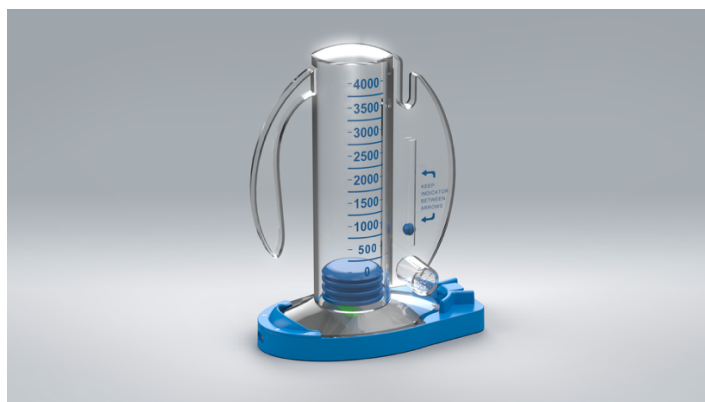
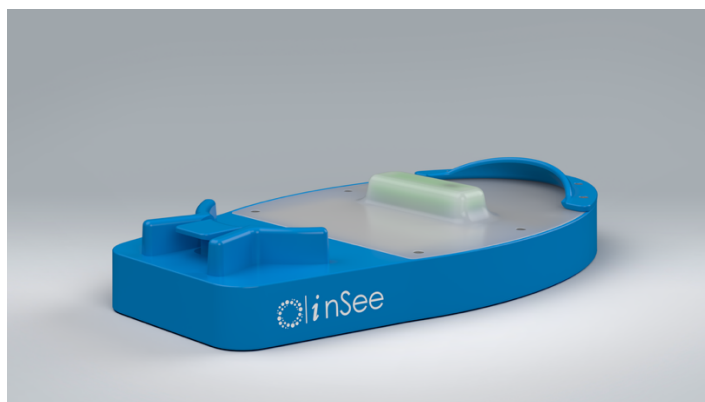


INSTRUCTIONS FOR USE

InSee®

Accessory for AirLife® Volumetric Incentive Spirometer 4000 mL

Manufactured by Tidal Medical Technologies



INSTRUCTIONS FOR USE

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Manufactured by
Tidal Medical Technologies
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Plano, TX 75075

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The information contained in this manual is confidential and proprietary to Tidal Medical Technologies.

YOUR SERIAL NUMBER

Record your device serial number below and retain these Instructions for Use for future reference.

Serial Number: _____

INSTRUCTIONS FOR USE

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INSTRUCTIONS FOR USE

WELCOME

Thank you for purchasing InSee® from Tidal Medical Technologies. These Instructions for Use contain important SAFETY and TECHNICAL information regarding the proper operation and use of the InSee system. To ensure safe and effective operation, read all sections of this manual carefully before using the device. Keep these Instructions for Use in a safe location for future reference. If you require assistance with setup, operation, or service of your InSee system, contact Tidal Medical Technologies using the contact information provided on page 2.

Document Conventions

The InSee Instructions for Use applies the following conventions to communicate important information:

- Standard text for general information.
- Bold text to emphasize important information.
- In this document the “user” is the clinician

NOTE: Notes provide additional information that may assist with operation or use of the device.

WARNING

WARNINGS IDENTIFY INFORMATION THAT MAY IMPACT PATIENT OR USER SAFETY. FAILURE TO FOLLOW WARNINGS MAY RESULT IN PATIENT OR USER INJURY.

CAUTION

CAUTIONS IDENTIFY INFORMATION THAT MAY IMPACT DEVICE PERFORMANCE OR EQUIPMENT SAFETY. FAILURE TO FOLLOW CAUTIONS MAY RESULT IN DAMAGE TO THE DEVICE OR IMPROPER OPERATION.

INSTRUCTIONS FOR USE

DEVICE & LABELING SYMBOLS

PRODUCT SYMBOL	MEANING
	Manufacturer
	Manufacture Date
	Reference Number
	Serial Number
	Lot Number
	Type BF Equipment
 Li-ion	Recycle batteries in accordance with local, state & federal regulations if possible.
	Temperature limit

PRODUCT SYMBOL	MEANING
	Direct Current
	Keep Dry
	Prescription Only
	Read Instructions for Use
	Caution
	Warning
	Humidity Limitation
	Atmospheric Pressure Limitation

 Waste electrical and electronic equipment; do not dispose in household waste. Dispose of equipment in accordance with all relevant local, state and federal regulations. Source: ISO15233-1

Waste electrical and electronic equipment shall not be disposed of with household waste. Dispose of the device in accordance with applicable local, state, and federal regulations. Recycle batteries in accordance with applicable local regulations whenever possible.

INSTRUCTIONS FOR USE

GETTING STARTED WITH INSEE

Indications for Use

InSee is an accessory designed for use with the AirLife® Volumetric Incentive Spirometer 4000 mL manufactured by Vyaire Medical. InSee is intended to support incentive spirometry therapy by monitoring incentive spirometer activity, tracking therapy performance, providing patient reminder alerts, and recording usage-related information. The device is intended for use in hospital environments by clinicians and patients. InSee is a non-invasive, reusable device intended for use by a single patient.

Indications and Contraindications of the incentive spirometer:

The indications for use, contraindications, warnings, precautions, and patient selection criteria of the InSee are those of the AirLife Volumetric Incentive Spirometer. Users should consult the Instructions for Use of the AirLife Volumetric Incentive Spirometer prior to use.

NOTE: Read all instructions before using InSee.

WARNING

USERS OF THE DEVICE SHOULD BE ABLE TO READ AND UNDERSTAND THE ENGLISH LANGUAGE USED IN THIS MANUAL. AN APPROXIMATE 8TH GRADE READING LEVEL OR EQUIVALENT IS RECOMMENDED.

Intended Patient Population

InSee is intended for use by patients who have been prescribed incentive spirometry therapy by a physician. InSee users include clinicians and patients within the hospital environment.

INSTRUCTIONS FOR USE

Method

InSee monitors incentive spirometer usage by tracking piston movement. Users can configure target volume settings. Recorded measurements can be cleared using the Reset button. Resetting the device restores the default settings.

CONDITIONS AND PRECAUTIONS

⚠ WARNING: IF ANY CONDITIONS EXIST THAT COULD CAUSE USE OF INSEE TO PRESENT A RISK TO THE PATIENT, DO NOT USE THE DEVICE EXCEPT AS DIRECTED BY A PHYSICIAN.

Conditions	Precautions
• Patients who cannot use the Incentive Spirometer appropriately or require supervision at all times • Patients who are noncompliant or do not understand or demonstrate proper use of the device • Very young patients or pediatrics with developmental delay • Hyperventilation or Fatigue • Hypoxaemia secondary to interruption of oxygen therapy • Patients unable to take deep breathe effectively due to pain, diaphragmatic dysfunction, or opiate analgesia. • Patients who are heavily sedated or comatose • The device is not suitable for people with severe dyspnoea.	• Hyperventilation may result from improper technique. • There is potential for barotrauma in emphysematous lungs. • Discomfort may occur secondary to uncontrolled pain. • Development of bronchospasm may occur in susceptible patients. Close monitoring of patients with hyper-reactive airways should be maintained. • Caretakers should assess patients for adverse reactions on the skin where the device has contact, such as redness (erythema), swelling (edema), irritation, sensitization (delayed Type IV hypersensitivity), allergy, immune response, or other reactions.

INSTRUCTIONS FOR USE

PRODUCT SUPPORT

Tidal Medical Technologies provides support to clinicians to assist with the setup and use of the InSee device. Support is available for:

- Attaching and configuring the InSee device
- Reviewing setup and operating procedures
- Understanding reminder alerts and display indicators
- Troubleshooting basic operational issues

For assistance, contact Tidal Medical Technologies using the contact information on page 2.

INSTRUCTIONS FOR USE

SAFETY INFORMATION

 **WARNING:** WHEN USING ELECTRICAL MEDICAL EQUIPMENT, BASIC SAFETY PRECAUTIONS SHOULD ALWAYS BE FOLLOWED. FAILURE TO FOLLOW THESE INSTRUCTIONS MAY RESULT IN PERSONAL INJURY OR DAMAGE TO THE DEVICE.

Use As Intended

- Use this product only as described in this manual
- No modification of the device is permitted
- Use only accessories approved by Tidal Medical Technologies
- Read and follow all setup, operation, and cleaning instructions
- Federal law restricts this device to sale by or on the order of a physician
- If conditions exist that prohibit use of the device, do not use the system
- If the display is not functioning properly, discontinue use of the device

YOUR ENVIRONMENT

- Do not use the device near excessive heat sources
- Do not use the device in dusty environments
- Do not use the device in high-moisture environments
- Do not immerse the device in water or other liquids
- Do not charge the device if the device, the charger, or charging cable is wet or damaged

Cleaning

Spot clean only using the instructions provided in the Clean and Store section.

INSTRUCTIONS FOR USE

BATTERIES, POWER, AND CHARGING

- Do not use extension cords during charging
- Keep charging cables away from heated surfaces
- Do not pull charging cables over sharp edges or allow cables to kink
- Do not lift the device using the charging cable
- Never disconnect the power plug with wet hands
- Charge the device only using the supplied USB-C cable and approved charger
- Do not use micro-USB, Lightning, or other incompatible charging cables
- Improper battery use may result in fire, explosion, or other hazards
- If the charger, cable, or device appears damaged, discontinue use and contact Tidal Medical Technologies

Service, Returns, and Disposal

Service and maintenance shall only be performed by authorized personnel. Do not open or attempt to disassemble the device under any circumstances.

WARNING

LITHIUM-ION BATTERIES AND DEVICES CONTAINING LITHIUM-ION BATTERIES SHALL BE DISPOSED OF IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, AND FEDERAL REGULATIONS. LITHIUM-ION BATTERIES AND PRODUCTS THAT CONTAIN LITHIUM-ION BATTERIES CAN EXPOSE YOU TO CHEMICALS INCLUDING COBALT LITHIUM NICKEL OXIDE, AND NICKEL, WHICH ARE KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER AND BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM. FOR MORE INFORMATION, GO TO www.P65Warnings.ca.gov

NOTE: If service is necessary, contact Tidal Medical Technologies using the contact information provided on page 2. Save these Instructions for Use.

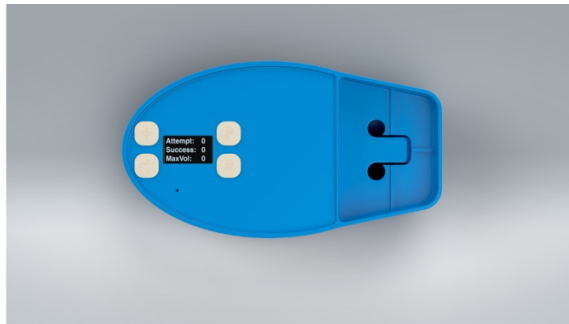
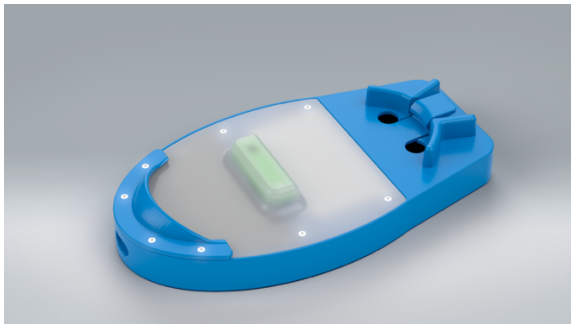
INSTRUCTIONS FOR USE

INSEE FEATURES

InSee At A Glance

When unpacking the InSee system, verify that all components are included and undamaged.

A. InSee Device



Components:

- OLED Display
- Control Buttons (+, →, P, R)
- LED Status Indicators
- Rechargeable Lithium-Ion Battery
- USB-C Charging Port
- Case and Incentive Spirometer Latch

INSTRUCTIONS FOR USE

Device Label:

INSEE INSTRUCTIONS FOR USE

(P) **Power.** Hold 5 sec

(R) **Reset.** Hold 5 sec

(+) **Set goal.** 250 to 4000mL

(→) **Next screen**

INSEE PRODUCT LABEL

InSee

REF INSEE01

SN XXXXX

 2023-05-25

 (01)10860011236402
(11)230525
(21)XXXXXX

 Tidal Medical Technologies
2024 W. 15TH ST., STE F-336,
PLANO TX 75075

DC 5.0 V  2.1A Max.

Use with Power Supply:
REF TMASKU00001

   **MD** **R_xonly**

LA195.E

INSTRUCTIONS FOR USE

B. Charger and Charging Cable

The InSee package includes a USB charger and USB-C charging cable for charging the device. Use only the charger and USB-C cable provided with the InSee device. Use of other chargers or cables may result in improper operation.



C. Documentation

A printed quick start guide for both patients and clinicians is included in the packaging. Additional product information may be available through Tidal Medical Technologies.

D. Packaging

The InSee package includes:

- InSee device
- USB charger
- USB-C charging cable
- Quick start guide

Before use, verify that all components are included and undamaged.



INSTRUCTIONS FOR USE

Battery

The InSee device contains an internal rechargeable lithium-ion battery. The battery is housed inside the device and is not user-replaceable.

 CAUTION

Use only the charger and USB-C cable provided with the InSee device.

 WARNING

NEVER ATTEMPT TO OPEN THE DEVICE OR REPLACE THE BATTERY.

 WARNING

DO NOT USE THE DEVICE FOR TREATMENT WHILE IT IS CONNECTED TO THE CHARGER.

Charging the InSee

- Charge the device using the provided USB-C cable and charger.
- Connect the USB-C cable to the charging port on the InSee device.
- Connect the charger to a power outlet.
- Allow the device to fully charge before use.
- Typical charging time is approximately 8 hours.
- The device shall not be used while charging. Keep the incentive spirometer connected to the InSee during the charge.

NOTE: Charging status is indicated by the device LED. Refer to the Visual and Audible Indicators section for LED indicator descriptions.

LED COLOR	BLINK RATE	DESCRIPTION
Green	Solid	Charging completed
Yellow	Solid	Charging

INSTRUCTIONS FOR USE

USING THE INSEE

Setting Up the InSee

 CAUTION

InSee is intended for use in hospital environments by clinicians and patients. The device should be properly attached to a compatible incentive spirometer before use. This device is only compatible with the AirLife® Volumetric Incentive Spirometer 4000 mL manufactured by Vyair Medical.

 CAUTION

Always attach the incentive spirometer before turning ON the device or performing a Reset operation. Failure to do so may result in improper operation or inaccurate measurements.

 CAUTION

Always power OFF the device before removing the incentive spirometer.

 WARNING

DO NOT CONNECT THE DEVICE TO THE CHARGER DURING THERAPY.

Before Using InSee

Before using the device:

- Follow the instructions supplied with the AirLife® Volumetric Incentive Spirometer.
- Verify that the incentive spirometer is securely attached to the InSee device.
- Verify that the device does not display any error messages.
- Ensure that the battery is sufficiently charged.
- Ensure that the device has completed its startup and calibration sequence before therapy begins.

INSTRUCTIONS FOR USE

Reading the InSee Display

InSee display has three screens. The default is on Performance screen. Press the “→” button to cycle through the screens.

Performance	Time	Configuration & Status
Attempt: 12 Success: 3 MaxVol: 1.5	12:43 Sleep Time: 20:00 - 06:00	Target: 1.5 Alert: 60 Battery: ***

Performance Screen – Default

The Performance screen is the default screen and displays the patient engagement information.

Attempt: Indicates the number of inspiratory attempts at or above 250 mL.

Success: Indicates the number of successful inspiratory attempts that meet or exceed the configured target volume.

MaxVol: Indicates the maximum achieved volume recorded since the device.



To RESET, Press the “→” button twice to get to the Configuration * Status screen, then press and hold the R button.

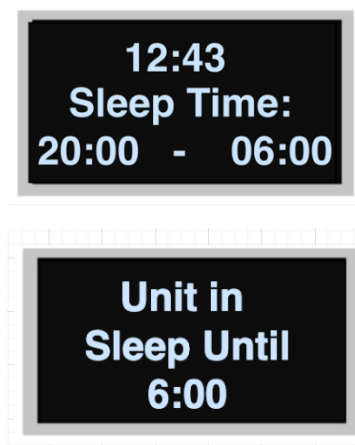
INSTRUCTIONS FOR USE

Time Screen

The Time Screen displays the preprogrammed current device time and the Sleep Time interval, in 24-hour format. The Sleep Time Interval defines the period during which the device automatically enters Sleep Mode and suspends normal operation. During the Sleep Time interval, the device displays the message: **Unit in Sleep Until hh:mm** and automatically returns to normal operation at the programmed wake-up time.

NOTE: The current time and Sleep Time interval are preprogrammed in the device and cannot be modified by the user.

NOTE: While the device is in Sleep Mode, configuration settings cannot be modified.



Configuration and Status Screen

The Configuration and Status screen displays configurable therapy settings and battery status.

- Target: Indicates the configured target volume in mL.
- Alert: Indicates the configured inactivity reminder interval in minutes.
- Battery: Indicates the battery charge status. (***) indicates full, ** . indicates medium, *. indicates low battery charge level)



Important Notes

NOTE: The Target Volume button (+) and RESET button (R) are only active when the Configuration and Status screen is displayed.

INSTRUCTIONS FOR USE

InSee Buttons

InSee contains four control buttons used to operate and configure the device.

“→” Button: Change LCD display

Cycles through the display screens in the following order: Performance screen, Time screen, and Configuration and Status screen.

Pressing the “→” button three times returns the display to the Performance screen.

“+” Button: Change target volume

Increases the target volume in 250 mL increments. The target volume can only be adjusted while in the Configuration and Status screen.

“P” Button: Power ON/OFF

Press the **P** button to power the device ON. Press and hold the **P** button for minimum of 5 seconds to power the device OFF. The incentive spirometer must be connected to the InSee while the device is OFF and turn the device ON while the incentive spirometer is connected to the InSee

“R” Button: Reset parameters

Press and hold the Reset button for approximately 5 seconds to clear data and restore default settings. Resetting the device clears: Attempts count, Success count, and Maximum recorded volume and rests the target volume to 1000 mL.



INSTRUCTIONS FOR USE

Attaching the Incentive Spirometer

Step 01: Verify that the InSee device is powered OFF.

Step 02: Align the AirLife® Volumetric Incentive Spirometer (IS) with the InSee attachment mechanism. The handle of the IS must point the front the InSee. Slip the IS front base into the front lip of the InSee.

Step 03: Insert the back base of the IS in the InSee latch. Using your thumb, press firmly on the back base of the incentive spirometer until it snaps securely into place.

Step 04: Verify that the incentive spirometer is fully seated and securely attached before operating the device.



INSTRUCTIONS FOR USE

Removing the Incentive Spirometer

Step 01 Verify that the InSee device is powered OFF.

Step 02: Press the latch to release the incentive spirometer.

Step 03: Using the spirometer handle, pull the incentive spirometer straight out of the InSee device.

Step 04: Verify that the incentive spirometer has been completely removed from the attachment mechanism.

⚠ CAUTION: Always power OFF the InSee device before removing or reinserting the incentive spirometer.



INSTRUCTIONS FOR USE

Turning the InSee ON

Step 01: Make sure the InSee is securely attached to the incentive spirometer (IS).

Step 02: Tilt the InSee+IS no more than 90 degrees & ensure the piston is in the rest position at the bottom of the IS.

Step 03: Press and hold the power (P) button for 5 seconds. LED lights will flash on the InSee and the LCD display will show “initializing...” momentarily, then place the InSee+IS upright on a flat surface for 5 seconds so it calibrates. During calibration, the InSee LED’s will flash stop, then Performance screen is displayed on the LCD. Now the InSee is ready to use.

 **WARNING**

AFTER PRESSING THE ON BUTTON MAKE SURE THE PISTON IS IN ITS REST POSITION TO ENSURE SELF CALIBRATION.

Turning the InSee OFF

Step 01: Make sure the InSee is securely attached to the IS.

Step 02: Tilt the InSee+IS no more than 90 degrees & ensure the piston is in the rest position at the bottom of the IS.

Step 03: Press and hold the power (P) button until the display turns off.

Note: The unit will save the current measurements and settings following a power down.

INSTRUCTIONS FOR USE

Resetting the InSee

The Reset function clears recorded information and restores the default device settings.

Step 01: Press the → button until the **Setting and Status Screen** is displayed.

Step 02: Press and hold the **R** (Reset) button for approximately 5 seconds.

Step 03: Release the **R** (Reset) button after the device displays "Initializing...", indicating that the reset process has started. Place the InSee+IS upright on a flat surface for 5 seconds so it recalibrates. During recalibration, the InSee LED's will flash stop, then Performance screen is displayed on the LCD. Allow the device to complete its recalibration sequence before resuming operation.

The Reset function clears the Attempts count, Success count, Maximum recorded volume

NOTE: The current time, Sleep Time interval, and Alert interval are preprogrammed in the device and are not affected by the Reset function. Following a reset, the device performs an automatic calibration sequence before returning to normal operation.

WARNING

AFTER PRESSING THE ON BUTTON MAKE SURE THE UNIT IS IN REST POSITION FOR 5 SECONDS TO CALIBRATE.

Configuring the InSee Target Volume (Goal)

Configuration settings can only be modified while the **Setting and Status Screen** is displayed.

Step 01: Press the → button until the Setting and Status Screen is displayed.

Step 02: To adjust the target volume (goal), press the + button. Each press increases the target volume setting by 250 mL.

The target volume setting may be adjusted from 250 mL up to 4000 mL. After reaching the maximum setting, the value returns to the minimum setting.

INSTRUCTIONS FOR USE

Step 03: After configuration is complete, press the → button to return to the desired display screen.

NOTE: While the Unit in Sleep Until *hh:mm* message is displayed, the device is operating in Sleep Mode. Target settings and other configuration parameters cannot be modified until the device returns to normal operating mode.

NOTE: The Alert Interval is preprogrammed in the device and cannot be modified by the user.

NOTE: The Performance screen is displayed by default following startup.

NOTE: Target setting as well all performance statistics are retained when the device is powered OFF.

INSTRUCTIONS FOR USE

STATUS AND ERROR MESSAGES

InSee displays status and error messages to notify the user of operating conditions that may require attention or corrective action.

Error messages indicate a condition that prevents normal operation and requires corrective action before therapy can continue. Status messages provide information regarding device operation and may not require user action.

Display Message	Description	LED Indication	Required Action
BATTERY CHARGING	USB charger is connected and the battery is charging.	Solid Yellow LED	Allow the battery to charge fully before use.
CHARGING COMPLETED	USB charger is connected and battery charging is complete.	Solid Green Charge Indicator LED	Battery fully charged. Charging may be discontinued.
LOW BATTERY Charge Unit	Battery charge level is too low for normal operation.	Slow Blinking Red LED	Recharge the device using the supplied charger and USB-C cable.
Unit in Sleep Until XX:XX	Device is currently in Sleep Mode and will automatically resume operation at the displayed time.	NONE	No action required.
UNIT LOCKED CALL TIDAL	Device has been locked and requires service or authorization.	Solid Red LED	Contact Tidal Medical Technologies.
NO SPIROM. Power Off / On	Incentive spirometer is not detected.	Solid Red LED	Re-attach the spirometer first, and place the unit in rest position for 5 seconds for the error to clear.
REBOOT Power Off / On	Internal system fault detected.	Solid Red LED	Turn the device OFF and make sure the spirometer is properly attached. Then, turn the device ON. If the problem persists, contact Tidal Medical Technologies.

INSTRUCTIONS FOR USE

Display Message	Description	LED Indication	Required Action
NOT READY Power Off / On	Device is unable to enter normal operating mode.	Solid Red LED	Turn the device OFF and then ON. If the problem persists, contact Tidal Medical Technologies.

NOTE: The Sleep Time and Sleep Interval are preprogrammed in the device and cannot be modified by the user.

NOTE: While the *Unit in Sleep Until XX* or *Low Battery – Charge Unit* message is displayed, the user may press the → **(Display)** button to temporarily access the Performance screen.

 **WARNING**

DO NOT USE THE DEVICE FOR THERAPY IF AN ERROR MESSAGE IS DISPLAYED.

INSTRUCTIONS FOR USE

VISUAL AND AUDIBLE INDICATORS

InSee uses display messages, LEDs, and audible indications to provide feedback regarding device status, therapy progress, and alert conditions.

Therapy Feedback Indicators

CONDITION	LED INDICATION	AUDIBLE INDICATION	DESCRIPTION
Successful Therapy Event (Target Volume Reached)	Green LED illuminates while the confirmation melody is played	Confirmation melody sounds	Confirms successful completion of a therapy attempt. That is the inhalation volume met or exceeded the configured target volume.

Reminder Alert Indicators

CONDITION	LED INDICATION	AUDIBLE INDICATION	DESCRIPTION
Inactivity Reminder Alert – First Reminder	Blinking Red LED	NA	Indicates that no qualifying therapy activity has been detected within the configured alert interval.
Inactivity Reminder Alert – Second Reminder	Blinking Red LED	Reminder melody sounds repeatedly	The reminder alert is activated when no qualifying therapy activity has been detected for the configured Alert Interval plus an additional 5 minutes.

NOTE: The Alert Interval is preprogrammed in the device and cannot be modified by the user.

NOTE: Reminder indications remain active for up to 2 minutes or until a qualifying therapy event is detected.

INSTRUCTIONS FOR USE

Charging Indicators

CONDITION	LED INDICATION	AUDIBLE INDICATION	DESCRIPTION
Battery Charging	Solid Yellow LED	None	Indicates that a USB charger is connected and battery charging is in progress?.
Battery Fully Charged	Solid Green Charge Indicator LED	None	Indicates that a USB charger is connected and battery charging is complete.

Startup Indicators

CONDITION	LED INDICATION	AUDIBLE INDICATION	DESCRIPTION
Device Startup	LEDs cycle through a startup self-test sequence	Brief startup tone	Indicates the device is powering ON and performing initialization and self-test functions.

Warning Indicator

CONDITION	LED INDICATION	AUDIBLE INDICATION	DESCRIPTION
Low Battery	Slow Blinking Red LED	None	Battery charge level is low to continue normal operation. Recharge the device before further use.

INSTRUCTIONS FOR USE

Error Indicators

CONDITION	LED INDICATION	AUDIBLE INDICATION	DESCRIPTION
No Spirometer Detected	Solid Red LED*	None	The device does not detect a compatible incentive spirometer.
Reboot Error	Solid Red LED	None	An internal system fault has been detected.
Not Ready Error	Solid Red LED	None	The device is unable to enter normal operating mode.
Unit Locked	Solid Red LED	None	The device has been locked and requires service or authorization.

(*) Refer to the Status and Error Messages for the details.

NOTE: Refer to the Status and Error Messages section for additional information regarding corrective actions associated with each displayed message.

NOTE: If service is necessary, contact Tidal Medical Technologies using the contact information provided on page 2.

INSTRUCTIONS FOR USE

Using InSee During Treatment

While using InSee for treatment, keep the following in mind:

- Always allow at least 3 seconds between each inspiratory attempt.
- When the piston reaches the target volume, the LED flashes green and a confirmation melody sounds for about one second.
- If the Alert (inactivity) interval elapses with no detected activity, the inactivity reminder activates: the LED blinks red and, if inactivity continues, a reminder melody sounds.
- To clear the reminder, take an inspiratory effort through the incentive spirometer that moves the piston past the 250 mL mark.
- Never flip or invert the unit — flipping it stops the device from recording.
- Each inspiratory attempt that exceeds 250 mL increases the Attempts count on the display.
- Each inspiratory attempt that reaches or exceeds the target volume increases the Success count on the display.

 **WARNING** — BEFORE USING INSEE READ AND FOLLOW THE INSTRUCTIONS FOR THE INCENTIVE SPIROMETER.

 **CAUTION** — Do not press against the lever, as it may cause the incentive spirometer to pop out, resulting in error message.

INSTRUCTIONS FOR USE

CLEAN AND STORE

- A. Using a Super Sani-Cloth Wipe, wipe the device to remove visible soil.
 - Visually inspect the device for any residual soil.
 - Use additional wipes as necessary to remove all residual soil.
- B. Using a new Super Sani-Cloth, wipe the article and allow the surface to remain wet for 2 minutes.
 - Multiple wipes may be used to ensure the 2-minute contact time.
- C. Allow the article to air dry before use.

CAUTION

- Do not immerse in liquid
- Do not autoclave

The **InSee** has been tested for compatibility with cleaning with Supper Sani Cloth sanitizing wipes. When cleaning, ensure that InSee is unplugged from all power sources.

DO NOT submerge InSee in water or any solution

NOTE: ADHERING TO THE CLEANING PROCESS DESCRIBED IN THIS SECTION WILL NOT DEGRADE OR DAMAGE THE InSee DEVICE.

 **WARNING — NEVER ATTEMPT TO OPEN THE INSEE DEVICE. DOING SO VOIDS ANY AND ALL WARRANTY PROTECTION. THE POTENTIAL FOR ELECTRICAL SHOCK EXISTS WITH ELECTRICAL EQUIPMENT. UNPLUG THE UNIT FROM ITS POWER SOURCE PRIOR TO CLEANING.**

 **WARNING — USE CLEANING PRODUCTS IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS. INSPECT THE PRODUCT BEFORE EACH USE. IN ADDITION, AFTER EACH CLEANING CYCLE, VISUALLY INSPECT EACH COMPONENT FOR ANY WEAR, TEAR, OR DEFORMITY. IF YOU HAVE ANY CONCERN ABOUT A COMPONENT, DO NOT USE IT AND CONTACT TIDAL MEDICAL TECHNOLOGIES FOR MORE INFORMATION.**

INSTRUCTIONS FOR USE

STORAGE AND TRANSPORT

 **CAUTION** — Retain the original packaging material. If shipping is required, the original packing material provides the best protection for the InSee system.

Between uses, you should keep InSee out of:

- Direct sunlight
- Wet or humid conditions
- Extreme temperatures

Please also see **Storage and Transportation Environment** Section.

INSTRUCTIONS FOR USE

SERVICE

 **WARNING** — ONLY AUTHORIZED PERSONS SHOULD SERVICE THE INSEE SYSTEM OR REPLACE ANY PARTS. SERVICE BY UNAUTHORIZED PERSONS CAN PLACE THE USER AT CONSIDERABLE RISK AND MAY DAMAGE THE INSEE SYSTEM.

 **WARNING** — ITEMS NOT SPECIFIED AS PART OF THE DEVICE IN THIS MANUAL SHOULD NOT BE CONNECTED TO THE DEVICE.

While it's unlikely that you'll need any maintenance on your InSee system, all maintenance related issues and questions should be directed to Tidal Medical Technologies using the contact information found on page 2.

There are NO servicing and/or maintenance activities that can be performed by the users themselves. DO NOT attempt to perform any servicing and/or maintenance on the device before, during, or after use.

INSTRUCTIONS FOR USE

EXPECTED LIFE

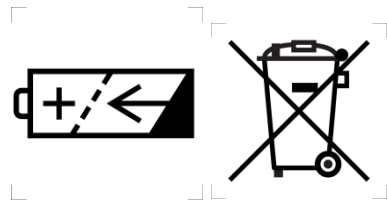
With proper care, your InSee will reward you with a trouble-free service life of approximately 2 years.

DISPOSAL

⚠ WARNING — DISCARD THE INSEE PRODUCT IN ACCORDANCE WITH YOUR LOCAL GOVERNMENT REGULATIONS.

Electrical and electronic products must be disposed of separately from any household waste at the end of their service. To ensure that these products are recycled effectively, deposit them at municipal collection points for recyclable materials where they may be accepted free of charge.

Correct disposal of products will help protect the environment and avoid harmful effects to human beings and the environment that may arise from incorrectly handling devices at the end of their service life. Please contact local authorities to determine the proper method of disposal.



INSTRUCTIONS FOR USE

SPECIFICATIONS

General Information

Parameter	Specification
Weight	4.2 oz
Dimensions	6.24 in × 3.45 in × 0.98 in
Viewable Display Area	23.96 mm × 13.08 mm
User Controls	Power Button, Display Change Button, Reset Button, Target Volume Button
Accessories	USB Charger, USB-C Cable, Quick Start Guide
Compatible Incentive Spirometer	AirLife® Volumetric Incentive Spirometer 4000 mL, manufactured by Vyair Medical
Power Source	Rechargeable Lithium-Ion Battery (2500 mAh)
Rechargeability	Rechargeable using USB-C
Battery Life per Charge	72 hours
Battery Charging Cycles	450
Charge Time	Approximately 8 hours
Service Life	2 years
Measurement Resolution	250 mL increments

Power Supply

Model: TMaskU00001

Specification: Input Voltage: 100V AC-240V AC, Input Current: 0.2 A @ 115 V AC,
Frequency: 0.15 A @ 230 VA, 50Hz/60Hz

INSTRUCTIONS FOR USE

Storage Environment

Parameter	Specification
Temperature	-5°C to +30°C (23°F to 86°F)
Relative Humidity	Up to 20% RH, non-condensing
Storage Duration	30 days

Transportation Environment

Parameter	Specification
Temperature	0°C to +40°C (32°F to 104°F)
Relative Humidity	Up to 90% RH, non-condensing
Transportation Duration	72 hours

Operating Environment

Parameter	Specification
Temperature	+10°C to +30°C (50°F to 86°F)
Relative Humidity	30% to 75% RH, non-condensing
Intended Environment	Indoor Hospital Environment

Classifications and Standards

Parameter	Specification
Safety Classification	Class II
Battery Compliance	IEC 62133-2:2017/AMD1:2021
Device Safety Standard	IEC 60601-1:2005 + Amendment 1:2012 + Amendment 2:2020 (Edition 3.2)

INSTRUCTIONS FOR USE

Parameter	Specification
Device Labeling Symbols	ISO 15223-1

NOTE: The device maintains safety and performance only when used, stored, and transported within the environmental conditions specified above.

 WARNING

USE ONLY THE CHARGER AND USB-C CABLE SUPPLIED WITH THE DEVICE. USE OF OTHER CHARGERS OR CABLES MAY RESULT IN IMPROPER CHARGING OR DAMAGE TO THE DEVICE.

INSTRUCTIONS FOR USE

TROUBLESHOOTING

The following table provides guidance for resolving common issues that may occur during normal operation of the InSee system.

Problem	Corrective Action
No Spirometer – Power Off / On message is displayed.	Reinsert the incentive spirometer fully. The device may automatically detect the spirometer and resume normal operation. If the message remains displayed or the LEDs start blinking, turn the device OFF and then ON.
Low Battery – Charge Unit message is displayed.	Connect the device to the supplied charger and allow the battery to charge fully.
Reboot – Power Off / On message is displayed.	Make sure the spirometer is inserted in the device properly. Turn the device OFF and then ON. If the problem persists, contact Tidal Medical Technologies.
Not Ready – Power Off / On message is displayed.	Make sure the spirometer is inserted in the device properly. Turn the device OFF and then ON. If the problem persists, contact Tidal Medical Technologies.
Unit Locked – Call Tidal message is displayed.	Contact Tidal Medical Technologies.
The startup LED sequence completes, but the display remains blank or does not respond.	Press and hold the Power Button for 5 seconds to turn the device OFF. Wait 5 seconds, then turn the device ON.
The device begins the startup sequence but turns OFF before startup is complete.	Connect the device to the supplied charger and allow the battery to charge.
The device does not turn ON when the Power Button is pressed.	Connect the device to the supplied charger and allow the battery to charge.
The device does not fully charge.	If the device does not fully charge after approximately 8 hours of charging, contact Tidal Medical Technologies for service.

⚠ WARNING: ONLY AUTHORIZED PERSONNEL SHALL SERVICE THE INSEE SYSTEM OR REPLACE ANY PARTS. IF SERVICE OR MAINTENANCE IS REQUIRED,

INSTRUCTIONS FOR USE

CONTACT TIDAL MEDICAL TECHNOLOGIES USING THE CONTACT INFORMATION PROVIDED ON PAGE 2.

 **WARNING:** ALWAYS INSERT THE INCENTIVE SPIROMETER BEFORE TURNING THE DEVICE ON. ALWAYS TURN THE DEVICE OFF BEFORE REMOVING THE INCENTIVE SPIROMETER.

INSTRUCTIONS FOR USE

EMC SPECIFICATIONS

This section specifies special precautions regarding EMC and needs to be installed and put into service.

⚠ WARNING — 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 TIDAL MEDICAL TECHNOLOGIES INSEE, MODEL INSEE, INCLUDING CABLES SPECIFIED BY THE MANUFACTURER. OTHERWISE, DEGRADATION OF THE PERFORMANCE OF THIS EQUIPMENT COULD RESULT.

⚠ WARNING — A RISK OF INCREASED EMISSIONS OR DECREASED IMMUNITY MAY RESULT IF ANY ADDITIONAL CABLES ARE ATTACHED.

⚠ WARNING — THIS DEVICE HAS NOT BEEN TESTED FOR COMPATIBILITY WITH ALL OTHER POSSIBLE RF EMITTERS SUCH AS X-RAY, METAL DETECTORS, ELECTROSURGICAL EQUIPMENT, DIATHERMY EQUIPMENT, 5G CELLULAR, NFC, WPT, OR ELECTRONIC ARTICLE SURVEILLANCE (EAS) DEVICES. CAUTION SHOULD BE USED IF SUCH EMITTERS ARE PRESENT WITHIN THE USE ENVIRONMENT.

⚠ WARNING

USE OF THIS EQUIPMENT ADJACENT TO OR STACKED WITH OTHER EQUIPMENT SHOULD BE AVOIDED BECAUSE IT COULD RESULT IN IMPROPER OPERATION. IF SUCH USE IS NECESSARY, THIS EQUIPMENT AND THE OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THAT THEY ARE OPERATING NORMALLY.

⚠ WARNING

USE OF ACCESSORIES, TRANSDUCERS, AND CABLES OTHER THAN THOSE SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THIS EQUIPMENT COULD RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THIS EQUIPMENT AND RESULT IN IMPROPER OPERATION.

INSTRUCTIONS FOR USE

Guidance and Manufacturer's Declaration Electromagnetic Emissions

The Tidal Medical Technologies InSee, model InSee is intended for use in the electromagnetic environment specified below. The customer or the user of the Tidal Medical Technologies InSee, model InSee should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Tidal Medical Technologies InSee, model InSee uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Tidal Medical Technologies InSee, model InSee is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public 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 Tidal Medical Technologies InSee, model InSee or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

INSTRUCTIONS FOR USE

Guidance and manufacturer's declaration – electromagnetic immunity

The Tidal Medical Technologies InSee, model InSee is intended for use in the electromagnetic environment specified below. The customer or the user of the Tidal Medical Technologies InSee, model InSee should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+8kV contact +15kV air	+8kV contact +15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+2kV for power supply lines	+2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	+1kV line(s) to line	+1kV line(s) to line	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Tidal Medical Technologies InSee, model InSee requires continued operation during power mains interruptions, it is recommended that the Tidal Medical Technologies InSee, model InSee be powered from an uninterruptible power supply or a battery.

INSTRUCTIONS FOR USE

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the A.C. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The Tidal Medical Technologies InSee, model InSee is intended for use in the electromagnetic environment specified below. The customer or the user of the Tidal Medical Technologies InSee, model InSee should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF	3 Vrms 0,15 MHz – 80 MHz	3 Vrms 0,15 MHz – 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Tidal Medical Technologies InSee, model InSee, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [3.5/10] \sqrt{\sqrt{P}}$ 80 MHz to 800 MHz $d = [7/10] \sqrt{\sqrt{P}}$ 800 MHz to 2.7 GHz
IEC 61000-4-6	6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	

INSTRUCTIONS FOR USE

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Tidal Medical Technologies InSee, model InSee is used exceeds the applicable RF compliance level above, the Tidal Medical Technologies InSee, model InSee should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Tidal Medical Technologies InSee, model InSee.			

INSTRUCTIONS FOR USE

Guidance and manufacturer's declaration – electromagnetic immunity

The Tidal Medical Technologies InSee, model InSee is intended for use in the electromagnetic environment specified below. The customer or the user of the Tidal Medical Technologies InSee, model InSee should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
IMMUNITY to proximity fields from RF wireless communications equipment	MHz / Modulation / Field Strength: 385 / 18 Hz / 7 V/m; 450 / 18 Hz / 28 V/m; 710 / 217 Hz / 9 V/m; 745 / 217 Hz / 9 V/m; 780 / 217 Hz / 9 V/m; 810 / 18 Hz / 28 V/m; 870 / 18 Hz / 28 V/m; 930 / 18 Hz / 28 V/m; 1720 / 217 Hz / 28 V/m; 1845 / 217 Hz / 28 V/m; 1970 / 217 Hz / 28 V/m; 2450 / 217 Hz / 28 V/m; 5240 / 217 Hz / 9 V/m; 5500 / 217 Hz / 9 V/m; 5785 / 217 Hz / 9 V/m; 0.1342 / 2.1kHz / 65 A/m; 13.56 / 50kHz / 7.5 A/m; 0.030 / CW / 8 A/m	MHz / Modulation / Field Strength: 385 / 18 Hz / 27 V/m; 450 / 18 Hz / 28 V/m; 710 / 217 Hz / 9 V/m; 745 / 217 Hz / 9 V/m; 780 / 217 Hz / 9 V/m; 810 / 18 Hz / 28 V/m; 870 / 18 Hz / 28 V/m; 930 / 18 Hz / 28 V/m; 1720 / 217 Hz / 28 V/m; 1845 / 217 Hz / 28 V/m; 1970 / 217 Hz / 28 V/m; 2450 / 217 Hz / 28 V/m; 5240 / 217 Hz / 9 V/m; 5500 / 217 Hz / 9 V/m; 5785 / 217 Hz / 9 V/m; 0.1342 / 2.1kHz / 65 A/m; 13.56 / 50kHz / 7.5 A/m; 0.030 / CW / 8 A/m	Portable and mobile RF communications equipment should be used no closer to any part of the Tidal Medical Technologies InSee, model InSee, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $E = [6/d] \sqrt{\sqrt{P}}$, $d = [6/E] \sqrt{\sqrt{P}}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in

INSTRUCTIONS FOR USE

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
			the vicinity of equipment marked with the following symbol:

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

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the Tidal Medical Technologies InSee, model InSee.

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

Rated maximum output power of transmitter (W)	80 to 800 MHz $d = [3.5/3] \sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3] \sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9] \sqrt{P}$	385, 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28] \sqrt{P}$
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

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

INSTRUCTIONS FOR USE

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

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

Supplier's Declaration of Conformity 47 CFR § 2.1077
Compliance Information

INSTRUCTIONS FOR USE

PRODUCT IDENTIFICATION: InSee, model InSee

RESPONSIBLE PARTY (U.S. Contact Information required):

Tidal Medical Technologies
2024 W. 15th St., Ste. F-336
Plano, TX 75075

CONTACT NAME: Mehdi Arani

TELEPHONE NUMBER AND/OR E-MAIL ADDRESS: 214.864.5629 /
Mehdi@tidalmed.tech

FCC COMPLIANCE STATEMENT:

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

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

THIRD PARTY TESTING:



16740 Peters Road
Middlefield, OH 44062 USA
Phone: 440.632.5541
Fax: 440.632.5542
Toll Free: 877.405.1580

www.f2labs.com

INSTRUCTIONS FOR USE

Scan the QR code or go to <https://www.TidalMed.Tech/support>

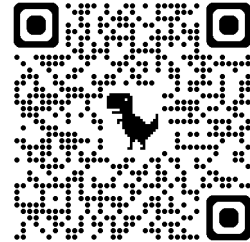
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