

Avie™ A1c Reader
User's Manual

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I. INSTALLATION AND INFORMATION

1.1 Introduction

This manual will provide you with useful information that you will need to know in order to perform Hemoglobin A1c (A1c) testing on the *Avie*TM A1c Reader.

Note: Please read the entire manual before using the AvieTM system

The *Avie*TM A1c System provides quantitative measurement of the percent of glycated hemoglobin levels in fingerstick (fresh capillary) whole blood samples. The test is for professional use and physician directed home use at the point of care, to monitor glycemic control in diabetic patients. The *Avie*TM A1c Test System provides a simple, reliable way to monitor glycemic control.

The *Avie*TM A1c System is for *in vitro* diagnostic use only.

Please see the Package Insert that accompanies the *Avie*TM A1c Cartridge for additional information.

MEC Dynamics Technical Support and Customer Care contact information:

MEC Dynamics Corp

2225 Martin Ave. Suite I

Santa Clara, CA 95050

Phone: 408-844-9280

Toll Free: 888-376-1081

Fax: 408-844-9285

Hours: 6:00 am - 6:00 pm Pacific Standard Time, Monday - Friday

Web: www.mecdynamics.com

1.2 Installation

Your Avie™ A1c Test System includes:

- Avie™ A1c Reader (Battery power pack is optional)
- Universal Power adapter
- Avie™ A1c System Users Manual
- Quick Reference Guide
- Avie™ A1c Test Cartridge
- Pipette and Tips
- Diluent
- Warranty registration card

You will also need:

- Lancets
- Isopropyl alcohol or alcohol wipes
- Gauze or cotton balls
- Puncture resistant container (SHARPS container)



See the “**Battery**” section for more information and instructions on installing the batteries if a battery power pack is to be used.

Special Requirements

To ensure that your Avie™ A1c Reader operates correctly, be sure the following conditions are met:

- Room temperature should be between 65° F and 82° F (18° C and 28° C) for testing.
- Relative humidity should be between 10% and 80%, without condensation, for testing.
- The Avie™ A1c Reader should be transported in a secure container if there is a need to move it.
- Avoid dropping the reader, or treating it roughly.
- Use the Reader only on a level non-vibrating surface.

II. PRINCIPLES OF OPERATION

The Avie A1C test system utilizes immunochemistry and general chemistry to quantify %A1C levels (glycated hemoglobin) in whole blood. The system consists of a small electronic instrument (Reader), a single-use diluent solution vial, and single-use reagent test cartridge.

To perform one test, the Reader is turned on. When the LCD display denotes “Ready” a test cartridge is inserted into an unambiguous slot in the reader. A small amount of whole blood is added to the diluent vial. This blood is immediately lysed and the hemoglobin is converted to met-hemoglobin. At the instruction of the reader (LCD display), three drops of diluted blood are applied to the well on the cartridge. The reactions then proceed automatically and no procedural steps are required. The test is complete in less than 4 minutes.

The A1C test consists of two distinct quantitative areas of measurement. The first area consists of a chamber where the met-hemoglobin is photometrically read at 420 nm. The optical density of the met-hemoglobin is proportional to the concentration of total hemoglobin. The second area consists of a mixing chamber where the diluted blood is mixed with anti hemoglobin antibodies conjugated to blue microparticles. After a predetermined time the microparticle mixture is automatically released onto a reagent strip where the reacted and unreacted microparticle species are separated and read optically. The concentration of these species is used to calculate the amount of A1c. The final displayed result is expressed as;

$$\%A1C = (A1C \div \text{TOTAL HB}) \times 100$$

If attached to an ancillary printer, the test results will be automatically printed out at the end of the test.

1.3 *Avie™ A1c Reader*

Study the following illustrations to become familiar with the major components of your Avie™ A1c Reader:

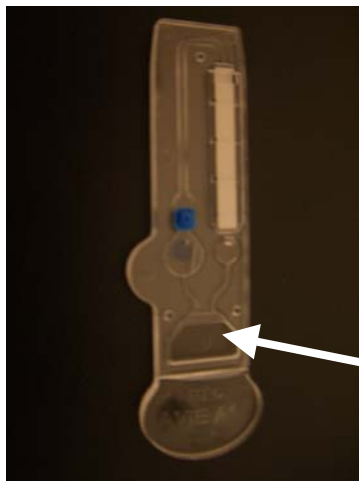


Power Button: Turns the Reader on

Display: Screen shows test results and error messages

Test Cartridge Guide: Holds a test cartridge in place during testing

Avie™ A1c Test Cartridge



Application Well

III. PERFORMANCE CHARACTERISTICS AND PRODUCT SPECIFICATIONS

1.4 Performance Characteristics

1.4.1 Expected Values

<i>GHB(%)</i>	Approximate Mean Plasma Glucose*		<i>Interpretation</i>
	<i>mg/dL</i>	<i>mmol/l</i>	
4	65	3.5	Non-Diabetic Range
5	100	5.5	
6	135	7.5	
7	170	9.5	ADA Target [#]
8	205	11.5	Above Target
9	240	13.5	
10	275	15.5	
11	310	17.5	
12	345	19.5	

* Mean blood glucose results are 10-15% lower. Most blood glucose Readers are calibrated to read as plasma glucose.

[#]*Diabetes Care* 2004;27 (Suppl. 1):S91 - S93

1.5 **Product Specifications**

Battery lifetime: Variable. Approximately 50 tests.

Mode of operation: Continuous

Operating Conditions:

Operating temperature: 65 to 82°F (18 to 28 °C)

Operating humidity: 10% to 80% (non-condensing)

Degree of protection against ingress of water: Ordinary equipment

Power supply: AC: Input 120V
4 AA Alkaline 1.5-volt batteries
Output: 6V @ 700 mA

Battery voltage: 6V @ 700 mA

Result range: A1c values 5% to 14% are reported.

Sample type: Fingerstick (fresh capillary) whole blood samples

Sample volume: 4 micro liters

Reader Storage and transportation

Temperature: 0° F to 131°F (-17° C to 55°C)

Humidity: 10% - 80% (non-condensing)

Atmospheric pressure: 500 hPa -1060 hPa

- Equipment complies with EM 61010-1
- Classification is with respect to electric shock, fire, and mechanical hazards only in accordance with EN61010-1.
- Internally powered and Class II equipment.
- Type BF patient applied parts.
- System complies with EN 61326.
- EN61326-1 EMC Medical Products Warning: This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, could cause interference to adjacent equipment. There is no guarantee that interference will not occur in a particular installation if the instructions are not followed. The user can determine if the interference is caused by the equipment by turning the unit off. If interference is caused by the equipment, you should try moving the equipment away from the other unit.
- 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.

1.6 **Symbols and Explanations**



In vitro Diagnostic: The Avie™ A1c system is for *in vitro* diagnostic use only



SN

Consult Instructions for Use prior to using the Avie™ A1c System

Serial Number: The Reader serial number is located on the bottom of the Reader



Temperature Limitation: The Avie™ A1c system is intended to be used between 65 to 82°F (18 to 28 °C) 10 to 80% non-condensing relative humidity



Do Not Reuse: The Test Cartridges and Diluent vial are intended for one time use only



Use By: Test Cartridge, Diluent, and Controls must be used by the expiration date marked on their labels.



Batch Code: The lot number of the Test Cartridge may be found on the cartridge vial and the Diluent on the vial and outer packaging.



Manufacturer: MEC Dynamics, Inc.
2225 Martin Ave. Suite I
Santa Clara, California 95050

1.7 **Ordering Information**

You may order the following products through your authorized MEC Dynamics Corp. distributor or by contacting the Customer Service Department at MEC at 408 844 9280

Part Number	Description
FIN0003	Avie™ A1c Physician Directed Home Use System Kit
FIN0004	Avie™ A1c Professional System Kit
FIN0005	Avie™ A1c Reader
FIN0006	Avie™ A1c Professional Test Cartridge (box of 100 with diluent)
FIN0007	Avie™ A1c Physician Directed Home use Test Cartridge (box of 5 with diluent)
FIN0009	Avie™ A1c Battery Power Pack
FIN0010	Avie™ A1c Printer and Cable
LBM0001	Avie™ A1c System User's Manual
LPC0002	Avie™ A1c Use Quick Reference Guide
FIN011	Avie™ A1c System Control Level I
FIN012	Avie™ A1c System Control Level II

IV. OPERATING INSTRUCTIONS

1.8 Initial Set-up

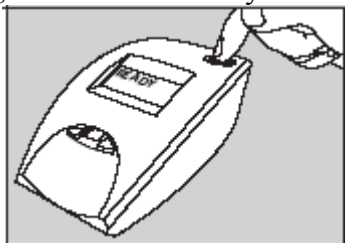
Your Avie™ A1c Reader is ready to test when you receive it. Just plug it in and follow the instructions below. If you prefer to run the Reader on batteries, see section IX. Maintenance and Cleaning, for use of the battery pack.

Running an A1c Test

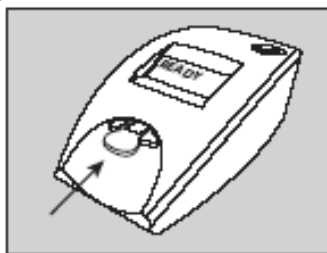
Check the expiration date on the cartridge vial, the diluent vial, and the control bottles. Do not use items after their expiration date.

If the Test Cartridge Vial or Reader have been recently at high or low temperatures (above 82°F or below 65°F), allow ALL parts to come to room temperature for at least 1 hour before running the test. Leave the cartridge in the sealed vial while doing this. Avoid running the test in direct sunlight, on hot, cold, or vibrating surfaces, or near sources of heat or cold. Do not reuse the cartridge or diluent vial.

1. Use the cartridge within 2 minutes after removing it from the vial.
2. Turn the Reader on by pressing the ON button. When “READY” is shown on the display, the Reader is ready to start a test.

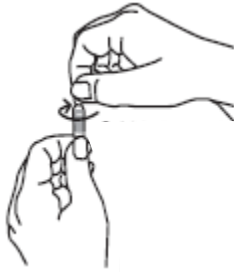


3. Touch the side of the cartridge vial to the middle side right side of the Reader to transfer cartridge specific information. The reader will beep. Slide the test cartridge into the Reader test cartridge guide in the direction of the arrow as far as it will go.



4. The Reader will beep and show “APPLY DILUENT”.
5. The patient should wash their hands with soap and water.

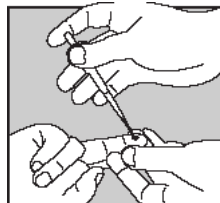
6. Open the Diluent vial by holding on the bottom fin of the vial and twisting off the vial cap. You may lay the vial down as it will not leak unless squeezed.



7. Firmly apply a clean unused pipette tip onto the end of the pipette giving it a slight twist to make sure there is an airtight seal.
8. Obtain a sample by means of a fingerstick. If you are performing a control test pipette a control sample directly from the control bottle (see step 9).

Performing a fingerstick

- a. Clean the desired finger with alcohol or soap and warm water and then dry hands thoroughly before lancing the finger.
 - b. Position the lancet on the puncture area (side of a fingertip, away from any calluses or scars).
 - c. Use the lancet as directed to puncture the skin.
 - d. Apply gentle, continuous pressure across the entire finger to form a hanging drop, do not milk the finger (see step 9 for collection of the sample).
 - e. Hold a cotton ball or gauze firmly over the puncture site until the bleeding stops.
 - f. Place a band aid over the puncture on the finger if desired.
9. Collect the Sample:
 - a. Push the plunger on the pipettor all the way down and hold it down as far as it will go.
 - b. Holding the pipettor at an upright angle, gently place the pipette tip in the finger stick blood drop. If you are testing controls place the pipette into the liquid sample in the control bottle.
 - c. Release the plunger slowly, drawing up the sample. Be careful not to have an air gap or bubble form. The blood should be solid red with no spaces or bubbles. Collect a new sample if this occurs.



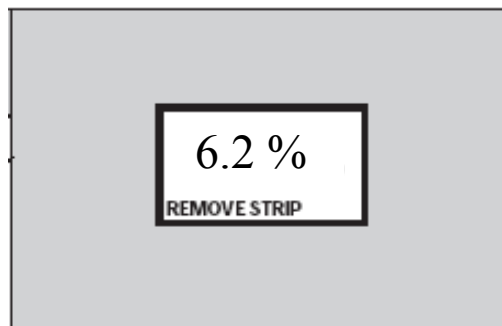
10. Place the sample in the diluent vial:
- Holding the vial upright by the fin, insert the pipette tip into the liquid.
 - Slowly depress the plunger to add all the blood to the liquid.
 - Keeping the pipettor depressed, remove the pipette tip out of the vial before releasing the plunger. This will prevent blood sample from being drawn back into the tip.
 - Remove the pipette tip and discard it in a biohazard waste container.
 - Invert the vial 5 times to mix the blood with the diluent. **DO NOT SHAKE.** The tube will not spill in the inverted position unless squeezed.



11. Apply the sample. Squeeze 3 drops of the mixture (diluted sample) into the application well located on the top of the cartridge.



12. The Reader will count down before the result is shown.
13. When the test is complete, the Reader will beep and the results will be shown on the screen. Remove and discard cartridge in puncture proof container.



If the results are suspect and not in the expected range or if the controls are not within the range given with the control sample repeat the test with a fresh sample.

14. If the meter has timed out (left idle for 5 minutes) and shutdown, press the power button to briefly show the last test result.
15. Discard the lancet, pipette tip, and used cartridge using Universal Biohazard Precautions.

V. READER FUNCTIONS

When the Reader is turned on, it performs a self-check (optics and software). If a malfunction is detected, the Reader displays an error message on the LCD display. See the troubleshooting section if this should occur.

VI. CALIBRATION AND QUALITY CONTROL

The MEC A1C System is Factory Calibrated. MEC Avie A1C System Control Level I and Level II are available for purchase. MEC Dynamics recommends that external controls be tested at the following times:

- Prior to home testing or at the start of each testing day.
- Upon receipt of each new shipment or use of a new lot of cartridges
- Whenever storage room conditions have been above 28°C (82°F).
- To become familiar with the process or to perform training or retraining of testing personnel.
- Whenever Avie™ A1c results do not match other clinical findings or symptoms.

The controls are tested identically to a blood sample. See section IV Operating Instructions. If the results are out of range when compared to the number supplied with the control bottle repeat the test with a fresh sample. Check to ensure all materials are within dating (cartridge, diluent, & control have not expired). If the result is still out of range contract the MEC Technical Support at: 888-376-1081. Do not perform a test until the quality control sample is within the given range.

VII. OPERATIONAL PRECAUTIONS AND LIMITATIONS

- The Avie™ A1c system is for *in vitro* diagnostic use only.
- Use fingerstick (fresh capillary) whole blood samples for testing.
- The fingerstick site must be completely dry. If any alcohol remains on the finger, it may cause inaccurate results.
- The cartridges and diluent vials are for one use only. Do not reuse them.
- Do not move or touch the Reader while it is running a test.

VIII. HAZARDS AND SYMBOLS



Caution: The Reader generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with instructions, it may cause interference to other devices in the vicinity. Call MEC Dynamics Technical Support for help in determining whether your Reader is causing interference and how to correct any interference.



Caution: Use only Avie™ A1c AC Adapter or damage to Reader may result.



Class II Equipment: The Reader is double insulated.



Biological Risk: Disposable items pose biological risks. Use Universal Precautions



Type BF materials supplies

IX. MAINTENANCE AND CLEANING

Use Universal Biohazard Precautions. Clean the Reader only as needed. Do not turn the meter on when cleaning.

External Cleaning

Use clean cloth lightly dampened with bleach solution. Use only 10% household bleach solution, i.e., 10% Clorox® solution (1 part bleach + 9 parts water) or an alcohol wipe (70% Isopropyl alcohol) to clean the Reader.

Internal Cleaning

Only the test cartridge guide needs cleaning.

CAUTION: DO NOT FLOOD READER WITH CLEANING SOLUTION!

1. Check for blood, lint or debris on the test cartridge guide. If present,
2. Remove by wiping with lint free cloth dampened with dilute (10%) bleach and water solution or alcohol wipe (70% Isopropyl alcohol).
3. Dry the cartridge holder with a dry, lint free cloth.

Loading Batteries

Insert 4 AA batteries (only alkaline batteries) according to battery position diagrams inside the battery pack, and then plug into power port.

Note: If Reader turns on at the push of the power button, the batteries are properly installed.

Troubleshooting

The Avie™ A1c Reader displays error codes to indicate problem with the system. If you are uncertain of an error or how to resolve a problem, contact MEC Technical Support at: 408 844 9280 or 888-376-1081

These messages are possible errors that may occur. If your problem still persists, please MEC Dynamics Technical support at 408-844-9280 or 888-376-1081

Error Code	ERROR	CAUSE	ACTION
	No display	Monitor has shut down after sitting idle for 5 minutes.	Press power button.
LOWBAT	Low Batteries	Battery power is running low	Change batteries or use AC adapter
REMOVE STRIP	Remove Cartridge	Reader turned on with test cartridge already inserted	Remove cartridge; if new, restart Reader and reinsert cartridge. If cartridge is used, discard it.
ERROR REMOVE STRIP	Remove Cartridge	Cartridge not properly inserted or used cartridge inserted	Be sure cartridge is fully inserted and is properly aligned and has not been previously used. If error continues call MEC Technical Support
ERROR 01	Meter Error	Meter issue identified during self check	Call MEC Technical Support
ERROR 02	Cartridge Error	All cartridge malfunctions during testing, or cartridge is removed before completion of test or delayed sample application	Repeat test with new cartridge and new sample. Be sure cartridge is fully inserted. If error continues call MEC Technical Support

Error Code	ERROR	CAUSE	ACTION
ERROR 03	Meter Error	Meter malfunctions after self-check	Repeat test with new cartridge and new sample. If error continues call MEC Technical Support
ERROR LO	Result out of Range	Result below 5% A1C	Repeat test, if error recurs, test by another method
ERROR HI	Result out of Range	Result more than 14% A1C	Repeat test, if error recurs, test by another method
ERROR LA	Result out of Range	Result below 0.45 g/dL A1C	Repeat test, if error recurs, test by another method
ERROR HA	Result out of Range	Result above 2.8 g/dL A1C	Repeat test, if error recurs, test by another method
ERROR LH	Result out of Range	Sample below 9 g/dL Hb	Repeat test, if error recurs, test by another method
ERROR HH	Result out of Range	Sample above 20g/dL Hb	Repeat test, if error recurs, test by another method

Warranty

30 Day Money Back Guarantee

Rev. 11/08