

CUBEscan[™]

BioCon-V

Operator's Manual



Mcube Technology Co., Ltd.

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REF BioCon-V

Bladder Volume Measurement System

Operator's Manual

This product is a medical device. Please read the precautions and instructions carefully before use.

Please note that the information in this manual is subject to change without prior notice.

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The figures and examples in this document are not based on actual patient data. For the latest user information, please contact your sales representative or Mcube Technology Co., Ltd.

The appearance, specifications, features, application screens, and image content of the product in this guide are subject to change without prior notice to improve the product's performance.



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1. GENERAL INFORMATION

1.1. PRODUCT DESCRIPTION

CUBEScan BioCon-V (Ultrasound Bladder Volume Measuring Device) is a safe, easy-to-use, non-invasive device capable of measuring bladder volume (residual urine volume). This device consists of a probe and a cradle.

BioCon-V is a B-mode ultrasound device powered by a battery built into portable probe. The probe's battery can be recharged using the charging cradle.

The internally mounted 3D-mechanical sector transducer captures the bladder in 12 cross-sectional views and calculates bladder volume based on these images. The captured 12 cross-sectional images are displayed to the user via the probe's LCD screen. Additionally, the Pre-Scan feature allows the user to confirm the bladder's position before scanning, enabling more accurate and easier measurement. Measurement results can be transmitted to a computer or tablet via Wi-Fi, and data management and device settings can be performed using CubeLite (PC software) and BioCon-V Manager (tablet app).

1.2. INTENDED PURPOSE

CUBEScan BioCon-V is a B-mode pulsed-echo ultrasound device. BioCon-V projects ultrasonic energy through the lower abdomen of a patient to non-invasively obtain images of the bladder to calculate the urine volume. The BioCon-V is intended to be used by a qualified medical professional in hospitals and other healthcare facilities to non-invasively measure the urine volume in the bladder.

1.3. PATIENT/USER CHARACTERISTICS

1.3.1. PATIENT POPULATION AND MEDICAL CONDITIONS

Patients whose bladder volume needs to be measured.

1.3.2. INTENDED USER

Physicians and medical professionals.

1.3.3. ENVIRONMENTS OF INTENDED USE

The CUBEScan BioCon-V is intended for use in professional healthcare environments including hospitals, doctor's office, clinics, and examination rooms.

1.4. UNDESIRABLE SIDE EFFECTS

No Undesirable side-effects were observed during the clinical evaluation and post-market surveillance conducted by Mcube Technology Co., Ltd.

1.5. SERVICES

If you have difficulties in using the system due to failure or lack of education, please contact your local dealer or Mcube Technology at mcube@mcubetech.co.kr.

1.6. INCIDENT REPORTING (VIGILANCE SYSTEM)

Any serious incident that has occurred in relation to the BioCon-V should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Please contact your local distributors or Mcube Technology Co., Ltd.

2. SAFETY INFORMATION

2.1. NOTICE TO ALL USERS

This operator's manual contains essential information required for the use of BioCon-V, including its components, functions, maintenance, environmental conditions, and cautions. All users must read and understand the contents of this manual before operating the BioCon-V.

Safety Information includes critical safety guidance that must be followed when using the BioCon-V.

2.2. CONTRAINDICATIONS



WARNING *AVERTISSEMENT*

- **DO NOT use the Biocon-V in the following cases.**

NE PAS utiliser Biocon-V dans les cas suivants.

- For fetal use or on pregnant patients

Pour une utilisation fœtale ou sur des patientes enceintes

- Patients with ascites

Patients atteints d'ascite

- Patients with open skin or wounds in the suprapubic region

Patients présentant des lésions cutanées ouvertes ou des plaies dans la région sus-pubienne

2.2.1. BIOLOGICAL SAFETY

According to the latest data, there are no known adverse effects from using ultrasound devices that emit pulsed ultrasound signals. The BioCon-V is intended to be used by medical professionals or under their guidance. The ultrasound acoustic energy emitted by the BioCon-V is limited to a minimal level sufficient to accurately measure bladder volume. For details on the acoustic output levels, refer to the relevant section.

2.3. ELECTRICAL SAFETY

This device is designed in accordance with IEC 60601-1 as a Class I, Type BF device.

It also complies with the essential safety requirements for medical electrical equipment set by CSA (Canadian Standards Association), UL (Underwriters Laboratories), and European harmonized standards. To prevent electrical or mechanical shock or injury, follow all warnings and precautions provided with the device.



WARNING *AVERTISSEMENT*

- **To avoid the risk of electrical shock, the device must be connected to a properly grounded power supply. Ground reliability can be ensured only when using a Hospital Grade (UL Green Dot) power cord or a Medical Grade power supply compliant with IEC 60601-1.**

Pour éviter tout risque de choc électrique, l'appareil doit être raccordé à une source

d'alimentation correctement mise à la terre. La fiabilité de la mise à la terre n'est garantie que si un cordon d'alimentation de qualité hospitalière (UL Green Dot) ou une alimentation de qualité médicale conforme à la norme IEC 60601-1 est utilisé.

- Do not operate the device in an environment where flammable gases or flammable anesthetic mixtures are present.

N'utilisez pas l'appareil dans un environnement où sont présents des gaz inflammables ou des mélanges anesthésiques inflammables.

- Do not use the device simultaneously with a defibrillator or high-frequency (HF) surgical equipment.

N'utilisez pas l'appareil en même temps qu'un défibrillateur ou un équipement chirurgical à haute fréquence (HF).

- All service and maintenance must be performed only by service engineers authorized by Mcube Technology Co., Ltd.

Tout entretien et toute maintenance doivent être effectués uniquement par des techniciens agréés par Mcube Technology Co., Ltd. Electrostatic discharge (ESD) is a natural phenomenon that occurs frequently in low-humidity environments caused by heating or air conditioning. Co.,Ltd.

- Before use, inspect the device exterior, power cord, and adapter for any visible damage. If any damage is found, do not use the device.

Avant utilisation, inspectez l'extérieur de l'appareil, le cordon d'alimentation et l'adaptateur afin de détecter tout dommage visible.

- Do not use the device if the probe is fully submerged in liquid.

N'utilisez pas l'appareil si la sonde est entièrement immergée dans un liquide.

- Connect only to an adapter rated for AC 100–240 V, 50/60 Hz as specified by the manufacturer.

Connectez uniquement à un adaptateur conçu pour une tension alternative de 100 à 240 V, 50/60 Hz, conformément aux spécifications du fabricant.

- Do not disassemble or modify the device. Doing so may result in serious injury to the patient or operator.

Ne démontez pas et ne modifiez pas l'appareil. Cela pourrait entraîner des blessures graves pour le patient ou l'opérateur.

- Using cables or accessories other than those specified or provided by the manufacturer may increase electromagnetic emissions or reduce the device's electromagnetic immunity, which could result in improper operation.

L'utilisation de câbles ou d'accessoires autres que ceux spécifiés ou fournis par le fabricant peut augmenter les émissions électromagnétiques ou réduire l'immunité électromagnétique de l'appareil, ce qui peut entraîner un fonctionnement inapproprié.

- Portable RF communication devices should not be used within 30 cm (12 inches) of any part of BioCon-V, including cables specified or provided by Mcube Technology Co., Ltd.

Les appareils de communication RF portables ne doivent pas être utilisés à moins de 30 cm (12 pouces) de toute partie du BioCon-V, y compris les câbles spécifiés ou fournis par Mcube

**CAUTION MISE EN GARDE**

- BioCon-V is designed to comply with IEC 60601-1-2, the general standard for electromagnetic safety. It is equipped with appropriate and reasonable protection against electromagnetic interference that may occur under typical installation and operating conditions. The device must be installed and operated as instructed in this operator's manual.

Le BioCon-V est conçu conformément à la norme IEC 60601-1-2, la norme générale relative à la sécurité électromagnétique. Il est équipé de protections appropriées et raisonnables contre les interférences électromagnétiques susceptibles de se produire dans des conditions normales d'installation et de fonctionnement. L'appareil doit être installé et utilisé conformément aux instructions de ce manuel d'utilisation.

- This device is intended for use in professional healthcare environments only.

Cet appareil est destiné à être utilisé uniquement dans des environnements de soins de santé professionnels.

- Medical electrical equipment may be affected by electromagnetic interference from portable and mobile RF communication devices. Ensure that such devices are turned off before use.

Les équipements électromédicaux peuvent être affectés par des interférences électromagnétiques provenant de dispositifs de communication RF portables ou mobiles. Assurez-vous que ces dispositifs sont éteints avant utilisation.

- Electrostatic discharge (ESD) is a natural phenomenon that occurs frequently in low-humidity environments caused by heating or air conditioning.

- *La décharge électrostatique (ESD) est un phénomène naturel qui se produit fréquemment dans des environnements à faible humidité, en particulier lorsque le chauffage ou la climatisation est en fonctionnement.*

- Even low levels of ESD can damage the device. To prevent ESD, use antistatic sprays, antistatic linoleum, or antistatic mats.

De faibles niveaux de décharges électrostatiques (ESD) peuvent endommager l'appareil. Pour éviter les ESD, utilisez des sprays antistatiques, du linoléum antistatique ou des tapis antistatiques.

- Due to its emission characteristics, BioCon-V is suitable for use in industrial areas and hospitals (CISPR 11 Class A). If used in a residential environment (where CISPR 11 Class B is generally required), the device may not provide adequate protection against radio frequency communication services. The user may need to take mitigation measures such as relocating or reorienting the device.

En raison de ses caractéristiques d'émission, le BioCon-V est adapté à une utilisation dans les environnements industriels et hospitaliers (CISPR 11 Classe A).

S'il est utilisé dans un environnement résidentiel (où la Classe B est généralement requise), il peut ne pas offrir une protection suffisante contre les services de communication radiofréquence.

L'utilisateur peut être amené à prendre des mesures d'atténuation telles que le déplacement ou la réorientation de l'appareil.

- If an error message is displayed on the device, note the error code and contact Mcube Technology

Co., Ltd. for assistance.

Si un message d'erreur apparaît sur l'appareil, notez le code d'erreur et contactez Mcube Technology Co., Ltd. pour obtenir de l'aide.

- To use the PC software (CubeLite) for data management, the computer must comply with IEC 62368-1 or IEC 60601-1 standards. In the operating environment, the complete system must also comply with the applicable requirements of IEC 60601-1, including Clause 16 for ME systems. If additional signal input/output terminals are to be added, the resulting system must also comply with the applicable requirements of IEC 60601-1, including Clause 16 for ME systems. For assistance, contact the biomedical engineering department of your hospital, your distributor, or Mcube Technology Co., Ltd.

Pour utiliser le logiciel PC CubeLite destiné à la gestion des données, l'ordinateur doit être conforme aux normes IEC 62368-1 ou IEC 60601-1. Dans l'environnement d'utilisation, le système complet doit également être conforme aux exigences applicables de la norme IEC 60601-1, y compris la clause 16 relative aux systèmes EM. Si des bornes d'entrée/sortie de signal supplémentaires doivent être ajoutées, le système résultant doit également être conforme aux exigences applicables de la norme IEC 60601-1, y compris la clause 16 relative aux systèmes EM. Pour obtenir de l'aide, contactez le service biomédical de votre hôpital, votre distributeur ou Mcube Technology Co., Ltd.

2.4. BATTERY SAFETY

BioCon-V must be operated using a lithium-ion battery.

If you experience any issues related to the battery, stop using the device immediately and contact your distributor or Mcube Technology Co., Ltd. (Contact Email: mcube@mcubetech.co.kr)

To ensure safe use of the battery, follow all warnings and precautions below.

WARNING *AVERTISSEMENT*

- The battery must be replaced only by service engineers authorized by Mcube Technology Co., Ltd.
La batterie doit être remplacée uniquement par des techniciens agréés par Mcube Technology Co., Ltd.
 - Charge the battery only using charging equipment provided by Mcube Technology Co., Ltd. (USB PD adapter, USB C to C cable, and wireless charging cradle).
Rechargez la batterie uniquement à l'aide des équipements de charge fournis par Mcube Technology Co., Ltd. (adaptateur USB PD, câble USB C-C et socle de charge sans fil).
 - Do not charge the battery in environments or under conditions not specified by the manufacturer, as this may cause overheating, explosion, or electrolyte leakage.
Ne rechargez pas la batterie dans des environnements ou des conditions non spécifiés par le fabricant, car cela pourrait provoquer une surchauffe, une explosion ou une fuite d'électrolyte.
 - If electrolyte leakage occurs, do not touch the liquid. If the liquid contacts your skin or eyes, seek medical attention immediately.
-

En cas de fuite d'électrolyte, ne touchez pas le liquide. Si le liquide entre en contact avec votre peau ou vos yeux, consultez immédiatement un médecin.

 CAUTION MISE EN GARDE

- If you detect any unusual signs from the battery such as strange odors or overheating, immediately stop using the device and contact your distributor or Mcube Technology Co., Ltd.
Si vous remarquez des signes inhabituels provenant de la batterie, tels qu'une odeur étrange ou une surchauffe, arrêtez immédiatement d'utiliser l'appareil et contactez votre distributeur ou Mcube Technology Co., Ltd.
- Do not charge the battery in environments with open flames or direct sunlight.
Ne rechargez pas la batterie dans des environnements exposés à des flammes nues ou à la lumière directe du soleil.
- If the device does not operate for more than 10 minutes after being fully charged, contact your distributor or Mcube Technology Co., Ltd.
Si l'appareil reste inopérant pendant plus de 10 minutes après une charge complète, veuillez contacter votre distributeur ou Mcube Technology Co., Ltd.
- The battery will gradually discharge when not in use. Fully charged the battery 1-2 days before use. Turning off the device when not in use will help extend battery life.
La batterie se déchargera progressivement lorsqu'elle n'est pas utilisée. Rechargez complètement la batterie un à deux jours avant l'utilisation. Éteindre l'appareil lorsqu'il n'est pas utilisé contribue à prolonger la durée de vie de la batterie.
- Long-term Storage: If the BioCon-V is not used for more than three months, store the device under appropriate environmental conditions to prevent battery depletion. It is recommended to recharge the battery every six months. For detailed storage conditions, refer to [17.5. ENVIRONMENTAL CONDITIONS](#).
- *Stockage à long terme: Si le BioCon-V n'est pas utilisé pendant plus de trois mois, conservez-le dans des conditions environnementales appropriées pour éviter la décharge de la batterie. Il est recommandé de recharger la batterie tous les six mois. Pour des conditions de stockage détaillées, reportez-vous à la section « 17.5. CONDITIONS ENVIRONNEMENTALES ».*
- To extend the battery lifespan, it is recommended to charge up to approximately 75% and discharge down to around 20% during normal use.
Pour prolonger la durée de vie de la batterie, il est recommandé de la recharger jusqu'à environ 75 % et de la décharger jusqu'à environ 20 % lors d'une utilisation normale.

2.5. DEVICE SAFETY

To ensure the safe use of BioCon-V and its components, you must follow the warnings and precautions below.



WARNING AVERTISSEMENT

- Do not modify or the device without the manufacturer's approval.
Ne modifiez pas et ne démontez pas l'appareil sans l'autorisation du fabricant.
 - Do not use the device if the probe is damaged.
N'utilisez pas l'appareil si la sonde est endommagée.
 - Use the device in a well-ventilated area to prevent overheating or damage.
Utilisez l'appareil dans un endroit bien ventilé afin d'éviter toute surchauffe ou tout dommage.
 - Do not use the USB cable while it is bent or twisted, as this may cause malfunction or charging failure.
N'utilisez pas le câble USB lorsqu'il est plié ou tordu, car cela pourrait provoquer un dysfonctionnement ou un échec de charge.
 - If the LCD screen is broken, avoid direct contact with the liquid crystal. If the liquid leaks and contacts your body, follow the instructions below.
Si l'écran LCD est brisé, évitez tout contact direct avec le cristal liquide. Si le liquide fuit et entre en contact avec votre corps, suivez les instructions ci-dessous.
 - If the liquid contacts your skin, wipe it off with a clean cloth and wash the area with soap and running water.
Si le liquide entre en contact avec votre peau, essuyez-le avec un chiffon propre, puis lavez la zone avec de l'eau et du savon.
 - If the liquid gets into your eyes, rinse your eyes with running water for at least 15 minutes and seek medical attention.
Si le liquide entre dans vos yeux, rincez-les à l'eau courante pendant au moins 15 minutes et consultez un médecin.
 - If the liquid is swallowed, rinse your mouth thoroughly with water, drink plenty of water, and induce vomiting. Then, visit a hospital and consult a physician immediately.
Si le liquide est avalé, rincez-vous soigneusement la bouche, buvez beaucoup d'eau et provoquez le vomissement. Rendez-vous ensuite immédiatement à l'hôpital pour consulter un médecin.
-

CAUTION MISE EN GARDE

- If the device will not be used for an extended period, unplug the cradle adapter and power off the device.

Si l'appareil n'est pas utilisé pendant une longue période, débranchez l'adaptateur du socle de charge et éteignez l'appareil.

- Use the device indoors only.

Utilisez l'appareil uniquement à l'intérieur.

- If the system behaves abnormally or operates inconsistently, stop using it. Power down the system and contact Mcube Technology or your distributor.

Si le système fonctionne de manière anormale ou incohérente, cessez immédiatement de l'utiliser. Éteignez le système et contactez Mcube Technology ou votre distributeur.

- Do not pour or spill any liquids (e.g., water) on the device.

Ne versez ni ne renversez aucun liquide (par exemple de l'eau) sur l'appareil.

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

Les modifications ou changements non expressément approuvés par la partie responsable de la conformité réglementaire peuvent annuler l'autorisation de l'utilisateur d'exploiter l'équipement.

2.6. SAFE HANDLING PROCEDURES FOR TRANSPORT

Packaging Damage: If the package has caused battery leakage or electrolyte discharge, safely isolate the affected part, seal it in a plastic bag, and contact the consignor for further instructions. Contact the consignor (sender) for instructions. The consignor will provide disposal or handling guidance. Until the product is inspected and, if necessary, repackaged, keep the damaged package separately in a designed area.

Product Damage: If the Package has resulted in battery leakage or electrolyte discharge, safely isolate the damage part, seal it in a plastic bag, and contact consignor for further instructions.

3. INTRODUCTION

3.1. PRODUCT FEATURES

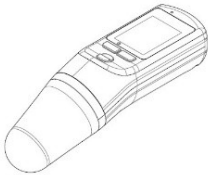
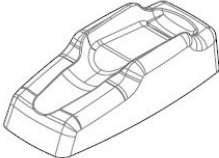
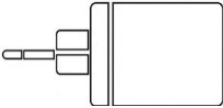
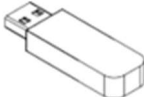
CUBEScan™ BioCon-V Consists of two main components: **BioCon-V Probe, Charging Cradle**



Key Features

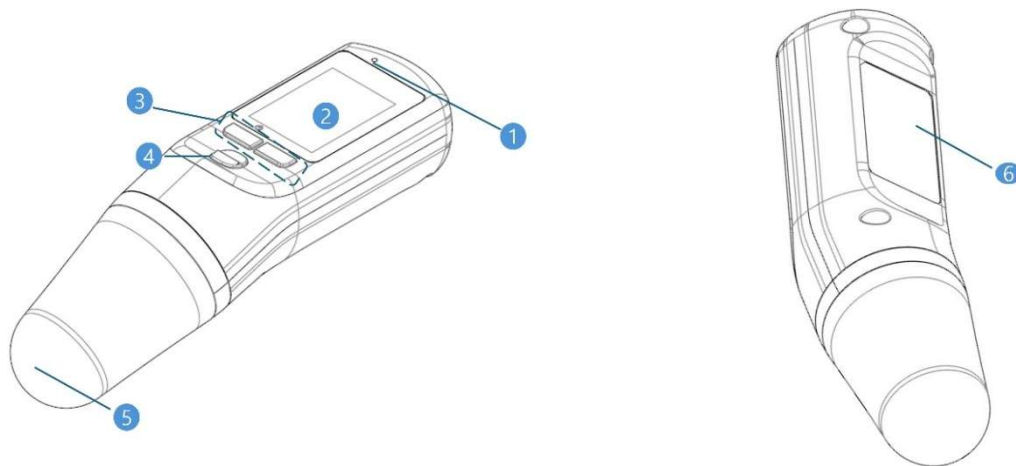
- The Probe is made of lightweight resin, and the Charging cradle is designed for portability.
- Measures bladder volume (residual urine) using ultrasound.
- Provides real-time bladder imaging through the Pre-Scan function.
- Enables quick and efficient measurements within a short time.
- Allows device management, measurement review, and configuration via a dedicated tablet application (BioCon-V Manager).
- The LED indicators on both the probe and the cradle clearly show charging status.

3.2. SYSTEM COMPONENTS

No.	Figure	Part	Qty	Description
1		Probe	1	● Ultrasound Bladder Volume Scanner ● Lightweight resin body with a built-in battery and wireless charging ● Three-button interface
2		Charging Cradle	1	Used for wireless charging of the probe.
3		Power Adapter	1	ATN045A3-W200U 100-240VAC, 50/60Hz, 1-0.5A
4		USB Cable	1	C to C 1.5m
5		External Memory	1	PC Software (CubeLite)

NOTE: For replacement parts, contact your distributor or Mcube Technology Co., Ltd.

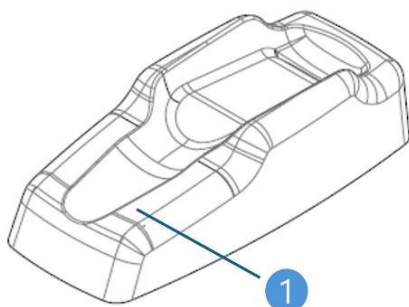
3.3. OUTER APPEARANCE – PROBE



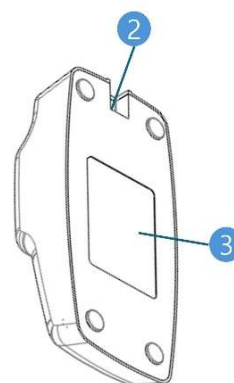
[Probe Appearance]

No.	Part	Purpose
1	Charging Status Indicator (LED)	Displays the charging status LED. ● Charging: Orange LED ON ● Charging error: Blinking Orange LED
2	LCD	Displays bladder volume, menu options, and information.
3	Menu Button	Used to switch to sleep mode, navigate through options, make changes, and save settings. ※ Power on/off is operated together with the Scan button.
4	Scan Button	Performs Pre-Scan and Normal Scan functions. ※ Power on/off is operated together with this button.
5	Probe Head	Contacts the patient's abdomen to transmit and receive ultrasound signals.
6	Back Label	Displays probe-related information. NOTE: Label contents are subject to change without prior notice.

3.4. OUTER APPEARANCE – CHARGING CRADLE



[Front View of the Charging Cradle]



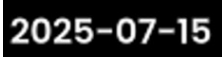
[Rear View of Charging Cradle]

No.	Part	Purpose
1	Battery Charging Indicator	Shows the charging status. ● Charging: Orange LED ON ● Standby: Green LED ON ● Charging error: Blinking Green & Orange LED ● Charging fault: Red LED ON
2	USB Adapter Port	Connect the USB cable and power adapter to provide power to the cradle.
3	Label	Displays cradle-related information. NOTE: Label contents are subject to change without prior notice.

3.5. INFORMATION SCREEN DISPLAY

3.5.1.STATUS BAR

(1) Date & Time Display

Icon	Description
	Displays the date. The date format follows the option selected in the Settings menu (e.g., YYYY-MM-DD, MM-DD-YYYY, DD-MM-YYYY).
	Displays the time in 24-hour format.

(2) Wireless Status

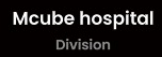
Icon	Description
	The wireless AP feature is enabled and connected to Cubelite or BioCon-V Manager app.
	The wireless AP feature is enabled but not connected to the Cubelite or BioCon-V Manager app.

(3) Battery Status (Level, Charging)

Icon	Description
	Battery fully charged
	Battery level: 80%
	Battery level: 60%
	Battery level: 40%
	Battery low
	Charging required immediately
	Indicates that the battery is currently charging.

3.5.2.Main Screen

(1) Home Screen

Icon	Description
	Displays the device name (BioCon-V).
	Displays the hospital name and department entered in the Settings menu.
	Shows the number of stored measurements and the maximum number of storable measurements.
	Opens the registered patient list screen.
	When the center button is pressed on the Home screen, a Pre-Scan is executed immediately.
	Opens the review list screen to view stored measurement results.

4. PREPARATION BEFORE USE

- Before using the device, be sure to read [5.1. MEASUREMENT ACCURACY](#).
- Check the battery icon on the status bar to ensure that the probe has sufficient power. If the battery level is low, fully charge the probe before use.
- Clean the probe before use. Moisten a soft cloth with a cleaning/disinfection solution and gently wipe the probe head. For detailed instructions, refer to [11. CLEANING AND DISINFECTION](#).

4.1. CHARGING CRADLE INSTALLATION

- Install the charging cradle on a stable, level indoor surface before use.
- Use only the charging cradle, USB cable, and power adapter provided or specified by Mcube Technology Co., Ltd.
- Connect the USB cable to the USB adapter port on the charging cradle.
- Connect the other end of the USB cable to the power adapter, then plug the power cord into a wall outlet.
- After power is applied, confirm that the cradle starts up properly. The cradle LED blinks green and orange four times, then changes to standby mode with the green LED on.
- Place the probe on the cradle and verify that the probe is seated correctly. During charging, the probe LED turns orange, the cradle LED turns orange, and the battery charging icon appears on the LCD screen.
- When charging is complete, the probe LED turns off and the cradle LED remains green.
- The charging cradle does not come into contact with the patient. Maintain a minimum distance of 2 meters from the patient during use.
- Do not use the charging cradle to charge any device other than the BioCon-V.

4.2. BATTERY CHARGING



WARNING *AVERTISSEMENT*

- The battery must be replaced by service authorized by Mcube Technology Co., Ltd.
La batterie doit être remplacée uniquement par un service agréé par Mcube Technology Co., Ltd.
 - Charge the battery only using the charging cradle, USB cable, and adapter provided by Mcube Technology Co., Ltd.
Rechargez la batterie uniquement à l'aide du socle de charge, du câble USB et de l'adaptateur fournis par Mcube Technology Co., Ltd.
 - Do not disassemble, heat, or incinerate the battery.
Ne démontez pas, ne chauffez pas et n'incinerez pas la batterie.
 - Handle the battery with care to prevent the risk of explosion or fire.
Manipulez la batterie avec précaution afin d'éviter tout risque d'explosion ou d'incendie.
 - The BioCon-V uses a lithium-ion battery as its power source. Follow the instructions below to reduce potential hazards when handling the battery:
-

Le BioCon-V utilise une batterie lithium-ion comme source d'alimentation. Suivez les instructions ci-dessous afin de réduire les risques potentiels lors de la manipulation de la batterie:

- Do not short-circuit the battery terminals or allow them to come into contact with conductive materials such as metal. Short-circuiting may cause fire, injury, or device damage.

Ne mettez pas en court-circuit les bornes de la batterie et ne les laissez pas entrer en contact avec des matériaux conducteurs tels que le métal. Un court-circuit peut provoquer un incendie, des blessures ou des dommages à l'appareil.

- Do not subject the battery to impact, vibration, or excessive pressure. Internal damage may result in overheating, sparks, leakage, explosion, or fire.

Ne soumettez pas la batterie à des chocs, des vibrations ou une pression excessive. Des dommages internes peuvent entraîner une surchauffe, des étincelles, des fuites, une explosion ou un incendie.

- Do not charge the device near open flames or under direct sunlight.

Ne rechargez pas l'appareil à proximité de flammes nues ou sous la lumière directe du soleil.

- Do not use the charging cradle to charge any device other than the BioCon-V.

N'utilisez pas le socle de charge pour recharger un autre appareil que le BioCon-V.



CAUTION MISE EN GARDE

- The charging cradle does not come into contact with the patient. Maintain a minimum distance of 2 meters from the patient during use.

Le socle de charge n'entre pas en contact avec le patient. Maintenez une distance minimale de 2 mètres du patient pendant l'utilisation.

- If you notice any unusual smell, heat, discoloration, or deformation from the battery, stop using the device immediately and contact the distributor or Mcube Technology Co., Ltd.

Si vous remarquez une odeur inhabituelle, une chaleur excessive, une décoloration ou une déformation de la batterie, cessez immédiatement d'utiliser l'appareil et contactez le distributeur ou Mcube Technology Co., Ltd.

Battery Charging Procedure:

No.	Procedure	Description
1	Fully charge before first use	When using the device for the first time, fully charge the probe battery before operation.
2	Connect the adapter	● Connect the AC/DC adapter cable to the charging cradle. ● Plug the power cord into a wall outlet.
3	Check cradle startup	● The cradle LED blinks green and orange four times to indicate that startup is complete. ● After startup, the cradle switches to standby mode (Green LED ON).
4	Place the probe on the cradle and check the charging status	● During charging: Probe (Orange LED ON), Cradle (Orange LED ON) ● BioCon-V LCD screen: Battery charging icon displayed on the status bar (e.g., )
5	Charging complete status	● When charging is complete: Probe (LED OFF), Cradle (Green LED ON)
6	Recharge status	● Wireless charging is automatically disabled when the probe battery reaches 100% while mounted in the cradle. ● Wireless charging is automatically re-enabled either when the battery level falls to 98% or below while the probe is in Sleep Mode, or when the probe wakes from Sleep Mode.

NOTE:

- A full charge of the usable capacity takes approximately 4 hours.
- The device automatically turns on when the power-off probe is placed on the charging cradle.

5. HOW TO USE

5.1. MEASUREMENT ACCURACY

The following cases may affect ultrasound transmission and measurement accuracy.

- Patients who have undergone suprapubic or pelvic surgery
- Patients with scars, sutures, staples or incisions in the suprapubic region
- Patients with bladder catheter
- Air gaps between the patient's skin and probe head
- Morbidly obese patients
- Contaminated probe head
- Inadequate patient posture
- In patients with myoma and cystic lesions, there is a possibility of overestimating bladder volume.

5.2. CHECK BEFORE USE

CUBEScan BioCon-V supports Pre-Scan function to help locate the patient's bladder.

It is recommended to perform measurements when the residual urine volume is at least 100 mL.



WARNING *AVERTISSEMENT*

- **DO NOT use the Biocon-V in the presence of flammable anesthetics. Explosion hazards exist.**

NE PAS utiliser le BioCon-V en présence d'anesthésiques inflammables. Il existe un risque d'explosion.

- **DO NOT use the Biocon-V in the following cases.**

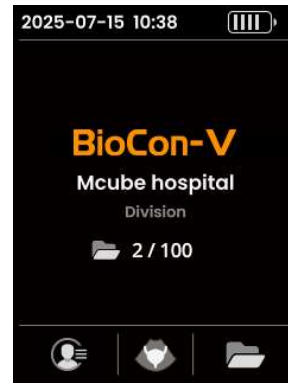
NE PAS utiliser le BioCon-V dans les cas suivants.

- For fetal use or on pregnant patients
 - *Pour un usage fœtal ou sur des patientes enceintes*
 - Patients with ascites
 - *Chez les patients présentant une ascite*
 - Patients with open skin or wounds in the suprapubic region.
 - *Chez les patients ayant une peau ouverte ou des plaies dans la région sus-pubienne*
-

5.3. TURN THE DEVICE ON/OFF



[BioCon-V Boot Screen]



[BioCon-V Home Screen]

5.3.1. POWER ON

- Press and hold the left button (Power, ) to turn on the device or exit Sleep Mode.
- When the device powers on, the BioCon-V boot screen appears.
- Once the boot process is complete, the home screen is displayed.

5.3.2. POWER OFF

- Press and hold the left button (Power, ) for more than 3 seconds to put the device into Sleep Mode (.
- Press and hold the left button () and the center button together for more than 3 seconds; the Power-off message () will be displayed.
- On the message window, press the left button (Confirm, ) to turn off the device.

5.4. BUTTON OPERATIONS GUIDE



[BioCon-V Physical Buttons]

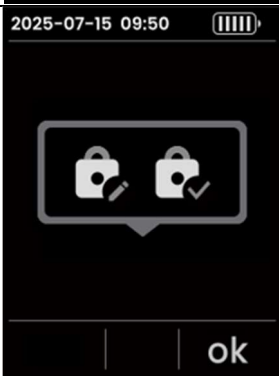
BioCon-V is operated using three physical buttons.

Button Position	Main Function
Left Button	Power ON/OFF, Menu navigation
Center Button	Start Scan, Confirm
Right Button	Menu Navigation

- Button operations for each function are described separately in the corresponding section.

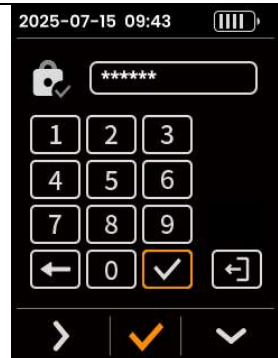
5.5. INITIAL SETUP

If you are using the Biocon-V for the first time, please follow the steps below to set your initial password.

Initial Setup Procedure	Screen
(1) Power On Press the left (power) button on the probe to turn on the device.	
(2) Initial Password Change Notice - When the device powers on, a message recommending that you change the initial password will appear. - When the device powers on, a message recommending that you change the initial password will appear. (3) Open the Settings Screen and Enter the Initial Password On the Settings screen, enter the default 6-digit initial password.	
(4) Enter the Current Password - Enter the initial 6-digit password. - Keypad Operation. - Left button (➡): Move the cursor to the right. - Right button (⬅): Move the cursor downward. - When the desired number is highlighted in orange (1), press the center button to select it. - After entering all 6 digits, the Enter icon (✓) becomes active. - Select the Enter icon (✓) and press the center button (✓) to confirm.	
(5) Enter the New Password - Enter a new 6-digit password. - The input method is the same as entering the current password. - After completing entry, select the Confirm icon (✓) and press the center button (✓) to save.	

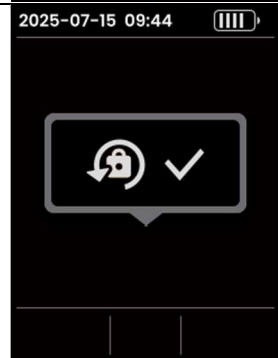
(6) Confirm the New Password (Re-enter)

- Re-enter the same 6-digit password.
- After completing entry, select the Confirm icon (🔑) and press the center button (✓) to save.



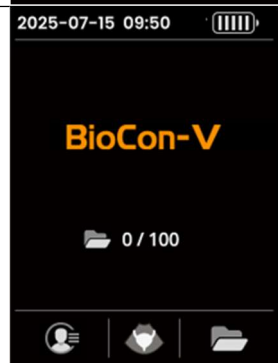
(7) Password Setup Complete

When the password is successfully saved, a "Password Setup Complete" message appears for approximately 3 seconds.



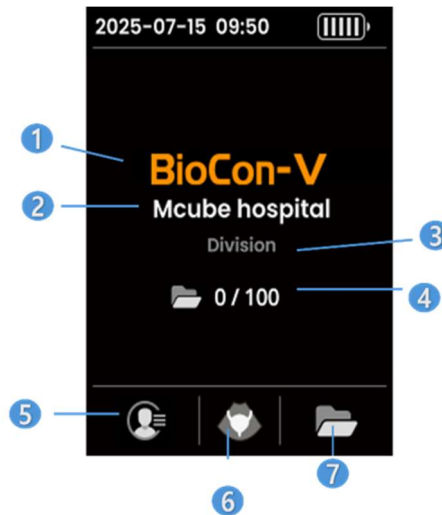
(6) Enter the Home Screen

After the message disappears, the device automatically moves to the home screen, completing the initial password setup.



5.6. HOME SCREEN

When the BioCon-V is powered on, the home screen appears, allowing you to check key information and access main functions.



[BioCon-V Home Screen]

No.	Item and Description
1	Device Model: BioCon-V
2	Hospital or Clinical Name
3	Department name
4	Number of stored scans / Maximum number of storable scans
5	Displays the registered patient list
6	Scan: Executes Pre-Scan and Normal Scan
7	Opens the list of stored scan results and the review screen

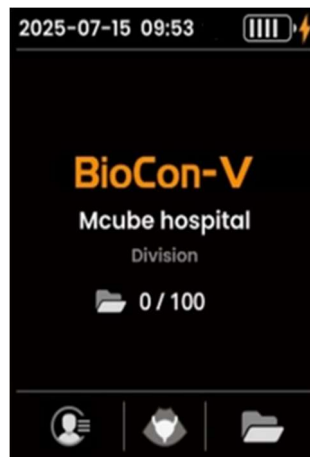
NOTE:

- Up to 100 review items can be stored. When the limit is exceeded, the oldest data is automatically deleted.
- Data is displayed in the order of most recent measurements first.
- After password entry, access to patient information remains enabled until the device enters sleep mode or is powered off.

5.7. SCAN PREPARATION

(1) Power on

- Press the left button on the probe to turn on the device.
- When the boot process is complete, the home screen appears.



[Home Screen]

(2) Prepare the Patient

- Position the patient in a comfortable supine position.
- Lift the clothing to fully expose the area from the pubic bone to the navel.



(3) Apply Ultrasound Gel

- Apply ultrasound gel evenly to the probe head.
- Ensure that no air bubbles remain inside the gel, as they may reduce measurement accuracy.

(4) how to Hold the Probe

On the Home Screen, press the Center button (Scan, ) and hold the probe so that you can face the probe display screen directly.

(5) Position the Probe

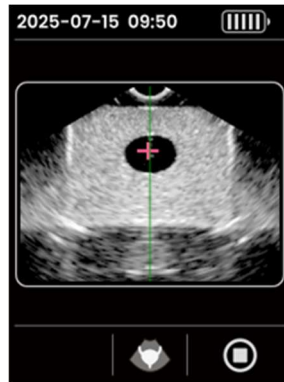
- Place the probe head firmly against the skin at a point approximately 3 cm above the patient's pubic bone.
- Adjust the position left and right along the straight line connecting the pubic bone and the navel to find the optimal scanning position.

5.8. LOCATING THE BLADDER (PRE-SCAN)

5.8.1. PRE-SCAN PROCEDURE

(1) Start Pre-Scan

When the bladder appears within the measurement area on the screen, press the center button (Scan, ) to start the Pre-Scan.



[Pre Scan Screen]

(2) Execute the Scan

On the Pre-Scan screen, press the center button (Scan, ) again to proceed with scanning.

(3) Find the Optimal Angle

Slowly tilt the probe left and right to find the angle at which the bladder appears the largest.

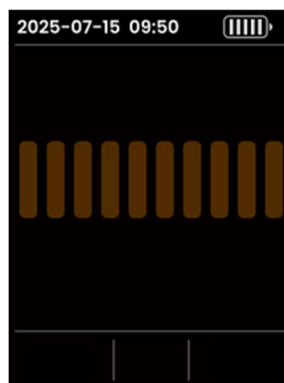
NOTE: The optimal scanning position is when the bladder image appears largest, and its center is positioned close to the midline.

(4) Stop the Pre-Scan

To stop the Pre-Scan or return to the information screen, press the right button (Stop, )

(5) Start Normal Scan

On the Pre-Scan screen, press the center button (Scan, ) to start a Normal Scan.



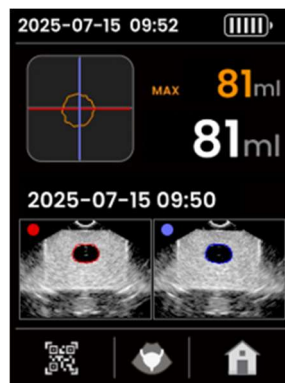
[Normal Scan Screen]

(6) Precautions During Scanning

- Hold the probe steady to prevent any movement during scanning.
- Any movement may affect the measurement accuracy.

(7) Scan Complete

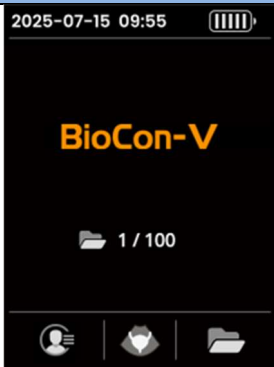
- When the Scan is finished, the Scan Result Screen will automatically appear.
- On the result screen, press the right button (Home, ) to return to the Home screen, the maximum value of the measurement session is saved automatically.
- For detail on viewing and using scan results, refer to [5.9. CHECK SCAN RESULTS.](#)



[scan Result Screen]

5.8.2.MEASURING A REGISTERED PATIENT

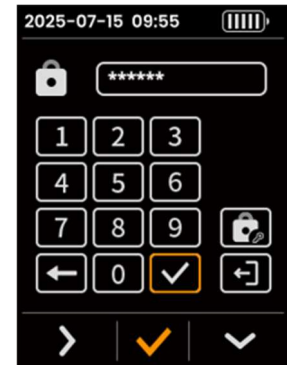
To measure a registered patient, follow the procedure below.

Measurement Method	Display						
(1) Home screen From the Home screen, press the left button (Patient List, ) to move to the Patient List screen.							
(2) Enter Password ● When the password input window appears, enter the 6-digit password. ● Keypad operation							
<table><tr><th>Button Icon</th><th>Function</th><th>Description</th></tr><tr><td> (Left Button)</td><td>Move cursor right</td><td>Move the cursor one space to the right.</td></tr></table>	Button Icon	Function	Description	 (Left Button)	Move cursor right	Move the cursor one space to the right.	
Button Icon	Function	Description					
 (Left Button)	Move cursor right	Move the cursor one space to the right.					

 (Right Button)	Move Down	Move the cursor down one space.
 (Center Button)	Select/Enter	Confirms and enters the selected number (highlighted in orange)
 (Orange Highlight)	Selected State	Indicates the currently selected keypad item
 (Enter Icon)	Confirm Password	After entering six digits, select this icon to confirm the password

● Input Procedure

- Use the left button to move the cursor right, and the right button to move the cursor down.
- When the desired number is highlighted in orange () , press the center button to enter it.
- Enter all six digits.
- Select the Input Complete icon () and press the center button () to finish password entry.



(3) Select the Patient

- Select the patient you wish to measure from the patient list to move to the Pre-Scan screen.
- For Pre-Scan instructions, refer to [5.8.1. PRE-SCAN PROCEDURE](#).

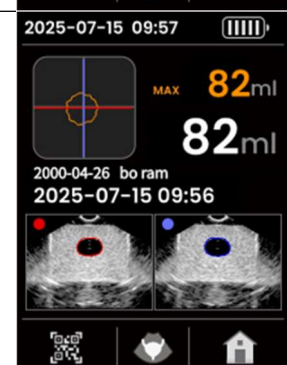
NOTE: After entering the password, access to patient information remains available until the device enters sleep mode or is powered off.



(4) After Completing the Scan

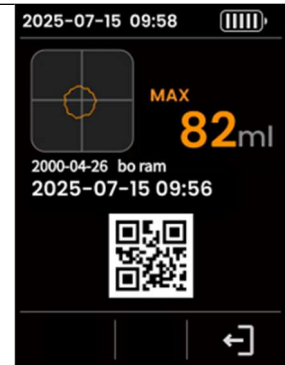
When the scan is complete, the result screen appears.

- Left button (): Moves to the maximum scan barcode screen.
- Right button (): Saves the maximum scan value for the current session, then returns to the home screen.



(5) Using the Barcode

- The maximum scan barcode screen is displayed along with the maximum measurement value (Max) of the session.
- You can scan the barcode using a barcode reader or a mobile device to input patient data

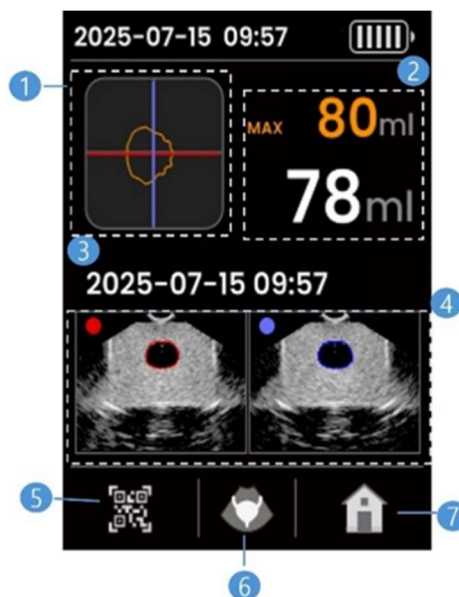


5.9. CHECK SCAN RESULTS

When the scan is complete, the scan result screen is displayed automatically.

On this screen, you can check the current residual volume, the maximum residual volume (Max), the patient's name, and the measurement date/time.

To measure the patient again, press the center button (Scan, ) on the scan result screen.



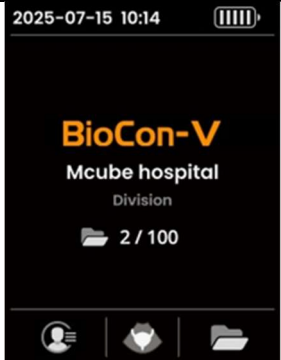
[Scan Result Screen]

No.	Description
1	Bladder Position/Orientation Indicator • Displays the bladder location and scan direction along with the crosshair. NOTE: Measurement accuracy is highest when the bladder center is positioned at the center of the crosshair. If the center is misaligned, refer to 5.8.1. PRE-SCAN PROCEDURE. and perform the scan again.
2	Measurement Value Display Area • Max (orange): The maximum residual volume recorded during the session • Current Value (white): The actual residual volume obtained from the most recent scan

3	Measurement Information Display Shows the measurement date/time and patient information (when measuring a registered patient).
4	Cross-Section Image Display - Displays the bladder ultrasound image for each cross-section and shows whether the bladder contour is aligned. - The circular icon at the upper-left corner of each cross-section image indicates its orientation (R-L, H-F).
5	Barcode Icon When selected, the maximum scan barcode screen is displayed, allowing data transfer using a barcode reader.
6	Scan Button (Center Button) Returns to the Pre-Scan screen and starts a re-scan.
7	Home Icon (Right Button) Saves the maximum scan value for the current session and returns to the home screen.

5.10. LAST SCAN RESULT

To review stored scan data, follow the steps below.

Procedure	Screen												
(1) Move to the Password Input Screen From the Home screen, press the right button () to move to the current password input screen.													
(2) Enter the Current Password ● When the password input window appears, enter the 6-digit password. ● Keypad operation <table><tr><th>Button Icon</th><th>Function</th><th>Description</th></tr><tr><td> (Left Button)</td><td>Move Cursor right</td><td>Moves the cursor one position to the right</td></tr><tr><td> (Right Button)</td><td>Move Cursor down</td><td>Moves the cursor one position down</td></tr><tr><td> (Center Button)</td><td>Select/Input</td><td>Enter the selected number (highlighted in orange)</td></tr></table>	Button Icon	Function	Description	 (Left Button)	Move Cursor right	Moves the cursor one position to the right	 (Right Button)	Move Cursor down	Moves the cursor one position down	 (Center Button)	Select/Input	Enter the selected number (highlighted in orange)	
Button Icon	Function	Description											
 (Left Button)	Move Cursor right	Moves the cursor one position to the right											
 (Right Button)	Move Cursor down	Moves the cursor one position down											
 (Center Button)	Select/Input	Enter the selected number (highlighted in orange)											

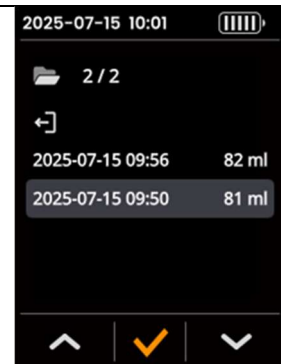
 (Orange Highlight)	Selected State	Indicates the currently selected keypad item
 (Input Complete Icon)	Completed Password entry	After entering all six digits, select to confirm the password

● Password Input Procedure

- Press the left button to move the cursor right and the right button to move the cursor down.
- When the desired number is highlighted in orange (), press the center button to enter it.
- Enter all six digits.
- Select the Input Complete icon () , then press the center button () to finish password entry.

(3) Select Data from the Review List

- On the Review List screen, select the data to review using the left () and right () buttons.
- After selecting the desired item, press the center button () to open the Image Review screen.



(4) Check the Image Review Screen

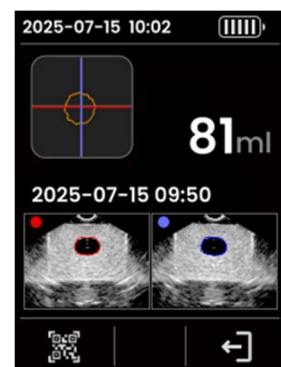
The Image Review screen displays the selected data, including cross-sectional scan images and measurement information.

(5) Move to the Maximum Scan Barcode Screen

From the Image Review screen, press the left button () to move to the Maximum Scan Barcode Screen.

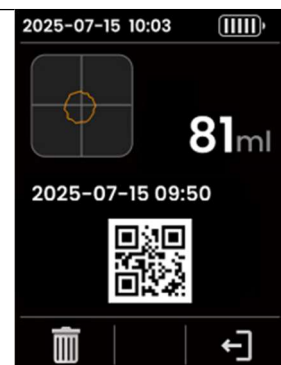
(6) Return to the Review List

On the Maximum Scan Barcode Screen or Image Review screen, press the right button () to return to the Review List screen.



(7) Deleted Stored Data

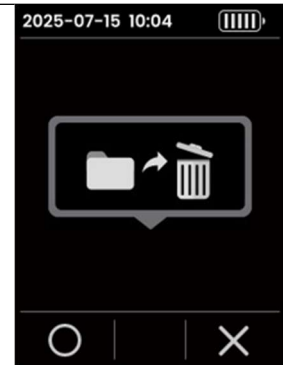
- In the Review List, select the data you wish to delete, then press the left button () .
- A deleted confirmation message will appear.



(8) Select Whether to Delete

When the deleted confirmation message appears, choose one of the following.

- Left button (○): Proceed with deletion → The data is deleted and the Screen returns to the Review List
- Right button (✕): Cancel deletion



NOTE:

- Up to 100 items can be stored in the review list; when the limit is exceeded, the oldest data is automatically deleted.
- Data is sorted in the order of most recent measurements first.
- Once the password is entered, access to patient information remains active until the device enters sleep mode or is powered off.

5.11. PASSWORD RESET PROCEDURE

If you forget your password, follow the steps below.

Procedure	Screen
(1) Enter the Password Input Screen From the Home screen, press the right button (➡) to move to the password input screen.	
(2) Select the Password Change Menu Keypad Operation ● Left button (➡): Moves the cursor to the right. ● Right button (⬅): Moves the cursor downward. ● When the desired item is highlighted in orange (🔒), press the center button (✓) to select it. ● Select the Password Change icon (🔒), then press the center button (✓) to move to the Lock Code screen.	

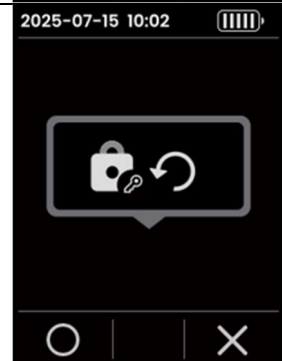
(3) Move to the Lock Code Menu

Press the left button (Generate, ) to display the Lock Code generation confirmation screen.



(4) Lock Code Generation Confirmation Screen

On the Lock Code generation screen, press the left button () to display the Lock Code generation screen.



(5) Generate the Lock Code

- Write down the generated lock code on paper or save it as a photo for safekeeping.
- The lock code remains valid until a new lock code is generated.

NOTE: The generated lock code must be provided to the manufacturer to receive a Key Code.

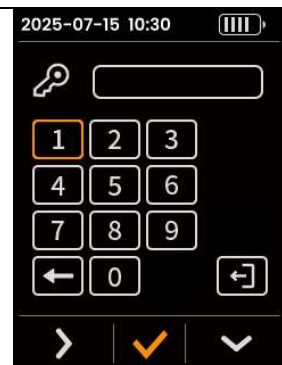


(6) Provide the Lock Code to the Manufacturer

- Send the lock code displayed on the screen to the manufacturer.
- The manufacturer will issue the Key Code corresponding to the lock code.
- Press the key icon (, center button) to move to the Key Code input screen.

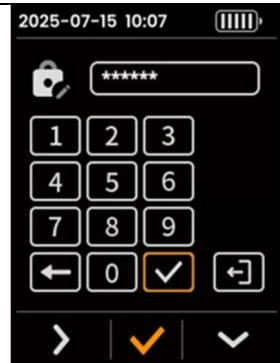
(7) Enter and Confirm the Key Code

- Enter the Key Code provided by the manufacturer using the keypad.
- After the input is complete, select the Complete icon () , then press the center button () .



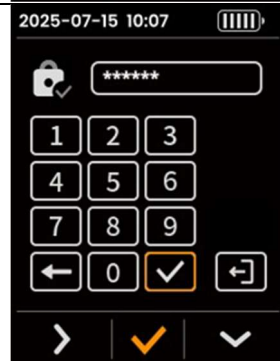
(8) Enter a New Password

- When the Key Code is verified successfully, the new password (6 digits) input screen appears.
- Enter the 6-digit password using the numeric keypad, select the Input.
- Complete icon (✓) and press the center button (✓).



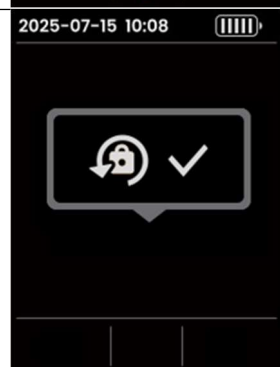
(9) Re-enter the New Password

- Re-enter the same 6-digit password to confirm it.
- After input is complete, select the Input Complete icon (✓), then press the center button (✓) to save it.



(10) Password Setup Complete

- When the password setup is complete, a completion message appears for approximately 3 seconds.
- After confirmation, the previous lock code is automatically deleted, and the screen returns to the Home screen.



5.12. AUTO SLEEP MODE

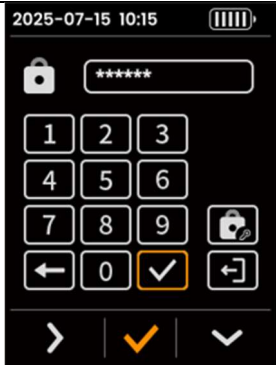
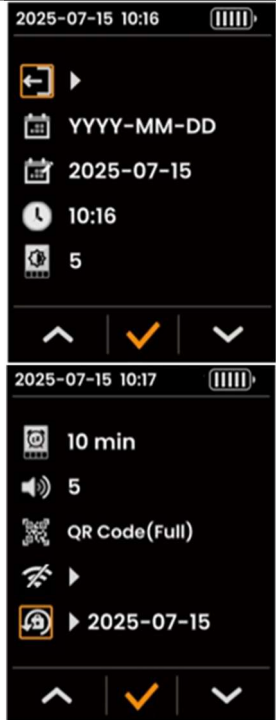
To conserve the device's battery power, Auto Sleep Mode is activated automatically under the conditions shown below.

When Auto Sleep Mode starts, a message appears for approximately 3 seconds, and the screen turns off automatically.

Description	Screen
Auto Sleep Activation Conditions ● When there is no activity on the probe for the set duration (2//5/10 minutes) - No scanning - No data transmission - No user input ● When there is no user input for approximately 10 seconds during wireless charging Exiting Auto Sleep Mode: Press the left button to exit Auto Sleep Mode and turn the screen back on.	 [Auto Sleep Mode Screen]

6. DEVICE SETTING

6.1. ACCESSING THE DEVICE SETTING MENU

Procedure	Screen
(1) Entering the Setting Menu From the Home screen, press and hold the center button and right button simultaneously for 3 seconds.	
(2) Entering the Password (6 digits) Keypad operation - Left button (➡): Move cursor to the right. - Right button (⬅): Move cursor downward. - Selected key is highlighted in orange (1) → Press the center button (✓) to enter. - After entering all 6 digits, select the Confirm icon (✓) → Press the center button (✓).	
(3) Selecting and Changing Settings - Use the left (⬅) or right (➡) button to select an item → Press the center button (✓) to activate it. - Use the left (⬅) or right (➡) button to adjust the setting. - After adjusting the setting, press the center button (✓) - to apply the change. NOTE: Once the password is entered and access is granted, the authorization remains valid until the device enters sleep mode or is powered off.	

6.2. SETTING DATA FORMAT

You can select one of the following date formats: YYYY-MM-DD / MM-DD-YYYY / DD-MM-YYYY.

[Procedure]

- Select the Date Format icon () , then press the center button () . (Activation example:
-  YYYY-MM-DD)
- Use the left button () or right button () to choose the desired date format.
- Press the center button () to apply the selected format.
- Once applied, the date displayed at the top of the screen is immediately updated to the new format.

6.3. SETTING THE DATE

The configured date will also be recorded in the scan results.

[Procedure]

- Select the Date icon () , then press the center button () .
- The fields are activated sequentially in the order of Year → Month → Day.
- Use the left button () and right button () to change the numbers in the active field
- After adjusting the number, press the center button () to move to the next field.

6.4. SETTING THE TIME

The time is set in the 24-hour format (HH:MM) and is also recorded in the scan results.

[Procedure]

- Select the Time icon () , then press the center button () .
- When the Hour field becomes active, press the left button () or right button () to adjust the value, then press the center button () .
- When the Minute field becomes active, set it in the same manner, then press the center button () to save.

6.5. ADJUSTING SCREEN BRIGHTNESS

The screen brightness can be adjusted from Level 1 to Level 5, with higher numbers indicating a brighter display.

[Procedure]

- Select the Screen Brightness icon () , then press the center button () .
- Press the left button () or right button () to choose the desired brightness level (1–5).
- Press the center button () to save the setting.

6.6. SETTING THE SLEEP MODE TIMEOUT

The device allows you to choose the duration before Sleep Mode activates.

The available options are 2 minutes, 5 minutes, and 10 minutes.

[Procedure]

- Select the Sleep Mode icon () , then press the center button ().
- Press the left button () or right button () to select the desired timeout (2 minutes, 5 minutes, or 10 minutes).
- Press the center button () to save the setting.

6.7. ADJUSTING THE VOLUME

The volume level can be adjusted from **0 to 5**, and the selected level is applied to the beep sound generated when a scan is completed.

[Procedure]

- Select the Volume icon () , then press the center button ().
- Press the left button () or right button () to select the desired volume level (0–5).
- Press the center button () to save the setting.

6.8. SELECTING THE BARCODE FORMAT

The selected barcode format is applied to measurement data and can also be used when transferring data to a PC.

[Procedure]

- Select the Barcode Format icon ().
- Press the left button () or right button () to choose the desired option.
- Press the center button () to save the selected format.

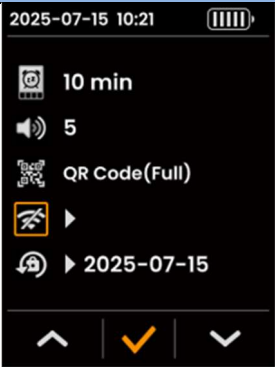
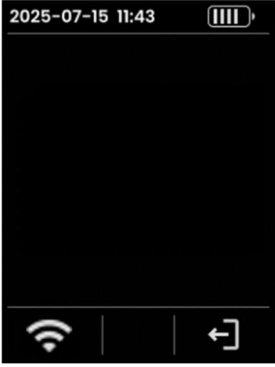
[Barcode Format Options Table]

Option	Description	Output Data	Barcode Format
Code-128 (Number)	Measures numeric amount only	80	
Code-128 (Volume)	Measures numeric amount + unit	80 ml	
Aztec Code (Number)	Measures numeric amount only	80	
Aztec Code (Volume)	Measures numeric amount + unit	80 ml	
Aztec Code (Full)	Measures date-time + amount	20250715-095703 80 ml	
QR Code (Number)	Measures numeric amount only	80	
QR Code (Volume)	Measures numeric amount + unit	80 ml	

QR Code (Full)	Measures date-time + amount	20250715-095703 80 ml	
Data Matrix (Number)	Measures numeric amount only	80	
Data Matrix (Volume)	Measures numeric amount + unit	80 ml	
Data Matrix (Full)	Measures date-time + amount	20250715-095703 80 ml	

6.9. ACCESSING THE WI-FI SETUP SCREEN

You can check the SSID and PW (Password) information required for registering the device in CubeLite (PC software) or BioCon-V Manager (tablet app).

Procedure	Screen
(1) Opening the Wi-Fi Menu - From the Home screen, select the Wi-Fi icon () , then press the center button () to enter the Wi-Fi menu. - Wi-Fi status indications - WiFi Off(): Wireless connection disabled - WiFi On(): Wireless connection enabled	
(2) Wireless Setting Disabled - When Wi-Fi is turned off, the Wi-Fi indicator () in the status bar disappears. - The SSID & PW screen also switches to the disabled state. - You can perform the following actions. - Wireless Enable icon (, left button): Turn Wi-Fi back on - Exit icon (, right button): Return to the Setting menu	
(3) Disabling the Wireless Setting - On the SSID & PW screen, select the Wireless Enable icon () . - An activation screen appears as shown on the right.	

(4) Checking SSID and PW Information

- When you enter the Wi-Fi menu, the device's SSID and PW information are displayed on the screen.
- Icon Functions

Button Icon	Function	Description
	Wireless icon(left)	Enable/disable wireless function
	Barcode icon (center)	Opens the wireless information barcode screen
	Exit icon (right)	Returns to the settings screen.



(5) Viewing the Wireless Information Barcode

- Press the Barcode icon () to display the wireless information barcode, which contains the SSID and PW.
- You can scan this barcode using a tablet camera or a PC barcode reader to automatically enter the SSID and PW.
- Press the Exit icon (, right button) to return to the SSID & PW screen.



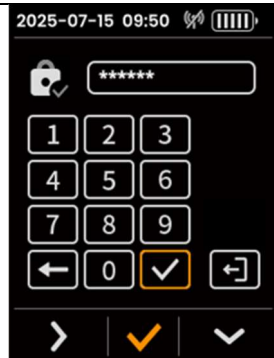
6.10. CHANGING THE PASSWORD

The Password Change menu allows you to set a new 6- to 10-digit lock password for the device.

Procedure	Screen
(1) Opening the Password Change Menu From the Setting screen, select the Password Change icon () , then press the center button () .	
(2) Entering a New Password - When the password keypad appears, enter a 6- to 10-digit password. - Keypad Operation - Left button(): Move the cursor to the right. - Right button (): Move the cursor downward. - Selected item is highlighted in orange () → Press the center button () to enter. - After entering all 6–10 digits, select the Confirm icon () → Press the center button () to confirm.	

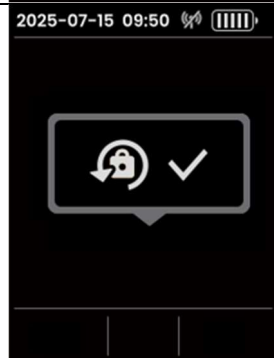
(3) Re-entering the New Password (Confirmation)

- Enter the same 6- to 10-digit password again to confirm.
- After completing the input, select the Confirm icon (✓), then press the center button (✓) to finalize the password change.



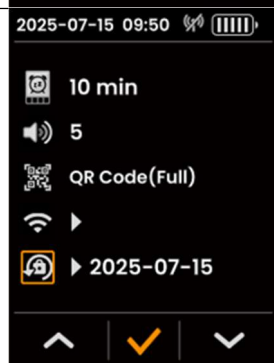
(4) Password Change Complete Message

A message confirming that the password change is complete is displayed for approximately 3 seconds.



(5) Return to the Setting Screen

- After the message disappears, the device automatically returns to the setting screen.
- The password change date is updated and displayed on the screen.



7. SOFTWARE (CUBELITE)

If you are not using CubeLite (PC software), you may skip this section.

7.1. GENERAL INFORMATION

This section provides detailed instructions on how to use CubeLite.

Before using CubeLite, be sure to read and fully understand the contents of this manual.

Mcube Technology Co., Ltd. shall not be held responsible for any problems that occur under the following circumstances.

- When the software is not used in accordance with the instructions in the operator's manual
- When the PC software is modified by a non-professional or by the user without authorization
- When using assembled PCs or tablets that are not covered by the manufacturer's warranty



CAUTION *MISE EN GARDE*

- It is strongly recommended to install security software on all computers where CubeLite is installed and executed.

Il est fortement recommandé d'installer un logiciel de sécurité sur tous les ordinateurs où CubeLite est installé et utilisé.

- To protect personal information, avoid using easily guessable passwords and change your password regularly.

Pour protéger les informations personnelles, évitez d'utiliser des mots de passe faciles à deviner et changez-les régulièrement.

- To prevent loss of patient data, perform regular backups.

Pour éviter la perte de données patients, effectuez des sauvegardes régulières.

Precautions When Connecting to a Computer:

- The computer used with this device must comply with IEC 62368-1 or IEC 60601-1 and must be installed and operated in accordance with the manufacturer's instructions.

L'ordinateur utilisé avec cet appareil doit être conforme aux normes IEC 62368-1 ou IEC 60601-1 et doit être installé et utilisé conformément aux instructions du fabricant.

- If a cybersecurity threat is detected while using the software, immediately disconnect the internet and power off the device.

Then, contact Mcube Technology Co., Ltd. for assistance:

Phone: +82-2-3421-7780

Email: mcube@mcubetech.co.kr

Si une menace de cybersécurité est détectée lors de l'utilisation du logiciel, déconnectez immédiatement Internet et éteignez l'appareil.

Contactez ensuite Mcube Technology Co., Ltd. pour obtenir de l'assistance.

Security Measures Required Before Using the Software

Mesures de sécurité requises avant d'utiliser le logiciel

- User access control
Contrôle d'accès utilisateur
- Antivirus and anti-malware software
Logiciel antivirus et anti-malware
- Firewall configuration
Configuration du pare-feu
- Session management procedures
Procédures de gestion de session

7.2. PURPOSE OF SOFTWARE

CubeLite allows users to transfer PDF or JPG files generated by the BioCon-V device to a computer.

7.3. MAIN FUNCTIONS

The CubeLite Software provides the following main functions: Export scan results in PDF or JPG format via Wi-Fi (wireless connection).

7.4. INSTALL CUBELITE

7.4.1.INITIAL INSTALLATION OF CUBELITE

- Connect the installation USB to the computer.
- Run the CubeLite Install Manager file.
- When the Administrator Password window appears, enter the password and click the [Update] button.
- On the initial installation screen, click the [Next >] button.
- On the Select Installation Folder screen, install to the default folder or click [Browse...] to specify a folder, then click [Next >] to continue.
- On the Confirm Installation screen, click the [Next >] button to start the installation ((The Installing CubeLite window will appear and show the installation progress).
- When the Installation Complete screen appears, click the [Close] button to finish the installation.

7.4.2.UPGRADE INSTALLATION OF CUBELITE

- The upgrade procedure is identical to the initial installation process described in [7.4.1. INITIAL INSTALLATION OF CUBELITE](#).
- During the upgrade process, an administrator password prompt may appear.
- If the password has been forgotten, it must be reset before performing the upgrade.

7.5. REMOVE CUBELITE

7.5.1.REMOVE USING THE CONTROL PANEL

- Open the Control Panel.
- Select Uninstall a program.
- From the list, select CubeLite and click [Uninstall].

7.5.2.REMOVE USING THE SOFTWARE

- Run the CubeLite Installer Manager.
- In the Administrator Password window, enter the password and click [Update].
- On the "Welcome to the CubeLite Installer Setup Wizard" screen, select Remove CubeLite, then click [Finish].
- The Removing CubeLite progress window will appear, and the uninstallation will begin.
- When "CubeLite was successfully removed" appears, click [Close] to finish.

[Password Reset Procedure]

If you forget your password, follow the steps below.

- Click the [Forgot] button to Open the Reset Password window.
- Click the [Generator] button to create a Lock Code (e.g., fab51).
- Send the generated Lock Code to the manufacturer via email mcube@mcubetech.co.kr
- Enter the issued Key Code, then click the [Reset] button to complete the process.

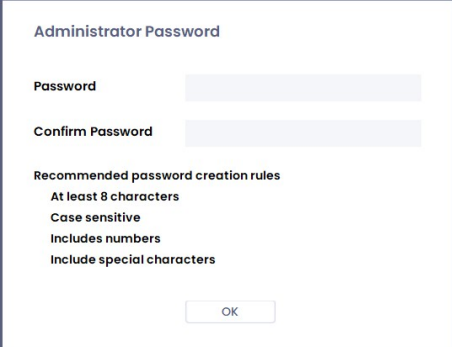
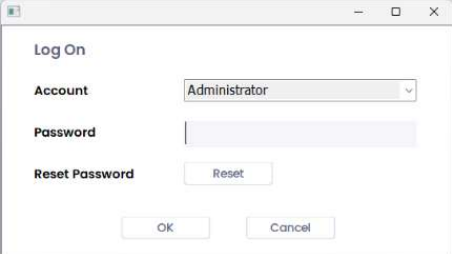
7.6. ADMINISTRATOR SETTING

7.6.1. ADMINISTRATOR PASSWORD SETTING

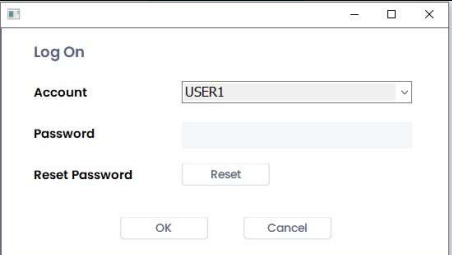
To prevent unauthorized access to CubeLite, you must register an administrator password when using the program for the first time.

For details on changing the password, adding user accounts, and other security-related settings, refer to [7.10.3 Security Settings](#).

(1) First-Time Login

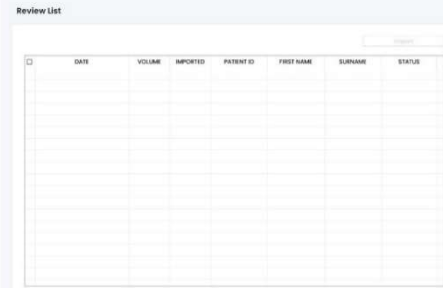
Procedure	Screen
(1) Run CubeLite Double-click the CubeLite icon on the PC desktop to launch the program.	
(2) Register Administrator Password When the password registration window appears, enter your desired password. Click [OK] after entering the password.	
(3) Setup Complete Once the password is registered, CubeLite will be available in Administrator Mode.	

(2) User Login

Procedure	Screen
(1) Run CubeLite Double-click the CubeLite icon on the PC desktop to launch the program.	
(2) Select Account In the login window, select USER.	
(3) Enter Password Enter your user password and click [OK].	

(4) Login Complete

After login, CubeLite will run in User Mode.



NOTE:

- For instructions on how to register a user account, refer to [7.10.3. SECURITY](#).
- In User Mode, the settings menu is disabled and cannot be accessed.

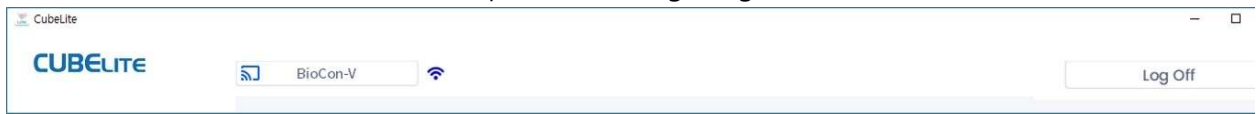
7.6.2. Administrator Password Reset

If the administrator or user password is lost, it can be reset by following the procedure below.

Procedure	Screen
(1) Click the Reset Button In the password input window, click the [Reset] button.	
(2) Generate a Lock Code Click the [Generate] button to create a new lock code. (3) Provide the Lock Code Send the generated lock code to the distributor or manufacturer. (4) Enter the Key Code Enter the key code issued by the distributor or manufacturer. (5) Password Reset Complete The password will be reset, and you can register a new password. The new password must meet at least three of the following requirements. ● At least 8 characters ● Includes both uppercase and lowercase letters ● Includes numbers ● Includes special characters	

7.6.3.LOG OFF

When you log off from CubeLite, the log-on window appears, allowing you to select an account (Administrator or User) and re-enter the password to log in again.



(1) How to Log Off

- Click the [Log Off] button at the top right of the screen.
- The system will log off, and the log-on window will automatically appear.

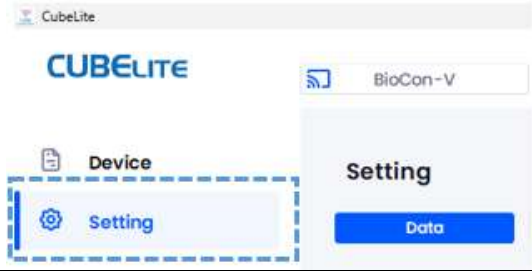
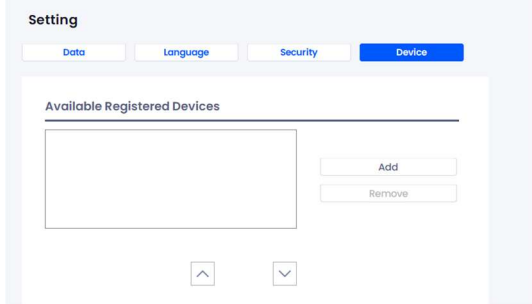
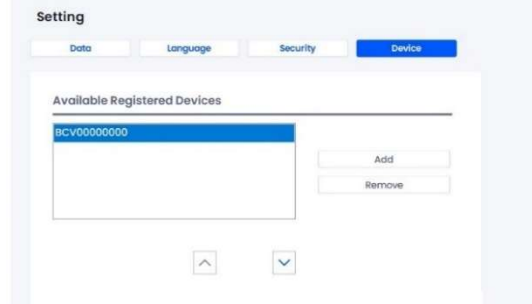
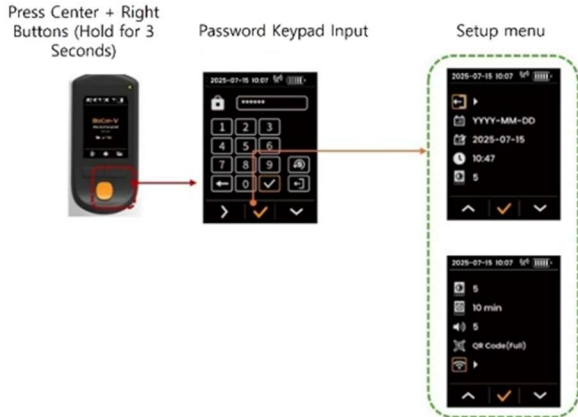
(2) Logging In Again

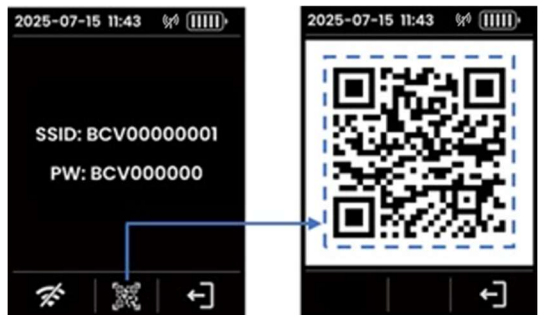
- In the log-on window, select an account (Administrator or User).
- Enter the password and click the [OK] button to access CubeLite.
- ③ If you click the [Cancel] button or enter an incorrect password, login will not be possible.

7.7. SELECTING A DEVICE

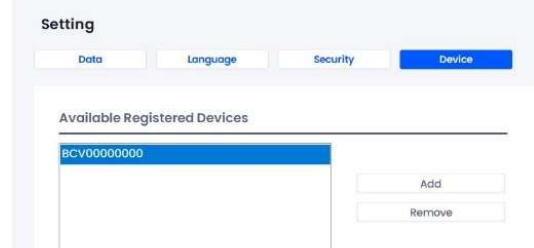
Selecting the Device	
(1) Click the Device Selection field.	
(2) When the message "Please select the device you want to use" appears, the device selection window will open.	
(3) Select BioCon-V, then click the [OK] button.	
Checking BioCon-V Status	
(1) Connecting Automatically A circular loading icon appears on the screen, indicating that the device is automatically connecting to Wi-Fi.	 [Connecting Status Screen]
(2) Wi-Fi Connection (Icon turns blue) When the Wi-Fi indicator turns blue, the connection has been successfully established. ● The same connection status is also shown on the BioCon-V LCD screen.	 [Connection Complete Screen]
 [Connection Screen on BioCon-V]	

7.8. REGISTERING THE DEVICE

Configuring the Device in CubeLite	
(1) Press the Settings button to open the Settings menu.	
(2) In the Settings menu, select the Device tab.	
(3) In the Available Registered Devices field, click the [Add] button.	
(4) The SSID and Password input window will appear.	
Checking Device Connection Information on BioCon-V	
(1) On the BioCon-V device, go to the Settings screen. - From the Home screen, press and hold the center and right buttons simultaneously for 3 seconds. (2) When the password entry window appears, enter your password. - Left button (➡): Move right - Right button (⬅): Move down - Center button (⏹): Select/Enter - The selected item is highlighted in orange	Press Center + Right Buttons (Hold for 3 Seconds) Password Keypad Input Setup menu 

(1). (3) The Enter icon() becomes active once six or more digits are entered. ● Select the icon and press the Center button () to confirm.	
(4) Entering SSID and Password Choose one of the following two methods. [Manual Input] Manually enter the SSID and PW displayed on the device screen into the tablet. [Using the Barcode Reader] ● On the SSID & PW screen, press the center button () to display a barcode containing the SSID and password. ● Scan the barcode with the barcode reader to automatically enter the SSID and password. NOTE: You can register multiple BioCon-V devices using the same method.	 [SSID & PW Barcode Screen]

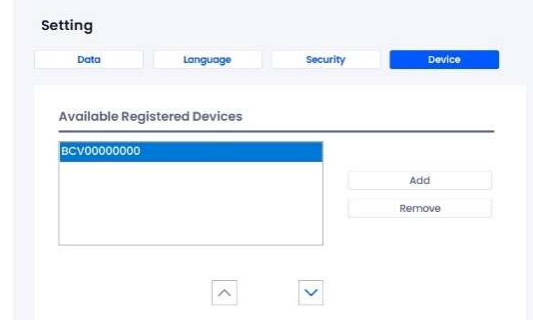
Completing Device Registration in CubeLite

(1) After entering the SSID and password, click the [OK] button.	
(2) Confirm that the device has been added to the Available Registered Devices list.	

Registering the Device for Automatic Connection

(1) In the Network Adapter field, select the network card currently in use.	
--	--

(2) Select the device name (e.g., BCV00000000), then click the down arrow button (▼).



(3) Once the automatic connection is complete, the device name will be automatically displayed in the Device field.



(4) Select the Device menu.



(4) Once BioCon-V and Cubelite are properly connected, the measured data automatically appears in the Review List.



NOTE: When you run Cubelite afterward, it will automatically connect to the BioCon-V device.

7.9. DATA MANAGEMENT

7.9.1.IMPORTING DATA

Imported data is saved to the designated folder.

- Saved contents: Scan date/time, aiming information, measured volume, and all captured cross-sectional images.
- Saved data can be printed as needed.

[Import Procedure]

(1) Connect BioCon-V to Cubelite

Once BioCon-V and Cubelite are properly connected, the measured data will automatically appear in the Review List.

(2) Select the data to import

- In the Review List, check the box (☒) next to the patient data you want to import.
- When selected, the progress status will display "0%".

Review List

Import

☐	DATE	VOLUME	GENDER	IMPORTED	PATIENT ID	FIRST NAME	SURNAME	STATUS
☒	2025-12-22, 04:41	88	Female	N	pid0016	bo ram	an	0%
☒	2025-12-19, 04:41	88	Female	N	pid0015	sang rang	kim	0%
☒	2025-12-19, 03:41	89	Male	N	pid0014	gang min	choi	0%
☒	2025-12-18, 05:41	88	Male	N	pid0013	jang hee	lee	0%
☒	2025-12-17, 04:41	88	Female	N	pid0012	sam sun	kim	0%

(3) Start Importing

Click the [Import] button.

(4) Check Progress

The progress window displays the import status for each data item.

Review List

Import

☐	DATE	VOLUME	GENDER	IMPORTED	PATIENT ID	FIRST NAME	SURNAME	STATUS
☒	2025-12-22, 04:41	88	Female	Y	pid0016	bo ram	an	100%
☒	2025-12-19, 04:41	88	Female	Y	pid0015	sang rang	kim	100%
☒	2025-12-19, 03:41	89	Male	N	pid0014	gang min	choi	100%
☒	2025-12-18, 05:41	88	Male	N	pid0013	jang hee	lee	0%
☒	2025-12-17, 04:41	88	Female	N	pid0012	sam sun	kim	0%

(5) Import Complete

When all data has been transferred, a message will appear stating "Import completed successfully".

(6) Close the Window

Click [OK] to close the window.

7.9.2.EXPORTING DATA

Saved data can be exported in either PDF or JPG format.

- To change the output format: go to CubeLite Settings → Data → Image Format.
- For detailed instructions on how to configure the format, refer to [7.9.1. IMPORTING DATA](#).

Data Included in Exported Files:

Patient ID, First Name, Sur Name, Gender, Date of birth, Age, Operator ID, Scan Aim

7.10. SETTINGS

The Settings menu of CubeLite is available only when logged in with an administrator account.

7.10.1.DATA SETTINGS

In the [Data] tab, you can configure the storage location of measurement data, image format, date format, and file-naming format.

Setting

Data | Language | Security | Device

Folder Setup

C:\Mcube Technology\CubeLite\Import\

Image Format

☒ PDF ☐ JPG

Date Format

☒ YYYY-MM-DD ☐ MM-DD-YYYY ☐ DD-MM-YYYY

Report File Name

File Name: S-Date_S-Time Name Rule

Item	Description
Folder Setup	Click the [Browse (...)] button to select the folder where data will be saved. Default path: C:\Mcube Technology\CubeLite\Import
Image Format	Select the file format for exported data: PDF or JPG.
Date Format	Select your preferred date display format. ● YYYY-MM-DD (Year-Month-Day) ● MM-DD-YYYY (Month-Day-Year) ● DD-MM-YYYY (Day-Month-Year)
Report Format Name	Click the Name Rule icon to configure the naming rule for report files.

[Name Rule Setting Screen]

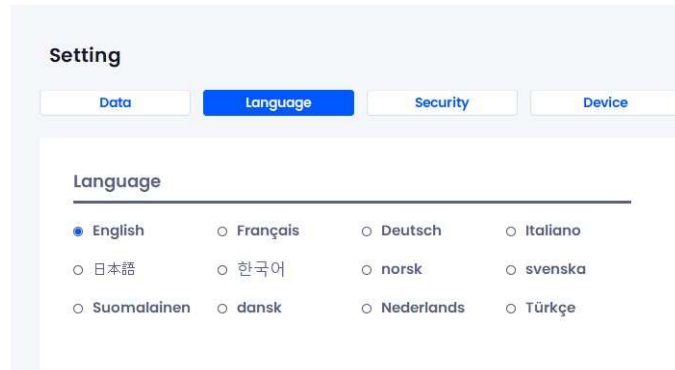
[Report File Name Configuration]

You can configure the report file name using combinations of the following items: Patient ID (PID), First Name, Surname, Gender, User Date, Scan Date (S-Date), Scan Time (S-Time), etc.

No. & Item	Description
①	Use the (➤) Add icon to move the selected format item to section ②.
②	Format Items Included in the Report File Name Use the (➤) Remove icon to remove items from the file name. Use the (⬅, ⬆, ⬇) arrow icons to change the order in which the items appear in the file name.
User Defined	You may define your own custom format. After entering the format, use the (➤) Add icon to add it to section ②.
Delimiter	You can select a delimiter to separate each format item. (None, /, comma (,), underscore (_), hyphen (-)).
Space Around Delimiter	You can choose whether to include spaces before or after the delimiter. (None, Before, After, Both)
File Name Preview	Displays a real-time preview of the file name according to the selected format. (e.g., S-Date-S-Time)

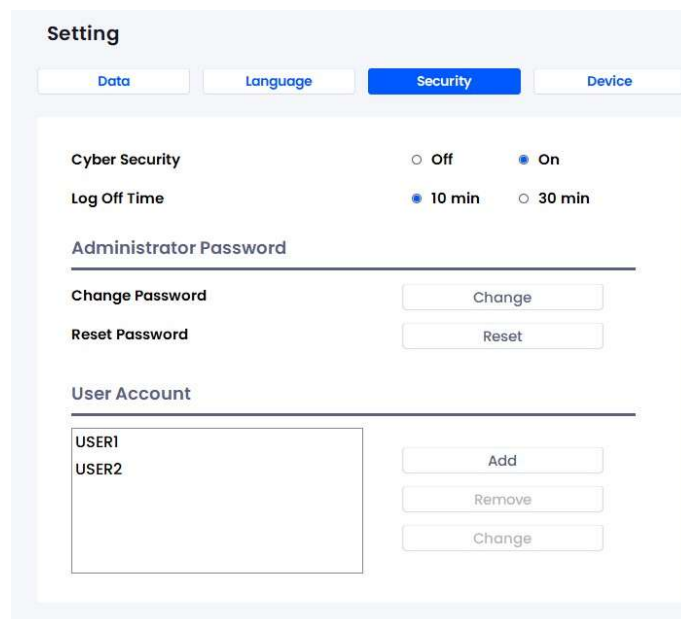
7.10.2. LANGUAGE SETTINGS

In the [Language] tab, you can select the display language for the program.
The program interface will switch to the selected language immediately.

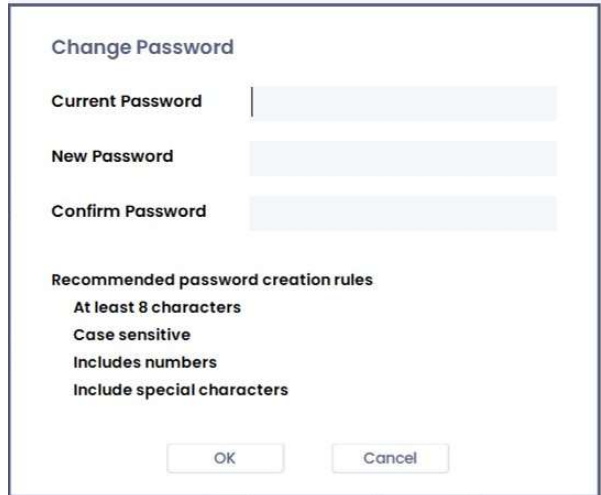


7.10.3. SECURITY

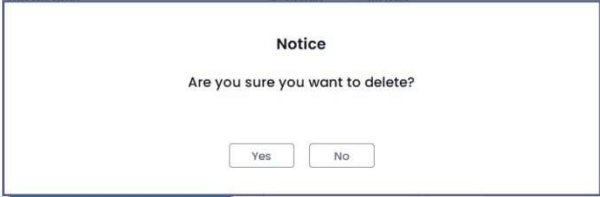
In the [Security] tab, you can configure security-related features such as passwords, automatic logoff, and user accounts.



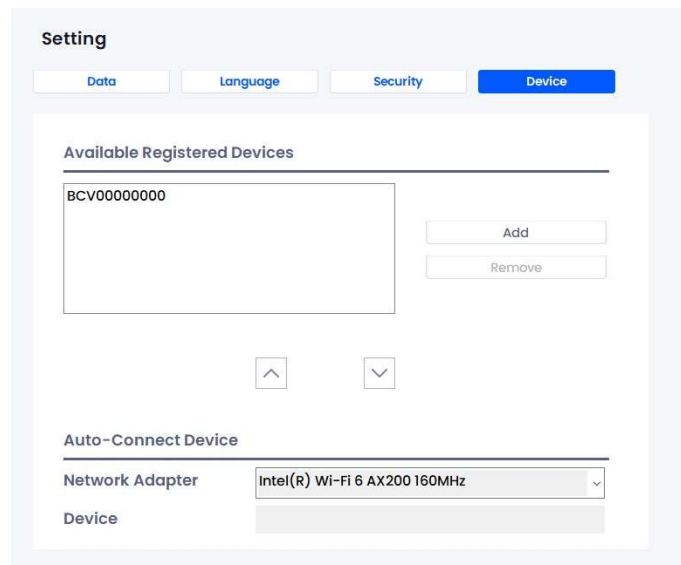
Item	Description
Cybersecurity	Enables or disables the program's security features.
Log Off Time	Automatically logs off the program after the specified period of inactivity. Re-entering the password is required when logging back in.
Change Administrator Password	The administrator password can be changed by following the steps below. ● Click the [Change] button. ● When the administrator password window appears, enter the current password.

	 Administrator Password OK Cancel ● The password change window will open.  Change Password Current Password New Password Confirm Password Recommended password creation rules - At least 8 characters - Case sensitive - Includes numbers - Include special characters OK Cancel ● In the Current Password field, enter the existing password. ● In the New Password field, enter the new password you want to set. ● In the Confirm Password field, re-enter the same password entered in Step 5. ● Click [OK] to complete the password change. NOTE: ● The new password must meet all of the following conditions. ● It must be at least 8 characters long. ● It must include a combination of uppercase letters, lowercase letters, numbers, and special characters. ● Passwords are case-sensitive.
Reset Password	If you forget the existing password, you can reset it as follows.  Administrator Password Lock Code Generate Key Code Reset Close ● Click the [Reset] button to open the administrator password window.

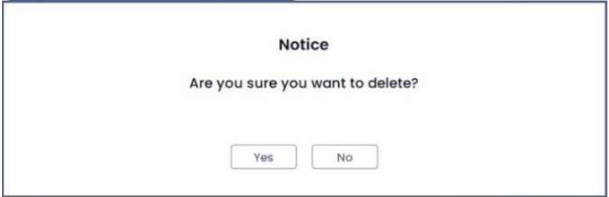
	● Click the [Generate] button to create a new lock code. ● Provide the generated lock code to the distributor or manufacturer. ● Enter the key code issued by the distributor or manufacturer. ● 5) Click [Reset] to complete the password reset.
User Account	You can add, remove, or modify user accounts. [Add User Account] ● Click the [Add] button. ● In the Add User window, enter the Name, Password, and Confirm Password fields. The password must satisfy at least three of the following conditions (8 characters or more, uppercase/lowercase rule, numbers, special characters). ● Click [OK] to create the new user account. [Remove User Account] ● Select the user account you want to delete from the list. ● Click [Remove]. ● When the message "Are you sure want to delete?" appears, click [Yes].

	
	● The selected user account will be removed from the list.

7.10.4.DEVICE



Item	Description
Available Registered Device	(1) Click [Add] In the Available Registered Devices field, click the [Add] button. (2) Device Add Window Appears The SSID and Password input fields will be displayed.  (3) Enter Information and Connect Enter the SSID and password, then click [OK].

	(4) Confirm Addition The newly added device will appear in the Available Registered Devices list. 
Remove Device	(1) Disable Auto-Connect (if enabled) ● If the device to be removed is set as "Auto Connect," click the [Disable] button () on the right side to turn off auto-connection. ● Once Auto-Connect is disabled, the [Remove] button becomes active in the Available Registered Devices list. (2) Execute Removal Select the device to remove and click the [Remove] button.  (3) Confirm Removal When the message "Are you sure you want to delete?" appears, click [Yes]. (4) Completion The selected device will be deleted from the list.
Auto Connect Device	CubeLite can automatically connect to the selected device when the program starts. (1) Select Device In the Available Registered Devices list, select the device you want to set for Auto Connect.

Available Registered Devices

BCV00000000	Add Remove
-------------	---

(2) Enable Auto-Connect

- Click the [Auto Connect] button (☐) next to the selected device.
- A status window will appear showing "Connecting to device..."

(3) Registration Complete

After setup, CubeLite will automatically connect to the device (e.g., BCV00000000) each time it is launched.

Auto-Connect Device

Network Adapter	Intel(R) Wi-Fi 6 AX200 160MHz
Device	

8. TABLET PC APPLICATION - BIOCON-V MANAGER

8.1. INFORMATION

8.1.1. GENERAL INFORMATION

This section explains how to use the BioCon-V Manager application.

Product specifications or the contents of this operator's manual are subject to change without prior notice for the purpose of product performance improvement.

Before using the application, please read and fully understand the contents of this manual.

Mcube Technology Co., Ltd. shall not be held responsible for any problems that occur under the following circumstances.

- When the software is installed and used on a smart device other than a tablet (only tablets are supported).
- When the software is not used in accordance with the instructions provided in this operator's manual.
- When the software is modified arbitrarily by non-professionals or users.
- When the tablet used does not meet the minimum supported specifications.
- When the tablet has been altered or modified in a way that voids the manufacturer's warranty.



CAUTION *MISE EN GARDE*

- It is recommended that all devices on which BioCon-V Manager is installed and operated have appropriate security software installed.

Il est recommandé d'installer un logiciel de sécurité sur tous les appareils où BioCon- V Manager est installé et utilisé.

- To protect personal information, avoid using weak passwords and change your password regularly.
Pour protéger les informations personnelles, évitez d'utiliser des mots de passe faibles et changez-les régulièrement.

- To prevent data loss, back up patient data periodically.

Pour éviter toute perte de données, sauvegardez régulièrement les données des patients.

8.1.2. Purpose of Software

BioCon-V Manager is a dedicated application designed for managing the configuration of the BioCon-V device and handling patient information.

8.1.3. Main Function

- Change and manage BioCon-V settings.
- Perform BioCon-V maintenance.
- Manage patient data such as transferring or deleting patient information.

8.2. INSTALLING ON A SMART DEVICE

This section explains how to install BioCon-V Manager on a supported smart device.

[Supported Device Specifications]

Only Android OS is supported.

Device	CPU	RAM	Operating System	Resolution
Tablet	Exynos 1280 or higher	4 GB or more	Android 11 or higher	2000x1200 px or higher

NOTE:

- Smart devices other than tablets are not supported.
- Only Android operating systems are supported.
- Before installing the app, make sure your tablet meets the minimum system requirements.
- Updating the tablet's OS after installation may cause the app to malfunction.
- Do not install the app on tablets that have been modified or tampered with (e.g., through hacking). The app may not operate properly.

8.2.1. INSTALLING ON AN ANDROID SMART DEVICE

(1) Open the Play Store

On your Android smart device, tap the Play Store icon ().

(2) Searching for the App

In the Play Store search bar, type "BioCon-V Manager" and tap the Search icon ().

(3) Selecting and Install the App

From the search results, select BioCon-V Manager and tap Install.

(4) Opening the App After Installation

Once the installation is complete, tap Open.

(5) Running the App

The BioCon-V Manager app will launch automatically.

8.2.2.FIRST-TIME LAUNCH

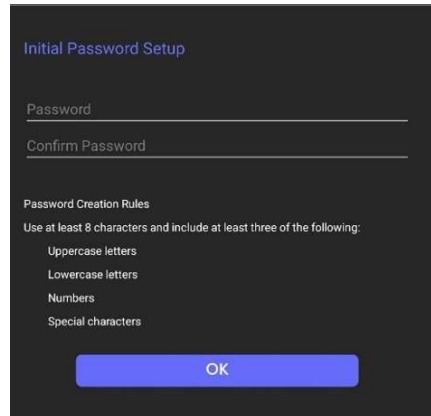
(1) Launching the App

On your tablet, open the BioCon-V Manager app.

(2) Password Setup Screen

When launching the app for the first time, the Password Setup screen appears.

This screen is displayed only once during initial setup.

The image shows a dark-themed screen titled "Initial Password Setup". It features two input fields: "Password" and "Confirm Password". Below these fields, the text "Password Creation Rules" is displayed, followed by the instruction "Use at least 8 characters and include at least three of the following:". A list of requirements follows: "Uppercase letters", "Lowercase letters", "Numbers", and "Special characters". At the bottom of the screen is a large blue button labeled "OK".

[First Login Screen]

NOTE: Required App Permissions

- Location Permission: Required for Wi-Fi scanning and connection functions. Location information is not stored.
- Camera Permission: Used for QR code scanning. Captured images are not saved.
- Network Permission: Required for communication with the device and connection to the server.
- Wi-Fi Permission: Required to connect to and disconnect from Wi-Fi networks.

(3) Creating a Password:

The password must be at least 8 characters long and include a combination of three of the following. uppercase letters, lowercase letters, numbers, and special characters.

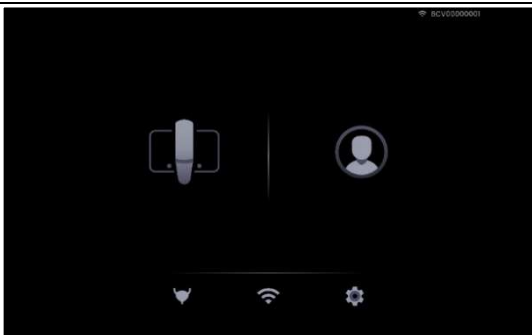
(4) Entering the Password

Enter the new password in the New Password field, then re-enter the same password in the Confirm Password field.

(5) Completing the Password Setup

- Tap the [OK] button to complete the password setup.
- After confirming the password on the Password Settings screen, the Login screen will appear.

8.3. LOG IN

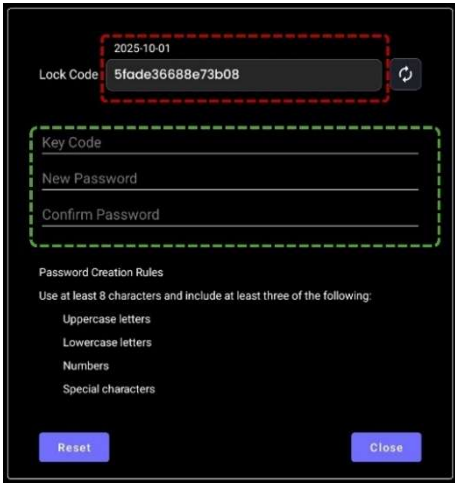
Procedure	Screen
(1) Launch the App When you open the BioCon-V Manager app on your tablet, the startup screen appears.	 The startup screen is black with the CUBEScan™ logo in the center.
(2) Login Screen and Password Entry - After about 2 seconds, the Login screen is displayed. - Enter your password and tap the [OK] button.	 The login screen is black with a central white box containing the CUBEScan™ logo, a dropdown menu set to 'Administrator', a 'Password' input field, an 'OK' button, and a 'Forgot' link.
(3) Home Screen If the password is entered correctly, the BioCon-V Home Screen appears.	 The home screen is black with a central white box containing a fingerprint icon and a user profile icon. At the bottom, there are icons for a downward arrow, Wi-Fi, and settings. The top right corner shows the ID 'BCV0000000'.

NOTE:

- You cannot proceed to the Home screen if the password is entered incorrectly.
- The password is case-sensitive, so be sure to enter it exactly as it was set.

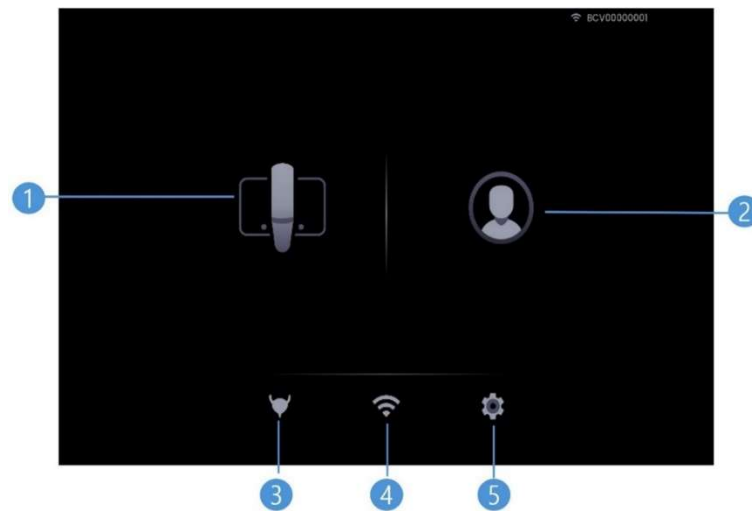
8.4. RESETTING THE PASSWORD

If you forget your password, follow the steps below to reset it.

Procedure	Screen
(1) Select the Reset Button ● Launch the BioCon-V Manager app. ● On the startup screen, tap the [Reset] button.	
(2) Check and Send the Lock Code ● A Lock Code is generated on the Password Reset screen. ● Send the generated lock code to the distributor or manufacturer. (3) Enter the Key Code Enter the key code issued by the distributor or manufacturer.	
(4) Set a New Password ● Enter the new password in the New Password field. ● Re-enter the same password in the Confirm Password field. ● Tap the [Reset] button to complete the password reset. NOTE: ● The password must contain at least 8 characters and include three or more of the following: uppercase letters, lowercase letters, numbers, and special characters. ● After resetting the password, the app will move to the Login screen, where you can log in using the new password.	

8.5. HOME SCREEN

On the Home screen, tap any icon to access its corresponding function.



No.	Item	Description
①	Device Settings	● Check the device status and change settings. ● If the auto-connect device is not registered, the message "No auto-connect device is registered. Please register an auto-connect device from the Wi-Fi screen first." appears. ● For details, refer to 8.6 Connecting the Device.
②	Patient DB Management	View and manage the list of patients registered on both the device and the tablet.
③	Scan	● Performs Pre-Scan and Normal Scan. ● If the auto-connect device is not registered, the message "No auto-connect device is registered. Please register an auto-connect device from the Wi-Fi screen first." appears. ● For details, refer to 8.10 Scan Mirroring.
④	Wi-Fi Settings	● Connect the tablet and the device via Wi-Fi. ● For details, refer to 8.11 Wi-Fi Settings.
⑤	Tablet Settings	You can configure the following features. ● Data Format ● Change Password ● Log-off Time ● Language ● Activity Log ● For details, refer to 8.12 Settings (Tablet Settings).

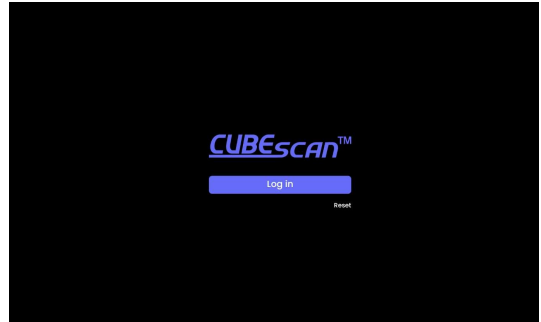
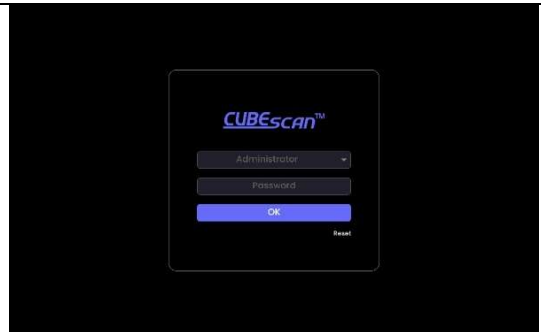
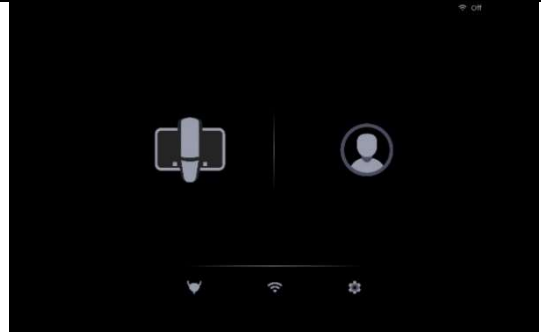
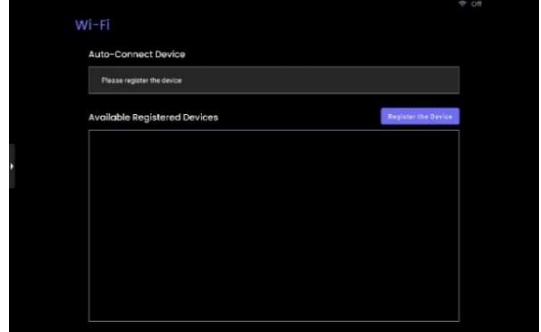
8.6. CONNECTING THE DEVICE

The BioCon-V Manager app connects to the BioCon-V device via Wi-Fi.

During use, the tablet and the device must remain connected to the same Wi-Fi network.

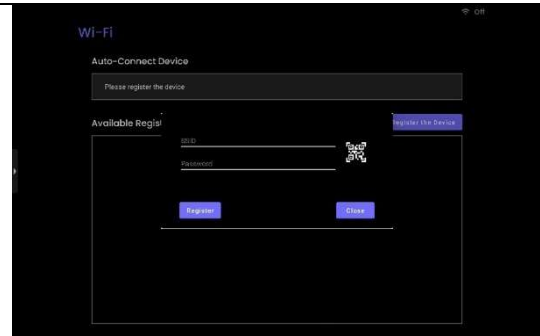
8.6.1. CONNECTING THE ANDROID APP TO THE DEVICE

To connect the BioCon-V Manager app to the device, follow the steps below.

Preparing the Tablet for Connection	
(1) Turn on Wi-Fi on the Tablet & Launch the App ● Turn on the tablet's Wi-Fi. ● Launch the BioCon-V Manager app. ● The startup screen appears. (2) Select the [Log in] Button On the startup screen, tap the [Log in] button.	
(3) Log In When the Login screen appears, enter the currently set password.	
(4) Go to the Wi-Fi Menu On the Home screen, tap the Wi-Fi icon (📶).	
(5) Open the Device Registration Menu When the Wi-Fi settings window appears, tap [Register the Device].	

(6) SSID and Password Input Fields

- The input fields for SSID and Password appear.
- To obtain this information, check the SSID/PW on the BioCon-V device



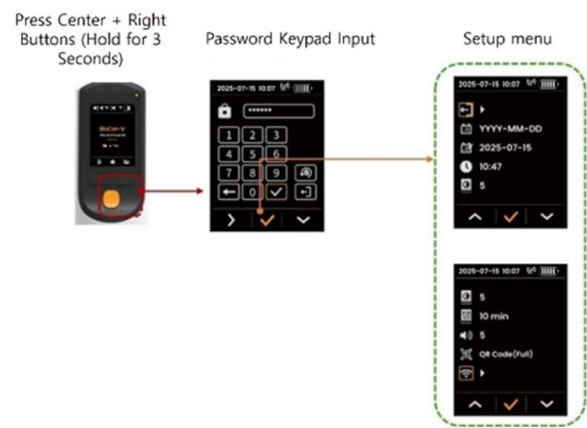
Checking Connection Information on the BioCon-V Device

(1) Enter the Setting Screen

On the BioCon-V device, press and hold the center button and right button for 3 seconds.

(2) Enter the Password

- When the password entry window appears, enter the password.
- Left button (➡): Move cursor to the right
- Right button (⬅): Move cursor downward
- Center button (⏎): Select/Confirm



(3) Open the Barcode Menu

In the Setting menu, use the left (⬅) and right (➡) buttons to select the Barcode icon (📶), then press the center button (⏎).

(4) Display the SSID and PW Information

The SSID & PW Information screen is displayed first (You can check the device-generated Wi-Fi name (SSID) and password (PW)).



[SSID & PW Screen]

Entering the SSID & PW to Connect the Device

Choose one of the following two methods.

(1) Manual Input

- Manually enter the SSID and PW displayed on the device screen into the tablet.
- After entering the information, tap the [Register (Register)] button on the tablet to



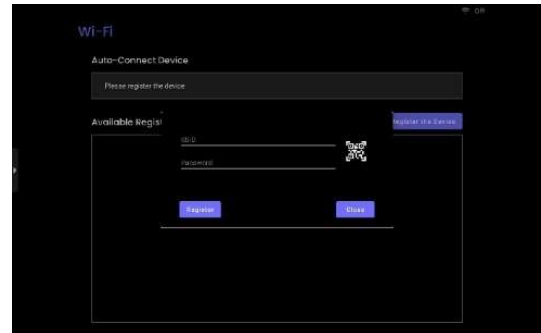
complete the registration.

(2) Automatic Input

- On the SSID & PW screen, press the center button () to display a barcode containing the SSID and password.
- Scan the barcode using the tablet's camera. The SSID and PW are entered automatically.
- After automatic input, tap the [Register ()] button to complete registration.

NOTE: You can register multiple BioCon-V devices consecutively using the same procedure

[SSID & PW Barcode Screen]



[Tablet SSID/PW Input Screen]

8.6.2.REGISTERING A DEVICE FOR AUTOMATIC CONNECTION

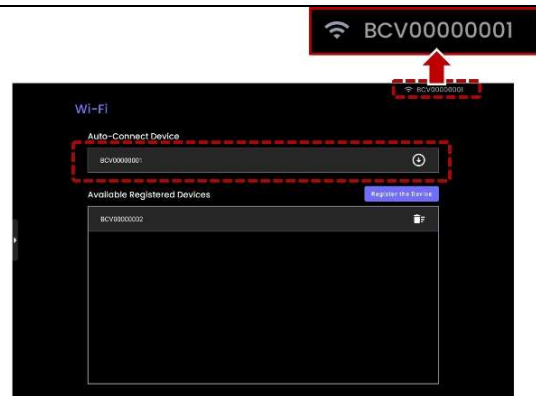
(1) First-Time Connection

To use the automatic connection feature, the device must first be registered on the tablet. Follow the steps below to complete the initial registration.

Procedure	Screen
(1) Select the Device In the [Available Registered Device] list, tap the BioCon-V device you want to register.	
(2) Confirm the Connection Approval Message ● An Android system popup appears displaying the message: "Do you want to connect to this device?" ● Tap [Connect] to approve the connection.	
(3) Automatic Registration Process The automatic registration progress screen appears, and the registration proceeds automatically.	

(4) Confirm Registration Completion

- When registration is complete, the device appears as an auto-connect target on the [Auto-Connect Device] screen.
- You can also check the connection status from the tablet's Status Bar.



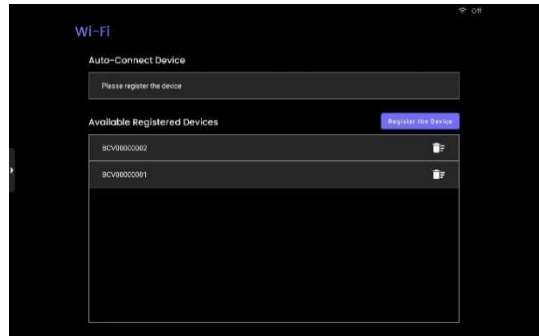
NOTE: If the tablet or the device enters Auto Sleep Mode, the following message may appear: "Unable to connect the device. Would you like to try connecting again?" Tap [Yes] to attempt reconnection.

(2) Setting Automatic Connection for an Already Registered Device

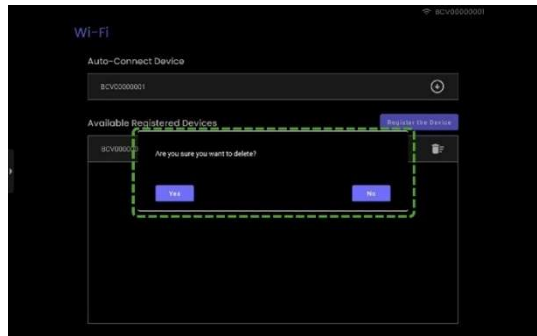
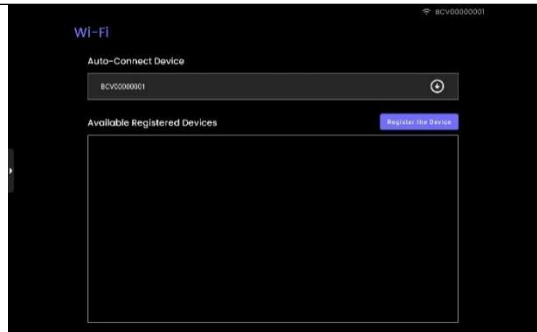
To set a previously registered BioCon-V device for automatic connection, follow the steps below.

Procedure	Screen
(1) Select the Device In the [Available Registered Device] list, tap the device you want to set for automatic connection	
(2) Registration in Progress A progress screen for automatic connection registration appears.	
(3) Confirm Completion ● On the [Auto-Connect Device] screen, confirm that the device has been successfully registered for automatic connection. ● You can also check the connection status from the tablet's Status Bar.	

(3) Cancel Auto-Connect Registration

Procedure	Screen
(1) Select the Delete Button - In the [Auto-Connect Device] list, tap the [Cancel (🗑️)] button. (2) Completion of Cancellation ● The selected device is removed from the Auto-Connect list. ● The removed device will no longer connect automatically, and it can be re-registered again if needed.	

(4) Deleting a Registered Device from the List

Procedure	Screen
(1) Select the Delete Icon In the [Available Registered Devices] list, tap the Delete icon (🗑️) next to the device you want to remove. (2) Confirm Deletion When the message "Are you sure you want to delete?" appears, tap [Yes] to proceed with deletion.	
(3) Confirm Removal from the List Once deletion is complete, the device will be removed from the [Available Registered Devices] list.	

8.7. QUICK TAB

The Quick Tab is a fast-access menu displayed when you tap the Tablet Settings icon on the tablet screen. It allows you to immediately launch key functions.

The functions of each icon are as follows.



No.	Item	Description
①	Device Settings	● Check the device status and change settings. ● If the auto-connect device is not registered, the message "No auto-connect device is registered. Please register an auto-connect device from the Wi-Fi screen first." appears. ● For details, refer to 8.6 Connecting the Device.
②	Patient List	View the list of registered patients, register new patients, and modify existing patient information.
③	Scan	● Performs Pre-Scan and Normal Scan. ● If the auto-connect device is not registered, the message "No auto-connect device is registered. Please register an auto-connect device from the Wi-Fi screen first." appears. ● For details, refer to 8.10 Scan Mirroring.
④	Wi-Fi Settings	● Menu for connecting the tablet to the BioCon-V device via Wi-Fi. ● For details, refer to 8.12 Wi-Fi Settings.
⑤	Settings	Configure the following features. ● Data Format ● Change Password ● Log-off Time ● Language ● Activity Log ● For details, refer to 8.12 Settings (Tablet Settings).
⑥	Log out	● Performs logout. ● A confirmation message appears; selecting [Yes] completes the logout and returns to the Login screen.

8.8. DEVICE SCREEN

[Function Overview]

The Device screen provides an integrated view of the key functions linked to the BioCon-V device.

These functions are available only when the BioCon-V device and the tablet are properly connected.

The Device screen consists of the following five main functions.

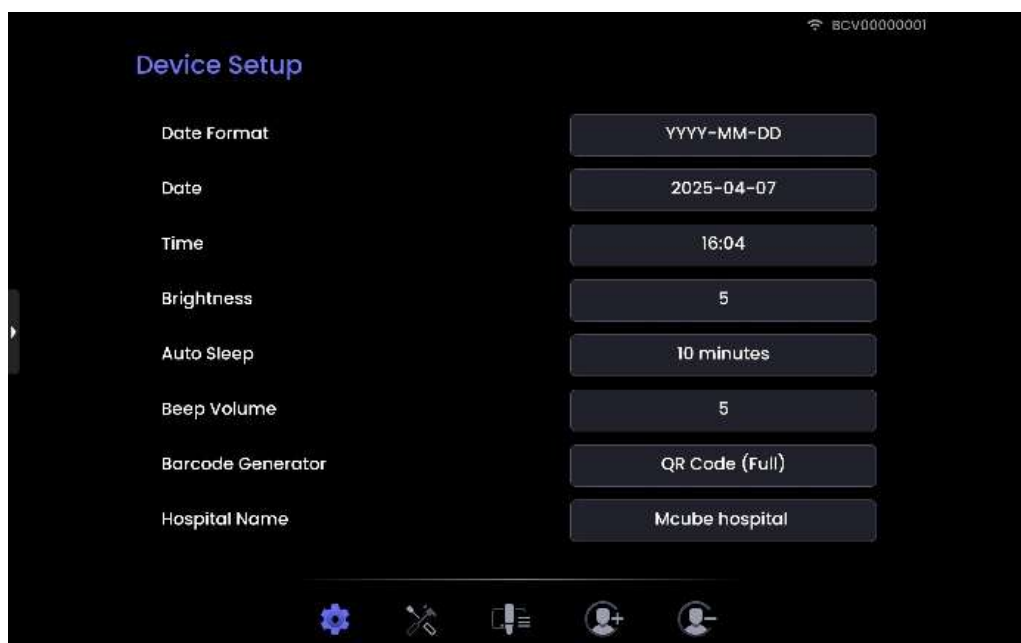
Function	Description
Device Setup	Changes the device's date format/time, screen brightness, auto sleep, volume, and other settings.
Device Maintenance	Executes device inspection and maintenance functions.
Device Data List	Displays the measurement data stored in the device.
Device Patient Add	Registers a new patient directly on the device.
Device Patient Delete	Deletes stored patient information from the device.

[How to Access the Device Screen]

- Launch the BioCon-V Manager app and log in.
- On the Home screen or at the bottom of the Quick Tab menu, locate and tap the Device icon (🔧).
- The Device Setup screen appears first. You can navigate to Device Setup / Device Maintenance / Device Data List / Device Patient Add / Device Patient Delete using the top tabs or the screen switching menu.

8.8.1.DEVICE SETUP SCREEN

The Device Setup screen allows you to change the primary BioCon-V settings directly from the tablet.



Item	Description																																									
Data Format	● Sets the date format. (e.g., DD-MM-YYYY, YYYY-MM-DD, MM-DD-YYYY) ● The selected format is applied immediately across both the device and the app.																																									
Date	In the pop-up window, select Year → Month → Day, then tap [OK].																																									
Time	● In the pop-up window, select the hour and minute and tap [OK], or tap the ● keyboard input field to enter the time directly.																																									
Brightness	● Adjusts the screen brightness from Level 1 to Level 5. ● Higher numbers indicate a brighter screen.																																									
Auto Sleep	● Selects the automatic sleep (auto screen-off) time. (Options: 2 minutes / 5 minutes / 10 minutes)																																									
Beep Volume	● Sets the beep volume (heard when a scan is completed) from Level 1 to Level 5. ● Higher numbers indicate a louder beep.																																									
Barcode Generator	Select the barcode format to be used when generating barcodes for measurement data.																																									
	<table><tr><th>Option</th><th>Description</th><th>Output Data</th><th>Barcode</th></tr><tr><td>Code-128 (Number)</td><td>Measures numeric amount only</td><td>80</td><td rowspan="2"></td></tr><tr><td>Code-128 (Volume)</td><td>Measures numeric amount + unit</td><td>80 ml</td></tr><tr><td>Aztec Code (Number)</td><td>Measures numeric amount only</td><td>80</td><td rowspan="3"></td></tr><tr><td>Aztec Code (Volume)</td><td>Measures numeric amount + unit</td><td>80 ml</td></tr><tr><td>Aztec Code (Full)</td><td>Measures date-time + amount</td><td>20250715-095703 80 ml</td></tr><tr><td>QR Code (Number)</td><td>Measures numeric amount only</td><td>80</td><td rowspan="3"></td></tr><tr><td>QR Code (Volume)</td><td>Measures numeric amount + unit</td><td>80 ml</td></tr><tr><td>QR Code (Full)</td><td>Measures date-time + amount</td><td>20250715-095703 80 ml</td></tr><tr><td>Data Matrix (Number)</td><td>Measures numeric amount only</td><td>80</td><td rowspan="3"></td></tr><tr><td>Data Matrix (Volume)</td><td>Measures numeric amount + unit</td><td>80 ml</td></tr><tr><td>Data Matrix (Full)</td><td>Measures date-time + amount</td><td>20250715-095703 80 ml</td></tr></table>	Option	Description	Output Data	Barcode	Code-128 (Number)	Measures numeric amount only	80		Code-128 (Volume)	Measures numeric amount + unit	80 ml	Aztec Code (Number)	Measures numeric amount only	80		Aztec Code (Volume)	Measures numeric amount + unit	80 ml	Aztec Code (Full)	Measures date-time + amount	20250715-095703 80 ml	QR Code (Number)	Measures numeric amount only	80		QR Code (Volume)	Measures numeric amount + unit	80 ml	QR Code (Full)	Measures date-time + amount	20250715-095703 80 ml	Data Matrix (Number)	Measures numeric amount only	80		Data Matrix (Volume)	Measures numeric amount + unit	80 ml	Data Matrix (Full)	Measures date-time + amount	20250715-095703 80 ml
	Option	Description	Output Data	Barcode																																						
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	QR Code (Number)	Measures numeric amount only	80																																							
	QR Code (Volume)	Measures numeric amount + unit	80 ml																																							
	QR Code (Full)	Measures date-time + amount	20250715-095703 80 ml																																							
	Data Matrix (Number)	Measures numeric amount only	80																																							
Data Matrix (Volume)	Measures numeric amount + unit	80 ml																																								
Data Matrix (Full)	Measures date-time + amount	20250715-095703 80 ml																																								
Hospital Name	Enter the name of the hospital or clinic.																																									

Item	Description								
Depart Name	Enter the name of the department.								
Patient List Format	Select how patient information is displayed in the patient list (up to 3 items). The selected format is applied immediately. <table> <tr> <th>Option</th><th>Display Format</th></tr> <tr> <td>Date of Birth + First Name</td><td>Displays Date of Birth + First Name</td></tr> <tr> <td>Date of Birth + Surname</td><td>Displays Date of Birth + Surname</td></tr> <tr> <td>Date of Birth + Patient ID</td><td>Displays Date of Birth + Patient ID</td></tr> </table>	Option	Display Format	Date of Birth + First Name	Displays Date of Birth + First Name	Date of Birth + Surname	Displays Date of Birth + Surname	Date of Birth + Patient ID	Displays Date of Birth + Patient ID
Option	Display Format								
Date of Birth + First Name	Displays Date of Birth + First Name								
Date of Birth + Surname	Displays Date of Birth + Surname								
Date of Birth + Patient ID	Displays Date of Birth + Patient ID								
Change Password	[Procedure] Changes the Wi-Fi password of the device. (1) Tap the button next to Change Password. (2) Review the confirmation message and tap [Yes]. ● Message: Changing the password will also change the device's Wi-Fi password. After the password is changed, you must reconnect to the device using the new password. Changing the password will also change the device's Wi-Fi password. Once the password change is complete, you will need to reconnect to the device using the new password. Do you still wish to proceed? Yes No (3) The password input window appears: ● Current Password: Enter the current password. ● New Password: Enter a new password.								

- Confirm Password: Re-enter the new password.

(4) Tap [Change] to complete the password change.

※ After the password is changed, the updated change date is displayed in the tab.

Resets the device's Wi-Fi password to the default value.

(1) Tap Reset Password.

(2) When the confirmation message appears, tap [Yes].

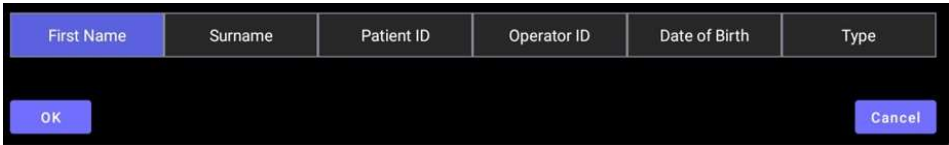
- Message: Resetting the password will also change the device's Wi-Fi password. After the reset, you must reconnect using the new password. Do you want to continue?

(3) A Lock Code will be generated. Provide this code to the manufacturer.

Reset Password

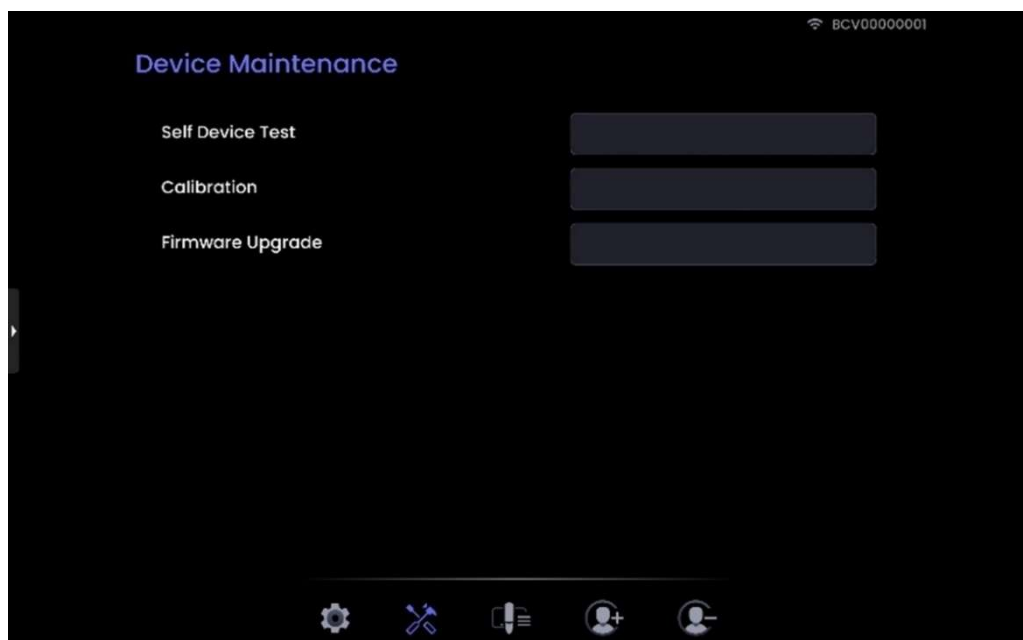
(4) After receiving a Key Code from the manufacturer, enter:

- Key code:
- New Password
- Confirm Password

	(5) Tap [Reset] to complete the password reset. ※ After the reset is complete, the updated change date is displayed on the screen.
Serial Number	Displays the serial number of the BioCon-V device.
Information to Display In Patient List	Select up to 3 types of information to display in the patient list. Options: First Name, Surname, Patient ID, Operator ID, Date of Birth, Type [Setting Method] (1) Tap the item you want to modify (e.g., First Name). (2) In the selection window, choose the desired information type and tap [OK]. 
Audit Log	Press the Export button to export the audit log.

8.8.2.DEVICE MAINTENANCE SCREEN

The Device Maintenance screen allows you to perform inspection and maintenance functions for the BioCon-V device. Each function is used to check device status, detect errors, and maintain performance.



Item	Description
Self-Device Test	Performs a self-diagnostic test on the device. ※ For details, refer to 16.2 Self-Device Test.
Calibration	Performs device calibration.

	※ For details, refer to 16.3 Calibration.
Firmware Upgrade	Updates the device firmware to the latest version. ※ For details, refer to 16.4 Firmware Upgrade.

8.8.3.DEVICE DATA LIST SCREEN



- Displays the name of the registered BioCon-V device.
- Select the data you want to delete, then tap the [Delete] button to remove it.
- Displays the list of measurement data stored on the BioCon-V device.

8.8.4.DEVICE PATIENT ADD SCREEN

On the Device Patient Add screen, you can transfer patient information stored on the tablet to the BioCon-V device.



No.	Description
①	Displays the list of patient information stored on the tablet. ※ For details on how to enter patient information, refer to 8.9.1 Patient Edit.
②	Select the patient information you want to transfer to the BioCon-V.
③	Displays the list of patient information currently stored on the BioCon-V device.
④	Transfers the selected patient information to the BioCon-V device. - When you tap the [Transfer (➤)] button, a confirmation message appears. - Tap [Yes (Yes)] to complete the transfer to the BioCon-V.

※ For instructions on how to perform a measurement using transferred patient information, refer to 5.8.2 Measuring Using Registered Patient Information.

8.8.5.DEVICE PATIENT DELETE SCREEN

On the Device Patient Delete screen, you can delete patient information stored on the BioCon-V device.



No.	Description
①	Select the checkbox for the patient information you want to delete.
②	The Data List view displays the measurement data stored for the selected patient.
③	After selecting the data to delete, tap the [Delete] button. When the message 'Are you sure you want to delete?' appears, tap [Yes] to delete the selected data.

8.9. PATIENT LIST SCREEN

On the Patient List screen, you can view, register, edit, and delete patient information.

(1) Launch the BioCon-V Manager app and log in.

(2) Select the Patient DB Management tab from the Home screen, or tap the Patient icon (👤) in the Quick Tab.

(3) To register a new patient, tap the Add button (👤). For details, refer to 8.9.1 Patient Edit.



8.9.1. PATIENT REGISTRATION

On the Patient List screen, you can view, register, and delete patient information.

New Patient Registration

First Name

Surname

Patient ID

Operator ID

Date of Birth

Type

Male

Add

Close

Item	Description
First Name	Tap the input field and enter the information using the on-screen keyboard.
Surname	Tap the surname field and enter the information using the on-screen keyboard.
Patient ID	Tap the Patient ID field and enter the ID using the on-screen keyboard.
Operator ID	Tap the Operator ID field and enter the information using the on-screen keyboard.
Patient ID	Tap the Patient ID field and enter the ID using the on-screen keyboard.
Date of Birth	Use the '<' and '>' buttons to navigate through the year and month, then select the date. Tap [OK] to confirm.

Type	Select one of the following options: Male, Female, Child.
------	---

Registration Completion Notice:

Tap the [Add] button to finalize the registration. When the registration is successfully completed, the message "Patient information has been saved successfully" appears and disappears after 2 seconds.

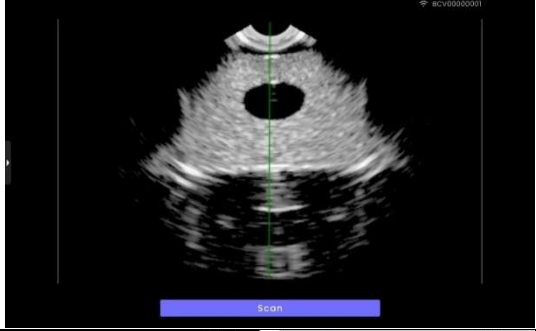
8.9.2. Patient Delete

Procedure	Screen																																																																																											
(1) Select the patient you want to delete by checking the box next to the patient's name. (2) Tap the [Delete] button.	Patient List ADD DELETE <table><tr><th>☐</th><th>First Name</th><th>Surname</th><th>Patient ID</th><th>Operator ID</th><th>Date of Birth</th><th>Type</th></tr><tr><td>☒</td><td>gi lee</td><td>choi</td><td>pid0017</td><td>lee</td><td>2000-08-19</td><td>Male</td></tr><tr><td>☐</td><td>lee nam</td><td>an</td><td>pid0016</td><td>lee</td><td>2000-04-25</td><td>Female</td></tr><tr><td>☐</td><td>namg nam</td><td>kim</td><td>pid0015</td><td>lee</td><td>2000-04-13</td><td>Female</td></tr><tr><td>☐</td><td>gang min</td><td>choi</td><td>pid0014</td><td>lee</td><td>1999-10-17</td><td>Male</td></tr><tr><td>☐</td><td>jang hee</td><td>lee</td><td>pid0013</td><td>kim</td><td>1986-05-22</td><td>Male</td></tr><tr><td>☐</td><td>nam nam</td><td>kim</td><td>pid0012</td><td>lee</td><td>1999-06-14</td><td>Female</td></tr><tr><td>☐</td><td>jin sung</td><td>park</td><td>pid0010</td><td>kim</td><td>2001-01-18</td><td>Female</td></tr><tr><td>☐</td><td>sung ha</td><td>yeo</td><td>pid0009</td><td>kim</td><td>2000-06-22</td><td>Female</td></tr><tr><td>☐</td><td>gi na</td><td>yeo</td><td>pid0007</td><td>lee</td><td>1981-05-25</td><td>Female</td></tr><tr><td>☐</td><td>ku jin</td><td>choi</td><td>pid0008</td><td>lee</td><td>2000-03-24</td><td>Female</td></tr><tr><td>☐</td><td>min young</td><td>kim</td><td>pid0005</td><td>kim</td><td>1990-04-14</td><td>Female</td></tr><tr><td>☐</td><td>hang jin</td><td>nam</td><td>pid0005</td><td>kim</td><td>1990-03-09</td><td>Female</td></tr></table>	☐	First Name	Surname	Patient ID	Operator ID	Date of Birth	Type	☒	gi lee	choi	pid0017	lee	2000-08-19	Male	☐	lee nam	an	pid0016	lee	2000-04-25	Female	☐	namg nam	kim	pid0015	lee	2000-04-13	Female	☐	gang min	choi	pid0014	lee	1999-10-17	Male	☐	jang hee	lee	pid0013	kim	1986-05-22	Male	☐	nam nam	kim	pid0012	lee	1999-06-14	Female	☐	jin sung	park	pid0010	kim	2001-01-18	Female	☐	sung ha	yeo	pid0009	kim	2000-06-22	Female	☐	gi na	yeo	pid0007	lee	1981-05-25	Female	☐	ku jin	choi	pid0008	lee	2000-03-24	Female	☐	min young	kim	pid0005	kim	1990-04-14	Female	☐	hang jin	nam	pid0005	kim	1990-03-09	Female
☐	First Name	Surname	Patient ID	Operator ID	Date of Birth	Type																																																																																						
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☐	gi na	yeo	pid0007	lee	1981-05-25	Female																																																																																						
☐	ku jin	choi	pid0008	lee	2000-03-24	Female																																																																																						
☐	min young	kim	pid0005	kim	1990-04-14	Female																																																																																						
☐	hang jin	nam	pid0005	kim	1990-03-09	Female																																																																																						
(3) When the confirmation message “Are you sure you want to delete?” appears, tap [Yes]. (4) The selected patient information will be deleted.	Are you sure you want to delete? Yes No																																																																																											

8.10. SCAN MIRRORING

When BioCon-V and the tablet are properly connected via Wi-Fi, you can monitor and perform scan measurements in real time through the tablet screen.

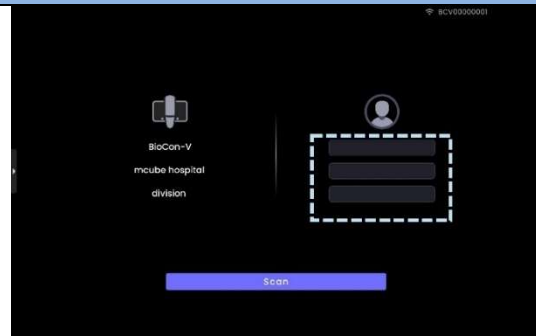
8.10.1. SCAN MEASUREMENT

Unregistered Patient Measurement (Anonymous Measurement)	
(1) Start Scan While Connected to the Device When the tablet is connected to the device, tap the Scan icon (📶) in the Quick Tab.	
(2) Scan Preparation Screen • The scan preparation screen appears on the tablet. • If no patient information is entered, tap the [Scan] button immediately. • Alternatively, press the center button on the BioCon-V device to start.	
(3) Perform Pre-Scan • The Pre-Scan screen appears. • For proper Pre-Scan instructions, refer to 5.8. LOCATING THE BLADDER (PRE-SCAN).	
(4) Perform Normal Scan Tap the [Scan] button on the tablet or press the device's center button to start the Normal Scan.	
(5) Scan Result Screen The scan result screen appears. • To re-scan the same patient: tap [Scan]. • To scan a new patient: tap [New Patient].	

Registered Patient Measurement

(1) Select Patient

Tap the list area on the right side of the screen and select the patient to be measured.



(2) Confirm Patient Selection

After selecting the patient from the list, tap [OK].

NOTE: The displayed patient list is from the BioCon-V device database, *not* the tablet database.



(3) Start Pre-Scan

- Tap the [Scan] button on the tablet, or press the center button (Scan) on the device to begin Pre-Scan.
- For proper Pre-Scan instructions, refer to [5.8. LOCATING THE BLADDER \(PRE-SCAN\)](#).



(4) Start Normal Scan

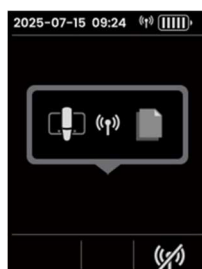
Tap the [Scan] button on the tablet, or press the device's center button to start the Normal Scan.



(5) Check Scan Results

The scan result screen appears.

- Re-scan the same patient: tap [Scan]
- Scan a new patient: tap [New Patient]
- How to disconnect from the BioCon-V: Press the right button (📶) on BioCon-V to disconnect from the tablet.



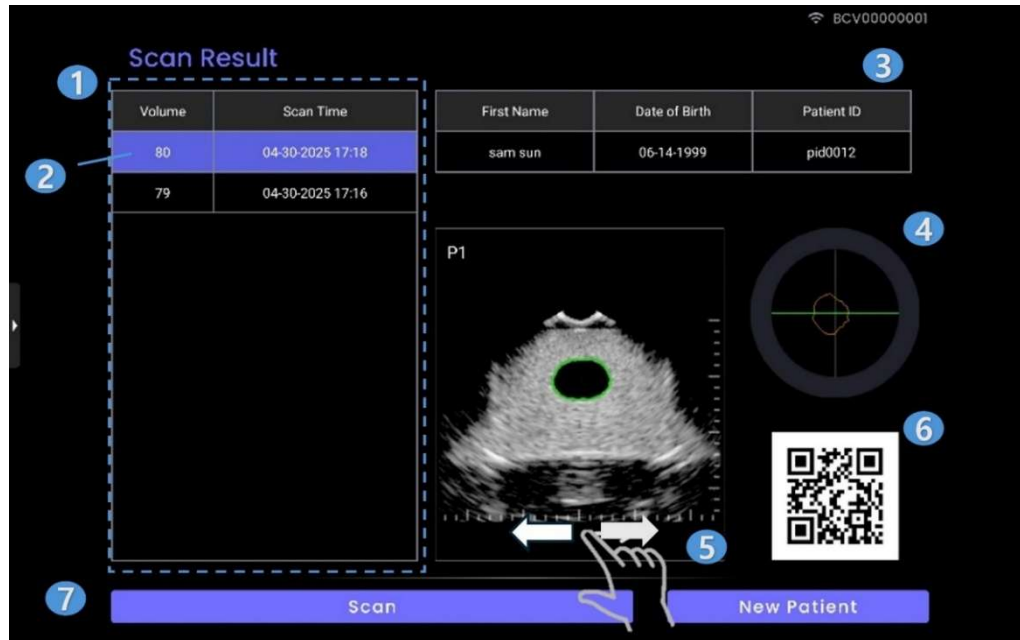
[BioCon-V Device Screen]



8.10.2. SCAN RESULT SCREEN

When the scan is completed, the Scan Result screen appears on the tablet.

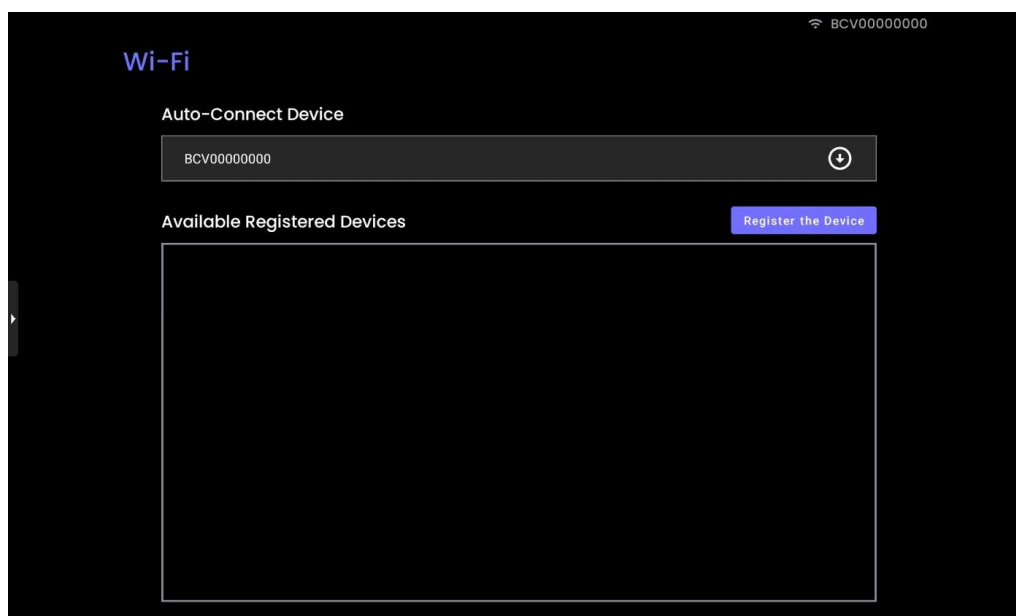
Each item on the screen functions as follows.



No.	Description
①	A new scan result is added to the list. Up to 10 results can be stored; when the limit is exceeded, the oldest data is automatically deleted.
②	Tap any item on the left-side list to view the previous scan result for that selection.
③	Displays the registered patient information (First Name, Date of Birth, Patient ID). For changing displayed patient information, refer to 8.8. DEVICE SCREEN .
④	Shows the bladder scan position and orientation. Each swipe of the cross-section image rotates the plane by 15°.
⑤	Swipe left or right on the plane-image area to browse through other plan images (P1–P12).
⑥	Outputs the current scan result as a barcode. The barcode can be scanned using a barcode reader or mobile device camera to retrieve the measurement value. For barcode format settings, refer to 8.8. DEVICE SCREEN .
⑦	Repeat Measurement and New Measurement Options ● Re-scan the same patient: Tap [Scan] to perform another measurement on the same patient. ● Measure a new patient: Tap [New Patient] to return to the home screen and begin a new measurement.

8.11. WI-FI SETTING

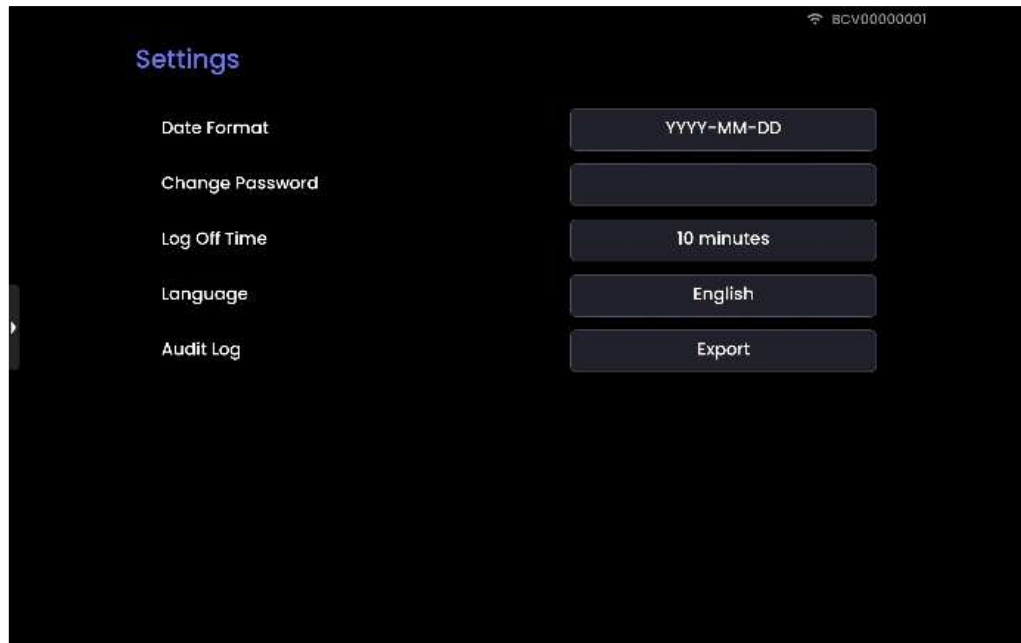
In the Wi-Fi Settings menu of the BioCon-V Manager app, you can manage functions such as automatic connection setup, device registration, viewing the list of registered devices, and deleting or re-registering devices.



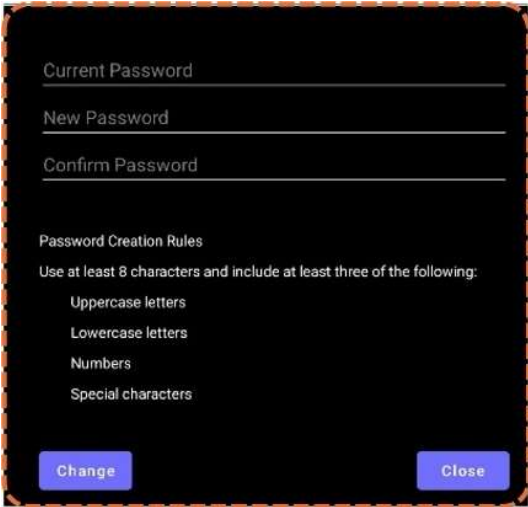
Item	Description
Auto-Connect Device	Displays a list of BioCon-V devices that are set to automatically connect to the tablet. Automatic connection can also be disabled from this menu.
Available Registered Device	Displays the list of BioCon-V devices registered on the tablet. ※ To register a new device, tap the [Register the Device] button. → For detailed registration steps, refer to 8.6.2. REGISTERING A DEVICE FOR AUTOMATIC CONNECTION.

8.12. SETTINGS (TABLET SETTING)

The Settings screen allows you to change key tablet environment settings such as date format, password, auto log-off time, and language.



Item	Description
Date Format	● Tap the format displayed on the right side of Date Format (e.g., YYYY-MM-DD). ● In the pop-up window, select one of the date formats (YYYY-MM-DD, MM-DD-YYYY, DD-MM-YYYY). ● After selecting the format, tap [Close] to apply the setting.

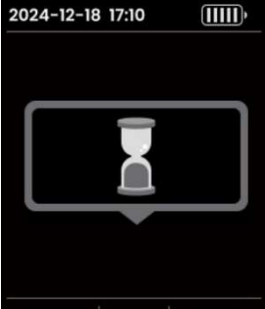
Change Password	Follow the steps below to change the password. (1) Tap the Change Password field. A password input pop-up window appears.  (2) Current Password: Enter the current password. (3) New Password: Enter the new password. (4) Confirm Password: Re-enter the same new password. (5) Tap [Change]: Once completed, the password change date is updated and displayed in the Settings screen.  NOTE: ● The password must contain at least 8 characters and include a combination of three or more of the following - Uppercase letters, lowercase letters, numbers, or special characters ● The new password must be different from the current password.
Log Off Time	Sets the automatic log-off time. (1) Select the desired time option (10 minutes or 30 minutes). (2) Tap [Close] to save the setting.

		 The screenshot shows a 'Log Off Time' dialog box. It has a title bar 'Log Off Time'. Below it, there are two radio button options: '10 minutes' (which is selected with a checkmark) and '30 minutes'. At the bottom right, there is a 'Close' button.
Language	(1) Tap the currently selected language (e.g., English) to open the language selection window. (2) When the list of supported languages appears, select the desired language. (3) Tap [Close] to apply the setting. *The selected language is applied immediately after tapping [Close].	 The screenshot shows a 'Language' selection screen. It has a title bar 'Language'. Below it, there is a list of languages: English, 한국어 (Korean), 日本語 (Japanese), Deutsch (German), Français (French), Italiano (Italian), Nederlands (Dutch), Svenska (Swedish), Türkçe (Turkish), Norsk (Norwegian), Suomi (Finnish), and Dansk (Danish). The '한국어' option is selected and highlighted with a blue bar. At the bottom right, there is a 'Close' button.
Audit Log	The Audit Log records the following information. ● User activity history ● Timestamp of performed actions ● System responses and event logs Only anonymized information unrelated to personal patient data is stored. [How to Export Logs] ● Tap [Export]. ● Select the desired file save location. ● The audit log file will be saved to the designated location.	

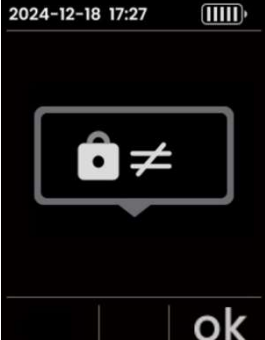
9. NOTIFICATION MESSAGES

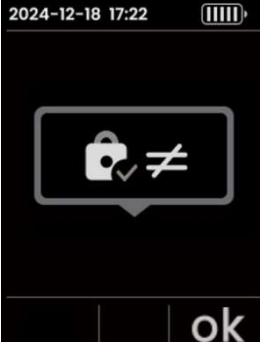
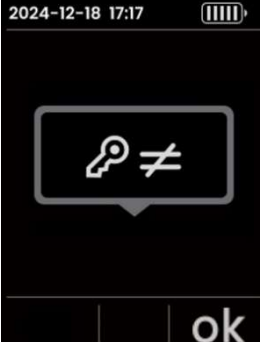
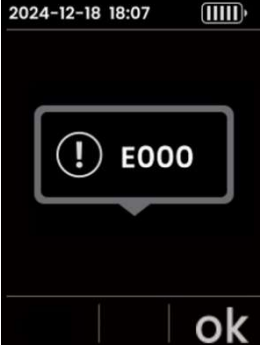
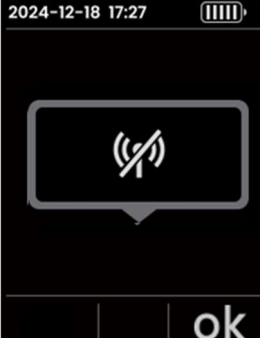
9.1. PROBE POP-UP MESSAGES

Popup Message	Description	Condition
	Power Sleep	● When there is no measurement, data transmission, or user input during the Auto Sleep time set in the probe settings. ● When there is no user input for approximately 10 seconds while wireless charging. ● When the sleep command is triggered by pressing the left button for more than 3 seconds.
	Low Battery	● Displayed when the battery level is below 5%. ● Displayed when essential functions are restricted due to low battery.
	Password Change Complete	Displayed when the changed password has been set and saved.
	Power Off Restricted	● Displayed when attempting to power off while wireless charging. ● Power-off is restricted to ensure stable wireless charging.

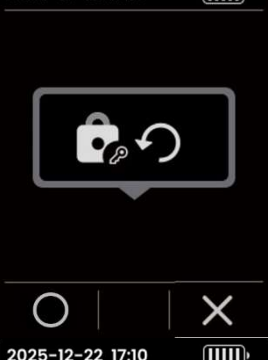
	Scan Restricted During Charging	Displayed when a scan is attempted during wireless charging.
	In Progress	Displayed when the system requires waiting for the current operation to complete.
	Oil Heating	• Displayed when the system requires waiting for oil heating to complete. • The displayed number indicates the progress.

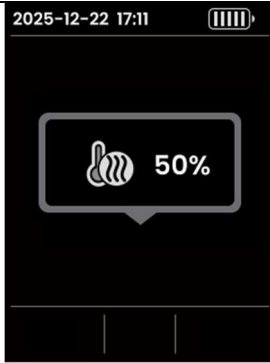
9.2. PROBE NOTIFICATION MESSAGES

Popup Message	Description	Condition
	Current Password Mismatch	The value entered on the keypad does not match the stored current password. ok Confirm icon

	New Password Mismatch	The new password and the confirmation password do not match. ok: Confirm icon
	Key Code Mismatch	The entered key code does not match the generated key code based on the stored lock code. ok: Confirm icon
	Error Code	Displays an error code. ok: Confirm icon
	Remote Connection Lost	Display when a remote connection is disconnected. ok: Confirm icon

9.3. PROBE SELECTION MESSAGE (ACCEPT/DECLINE OPTION)

Popup Message	Description	Condition
	Power Off	When the left + center buttons are pressed and held for more than 3 seconds: ●  (Left button): Execute power off ●  (Right button): Cancel power off and return to the previous screen
	Delete Stored Data	When the delete icon is selected on the Barcode Review screen: ●  (Left button): Delete the selected data and return to the Review List screen ●  (Right button): Stay on the Barcode Review screen
	Disconnect Remote Connection	When the disconnect icon is selected during a remote connection session: ●  (Left button): Disconnect ●  (Right button): Cancel
	Generate Lock Code	When the generate icon is selected on the Lock Code screen: ●  (Left button): Delete the existing lock code, generate a new lock code, and move to the Lock Code screen ●  (Right button): Stay on the Lock Code screen
	Low Temperature	Displayed when a scan is attempted while the system's internal temperature is 10 °C or lower: ●  (Left button): Performs an operation to heat the oil inside the system to increase the temperature. While oil heating is in progress, the message below appears and automatically disappears when it reaches 100%.

		 ●  (Right button): Cancel
--	--	--

9.4. REMOTE CONNECTION MESSAGES (TABLET/PC)

Popup Message	Description	Condition
	Remote Setup	Indicates that the tablet and the probe are connected for configuration changes. : Disconnect
	Remote Scan	Indicates that the tablet and the probe are connected for scan mirroring. ● : Scan Settings ● : Disconnect
	Remote Transfer	Indicates that the CubeLite and the probe are connected for transmitting scan results (PDF/JPG) : Disconnect

10. MAINTENANCES

10.1. DEVICE ERRORS

Error Message	Description	Action
	Displayed when attempting to power off the device during wireless charging.	Stop wireless charging and try again.
	Displayed when attempting to start a scan during wireless charging.	Stop wireless charging and try again.
	Displayed when the battery level is low.	Charge the device before use.
	Displayed when the wireless connection is lost.	Attempting to reconnect to the wireless connection near the probe.
	Displayed when a password change is required (initial password status or more than 6 months have passed since the last change).	Change the password in the Settings menu.
	Displayed when the password entered via keypad does not match the current password.	Check the password and try again.
	Displayed when the new password and the confirmation password do not match during the password change process.	Enter the same password in both the New Password and Confirm Password fields.
	Displayed when the entered Key Code does not match the Key Code generated from the stored Lock Code.	To reset your password, contact the distributor or manufacturer.
	Displayed when an error occurs (xxx = error number).	Refer to 10.2. DEVICE & SCAN ERROR MESSAGE and 10.3. CALIBRATION AND SELF-TEST ERROR MESSAGES for actions related to each error code.

10.2. DEVICE & SCAN ERROR MESSAGE

Operation	Error Code	Action
Pre-Scan and Normal Scan	1	● Please perform the scan operation again.
	2	● Turn the power off and on, then perform the scan again.
	3	● If the error persists, please contact our Customer Support Department for assistance.
	4	
	5	
	6	
	7	
	8	● Allow the device to cool down sufficiently, then perform the scan again. ● Turn the power off and on, then perform the scan again. ● If the error persists, please contact our Customer Support Department for assistance.

10.3. CALIBRATION AND SELF-TEST ERROR MESSAGES

Operation	Error Code	Action
Calibration step 1 (with Calkit)	0	This error code appears when the stop button is pressed.
	101	● Perform Calibration Step 1 (Calkit) again. ● If the error persists, please contact our Customer Support Department.
	102	
	103	
	104	
	105	
	106	
	107	● Allow the device to cool down sufficiently, then perform Calibration Step 1 (Calkit) again. ● If the error persists, please contact our Customer Support Department.
	201	● Perform Calibration Step 1 (Calkit) again. ● If the error persists, please contact our Customer Support Department.
	202	
	203	
	204	
	205	● Check that the Calkit is filled with enough water up to the water level mark. If not, fill it with water to the indicated level. ● Ensure that the probe is correctly mounted on the Calkit.
	206	● Perform Calibration Step 1 (Calkit) again. ● If the error persists, please contact our Customer Support Department.

	207	● Ensure that the probe is correctly mounted on the Calkit. ● Check for any air bubbles inside the outer wall or target area of the Calkit. The Calkit must be free of air bubbles. ● Confirm that the water temperature inside the Calkit is between 20°C and 24°C.
	208	● Perform Calibration Step 1 (Calkit) again. ● If the error persists, please contact our Customer Support Department.
Calibration step 2 (with Phantom)	0	This error code appears when the stop button is pressed.
	301	● Perform Calibration Step 2 (Phantom) again.
	302	● If the error persists, please contact our Customer Support Department.
	303	
	304	
	305	● Ensure that the probe is correctly mounted on the Phantom. ● Check that the surface of the Phantom has sufficient water. ● Confirm that the water temperature of the Phantom is between 20°C and 24°C. ● Perform Calibration Step 2 (Phantom) again. ● Replace the Phantom with a new one and perform Calibration Step 2 again. ● If the error persists, please contact our Customer Support Department.
	306	● Perform Calibration Step 2 (Phantom) again.
	307	● If the error persists, please contact our Customer Support Department.
	308	
	309	● Allow the device to cool down sufficiently, then perform Calibration Step 2 (Phantom) again. ● If the error persists, please contact our Customer Support Department.
	401	● Perform Calibration Step 2 (Phantom) again.
	402	● If the error persists, please contact our Customer Support Department.
	403	
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	407	
Self-Scan Test	0	This error code appears when the stop button is pressed.
	601	● Perform the Self-Scan again.
	602	● If the error persists, please contact our Customer Support Department.
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	611	
	612	● Allow the device to cool down sufficiently, then perform the Self-Scan again. ● If the error persists, please contact our Customer Support Department.

10.4. SERVICE AND TECHNICAL SUPPORT

If you need technical support, or if you experience any malfunction or other unexpected issue with the device, please contact your distributor or the manufacturer.

You can reach us by e-mail at mcube@mcubetech.co.kr or visit our website at www.mcube.co.kr for inquiries.

11. CLEANING AND DISINFECTION



WARNING *AVERTISSEMENT*

- Cleaning must always be performed before disinfection. If cleaning is not done properly, contamination may remain even after disinfection.
Le nettoyage doit toujours être effectué avant la désinfection. Si le nettoyage n'est pas correctement réalisé, une contamination peut subsister même après la désinfection.
- Improper cleaning or disinfection may cause permanent damage to the device.
Un nettoyage ou une désinfection inapproprié(e) peut endommager définitivement l'appareil.
- Do not use solvents such as thinner or benzene, or any abrasive materials.
N'utilisez pas de solvants tels que le diluant ou le benzène, ni de matériaux abrasifs.
- This device is not designed for sterilization.
Cet appareil n'est pas conçu pour être stérilisé
- Do not immerse the device (except for the probe head) in any solution.
Ne plongez pas l'appareil (sauf la tête de la sonde) dans une solution.
- When cleaning or disinfecting the probe or charging or cradle, do not submerge them in liquid.
Lors du nettoyage ou de la désinfection de la sonde ou du socle de charge, ne les immergez pas dans un liquide.
- Do not use metal brushes or abrasive pads, as they may scratch the surface.
N'utilisez pas de brosses métalliques ni de tampons abrasifs, car ils peuvent rayer la surface.
- Always wear protective gloves when cleaning and disinfecting the device.
Portez toujours des gants de protection lors du nettoyage et de la désinfection de l'appareil.
- Compatibility may vary depending on the type of cleaning or disinfectant solution. Since it is impossible to verify all products for safety, contact the manufacturer before use.
La compatibilité peut varier selon le type de solution de nettoyage ou de désinfectant. Étant donné qu'il est impossible de vérifier la sécurité de tous les produits, contactez le fabricant avant utilisation.
- Do not spray disinfectant directly onto the BioCon-V, charging cradle, outer surfaces, or into gaps and openings.
Ne vaporisez pas de désinfectant directement sur le BioCon-V, le socle de charge, les surfaces extérieures ou dans les interstices et ouvertures.



CAUTION *MISE EN GARDE*

- The device must be cleaned and disinfected according to the approved procedures described in this operator's manual.
L'appareil doit être nettoyé et désinfecté conformément aux procédures approuvées décrites dans ce manuel d'utilisation.
- This procedure has been prepared with consideration for material compatibility; the manufacturer recommends strict compliance with it.
Cette procédure a été élaborée en tenant compte de la compatibilité des matériaux ; le fabricant

recommande de s'y conformer strictement.

- Handle and dispose of disinfectants in accordance with the instructions provided in this manual.

Manipulez et éliminez les désinfectants conformément aux instructions fournies dans ce manuel.

11.1. COMPATIBILITY

The following products have been verified to be effective and compatible for cleaning and disinfection.

- Metrex® CaviWipes™
- Metrex® CaviCide™ Spray

11.2. CLEANING

11.2.1. PREPARATION

- Unplug the charging cradle's power cord from the wall outlet and disconnect the USB cable.
- Wipe off ultrasound gel, dust, or dirt using a paper towel or a soft, lint-free cloth.

11.2.2. CLEANING-CHARGING CRADLE

- Put on a new pair of gloves.
- Spray Metrex® CaviCide™ onto a soft brush until it is thoroughly moistened. Using the dampened brush, clean the cradle's surface, recessed areas, and hard-to-reach spaces until no visible contaminants remain.
- Wipe the surface thoroughly using a Metrex® CaviWipe™ towel.
- Using a new Metrex® CaviWipe™ towel, wipe the surface of the charging cradle again and leave it for approximately 2 minutes.
- If additional Metrex® CaviWipe™ towels are used, ensure a minimum contact time of 2 minutes.
- Visually inspect the surface of the charging cradle to ensure there are no remaining contaminants.
- Allow the charging cradle to air dry completely.



[Charging Cradle]

NOTE: Ensure that water, isopropyl alcohol, or ethanol does not enter the USB power port. If any liquid has entered, make sure to dry it completely before use.

11.2.3. CLEANING THE PROBE

- Put on a new pair of gloves.
- Spray Metrex® CaviCide™ generously onto a soft brush until it is well moistened.
- Using the brush, clean the probe surface, grooves, and crevices until no visible contamination remains.
- Wipe the surface thoroughly with a Metrex® CaviWipe™ towel.
- Wipe again using a new Metrex® CaviWipe™ towel and leave it for approximately 2 minutes.
- If additional Metrex® CaviWipe™ towels are used, maintain a contact time of at least 2 minutes.
- Visually inspect the probe for any remaining contaminants, then allow it to air dry completely.

11.3. DISINFECT THE PROBE

Although this procedure provides low-level disinfection, it must be performed before scanning a new patient.

- Put on a new pair of gloves.
- Spray the probe head thoroughly with Metrex® CaviCide™ Spray until it is visibly wet.
- Allow the probe head to remain wet for at least 3 minutes.
- If additional spraying is needed, ensure the total contact time remains at least 3 minutes.
- Allow the probe head to air dry completely.
- Using a new Metrex® CaviWipe™ towel, thoroughly wipe the probe head.
- After wiping, ensure the surface remains wet for at least 3 minutes.
- Allow the probe to air-dry. Then, using a sterile, lint-free cloth moistened with RO/DI (reverse osmosis/deionized) water, wipe the probe head thoroughly for at least 1 minute.
- Using a new sterile lint-free cloth, wipe again for 1 minute.
- To completely remove any residual disinfectant, wipe once more using a sterile cloth moistened with RO/DI water.
- Allow the probe to air-dry completely before using it on a new patient.

12. BATTERY

The user cannot remove the probe battery. If you do not plan to use the probe for an extended period, switch the probe to shutdown mode to prevent the battery from becoming fully discharged. Store the device under appropriate environmental conditions, and it is recommended to charge the device at least once every 6 months. Refer to [17.5. ENVIRONMENTAL CONDITIONS](#).

13. REGULAR INSPECTION

Once a week, you should inspect the BioCon-V as below.

- Check the probe head for abnormal sound during scanning.
- Check the probe for cracks and oil-leakage.
- Check the exterior surface of the device for physical damage or deformation.
- Cracks that allow the fluid ingress into the device may affect the performance of the BioCon-V.

If oil leakage or damage to the probe head is observed, stop using the device immediately and contact the service center.

If oil leakage or physical damage is observed, stop using the device immediately and contact the manufacturer

Handle the device carefully during use, storage, and transportation to prevent any damage that may lead to oil leakage.

14. DISPOSAL OF THE DEVICE

The device and its components contain environmentally hazardous substances such as mineral oil and lead. When the device or its components reach the end of their service life, please dispose of them in accordance with your local regulations for medical device disposal, or return them to Mcube Technology Co., Ltd.

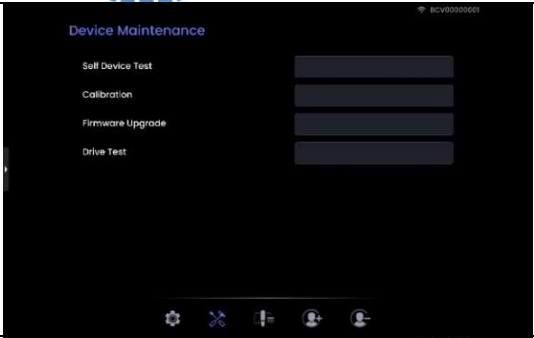
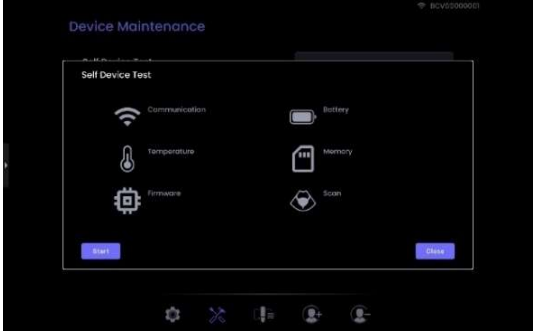
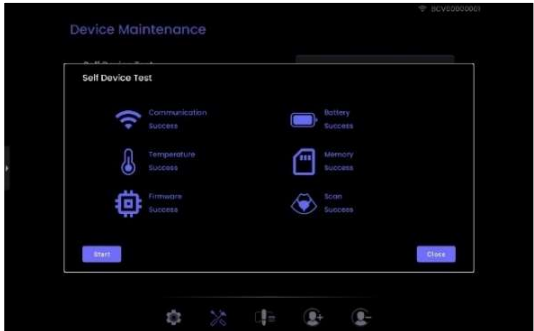
15.REPAIRS OF THE DEVICE

Only authorized service technicians designated by our company are permitted to disassemble and repair this device. If a problem occurs that is not described in [10.1. DEVICE ERRORS](#), Trobe shooting, please contact your distributor or Mcube Technology Co., Ltd.

16.SELF-SCAN TEST AND CALIBRATION

16.1. SELF-DEVICE TEST

The Self-Device Test function automatically checks the device's major operating components. Each diagnostic step runs sequentially, and the final results are displayed upon completion.

ACCESSING THE SELF-DEVICE TEST	
(1) On the bottom menu, select the Device Maintenance icon ().	
(2) On the Device Maintenance screen, tap Self-Device Test.	
(3) Tap the [Start] button to begin the test. The device will automatically run the diagnostic steps in the order shown below.	
RESULT SCREEN	
● When all tests are completed successfully, each item will display "Success". ● If an issue is detected during testing, the corresponding error code will be displayed.	
EXIT AND ADDITIONAL FUNCTIONS	
● After the test is completed, tap the Close button () to return to the Device Maintenance screen.	

- To stop the test during operation, tap the Stop icon (⏏) to end the test
 - If the Self-Device Test is activated unintentionally, you may exit at any time by pressing the Close button (Close).
-

16.2. CALIBRATION

BioCon-V does not require regular calibration during normal operation.

However, calibration may be performed as a preventive measure when required by institutional policies or regional regulations, or when the probe has been dropped, subjected to impact, or unused for an extended period.

NOTE:

- Perform calibration only when the battery level is at 60% or higher.
- If a low-battery error occurs, charge the device before performing calibration.
- Only use the Calibration Phantom and Calkit provided by Mcube Technology Co., Ltd.
- If the Calibration screen is opened unintentionally, tap the Close button (Close) to return to the Device Maintenance screen.

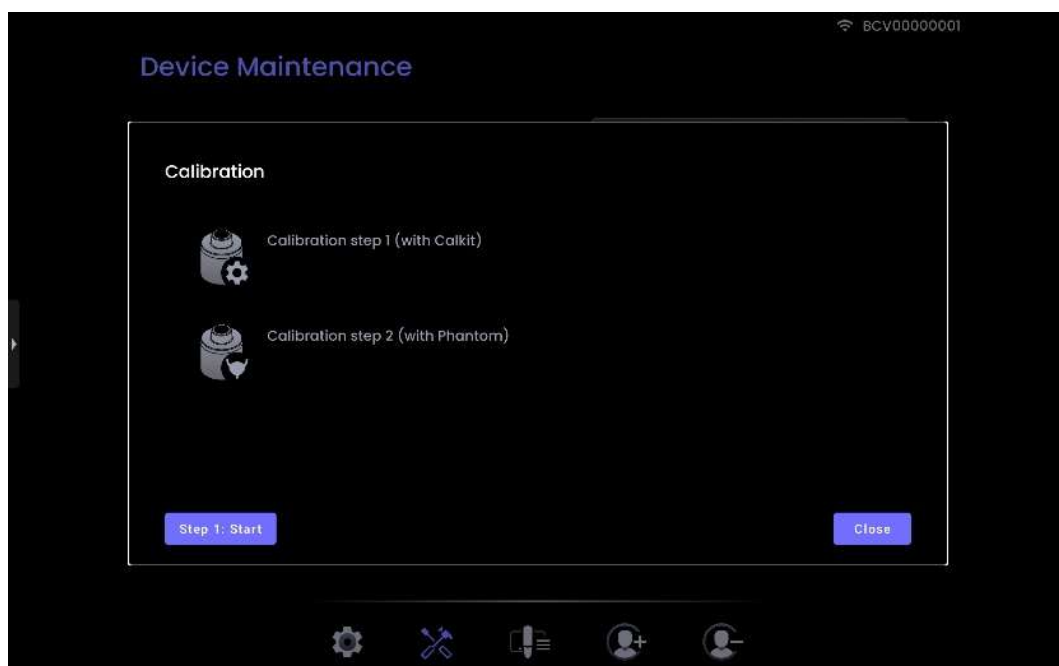
[Calibration Structure]

Calibration consists of two steps.

Step 1 – Calibration using the Calkit

Step 2 – Calibration using the Phantom

NOTE: If calibration is interrupted during the process, the entire procedure must be restarted from Step 1.



Step 1: Calkit Calibration

(1) Prepare the Calkit

Open the lid of the calibration Calkit and fill it with water.

*Optimal calibration conditions: You may use distilled water instead of saline. Before starting calibration, make sure there are no air bubbles inside the Calkit.

Begin calibration only after confirming that all bubbles have disappeared.



(2) Fill to the Water Level mark

- Inside the Calkit, a water Level marking is provided.
- Fill the Calkit with water up to this mark.

The marking is located one step below the top edge.



(3) Close the Calkit lid

Close the lid so that the arrow on the lid aligns with the nipple on the body.



(4) Mount the probe

Align the direction of the probe's scan button with the arrow on the lid, then securely place the probe head into the probe holder.



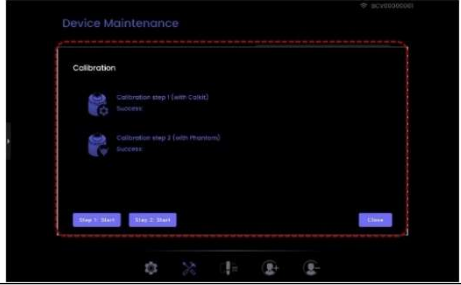
(5) Enter the Calibration menu

- Go to Device Maintenance (🔧).
- Tap the [Calibration] button.

(6) To begin, tap the Step 1: Start icon (Step 1: Start).

(7) After completing Step 1 (Calkit Calibration)

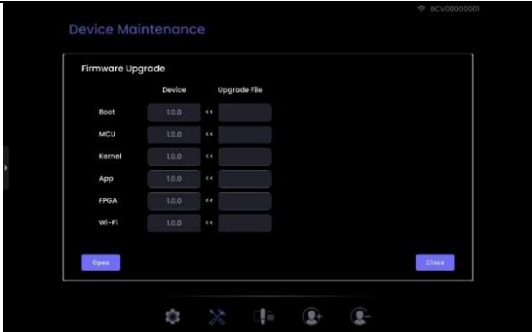
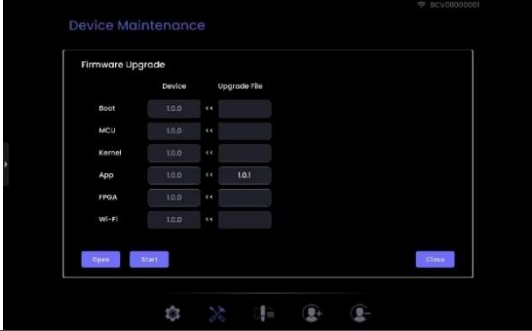
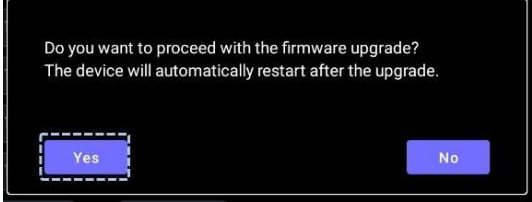
- proceed to Step 2: Phantom Calibration.
- The Step 2: Start button (Step 2: Start) will appear on the screen.

Step 2: Phantom Calibration	
(1) Place the calibration phantom on a flat, stable surface and open the lid.	
(2) Pour approximately 140–160 mL of water onto the top surface of the phantom.	
(3) Place the lid holder on top of the phantom. Ensure that the lid holder is stable and positioned evenly.	
(4) Securely place the probe head into the probe holder. (5) Before starting Phantom Calibration (Step 2) confirm that Calkit Calibration (Step 1) has been successfully completed.	
(6) Tap the Step 2 Start icon (Step 2: Start) to begin Phantom Calibration. Once calibration is successfully completed, each step will be marked as "Success" on the result screen.	
(7) After completing both Step 1 (Calkit Calibration) and Step 2 (Phantom Calibration), tap the [Close (Close)] button to return to the Device Maintenance screen.	

16.3. FIRMWARE UPGRADE

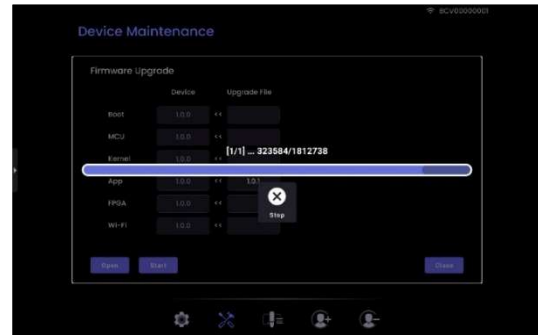
You can update the BioCon-V device firmware to the latest version.

The upgrade process is performed through the tablet, and the device will automatically reboot once the update is complete.

Firmware Upgrade Procedure	
(1) Open the Device Maintenance screen From the bottom menu, tap the Device Maintenance icon ().	
(2) Run the Firmware Upgrade function - In the Device Maintenance screen, tap Firmware Upgrade. - Tap the Open button () to browse and select the upgrade file.	
(3) Select the upgrade file Navigate to the folder where the firmware upgrade file is stored and select the file.	
(4) Check the selected version and start the upgrade - The selected firmware version information will be displayed on the screen. - Tap the Start button () to begin the upgrade.	
(5) Confirm the upgrade - A confirmation message will appear. - Tap Yes () to proceed with the upgrade.	

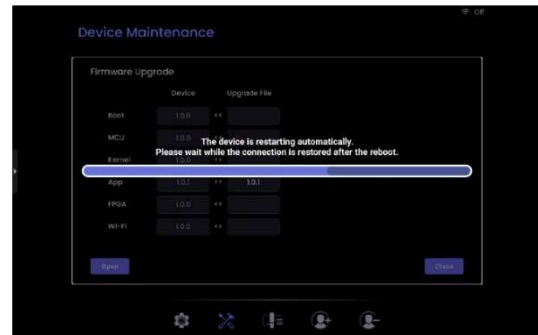
(6) Transfer the upgrade file

- The upgrade progress will be shown on the status bar.
- Please wait while the file is transmitted to the BioCon-V device.



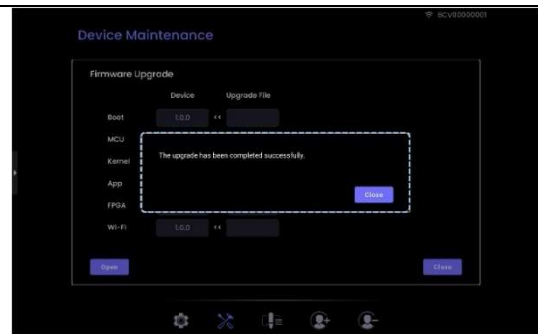
(7) Automatic device reboot

- After file transmission, the BioCon-V device will verify the upgrade file and automatically reboot.
- During this time, the tablet displays: "The device is restarting automatically. Please wait while the connection is restored after the reboot."



(8) Confirm upgrade completion

- Once the device restarts and the connection is restored, a success message appears: "The upgrade has been completed successfully."
- Tap Close (**Close**) to return to the Device Maintenance screen.



NOTE:

- Ensure that the battery level is at least 60% before starting the upgrade.
- If a low-battery warning appears during the upgrade, fully charge the device before retrying.
- If you do not wish to proceed with the upgrade or if you accessed the menu unintentionally, tap Close (**Close**) to return to the Device Maintenance screen.

17. SPECIFICATIONS

17.1. ACOUSTIC OUTPUT TABLE



WARNING *AVERTISSEMENT*

- The ALARA principle (As Low As Reasonably Achievable) should be used for all medical ultrasound exposures.

Le principe ALARA (Niveau le plus bas qu'il soit raisonnablement possible d'atteindre) devrait être utilisé pour toutes les expositions à l'échographie médicale.

- The user cannot adjust the acoustic output energy of the BioCon-V. The output level is lower than the levels mentioned in AIUM (Medical Ultrasound Safety, American Institute of Ultrasound in Medicine, 2014) and there are no reported biological effects below this level. However, to minimize exposure, measurements should be as short as possible.

L'utilisateur ne peut pas ajuster l'énergie de sortie acoustique du BioCon-V. Le niveau de sortie est inférieur aux niveaux mentionnés dans AIUM (Medical Ultrasound Safety, American Institute of Ultrasound in Medicine, 2014) et il n'y a aucun effet biologique signalé sous ce niveau. Toutefois, pour minimiser l'exposition, les mesures doivent être aussi courtes que possible.

ACOUSTIC OUTPUT TABLE Track 3 - IEC 60601-2-37:2024

Transducer: BioCon-V

MODE: B-MODE

Index Label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		0.4302	0.01032		0.0136		n/a
Index component value		0.4302	0.01032	n/a	0.0136	n/a	---
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.7258	---	---	---	---	---
	P (mW)	---	0.7617		0.7617		n/a
	P_{1x1} (mW)	---	0.7617		0.7617		---
	z_s (cm)	---	---	n/a	---	---	---
	z_b (cm)	---	---	---	---	n/a	---
	$z_{pii,\alpha}$ (cm)	3.38	---	n/a	---	n/a	---
	z_{MI} (cm)	3.2	---	---	---	---	---
	f_{awf} (MHz)	2.846	2.846		2.846		n/a
Other Information	t_d (μsec)	1.035	---	---	---	---	---
	prr (Hz)	325	---	---	---	---	---
	srr (Hz)	5.5	---	---	---	---	---
	p_r at z_{pii} (MPa)	1.027	---	---	---	---	---
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	24.25	---	---	---	---	---
Operating control conditions	Not user adjustable; fixed B-mode output						
NOTE 1 Only one operating condition per index.							
NOTE 2 Data for "at surface" and "below surface" are entered in both the columns related to <i>TIS</i> or <i>TIB</i> .							
NOTE 3 Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.							
NOTE 4 If the requirements of 201.12.4.2a) or b) are met, it is not required to enter any data in the columns related to <i>TIS</i> , <i>TIB</i> or <i>TIC</i> .							
NOTE 5 If the requirements of 201.12.4.2c) are met, it is not required to enter any data in the column related to <i>MI</i> .							
NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.							
*Since the intended use of BioCon-V does not involve transcranial applications, <i>TIC</i> is not calculated.							

NOTE:

- It is not necessary to provide information on the *TIS* formula when the maximum *TIS* value is not calculated for the applicable mode.
- For transducer assemblies that are not used for transcranial or neonatal head applications, *TIC*-related information does not need to be provided.
- If the equipment meets all exemption conditions specified in 51.2 aa) and 51.2 dd), information

regarding MI and TI does not need to be provided

Symbols used in Acoustic Output Table are described below.

Symbol	Definition
<i>MI</i>	Mechanical index
<i>TIS</i>	Soft-tissue thermal index
<i>TIB</i>	Bone thermal index
<i>TIC</i>	Cranial-bone thermal index
$p_{r,\alpha}$ at z_{MI}	Attenuated peak-rarefactional acoustic pressure at depth for mechanical index
<i>P</i>	Output power
$P_{1 \times 1}$	Bounded-square output power
z_s	Depth for <i>TIS</i>
z_b	Depth for bone thermal index
$z_{pii,\alpha}$	Depth for peak pulse-intensity integral
z_{MI}	Depth for mechanical index
f_{awf}	Acoustic working frequency
t_d	Pulse duration
<i>pr</i>	Pulse repetition rate
<i>srr</i>	Scan repetition rate
p_r at z_{pii}	Peak-rarefactional acoustic pressure at depth for peak pulse-intensity integral
$I_{pa,\alpha}$ at $z_{pii,\alpha}$	Attenuated pulse-average intensity at depth for peak attenuated pulse intensity integral

17.2. COMPONENT SPECIFICATIONS

17.2.1. PORBE

Item	Specification	
Model Name	BioCon-V	
Bladder Volume Range	0-999ml	
Accuracy	0-99ml $\pm$ 7.5ml, 100 - 999ml $\pm$ 7.5% When measured using the bladder phantom of Mcube Technology Co., Ltd. in accordance with this user manual.	
Scan Time	Approx. 2 Seconds (Normal scan)	
Input Power	Internal Powered	● RRC-1120 (Rechargeable lithium- ion battery) - Voltage: 3.6V (Nominal) - Capacity: 2350 mAh ● Wireless charging current: 0.56 A ● Sleep mode current consumption: $\leq$ 2 mA (automatically powers off after 8 hours in sleep mode) ● Usage per Charge: Approx: 100 scans - Based on a fully charged new Battery - Under Mcube Technology's test conditions
	Charging	< 5.4 W (9 V, 0.6 A) - Charging time: Appex.5 hours from fully discharged to fully Charged. - When using the BioCon-V Charging cradle
Expected Lifetime	7 years	
Display	● TFT-LCD 2.0 inch ● 240 X RGB X 320	
User Interface	● LCD Icon ● 3 Physical buttons	
Water Resistance	IPX3	
Probe Head	● 14mm Transducer diameter: 14mm ● Sector scanning method ● Ultrasound frequency: 2.8MHz ● B-mode scan image ● Scan angle: 120 ● Applied Part: Probe head ● Penetration depth; (generation patient): 23cm ● Type BF applied part	
Operation Mode	Continuous operation	
Weight	313 g	
Compatible Devices	● Tablets and laptops with built-in Wi-Fi	

	● Desktops with a Wi-Fi module on the mainboard or a USB Wi-Fi dongle
Others	● Battery charging temperature range: 0–55 °C ● Operating ambient temperature: 10–35 °C ● Sleep mode current consumption: ≤ 2 mA (automatically powers off after 8 hours in sleep mode)
Wireless	WLAN ● IEEE 802.11a/n/ac (20/40/80 MHz) ● Operating Frequency band: 5725-5850 MHz ● Encryption: WPA2 ● Modulation: OFDM ● Output power (e.i.r.p): 13 dBm (Average power)
	Wireless transmitting power (Receiving only)

17.2.2. CHARGING CRADLE

Item	Specification	
Model Name	BioCon-V Charger	
Usage	Wireless charging (Indoor use only)	
Main Chipset	Infineon (WLC1115)	
Coil Type	1 Coil (A11)	
Input Power	Charging cradle	5 Vdc, 3.0 A (Stand-by)/9 Vdc, 3.0 A (Charging)
Output Power	15 W Max.	
Charging Efficiency	70%	
Modulation Method	Frequency Modulation	
Temperature Sensor	NTCG164KF104FT1	
Operating Frequency	128 kHz	
Insulation Class	Class II equipment	
Water Resistance	IPX 3	
LED Indicator	Multi-Color LED (Red:1, Green:1, Orange:1)	
Weight	204 g (Power adapter not included)	

17.2.3. POWER ADAPTER

Item	Specification
Model Name	ATN045A3-W200V
Input Power	100-240 V~, 50/60 Hz, 1.0-0.5 A
Output Power	5.0 Vdc, 3.0 A, 15W/9.0 Vdc, 3.0 A, 27 W/12.0 Vdc, 3.0 A, 36 W/15.0 Vdc, 3.0 A, 45 W/20.0 Vdc, 2.25 A, 45 W (MAX)
Weight	142 g (USB cable not included)

17.2.4. PC

Contents	Specification
Operating System (OS)	Windows 7, Windows 8.1, Windows 10, Windows 11
CPU	Pentium 500 MHz or higher (minimum requirement)
Main Memory	256MB
Hard Disk Capacity	100MB
Others	● Display: Monitor with a minimum resolution of 1024 × 768 ● Printer: Local printer or network printer ● User Input: Keyboard and mouse

17.2.5. TABLET

Contents	Specification
OS	Android 11 or higher
CPU	Exynos 1280 or higher
RAM	4 GB or higher
Resolution	2000 × 1200 pixels or higher

17.3. ELECTROMAGNETIC COMPATIBILITY

17.3.1. ELECTROMAGNETIC EMISSIONS

Guidance and Manufacturer'S Declaration – Electromagnetic Emissions

BioCon-V is designed for use in the electromagnetic environment specified below.

Customers or users of BioCon-V must ensure that it is used in such an environment.

EMISSIONS TEST	Compliance Limit	Electromagnetic Environment – Guidance
Mains terminal disturbance voltage CISPR 11	Group 1 Class A	The EMISSIONS characteristics of BioCon-V 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 disturbance CISPR 11	Group1, Class A	
Harmonics IEC 61000-3-2	Class A	The BioCon-V is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public

Voltage fluctuations/Flicker IEC 61000-3-3	Complies	low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the BioCon-V or shielding the location
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17.3.2. ELECTROMAGNETIC IMMUNITY

Guidance and Manufacturer'S Declaration – Electromagnetic Immunity

BioCon-V is designed for use in the electromagnetic environment specified below.

Customers or users of BioCon-V must ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	IEC 60601 Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV /Air	±8 kV/Contact ±2, ±4, ±8, ±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 %.
Radiated RF Electromagnetic Field IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	BioCon-V is suitable to use in professional healthcare environment. RF communication equipment is used no
Immunity to Proximity Fields from RF wireless Communications Equipment IEC 61000-4-3	28 V/m Max. 385-5785 MHz in according to table 9 in IEC 60601-1-2	28 V/m Max. 385-5785 MHz in according to table 9 in IEC 60601-1-2	closer than 30 cm to any part of the BioCon-V, including cables specified by Mcube Technology Co., Ltd.
Electrical Fast Transient /Burst IEC 61000-4-4	100 kHz repetition frequency ± 2 kV for power supply lines	±100 kHz repetition frequency ± 2 kV for power supply lines	The quality of supplied power should be suitable for general business site or hospital environment.

Surge IEC 61000-4-5	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV	The quality of supplied power should be suitable for general business site or hospital environment.
Conducted Disturbances Induced by RF fields IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	The strength of RF field in the frequency range higher than 150 kHz - 80 MHz, the strength of the RF field is smaller than 3 V.
Power Frequency (50/60 Hz) Magnetic Field 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 domestic, residential or Home Health Care environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11*	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 30 cycles Single phase: at 0° 0 % U_T ; 250/300 cycles	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles Single phase: at 0° 0 % U_T ; 250/300 cycles	Mains power quality should be that of a typical residential or hospital environment. If the user of the BioCon-V requires continued operation during power mains interruptions, it is recommended that the BioCon-V be powered from an uninterruptible power supply or a battery be used with the system power source.
Radiated fields in close proximity IEC 61000-4-39	65 A/m Max 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2	65 A/m Max 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2	BioCon-V is suitable to use in professional healthcare environment. Portable radio frequency (RF, RFID) communication devices can interfere with the medical electrical device. Therefore, do not use your mobile phone in a medical

office or hospital environment.

NOTE: U_T is the AC voltage of the power before using test level

17.3.3. RECOMMENDED SEPARATION DISTANCE

Recommended separation distances between portable and mobile RF communications equipment and the BioCon-V

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BioCon-V including cables specified by the manufacturer. If the distance is closer than 30 cm (12 inches), performance of the BioCon-V may decrease.

Immunity Test	Band ^{a)}	Service ^{a)}	Modulation	IEC 60601 Test Level	IEC 60601 Compliance Level
Proximity fields from RF wireless communications equipment	380-390 MHz	TETRA 400	Pulse modulation 18 Hz	27 V/m	27 V/m
	430-470 MHz	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704-787 MHz	LTE Band 13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800-960 MHz	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28 V/m	28 V/m
	1700-1990 MHz	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28 V/m	28 V/m
	2400-2570 MHz	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28 V/m	28 V/m

	5100-5800 MHz	WLAN 802.11 a/n	Pulse modulation 217 Hz	9 V/m	9 V/m
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NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) For some services, only the uplink frequencies are included.

17.4. FCC/ISED COMPLIANCE INFORMATION

BioCon-V complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions.

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

BioCon-V has been tested and found to comply with the limits for a Class B 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

Any changes or modifications to this device not expressly approved by Mcube Technology Co., Ltd. responsible for compliance could void your authority to operate the equipment.

[Industry Canada Statement]

This device complies with RSS-247 of the Industry Canada Rules. Operation is subject to the following two conditions.

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Ce dispositif est conforme à la norme CNR-247 d'Industrie Canada applicable aux appareils radio exempts de licence. Son fonctionnement est sujet aux deux conditions suivantes.

- *Le dispositif ne doit pas produire de brouillage préjudiciable.*

- *CE dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.*

17.5. ENVIRONMENTAL CONDITIONS

WARNING *AVERTISSEMENT*

- Do not store the device in a sealed vehicle or under direct sunlight. This may cause a fire hazard.

Ne stockez pas l'appareil dans un véhicule fermé ni sous la lumière directe du soleil. Cela pourrait présenter un risque d'incendie.

- Do not place the device on unstable surfaces. The device may fall, resulting in damage or potential injury.

Ne placez pas l'appareil sur une surface instable. L'appareil pourrait tomber, provoquant des dommages ou des blessures potentielles

CAUTION *MISE EN GARDE*

- Do not place heavy objects on the device. It may cause damage.

Ne placez pas d'objets lourds sur l'appareil. Cela pourrait l'endommager.

- Do not store the device in humid or dusty environments.

Ne stockez pas l'appareil dans un environnement humide ou poussiéreux.

- This device is intended for indoor use only and must be operated under the environmental conditions specified in the table below.

Cet appareil est destiné uniquement à une utilisation en intérieur et doit être utilisé dans les conditions environnementales spécifiées dans le tableau ci-dessous.

- Unplug the device from the wall outlet during thunderstorms or when it will be unused for an extended period to prevent damage.

Débranchez l'appareil de la prise murale pendant les orages ou lorsqu'il ne sera pas utilisé pendant une longue période afin d'éviter tout dommage.

- If the BioCon-V has been stored at temperatures below 10°C, do not use it immediately in a warmer environment. This may cause malfunction. Wait until the device reaches a temperature above 10°C before use.

Si le BioCon-V a été stocké à une température inférieure à 10 °C, ne l'utilisez pas immédiatement dans un environnement plus chaud. Cela pourrait provoquer un dysfonctionnement. Attendez que l'appareil atteigne une température supérieure à 10 °C avant utilisation.

- If the BioCon-V is not used for more than 3 months, store it under the recommended conditions and charge the battery at least once every 6 months.

Si le BioCon-V n'est pas utilisé pendant plus de 3 mois, conservez-le dans les conditions recommandées et rechargez la batterie au moins une fois tous les 6 mois.

- If the battery needs to be removed or replaced, please contact the distributor or Mcube Technology Co., Ltd.

Si la batterie doit être retirée ou remplacée, veuillez contacter le distributeur ou Mcube Technology

Co., Ltd.

Environmental Specifications	
Use	Indoor
Operating temperature	+10 ~ 35°C (+50 ~ 95°F)
Relative humidity	30 ~ 75% non-condensing
Atmospheric pressure	700 ~1060 hPa
Storage and Transportation Conditions	
Storage and transportation temperature	0 ~ +23°C (+32 ~ 73.4°F) ≤ 1 year
	0 ~ +45°C (+32 ~ 113°F) ≤ 3 months
	0 ~ +55°C (+32 ~ 131°F) ≤ 1 month
Relative humidity	20 ~ 80% non-condensing
Atmospheric pressure	600 ~1060 hPa

18. GLOSSARY

Probe	Main device with an LCD display.
Charging Cradle	Wirelessly charges the built-in battery of the probe.
Transducer	A device that converts one form of energy into another. An ultrasound transducer converts electrical energy into sound waves, or vice versa. In this manual, the term transducer refers specifically to an ultrasound transducer.
B-mode	A type of ultrasound imaging mode that displays the strength of the echo signal as brightness on the screen.
Pre-Scan	A general 2D real-time ultrasound scanning mode. The 2D images are displayed continuously in real-time. This helps the user locate the bladder and estimate the residual urine area.
Normal Scan	Captures 12-plane ultrasound images and calculates the residual urine in the bladder using 3D scanning.
Self-Test	Performs a self-diagnostic test and displays the result.
Phantom	Performs phantom-based calibration and displays the result.
Calkit	Performs calibration using a calibration kit (CalKit) and displays the result.

19.SYMBOL DIRECTORY

Symbol	Description	Symbol	Description
 WARNING	Risk of personal injury or serious system damage	 SN	Indicates the manufacturer's serial number
 CAUTION	Risk of system damage or failure	 REF	Indicates the manufacturer's catalog (part) number
 UDI	Unique Device Identifier for the product	 MD	Indicates the item is a medical device
 Person	Indicates a Type BF applied part complying with IEC 60601-1	 LOT	Indicates the manufacturer's batch code
 Date of manufacture	Indicates the date of manufacture	 Manufacturer	Indicates the medical device manufacturer
NOTE	Useful information for efficient device use	 Instructions for Use	Consult the Instructions for Use
IPX 3	Protection against spraying water	 WEEE	Indicates that separate collection for waste electrical and electronic equipment is required
 DC	Indicates on the rating plate that the equipment is suitable for direct current only	 Fragile	Handle with care; contents are fragile
 Upright	Indicates correct upright position	 No hooks	Do not use hooks for handling
 Rain/moisture	Keep the device away from rain/moisture	 Humidity	Permissible humidity range for storage/use
 Pressure	Permissible atmospheric pressure range	 Temperature	Temperature limit
RoHS	EU's restriction of hazardous substances	 CE 1639	European conformity (CE) mark with Notified Body identification number for Class IIa, IIb, III medical devices
 EC REP	European Authorized Representative	RX Only	Prescription use only (U.S. Federal Law)
 UL US	Certified to U.S. and Canadian safety standards		

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CUBEStim M1



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