Tec4med

NelumBox ✿ - The worlds most advanced **thermal solution**
for goods requiring temperature control

Operating manual

Content

Thank you for choosing NelumBox®!

In order to ensure a quick commissioning, it is necessary for you to thoroughly read and follow the subsequent notes and descriptions.

1.1 Identification of manufacterer

Name of manufacturer:	Tec4med Lifescience GmbH
Street:	Otto-Hesse-Straße 19 | T9
Town:	64293 Darmstadt
Telephone:	+49 (0) 6151 - 360 37 00
E-mail:	info@tec4med.com
Website:	www.tec4med.com

Quantity	Designation
1x	NelumBox®
2x	Li-Ion Battery
1x	Power Supply 100 - 240 V AC
1x	RFID card
1x	Docking-Station 100 - 240 V AC (optional)
1x	Replaceable NIST calibrated Pt-100 temperature sensor
1x	RFID token (optional)

Before putting the unit into operation, check that all parts belonging to the scope of delivery are present.

⚠ DANGER!

This symbol signifies **imminent danger** for the **life and health** of persons.

⚠ WARNING!

This symbol signifies **potential risks** to **property** and/or the **environment**.

ⓘ FACTS!

This symbol indicates **important facts** and especially **useful** items of **information**.

Tips for saving energy.

No spray water.

Electronic equipment may not be disposed of with household waste.

Environmentally hazardous.

3.1 Purpose of the operating manual

This operating manual contains important information for safe, correct and economical operation of the device. Observing the instructions will help to avoid dangers, reduce repair and increase the reliability and prolong the service life of the device.

Please keep the manual for future use.

Danger!

3.2 Liability and warranty coverage

All information in this manual are provided to the best of our knowledge, on the basis of our experience and findings to date.

The original version of this manual was drawn up in the German language and its technical correctness checked by our company. The translation into the customer's national language/the contractual language has been carried out by a recognised translation agency.

This manual has been drafted with the utmost care. Should you nevertheless establish any gaps and/or errors, please notify us at the abovestated address. Your suggestions for improvements will assist us in designing a user-friendly manual.

3.3 Copyright

All rights are expressly reserved. This manual may not be duplicated or its contents divulged to third parties in any form whatsoever without our written consent.

A basic prerequisite for safe handling and trouble-free operation of this device is acquaintance with the basic safety instructions. It is not permitted to use the device for a purpose other than that stipulated by the manufacturer.

Keep children away from the device at all times!

Never open the housing of the device.
Repair work on the device may only be carried out by Tec4med LifeScience GmbH or by authorised workshops.

Defective parts or components must only be replaced by parts approved of by Tec4med LifeScience GmbH.

- If the unit shows visible damage, it must not be put into operation.

- If the connecting cable of this unit is damaged, it must be replaced by the manufacturer or a similarly qualified person to avoid hazards.

- Repairs to this unit may only be carried out by qualified personnel. Improper repairs can pose considerable risks.

- Disconnect the unit from the power supply, before each cleaning and care; after each use.

- Medicines may only be stored in original packaging / secondary packaging or suitable containers.

- Compare the voltage information on the nameplate with the available power supply.

- Connect the unit only as follows:
  with the AC connection cable to the AC network.

- Never pull the plug out of the socket using the connection cable.

- The unit is not suitable for the transport of corrosive or solvent-containing substances.

- The insulation of the unit contains flammable cyclopentane and requires a special disposal process. Dispose the unit properly at the end of its service life.

Danger!

Danger!

Warning!

Danger!

Warning!

5.1 Functional description

The unit is suitable for both mobile and stationary use. It can
cool goods down to max. 28 C below ambient temperature or it can
heat goods up to max. 65 °C.

In principle, NelumBox® is designed for the temperature ranges 2-8 °C,
15-25 °C and 37 °C.

The unit is a wear-free Peltier cooling (thermoelectric cooling)
device with heat dissipation by a fan. The use of the device can be car-
ried out at up to 80% outside air humidity.

5.1 Design and components
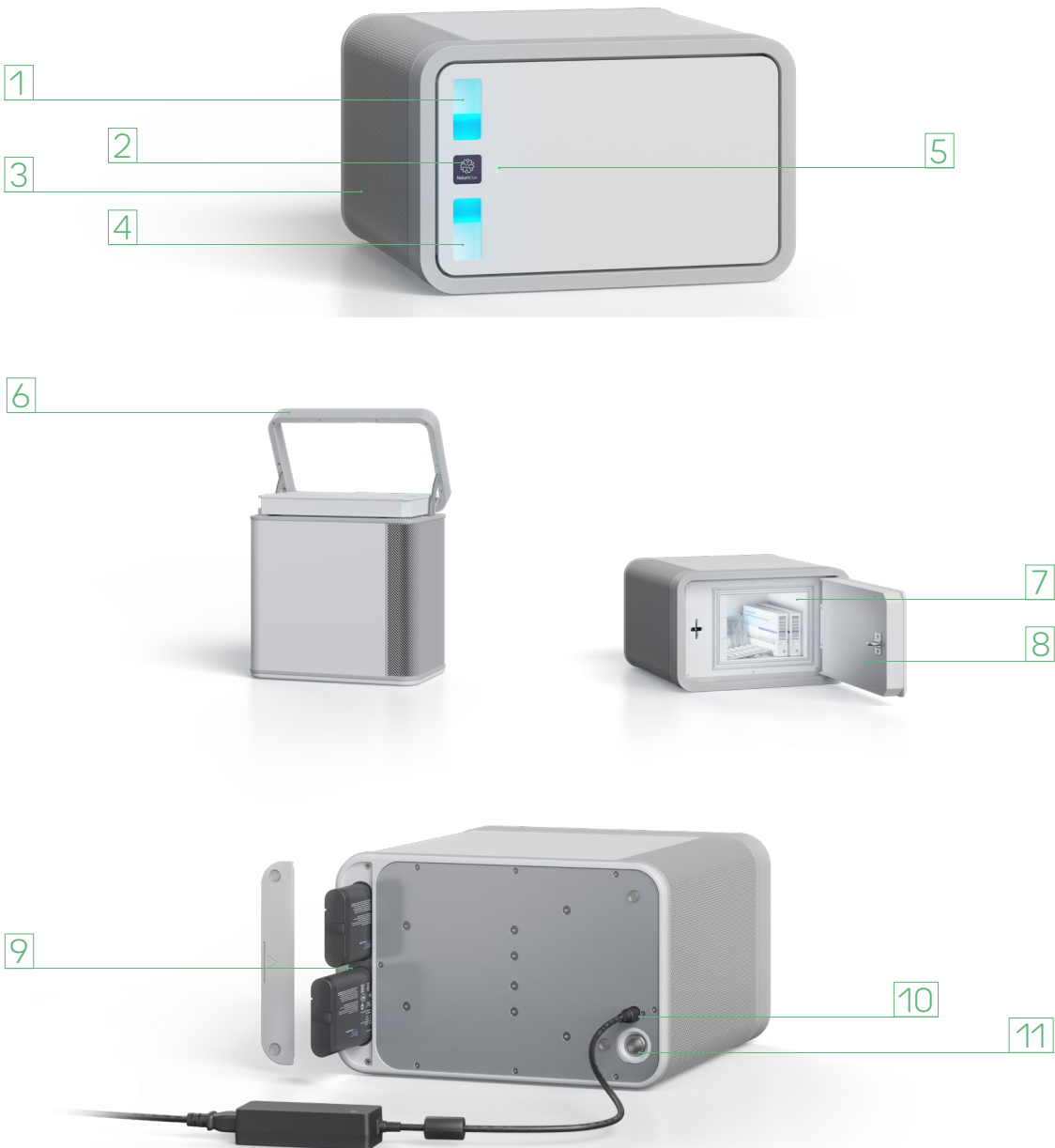
1	upper button	7	cooling/ heating chamber
2	display	8	door
3	cooling grid	9	battery compartment
4	lower button	10	DC connection
5	RFID sensor with green LED light	11	power switch
6	hinged handle		

Before commissioning, make sure that the supply cable and the plug are dry.

Danger!

- If the unit shows visible damage, it must not be put into operation.

- Do not use any electrical equipment inside the unit, unless this electrical equipment is recommended by the manufacturer.

- Do not place the unit near naked flames or other heat sources (heating, strong sunlight, gas oven, heater, etc.).

- Danger of overheating! Always ensure that heat generated during operation can be sufficiently dissipated. Ensure that the unit is at a sufficient distance (at least 10 cm) from walls or objects so that the air can circulate. Do not use the unit in closed systems with a volume of less than 1 m^3.

Danger!

- Make sure that the ventilation openings are not covered.

- Do not fill the inner container with liquids or raw ice.

- Never immerse the unit in water.

- Protect the unit and the cables from heat and moisture.

- Avoid throwing or skidding the box or applying excessive external forces.

6.1 Inteded use and foresseable misuse

NelumBox® is suitable for cooling and heating medical drugs and samples. All materials used are safe for medication.

NelumBox® can be used and transported in the aircraft as hand luggage.

NelumBox® may not be checked in as baggage and stored in the cargo hold (Li-Ion batteries).

Please check whether the capacity of the unit meets the requirements of the medication you want to keep at the right temperature.

Danger!

6.2 Tips for saving energy

A fan inside the unit circulates the air inside the chamber, resulting in better cooling / heating performance.

- Choose a well-ventilated place protected from solar irradiation.

- Do not open the unit more often than necessary.

- Do not leave the unit open longer than necessary.

- Once attached to the power grid, NelumBox® switches to AC-mode. In AC-mode, Nelumbox constantly keeps the temperature at the most efficient level to increase the runtime in mobile mode. Thus to increase runtime, keep NelumBox® attached to the power grid as long as possible before using the device in mobile mode.

6.3 General LED / display functions

After the selected temperature has been reached, the display turns off and the LED light is illuminated.

The LED light will be on, as long as the display is off and Nelumbox® is within the defined temperature range (without error messages).

The display can be activated by pressing one of the buttons. If there is no activity for more than one minute, the display is turned off again (if Nelumbox® is still within the defined temperature range).

6.4 General button functions

The buttons can illuminate in the following colors:

- Blue: NelumBox® cools down, but has not reached the target temperature range.

- Red: NelumBox® heats up, but has not reached the target temperature range. / Access via RFID denied. / Battery lower than 5%. / If the temperature deviates by more than +/-0.5°C degrees, after reaching the target temperature range.

- Not illuminated:
  NelumBox® has reached the target temperature range.

- Green: Access via RFID granted.

- Yellow: When attempting to open the door via button, but RFID is required. / Battery lower than 10%. / If the temperature deviates by up to +/-0.5°C, after reaching the target temperature range. / Door is opened longer than 22 seconds.

6.5 Connecting/ switching on NelumBox®

Make sure that only items or goods that may be cooled or heated to the selected temperature are stored in the device.

- Place the unit on a firm base.
- Close the door.
- If the batteries are discharged or the batteries are not used, connect the unit to an AC power socket using the supplied AC power connection cable. Close the door.

AC power socket
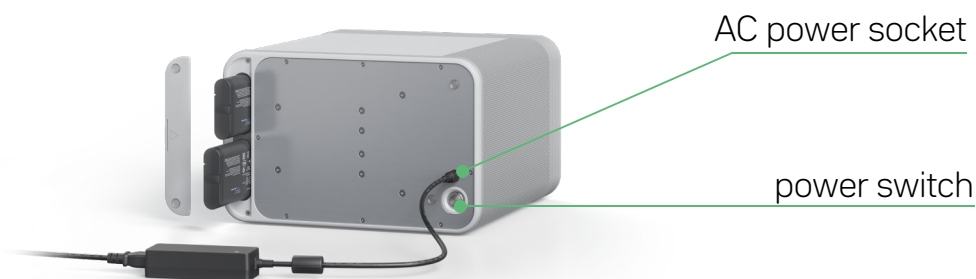
power switch

- Press the power switch on the back of NelumBox® to turn on the device. NelumBox® welcomes a successful start-up with the NelumBox® logo.
- The cooling unit now starts to heat or cool the interior to the previously set temperature.

After powering up, the battery status and interior temperature of NelumBox® immediately show up on the display. Before each transport, make sure that all general conditions for the transport are safely observed!

The batteries can be charged by the Docking-Station. For more information about that device read the RRC2054-2 manual or contact RRC power solutions GmbH.

Warning!

NelumBox® is equipped with an electronic access control using RFID technology (optional). If the electronic lock is activated, the door can only be unlocked by RFID tokens/cards or via NFC.

NelumBox® can only be opened when switched on (exception: emergency release; see chapter 6.4.1). To unlock NelumBox®, hold the RFID token/card to designated area at the front of the device. Successfully unlocking NelumBox® is confirmed by a green light on the buttons and via the display.

- The lock is unlocked by pulling either the upper or the lower button and by pulling the door. Prevented access is confirmed by the buttons glowing in red and on the display.

- If the electronic lock of NelumBox® is not activated, simply open the device by pulling either the upper or the lower button and by pulling the door.

If unlocking is prevented, do not attempt to open the door by force. This can lead to damage to the device.

- If the unit is opened for more than 22 seconds, a warning signal sounds and the door lights begin to shine in yellow. The signal warns to quickly close Nelumbox®'s door to avoid exceeding the set temperature. If the alarm message is ignored, the signal increases in intensity. The display also prompts the user to close the door.

- Close the door by applying pressure to the front of NelumBox®. Press on the area between the display and the hinged handle or on the LED to close the door.

- Do not press on the display and do not push any button while closing the door.

- After successfully closing the door, the audible signal, the lights and the warning on the display disappear.

Access
Granted

Access
Denied

Warning!

Close
Door

Warning!

13
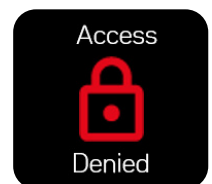
6.6.1 Emergency release

In cases of emergency, NelumBox® can also be opened without power supply via cable / battery.

In order to unlock NelumBox® via the emergency release mechanism, push through the sealed opening and trigger the emergency button on the downside of NelumBox® using a suitable device (e.g. a long pen). You can now open the door manually.

6.7 Transporting and storing NelumBox®

- If the unit shows visible damage, it must not be put into operation.

- Danger of overheating! Always ensure that heat generated during operation can be sufficiently dissipated. Ensure that the unit is at a sufficient distance (at least 10 cm) from walls or objects so that the air can circulate. Do not use the unit in closed systems with a volume of less than $1\,m^3$.

- Make sure that the ventilation openings are not covered.

- Protect the unit and the cables from heat and moisture.

- Avoid throwing or skidding the device or applying excessive external forces.

- The permissible maximum overall weight amounts to 15 kg.

- NelumBox® can be put in operation horizontally and vertically.

- To prevent damage make sure the power supply is not plugged in while using NelumBox® vertically.

Danger!

Warning!

horizontal operation   vertical operation

The control of the unit has a memory function: it remembers the selected temperature range for each mode (2-8 °C, 15-25 °C, 37 °C) once the device is shut off.

The previously selected temperature range is set each time the unit is switched on. The selected temperature range is indicated by a white background at the top of the display. The basic settings are cold chain „2-8 °C", ambient „15-25 °C" and incubation „37 °C".

Note that it may be intentional if the temperature range cannot be adjusted. The setting can be changed by authorized personnel or Tec4med.
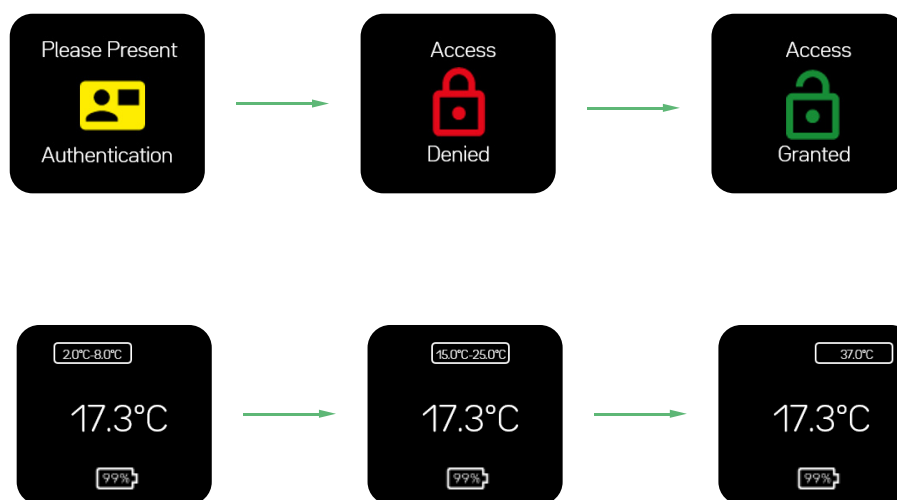
- You can switch between the different temperature ranges by pressing the upper button for 3 seconds. Once the time is up, switching to the next temperature range is acknowledged by a short beep and by the display highlighting the next temperature range at the top of the display. To switch to the next range, it is required to press the upper button for 3 seconds again.

- The heating process is indicated by a wave icon.

- The cooling process is indicated by a crystal icon.

- Once Nelumbox® has reached the designated temperature range and leaves the area, a temperature warning occurs. Hereby, Nelumbox® shows "Temperature Warning" (level 1) / "Temperature Alert" (level 2), the buttons start to flash in yellow / red and a warning sound appears, increasing in intensity. The sound can be disabled by pressing one of the buttons. The temperature warning / alert occurs until the temperature moves back to its designated temperature range. Otherwise the warning remains.

- Only use NelumBox® in the temperature profile of 2-8°C up to a maximum outdoor temperature of 35°C. Otherwise the desired temperature cannot be guaranteed.

Warning!

- NelumBox® is operated via the included power supply with the respective country adapter (100 - 240 V AC).

- NelumBox® indicates the state of charge independent of its charging level by the appearance of power plug icon in the battery symbol.

- If NelumBox® is switched off, it is not possible to charge the batteries. Leave NelumBox® switched on to charge the batteries.

- If there is no charging in progress, the battery status is displayed as a percentage.
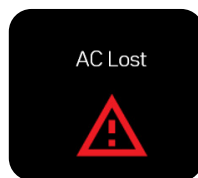
- If NelumBox® is supplied completely without inserted batteries and only with mains voltage, the battery indicator on the display disappears completely. Please note that in this condition, disconnecting the power supply will cause NelumBox® to switch off immediately.

- For all intermediate states of battery level, the respective battery status is shown on the display. If the charge level is less than 10%, NelumBox® displays the following warning. Also, the buttons start to flash in yellow and Nelumbox sends a beep every minute. Once the battery charge drops below 5%, NelumBox® starts to beep every 10 seconds and the buttons start to flash in red. All cooling functions go to passive mode. In this case, please connect NelumBox® to mains power immediately.

6.10 Switching batteries

To operate Nelumbox® properly, the system must either be powered by mains power or by charged batteries. If both batteries are removed at the same time without mains power, Nelumbox® immediately switches off completely! Under certain circumstances, this may lead to damage to the loaded goods.

Use Nelumbox® only with batteries provided and approved by the manufacturer. The use of other types of batteries can lead to failure or severe damage to the device.
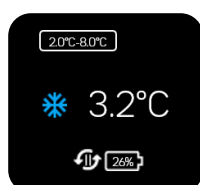

- To change the batteries, open the battery compartment and pull the respective battery out using the tab. (The batteries fit only in one direction.)

- Batteries can have a different charge level. If two batteries are inserted, the charge level shown on the display is always the average charge level of both batteries.

⚠️ Warning!

⚠️ Warning!

- Nelumbox® indicates the battery being due for change on the display by indicating either "I" or "II" within the changing icon.

- Please make sure to switch the correct battery.

battery I

battery II
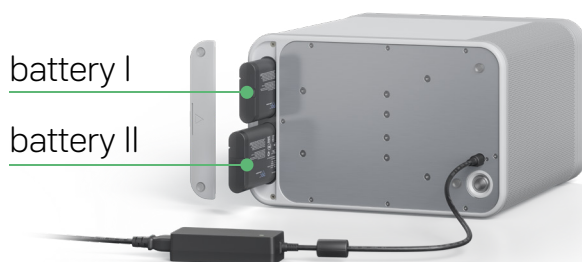
- Do not change the batteries at the same time to maintain the function of the Nelumbox®. First replace the first accumulator with a fully charged system before replacing the other accumulator with a fully charged system.

- To avoid failure when replacing the batteries, it is recommended to replace the batteries as soon as they fall below a charge level of 10%.

- Please note, that the batteries must be declared as UN3481 once being packed and delivered by mail. The declaration must state: "Lithium ion batteries in compliance with Section II of PI966".

- Both batteries are fully IATA-compliant and can be carried as hand luggage.

Always disconnect the unit from the power supply or remove the batteries before cleaning and maintenance.

Danger!

Never clean the unit under running water or in rinse water. Do not use strong cleaning agents or hard objects for cleaning, as these can damage the device.

- Clean the inside and outside of the unit occasionally with a damp cloth.

- Make sure that the ventilation openings of the unit are free of dust and impurities so that the heat generated during operation can be dissipated and the unit is not damaged.

Warning!

Electronic equipment may not be disposed of with household waste!

The insulation of the unit contains flammable cyclopentane and requires a special disposal process. Dispose the unit properly at the end of its service life.

The RRC-Li-Ion batteries are part of the GRS-battery system and can be returned at any GRS collecting point globally. Returning the batteries is free of charge! For more information visit: www.grs-batterien.com/

Caution – The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above the maximum temperature limit of 45 °C / 113° F, or incinerate. Replace battery with RRC 2054-2 only. Use of other battery may present a risk of fire or explosion.

Danger!

Dispose of used battery promptly. Keep away from children. Do not disassemble and do not dispose of in fire.

Warning!

The device and all its accessories must be disposed professionally by the manufacturer. Please also contact the manufacturer in the case of disruptions and emergencies.
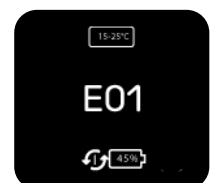
Tel.: +49 (0)6151 – 360 37 00

Email: help@tec4med.com

Return to:
TEC4MED LifeScience GmbH, Otto-Hesse-Str. 19, T9,
64293 Darmstadt

If the display shows an error code (E01 - E99) restart the box. If the error code does not disappear or if it returns, contact Tec4med or the source of supply / authorized retailer immediately.
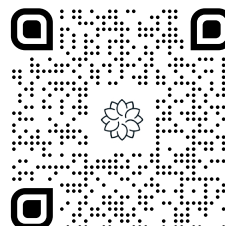
NelumBox

UDI 0 42 6063688 001X XXXXX1

FCC ID:	2AUKO-T4MNLMBXG
IC:	25600-T4MNLMBXG
HVIN:	T4MNLMBXG
Voltage:	20 VDC
Power:	100 W
Current:	5 A
Weight:	10,5 kg
W x L x H:	353 x 360 x 225 mm
Net Volume:	4,7 l
IP:	IP20
Ambient temp. charging:	Min. 0°C/32°F; max. 45°C/113°F
Ambient temp. battery mode:	Min. -10°C/14°F; max. 45°C/113°F
Ambient relative humidity:	Max. 80%

c (UL) us
LISTED
LABORATORY EQUIPMENT
E505918

Scan code for
service website.

Tec4med LifeScience GmbH
Otto-Hesse-Straße 19
64293 Darmstadt. Germany
+49 6151 360 37 00

2019

CE

NelumBox® is designed and assembled in Germany.

Supplier's Declaration of Conformity

Unique Identifier: NelumBox®

Party issuing Supplier's Declaration of Conformity:

TEC4MED LifeScience GmbH
Otto-Hesse-Str. 19 Block T9
Darmstadt, Hessen
64293
Germany
Telephone: +49(0)6151-360 37 00
Email: info@tec4med.com
Website: www.tec4med.com

Responsible Party U.S. Contact Information:

Mr. Gustaf Sandahl
sgu@bito.dk
Tel. +1 410 892 6658
BITO Storage Solutions US, Inc.
8314 Sherwick Ct
20794 Jessup (MD)

**Responsible Party Canada Contact Information:**

Company Name: Celltech Labs Inc.
Address: 21-364 Lougheed Road, Kelowna, BC V1X 7R8
Contact Name: Ben Hewson
Telephone No.: (250) 765-7650 ext. 201
Email: IC-Rep@celltechlabs.com

Innovation, Science and Economic Development Canada ICES-003 Compliance Label: CAN ICES-3 (B)/NMB-3(B)

- This device complies with Industry Canada's license-exempt RSSs. Operation is subject to the following two conditions: (1) This device may not cause interference; and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

- Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:
  1) l'appareil ne doit pas produire de brouillage;
  2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

- Antenna Information:
  RFID antenna with five windings
  Total area: 25x25 mm
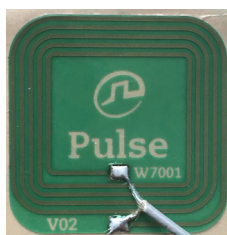
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate 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.

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.

The Federal Communications Commission (FCC) warns the users that changes or modifications to the unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.