insulCHECK DOSE

Insulin Injection Tracker

User Manual

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Applicant:Innovation Zed Ltd.
P/N:InsulCheck DOSE
Model: IC-Dose
Brand: InsulCheck
FCC:2A9FH-IZDOSE001

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Ireland

REF **IC-Dose**





IP22

Thank you for using InsulCheck DOSE. This User Manual provides important information to help you use your InsulCheck DOSE correctly and get the most benefit from its use. Before using the product, please read it carefully.

If you have any questions about this product, please:

- Consult our website www.innovationzed.com
- Email our Customer Support Team info@innovationzed.com

IMPORTANT

Read all instructions and warnings before use.

Innovation Zed only accepts responsibility for the equipment's safety, usability, and performance if:

- the equipment is used in accordance with its intended use and
- the equipment is used in accordance with the product documentation

InsulCheck DOSE does not make any decisions or suggestions about your injection regime.

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1 Introduction

1.1 Definitions

Device InsulCheck DOSE
User Insulin pen user, Patient or Operator

1.2 General description

InsulCheck DOSE helps you track your insulin injections. It can streamline your diabetes management by automatically logging injections events into a paired diabetes management app. You can easily identify the previous dosage amount dialled and the time since last injection on the display, helping you to stay on top of your injection routine. InsulCheck DOSE is clipped-on to your insulin injection pen.

InsulCheck DOSE must not be used as the only indicator to decide when or how much insulin to inject. You must rely on your own memory and knowledge, your blood glucose level and your healthcare provider's advice when deciding to inject.

1.3 Intended Use

InsulCheck DOSE is an add-on device for insulin injection pens to support users by automatically capturing and displaying injection event data, such as time of injection and the dialled dosage.

InsulCheck DOSE does not change or modify the function of the injection pen, nor does it make any decisions or recommendation as to the timing or dosage to be administered.

The Device is intended to be used in common environments such as your home, office, or school.

The Device is intended for users who see a benefit in logging their injection event data. This data can be logged either manually by the user or automatically by wireless transmission.

InsulCheck DOSE should not be used as the sole or primary source for informing injection decisions.

1.4 Intended Users

InsulCheck DOSE is intended for people with at least 8 years of school education living with diabetes who are able to manage their treatment without the use of the device, and their care givers.

The intended users are expected to be familiar with the normal aspects of insulin usage and the operation of injection pens.

1.5 Normal use

InsulCheck DOSE is mounted on the insulin pen by the user. The device is on the pen when injecting. The time since previous injection and dose dialled is displayed on the display screen.

Once mounted, the device need not be removed from reusable pens. When used with disposable pens, once the insulin runs out, the device is removed and mounted on a new disposable pen.

InsulCheck DOSE has a lithium-ion battery that is rechargeable when a low battery is indicated

Using Bluetooth® technology, data from the Device can be transferred to a compatible connected app (e.g., smartphone app). For users who see a benefit to logging their injection events to keep track of their usage behaviour and of monitoring their drug adherence record.

1.6 Contraindications

InsulCheck DOSE should not be used by users who are unable to manage their treatment without the use of the Device.

2 Device Description

2.1 Package contents

Included in the box is:

a) InsulCheck DOSE (Device)

b) Documentation (Quick Start Guide)

c) USB charging cable

⚠ *Do not use the Device if packaging is damaged or opened*

⚠ *Do not use InsulCheck DOSE if any part appears to be broken or damaged. InsulCheck DOSE supports a variety of insulin pens. Each device designated to work with only one specific pen model (see section 2.3 for supported pens). InsulCheck DOSE cannot detect that it is fitted on the wrong pen*

⚠ *Use the cable supplied with the device to connect it to a USB power port. Do not use any other cable.*

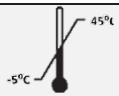
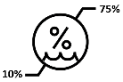
⚠ *Connect the USB cable to a power source compliant with the IEC 60601-1.*

⚠ *Before using, please check that you have purchased the Device designated for the model of pen you use.*

It is your responsibility to ensure that you are using the correct Device for your pen. Consult your healthcare provider if you are unsure which insulin pen model you are using.

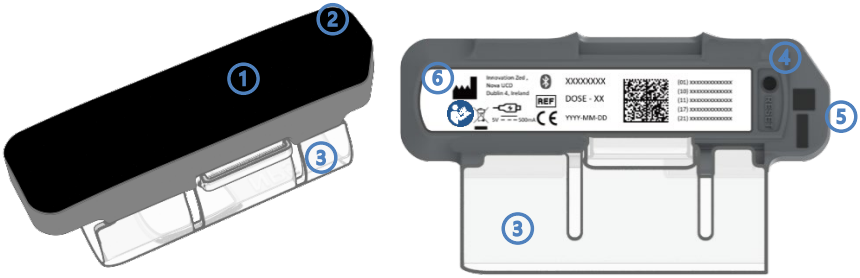
2.2 Symbols

The following table describes the meaning of the symbols used in the User Manual, the Packaging and the Label on the bottom of the Device.

Symbol	Meaning
	This action is prohibited. User should read very carefully.
	Important information, warning or precaution. User should read carefully.
	Consult instructions before use, electronic form available from http://innovationzed.com/**ifu-documents**
	Name and address of manufacturer. Year-month of manufacture.
	Model number of the Device.
	BLE (Bluetooth® Low Energy) name of the Device.
	Rating of the USB charger.
	Do not dispose as normal household waste. Dispose separately as Electronic Equipment waste.
	The Device Complies with relevant EU Regulations.
	Do not use the Device if packaging is damaged or opened.
IP22	Degree of enclosure protection.
	Protect Device from moisture.
	Avoid using the Device under direct sunlight.
	Range of temperature (upper and lower limit) to which the Device can be safely exposed to during transportation and storage.
	Range of humidity (upper and lower limit, noncondensing) to which the Device can be safely exposed to during transportation and storage.

2.3 InsulCheck DOSE terminology

The following images describe the key components of InsulCheck DOSE.



① **Display screen** – Timer and other information are displayed on it.

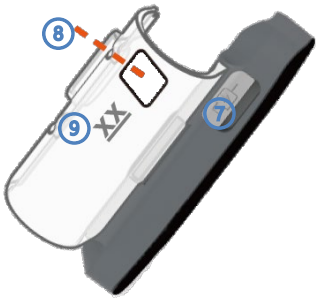
② **Charging indicator** – Displays the charging status.

③ **Sleeve** – The sleeve can only be fitted properly on a specific pen model.

④ **Reset button** – Hole for accessing the reset button using a paperclip or similar tool.

⑤ **Sensor Windows** – used by sensors to detect Pen motion.

⑥ **Bottom label** – Carries Device identification and other important information.



⑦ **Dust Cover** – Protects the charging inlet.

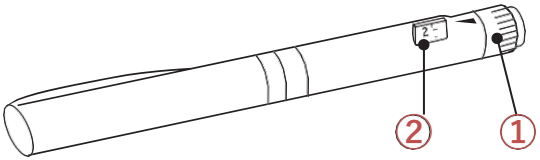
⑧ **Sleeve Window** – Aligns with Dose window of insulin pen.

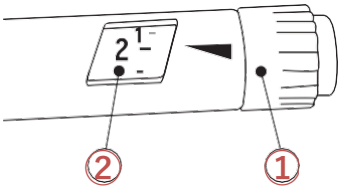
⑨ **Pen Model** – 2 digit code indicating insulin pen supported by the sleeve.

2.4 Insulin pen terminology

① **Dose-knob** – the knob at the end of the insulin pen which is dialled to adjust the desired dosage of insulin.

② **Dose-indicator** – the number of dialled-out insulin units. After mounting the InsulCheck DOSE on a pen, the dose-indicator is visible through the window in the sleeve.





2.5 Supported pens

InsulCheck DOSE is clipped onto the insulin pen using the sleeve, hinge mechanism and mounting mechanism.

The unique design of the sleeve means that the device will only fit properly and operate correctly on the designated model of pen. The abbreviation for the pen names the device is designated for, is embossed on the sleeve.

The following table provides a list of pen models supported by InsulCheck DOSE together with their abbreviation.

Pen Manufacturer	Pen model	Pen Code.	Supported Drug Variation	
Novo Nordisk	NOVOPEN5	NP5		
Novo Nordisk	Flextouch	FT		
Eli Lily	Kwikpen	KP	Mix25 Mix50 U100 U200 Abasglar	
Sanofi	Solostar	SS	Toujeo Lantus	

⚠ *Ensure that the correct device variation is used with your pen*

2.6 Function description

InsulCheck DOSE is clipped-on to your insulin injection pen. InsulCheck DOSE is secondary aid in diabetes management, by providing information about the timing of injections and number of units of insulin dialled.

You can easily identify the previous dosage amount dialled and the time since last injection on the device display at any time, helping you to stay on top of your injection routine.

The sleeve, hinge mechanism and mounting mechanism are used to clip the Device onto the pen. Each Device is designated to be used with a specific model of insulin pen. This is due to the unique design of its sleeve that will only fit properly on the designated model of pen. The internal sensors detect dialling-in and out of the dose-knob only if the Device is correctly mounted on the pen.

InsulCheck DOSE helps you track your insulin injections. It can also be used to streamline your diabetes management by automatically logging injections events into a paired with a compatible diabetes management app.

InsulCheck DOSE must not be used as the only indicator to decide when or how much insulin to inject. You must rely on your own memory and knowledge, your blood glucose level and your healthcare provider's advice when deciding to inject.

2.7 Performance

When the operating instructions, safety regulations and care requirements are properly followed, InsulCheck DOSE will continue to automatically detect and record injection time, date and dosage dialled and if paired with an app, transfer data to connected apps, as described in this manual during its service life.

> ⚠ *Do not use the Device if you observe a deterioration in any of these functions.*

A decrease in charging interval can be expected due to normal battery degradation.

Contact our customer support team at info@innovationzed.com if the Device does not behave as specified in this manual, especially if proper screens are not displayed or the detection threshold increases.

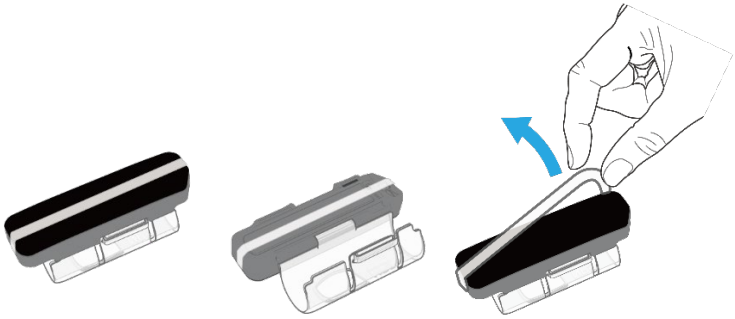
Nominal InsulCheck DOSE performance listed is based on standard test bench conditions.

Dialled dosage detection	95% +/- 1U
Injection detection	99%

3 Operating instructions

3.1 First time use

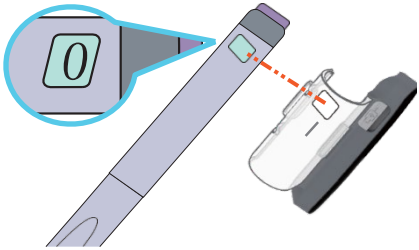
Remove the protective strap around device



3.2 Mount Device on the Injection pen

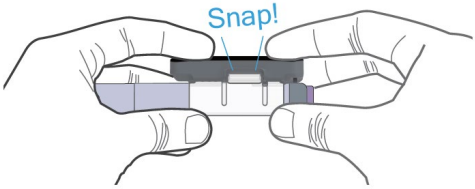
> ⚠ *Always ensure that the needle is covered before attching or removing the device.*

a. Align the dose-indicator window on the sleeve with the dose- indicator on the pen. Confirm the chamfered edge of the InsulCheck DOSE is positioned near the dose knob of pen.

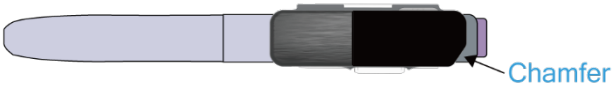


b. Push the sleeve onto the pen

c.Press (click) together the mounting mechanism to fasten the Device on the pen



If mounted correctly the Chamfer ed of the device should be near the Injector button of the pen as shown here.

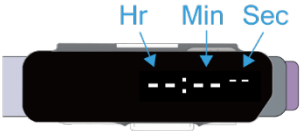


On first mounting the device powers on and the InsulCheck insignia is displayed

The mounted-on pen animation is displayed when device is locked in place securely to the injection pen. Followed by the dashed timer is displayed and dashed Dose display since no injection has been detected yet

Mounting Successful Display

Dashed Unit Display



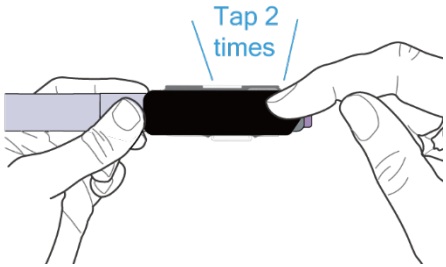
Dashed Timer Display

To save power, the screen will turn off after a few seconds.

⚠ *Always ensure that the device is fitted firmly and securely when attaching to a new pen*

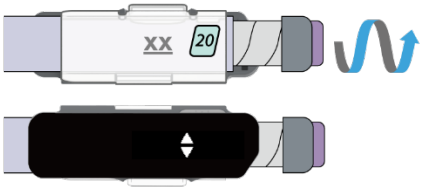
3.2 Normal Injection Routine

Ensure that the device is attached to the pen and the display area is face up the Display will turn on and device will "wake-up" when the device detects any motion or when the display is "double tapped"

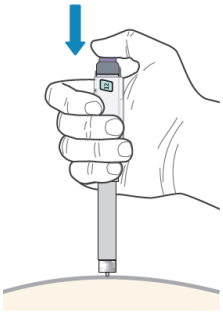


> ⚠ *NOTE: The device display must be on before dialling any dose. If the device display is not on, double tap screen to turn on*

When dialling out the dosage the InsulCheck DOSE will automatically begin tracking the dosage dialled – it will display the image below while dialling.



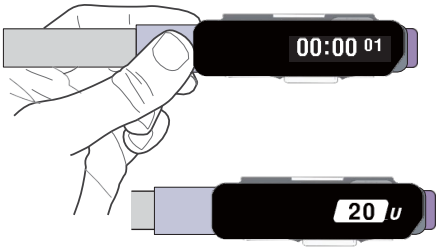
When desired dose is set perform the injection according to your therapy



When injection is completed the timer resets due to the new injection and starts counting up.

After 10 Sec the display will also show the number of units dialled for the last

injection and then toggle between the elapsed time and the dose every 5 sec.



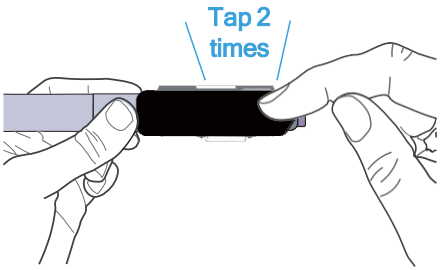
The display will automatically dim and turn off after 20 Sec to conserver power.

> ⚠ *For effective tracking of injection dose, do not combine priming amount into amount dialed for medication.*

3.3 Checking last injection status

Ensure that the device is attached to the pen and ensure that the display area is always face up and double tap the screen to turn on the display and wake up device.

If there are no warnings, the device display will turn on and show the elapsed time since the last injection and after 3 sec will display the last dose



Time elapsed since the last injection

last injection dosage

The display will automatically dim and turn off after 20 Sec to conserver power.

3.4 Battery status

Double tap the screen to turn on the display and wake up device

If the battery is low, the following battery warning is displayed for a few seconds

Low battery 

the device display will turn on and show the elapsed time since the last injection and after 3 sec will display the last dose

> ⚠ *Your injection time will be detected even after a low battery warning is displayed, but you should charge the device before the next injection.*

If the battery is critical, the following battery warning is displayed for a few seconds

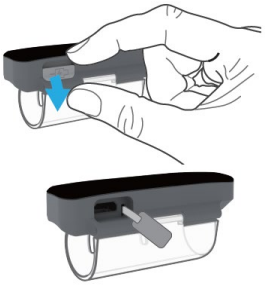
Critical Battery 

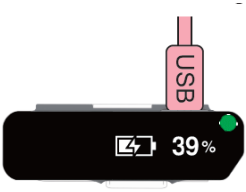
The display will turn off immediately

> ⚠ *If the device is blinking critical battery warning it may not record your next injection. it is important that you charge the device immediately.*
>
> ⚠ *NOTE: Keep your Device charged for optimised operation*

3.4 Charging

Open the dust cover protecting the charging port and connect the micro-USB charging cable





The LED on the top display will light up as soon as the USB charger is connected.

Pulsing Green
(Charging in progress)

Constant Green
(Fully charged

In addition to the LED lighting up, the display will show a charging animation along with an approximate % indicating charge capacity.

After 5 sec showing charging animation the display will show the last injection time and Dose for 20 sec before turning off.

The device can be safely charged while attached to the pen. The user should not perform injections with the charger cable connected to the device

The Device can be disconnected from mains power at any time by removing the charging cable from the Device or from the charger, or by removing the charger from the mains outlet.

It will take approximately 2 hours to fully charge from low battery.
When fully charged the device can operate for 7-10 day in typical use.

⚠ *While the device is connected to a charger the user shoud not perform an injection.*

⚠ *The following Icon*  *will appear as a reminder not to perform injection while charging.*

3.5 Bluetooth® pairing

The information on time intervals between injections is stored on the Device for up to 40 days. You can transmit this information to your smartphone app via Bluetooth®

To initiate the pairing process please refer to your specific smartphone app.

1. Wake up your device by double tapping on the screen
2. Follow your app instructions to scan for available devices
3. On the app select the Device from the list of available devices. The **BLE name** of your Device is written on the **label** on the **underside** of the Device and on the **packaging**
4. Wait for the Device to display the passkey

5. Type the passkey into the prompt on your app or phone
6. If pairing is successful, the animation below will be displayed

a. If pairing is un-successful, the animation below will be displayed. If this occurs follow the instruction on your app to try again.

7. Follow the instructions on the paired device to transfer the data saved on InsulCheck DOSE. Depending on the connected app you can monitor your adherence to your medication regime and keep track of your usage behaviour

> ⚠ *Always check the transferred data (the log of the time and dose dialled) with your personal diary or memory of time and dose. Most 3rd party apps will allow inaccuracies to be corrected within the app.*

3.5.1 Maximum number of pairings

InsulCheck DOSE can be paired with a maximum of 3 different client devices (e.g. different smartphones or apps). When you pair with a fourth client device your InsulCheck DOSE will automatically drop the first client device you connected with to accommodate the new client.

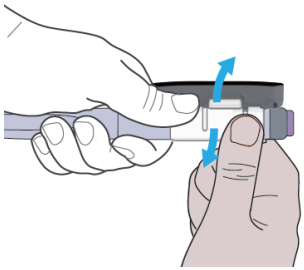
3.6 Clearing paired devices

The device can be unpaired via the smartphone app, please see your app instructions for specific details.

3.7 Changing Pen

To remove the device from a used pen and to attach it to your new pen

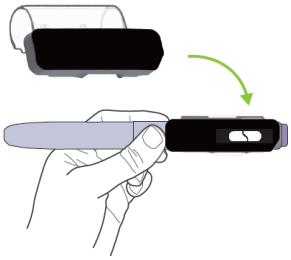
1. Open the clasp and remove the Device from the current injection pen



2. When the clasp is opened, the unmounted from pen animation (See below) is displayed on the screen

Mount the Device on your new injection pen after aligning the Sleeve Window with the Dose window of the insulin pen.

3. Press (click) together the mounting mechanism to fasten the Device on the pen



4. If the Device is correctly mounted, the animation below is displayed.

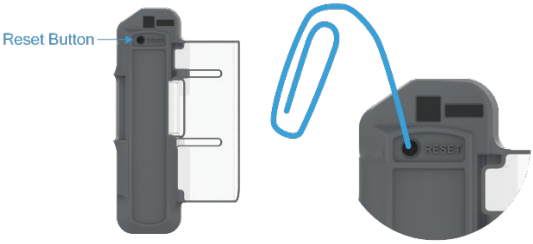
5. After the change, the timer will show the last dose and time as normal

3.8 Factory reset

All the data stored in the InsulCheck DOSE memory as well as the pairing data can be deleted by doing a Factory Reset. InsulCheck DOSE also reboots as a result of a factory reset.

1. Unmount the Device from the pen

2. Turn the Device around so that the hole for accessing the reset button is exposed and push the reset button with a paper clip or similar tool and keep it pressed for more than 10 second



3. The Device reboots and the InsulCheck insignia is displayed confirming that a factory reset has been triggered

4 Cleaning and care

4.1 General cleaning

The display and outside body of your InsulCheck DOSE can be cleaned while mounted on the pen by wiping it gently with a clean cloth lightly moistened with water. The cloth should not leave any water droplets on the surface of the Device.

4.2 Sensor Cleaning

If the following Icon is displayed

This indicates that the sensor windows should be cleaned.

The device should be unmounted as described in section 3.7

The sensor should be cleaned with a dry lint free cloth similar to that used for cleaning glasses.

- *There should not be any smudges lint or dust on the sensor windows for best performance.*
- *Do not use any other liquids or solvents when cleaning the Device.*
- *Do not expose the Device to open flame or put it too close to a heated surface.*
- *Device is not waterproof and does not hold protection against excessive infiltration to water.*
- *Never pour water or other liquids on the Device. Never submerge the Device in water or other liquids. If this occurs, dry off quickly with a clean cloth.*
- *Do not store the Device in a freezer.*
- *Do not place Device in Microwave.*
- *Do not dissasemble Device.*

- *Do not use the Device if abnormal heat, odour, discolouration, deformation, or other abnormal condition is detected during use, charging, or storage.*
- *Do not use the Device in oxygen-rich environments*
- *Make sure that no excessive dust, moisture, water or other agent builds-up on the optical sensor of the Device. Clean the optical sensor with a clean dry or slightly moistened cloth if any build-up appears.*
- *Keep the Device within the specified temperature, humidity and atmospheric pressure ranges.*

5 Disposal

At the end of the Device's service life, it should be disposed as electrical waste according to local regulations.

6 General safety advice

⚠ *Only use a certified 5V USB charger from a legitimate supplier with the Device (for example, CE marked, etc.) to minimize the risk of electric shock and damage to the Device.*

⚠ *In the unlikely event of deterioration in the functionality of nearby equipment in the presence of InsulCheck DOSE, remove the Device from the vicinity.*

⚠ *To avoid degradation in performance of InsulCheck DOSE, radio equipment (such as phones, computers, wireless devices, antennas, antenna cables etc.) should not be used closer than 30 cm (12 inches) from the Device. This distance should also be observed for the charging cable if it is plugged-in to the Device.*

⚠ *To reduce the risk of interference from outside sources, avoid using InsulCheck DOSE near strong sources of electromagnetic radiation (e.g. CT, MRI, X-ray equipment, etc.).*

⚠ *To ensure proper operation of the Device, avoid using it adjacent to or stacked with other electrical equipment.*

⚠ *Electrical medical devices and systems are subject to special measures concerning electromagnetic compatibility (EMC) and must be installed in accordance with the EMC instructions contained in this enclosed document.*

⚠ *Do not attach or tighten cable to or around the head or neck. Cable can cause **strangulation**.*

⚠ *Do not place the Device in a **microwave**.*

⚠ *Avoid continuous contact with device for several hours at a time.*

⚠ *Do not leave your Device and its accessories within the reach of small children or allow them to play with it. They could hurt themselves or others or could accidentally damage the Device. The Device contains small parts that may detach and create a **choking** hazard.*

⚠ *The Device is not waterproof. Do not immerse the device in water and do not clean it under running water*

⚠ *Do not use Device with items not described in this manual*

⚠ *Do not disassemble, modify or repair the device by yourself. Otherwise, it may cause fire,electrical shock, bodily injury, or device malfunction.*

7 Troubleshooting

7.1 Injection not detected

There are several reasons that injections are not detected consistently. The following can be helpful in fixing the issue:

- Make sure that the Device is designated for the pen model it is mounted on (see section 2.5).
- Make sure that the Device is fitted and positioned correctly on the pen i.e. the optical sensor is positioned close to the dose-knob after mounting (see section 3.1).
- Press (check for click) the mounting mechanism together to ensure that the Device is properly mounted on the pen. The 'mounted on pen' animation appears when the Device is properly mounted (see section 3.1).
- Make sure that there is no build-up of dirt, etc. on the optical sensor (see section 3.12 for cleaning instructions).
- If it is still not working, unmount and re-mount the Device on the pen (see section 3.8)
- If injections are still not detected contact our Customer Support Team.

7.2 Blinded sensor

The optical sensor of the Device is blinded when exposed directly to intense light (e.g. bright sunlight) and cannot detect the activity of the dose- knob. The screen will display the blinded sensor warning.

If this happens, take the device out of the intense light until the warning is no longer displayed. The Device can now be used normally.

7.3 Spillage

Should an accident occur exposing InsulCheck DOSE to a liquid (e.g. a cup getting knocked over causing spillage), remove it from the pen, dry it by wiping gently with a clean dry cloth, and set the Device aside for several hours before resuming its use.

⚠ The Lithium-Ion battery should not be exposed to water or other liquids.

7.4 System error

If the InsulCheck insignia is displayed periodically on the screen, this means that the Device has a repeating system error which it cannot recover from. If that happens,

stop using the Device and contact our Customer Support Team at info@innovationzed.com

7.5 Unsuccessful pairing

If the device displays the following screen, there was a problem paring the device to the app

There are several reasons for an unsuccessful Bluetooth® pairing. The most common reasons are:

1.It may be that the passkey was mistyped into the app or phone. Repeat the process or follow the instructions on your phone or app.

2. Check that your smartphone or app supports connection to your InsulCheck DOSE.

3. The Bluetooth® functionality is implemented in different ways by mobile device manufacturers and by app developers. There may be an incompatibility issue which cannot be resolved.

If you still cannot pair with the desired client device, please contact our Customer Support Team at info@innovationzed.com

7.6 Critical Battery

Battery level is critically low. Please charge the device with the USB cable as soon as possible.

7.7 Injecting while charging

Do not inject while charging. Please use the device after charging.

7.8 High temperature indication

The pen has been exposed to temperatures above typical recommended temperatures for insulin (nominally < 28C°). Suggest checking insulin.

7.9 Low temperature indication

The pen has been exposed to temperatures below typical recommended temperatures for insulin (nominally > 2C^0). Suggest checking insulin.

7.10 Long delay indication

There was a long pause between dials. The screen is showing the previous injection record. Please dial the dose knob back to 0 unit and then re-close the latch.

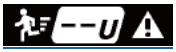
7.11 incorrect mounting indication

The device is mounted incorrectly. Please re-mount the device and ensure the Sleeve window aligns with the dosage window.

7.12 firmware update indication

The device software is updating. Please use the device after the update completes.

7.13 long delay injection indication



There was a long pause between dialling and injecting so no dosage is recorded. Please continue the injection after dialling next time. The next correct injection record can update the no dosage record displayed.

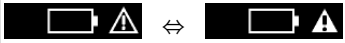
7.14 too fast dialling indication

The dose knob was dialled too fast, so no dosage is recorded. Please dial slower next time. The next correct injection record can update the no dosage record displayed.

7.15 Sensor cleaning indication

Sensor area needs cleaning. Please refer to section 4. For cleaning instructions.

8 Display guide

UI name	Artwork layout
Charging progress	*Animation:* 
Green light (LED)	n/a
Battery full	
Device logo	
Firmware version	 e.g., 
Mounting progress	*Animation:* 
Unmounting progress	*Animation:* 
High-temperature warning	*Toggle:* 
Low-temperature warning	*Toggle:* 
Saturation warning	*Toggle:* 
Battery low warning	
Critical battery warning	*Toggle:* 
Screen off	
The last injection time: Blank time	
Time since the last injection (right after performing an injection)	
The last injection time: < 24 hrs	
The last injection time: > 24 hrs	 [contains day count (max 99)]
The last injection dose: Blank dose	

UI name	Artwork layout
The last injection dose: Normal use display of units recorded	
Error reason: **Too fast dialling**	*Toggle:* 
Error reason: **Opened sleeve**	*Toggle:* 
The last injection dose with error reason: **Incomplete injection**	*Toggle:* 
Detecting the turned knob	
Warning of too fast dialling	*Toggle:* 
Unmounting warning	*Toggle:* 
Interrupted injection warning	*Toggle:* 
"Do not inject while charging" warning	*Toggle:* 
Stand by (screen off)	
Passkey	
Successful bonding	
Un-bonding / Unsuccessful bonding	
System error and failed system upgrade	*Toggle:* 
System upgrade progress	*Animation:* 
Sensor area needs cleaning. Please use a lens tissue for cleaning	*Toggle:* 

9 Contact information

9.1 Support

Web: www.innnovationzed.com
Email: info@innovationzed.com

9.2 Manufacturer

Manufactured for ***Innovation Zed Ltd.,***

NovaUCD, Belfield Innovation Park,
Belfield, Dublin 4, Ireland

by ***Scandinavian Healthcare Ltd.*** Taiwan

9.3 Warranty

For the terms and conditions of the warranty, please see the separate warranty card (included in the package or provided by the local distributor).

9.4 Disclaimers

⚠ *The manufacturer is not responsible for any problems, damages or malfunctions arising from unforeseeable circumstances.*

⚠ *Modification and taking apart the Device is not allowed and may interfere with performance and safety.*

10 Technical specifications

10.1 Specifications

Name	InsulCheck DOSE
Model	IC-Dose
Service life	2 Years
Dimensions	64 x 31 x 31 mm (with Sleeve)
Weight	20 grams
Accuracy of the timer	<5 minute/month drift
Data Storage	Approximately 30 days
Battery	Li-ion rechargeable battery, 3.7VDC (nominal), 80mAh,500 recharge cycles
Power consumption	Max. 155 mW
Charger rating	USB 5VDC, min. 500mA
Maximum internal working voltage	9VD
Radio	Communication: Wireless Bluetooth® Low Energy (BLE) Tx & Rx freq.: 2400 – 2800 MHz Max. Tx power:0-4dBm
Temperature Accuracy	+/- 2 degrees Celsius

10.2 Environment and operating

Normal Operation	-5ºC to 35ºC @ 10-75% RH (Non-Condensing)
Transport/Storage	-5ºC to 45ºC @ 10-75% RH (Non-Condensing)
Degree of enclosure	**IP22**
Vibration/ Shock/ Bump/ Drop/ Free fall	60601-1-11
Pressure	700hPa to 1060hPa

10.3 Electromagnetic compatibility

RF Emissions Test	Compliance	Electromagnetic environment guidance
RF emission CISPR 11, IEC 60601-1-2	Group 1, Class B	The device RF emissions are not likely to cause interference in nearby electronic equipment.

Electromagnetic environment guidance: The device is suitable for use in domestic and home healthcare environments.

Immunity Test	Test Level	Compliance level / performance criterion
Electrostatic discharge (ESD) ETSI/EN 301 489-1 ETSI/EN 301 489-17 IEC 60601-1-2 ISO 11608-1 ISO 11608-4	±2, ±4, and ±8 kV contact discharge ±2, ±4, ±8, ±10, ±12 and ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge

Power frequency magnetic field IEC 60601-1-2	30 A/m	30 A/m
Radiated RF ETSI/EN 301 489-1 ETSI/EN 301 489-17 EN/IEC 60601-1-2 ISO 11608-4	10 V/m 26 MHz – 6 GHz Immunity to proximity fields from RF wireless communication equipment as defined in Table 9 of IEC60601-1-2	10 V/m CT for transmitters, CR for receivers

Portable RF (radio frequency) communications equipment should be used no closer than 30 cm to any part of the device; otherwise, degradation of the performance of the device could result. InsulCheck DOSE is a Bluetooth® device using the 2.4GHz transceiver. In review of IEC 60601-1-2, subclause 8.10 the testing requirements in table 9 for the test frequency 2,450 MHz are acceptable for testing InsulCheck DOSE with the minimum separation distance as 30 cm. There are no foreseeable use cases that would require the InsulCheck DOSE to be used within the 30 cm separation distance.
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

10.4 Accuracy

Measurement Accuracy	99%*

⚠ ** Test bench results. External factors may affect the dose measurement accuracy.*

11 Declarations

Transportation worldwide by air, road, ship and train This device has been tested to meet the electrical and safety requirements of:

Medical Electrical Equipment

EN61000-6-3: 2007+A1:2011, EN61000-6-1 : 2007, EN61000-4- 2 : 2008, IEC 61000-4-3 : 2006+A1:2007+A2:2010, IEC 61000-4-8 :
2009, EN 62479:2010, EN5514-2:1997+A1:2001+A2:2008

RoHS Directive 2011/65/EU - IEC 62321-1:2013:

Electromagnetic compatibility

CFR 47: part 15 sub part b (FCC ID: 2A9FH-IZDOSE001 see FCC NOTICE below)

ANSI 63.4 of 2014

RED – Radio Equipment Directive 2014/53/EU

FCC (USA) - FCC ID: 2A9FH-IZDOSE001

FCC NOTICE:

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.

"You are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void your authority to operate the equipment."