

AGE Scanner

User Manual



Introduction

The 'AGE Scanner' developed by Diagnoptics is an optical instrument based on measurements of fluorescence of advanced glycation endproducts (AGE's) in the human skin, to provide the amount of AGEs in skin tissue. The 'AGE Scanner' uses a light source in a specific ultraviolet-blue wavelength range and photodiodes with optical filters sensitive in the concomitant fluorescent wavelength ranges.

AGEs play a pivotal role in healthy living. Beginning at birth our bodies have the unique ability to grow and heal quickly, our cells, muscle tissue, bones, skin, hair, and vital organs all continue to resist aging. When we stop growing and reach our prime bodies strength, youth and stamina are unmatched by any other time in our life. However, after this our physiological body begins to decline. Many medical doctors and research scientists from around the world have come to agreement that in the decline of the body and ultimately aging an unfamiliar compound called AGE's (Advanced Glycation End products) plays a very important role.

Advanced Glycation End-products or A.G.E.s are harmful compounds that form when sugar and protein molecules bind together. AGEs are created when we cook our food. They are also formed inside of the body. While our bodies need sugars and proteins to fuel normal body functions, too much of either nutrient in the blood can result in higher than normal levels of AGEs. Eventually, these high levels lead to a build-up of AGEs in the tissues.

Higher than normal levels of AGEs accelerate aging from the inside out. But what's far more important than wrinkles is the aging of internal organs. As the organs age, they do not function as efficiently. High levels of AGEs attack the organs. When the body is no longer able to fight off AGEs, the accumulation accelerates the aging process.

1 Getting started

1.1 What's in the box

The following items are included in the package:



AGE Scanner

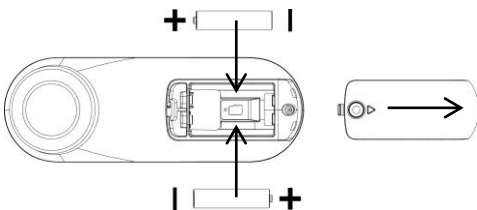


AAA Batteries (2x)

1.2 (Re)Place batteries

Before the AGE Scanner can be used, the batteries have to be installed. To access the battery compartment, slide the battery cover located at the bottom of the device of with a gentle pressure on the embossed ring. Pay attention to the polarity of the batteries.

Recommended battery AAA types are alkaline batteries or rechargeable NiMH batteries.



1.3 Starting and connecting your device

The AGE Scanner app is compatible with mobile devices running iOS and Android (version 4.3 or higher) operating systems and support Bluetooth 4.1 or higher (BLE). To get started:

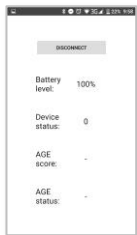
1. Install the AGE Scanner app from one of these locations:
 - The Apple® App Store® for iOS devices such as an iPhone® or iPad®.
 - The Google Play™ Store for Android devices.
 - The Diagnostics website, www.diagnostics.com.
2. Turn on the Bluetooth function of your device. If you use an Android device, open the Bluetooth settings menu on your device. Enable the setting that makes your device visible to other Bluetooth devices.

Start the AGE Scanner by pressing the button on the top of the device. During start-up, the ring around the button lights up blinking blue as it searches for a Bluetooth® device to pair with and the App will display the available devices. Select the serial number of the AGE Scanner you want to connect to.



During the initialization the device's internal light sources are tested, you may notice that some light will be emitted from the measurement window for a short period during this phase. This is completely harmless.

When a Bluetooth® connection is established, the ring around the button lights up continuously green and the App will display the device status and a button to disconnect.



When no Bluetooth® connection can be established, the AGE Scanner will turn itself off in 1 minute.

1.4 Switching the AGE Scanner off

The AGE Scanner will turn itself off after 5 minutes of inactivity.

2 Performing measurements

2.1 Preparations for the measurement

The accuracy of the measurement result can be influenced if situations mentioned below are present.

- AGE measurements should be performed directly on intact healthy skin. The skin at the measuring area should be healthy, homogeneous and free of birthmarks, tattoos or excessive hair growth and without recent exposure to skin creams or any substance that may have fluorescent properties. Self-tanning agents should not be used for at least 10 days before measurement. Sun-blockers and other skin care products should be removed before measurement.
- Correct positioning of the arm over the window is essential. The AGE Scanner should be kept in a steady position during the measurement process.
- The measurement window should always be kept clean (see chapter 4.1).

2.2 Performing the measurement

1. Establish a Bluetooth® connection, see chapter 1.3.
2. The AGE Scanner should be placed on the subject's dominant forearm with a gentle pressure to avoid light from the surroundings entering the device.
3. Start the measurement by pressing the button on top.
4. During the measurement, the ring around the button lights up yellow. Avoid arm movements during the measurement.
5. When the measurement is successfully completed, the ring around the button lights up blinking green for four seconds and the measurement result will be displayed in the App.



2.3 Problems during the measurement

When the AGE Scanner is unable to successfully perform a measurement it will abort the measurement and the app will display an error indication. There are three error indications:

- Measurement setup error
- Low signal error
- Internal error

2.3.1 Measurement setup error

If the device is not placed properly on the subjects arm, ambient light can 'leak' into the window, causing interference measurement fault. The AGE Scanner is capable of detecting light leakage to a certain extent. If this occurs, the device will abort the measurement and the display 'Measurement setup error'.

2.3.2 Low signal error

If the measured signal from the arm is too low, the device is unable to perform a reliable measurement. It will abort the measurement and display 'Low signal error'. In general, a 'low-signal error' is the result of a patient's skin having too much pigment. This can be caused by e.g. birth marks, freckles or strongly pigmented skin.

2.3.3 External error

The External error is displayed when any of the measurement parameters has an out-of-bounds value that cannot be directly related to the use of the AGE Scanner. If the 'External error' indication persists please contact Diagnostix for support.

3 Update your device

The AGE Scanner can receive new firmware by means of two methods, Over The Air (OTA) through the Bluetooth® connection or by inserting a Micro-SD card containing the firmware update.

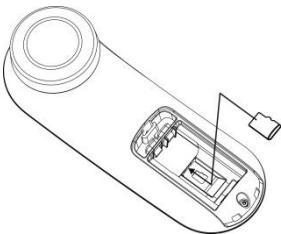
3.1 Over The Air (OTA)

An update can be delivered by the app running on the connected device. Follow the instructions on the screen to update your device.

3.2 Micro-SD card

An update can be delivered on a Micro-SD card, follow the procedure below to update your device:

1. Remove the batteries, see chapter 1.2.
2. Insert the Micro-SD card containing the new firmware in the slot at the bottom of the battery compartment and slide it forwards.
3. Replace the batteries and the battery cover.
4. Turn on the device, the update starts automatically. During the update, the ring around the button lights up blinking orange.
5. When the update is finished, the ring around the button lights up continuously blue.
6. The Micro-SD card should now be removed.

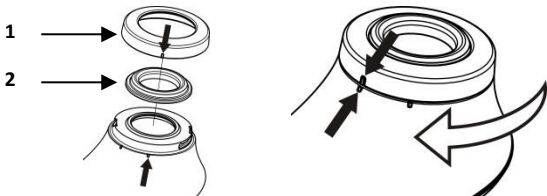


4 Cleaning & maintenance

4.1 Cleaning instructions

4.1.1 Measurement window:

The measurement window must be kept clean. To clean the window, carefully remove chrome bayonet ring (1) by rotating it counterclockwise and remove the skin interface (2) to access the measurement window. Clean the window with a slightly damp soft non-fluorescent cleaning wipe (for example, a soft reusable cleaning wipe used for spectacles), using a standard 70% alcohol solution. Avoid scratching the window and ensure that no fibers remain on the window. Residual fibers may influence the measurement result! To replace the bayonet ring, align the nudge on the bayonet ring with the outer nudge on the housing and rotate it counterclockwise till it aligns with the center nudge.



4.1.2 Skin Interface:

The skin interface can be cleaned with standard mild cleaning agents. If desired, the armrest can be disinfected with alcohol or chlorohexidine.

4.1.3 Enclosure:

The enclosure can be cleaned with the microfiber cloth or with a slightly moistened cloth with standard mild cleaning agents. Make sure no fluids enter the enclosure!

4.2 Maintenance instructions

No changes should be made to the system by the user!

This system does not contain parts that can be serviced by the user.

Replacement parts are available for the skin interface and bayonet ring

To order a replacement part, please contact Diagnostics.

5 Troubleshooting

6 Product specifications

6.1 Technical specifications

- Operation Continuous operation
- Power 3 VDC from exchangeable AAA battery
- Output UV-A light $\lambda_p = 375\text{nm}$ $E = 7,81\text{E-}01 \text{ W/m}^2 @ 0,2\text{m}$
Blue light $\lambda_p = 460\text{nm}$ $E = 1,83\text{E-}01 \text{ W/m}^2 @ 0,2\text{m}$
Green light $\lambda_p = 525\text{nm}$ $E = 6,26\text{E-}02 \text{ W/m}^2 @ 0,2\text{m}$
- Dimensions Width: 60mm, Depth: 170 mm, Height: 55 mm
- Weight: 0,15kg
- Operating Conditions:
 - temperature range: Lower limit 0°C - Upper limit + 40°C
 - Relative humidity: 20% to 75% non-condensing
- Storage & Transport Conditions:
 - temperature range: Lower limit - 40°C - Upper limit + 70°C
 - Relative humidity: 10% to 100% non-condensing
- Wireless communication by Bluetooth.
 - BLE is implemented
 - ISM frequency band of operation: 2402 – 2480MHz
 - Rated power: 6 mW

6.2 Classifications

- Protection against elec.shock: Class III equipment
- Standard(s):
 - Electrical Safety: EN 60950-1:2006 (up to: A12:2011)
 - EMC: EN 301 489-1 & EN 301 489-17 V2.2.1
 - Telecom: EN 300 328 v 1.9.1
 - FCC: 47 CFR part 15, Subpart 15C & 15.247
 - EM Exposure Safety: EN 62479:2010
 - Japanese Radio Law:
 - Safety of lamps: IEC 62471:2008
 - Hazardous Substances: 2011/65/EU (ROHS II)
 - Waste: 2012/19/EU (WEEE)

7 Regulatory & Safety Notices

7.1 Safety statement

This equipment has been tested to comply with safety certification in accordance with the specifications of EN Standard: EN60950-1:2006 up to: A12: 2011.

7.2 USA: Federal Communications Commission (FCC) statement

This device complies with FCC part 15 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.

FCC Warning

Changes or modifications not approved by Diagnostics Technologies B.V., could void the user's authority to operate the equipment.

This device meets the FCC requirements for RF exposure in public or uncontrolled environments.

FCC ID: 2AKA5-MFR

7.3 European Union (EU)

Declaration of Conformity with Regard to the EU Directive 1999/5/EC R&TTE. Diagnostics Technologies B.V. is authorized to apply the CE Mark on, device type MFR00101, thereby declaring conformity to the essential requirements and other relevant provisions of Directive EN 300 328 V1.8.1 and other applicable Directives.

7.4 Japan

7.5 China

产品中有害物质的名称和内容

Names and Contents of the Hazardous Substances in Product



部件名称 Part name	有毒有害物质或元素 Hazardous Substance					
	铅 (Pb)	汞 (Hg)	镉 (Cd)	六价铬 (Cr+6)	多溴联苯 (PBBB)	多溴二苯醚 (PBDE)
外壳 Housing	o	o	o	o	o	o
电路板 Circuit Board	o	o	o	o	o	o
皮肤界面 Skin Interface	o	o	o	o	o	o

此表是按照SJ / T11364的规定编制

This table is prepared in accordance with the provisions of SJ/T11364

O 表明所述包含在该部件所有均质材料中的有害物质低于GB/ T26572的限量要求。

Indicates that said hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement of GB/T 26572.

X 表示所述包含在用于该部分的均质材料中的至少一种有害物质是上述GB / T26572的限制要求。

Indicates that said hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement of GB/T 26572.

在一个X显示所有的情况下，AGE Scanner 使用允许的豁免。

In all cases where an X is shown, AGE Scanner uses an allowable exemption.

8 Important safety instructions

8.1 Caution:

- This product is not a medical device, and is not intended to diagnose, treat, cure, or prevent any disease.
- This device emits UV-A radiation.
- Prolonged contact may contribute to skin irritation or allergies in some users. If you notice any signs of skin redness, swelling, itchiness, or other skin irritation, please discontinue the use of the product.
- The device contains electrical equipment that could cause injury if not handled properly.
- This product is not a toy. Do not allow children or pets to play with your AGE Scanner product.
- The measurement window must be kept clean.
- Clean your AGE Scanner product regularly, particularly the parts that come in to contact with the skin. Use a clean, damp cloth. Do not wash the product under a faucet, do not let fluids ingress.
- Maintenance and repairs should only be carried out by Diagnoptics or authorized representatives, ship in original package.
- Do not use your AGE Scanner if there is visible damage and/or when the device has sharp edges..
- Substances in this product and its batteries may harm the environment or cause injury if handled and disposed of improperly.
- Do not place your AGE Scanner product in a dishwasher, washing machine, or dryer.
- Do not expose your AGE Scanner product to direct sunlight for an extended period of time or extremely high or low temperatures.
- Do not dispose of your AGE Scanner product in a fire. The batteries could explode.
- Do not use abrasive cleaners to clean your AGE Scanner product.
- Remove your AGE Scanner product if it feels warm or hot.

8.2 Disposal and recycling information



The symbol on the product or its packaging signifies that this product must be disposed of separately from ordinary household wastes at its end of life. Please kindly be aware that it is your responsibility to dispose of electronic equipment at recycling centers to help conserve natural resources.

Each country in the European Union should have its collection centers for electrical and electronic equipment recycling. For information about your recycling drop off point, please contact your local related electrical and electronic equipment waste management authority or the retailer where you bought the product.

- Do not dispose of your AGE Scanner product with household waste
- Disposal of the packaging and your AGE Scanner product should be done in accordance with local regulations.
- Batteries are not to be disposed of in the municipal waste stream and require separate collection.

Footnote

“The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by ‘Diagnoptics Technologies B.V.’ is under license. Other trademarks and trade names are those of their respective owners.

9 Liability and warranty

9.1 Liability

Diagnoptics Technologies B.V. and its respective directors, officers, employees and agents and their respective successors, heirs and assignees, are not liable for any damages, losses, obligations, costs and expenses, including attorney's fees that may be incurred by third parties in connection with a claim for damage to or loss of tangible personal property, breach of warranty, or for bodily injury, sickness and/or death sustained by any customer (collectively "Damage") if or where the damage is caused by or arises from any instance regarded as (a) improper use of the AGE Scanner, (b) unauthorized modification of the AGE Scanner, (c) fault or negligence by the user, (d) breach of any warranty or other obligation by the user or (e) invalid or incorrect conclusions, and any consequences thereof, drawn by third parties from the measurement results provided by the AGE Scanner.

9.2 Warranty

The warranty supplied with this AGE Scanner System is provided separately.

9.3 Declaration of Conformity

The Declaration of Conformity can be provided on your request. Please e-mail support@diagnoptics.com to request a copy of the Declaration of Conformity.

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