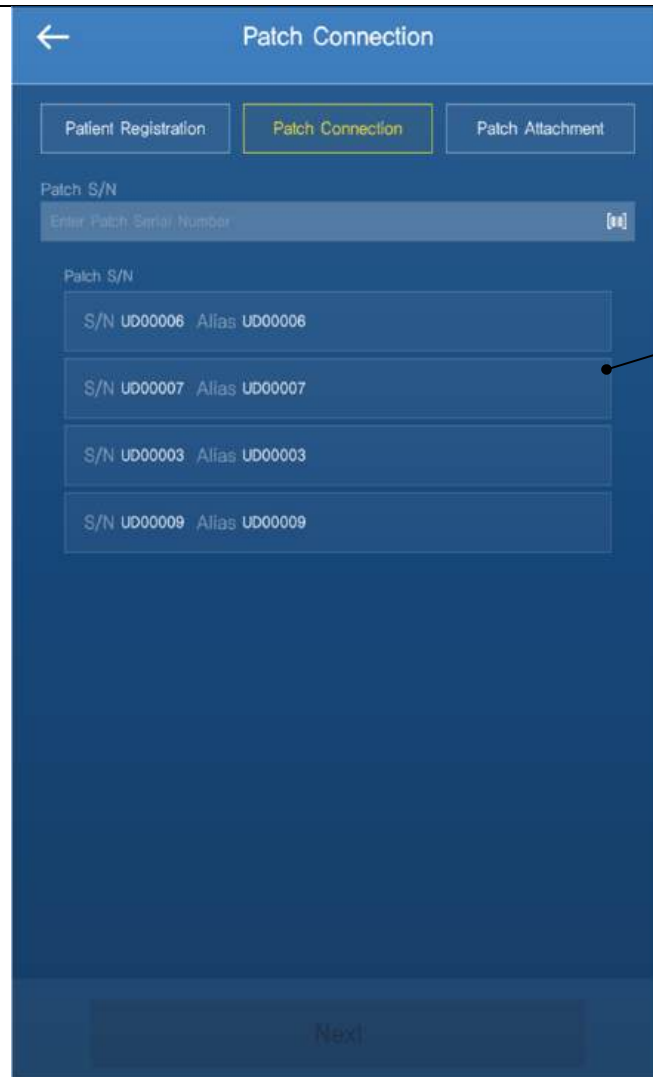
	Current time 8:52 start -> 9:00 (on the hour) measurement -> bladder volume value is automatically measured at 9:10. When selecting the measurement frequency as '20 minutes' with 'Hourly Measurement', Current time 9:33 start -> 9:00 (on the hour) 40 minutes measurement -> 10:20 bladder volume value is automatically measured
Voiding Notification (0 to 999 mL)	You can choose to enable/disable voiding notification settings. - If you activate the voiding notification setting, the bladder volume limit input field will be activated so that you can enter the bladder volume limit value. If the bladder volume value entered during monitoring is measured, a notification will appear in the application. - If you deactivate the voiding notification setting, the bladder volume limit input window will be deactivated.
Previous 	Back to the previous screen (Home screen).
Next	Once the patient registration entry is completed, tap the Next button. If the required entry items (Patient's ID and Name) are not entered, the Next button will not be activated. .

1.5.2 Patch Connection

This is the step to select the patch to be used for bladder volume measurement. You cannot register a new patch on the patch connection screen, so you must pre-register it in Settings – Patch Management.

The patch list displays the registered patches, distinguished by serial number and name. You can quickly find the patch to be used by selecting the patch to be used from the patch list or by scanning the QR barcode attached to the patch.

	NOTE The 'Next' button is disabled when the patch is not selected.
--	---



List of pre-registered patch

[Patch Connection screen]

1. Select one patch you want to use in the pre-registered patch list.

	NOTE If there are several pre-registered patches in the patch list, you can easily find the patch using the camera of your mobile device. 1. Tap the barcode () icon in the Patch S/N input field. 2. When you align the QR code attached to the patch within the square screen of the application, it will be automatically captured and the serial number of the patch will be automatically recognized and displayed.
--	---

2. Tap Next button.

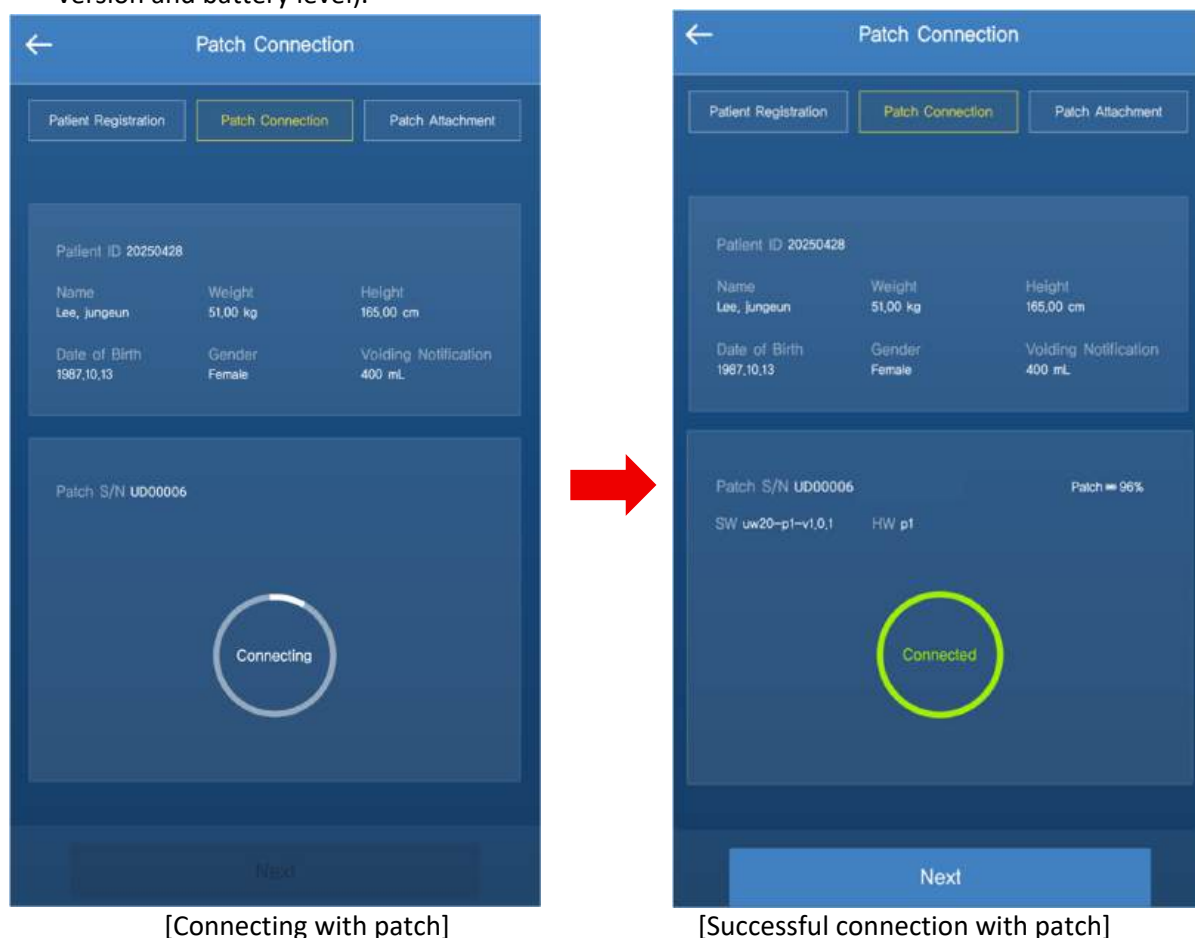
1.5.3 Patch connecting (Pairing)

After selecting the patch, this is the step to establish a connection between the selected patch and the application.

The registered patient information is displayed in Patch Connection screen.

	NOTE It is advised to keep a 30 cm separation distance in between the Patch and the mobile device running application.
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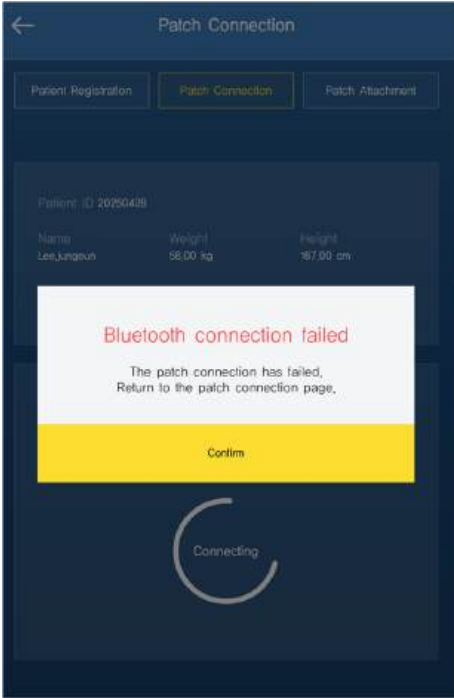
1. If the patch is not powered on, tap the power button on the patch.
2. The connection between the patch and the application will start automatically. Wait until the connection between the patch and the application is completed.
3. If the application and the patch are connected normally, the phrase 'Connection successful' will be displayed along with the details of the patch (patch serial number, software version, hardware version and battery level).



	NOTE Data communication between patch and mobile application are encrypted using WPA/PSK during monitoring.
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4. After checking the patient information and patch details, click the 'Next' button.

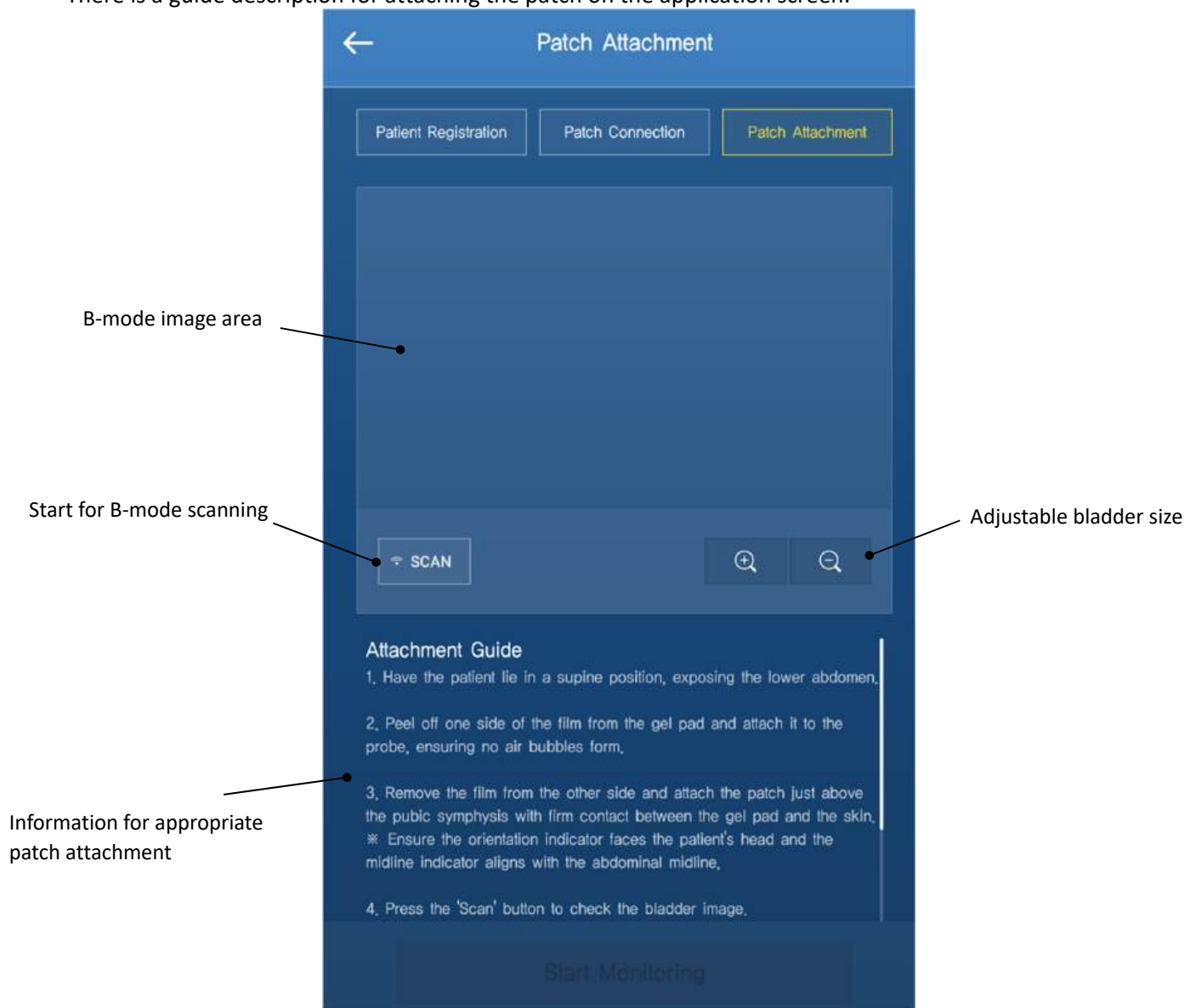
NOTE													
	The battery icon status according to the remaining battery level of the patch is as follows. <table border="1"> <thead> <tr> <th>Battery icon</th><th>Description</th></tr> </thead> <tbody> <tr> <td></td><td>The battery of the patch is fully charged.</td></tr> <tr> <td></td><td>The battery of the patch is less than 75%.</td></tr> <tr> <td></td><td>The battery of the patch is less than 50%.</td></tr> <tr> <td></td><td>The battery of the patch is less than 25 %, it is recommended to replace it with a new patch.</td></tr> <tr> <td></td><td>The battery of the patch is less than 5%. Monitoring is not possible.</td></tr> </tbody> </table>	Battery icon	Description		The battery of the patch is fully charged.		The battery of the patch is less than 75%.		The battery of the patch is less than 50%.		The battery of the patch is less than 25 %, it is recommended to replace it with a new patch.		The battery of the patch is less than 5%. Monitoring is not possible.
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	The battery of the patch is less than 50%.												
	The battery of the patch is less than 25 %, it is recommended to replace it with a new patch.												
	The battery of the patch is less than 5%. Monitoring is not possible.												

CAUTION	
	If the connection between the patch and the application fails as described below, a notification popup will appear for user's recognition. • Patch power turns off. • The Wi-Fi connection of the mobile device is disabled. • The Bluetooth connection of the mobile device is disabled. • The battery level of the patch is very low (<5%). • If data acquisition from the patch fails at the measurement frequency point. After resolving the issue, It is recommend rebooting the patch to reconnect the patch and the application.
	 [Example message screen - Bluetooth connection failed]

1.5.4 Patch attachment

By attaching the patch to the patient's abdomen, you can check the ultrasound B-mode image of the bladder and start monitoring the bladder volume.

There is a guide description for attaching the patch on the application screen.



[Patch Attachment screen]

Start monitoring by attaching the patch to the patient's abdomen according to the procedure below.

1. Patient Preparation

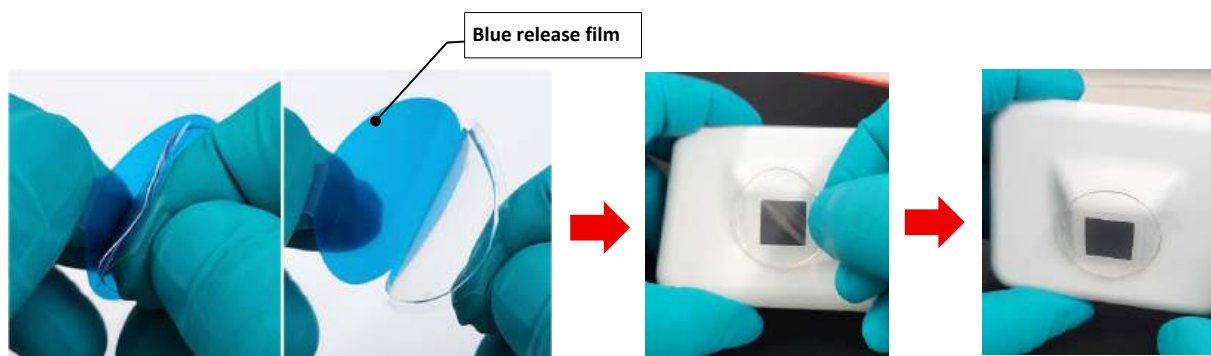
1) Make sure that the patient is in supine position and adjust the clothing so that the lower abdomen is visible.

	NOTE If necessary, shave the attachment area (above the pubic bone).
---	---

2) Clean the lower abdomen area where the patch will be applied with an alcohol swab.

2. Attaching a gel pad to the patch

- 1) Open the seal packaging and then take out the EdgeFlow GEL PAD.
- 2) Remove the blue release film of the gel pad and attach it to the patch probe surface.



CAUTION

The presence of foreign material or air bubbles on the patch probe during gel pad application may compromise the accuracy of bladder measurements.



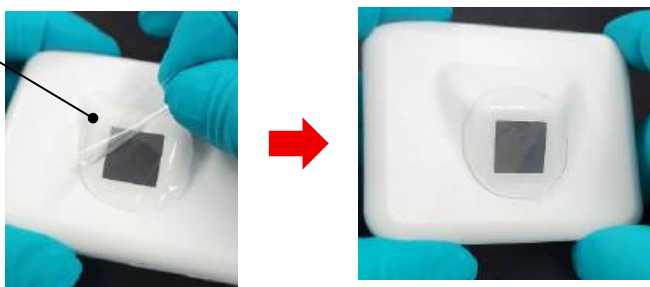
NOTE

The gel pads are available for purchase separately.

3. Attaching a patch to the patient

- 1) Remove the transparent release film of gel and apply the probe to the patient's skin, avoiding air bubbles.

Transparent release film



NOTE

Attach the patch to the pubic bone so that the center of the patch is aligned with the patient's navel.

- 2) Press lightly for 5 seconds to ensure adhesion.
- 3) To prevent displacement of the UW20 patch during monitoring, it must be securely affixed to the affected area using medical tape.



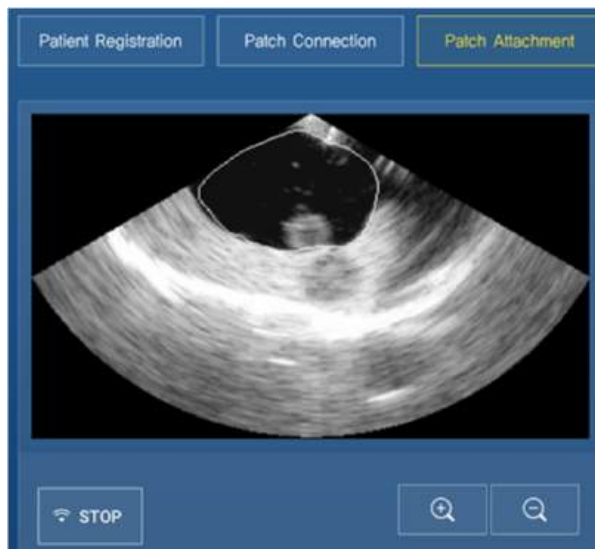
NOTE

3M™ Micropore S™ Surgical Tape is recommend. If you use tape other than medical tape, skin disease may occur.

4. Checking bladder ultrasound image

1) When tap the SCAN button (), a real-time bladder ultrasound image appears on the screen.

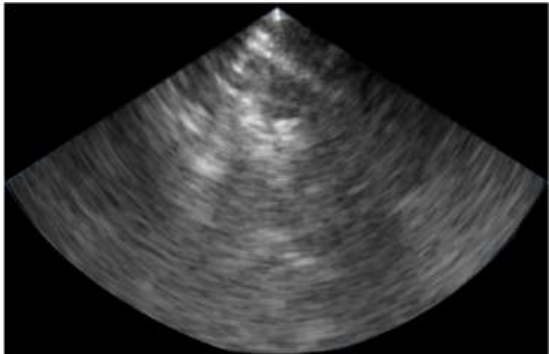
When the system detects the bladder in the ultrasound field of view (FOV), the edge of the bladder is highlight in white line.

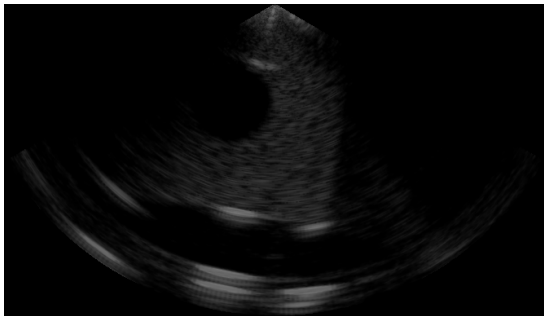


NOTE	
	
	If you want to stop the B-mode image scanning, tap the STOP button (). And then the STOP button is changed to SCAN button (). You want to restart the B-mode image scanning tap SCAN button again.

NOTE	
	
	The bladder size in the field of view can be adjusted in four steps. • (+) button: increase the bladder size in the field of view. • (-) button: decrease the bladder size in the field of view.

2) Make sure that the bladder image is clearly visible in the field of view.

NOTE	
	
	To ensure accurate bladder volume measurement, the patch should be located such that the patient's bladder is centered within the field of view (FOV). Accurate measurement of the bladder cannot be guaranteed under the following conditions. Case 1. The bladder is not within the field of view.  When the patch is on the uncorrected patient's bladder location, user must move/attach the patch on the corrected bladder location again.

	Case 2. The one side of the bladder is outside the field of view.  When the patch is on the uncorrected patient's bladder location, user must move/attach the patch on the corrected bladder location again.
	Case 3. The bladder image is too dark.  If the patch is not properly adhered to the patient's skin, the ultrasound image may appear dark. In this case, more press the patch to improve contact or use additional medical tape to secure it in place.
	CAUTION During prolonged B-mode scanning, the patch temperature may increase. If the temperature exceeds a certain threshold, B-mode scanning is automatically stopped. At this time, the LED indicator on the top of the patch turns red, and a 'The temperature of the patch is high' message is displayed in the mobile application.

5. Monitoring starting

- 1) After completing the proper bladder location in the field of view, tap the 'Start Monitoring' button to initiate monitoring.
- 2) The users conduct the check for acoustic coupling during monitoring through
 - evaluation of ultrasound image every set time interval
 - visual inspection of patch's position status every six hours

1.6 Monitoring of bladder volume measurements

Monitoring for the actual patient's bladder volume measurement and urination pattern function test related records begins.

The patient's name, ID, the current date and time (yyyy-mm-dd/hh:mm) and battery level of the patch are displayed.



	NOTE
	A notification message will appear in the following situations: • When the battery level of your patch drops below 25%, a notification will appear recommending replacement. • When the measurement fails from patch. Automatic measurement failed. • Manual measurement → Click the power button • Patch-App reconnect → Go to "Reattach Patch" OK 2025-04-28 13:18 [Example] screen of measurement failed] • A notification will be displayed indicating that replacement is required if the gel pad is attached for more than 24 hours. (The 24-hour countdown starts from the start of monitoring.)

1.6.1 Bladder volume measurements

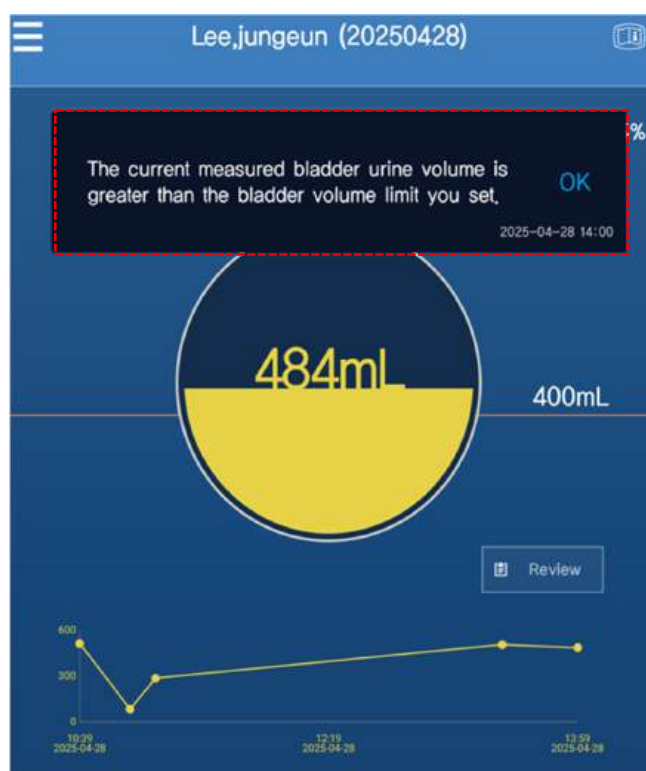
The patient's bladder volume is automatically measured and bladder volume value displayed according to the set measurement frequency.

Alternatively, you can manually measure it in addition to the measurement frequency by taping the power button on the patch. The measured bladder volume value is automatically saved and can be checked through the Review menu.

	NOTE
	To measure accurate bladder volume, the patient must be in a supine position for the set measurement time.

1.6.2 Voiding notification

If you have activated the voiding notification and set a threshold residual urine volume criterion, the application will display a notification if the bladder volume measured automatically according to the measurement cycle exceeds the threshold residual urine volume criterion you have set.



	NOTE
	The EdgeFlow UW20 system does not assign any clinical responsibility to the patient. System notifications or display features are intended solely to inform the healthcare professional of device status or measurement availability. Patients are not required to respond to alerts or make clinical decisions.

1.6.3 User Manual

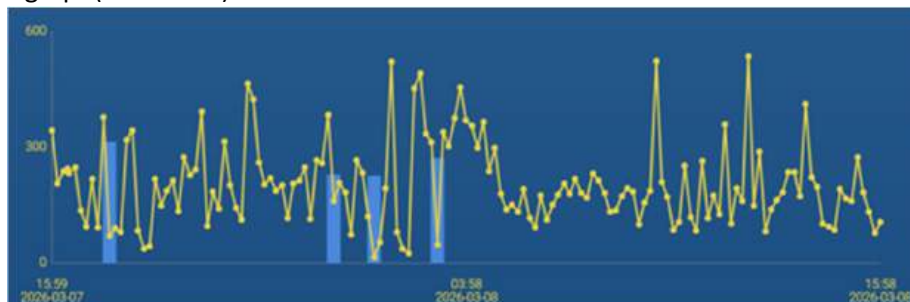
You can view the EdgeFlow UW20 user manual for more information of use, when taping User Manual icon



1.6.4 Measurement Graph

You can see the trend of the patient's bladder volume size over the measurement time in a graph. You can zoom in or out of the graph by pinching or spreading two fingers on the graph area.

- Trend(yellow color) means the measured bladder volume.
- Bar graph(blue color) means the urine volume.



1.6.5 Record

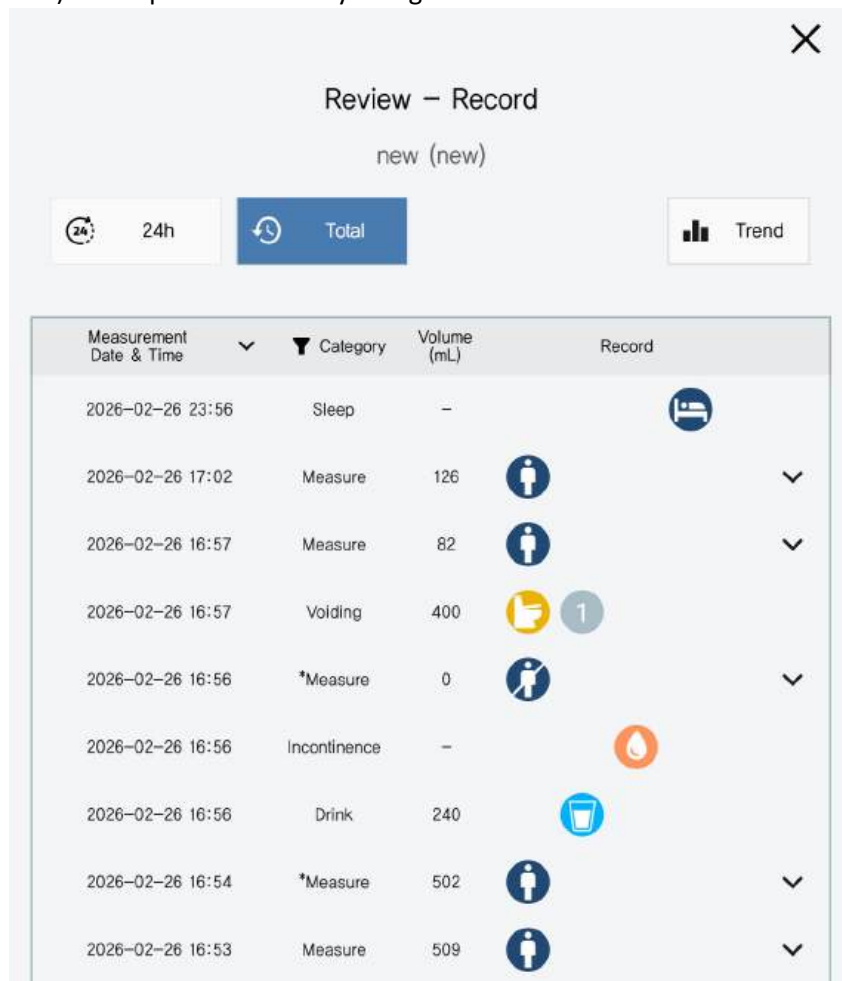
You can directly record the following four items. You can check the recorded information by taping the Review button.



Items	Description
Voiding	After voiding, select the answers to the following questions and tap the Save button. • Intensity of urgency perceived before voiding: Select one of the five answers. • Detected urine volume: The numerical value of urination is automatically displayed. The displayed numerical value can be modified. • Incontinence in underwear: Select No/Yes. • Urination during sleep: Select No/Yes.
Leakage	Leakage in underwear: Select No or Yes. After selecting the answer, tap the Save button.
Wake-up/Sleep time	After entering Sleep time and wake-up time, tap the Save button.
Intake	Select the intake amount (120 mL, 240 mL, 360 mL) or enter the intake amount directly and tap the Save button.

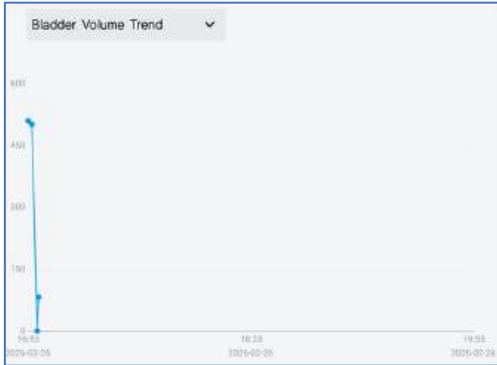
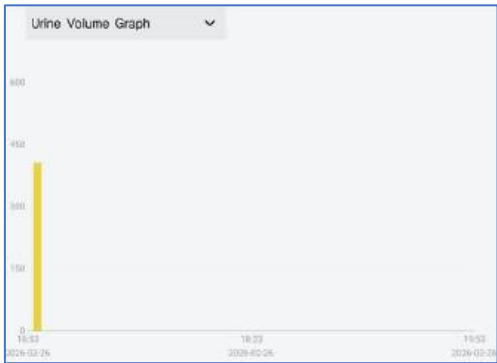
1.6.6 Review

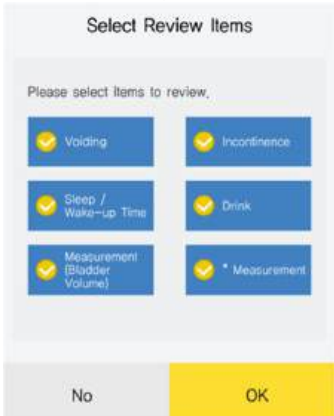
You can check the bladder volume measurement values and all recorded information (Voiding, Leakage, Wake-up/Bedtime and Intake) of the patient currently being monitored.



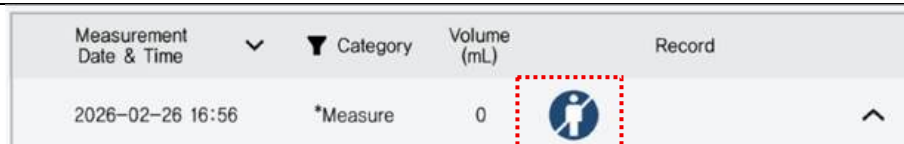
[Review screen]

Icons	Description
	Shows the records monitored over a 1-day period. When tapping this button (), Total Urination Volume and Total Urination Count appear on the bottom of the Review screen for one day.
	Shows all records from the start of monitoring to the present.
	User can review trend or bar graph as Bladder volume trend, Urine volume trend or Badder & Urine. You can zoom in or out of the graph by pinching or spreading two fingers on the graph area. Select the desired trend record in drop box.

	Bladder Volume Trend ▾ Bladder Volume Trend Urine Volume Graph Bladder & Urine [Bladder Volume Trend] The measured bladder volume is presented as trend graph in the blue color.  The graph displays bladder volume over time. The y-axis ranges from 0 to 600 mL. The x-axis shows timestamps: 16:53, 18:23, and 19:53. A blue line starts at approximately 500 mL at 16:53, drops sharply to near 0 mL by 18:23, and remains low until 19:53. [Urine Volume Graph] The urine volume is presented as a bar graph in the yellow color.  The graph displays urine volume over time. The y-axis ranges from 0 to 600 mL. The x-axis shows timestamps: 16:53, 18:23, and 19:53. A single yellow bar is shown at 16:53, reaching approximately 450 mL. [Bladder & Urine] The measured bladder and the urine volume are presented all.  The graph displays both bladder and urine volume over time. The y-axis ranges from 0 to 600 mL. The x-axis shows timestamps: 16:53, 18:23, and 19:53. A blue line represents bladder volume, peaking at 16:53 and dropping to near 0 by 18:23. A yellow bar represents urine volume, also peaking at 16:53. User want to show the recorded information as table, tap Record button. Or you want to go back Monitoring screen, tap X button.
Volumn (mL)	Display the recorded volumes, including the measured bladder volume, incontinence volume, fluid intake, and urine output.

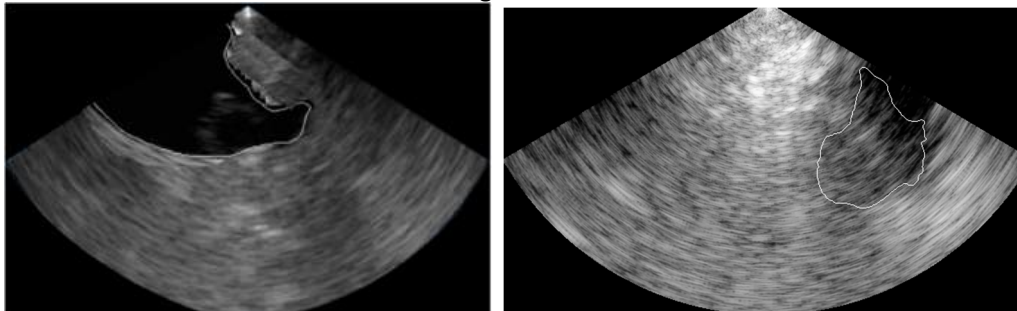
	You can filter the following items (Voiding, Incontinence, Sleep/Wake-up Time, Drink, Measurement and *Measurement) as desire.  Select the items you want and then tap OK button. When a filter is applied to the selected item, the icon changes to ().
 Supine position	This icon means that the measurement of bladder volume has been conducted in supine position. This is the patient's correct position for accurate measurement.
 Non-supine position	This icon means that the measurement of bladder volume has been conducted in non-supine position. This case will measure the invalid measurement value.
 Intake	This icon means drink recording
 Voiding	This icon means voiding. When the latest measured bladder volume is smaller than the previous value, the decrease is automatically calculated as void volume and reflected in the urination record. When manually recording urination values, the selected urine intensity (levels 1–5) is displayed along with it.
 Incontinence	This icon means leakage.
 Wake-up	This icon means wake up recoding.
 Sleep	This icon means sleep recording.

Showing B-mode image	Show the B-mode ultrasound image of the measured bladder. To hide it, tap hide button().
	Caution Invalid measurements that require confirmation by a healthcare professional for bladder volume measurements will be marked as '*Measure' instead of 'Measure' in the category column on the Results Review screen. * Invalid measurements may occur; The acoustic coupling is failure When the patch is dropped from a patient's skin or patch is in on the uncorrected patient's location, the bladder image does not appear or is too dark. When the patch is on the uncorrected patient's bladder location, user must move/attach the patch on the corrected bladder location again. In this case, the message 'Please reattach the patch for accurate measurement' appears. The measurement has been performed in a non-supine position. When the measurement has been performed in a patient's non-supine position , the measured value is not inaccurate. In case of this, an icon () appears in Record column.



3. The one side of the bladder is outside the field of view.

When the patch is on the uncorrected patient's bladder location, user must move/attach the patch on the corrected bladder location again.

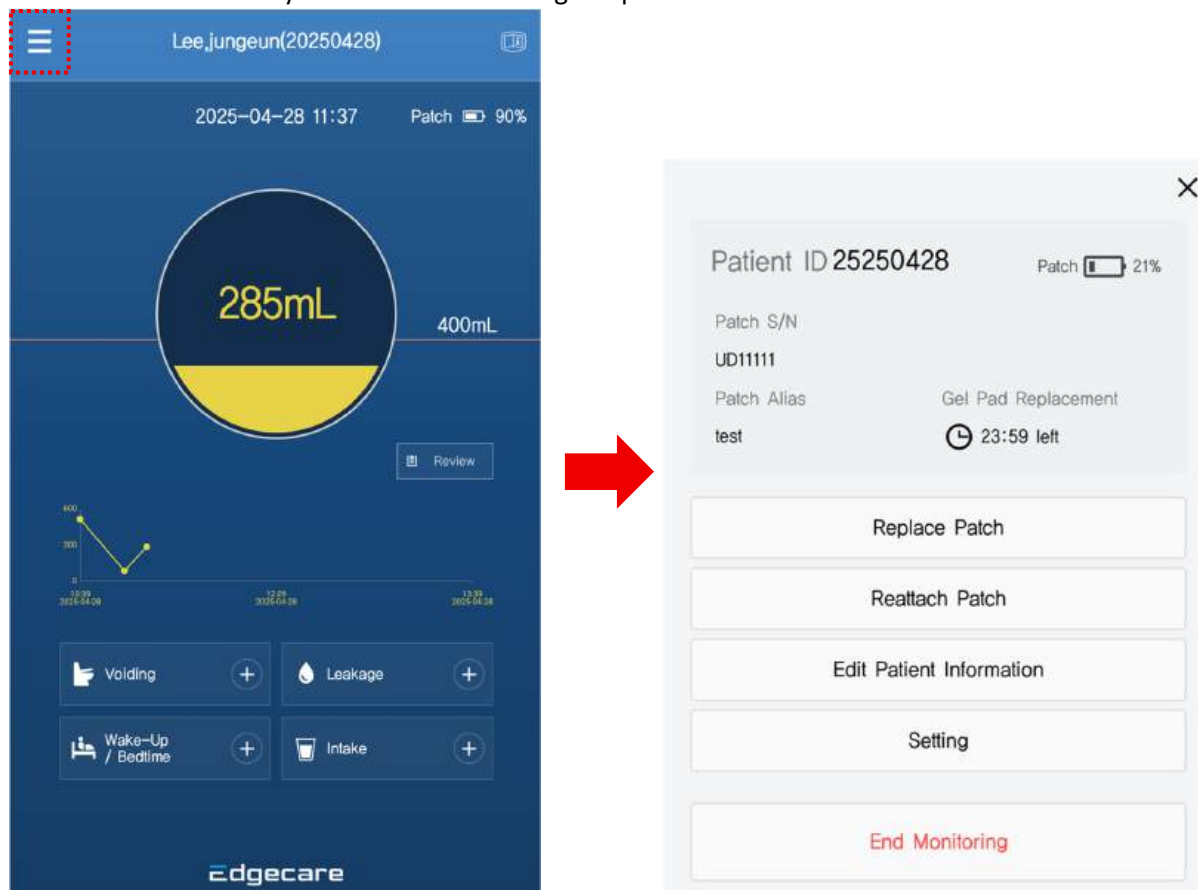


1.6.7 Menu

This menu is for replacing patches, reattaching patches, modifying patient information, setting, and terminating monitoring.

Contains information about the patch (battery level, serial number, alias) and the gel pad replacement time.

All buttons in the menu can only be used after entering the password.



[Menu screen]

1.6.7.1 Patch replacement

If the battery level of the currently connected patch is low or there is an abnormality in bladder measurement, it needs to be replaced with a new patch.

Replace the patch according to the order below.

1. Tap the menu button () on the left of top.
2. Tap the Patch Replacement set button.
3. Enter the password you set and tap the confirmation button.

	CAUTION When replacing the patch, you must use a new gel pad.
---	--

4. Press and hold the power button on the patient's attached patch to turn it off, attach a new patch to the lower abdomen, and then turn it on.
5. When you tap the Confirm button, you will be taken to the patch connection screen.
6. Select the patch you replaced from the patch list, and then tap the Next button. (If there is no patch you replaced in the list, enter the patch information directly via the QR barcode or keypad.)
7. When the patch connection screen is successful, tap the Next button.
8. On the patch attachment screen, tap the scan button () to check if the bladder appears well in the real-time B-mode image.
9. When the bladder appears well, tap the Start Monitoring button and restart monitoring.

1.6.7.2 Patch reattachment

If the patch falls off due to patient movement or the adhesiveness of the gel pad weakens, or if the bladder image is out of focus in B-mode, reattachment of the patch is necessary.

Reattach the patch according to the following sequence:

1. Tap the menu button () on the left of top.
2. Tap the Patch Reattachment button.
3. Enter the password you set and tap the confirmation button.
4. Reattach the patch to the lower abdomen and turn on the patch power.

	CAUTION
	When reattaching the patch, you must use a new gel pad.

5. When you tap the confirmation button, you will be taken to the patch attachment screen.
6. On the patch attachment screen, tap the scan button () to check if the bladder appears well in the real-time B-mode image.
7. When the bladder appears well, tap the Start Monitoring button and restart monitoring.

1.6.7.3 Modify patient information

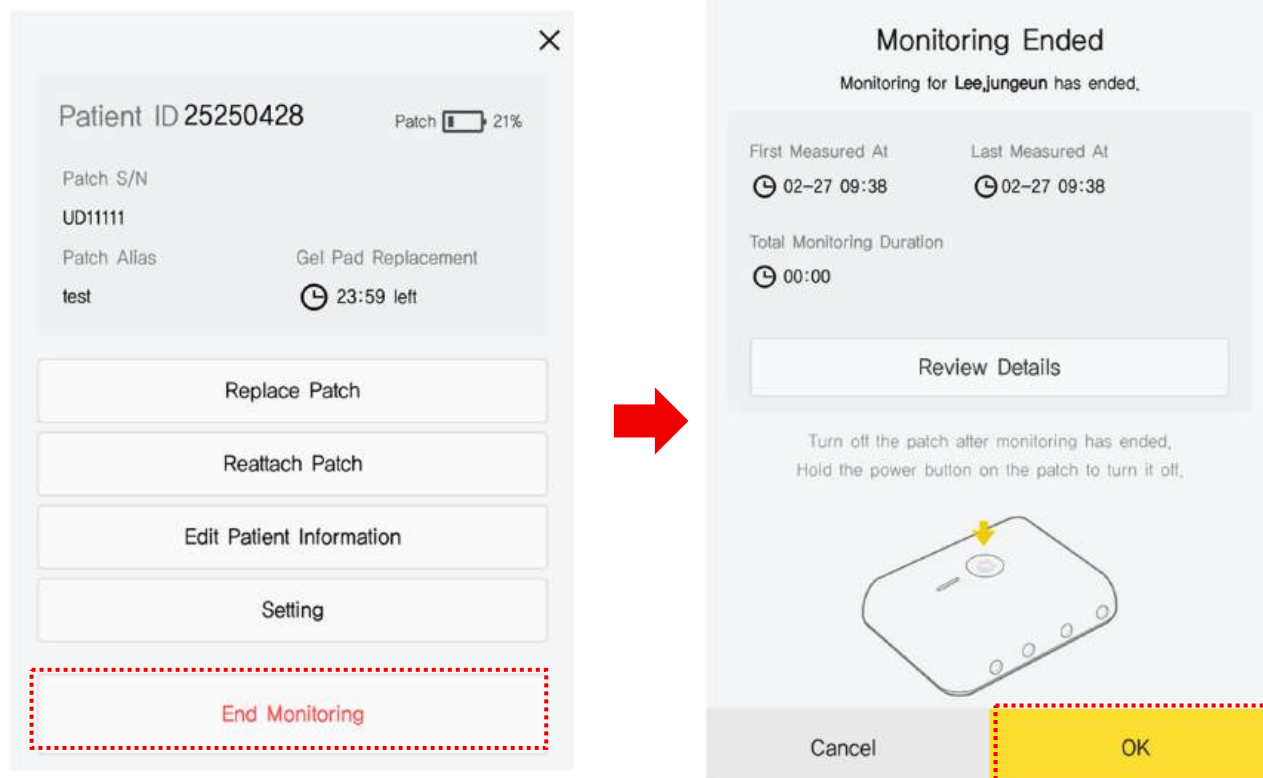
If a patient's information needs to be modified during monitoring, modify the patient's information in the following order.

1. Tap the menu button () on the left of top.
2. Tap the Edit Patient Information button.
3. Enter the password you set and tap the confirmation button.
4. After modifying the patient's information and then taping the Save button, the changed patient information will be applied.

1.7 End Monitoring

When you want to stop monitoring a patient who is currently undergoing bladder measurement monitoring, follow the steps below.

1. Tap the menu button () on the left of top and then tap 'End Monitoring' button.
2. Enter the password you set and tap the confirmation button.
3. A screen containing the monitoring information of the patient will appear.



4. If you want to see the monitoring information in more detail, tap the 'Review Details' button.
5. Tap the OK button to go to the home screen.
6. To turn off the patch, press the power button on the patch for 2 seconds than more. .

1.8 Patch Power Off

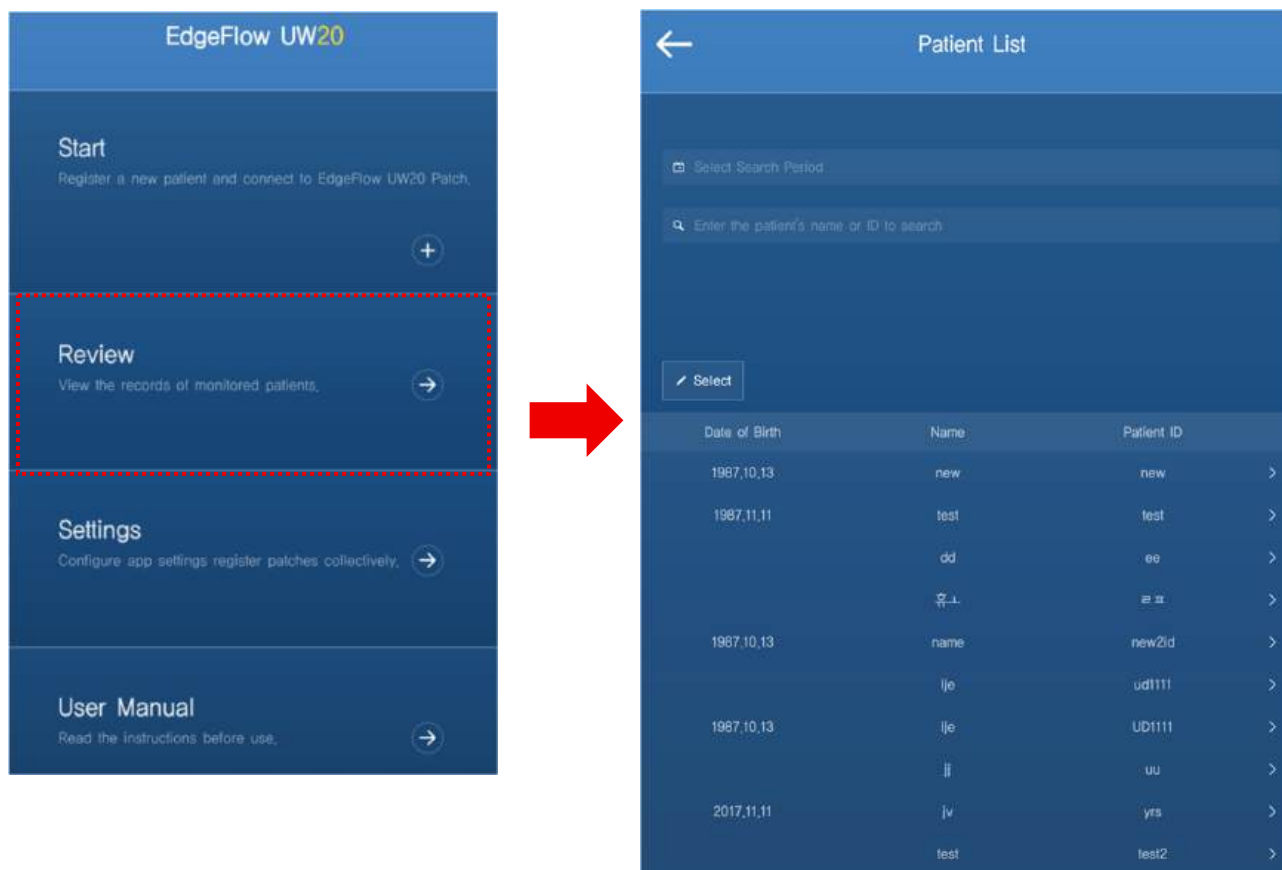
To power off the patch, press and hold the power button on the top of the patch (for more than 2 seconds) and the power LED light will go out.

	CAUTION
	After each use, the patch is properly cleaned and disinfected. and then store patch on the charging station for battery charging.

1.9 Review

To review the data of previously monitored patients, select Review menu on Home screen. The operator password is required to enter the review screen.

The most recently monitored patient is displayed at the top of the list, and all items (date of birth, name, patient ID) can be sorted in ascending and descending order.



To go back to the Home screen, tap the previous screen () button.

1.9.1 Patient Search

Patient search is possible by date range and patient information (ID, name).



1. Date Search

If you want to find a patient by date range, tap on the date search input field and a calendar will appear. When you select a start date and an end date, the corresponding patients will automatically be retrieved from the list.

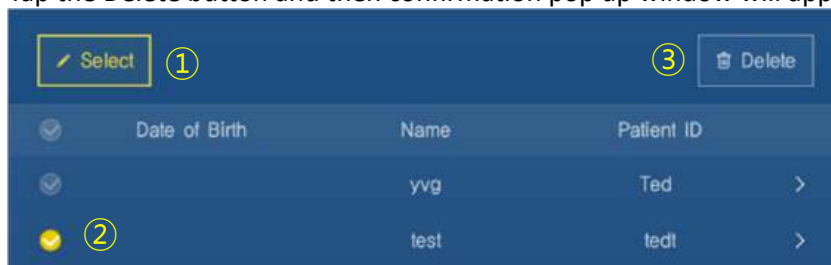
2. Patient information Search

If you want to find a patient as ID or name, enter it by using keypad on input field. The corresponding patient will automatically be retrieved from the list.

1.9.2 Delete Patient

You can delete the existing patient data.

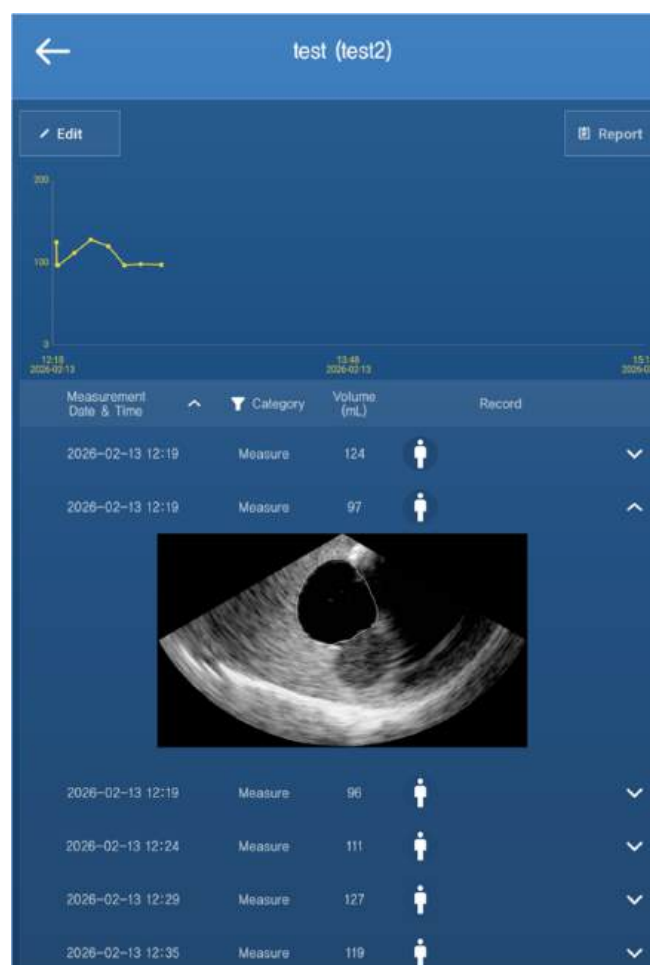
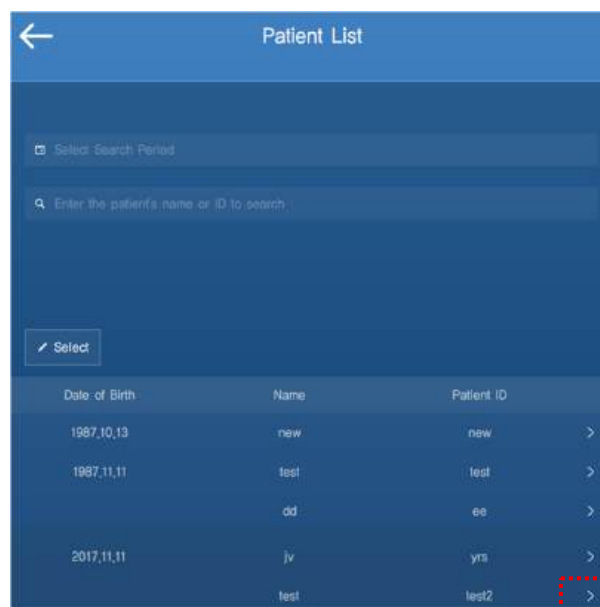
1. Tap the Select button and then the Delete button will appear.
2. Select one or more patients you want to delete.
3. Tap the Delete button and then confirmation pop up window will appear.

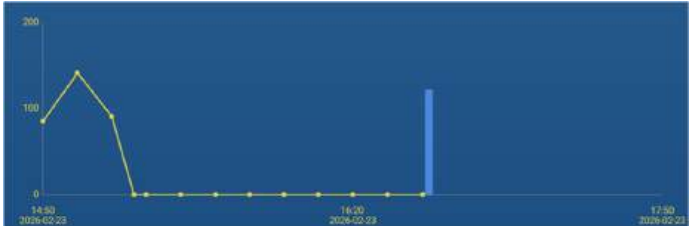


4. Tap the Yes button and enter the operator password.
5. The selected patient(s) will be deleted from the list.

1.9.3 Detailed Review

When you want to review the detailed monitoring recording (Voiding, Leakage, Wake-up/Bedtime or Intake etc.) of a patient listed, tap the detailed review button (➤).



Items	Description
	You can edit the measurement on Category column or add the recording(Voiding, Incontinence, Sleep/Wake-up time or Dirnk) on Record column.
	Export a report with monitoring data (Voiding, Leakage, Wake-up/Bedtime or Intake etc.)
	You can filter the following items as desire. - Voiding - Incontinence - Sleep/Wake-up Time - Drink - Measurement(Bladder Volume) - * Measurement If a filter is applied, the category icon changes to ().
Trend view	The measurement values and urine volume of the bladder is displayed as trend or bar graph. - Trend(yellow color) means the measured bladder volume. - Bar graph(blue color) means the urine volume 
 Intake	This icon means drink recording
 Voiding	This icon means voiding.
 Incontinence	This icon means incontinence
 Wake-up	This icon means wake up recoding.
 Sleep	This icon means sleep recording.
 Supine position	This icon means that the measurement of bladder volume has been conducted in supine position. This is the patient's correct position for accurate measurement.
 Non-supine position	This icon means that the measurement of bladder volume has been conducted in non-supine position. This case had measured as the invalid measurement value.

▼

Show the B-mode ultrasound image of the measured bladder. To hide it, Tap
^ button.

Measurement
Date & Time

2026-03-07 17:58

Category
Measure

Volume
(mL)
147

Record

▼

Measurement
Date & Time

2026-03-07 17:58

Category
Measure

Volume
(mL)
147

Record

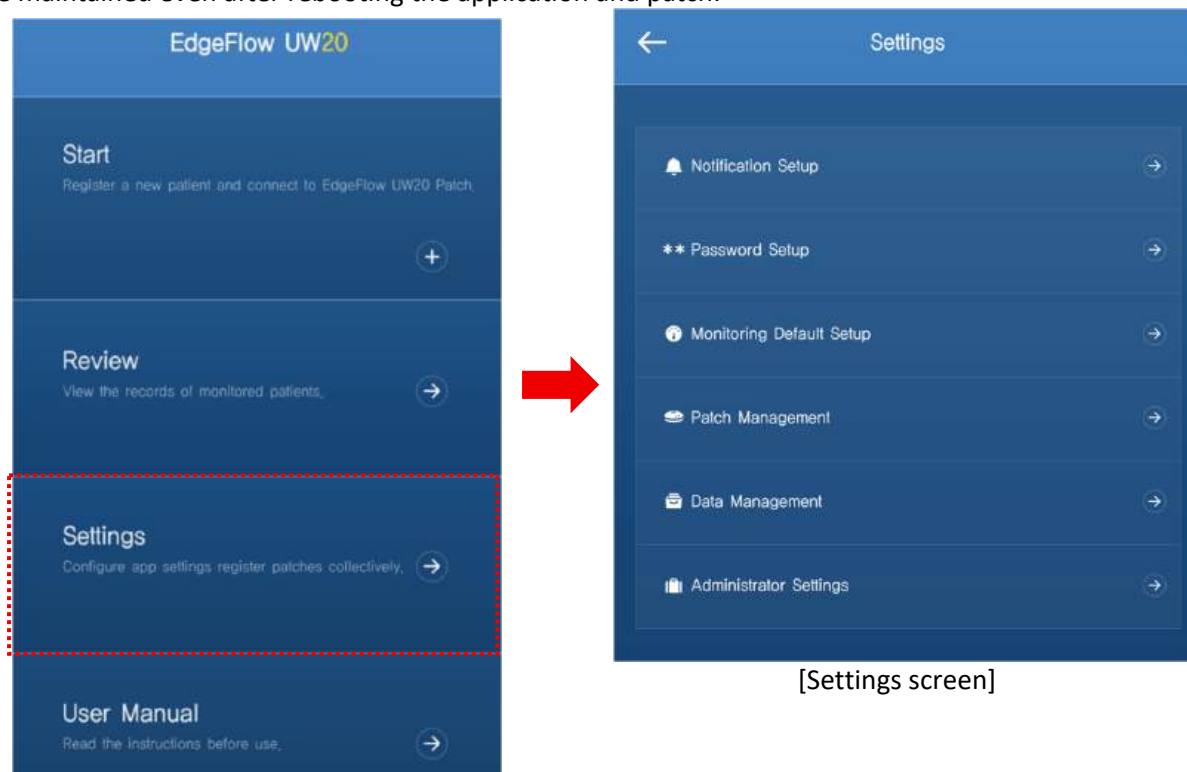
^



Chapter4. System Settings

1. Setting

Used to set default values for EdgeFlow UW20 system functions. System defaults are the default settings that are maintained even after rebooting the application and patch.



[Settings screen]

The following functions are provided in the Settings menu:

Items	Description
Notification Setting	Set the notifications that occur in the application.
Password Setting	Set the password that is entered when logging in to the application and replacing/reattaching patches, modifying patient information and when monitoring is end.
Monitoring defaults Setting	Set the automatic measurement frequency and urination notification criteria during monitoring.
Patch Management	Register new patches to the application and manage patches.
Data Management	Set monitoring-related data and application initialization.
Administrator Setting	Only authorized administrators can set patch setting (software update) and image resolution, etc.

1.1 Notification Setting

Set the notifications that occur in the application.

1.1.1 Daytime Notification

- Turn notifications on/off: You can turn notifications on/off. If you turn notifications off, no notifications will occur in the application.
- Volume: You can set the volume of the notification. The higher the value you set, the louder the sound that appears when a notification occurs.
- Turn vibration on/off: You can turn vibration on/off. If you turn vibration on, when an alarm occurs, the mobile device will vibrate along with the sound.

1.1.2 Nighttime Notification

- Turn notifications on/off: You can turn notifications on/off during the set nighttime.
- Volume: You can set the notification volume. The higher the value you set, the louder the sound that appears when a notification occurs.
- Turn vibration on/off: You can set vibration on/off. If you turn the vibration on, the mobile device will vibrate along with the sound when an alarm occurs.
- Time: You can set the start and end of the nighttime.
-

1.2 Password Setting

Set the password that is entered when logging in to the application and replacing/reattaching patches, and when monitoring is end.

1.2.1 Enabled/Disabled Password

You can set the password to be enabled/disabled.

When you enable the password, the password entry window will appear in the following situation.

- Starting the application
- Reattaching/replacing the patch during monitoring and modifying patient information
- Monitoring ends

1.2.2 Change Password

1. Tap the Change button.
2. Enter your existing password and tap the Confirm button.
3. Enter your new password and tap the Confirm button.
4. Enter the same password again and tap the Confirm button to complete the change.

	NOTE Enter a password with at least 8 characters, including at least 1 number and 1 alphabet.
---	--

1.3 Monitoring Default Setting

You can set the default values for the automatic measurement frequency and urination notification criteria.

- Measurement frequency: The bladder volume is automatically measured during monitoring according to the set measurement frequency (10 minutes, 20 minutes, 30 minutes and 1 hour). When registering a patient, the set measurement frequency value appears as the default value.
- Measurement on the hour: The bladder volume is automatically measured according to the set measurement frequency from the current time on the hour.
- Urination notification criteria: If you set the urination notification criteria, the application will generate an alarm when the measured bladder volume exceeds the urination notification criteria.

1.4 Patch Management

Patches can be registered and unregistered with the application.

1.4.1 New Patch Registration

If you pre-register a patch in the application, the registered patch will appear in the list on the patch connection screen. To register a new patch, follow these steps:

1. Align the QR code attached to the patch with the screen space of the application.
2. The serial number of the patch will be automatically recognized and displayed in the input field.
3. (Optional) Enter the 5-digit code number managed within the hospital.
4. If the serial number and code number are entered correctly, tap the Register button.
5. The new patch registered in the patch list will appear with the registration information (registration date, patch serial number, patch code number).

1.4.2 Delete the registered Patch

If you want to delete a registered patch from the list, tap the Delete button.

1.5 Data Management

1.5.1 Delete all data

You can delete all patient information and measured bladder volume data stored in the application. When deleting all data, all patient examination data will be deleted and not displayed in the list on the review screen.

1.5.2 Application initialization (removing settings)

You can reset all settings of your application to their default values.

1.6 Administrator Settings

This menu is to set mobile application and patch system. (Software update, Image resolution setting, Image mode setting etc.)

Only authorized administrators enter this menu via an administrator password.

1.6.1 Patch settings

Scan Mode: You can set the scan mode value from 0 to 100.

1.6.2 Image resolution

You can select between high/low resolution. The selected image resolution will be reflected in the real-time B-mode image.

1.6.3 Image mode

You can choose between Fundamental/Harmonic. The selected image mode is reflected in the real-time B-mode image.

1.6.4 Patch factory reset/Path test

- Patch Factory Reset: Resets the patch settings.
- Patch Test

Chapter5. Notification Message

1. Notification List

EdgeFlow UW20 notifications are displayed as notification messages on the mobile application. When a notification appears, the user follows the suggested actions.

	NOTE
	The EdgeFlow UW20 system does not assign any clinical responsibility to the patient. System notifications or display features are intended solely to inform the healthcare professional of device status or measurement availability. Patients are not required to respond to alerts or make clinical decisions.

Notification Message on Apps	Description	Suggested action
The battery level of the patch is low.	When the battery of the patch is less than 25%.	• If there are two or more patches, replace them with another patch that is fully charged. • If there is only 1 patch, use it after fully charging it. • If the problem persists, contact your Field Service Representative.
The battery level of the patch is very low. Monitoring is not possible.	When the battery of the patch is less than 5%.	• If there are two or more patches, replace them with another patch that is fully charged. • If there is only one patch, use it after fully charging it. • If the problem persists, contact your Field Service Representative.
The gel pad needs to be replaced.	If more than 24hours have passed since the attachment of patch was first applied/reapplied to the patient.	Replace with new gel pad.
The temperature of the patch is high.	When the temperature of the patch is 15 degrees higher than room temperature (during Live B-mode scanning).	• If there are two or more patches, replace the patch with another patch with a lower temperature. • If there is only one patch, use it after the temperature of the patch has sufficiently cooled. • If the problem persists, contact your Field Service Representative.
Connection with the patch has been lost.	When the connection between the patch and the application is lost.	• Make sure Wi-Fi is turned on mobile device. • Make sure Bluetooth is turned on mobile device.

		• Press the power button on the patch to reconnect the patch and the application. • If the problem persists, contact your Field Service Representative.
Data collection is missing. Connect the patch and the application by taping the power button on the patch once.	If data is not collected even after the monitoring measurement frequency has passed.	• Press the power button on the patch to reconnect the patch and the application. • If the problem persists, contact your Field Service Representative.
The current measured bladder urine volume is greater than the bladder volume limit you set.	When the bladder volume measured automatically according to the measured frequency is measured to be greater than the set bladder urine volume limit value.	Tap the OK button on the screen.
Bluetooth connection failed	Failure of connection between patch and mobile application.	• Make sure that Bluetooth is turned on mobile device. • Press the power button on the patch again. • If the problem persists, contact your Field Service Representative.
Wi-Fi connection failed	Failure of connection between patch and mobile application.	• Make sure that Wi-Fi is turned on mobile device. • Press the power button on the patch again. • If the problem persists, contact your Field Service Representative.
Please reattach the patch for accurate measurement.	When the bladder volume had measured as invalid value.	• Make sure the status of patch's attachment or location. • If the patch is located on the uncorrected bladder position, reposition it to the corrected bladder position. • If the problem persists, contact your Field Service Representative.

Chapter6. Product Management

1. Cleaning & Disinfection

1.1 Introduction

EdgeFlow UW20 system is a reusable medical device that involves the risk of contamination by patient and environmental materials through routine handling by health care personnel. EdgeFlow UW20 system requires manual cleaning and disinfection on a routine basis to ensure that it is safe and effective for its intended use. Only trained personnel should carry out these procedures.

This chapter describes cleaning and disinfection requirements that must be performed regularly to maintain hygienic condition of all component of EdgeFlow UW20 system.

1.2 Periodicity

The following periodicity for cleaning & disinfection must be performed at least. Do follow the specific cleaning and disinfection procedures provided in this chapter and the disinfectant manufacturer's instructions.

Do the following	Daily	After Each Use / Point of Use	As Necessary
Clean and disinfect the Patch (all part - enclosure and probe)	O	O	O
Clean and disinfect charging Station	O	-	O

1.3 Level of hygienic maintenance

One or more of the following levels of hygienic maintenance will be required by components of the EdgeFlow UW20, depending on the type of contact they have with patients and user.

Component		Packaged	Use	Spaulding Classification	Cleaning	Disinfection Level		
						Low	Intermediate	High
Patch	Enclosure	Nonsterile	Reusable	Noncritical	O	O	-	-
	Probe	Nonsterile	Reusable	Noncritical	O	O	-	-
Charging Station		Nonsterile	Reusable	Noncritical	O	O	-	-

1.3.1 Cleagning

Cleaning is a physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use.

1.3.2 Low-level disinfection

Low-level disinfection inactivates most vegetative bacteria, some fungi, and some viruses but cannot be relied on to inactivate resistant microorganisms (e.g., mycobacteria or bacterial spores).

1.3.3 Intermediate level disinfection

Intermediate-level disinfection inactivates viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores.

1.3.4 High-level disinfection

High-level disinfection inactivates vegetative bacteria, mycobacteria, fungi, and viruses but not necessarily high numbers of bacterial spores. The FDA further defines a high-level disinfectant as a sterilant used under the same contact conditions except for a shorter contact time.

1.4 Preparation for Cleaning & Disinfection

	WARNING To avoid damage to the equipment, poor imaging performance or increasing the risk of electric shock, ensure that proper cleaning methods are used as described in this manual or in the manufacturer's instructions. Avoid using cleaning and disinfecting agents that may damage the equipment.
	WARNING To avoid the risk of electric shock or short-circuiting electrical contacts, first ensure that the patch is power OFF. Also, the charging station is completely disconnected from the power cord.
	CAUTION To avoid possible damage to equipment or injury: • Do not use high temperatures. • Use suitable hygiene products. Consult the list of suggested hygienic cleaning products in this manual. • Clean, disinfect, rinse and dry the parts that come into contact with a patient before each new monitoring is started.
	CAUTION To avoid damaging the equipment, do not allow liquids to enter the equipment: • Never allow liquids to enter the internal parts of the equipment. • Do not apply cleaning sprays or liquids directly to the equipment; always apply such products by using a clean cloth dampened with the spray or liquid, in accordance with the manufacturer's instructions.
	CAUTION To avoid damage to the equipment, do not immerse electrical or metallic components in liquids. • Never immerse equipment parts that enclose electrical components in any liquid. • Clean with a soft dampened cloth, taking special care not to allow liquids to enter the equipment
	CAUTION To avoid possible skin irritation, always rinse the cleaned surface thoroughly after using a cleaning agent or disinfectant that could cause irritations.
	CAUTION Wear appropriate personal protective equipment before cleaning and disinfecting.
	CAUTION Dispose of tissues or cloths used for cleaning and disinfection according to national regulations regarding disposal of medical materials.

1.5 Suggested Cleaning & Disinfection Agent

[Cleaning OR Low-Level Disinfection (LLD)]

The cleaning & disinfection agent summarized in the tables below are tested and known to not damage the EdgeFlow UW20 system and its components. The suggested products below have been tested, and found to be compatible with the materials used in the EdgeFlow UW20 .

Agent	Manufacturer	Use		Component
Sani-Cloth® Prime	PDI	Cleaning	Disinfection	• Patch enclosure • Patch probe • Charging station
CaviWipes™	Metrex	Cleaning	Disinfection	• Patch enclosure • Patch probe • Charging station
CaviCide™	Metrex	Cleaning	Disinfection	• Patch enclosure • Patch probe • Charging station

1.6 Cleaning & Disinfection of Patch (including Probe)

[Cleaning]

1. Put on new gloves.
2. Gather approved agent(s).
3. If using a spray, spray onto a clean lint-free cloth to use as a wipe.
4. Use fresh **one** wipe to clean all surfaces of the component until no visible contamination remains.
5. Ensure all parts (Patch enclosure and probe) are visually clean. .
6. Throw away used wipes and gloves.

[Disinfection]

1. After cleaning, put on new gloves again.
2. For Patch (including Probe) disinfection, using **new one** fresh wipe, wipe the patch thoroughly wet.
3. Ensure that the device remains wet for the time specified in the agent's direction for use.
4. Throw away used wipes and gloves.



NOTE

Use one wipe for minimum cleaning and one for disinfection (at least 2 wipes). If necessary additional wipes may be used.

1.7 Cleaning & Disinfection of Charging station

[Cleaning]

1. Put on new gloves.
2. Gather approved agent(s).
3. If using a spray, spray onto a clean lint-free cloth to use as a wipe.
4. Use fresh **one** wipe to clean all surfaces of the component until no visible contamination remains.
5. Ensure all parts of charging station are visually clean..
6. Throw away used wipes and gloves.

[Disinfection]

1. After cleaning, put on new gloves again.
2. For Charging station disinfection, using **new one** fresh wipe, wipe the charging station thoroughly wet.
3. Ensure that the device remains wet for the time specified in the agent's direction for use.
4. Throw away used wipes and gloves.



NOTE

Use one wipe for minimum cleaning and one for disinfection (at least 2 wipes). If necessary additional wipes may be used.

1.8 End of process

If the device is not visibly clean at the end of the cleaning/disinfection process, the process should be repeated until visibly clean.

2. Maintenance

2.1 Expected Service Life

The expected service life of EdgeFlow UW20 is **3.5 years**, depending on the use.

2.2 Warranty

Please contact your local distributor about the warranty frequency.

Device failure or damage related to the following situations during the guarantee frequency covered by this warranty.

- Installation, transfer installation, maintenance, and repairs by any person other than an authorized Edgecare Inc. employee or technician specified by Edgecare Inc.
- Damage caused by product(s) from another company excluding products delivered by Edgecare Inc.
- Damage – caused by mishandling and/or misuse – is the responsibility of the user.
- Maintenance and repairs utilizing maintenance components that are not specified by Edgecare Inc.
- Device modifications or use of accessories not recommended by Edgecare Inc.
- Damage caused by accidents or natural disasters (earthquakes, flooding, etc.)
- Damage due to neglect of specified maintenance checks

Please contact your local distributor if there is any problem that occurs for the use.

2.3 Return

If any damage of the device or components is found, contact your local supplier immediately other than continuing opening. Please pack all components in its shipping carton as it is packed originally. Ship the product according to instructions received from Edgecare Inc.

2.4 Service

The system components are not user-serviceable. Edgecare Inc. does not make available any circuit diagrams, component parts list, descriptions, or other information that would be required for repairs. All service must be performed by a qualified technician. If any technical information is needed, please contact your local supplier.

2.5 Frequency Maintenance

Frequency maintenance is recommended at least yearly.

- Inspect EdgeFlow UW20 for mechanical and functional damage.
- Inspect the external safety labels for legibility.

2.6 Transducer Element Test

2.6.1 Purpose

The transducer elements must be inspected to ensure proper acoustic performance and to prevent image degradation that could result in mismeasurement.

The transducer element test must be performed as specified by an authorized user, field service representatives or the qualified technician daily before initiating bladder volume monitoring.



WARNING

Use of a transducer with damaged or malfunctioning elements may result in degraded image quality and could lead to inaccurate clinical assessment.

2.6.2 Procedure

	CAUTION
	Always make sure to clean the probe surface before transducer element test.

1. Enter the Settings menu and then tap Administrator Settings menu. (Settings menu and Administrator Settings menu are required admin's password)
2. Tap the Patch Diagnostic Test.
3. Select the patch you want to test and then tap the Register button. (It needs to turn on the Patch.)
4. Press power button to turn on Patch.
5. Tap the "Channel test start" button for staring test.
6. When transducer element test is completed, the result is displayed.

	WARNING
	If any abnormality is detected during inspection: • Immediately discontinue use of the transducer. • Do not attempt to repair or modify the transducer. • Contact the manufacturer or authorized service personnel for evaluation or replacement.

2.7 Store Device

- Store the EdgeFlow UW20 patch and charging station in a clean, dry, and well-ventilated area.
- Since the EdgeFlow UW20 patch has a probe attached, store it mounted on the charging station to prevent damage to the probe and foreign matter.
- If you plan to store the patch for an extended frequency after use, fully charge the battery of the patch before doing so.

2.8 Recycling and Disposal

At the end of their service life, batteries in this product must be recycle or disposed of in accordance with local or national regulations.

	NOTE
	EdgeFlow UW20 should be disposed of separately from the municipal waste stream according to regulations by governmental or local authorities.
	NOTE
	The correct disposal will help prevent potential negative consequences for the environment and human health.
	NOTE
	For more detailed information about recycling and disposal of your old appliance, please contact your city office, waste disposal service or your local supplier.

Chapter7. Specifications

1. Product Specifications

1.1 Environmental requirements

Transport and storage conditions requirements			Operating requirements		
Temperature (°C)	Relative humidity (%) * non-condensing	Atmospheric pressure (kPa)	Temperature (°C)	Relative humidity (%) * non-condensing	Atmospheric pressure (kPa)
-10 ~ 45	5 ~ 90	60 ~ 106	0 ~ 40	5 ~ 90	70 ~ 106

1.2 Performance specifications

[Accuracy specifications]

Items		Specification
Measurements range of bladder volume (mL)		0 ~ 999 mL
Volume measurement accuracy	0 ~ 100 mL	± 20 mL
	101 ~ 999 mL	± 15 %

NOTE	
	The accuracy of bladder volume measurement specifications assumes that the device is being used according to the instructions provided by Edgecare Inc. while scanning a tissue equivalent phantom.
	EdgeFlow UW20 cannot guarantee the accuracy of measurements outside of the stated specifications (above 999 mL).

1.3 Physical specifications

- Patch specification

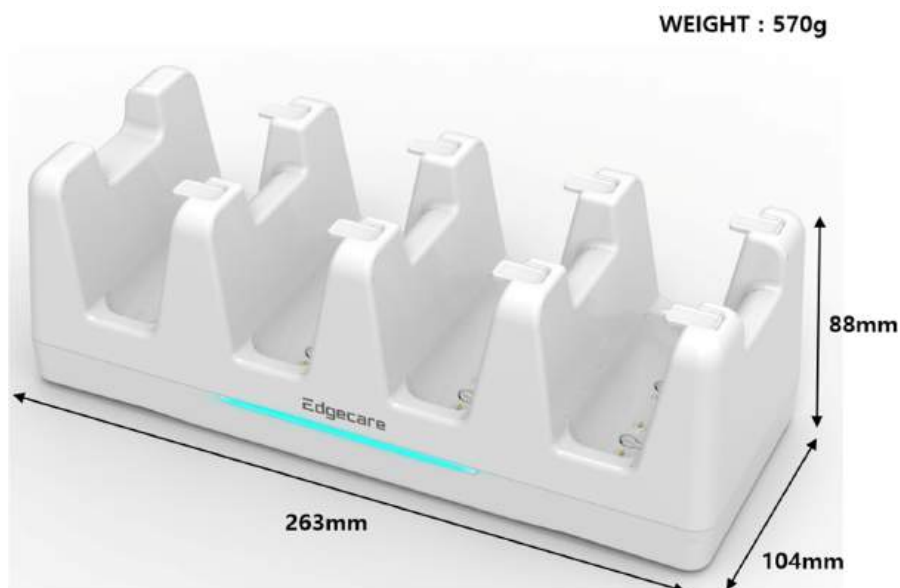
Items		Specification
Product Name		Ultrasound Bladder Scanner
Model Name		EdgeFlow UW20
Degree of protection against electric shock		Internally powered, Type BF (Probe)
Applied part		Probe
Input power		3.7 V / 1 A
Dimensions (Width x Depth x Height)		82 mm (W) x 64 mm (D) x 24 mm (H)
Weight		110 g
Ingress protection against water		IPX7
Probe	Center frequency	2.4 MHz $\pm$ 10 %
Battery	Battery type	Lithium-ion rechargeable battery
	Nominal voltage	3.7 V
	Standard Capacity	1200 mAh (Continuous scanning possible for approximately 2 hour)
	Maximum discharge current	1 C (1200 mA)
	Charging time	2 hours approximately

NOTE	
	• To avoid degradation of battery performance, do not store the battery for long frequency of time outside of its storage and operating temperature range. • Battery power consumption may vary depending on the Wi-Fi environment, which may affect the patch's usage time.



- **Charging station specification**

Items	Specification
Input power	5V / 5.63A
Overcurrent protection	2A / Port
Dimensions (Width x Depth x Height)	263 mm (W) x 104 mm (D) x 88 mm (H)
Weight	570 g



- **Power adapter specification**

Items		Specification
Manufacturer		MEAN WELL
Model name		NGE45I05-P1J (Interchangeable AC plugs (I-Type))
Input	Voltage range	100-240 Vac,
	Frequency	50/60 Hz
	AC current	1.0-0.6 A
	AC plug (Interchangeable type)	EU / US / UK / AU / CN / KR / IN
Output	Direct current	5 V
	Rated current	5.63 A
Isolation		Class II power
Overcurrent protection		110% ~ 150% rated output power

- **Supported Mobile devices**

It is recommended a mobile device that meets at least the specifications listed below.

Items	Specification
Operating system option	Android tablets with OS version 13 or more
Screen requirement	• Size: 10 inch or more • Resolution: 2000 X 1200 pixel or more
RAM requirement	4 GB or more
Storage space requirement	64 GB or more
Connectivity requirements	• Wi-Fi 2.4GHz (802.11, 802.11b, 802.11g and 802.11n) • Bluetooth Classic 4.2



NOTE

- If you use the application on a mobile device that does not meet the minimum requirements, the application may not work and the video quality may be degraded, resulting in unexpected results.
- This application may not work on some devices.

Chapter8. Privacy& Security

1. Privacy & Security

1.1 Privacy and Security Capabilities

EdgeFlow UW20 incorporates functionality to enable Privacy and Security.

1.2 Identity Provisioning & Assigning Access Rights

Here are some steps you can take to help protect the overall security of your EdgeFlow UW20.

- **Physical Access:** Restrict EdgeFlow UW20 usage to authorized users.
- **Data Management:** EdgeFlow UW20 users must take steps to limit patient data retention. Patient monitoring must be terminated after patient monitoring is completed.
- **Device Security:** Only designated users can use the system settings function, and a password must be set to access the settings menu.

EdgeFlow UW20 authorizes menus via passwords as follows:

- **Application Access**
Users must set a password to access the application.
- **Patch Replacement and Reattachment**
Users must set a password to replace and reattach patches during measurement of residual urine in the bladder.
- **Patient Information Modification**
Users must set a password to modify patient information during measurement of residual urine in the bladder.
- **End monitoring**
Users must set a password to end the measurement of residual urine in the bladder.
- **Setting menu**
Only authorized users should set passwords for the above menus in the Settings menu.

1.3 Cybersecurity Recommendations

- When using the system for first time, the initial user password must be set.
- Use a strong and unique password in accordance with the password rule
- Delete all data before recycling or disposal of the EdgeFlow UW20.
- Software updates for EdgeFlow UW20 are conducted to maintain the device's cybersecurity. Only a designated person by Edgcare is permitted to update the software. Please contact your local supplier to inquire about software updates.



CAUTION

If the cyber security issues are detected during using the system, you should contact your local service representative or Edgcare Inc.

1.4 Patient Privacy Consent

Consent on patient privacy is different from other forms of consent such as the consent to treat. There is no integrated functionality in the system; operational routines must be established, if needed.

Chapter9. Appendix

1. Glossary

Refer to the following table for definitions of technical terms used in this manual or written on the product.

Terms and Abbreviations	Define
<i>A</i>	Ampere
<i>Ah</i>	Ampere hour
<i>ALARA</i>	As low as reasonably achievable
<i>B-mode</i>	B-mode (brightness mode) image, a two-dimensional ultrasound image and the most common type.
<i>C</i>	Celsius
<i>cm</i>	Centimeter
<i>DC</i>	Direct current
<i>EDS</i>	Entrance dimensions of the scan
<i>EMC</i>	Electromagnetic compatibility
<i>EMI</i>	Electromagnetic interference
<i>Essential performance</i>	The system performance necessary to achieve freedom from unacceptable risk.
<i>ESD</i>	Electrostatic discharge
<i>f_{awf}</i>	Acoustic working frequency
<i>f_c</i>	Center frequency
<i>GHz</i>	Gigahertz
<i>hPa</i>	Hectopascal
<i>Hz</i>	Hertz
<i>IEC</i>	International Electrotechnical Commission
<i>in</i>	Inch
<i>kHz</i>	Kilohertz
<i>I_{spta,α}</i>	Attenuated spatial-peak temporal-average intensity
<i>I_{spta}</i>	Spatial-peak temporal-average intensity
<i>m</i>	Meter
<i>MHz</i>	Megahertz
<i>MI</i>	Mechanical Index
<i>mL</i>	Milliliter
<i>mm</i>	Millimeter
<i>MPa</i>	Megapascal
<i>mW</i>	Milliwatt
<i>μsec</i>	Microsecond
<i>n_{pps}</i>	Number of pulses per ultrasonic scan line
<i>p_r</i>	Output power
<i>p_{ra}</i>	Peak-rarefactional acoustic pressure
<i>P₀</i>	Attenuated peak-rarefactional acoustic pressure
<i>P_{1×1}</i>	Ultrasonic power
<i>p_{rr}</i>	Bounded output power / Power emitted from the central 1cm of aperture
<i>srr</i>	Pulse repetition rate
<i>TI</i>	Thermal Index
<i>TIB</i>	Bone Thermal Index
<i>TIS</i>	Soft Tissue Thermal Index
<i>V</i>	Volt
<i>W</i>	Watt

Wh	Watt hour
X_{-6}, Y_{-6}	-6 dB output beam dimensions
Z_b	Depth for bone thermal index
Z_{bp}	Break-point depth
Z_{pii}	Depth for peak pulse-intensity integral
$Z_{pii,\alpha}$	Depth for peak attenuated peak pulse intensity integral
Z_{MI}	Depth for MI
Z_{sii}	Depth for peak sum of pulse intensity integrals
$Z_{sii,\alpha}$	Depth for peak sum of attenuated pulse intensity integrals
Z_s	Depth for TIS

2. AI/ML Algorithm Validation Summary

Algorithm Description: The EdgeFlow UW20 incorporates a locked two-stage deep learning pipeline: (1) a MobileNetV2-based segmentation/presence detection network that identifies and delineates the bladder region in sagittal ultrasound images, and (2) a MobileNetV2-style visual encoder with multi-scale tokenization and self-attention for bladder volume regression. Both models are deployed as fixed TensorFlow Lite assets with no on-device learning.

Test Dataset: The independent test dataset consisted of 32 adult patients (1,902 sagittal ultrasound images) acquired at Severance Hospital, Seoul, Korea under IRB No. 1-2025-0025, using the EdgeFlow UW20 acquisition system in an inpatient ward setting aligned with the intended clinical workflow. This dataset was fully sequestered from model development.

Patient / Image Counts: Development: 254 patients / 9,908 images (volume model training); 197 patients / 16,349 images (segmentation/classification training). Independent test: 32 patients / 1,902 images (volume); 57 patients / 3,710 images (segmentation/classification).

Demographics: All subjects are adults (≥ 18 years). Volume model training ($n=254$): 61.0% male, 39.0% female; age <50 yrs 27.9%, 50–70 yrs 57.1%, ≥ 70 yrs 15.0%; BMI normal 48.0%, overweight 40.6%, obese 11.4%. Segmentation/classification training ($n=197$): 64.5% male, 35.5% female; age <50 yrs 27.9%, 50–70 yrs 57.4%, ≥ 70 yrs 14.7%; BMI normal 47.7%, overweight 41.6%, obese 10.7%. Volume test ($n=32$): 62.5% male, 37.5% female; age <50 yrs 31.2%, 50–70 yrs 56.2%, ≥ 70 yrs 12.5%; BMI normal 59.4%, overweight 18.8%, obese 21.9%. Segmentation/classification test ($n=57$): 49.1% male, 50.9% female; age <50 yrs 28.1%, 50–70 yrs 56.1%, ≥ 70 yrs 15.8%; BMI normal 49.1%, overweight 36.8%, obese 14.0%. All subjects Korean (OUS; Severance Hospital). Scientific evidence supports applicability to U.S. adult population for this anatomical task.

Subgroup Analysis: Subgroup analyses performed across sex, age, BMI, and volume range. No systematic performance degradation identified in any evaluated subgroup. F1 range: 0.967–0.977; Dice range: 0.933–0.938; MAE range: 13.87–15.27 mL; MAPE range: 10.28–11.47%.

Equipment and Protocols: Data acquired under two IRB-approved protocols at Severance Hospital using two ultrasound acquisition systems (UH10 and UW20) in two distinct clinical environments (operating room and inpatient ward). Sagittal B-mode ultrasound images acquired using placement-based suprapubic protocol.

Reference Standard: Bladder segmentation: pixel-level binary masks generated by two blinded clinical labelers ($\text{IoU} \geq 0.90 \rightarrow$ consensus mask; $\text{IoU} < 0.90 \rightarrow$ independent Evaluator adjudication). Bladder presence: blinded dual-labeler review with Evaluator adjudication. Volume estimation: catheter-derived measurements with quality-control review. All truthing conducted by qualified clinical professionals (board-certified urologist + sonographers, 5–20+ years experience) independent from model development.

Data Independence: Development and test datasets are fully subject-independent with zero patient overlap. Volume test dataset (DS2) was sequestered from all development activities. Subject-independent partitioning applied within DS1 for segmentation/classification evaluation.

Performance Results: All functions passed prespecified locked acceptance criteria: Bladder Presence F1 = 0.975 ($\geq 0.90 \checkmark$); Semantic Segmentation Dice = 0.936 ($\geq 0.80 \checkmark$); Volume MAE = 14.43 mL (0–100 mL range, ≤ 20 mL $\checkmark$); Volume MAPE = 10.71% (101–999 mL range, $\leq 15\% \checkmark$). All with 95% CIs derived from $B=2,000$ bootstrap resamples.