

**Igloo Reader Pro
Instructions for Use**

CE UK
CA

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Introduction

Thank you for purchasing Igloo Reader Pro, an Dx365 product.

At Dx365, our mission is to make health diagnostics and testing simpler and more affordable.

Please read the below instructions carefully before using your reader.

Intended Use

The Igloo Reader Pro is a portable electronic IVD medical device designed for reading, processing, and analyzing qualitative, quantitative, and semi-quantitative in-vitro lateral flow immunochromatographic, colorimetric, and time-resolved fluorescence tests (LFT).

Its function is to assist in diagnostics related to specific lateral flow tests. Samples for these tests can come from any body fluids and extracts. The detection of a particular disorder, condition, or risk factor is based on the test-data set by the test manufacturer, which is pre-loaded into the Igloo Reader and using an bar-code or QR-code printed on test-cartridge for test identification. This manufacturer also specifies the target population for the test. Only professional users manually operate the application. The device can be used in a laboratory environment or close to the patient (NPT) by a healthcare worker such as pharmacists, therapists, nursing professions, biologists.

Reader tests

The clinical indications for using Igloo Reader Pro are limited by the limitations of each respective individual qualitative, quantitative or semi-quantitative in-vitro lateral flow immunochromatographic or colorimetric test.

The device can be used with following list of lateral flow tests:
Vitamin D, Ferritin - Affimedix Inc.

Before you use the test with the reader, you should check if it is possible to use this test with the device in the instructions for use for the test.

Customized adapters are not included in the delivery but can be ordered separately when ordering tests.

You need to connect device to Wi-Fi to upload calibration data to the device to each test batch or test type before using it for test reading. For using test metadata needs an Data Matrix or Barcode placed on the top of the test cassette with registrated test unique identifier. The full test specific metadata will be automatically stored to the Igloo Reader Pro by using Wi-Fi.

Symbols

	Caution
	Safety warning
	Consult User Manual
	Manufacturer
	In-Vitro Diagnostics
	Date of manufacture
IP20	Degree of enclosure protection (IP Code)

	<p>Non ionizing electromagnetic radiation</p>
	<p>Catalog number</p>
	<p>Protection class of electronic equipment</p>
	<p>European Conformity mark</p>
	<p>Do not use if the packaging is damaged</p>
	<p>Do not dispose with general waste. Please refer to the country-specific rules and regulations.</p>
	<p>For near patient testing</p>
	<p>Not for self-testing</p>

Safety Information

Please follow the mandatory safety information supplied with Dx365 Igloo Reader Pro. Please read this chapter carefully before using the device.

Safety Instructions

When used properly, the device cannot adversely affect the life and health of patients.

 Measurement results obtained using the device and rapid tests should be analyzed and interpreted only by professionals, in conjunction with other diagnostic procedures and clinical data, to eliminate any false-positive or false-negative results.

Cautions

 The device is equipped with a Li-ion battery. Do not heat it above the set temperature or expose it to direct sunlight.

 The risk of electric shock is minimized but cannot be eliminated. Observe necessary precautions when using electronic devices.

 When used properly, the device cannot be a source of infection. However, contamination due to the biological material being tested is possible. Always wear gloves and observe the specific laboratory precautions.

 Always follow the instructions in the in-vitro test's manual and this user manual.

 Use the device for its intended purpose only.

General Precautions

 Be aware that liquids can cause irreparable damage to Dx365 Igloo Reader Pro.

 Do not clean reader with excess liquid and do not spray disinfectants directly onto or into it. Considering these limitations, the

device can only be cleaned with a disinfectant solution (e.g. Mikrozid® AF Liquid, Aerodesin® 2000 or similar) applied to a cloth.



Do not expose the device to strong electromagnetic radiation. This may cause data to be lost.



Protect the device from dust as it can damage some of its parts and affect test results.



Do not heat the device above the set temperature and do not freeze.



Use the device with the supplied cable and with a recommended charger only. Using chargers that are not recommended may cause the device to malfunction.



Do not disassemble the device, otherwise the warranty will be automatically voided.



Do not insert non-intended tools or any other objects into the device slot, as they may cause the device to malfunction.



The device is not shockproof. Be careful as the device case is smooth enough for it to slip out.



The device is intended for use outside of the human body. Do not insert body parts into the device.



All in-vitro test measurements need to be done on a horizontal surface. Do not move or rotate the device during the measurement as this may cause its contamination or incorrect measurement results.



Preparing a test cassette without following the instructions may lead to incorrect test results.



Always check that you are using the appropriate cassette adapter with a specific test cassette.

Prerequisites

You need no special training or special skills other than reading and adhering to this manual.

Configuring the Igloo Reader Pro



Carefully read the End-User License Agreement (EULA) shown at first application startup. You may not use the product without accepting the End-User License Agreement.

You should set date and time in a reader settings. This is important for storing test results and usage logs.

Before You Begin

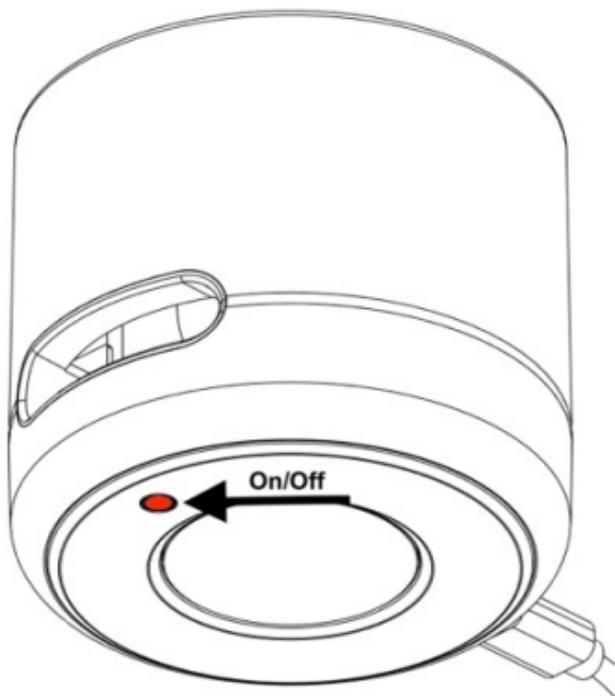
Prepare a work area for your Igloo Reader Pro.

Place reader on a flat surface away from any liquids as they could damage the device.

The work area should have enough free space to be able to easily insert and eject the test cassette adapter (cartridge).

To turn on your reader for further startups, either:

1. Pressing the button on bottom side of the reader.



2. The screen will turn on and after loading you will see a main menu of the reader.
3. After turning on the device, we recommend connecting it to your Wi-Fi network. Before the first use of a new LOT and REF test, the device needs to download interpretation data from our cloud. If the device has not previously read tests with this LOT and REF, it will prompt you to connect to Wi-Fi and restart the measurement. Once a test with a specific LOT and REF has been performed, the reader will store the interpretation data, allowing future measurements with the same LOT and REF to be done without a Wi-Fi connection. To connect to Wi-Fi, tap the Wi-Fi icon on the main screen or use the Wi-Fi option in the Settings menu.

You can now start working with your reader.

Measurement



Use gloves.

1. Switch on your reader.
2. Press "New measurement" and fill in the parameters: Patient ID, and optionally age and sex.
3. Choose one of the options: "Timer" switcher i.e. measurement within Dx365 Igloo Reader Pro using internal timer.



Device reads the incubation time and other important test ID information from the Data matrix or barcode placed on the test cassette. Prior to the measurement, make sure the Data matrix or barcode is located on the test cassette.

4. The device will prompt you to insert an adapter with the test cassette into the device.
5. Prepare the test cassette following its instructions for use.



Incorrect preparation of the test cassette can lead to incorrect test results.

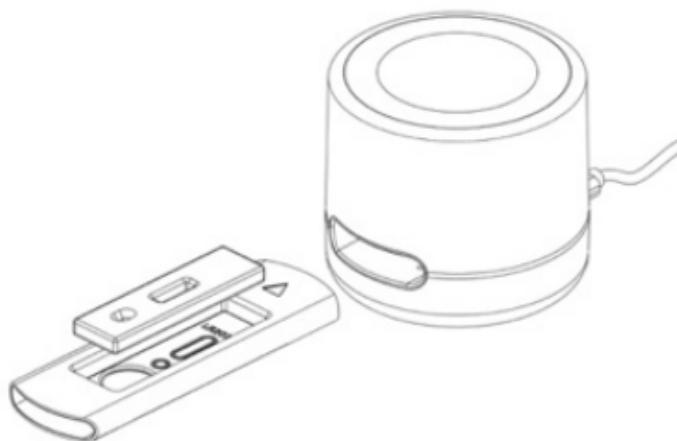
6. Place the test cassette into the cassette adapter with test strips facing up and insert them together into the device slot according to the adapter direction. **The sample well on the test cassette must be facing the outside of the device.**



The device is intended for use with various cassette adapters, but the test cassette must be suitable for the test cassette adapter.



In case barcode is not identified by the device using and device not connected to Wi-Fi - the device will ask you to connect to Wi-Fi to download the calibration data for this test.



7. Device will start measuring and showing the measurement progress. If you have inserted the adapter with the test cassette into the device before launching the application, eject the adapter and insert it again.

! The measurement process always starts with the countdown of the incubation time. Note that this process cannot be undone or paused once started.

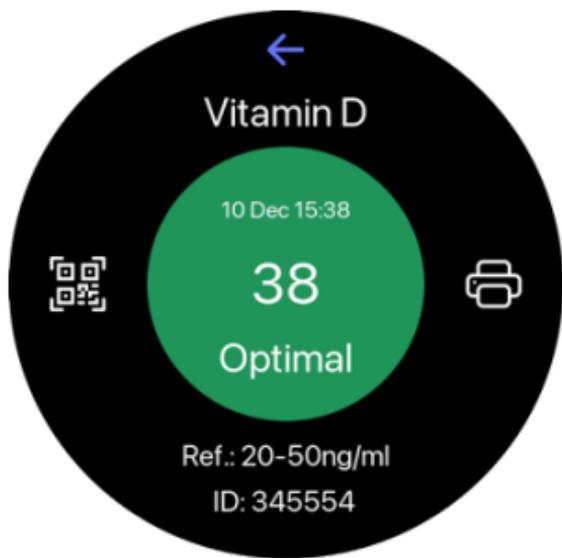
! Do not eject the cassette adapter until the reading is complete. If you eject the adapter for more than 10 seconds, the incubation time will be reset and the application will ask to start the measurement again. In this case inserting of the same test may lead to incorrect measurement results.

! If the user wants to conduct a measurement without the timer, they need to turn off the timer switcher. The device will then start measurement without a timer immediately after the cartridge is inserted. In this case, the user needs to manually measure the incubation time.



Do not move the device during the measurement as this may cause the cassette adapter to get ejected without your noticing it or lead to incorrect measurement results .

8. Upon successful measurement, the device will show the result on the screen.



9. If the test result is invalid or cannot be obtained from device, the application will show an appropriate message. In this case, use another test cassette to perform the test from the beginning.

10. Eject the cassette adapter and remove the used test cassette.



Remember that the test results can be false positive or false negative for a variety of reasons. Make sure to always have professionals double-check the results obtained using the approved comparable diagnosis technique.



A test cassette can only be used once.



Always follow the instructions for the correct disposal of used test cassettes.



Some lateral flow test manufacturers do not recommend evaluating test results after a certain time has passed, always follow IFU of the test.

The device is reusable. To continue measurements, save or export the test result using the application menu. To make another test, follow the instructions above.

Measurement History

The device has the ability to view the history of measurements made using a button on the main screen.

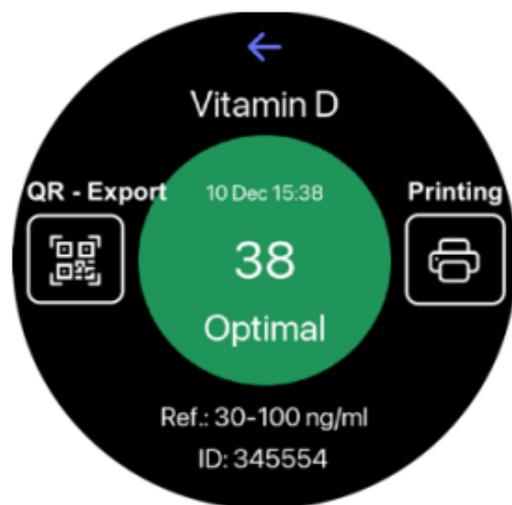


Exporting and printing measurements

After taking a measurement or viewing the measurement results in the measurement history, it is possible to print or export the measurement results to a mobile device.

To export measurement results to a mobile device, tap the QR-code icon. This will open a screen with a QR-code that can be read by the camera of the mobile device, which will generate a report with information about the measurement.

To print the result - click on the printer icon. The device will connect to the switched on printer and the result will be printed. The printer is not included in the device delivery set and must be purchased separately. Please contact your distributor or device legal manufacturer.



Cleaning, Turning off and Storing

In case the device has been contaminated, clean it with a disinfectant solution, such as Mikrozid® AF Liquid, Aerodesin® 2000 or similar applied to a cloth.

To avoid biological contamination, follow the cleaning recommendations after each use.

After 10 minutes of inactivity, the device indicator becomes less bright. After 15 minutes Dx365 Igloo Reader Pro automatically goes into standby mode.

If you touch the device before this time has passed, the indicator will start breathing slowly and the device will wait for a new interaction.

Another way to turn off the device is to press the off button on the main screen. The device will show you the screen where you can approve the turning off, with a long push on the off button.



Always store the device out of the reach of unrelated people or children.

The manufacturer recommends storing the device in a closed medical cabinet or desk.

Troubleshooting

#	Issue	Causes and recommendations
1	The device does not turn on.	Check the USB-C cable connection to your computer. Check the type of the cable used. Charge the device. Use the reset button (see #6).
2	The application can't connect to the device.	Check the type of the cable used. Restart the application. Check BLE configuration. Use the reset button to reload the device (see #6).
3	The measurement does not start.	The adapter wasn't inserted into the device correctly or sufficiently – check the cassette adapter. Check the Data Matrix barcode on the top of the cassette or review the Dx Care notification. Check availability of the internet for download metadata or use training cartridge with QR.

#	Issue	Causes and recommendations
4	No measurement result was obtained.	The adapter ejected before the measurement was complete, repeat the procedure with new test. The battery is insufficiently charged, connect the device via USB-C cable, results will be taken from the device if the measurement was finished.
5	Self-test error.	Contact support.
6	Device not responsive.	Use the reset button located on the rubber at the bottom of the device. Push the button within 10 seconds to reset reader to its factory firmware and settings.
7	Device behaves incorrectly.	Push twice the reset button, located under the rubber at the bottom of the device.
8	Device doesn't charge	Contact support.
9	The device does not turn off.	Disconnect the USB-C cable. Don't press the touch button and don't connect to the device from within the application. After 15 minutes, the device will go into standby mode.

Please note, that Reader with a set of lateral flow tests, is a single unit that is certified, produced, distributed and supported by its Legal Manufacturer**.

You can normally find Legal Manufacturer** name and contact information on kit packaging, additional sticker on reader bottom or via your distributor.

Quality Control Procedure

During factory production, the device undergoes a QC procedure with a special QC cartridge. The QC validity period is 1 year from the date of the procedure. In the Settings -> About, you can see the date until which the current QC is valid.



In case you need to do QC procedure you can additionally purchase a QC cartridge. The procedure is exactly the same as the normal measurement process of the device, after which you will see the result of the successful/unsuccessful procedure. In case of successful QC, the expiry date in the menu will be shifted one year forward from the date of the procedure.

Technical Specifications

The device is equipped with a Li-ion battery. Every device is shipped with a USB-C cable. The device User Manual is provided in an electronic form.

Cassette adapters are not included*. The availability of the adapter in the delivery package depends on the type of delivery.

Dx365 reserves the right to change the specifications at any time.

Technical Data

Device name	Igloo Reader Pro
SN	See type plate on the back of device
Test principle	The test is done by measuring of the different colored lines (test and control) on a test strip. The test lines are evaluated either qualitatively by checking whether the test band occurs at all or quantitatively / semi-quantitatively by calculating the color intensity according to the peak height or the surface area under the peak curve. Both methods can be used to determine the analyte concentration.
Measuring time	Several seconds excluding incubation time
Storage capacity:	Data store in the Dx365 Care application
Power supply	Rechargeable Li-ion Battery Voltage 3.7 V Rated capacity 2000 mAh

Accuracy	Inter-reader CV 2% Intra-reader CV 3%
Recommended charger (not included)	Type FW8002MUSB/05 Input 100-240V/50-60Hz/160-80 mA Output 5V/1400 mA
Environment	Working 5 – 40°C, 20% to 80% RH (non-condensing) Storage 0 – 45°C, 20% to 80% RH (non-condensing) Transportation – 10 – 60°C, 20% to 80% RH (non-condensing)
Input power	5V, 1400 mA
Weight	Approx. 270g
Dimensions	Height: 91 mm Width: 87,5 mm Depth: 87,5 mm
Connection	USB-C cable
Wi-Fi & Bluetooth Module	802.11 b/g/n, 2.4 GHz, powered up 100 mW

Degree of protection:	IP20
Warranty	One year

Scope of Delivery

1. Dx365 Igloo Reader Pro
2. USB-A to USB-C cable

Regulatory Information

Dx365 Igloo Reader Pro is CE marked in compliance with the essential requirements of the following European Commission (EC) Directives:

In Vitro Diagnostic Medical Devices Directive 98/79/EC

Restriction of Hazardous Substances Directive 2011/65/EU

Radio Equipment Directive Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at <https://support.dx365.world/legal>.

The disposal of Dx365 Igloo Reader Pro must be carried out in accordance with Regulation 2002/96/EC.

Users must report any serious incidents associated with the product to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Customer Support and Service Information

Dx365 Igloo Reader Pro is maintenance free.

The Dx365 Igloo Reader Pro is designed with a self-test function every time it is turned on. The camera sensor automatically calibrates at regular intervals throughout its life cycle.

Warranty period is limited to one year. The manufacturer guarantees the correct operation of the device in compliance with its operating instructions and recommendations.

If a defect is found in the device, it must be returned for repair or replacement.

The manufacturer does not assume warranty obligations in the following cases:

- if Reader was used for purposes other than its intended purpose;
- in case of violation of the rules and operating conditions;
- if Reader has traces of unqualified repair attempts;
- if the defect has arisen due to natural wear of the cable supplied;
- if the defect is caused by a change in the design or circuit of reader not provided by manufacturer;
- if the number of battery recharge cycles will exceed 500 during the first year, then warranty expires since the moment of this event.
- if the defect is caused by moisture, high or low temperatures, corrosion, oxidation, ingress of foreign objects, substances, insects, liquids inside the device.

The warranty does not cover the following defects of Dx365 Igloo Reader Pro:

- mechanical damage that occurred after the device was handed over to the consumer;
- malfunctions due to ignoring system requirements for work with Reader.

If you will keep the device clean and handle it carefully without damaging its internal parts, the device provides long-term and accurate measurements.

Reader lifetime is limited and depends on the number of measurements or battery recharges made.

Reader is anticipated to provide the expected performance for up to 500 battery charging cycles. However, in order to optimize this number, the device should not be stored continuously without being used for extended periods of time.

If stored for a long time, the reader should be fully charged, fully discharged and fully charged again at least once every 90 days. Otherwise, the functionality of the battery is not guaranteed. However, even in this scenario, no safety risks are anticipated.

The expiration of the warranty does not prohibit the use of reader, the manufacturer is not responsible for the results obtained after the device expiration.

More information is available at <https://support.dx365.world/>

For additional information and support please contact support@dx365.world

Users must report any serious incidents associated with the product to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Device is powered by a Li-Ion 2000 mAh battery, please follow the internal regulations of your country for the proper disposal of the device.

If returning the device to the manufacturer, make sure to disinfect it first according to this manual.

Disinfection Receipt

Due to potential contamination with infectious material during use, disinfection is required prior to return. The template on the following page can be used as proof of the disinfection of the device. Please enclose the disinfection slip with the delivery papers.

Attention: A reader sent in cannot be accepted without a signed disinfection receipt and will be returned unopened!

Device type:	Igloo Reader Pro
Reason for transmittal:	
Customer/company:	
Date of disinfection:	
Disinfection operator:	
Serial numbers of disinfected devices:	
The following disinfecting measures were executed on the above-mentioned devices:	<input type="checkbox"/> Cleaning of every surface of the device with paper tissue and disinfection solution suitable for laboratory devices (for instance Mikrozyd® AF Liquid or comparable product)
Place, date and signature	

The name and address of the Legal Manufacturer



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