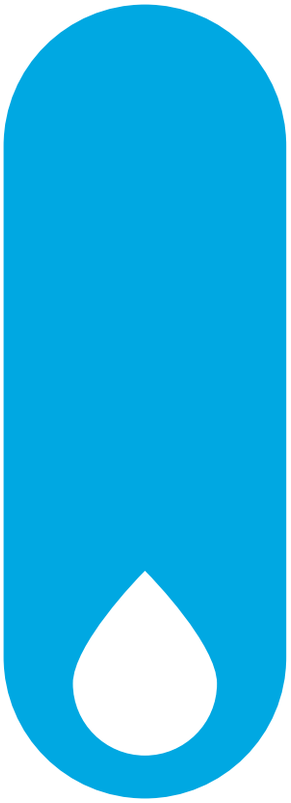


The Aina Device

Mobile HbA1c Analyzer

Diagnostics in the palm of your hand

Jana Care

User Manual Table of Contents

Key to Symbols


Manufactured by


Expiry date


This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices

Authorised Representative in the European Community

For in vitro diagnostic use


Please read instructions before use


Important information accompanies this product


Powered by DC power source


Storage temperature range


Not to be used in case package is damaged


Do not expose to sunlight


Do not reuse

Introduction

Hello!

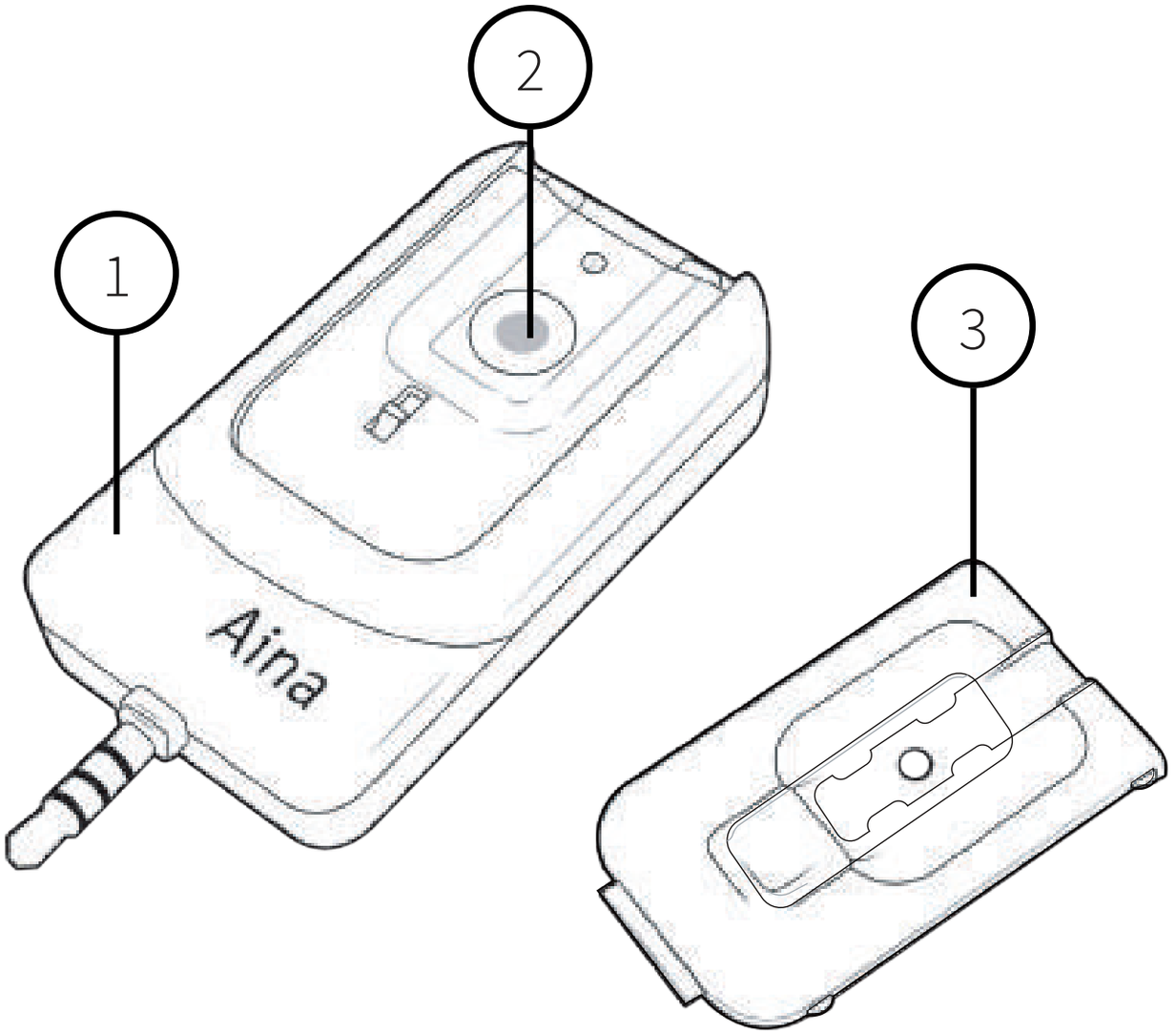
With The Aina Device, testing your HbA1c is as easy as looking into a mirror.

In this booklet, we will simplify the steps for conducting HbA1c tests on your new system.

Please carefully read all the instructions to understand your system better.

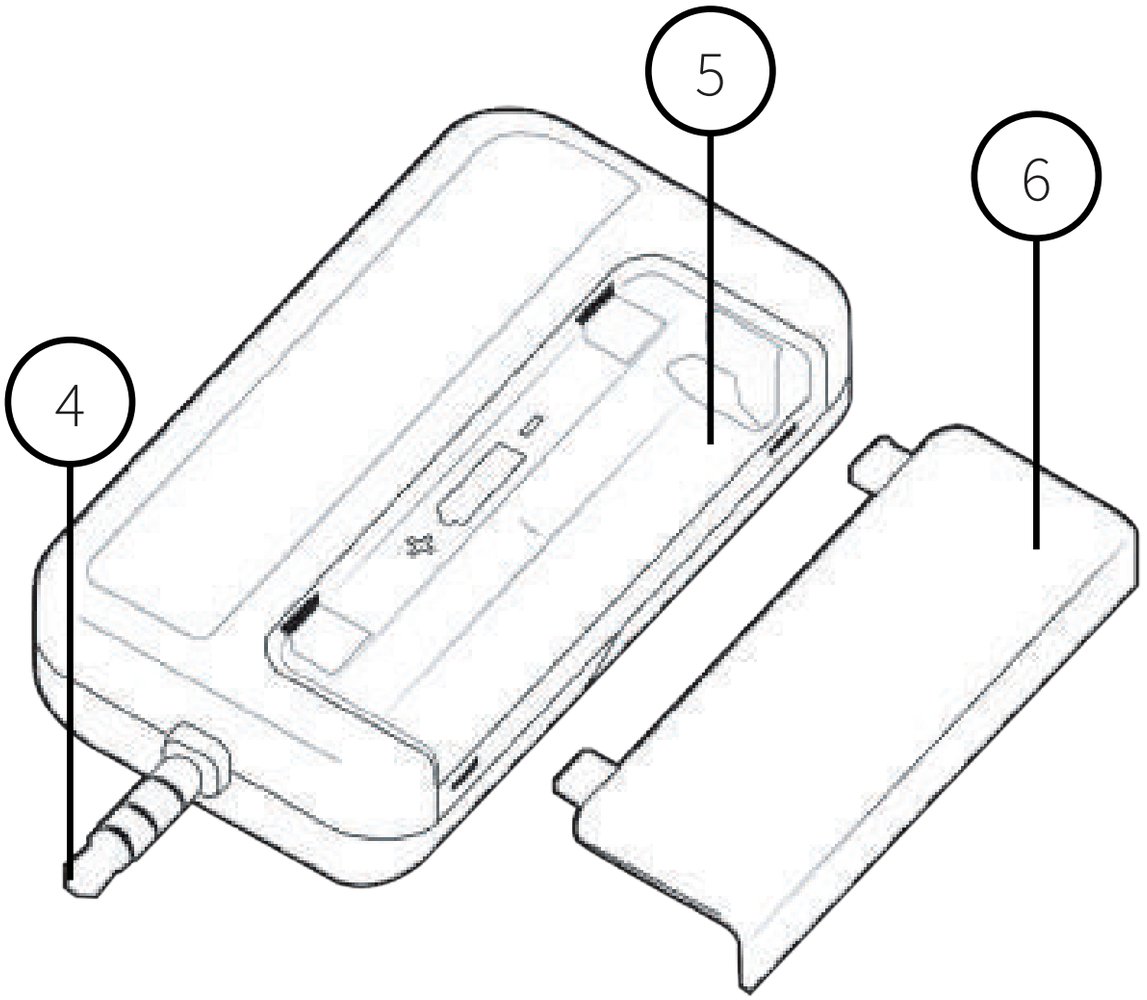
The Aina HbA1c Monitoring System is intended to be used for the quantitative measurement of glycosylated hemoglobin (HbA1c) levels in fresh fingerstick capillary blood or venous whole blood samples. The system is intended for clinical laboratory and point-of-care use to monitor long term glycemic control of persons previously diagnosed with diabetes.

Part Summary



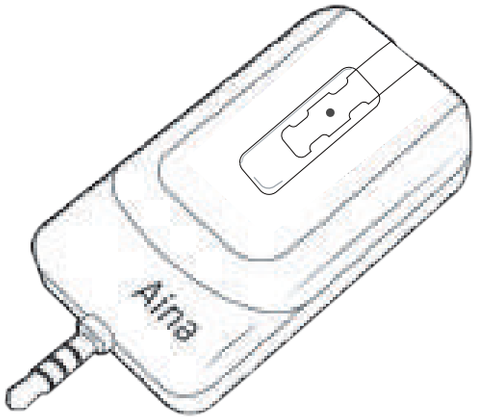
1. Device Body
2. Optical Window
3. Strip Adapter

Part Summary



4. Audio Plug
5. Battery Compartment
6. Battery Cover

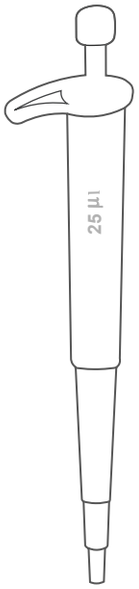
What’s Inside The Aina Device Box



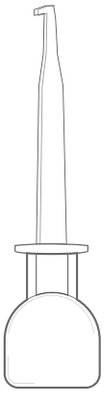
Aina Device

AAA battery

Aina booklet



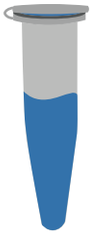
25 µL pipette



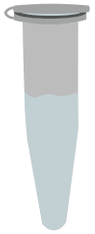
Capillary holder

Aina HbA1c Test Kit Contents

Box 1 - To be stored between 2 to 8°C



25 Reagent vials



25 Wash buffer vials

Box 2 - To be stored at room temperature

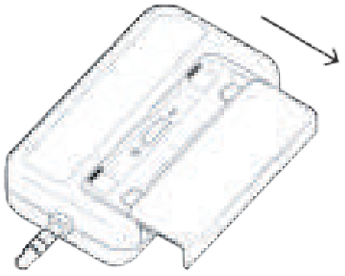
25 Test strips

25 Capillary tubes

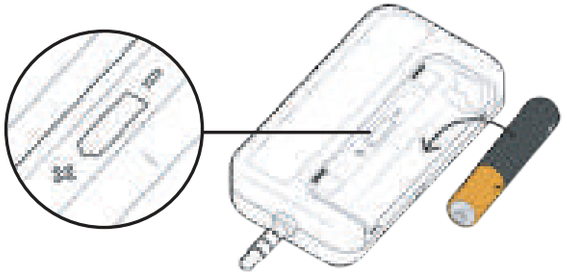
50 Pipette Tips

Inserting Battery

1. Open Battery Cover



2. Insert battery into device as indicated



3. Close Battery Cover

The Aina App

Initial Set Up

Go to **getaina.com** and install the companion app according to the instructions provided.

The Aina app needs permission to your phone's audio, camera and SD card to allow communication between your phone and the Aina Device, and to store the readings. The Aina app also needs access to mobile data to periodically download configuration files needed to perform tests.

One Time Set Up

Your phone may need to assess if it is compatible with the Aina Device. Please follow the instruction mentioned on screen.

The Aina App

Understanding the Interface

MENU

previous readings: see previous test results
settings: unit of measure option & clear data
help: basic instruction manual

EDIT

Use to edit code to match the code on the reagent pouch

NEXT

Press to confirm the code on the reagent pouch and begin the test

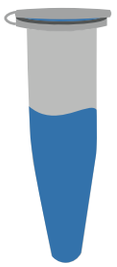
Test Procedure

This test is time-sensitive. Do not begin any steps until you have started the app. Complete each step only when you see it on the screen, not before.

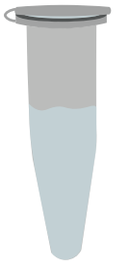
Gather the following consumables in addition to the Aina Device :

Alcohol swab, clean cotton, lancet, capillary tube in the capillary holder, reagent vial, wash buffer vial and 2 pipette tips.
Remember to wear a new pair of gloves for each new patient to avoid spreading disease from one patient to another.

1. Bring one reagent vial and one wash buffer vial to room temperature. It usually takes them 10 minutes to come to room temperature.



Reagent Vial



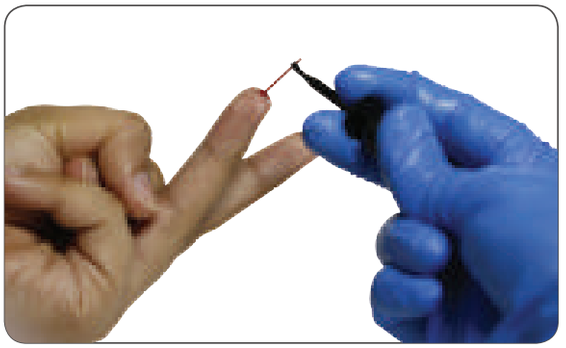
Wash Buffer Vial

2. Open the Aina app on your phone/tablet and follow the on-screen instructions.
3. Enter the 3-digit code printed on the reagent bag.

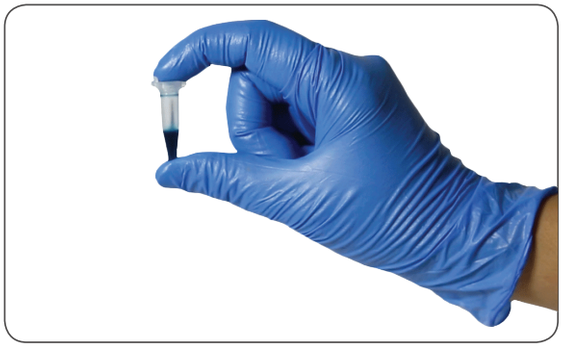
4. Plug in the Aina Device. The app advances to the next screen.
5. Insert a fresh HbA1c test strip into the Aina Device.

6. After the fresh strip is analyzed, take it out of the Aina Device. Invert it and keep it aside.

7. Wipe the fingertip with an alcohol swab. Let the alcohol evaporate completely before pricking the finger.
8. Prick the fingertip and wipe away the first drop of blood with a clean piece of cotton.
9. Fill the capillary tube with blood and place the tube inside of the reagent vial. As soon as you do this, click on ‘start timer’.

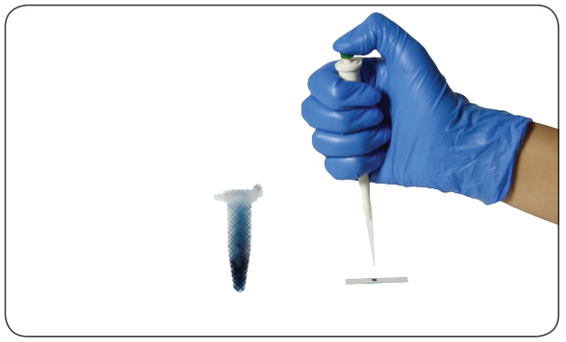


10. Shake the vial for 30 seconds following the Aina App timer.



11. Put the vial down and wait for 80 seconds following the Aina App timer. Fix a pipette tip on the pipette.

12. Shake the vial and fill the pipette tip with the mixture following the Aina App timer.
13. Dispense mixture onto the HbA1c strip following the Aina App timer. Avoid introducing air bubbles or touching the strip while dispensing.

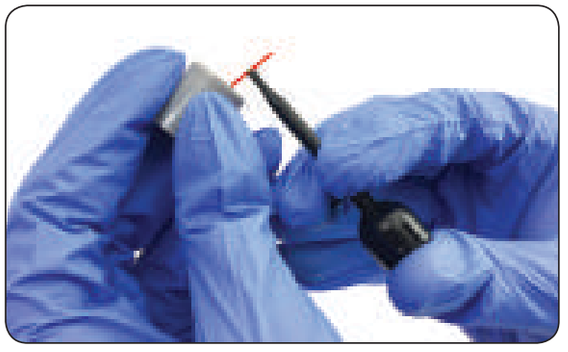


14. Change the pipette tip and pipette the wash buffer following the Aina App timer.
15. Dispense wash buffer onto the HbA1c strip following the Aina App timer. Avoid introducing air bubbles or touching the strip while dispensing.

16. Wait until the strip fully absorbs the wash buffer following the Aina App timer.
17. Immediately invert and insert the test strip into the Aina Device.
18. The Aina Device will automatically detect the strip, and analyze it, then provide a result in % or mmol/mol depending on the setting set by the user.

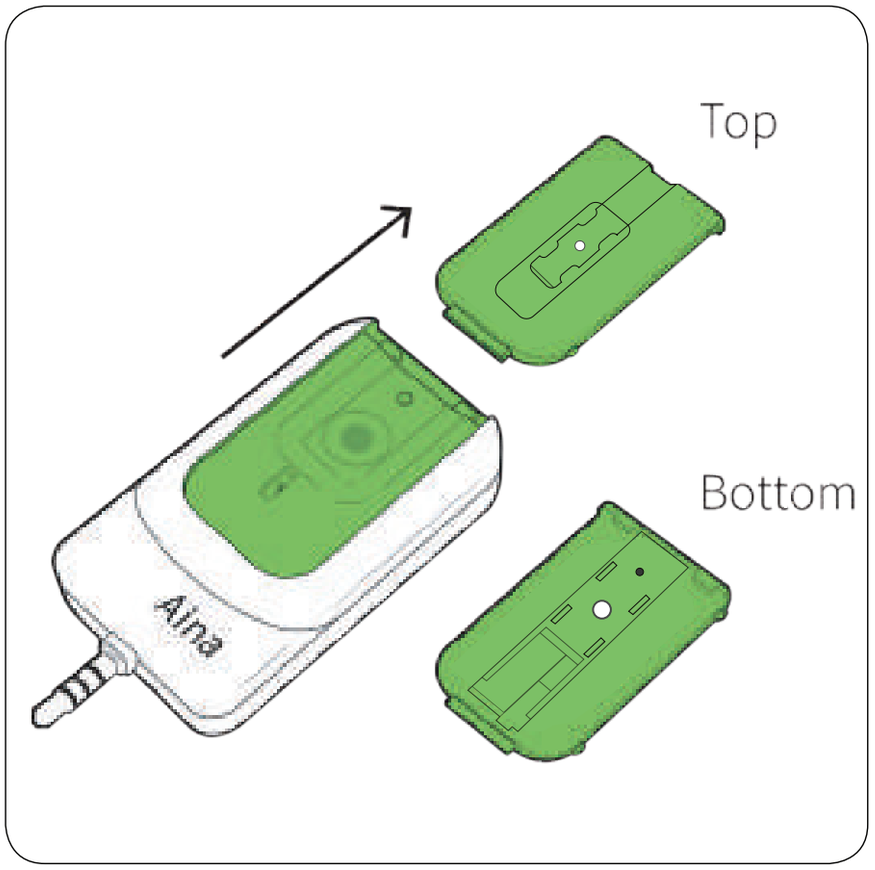
If you are using venous samples

Invert the vacutainer to ensure proper mixing of blood. Open the cap of the vacutainer and touch the capillary tube to the drop of blood retained on the cap.



Cleaning, Care and Storage

- Clean all outer surfaces of the Aina Device with isopropyl alcohol between each use, when taking out of storage, and when putting into storage.
- 70% Isopropyl Alcohol, commonly called IPA / medical spirit should be used for cleaning.
- Store in a cool, dry place. Keep away from moisture and dust.
- Avoid getting blood on the device. If you do, clean it immediately with isopropyl alcohol.
- Clean the optical window every day, and every time you observe dust or liquids on the optical window. Dust or liquids on the optical window can lead to inaccurate results.
- To clean the optical window, remove the strip adapter from the top of the device. Wipe the optical window using a soft cloth with isopropyl alcohol or an alcohol swab. Wipe the strip adapter with isopropyl alcohol or water and let it dry.



- Be careful not to get water into the Aina Device!
- Also avoid scratching the optical window!
- Clean the optical window, as well as the top and bottom of the strip adapter.

Storage and Handling Conditions

Store device in a cool, dry place at -20 to 50°C (-4 to 122°F).

Tests have to be performed between 18 to 40°C (64 to 104°F). The recommended ambient temperature range is 20 to 25°C (68 to 77°F).

Do not scrape, scratch, bang or bend the device.

Do not use strips exposed to the elements with this device.

Do not use a damaged device.

Do not use damaged test strips with this device.

Do not place the device inside a container that might damage it.

Do not casually toss or roughly handle the device.

Do not forcibly shove the device into a phone/tablet's audio jack.

Remove the AAA battery from the Aina Device when not in use.

Do not let someone who is unfamiliar with the device use it before getting familiar with this booklet.

If you encounter a problem, refer to Helpline and Contact section.

Troubleshooting

Problem Solving

Have you received a test result that seems improbable or the device is not functioning properly?

Try these few things:

- Repeat the test.
- Replace the battery.
- Clean the Aina Device.
- Make sure to wipe off the first drop of blood.
- Check expiration date of the Aina HbA1c Test Kit.
- If outside, try taking the test indoors.
- If the issue persists, refer to the Helpline and Contact.
- Samples with a hemoglobin concentration lower than 10 g/dL or higher than 20 g/dL can cause inaccurate test results.

Limitations

- For in vitro diagnostic use only.
- Test strips and reagent vials should be used once only.
- Do not carry out the test in direct sunlight.
- Not for neonatal use.
- Strong electromagnetic fields (e.g. microwave ovens) may affect performance. The Aina Device will detect this and an error message will be displayed.
- The reagent and wash buffer must be stored in the designated temperature range (2 to 8°C).
- If the reagent and wash buffer are stored in the temperature out of the designated range, the test results may be inaccurate.
- Do not use the reagent and wash buffer if kept at room temperature for more than 2 hours.
- Use only fresh capillary whole blood or venous blood. Do not use serum or plasma.

Interfering substances:

1. Venous blood collected with a K2-EDTA, K3-EDTA or Li-heparin anticoagulant may be used with this system.
2. Samples with a hemoglobin concentration higher than 10 g/dL or lower than 20 g/dL do not interfere with the test.
3. Elevated levels of HbF can cause inaccurate test results.

The effect of the following endogenous substances and pharmaceutical compounds on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on the HbA1c results was observed.

Compound	Concentration	Compound	Concentration
Glucose	500 mg/dL	K3-EDTA	10.8 mg/mL
Acetylsalicylic acid	20 mg/dL	Labile HbA1c	55 mM
Acetaminophen	30 mg/dL	Carbamyl Hb	5 mM
Ascorbic acid	6 mg/dL	Triglycerides	500 mg/dL
K2-EDTA	10.8 mg/dL	Cholesterol	351 mg/dL

Compound	Concentration	Compound	Concentration
Ibuprofen	50 mg/dL	Lithium heparin	75 IU/mL
Glyburide	20 mg/dL	Bilirubin unconjugated	15 mg/dL
Metformin	5.1 mg/dL		

Criterion: Recovery of ± 5 % of the initial value.

If you get unexpected results:

If your result is outside of the measuring range for HbA1c, please repeat the test by drawing a fresh sample.
If you continue to get unexpected results, check your system with the Streck A1c-Cellular HbA1c Control Kit. If you are experiencing symptoms that are not consistent with your results and you have followed all the steps described in your Aina Device instruction manual, call your healthcare professional and follow their treatment advice.

Checking your system:

To ensure that the device and strips are functioning properly and you are carrying out the test correctly, you may check the performance of the system with the Streck A1c-Cellular HbA1c Control Kit.
To perform a control solution test, follow the same test procedure that is used for a HbA1c test, substituting control solution for 5 µL of blood. The result obtained should fall within the acceptable range. If the result of a control solution test falls outside the range, repeat the test. If any issue with the device persists, please contact technical support as listed in the device instruction manual.

When to carry out a control test:

- If you obtain repeated unexpected results.
- After opening a new test kit.
- If you suspect that the Aina Device or any component of the test kit are not working properly.
- If you drop the Aina Device.

Warnings and Error Messages

If they occur, appropriate warning and error messages will be clearly shown in plain language on the mobile device screen. If an action is required, it will be clearly stated as well. If any of the on-screen instructions are unclear, refer to Helpline and Contact section below.

Errors will require an action to be taken by the user. Warnings are recommendations that may require future action. Below is an example of some warnings you may encounter while using Aina.

Temperature Warning

The ambient temperature is nearly outside the recommended temperature range for this test.

Strip Placement Warning

Strip is not detected properly, please push it in completely to continue.

Low Battery Warning

Aina device battery is low, please replace it soon.

Strip Detection Warning

Device has not detected strip.
Please insert the strip, or tap here if you have already inserted it.

Low Volume Warning

Please increase the phone volume to the maximum level.

Technical Data

Phone/Tablet Platforms	Android and iOS
Device Size	79.75mm x 36.5mm x 16mm
Battery	1x 1.5V AAA Battery
Battery Life	At least 200 Tests
Test Time	Approximately 3 minutes
Measuring Range	4.0 to 15.0 %
Operating Temperature	18 to 40°C (64 to 104°F)
Method	Boronate Affinity & Photometry
Blood Volume	5 µL
Blood Type	Whole Blood Capillary & Venous Blood (supported anticoagulant: K2-EDTA, K3-EDTA or Li-heparin)

Accuracy

Comparison using capillary whole blood against the Alere Afinion AS100 analyzer produced the following regression:

$Y(\%\ HbA1c) = 0.98x + 0.31,\ R^2 = 0.977$

Comparison using venous whole blood against the Alere Afinion AS100 analyzer produced the following regression:

$Y(\%\ HbA1c) = 0.985x + 0.202,\ R^2 = 0.973$

Bias	Target	Achieved (Venous Blood)	Achieved (Whole capillary blood)
Within ± 10% of reference method	90%	96.3%	94.9%
Within ± 15% of reference method	95%	100%	100%

Precision

A precision study was carried out using two levels of blood samples and control solutions. Each sample was tested in duplicates twice a day, for 5 days for a total of 20 measurements per level of sample. The repeatability obtained is shown in the following table:

Precision with blood samples (n=20)					
Level	Mean % HbA1c	Within run		Total precision	
		% CV	SD	% CV	SD
L1	6.0	2.30	0.14	3.10	0.19
L2	11.4	1.30	0.15	2.20	0.25

Precision with control solutions (n=20)					
Level	Mean % HbA1c	Within run		Total precision	
		% CV	SD	% CV	SD
L1	5.2	1.90	0.10	2.50	0.13
L2	13.4	1.40	0.1	1.80	0.24

Helpline and Contact

For product information, please visit www.getaina.com

Have a question?

Call us - International: +1 (855) 809-9558 / India: +91-8047092684
or email us at support@janacare.com

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CE

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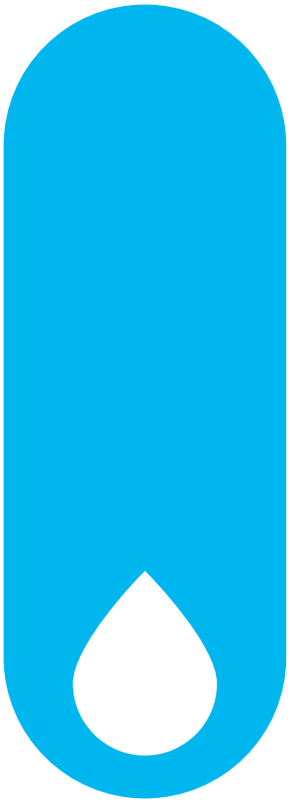
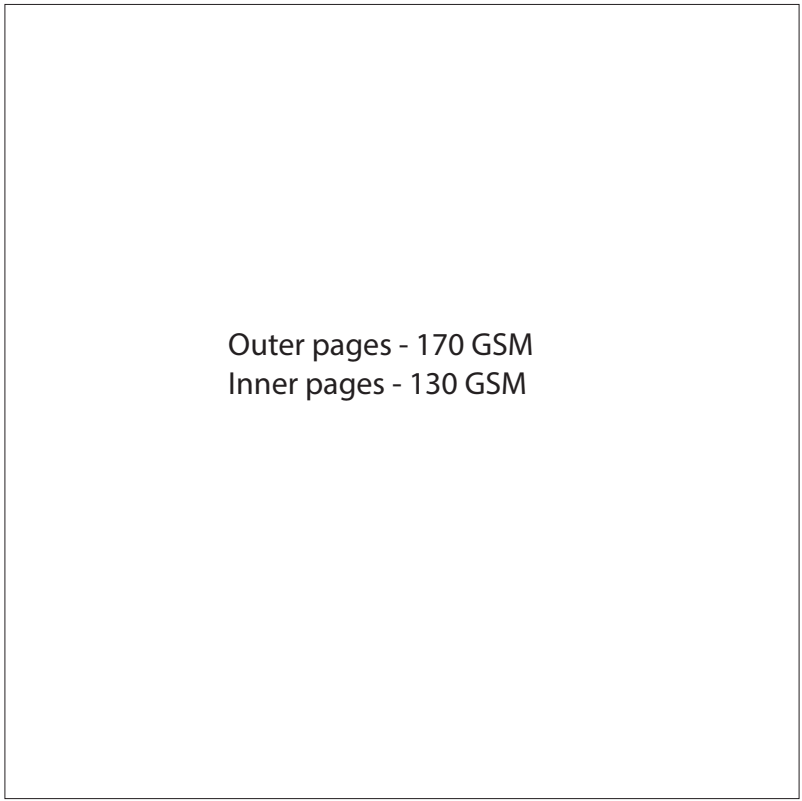


The Aina Device

Mobile HbA1c Analyzer

Diagnostics in the palm of your hand

JanaCare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