Polytel® GMA3™
Glucose Meter Accessory
Model PWR-11-01

USER MANUAL
Version: 2

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1. Introduction

1.1 Overview

Welcome to the world of wireless medical monitoring. In this pamphlet, you will learn how to use and maintain your Polytel® GMA Glucose Meter Accessory.

The GMA is an easy-to-use accessory that lets you send the glucose readings you take with your glucose meter wirelessly to a receiving station.

No more worrying about writing down the test results and carrying them in to your doctor every visit—it is all done automatically in your own home.

There are three parts to sending your readings wirelessly:

- You measure your glucose on the glucose meter.
- The GMA receives the reading from the meter and sends it wirelessly to the phone or receiving station.
- The phone receives, stores, and sends your readings to your service provider – often your doctor's office or a monitoring service. The receiving station is a separate device that is either a cell phone, a self-contained box, called an "access point," or your personal computer. Your monitoring service can explain how to use the receiving station.

- To use the GMA, all you have to do is take the reading using glucose meter as usual. For certain meter models, removing the test strip will start the data transmission; for others you may need to press a button. Please see below for details

To make sure all data is sent to your provider, if the GMA is unable to find a receiving station, it will save the reading along with the date and time you took it. The old reading will be sent along with the next reading.

1.2 Who is this for?

The GMA is intended for diabetic patients who want to monitor their glucose levels remotely. It can be used by patients in their homes and in their daily lives.

1.3 Configurations

The GMA is available in a number of different configurations, which determine which glucose meters are supported. Configurations are selected by inserting the proper cable into the GMA: **Cable must be firmly inserted until flush.**

- GMA3-LS for LifeScan meters using “LS” cable:

OneTouch® Ultra®
OneTouch® Ultra2®
OneTouch® UltraMini®
OneTouch® UltraEasy®
OneTouch® Select™
OneTouch® Basic™

- GMA3-BY for Bayer meters using “BY” cab

Contour®
Contour® TS
Contour® XT
Contour® Next EZ™
Breeze2®

- GMA3-AB for Abbott meters using “AB” cable:

FreeStyle® Lite
FreeStyle® Freedom® Lite

GMA3-NI for Nipro meters using “NI” cable:

TRUEresult™
TRUEbalance™
TRUEtrack™ (with cradle)
TRUEmetrix™ (with cradle)
(Nipro cradle can be obtained directly from Trividia/Nipro)

GMA3-US for micro-USB type glucose meters, using the “US” cable:
Accu-Chek® Aviva Connect™

2 Parts of the GMA

Your GMA is easy to maintain, set up and use.

The most important part to pay attention to is the indicator light on the device. Different blinking patterns tell you when the GMA is sending data, whether it was sent successfully or not, and when it is time to change the batteries.

2.1 Visual indicators

The GMA has small blue and red indicator lights in the pushbutton that blink in different patterns when it is doing different things.

Figure 1: Indicator light indicates status of the GMA. It may appear as blue or red, depending (see next page).

Here are the possible light patterns and their meanings:

Light looks like	Speed/Length	It means...
Blue on (no blinking)	Up to 60 seconds	GMA is getting data from glucose meter
Blue blinking	1 blink per second	GMA connecting to receiver. Please wait.
Blue, solid	steady on	GMA retrieving data from glucose meter
Blue, blinking	1 blink per second	GMA waiting for connection from phone
Blue, very fast blinking	2 blinks per second for 1-2 seconds	GMA connected to phone, phone retrieving data
Red and blue, blinking	1 blink per second	GMA waiting for connection from cell phone, pairable
Red, very fast blinking	2 blinks per second for 10+ seconds	GMA connected to phone, pairing.
Off	N/A	Successfully sent data

2.2 Battery Compartment

You can open the battery compartment by sliding the lid on the bottom open with your thumb.

Figure 2: battery lid

2.3 Size of your GMA

4.25 inches x 1.1 inches x 0.62 inches (108mm x 28mm x 16mm)

3 Operating Instructions

3.1 Changing the batteries

The GMA uses two alkaline AAA batteries that should last a couple of months.

Tip: Your batteries will last longer if you remove them if you will not be using the GMA for a month or longer.

It is time to change the batteries when the red light on the GMA blinks fast immediately after waking up. Here is how

you change the batteries

1. Open the battery compartment by sliding the lid (see figure 2)

Figure 3: Batteries should go in like this

2. Insert the batteries as shown in Figure 3.

Note: Always replace both batteries at the same time and make sure the batteries are from the same manufacturer.

3. Close the battery compartment by sliding it back into place.
4. If the red light still flashes for 10 seconds or longer, repeat steps 1 through 3 and:

- Check that you inserted the batteries in the right direction.
- Try replacing with a different pair of AAA size

batteries.

- If you are still having trouble, see the “Troubleshooting” section on page 19.

3.2 Connecting the devices

Before you can start using the GMA, you need to connect it to the glucose meter.

1. Slide the meter into the carrying case:.
2. Place the GMA in the carrying case. Many different cases are provided by the manufacturers, so details will vary.

Ultra2

Contour next EZ

FreeStyle Lite

3. Plug the cable from the GMA into glucose meter and press firmly into place.

ug in jack and press

NOTE: Connect the GMA ONLY to the meters approved for your configuration Connecting it to any other device may make your readings inaccurate or damage one or both devices

NOTE: Due to a recent Bayer decision, Contour XT meters with serial numbers above 6000001 and Contour Next EZ meters with serial numbers above A000001 require the GMA to be unplugged from the meter during measurements.

3.3 Placement of the GMA and receiving station

Various types of barriers, such as walls, can reduce the range of wireless devices. Your GMA will work best if it is in the same room as the receiving station. (Remember: your receiving station is the separate box, personal computer, cell phone, or handheld device.)
Warning: Do not put the GMA on a metal surface or in a metal box or enclosure. This may interfere with its ability to

send data.
When the devices are working together correctly, the light on the GMA comes on right after you take a new reading, then goes out when the reading is sent. See page 9 to learn more about the indicator light.

3.4 Pairing

In keeping with the Bluetooth Glucose Meter standard, before any readings can be sent the first time, the GMA must be paired with the phone.
To pair the GMA3, it needs to be made “pairable” by pressing the button on the GMA three times. The red LED will come on in addition to the blue LED. When, a few seconds, later, both LEDs start blinking, the GMA is ready for the phone to pair with it.

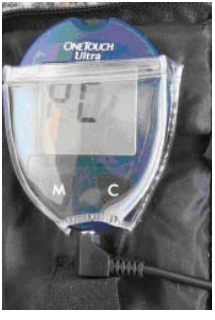
3.5 How to use your GMA

1. Insert the glucose test strip into the glucose meter and take your reading as you normally would. Instructions on using your glucose meter should have come with the original box.
2. Remove the test strip as usual.
3. After you remove the test strip:

- The blue light on the GMA turns on automatically.
- The meter will show activity:
- LifeScan meters display PC on the screen. This shows that it is sending the reading to the GMA. The PC indication will stay on for two minutes. This is

normal.

- Bayer meters show the number of measurements counting down. The display will stay on for two minutes. This is normal.
- Abbott meters show all the display elemets active (nothing readable).



- **Figure 4: PC shows on the glucose meter when the GMA is receiving your readings**
-

4. The GMA blue light turns on. This means that it is retrieving data from the meter.

NOTE:
Some meters automatically wake up the GMA. For those that do not, please see chart below:

Meter	GMA	How to send
OneTouch Ultra2 versions A & B	Automatic	
OneTouch Ultra2 newer versions	Manual	Press the button on the GMA
OneTouch Ultra Mini/Easy	Automatic	
OneTouch Select /Basic	Manual	Press the button on the GMA
Bayer Contour/ Breeze2	Some are automatic, some are manual	Press the “M” button on the meter itself
Abbott FreeStyle	Manual	Press the button on the GMA
Nipro TRUEresult, TRUEbalance	Manual	Press the button on the GMA
Accu-Chek Aviva Connect	Manual	Press the button on the GMA

After taking your glucose reading, it may take a minute or two to send the reading to the receiving station. **Please be patient**—do not press any buttons or disconnect the GMA until the light has completely stopped blinking or your results may not be sent.

Figure 5: Blinking light usually means your information is being sent. Please be patient.

IMPORTANT: If glucose meter screen does not show PC or the light does not come on shortly after taking a new reading:

- Check that the GMA cable is firmly plugged into the glucose meter
- Try replacing both batteries (see page 10).
- See page 20 if you are still having problems.

When the GMA sends your information, the power level of the batteries is sent along with your reading. Your monitoring service may tell you it is time to replace the

batteries, even before you notice any problems. That's it—you don't have to do anything more. After the reading reaches the phone, the GMA light turns off. On some meters, the "PC" indication will persist for a couple of minutes before turning off.

3.6 If the data was not sent

IDon't worry. Any measurements taken and not sent will be sent the next time the GMA and phone are both active. You can also make the GMA retry the transmission by pressing the button on the GMA after it has turned off.

3.7 Disconnected glucose meter

Any readings taken when the GMA is not connected to the OneTouch Ultra are stored along with the date and time taken. The next time you take a new reading after the devices are connected again, both the stored and new readings are sent to the phone.

3.8 Troubleshooting

What's wrong?	What caused it?	What to do
Blue light doesn't come on	Weak/missing batteries	Replace batteries (see p. 10)
	Disconnected cable	Plug cable firmly into glucose meter (see p. 14)
	GMA needs manual operation to start	Please see p. 17
Can't send even after several tries (light is on)	Phone app may not be working properly	Move phone closer to GMA or see manual for phone app
No response on meter display	Weak/missing batteries	Replace batteries (see p. 10)
	Disconnected cable	Plug cable firmly into glucose meter (see p. 14)
	Damage or frayed cable	Send GMA to Polymap Wireless for repair.

4 Safety Information

We are committed to your safety. Please read these warnings and cautions.
NOTE! Disregarding the safety information provided is considered abnormal use

4.1 Patient Safety

CAUTION! Do not share your glucose meter or GMA with anyone else. Letting someone else use your GMA will cause his or her readings to be mistaken for yours.

NOTE: Polymap Wireless is not responsible for the reading, diagnosis, or electrical safety of the glucose meter itself. The Polytel GMA is a data transmission system only.

WARNING: Changes made to the product, unless expressly approved by Polymap Wireless, LLC could void the user's license for and the warranty of the device.

4.2 Electrical Safety

Only authorized maintenance staff should disassemble the GMA. (This does not include changing the batteries.)

The GMA is classified as Class I Medical Devices per 21CFR, and under the IVDD directive for CE.

The various glucose meters are approved for use by their manufacturer. Polymap Wireless is not responsible for their diagnostic accuracy or their electrical safety.

4.3 Compliance Information

This section is about the telemetry system regulatory compliance requirements and the manufacturer's responsibilities.

4.3.1 Compliance Requirements

Polymap Wireless is responsible for the effects of safety, reliability, and performance of the GMA as long as:

- You use the equipment according to the instructions in this manual.
- All repairs, changes, assembly operations, and extensions are done only by Polymap Wireless.

4.3.2 Compliance Statement

Polymap Wireless states that this device conforms with the essential requirements of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Council Directive 2104/53/EU on Radio Equipment Directive and Council Directive 2011/65/EU on Restriction of the Use of Certain

Hazardous Substances in Electrical and Electronic Equipment, 2011/65/EU

4.4 About the label at the bottom of the GMA

The label on the side of your GMA shows the unique ID number (serial number) of your device as well as some other things you might need to know:

Seal/Mark	Meaning
	Device was tested to comply with the CE RED, IVDD and RoHS directives.
	You should read accompanying documents before use.
	Device uses Bluetooth Smart (BLE)
FCC ID: 2AAQS-ISP1507	FCC listing number for the radio module contained in the device.
IC: 11306A-ISP1507	Industry Canada listing number for the radio module contained in the device
S/N: 0015B4010204	Unique serial number

5 Operator Maintenance

5.1 Periodic Maintenance

Check your GMA now and then to make sure it is working properly and nothing is damaged. Make sure the cord that connects from your GMA to the glucose meter is not frayed or damaged.

If your GMA needs repair or is not working right, contact your monitoring service or Polymap Wireless for service right away.

5.2 Cleaning your GMA

Although you should not need to clean your GMA very often, here is how to do it:

1. Unplug the GMA from the glucose meter and remove it from the mesh pocket.
2. Take a soft cloth and dampen it with water or a weak solution of household dishwashing liquid mixed with water. Wring out the cloth.

Warning: Do not use any sprays or put your GMA in any liquid. Sprays and liquids may penetrate and damage the unit.

3. Gently wipe the outside of the unit with the damp cloth.
4. Reconnect the GMA to the glucose meter (see page 14), and close the mesh pocket.

6 Technical Specifications

6.1 Batteries

The GMA uses two AAA cells (1.5V each). Max. Power consumption: 0.5W.

6.2 Temperatures

- Use your GMA in temperatures ranging from 5º to 40º Celsius (41º to 104º Fahrenheit).
- Store your GMA in temperatures ranging from -40º to +70º Celsius (-40º to 158º Fahrenheit).
- If you move your GMA from a cold location to a warm location, please allow it to come up to room temperature before using it.

6.3 Compatibility with other electrical medical equipment

Like other electrical medical equipment, the GMA unit requires special precautions to make sure that it works with other electrical medical devices. This is called electromagnetic compatibility (EMC). As long as you install and use your GMA as noted in this manual, you should be fine.

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.

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

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

6.4 System Availability

If you end up needing to take a second reading shortly after a first reading, it is probably easiest to wait until the indicators on the meter have turned off.

There is no problem with taking several readings while out of range of the receiving station. The stored readings will all be sent the next time you take a new reading within range of the receiving station.

7 Trademarks

- Bluetooth® word mark and logos are owned by the Bluetooth SIG, Inc.
- Polytel® is a registered trademark of Polymap Wireless LLC.
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- FreeStyle® is a registered trademark of Abbott Diabetes Care.
- TRUEbalance and TRUEresult are trademarks of Trividia Health