User Guide
Innobyte™

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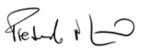
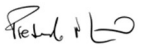
REVISION TABLE

Revision	Date modified	Modified by	Signature	Changes
KI_P_101 _V18	2023/05/18	Frederik Marcil, ing 5020748		Modifications to include the bilateral mouthpiece and its functionality
KI_P_101 _V19	2024/04/10	Frederik Marcil, ing 5020748		Modifications to update the contact information

1. CONSIDERATIONS

1.1 Getting Assistance:

Kube Innovation Inc. will provide technical assistance for your Innobyte™ for a period of 365 days following the date on which you received your device.

For any, issue, inquiry or product-related comments you can contact us at:

Kube Innovation Inc.
5524 Saint-Patrick, unit 315
Montreal, Qc, H4E 1A8
Phone: +1 (800) 511-8792
E-mail: info@kubeinnovation.com

Or visit our website at: www.kubeinnovation.com

1.2 Declaration of Conformity:

Kube Innovation Inc. is certified ISO 13485:2016 MDSAP.
Certificate number: 0098685
The Innobyte™ has been tested and conforms to the following standards for a "Medical Non-Active Measuring Device".

Canada:

Health Canada License: Class II medical device system (License #101055)
Components/Parts/Accessories/Devices for this Licence:
INNOBYTE ™:
Device ID: 1000820
Device Identifier: INNOCA01, INNOCP03
MOUTHPIECE:
Device ID: 1000821
Device Identifier: INNOMP01, INNOMP03

United States of America:

FDA: Title 21 CFR 888.1240, AC-Powered Dynamometer, Regulatory Class II (LBB)
(Registration # 3016076693)
Device Listing Number: D447457
INNOBYTE™:
Device Identifier: INNOCA01, INNOCP03
MOUTHPIECE:
Device Identifier: INNOMP01, INNOMP03

Safety standard:

- CSA 22.2 IEC 60601-1 3Rd Ed
- UL IEC 60601-1 3Rd Ed

EMC standard:

- IEC60601-1-2 4th Ed.

EMC Test standards and methods:

CISPR 11:2009 + A1:2010: Radiated radio frequency (RF) Emissions
IEC 61000-4-3:2006 + A1:2007 + A2:2010: Radiated RF EM Field
IEC 61000-4-3:2006 + A1:2007 + A2:2010: Proximity fields from RF wireless communication equipment
IEC 61000-4-2:2008: Electrostatic Discharge
IEC 61000-4-6:2013: Conducted disturbances induced by RF fields
IEC 61000-4-8:2009: Power-Frequency Magnetic Field

EMC Test Parameters

CISPR 11:2009 + A1:2010: Group 1, Class B Device

IEC 61000-4-3:2006 + A1:2007 + A2:2010: 3V/m, 80MHz to 2.7GHz, 80% AM at 1kHz

IEC 61000-4-3:2006 + A1:2007 + A2:2010: See Table 1

IEC 61000-4-2:2008: ±8kV contact, ±15kV air

IEC 61000-4-6:2013: 3V/m, 6V/m in ISM band, 150kHz to 80MHz, 80% AM at 1kHz

IEC 61000-4-8:2009: 30A/m, 50Hz and 60Hz

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

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

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Table 1. ISM Band Immunities

1.3 Warning and Contraindications:

1. There are no user serviceable parts. Do not service or take apart the Innobyte™ hardware. If the device does not perform as expected, contact Kube Innovation Inc.
2. Battery: do not attempt to replace the Innobyte™ battery yourself; you may damage the battery and cause overheating and/or injury. The Innobyte™'s lithium-ion battery should only be replaced or recycled by Kube Innovation Inc. It must be recycled or disposed of separately from household waste.
3. Do not use autoclave or heat to sterilize the mouthpiece. The use of standard disinfection products approved for medical use under the norms published by Health Canada and FDA are recommended.
4. Do not use the device if there is any visible damage to the charging or the connecting cable.
5. Medical equipment, such as the Innobyte™, needs specific precautions and considerations regarding electromagnetic interference (EMI). These can be found in Table 2.
6. Portable and mobile RF communication equipment can affect the medical device.
7. The use of cables and accessories not provided by Kube Innovation Inc. can disturb the RF emission and immunity of the device.
8. Never attach or use any third-party instruments or components to the Innobyte™ that are not provided and approved by Kube Innovation Inc.
9. EMI and/or electro-static discharge (ESD) can cause the device to become unresponsive. If this occurs, reset the device by inserting a small object at the back of the device to depress the reset button. If the issue persists after a reset, contact Kube Innovation Inc.
10. Use of the Innobyte™ adjacent to or stacked with other equipment should be avoided. This could result in improper operation. If such use is necessary, these respective pieces of equipment should be observed to verify their operational functionality.
11. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be kept at least than 30 cm (12 inches) away from any part of the Innobyte™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
12. When first unpacking the Innobyte™, the device needs to charge for at least 3 hours.

13. The Innobyte™ should only be used by health professionals such as dentists or denturists in healthcare facilities.
14. The Innobyte™ is not indicated in the investigation of the strength of any other muscle or muscle group besides the oral facial muscles.
15. The Innobyte™ is not used to diagnose illnesses. The data acquired should be interpreted by the professional using it.
16. Operating and transport conditions are specified in Table 4.
17. The Innobyte™ is not indicated for the diagnosis of bruxism, temporo-mandibular joint disorders, or periodontal diseases.
18. The Innobyte™ is not indicated for use with sharped damaged teeth.
19. The Innobyte™ must have antagonistic contact with all teeth.
20. The Innobyte™ has no essential performance characteristics in any fail mode. A hard reset should solve most issues. Contact Kube Innovation Inc. if the issue persists.
21. Do not charge the Innobyte™ while in use.
22. Do not service or perform any preventive maintenance on any components of the Innobyte™. Maintenance or service shall only be performed by Kube Innovation Inc.
23. Avoid covering or placing the Innobyte™ in an enclosed space while charging.
24. Do not charge the mouthpiece component of the device with the Lemo/USB cable.
25. Remove any debris and/or liquid from the Lemo connector port prior to use.
26. Do not leave mouthpiece component in the mouth for longer than 30 seconds.

Precaution	Test and Compliance	Electromagnetic Environment - Guidance
RF Emissions	CISPR11 Group 1, Class B	**1.** The Innobyte™ uses RF energy only for its internal circuitry. As such, the RF emissions of the device are very low and unlikely to cause any disturbance in nearby equipment. **2.** Due to its classification, the Innobyte™ can be used in any professional care environment with the exception of settings containing high frequency (HF) surgical equipment or RF shielded rooms.
Immunity Tests	IEC 61000-4-3:2006 IEC 61000-4-2:2008 IEC 61000-4-8:2009 IEC 61000-4-6:2013	**1.** The device operates at relatively low frequencies compared to the ISM's. As such, it is unlikely that any device in the ISM range should disrupt the Innobyte™. As a measure of precaution, do not use the Innobyte™ at a distance of less than 30 cm from any device operating in the ISM band. **2.** Due to its classification, the Innobyte™ can be used in any professional care environment with the exception of settings containing high frequency (HF) surgical equipment or RF shielded rooms. **3.** Should the Innobyte™ be subject to EMI, it has no essential performance characteristics. In such cases the device would simply freeze and resetting it should fix the issue.

Table 2. Immunity and Emissions Considerations

1.4 Sanitary precautions:

Use latex or nitrile gloves in order to handle the mouthpiece with care. The polyethylene disposable covers must be stored at room temperature, in a clean environment, away from all potential sources of contamination.

1.5 Storage:

The device must be kept dry in a clean environment. Prolonged UV exposure must be avoided.

Temperature	**5 to 35˚C (41 to 95F)**
Pressure	100 to 110 kPa
Humidity	20% to 95%

Table 3. Storage and Transport Conditions

1.6 Allergies:

If a patient indicates that he is allergic to silicone in any form, it is the responsibility of the health professional not to use the device, even though the silicone is covered by a polyethylene disposable cover. The medical form is a document that every patient needs to complete and update when appropriate. **Not made with natural rubber latex**.

1.7 Pain & Bleeding:

The health professional assumes the responsibility of using the device with consideration given to the patient's condition. The patient can have sensitive gums, for instance, which could cause pain or bleeding when biting the mouthpiece. Pain is a limiting factor that should be taken into account by the health professional.

1.8 How to dispose of the Innobyte™:

When the device's electrical component no longer powers on and/or the mouthpiece failed (see Section 1.9), the health professional is responsible for its adequate disposal at appropriate electronic recycling centers.

1.9 Reprocessing Instructions:

The Innobyte™ is a reusable medical device that must be reprocessed after use in patients. The Innobyte™ mouthpiece is always intended to be used in conjunction with the single-use disposable covers provided in the device packaging. Following patient measurement, the process below should be used

to limit patient contamination with harmful pathogens that may be introduced to the surface of the mouthpiece during use (always use caution when performing cleaning and disinfecting procedures):

1. Use latex or nitrile gloves while handling the mouthpiece after patient use to limit contamination of the surface.
2. Disassemble the device by unplugging the mouthpiece from the Lemo connector and carefully remove the disposable cover.
3. Discard the disposable cover in the appropriate waste container. Do not reuse the disposable cover.
4. Place the mouthpiece apart from possible sources of contamination.
5. Thoroughly clean all surfaces of the mouthpiece immediately with water, a brush, and instrument-grade detergent. Do not submerge any part of the device in a bath of liquid.
6. Rinse the surface of the mouthpiece with clean water and place it on a clean, dry surface apart from possible sources of contamination. Take care not to trap water in the Lemo connector port.
7. Wipe all visible surfaces of the mouthpiece with gauze soaked in 70% iso-propyl alcohol.
8. Ensure that all external surfaces of the mouthpiece are thoroughly dried prior to subsequent steps.
9. Inspect the device for any soiling with sufficient lighting and magnification. If any area is soiled, repeat process 4 - 7.
10. Inspect the device for leaks, cuts, and cracks as above. If present, the mouthpiece has failed and should be disposed (see Section 1.8).
11. If the mouthpiece has been contaminated during use, a high-level disinfection or sterilization process should be used. Do not place any parts of the device in a heated sterilization cycle.

1.10 High-level Disinfection Instructions:

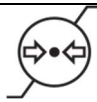
A high-level disinfection of the mouthpiece is required between each use to render it safe for subsequent patient use. Kube Innovation Inc. recommends using a high-level disinfectant such as Revital-Ox® RESERT® or 2% hydrogen peroxide. Follow the manufacturer's guidance for safe handling and use of High-level disinfectants. Below are the manufacturer's recommended processing conditions for Revital-Ox® RESERT®:

Contact Time	8 minutes
Temperature	20 °C / 68°F
Reusability	21 days
Rinse	Once with clean, sterile water

Table 4. Revital-Ox® RESERT® recommended processing conditions

1.11 Markings and symbols:

	This sign represents a general warning symbol. In this case, it is used for the warnings section of this document.
	This sign indicates that the device presents an allergic risk. In this case, the silicone used for the mouthpiece might represent an allergic risk.
	This sign indicates that the device cannot be disposed of in the garbage due to the materials used in its construction.
	This sign indicates that the device contains Type B applied parts.
	This sign indicates the device manufacturer.
	This sign indicates the date when the device was manufactured.
	This sign indicates the manufacturer's serial number so that a specific medical device can be identified.
	This sign indicates that the device has been tested for compliance with IEC60601 by Nemko Inc.
	This sign indicates that the device is subjected to the specified temperature limits.
	This symbol indicates to not reuse the part.
	This symbol indicates that it is mandatory to refer to the instruction manual before using the device.

	This label indicates that the device needs to be protected from moisture.
	This label indicates that the device is fragile.
	This label indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	This label indicates the range of relative humidity to which the medical device can be safely exposed.
	This label indicates: Caution: Federal law restricts this device to sale by or on the order of a Dentist or denturist. (USA only)

1.12 Warranty:

Kube Innovation Inc. - Limited 1-Year warranty

1. SHALL THE DEVICE PRESENT ANY DAMAGE, MALFUNCTION OR NOT MEET THE EXPECTED OPERATING CONDITIONS AS A RESULT OF IMPROPER WORKMANSHIP OR DEFECTIVE MATERIALS, Kube Innovation Inc. warrants the purchaser of this device:

A. Innobyte™ Main Device

The device functionality is covered for a period of one (1) year. In case any of the aforementioned issues occur, Kube Innovation Inc. will inspect the device and establish if it can be repaired or replaced by another device. All costs incurred, including shipping, will be covered by Kube Innovation Inc. except for cases where it is deemed that the damage or malfunction was caused by the purchaser's improper use of the device, then the purchaser will be responsible for all incurred costs. The repaired or replaced device will then be covered for the remainder of the original warranty.

B. Mouthpiece

The mouthpiece is covered for a maximum number of one thousand (1000) cycles[1]. In case any of the aforementioned issues occur, Kube Innovation Inc. will inspect the mouthpiece and establish if it can be repaired or replaced by

[1] A cycle is recorded when more than sixty (60) Newton of force is applied to the mouthpiece

another mouthpiece. All costs incurred, including shipping, will be covered by Kube Innovation Inc. except for cases where it is deemed that the damage or malfunction was caused by the purchaser's improper use of the mouthpiece, then the purchaser will be responsible for all incurred costs. The repaired or replaced mouthpiece will then be covered for the remainder of the original warranty.

C. Cable Assemblies

All cable assemblies are covered for a period of one (1) year. In case any of the aforementioned issues occur, Kube Innovation Inc. will inspect the cable and establish if it can be repaired or replaced by another cable. All costs incurred, including shipping, will be covered by Kube Innovation Inc. except for cases where it is deemed that the damage or malfunction was caused by the purchaser's improper use of the cable, then the purchaser will be responsible for all incurred costs. The repaired or replaced cable will then be covered for the remainder of the original warranty.

D. Wall charging adaptor

The wall charging adaptor is covered for a period of one (1) year. In case any of the aforementioned issues occur, Kube Innovation Inc. will replace the wall charging adaptor with a new one. All costs incurred, including shipping, will be covered by Kube Innovation Inc. except for cases where it is deemed that the damage or malfunction was caused by the purchaser's improper use of the charging adaptor, then the customer will be responsible for all incurred costs. The repaired or replaced charging adaptor will then be covered for the remainder of the warranty.

2. THIS WARRANTY DOES NOT COVER defects caused by modifications, alterations or repairs handled by anyone other than a Kube Innovation Inc. technician. Any physical abuse, misuse, liquid damage or operation in a manner contrary to recommended use will void the warranty. In addition, if the device and/or any of the above-mentioned accessories is resold without Kube Innovation Inc's. consent, then all warranty and safety responsibilities will be nullified.

3. TO OBTAIN WARRANTY SERVICE, contact Kube Innovation Inc. at +1 (514) 400-3713. If instructed to ship the device to Kube Innovation Inc., the company will be responsible for the shipping costs. Thereafter, if it is deemed that the issue is

not covered under the warranty, the purchaser shall repay Kube Innovation Inc. for said shipping costs.

2. INTRODUCTION

Although an essential tool for general assessment of one's bite force, the Innobyte™ is not intended to diagnose conditions. It is therefore mandatory that the person using the Innobyte™ and analyzing the collected data is a qualified clinician such as a dentist, denturist or health professional. Using their knowledge and professional skills, the clinician can adequately assess the condition of a patient. It is important to note that the Innobyte™ does not require any additional training to operate the device. The following key factors specify the main conditions of operation of the Innobyte™.

User profile: The Innobyte™ is intended to be used by a qualified professional, such as a dentist, denturist or other health professional.

Patient population: The Innobyte™ is intended to be used in order to assess the maximal bite force of the general population, with exception to pediatric patients (18 years of age and younger).

Medical purpose: The intended use of the Innobyte™ is primarily to measure the maximal bite force of patients.

Indication for Use: The Innobyte™ is a measurement device for dental clinicians in the quantitative evaluations of a patient's bite strength.

3. SYSTEM OVERVIEW

The mouthpiece, being the only applied part, is used to measure the bite force applied by human teeth. In order to achieve this measurement, the mouthpiece contains a fluid. When a force is applied to the mouthpiece, it transmits the applied force throughout the medium which is then read by the sensors. Thereafter, each mouthpiece is calibrated to correlate the pressure with an applied force in Newtons. Although every mouthpiece has slightly different characteristics, the accuracy under the conditions described in the technical specifications is verified to be within 5% for a range of 0 to 2000N.

As showcased in the following sections, the Innobyte™ has a minimalistic design. Its user interface is comprised of an LED screen and a multi-function capacitive sensor.

3.1 Components:

Each Innobyte™ system is provided with the following components. For a more thorough understanding, Figure 1 identifies a Innobyte Clinical Package (INNOCA01 or INNOCP03):

1. One (1) Innobyte™ Main Device (INNO_05)
2. One (1) Mouthpiece (INNOMP01 or INNOMP03)
3. One (1) Lemo/Lemo cable used to connect the mouthpiece
4. One (1) Lemo/USB cable used to charge Innobyte™
5. One (1) Wall adaptor
6. One hundred (100) Disposable Covers for the mouthpiece

Figure 1. Innobyte™ Main Device (INNO_05)[2]

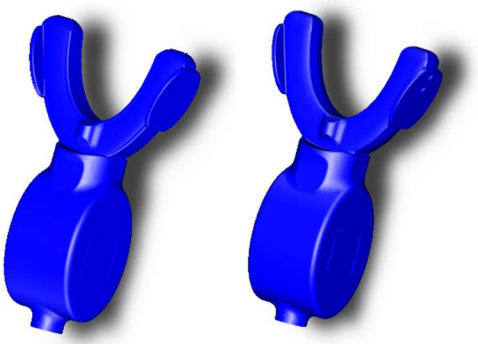


Figure 2. Mouthpiece (left: INNOMP01, right: INNOMP03)[2]

[2] Components may appear different from illustrations

Figure 3. Lemo/Lemo Cable[3]

Figure 4. Lemo/USB Cable[3]

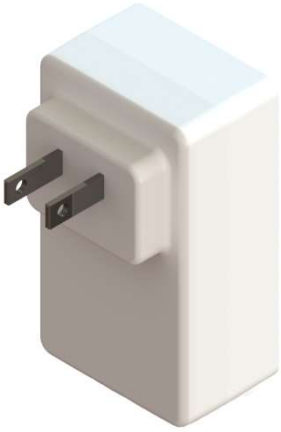


Figure 5. Wall charging adaptor[3]

4. SET-UP PREPARATION

4.1 Measurement recording set-up:

In order to perform recordings of the patient's bite force, the mouthpiece (Figure 2) needs to be connected to the Innobyte™ through the Lemo/Lemo cable (Figure 3). The connecting cable is bidirectional, meaning that it can be connected in any way. However, in order to comply with Immunity Standards, a ferrite (1) as shown in Figure 6, is clipped on the cable (2). Therefore, the end of the cable containing the ferrite must be connected closest to the Innobyte™.

[3] Components may appear different from illustrations

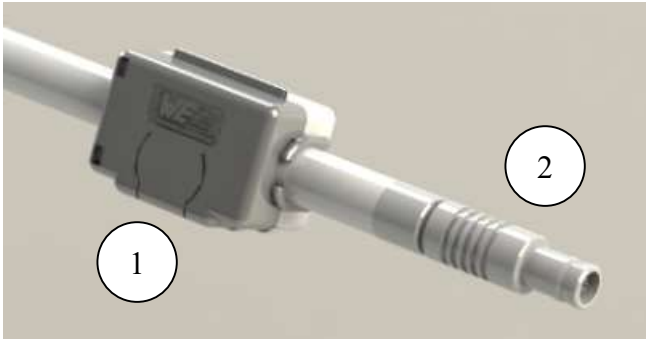


Figure 6. Mouthpiece Cable Ferrite[4]

In order to ensure durability and avoid possible damage caused by misconnections, the Lemo connectors feature a hardware keying for insertion. In order to properly connect them, the red dot of the plug, shown in Figure 7, needs to be aligned with the connecting component.

Figure 7. Lemo Connector Keying[4]

Under normal operational conditions, it is estimated that the device has a battery life of 21 hours if it is kept on all the time. However, as explained in the Normal Operation section, after a period of 5 minute of inactivity, the device enters into a sleep mode. In sleep mode, it is estimated that the device should last approximately 5 days without recharge. For good practice, please recharge the device at least every 2 days, depending on the usage. Table 5 summarizes the expected battery autonomy under different conditions.

[4] Components may appear different from illustrations

Condition	Autonomy
ON	21 hours
Standby	5 days
Mixed	2 days

Table 5. Battery Life Estimation

4.2 Charging set-up:

In order to charge the Innobyte™ you will need the wall adaptor (5) and the Lemo/USB cable (4). On one end of the Lemo/USB cable you will have a male USB connector. This USB connector should be inserted into the wall adaptor. The wall adaptor is an AC/DC power supply provided.

On the opposite end of the Lemo/USB cable, you will find the Lemo connector. To connect this to the Innobyte™, you must follow the guide given in the Device Operation section (page 19). This end outputs 5 VDC, for a maximum rating of 12W. Therefore, it is deemed suitable to use a power supply at 50% duty cycle.

Please note, the device can also be charged from a PC USB port. However, it is not guaranteed the device will charge at the specified rate considering the maximum power that can be delivered by a PC USB is 2.5W, and as such, would take double the estimated time to charge the Innobyte™. Table 6 summarizes the time to fully charge the Innobyte™ based on the power supply used.

Power Supply	Time to full charge
Innobyte wall adaptor	3 hours
PC USB Port	6 hours

Table 6. Charging Time Estimation

The Innobyte™ should be placed on a level surface while charging in order to avoid overheating and damage to the device. While charging, avoid covering it, placing it in an enclosed place, placing near sources of heat, or placing near sources of high electromagnetic energy.

5. DEVICE OPERATION

5.1 Device interface:

In order to create easy to use and elegant devices, Kube Innovation Inc. took a very minimalistic approach to the Innobyte™'s interface. Figure 8 and Figure 9 highlight the basic interface components of the Innobyte™. [5]

Figure 8. Innobyte™ Front

Figure 9. Innobyte™ Back

1. User Interface Display
2. Capacitive Sensing Button
3. Reset Push Button

During normal operation, the device's User Interface Display (1) will show the maximum/current bite force being measured, the Charging mode screen, the Standby On screen, or be blank when the device has entered Sleep mode. To wake the device from Sleep mode, or to reset measurement reading, press the capacitive sensing button (2). If no response occurs upon pressing the capacitive

[5] Components may appear different from illustrations

sensing button, reset the device using the Reset Push button (3), located at the back of the device.

6. FREQUENTLY USED FUNCTIONS

6.1 Power-up:

When the device is drained of charged, reset, or unpacked for the first time, the screen shown in Figure 10 will appear when booting.

Figure 10. Bootup screen

The screen should appear with the Kube Innovation Inc. Logo and the current official firmware version (upper right). This screen should appear for a period of approximately 10 seconds, during which the device performs its start-up procedure and assesses its status. For later reference, this state of the Innobyte™ will be referred to as Bootup. Following this screen, the device goes to the Standby On mode.

6.2 Standby On Mode:

When in this mode, as indicated in Figure 11, the device prompts the user to connect a mouthpiece in order to begin recording measurements.

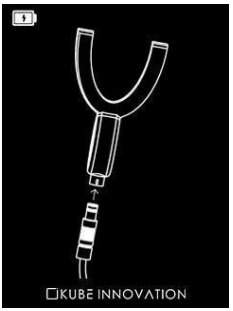


Figure 11. Standby On Mode Screen

Following the screen seen in Figure 11, if no user input is detected, the device will timeout after five (5) minutes, causing it to enter Sleep mode.

When the battery is fully charged, the battery icon displays 4 bars along with the remaining percentage. As the battery level begins to decrease with use, the battery bars will gradually disappear. When the battery reaches a charge level less than 50% or equal to 2 bars, its color will change to yellow. When the battery has one bar, or less than 25% left, it becomes red.

When the battery is drained, it will then show an empty rectangle. In this case, the device's shutoff is imminent. The device will need to be recharged.

6.3 Sleep Mode:

If the device senses no user input or change in state, it enters Sleep Mode. When in Sleep Mode, all functions, including the screen are turned off in order to preserve the battery charge level. Table 7 summarizes the conditions that cause the device to exit the Sleep mode.

Condition
Charger is plugged
Capacitive sensing button is activated

Table 7. Wakeup Conditions

6.4 Charging mode:

When the device is plugged and charging, the screen shown in Figure 12 is displayed. On this mode, as with the Standby ON mode, after five minutes of inactivity, the device will enter into Sleep mode.

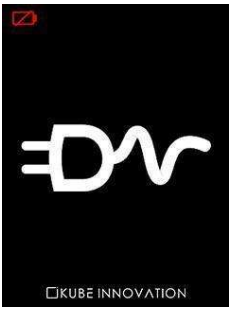


Figure 12. Charging screen

While charging, the same color/graphic representation as described in the Standby ON mode is used to indicate the battery level.

6.5 Measurement Recording Mode:

When a valid mouthpiece is connected to the device, the Innobyte™ then enters the Measurement Recording Mode. As shown on the Left of Figure 13, when using the Full Arch (INNOMP01), the maximum reading is displayed on the superior row of the screen and the current reading is displayed on the inferior row of the screen. On the Bilateral Mouthpiece (INNOMP03), the maximum total of the bite force reading is displayed on the superior row, and the maximum left and right-side bite forces (relative to the Mouthpiece) will be displayed on the inferior row. Once a maximum bite force is reached, this value in Newtons will remain on the superior row. In order to take consecutive measurements, the clinician must press on the capacitive sensing button after each measure. This will reset the displayed values to zero Newtons, ensuring the Innobyte™ is able to record the next maximal bite force value.

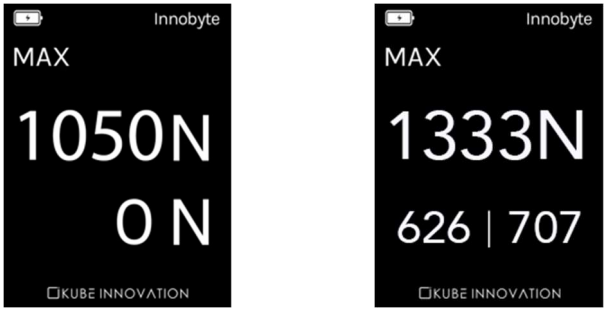


Figure 13. Measurement Display Screen (Left: Mouthpiece INNOMP01; Right: Mouthpiece INNOMP03)

7. TROUBLESHOOTING

In order to ensure optimal and repeatable measurements, Kube Innovation Inc. implemented a smart self-assessment and diagnostic capacity in the mouthpiece.

7.1 Extreme temperatures:

Through extensive tests, it has been determined that for a measurement to be viable, it must be taken at a temperature range from 5˚C to 35˚C. Therefore, the Innobyte™ constantly assesses the mouthpiece's temperature. In cases where the temperature range is exceeded, the measurement is halted, and the user is informed through the user interface display as shown in Figure 14.

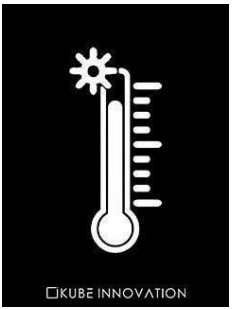


Figure 14. Out of Temperature Range Screen

In such a case, the mouthpiece cannot be used for accurate measurements. It is recommended to leave the mouthpiece at room temperature and unexposed to any source of radiant heat for at least 60 minutes. If the error persists, please contact Kube Innovation Inc. as this might indicate an issue with the device or the mouthpiece.

7.2 Extreme atmospheric pressure:

In order for the device to perform correct measurements, the atmospheric pressure needs to be considered. The mouthpiece is calibrated to work between 100 kPa and 110 kPa atmospheric pressure. When connecting a mouthpiece to the Innobyte™, the device assesses this condition. If the atmospheric pressure range is not respected, the measurement will be halted and the user is informed through the user interface display as shown in Figure 15.

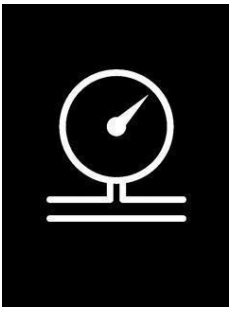


Figure 15. Atmospheric pressure warning

In such a case, the mouthpiece cannot be used. If possible, please ensure the atmospheric pressure is in the specified range. If the atmospheric pressure is in the specified range and the warning is still present, please contact Kube Innovation Inc. as this might indicate an issue with the Innobyte™ or the mouthpiece.

7.3 Mouthpiece cycles:

The mouthpiece is guaranteed to work for a maximum of one thousand (1 000) cycles. After that, due to material degradation and deformation, the mouthpiece measurements are no longer guaranteed to make accurate measurements and respect the acceptable margin of error that was assured at the time of calibration. As such, when the Innobyte™ determines that a mouthpiece has reached its 1000-cycle life span, it prevents the user from recording any more measurements with said mouthpiece and warns the user through the display as shown in Figure 16.

Figure 16. Replace Mouthpiece Screen

In order to anticipate the mouthpiece replacement, when a mouthpiece reaches 900 cycles, the icon shown in Figure 16 is shown every time said mouthpiece is connected to the Innobyte™, but will then disappear after activating the device. When the 1000-cycles limit is reached, the icon appears and it will remain on.

8. DEVICE NOT OPERATING AS INDICATED

In the event that the device does not perform as indicated in Sections 6 through 7, notify Kube Innovation Inc. immediately. Do not continue to use the device until indicated to do so by the manufacturer.

9. CALIBRATION

Every mouthpiece delivered to the client is calibrated and tested by Kube Innovation Inc. prior to delivery.

10. QUICK USE GUIDE

In order to perform a measurement on a patient, follow these steps:

1. Use latex or nitrile gloves when handling the mouthpiece. The Polyethylene disposable covers must be stored at room temperature, in a clean environment, away from all potential sources of contamination.
2. Clean the mouthpiece surface with a disinfecting wipe.
3. Connect the mouthpiece to the device using the Lemo/Lemo cable. Assure that the ferrite is within 3 inches (8cm) to the Innobyte™ Lemo connector.
4. Place a new disposable cover over the mouthpiece while holding the mouthpiece handle.
5. Insert the mouthpiece in the patient's mouth using the mouthpiece's handle.
6. Place the mouthpiece so that the patient's upper central incisors are against the protruding stop at the front of the mouthpiece, and the cheek guards are against the molars.
7. Ask the patient to bite on the mouthpiece with their maximum capacity for a duration of one (1) second. Examine the patient's maximum bite force as displayed on the screen and complete the patient's form.
8. It is recommended to take three (3) measurements with up to ten (10) seconds interval between each measurement, to allow the patient to rest.
9. To take a new measurement press the capacitive sensing button and ask the patient to bite on the mouthpiece once more.
10. Take the mouthpiece out of the patient's mouth using the handle.
11. Discard the disposable cover into the appropriate waste container.
12. Clean the mouthpiece with an appropriate cleaner and disinfectant wipes.
13. Complete the patient's form with appropriate data and notes.

11. TECHNICAL SPECIFICATIONS

Data Acquisition	
Scan Speed	Up to 100Hz
Measurement Range	0 to 2000N
Accuracy	5% of FS
Electrical Mouthpiece	
Power Source	Innobyte™ Main Device
Power Consumption	10mA MAX at 3.3V
Electrical Innobyte™ Main Device	
Power Source	Li-Ion, Single Cell Battery, 4.2V, 2100mAh
Power Consumption	100mA MAX at 4.2V
On Autonomy	Approx. 21 hours
Standby Autonomy	Approx. 5 days
Electrical Wall Adaptor	
Input Voltage	100-240VAC
Output voltage	5.1 VDC
Output Power	12 W
Mechanical Charging/Mouthpiece Cable	
Dimensions (Length, Approx.)	3 ft.
Weight (Approx.)	Approx. 52 g
Mechanical Mouthpiece	
Dimensions (LxWxH, Approx.)	**INNOMP01**: 101x63x32 mm **INNOMP03**: 101x63x32 mm
Weight (Approx.)	**INNOMP01**: 44 g **INNOMP03**: 56 g
Maximum number of cycles	1000
Mechanical Innobyte™ Main Device	
Dimensions (LxWxH, Approx.)	170x75x30 mm
Weight (Approx.)	Approx. 200 g
Mechanical Wall Adaptor	
Dimensions (LxWxH, Approx.)	76x46x58 mm
Weight	Approx. 82 g
Ambient Operating Conditions	
Temperature	5 to 35˚C (41 to 95F)
Pressure	100 to 110 kPa
Humidity	20% to 95%
Storage and Transport Use Conditions	
Temperature	5 to 35˚C (41 to 95F)
Pressure	100 to 110 kPa
Humidity	20% to 95%
Official Firmware Version	
Innobyte™ firmware	KI-V6.2.0

Table 8. Innobyte™ Technical Specifications

All Innobyte™ systems are subject to the above technical specifications.


KUBE INNOVATION