

AGE READER **mu**

Know their risk.



Instructions for Use



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1 Introduction

AGEs play a pivotal role in the development of chronic age-related diseases such as diabetes, renal failure and cardiovascular disease. The level of AGEs in long-lived tissues (not in blood!) serves as a memory of glycometabolic and oxidative stress and is a valuable predictor of cardiovascular complications.

Until now it has been complicated to measure tissue AGEs in patients because existing methods are expensive, time consuming, lack specificity, are poorly reproducible and/or are invasive. The AGE Reader mu is the answer to the need for measuring AGEs without the disadvantages of the existing methods. This state of the art device provides a simple non-invasive solution which allows users to determine the AGE level within 12 seconds. The information from the AGE Reader can assist physicians in focusing treatment on patients with the highest risk of complications. This includes patients suffering from diabetes mellitus, renal failure but also acute disorders like acute coronary syndromes and sepsis. Moreover it is an excellent tool for researchers in various fields.

The AGE Reader mu was developed and is being commercialized by DiagnOptics Technologies B.V, an innovative medical technology company in the Netherlands.

This user manual provides the instructions for use of the AGE Reader mu.

DiagnOptics Technologies B.V

2 Intended use

When used as intended, the AGE Reader mu non-invasively gives an evaluation of Advanced Glycation End products (AGEs) in tissue. Clinical evidence shows that AGE levels may assist the physician in clinical practice to assess the risk of cardiovascular disease.

The AGE Reader mu is intended to be used by trained personnel to assess the level of auto fluorescence in human skin. Users are expected to be familiar with standard medical practices as required for patient monitoring.

All instructions, procedures and information in this user manual and on the labelling on the device are to be regarded as the "Intended Use" and will fully inform the user about the correct and safe use and installation of the AGE Reader mu.

AGE measurements should be performed directly on intact healthy skin on the inner side of the dominant lower forearm. The skin at the measuring area should be healthy, homogeneous and free of birthmark, 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 2 days before measurement. Sun-blockers and other skin care products should be removed before measurement.

Pigmented skin

The device and its software have been validated in patients with skin reflection $\geq 8\%$ (Fitzpatrick class 1-4). If the UV reflectance is below 10%, the AGE Reader mu will give a warning that the signal is too low for valid results.

Radiation safety

Using the guidelines of NEN-IEC 62471, it is concluded that AGE Reader mu measurements, as intended, remain considerably below the maximum radiation exposure levels for skin and for the eye of both the operator and patient.

2.1 Conditions for which the device is not to be used

This device is not intended to be used on patients where the skin at the measuring area is:

- not healthy
- not homogeneous
- damaged or tattooed
- exposed to skin care creams or any other substance that may have fluorescent properties

The measurement result can be influenced if situations mentioned above are present.

3 Warnings and precautions

The following warnings and precaution are essential for correct and safe functioning of the AGE Reader mu as is intended by the manufacturer.

Table 1. Warnings & precautions

	The AGE Reader mu is intended for static use! It is not intended to be a portable device. Transportation must be done with great care at own risk.
	Protect against falls and mechanical shocks. Do not use the device if there is visible damage and/or sharp edges.
	This device emits UV-A radiation.
	Measurements should be done on the inner side of the lower forearm on healthy undamaged skin without birthmarks or excessive hair growth. Self-tanning agents should not be used for at least 2 days before measurement. Sun-blockers and other skin care products should be removed before measurement.
	Only use the accompanying external power supply (part.nr.: CFR51000 or CFR52000).
	The mains plug of the power supply is the separator that connects or disconnects the AGE Reader mu and its power supply from the mains. Avoid positioning the equipment such that access to the coupler, plug, etc. is limited (so that disconnection becomes difficult).
	Do not use excessive force or sharp objects on the touchscreen.
	To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	Always make sure that with the use of a computer or laptop approved for medical use, the system complies with IEC 60601-1-1 for medical systems. The USB-port should be a limited circuit with a maximum current of 8A.
	This device meets all requirements for electromagnetic compatibility of IEC 60601-1-2. If the user however notes unusual device behaviour, particularly if such behaviour is intermittent and associated with nearby usage of portable and mobile RF communications equipment, this could be an indication of electromagnetic interference. If such behaviour occurs, the user should try moving the interfering equipment further from this device. Failure to do so could result in the equipment not functioning properly.
	The use of accessories, transducers and cables other than those specified, with the exception of replacements parts sold by DiagnOptics, may result in increased emissions or decreased immunity of the AGE Reader mu.
	The AGE Reader mu should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the AGE Reader mu should be observed to verify normal operation in the configuration in which it will be used.
	The measurement window should always be kept clean.
	Never place anything else than intended on top of the device.
	Maintenance and repairs should only be done by DiagnOptics or authorized representatives.
	Correct positioning of the arm over the window is essential and the arm should be maintained steady during the measurement process.
	Do not let fluids ingress.
	The USB port is protected by a cover which can only be removed with a tool (small screwdriver, toothpick). Always place it back after use!

4 Description of the AGE Reader mu

The AGE Reader mu is a proprietary device to assist a physician in assessing cardiovascular risk. This way of non-invasive monitoring uses auto fluorescence excited by ultraviolet A light in human tissue.

The AGE Reader mu consists of a small enclosure (considered as applied part) and its detachable silicone mat for the patient to rest his arm on during the measurement. The AGE Reader mu is operated from a touchscreen with LED backlight, and controlled by an internal micro controller running dedicated AGE Reader mu Software. This software allows the user to change his preferences and calculates the AGE Reader measurement result. Results of the measurements are presented as an absolute value numerical and can be displayed in a graph on the screen. The AGE Reader mu is powered by an accompanying medically approved external power supply connected to the mains. The AGE Reader mu can also be powered from the internal rechargeable Lithium ion battery.

Contents of packaging:

- AGE Reader mu
- User manual
- External power supply part number CFR51000 or CFR52000
- Mains plug set to comply with regulations for use in country of usage

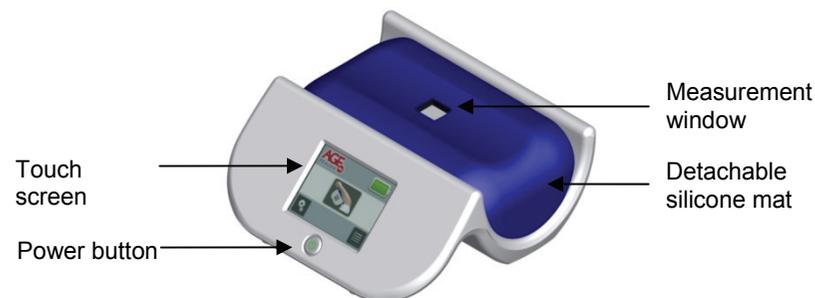


Figure 1. AGE Reader mu front side

The AGE Reader mu (figure 1) has the following external features:

- Enclosure with detachable silicone mat.
- 3,5" touchscreen from which the device is operated and all necessary information during use is presented visually to the user.
- Measuring window on the upper side of the AGE Reader mu.
- Power button to turn the device on and off.
- Rear panel at the back of the device (figure 2) with:
 - Power inlet for the medically approved power supply.
 - USB port for firmware upgrades (protected by a cover).
 - Blue LED to indicate when the internal battery is charging.

5 Installing the AGE Reader mu

1. Place the AGE Reader mu on a horizontal, flat and stable surface.
2. Attach the correct mains connector plug to the DiagnOptics power supply accompanying the device and plug it in to the mains outlet.
3. Insert the power plug in the power inlet, which is located on the rear panel at the backside of the AGE Reader mu (figure 2). A blue LED will light up when the battery is being charged.
4. The AGE Reader mu can now be turned on by the power button located on the front of the AGE Reader mu (figure 1). The 'standby' symbol on the button will light up green if the device is in its 'power on' state.
5. The dedicated AGE Reader mu Software is preinstalled and will start automatically.

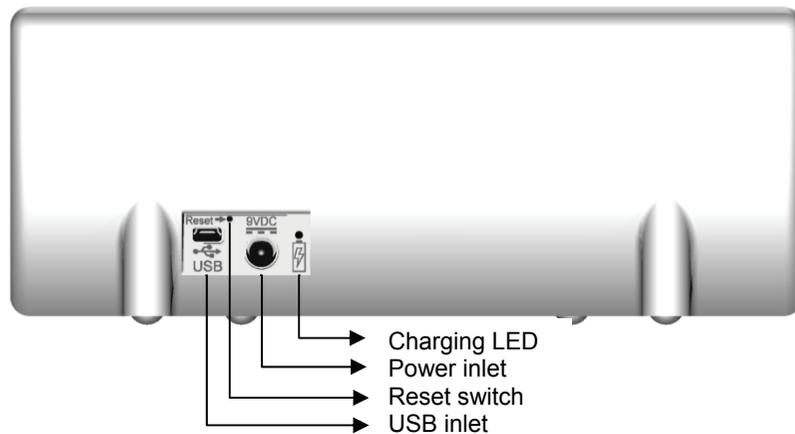


Figure 2. AGE Reader mu rear panel

IMPORTANT: ONLY USE USB CABLE INLET FOR FIRMWARE UPGRADES

6 Instructions for use

6.1 Starting the AGE Reader mu

When starting the AGE Reader mu for the first time it is recommended that you charge the internal battery completely before use. This will extend the battery life. Insert the power plug into the power inlet that is located on the rear of the AGE Reader mu, labelled as "Power Inlet" (figure 2). The blue charging LED will light up when the battery is charging, when the charging LED is off, the battery is fully charged.

Turn the AGE Reader mu on by pressing the 'power button' (figure 1). During the start-up phase nothing is displayed on the touchscreen and the power button will not be lit. Part of this initialization is a self-test of the AGE Reader mu's internal light sources. Notice that some light will be emitted from the measurement window for a short period during this phase this is completely harmless.

If the start-up is unsuccessful the power button will be lit red in a blinking fashion. The blinking pattern corresponds to the error code as described in section 9.2. Upon a successful start-up the graphical display will show the AGE Reader mu screen as shown below and the power button will be lit steady green.



Figure 3. Start screen

Shortly after displaying the start screen the AGE Reader mu main screen will become visible (see section 6.2) indicating that the AGE Reader mu is fully operational.

6.1.1 Turning the AGE Reader mu off

Turn the AGE Reader mu off by pressing the 'power button' (figure 1).

6.2 Main screen

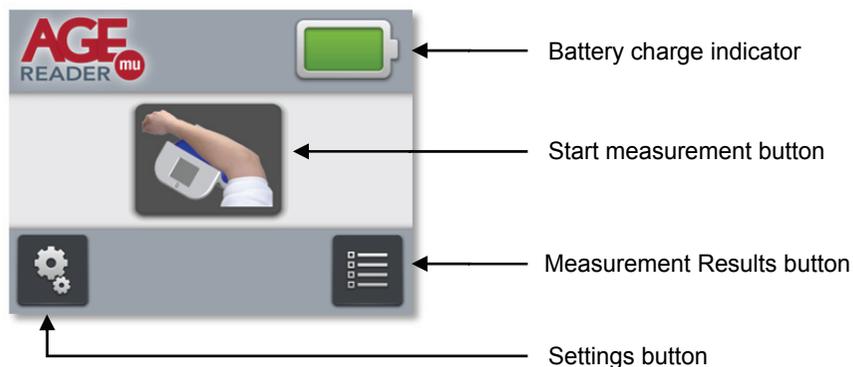


Figure 4. Main screen

The figure above shows the *Main screen* which appears when the AGE Reader has initialized successfully. The top section of the *Main screen* shows the AGE Reader mu logo and the *Battery charge indicator*.

Prominently present at the centre of the screen is the *Start measurement button* which, when pressed, starts an AGE Reader measurement (see section 6.3.3).

The last twenty measurement results are stored by the AGE Reader mu. A list of these measurement is available on the *Measurement Results Screen*. This screen is accessible by pressing the *Measurement Results button* at the bottom-right corner of the *Main screen*. If no measurement results are available yet, the *Measurement Results button* will be shown in inactive state.

In the bottom-left corner of the *Main screen* the *Settings button* is located. By pressing this button the user can navigate to the *Settings screen*. For more information see section 6.4 *Settings screen*.

6.3 Measurement

6.3.1 Prepare for measurement

Check if the measurement window of the Reader mu is clean, if not clean the measurement window first. See chapter 8 for instructions.

Ensure that the silicon mat is positioned properly. The silicon mat has a symmetrical shape to ease positioning on the AGE Reader mu.

The two notches on both side of the top surface align the mat with the measurement window of the AGE Reader mu (figure 5). Make sure that the mat touches the top surface of the AGE Reader mu everywhere mildly pressing the mat.



Figure 5. Silicon mat positioning

The patient's dominant forearm should be placed on the AGE Reader mu as indicated in figure 6. Ensure that the arm lies in a relaxed position to avoid arm movements during the measurement. Measurements are preferably performed on the inner side of the dominant lower forearm on healthy undamaged skin without birthmarks, excessive hair growth or tattoos (see chapter 2).



Figure 6. Patient arm position

6.3.3 Performing a measurement

A new measurement is started from the *Main screen* by pressing the *Measurement button* as indicated in the figure below.

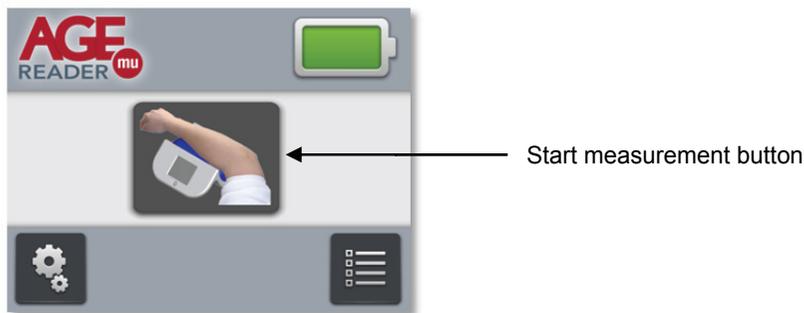


Figure 7. Measurement button on Main screen

After pressing the *Measurement button* the *Measurement progress screen* will be shown (figure 8). A measurement takes only a few seconds to complete.



Figure 8. Measurement progress screen

Upon a successful measurement the AGE Reader mu will advance to the *Measurement Results screen* (figure 9). This screen will show the last measurement at the top of the list of measurement results, which is marked with a red dot to distinguish it from the older measurement results.

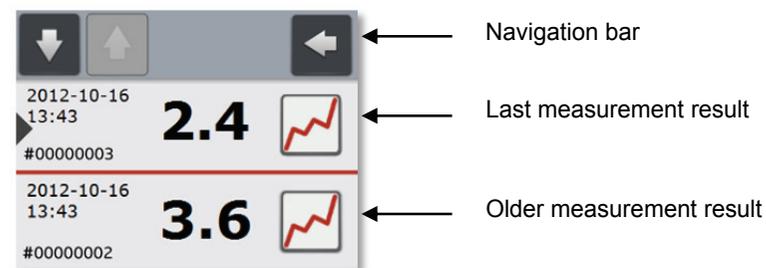


Figure 9. Measurement result screen

In order to properly describe the *Measurement result screen* each part is explained separately, starting off with the *Navigation bar*.



Figure 10. Navigation bar

To leave the *Measurement results screen* and return to the *Main screen* press the *Return button*. In order to navigate through the list of measurement results use the *Browse buttons* located at the top-left of the screen. When reaching the top or bottom of the list the *Up button* or *Down button* will be shown in inactive state (see figure 10) for the *Up button*. The navigation bar remains visible at the top of the screen at all times when browsing through the list.

Each measurement result is represented in the list as a row (figure 11).

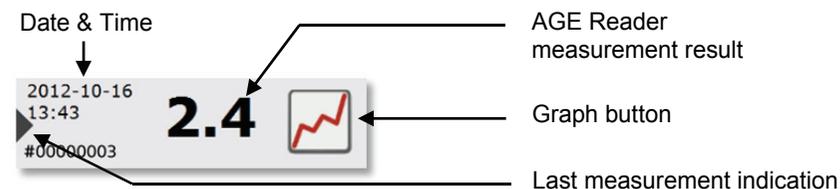


Figure 11. One single measurement result

The AGE Reader measurement result is displayed at the centre of the row in large font. The corresponding date and time of measurement are displayed at the top-left using the date and time formats as configured in section 6.4 Settings screen. The measurement results are listed in reverse order: the most recent measurement result is always at the top of the list and the oldest measurement result is at the bottom of the list. Put simply: browsing down the list is like going back in time. The *Last measurement indication* is visible for the most recent measurement result.

An on-screen measurement report will be generated when pressing the *Graph button* which is located at the right of each row. After doing so, it is required to enter the subject's age in the *Age screen* (figure 12).

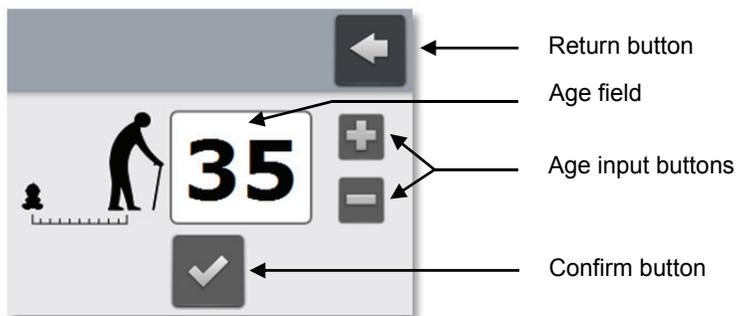


Figure 12. Age screen

When the *Return button* is pressed the generation of a measurement report is aborted and the *Measurement results screen* is presented again.

By default the *Age field* this will show the value 35. This value can be altered by operating the *Age input buttons*. Pressing the plus-sign will increase the age value and pressing the minus-sign will reduce the age value.

When the *Age field* properly reflects the subject's age press the *Confirm button* to generate the actual measurement report.

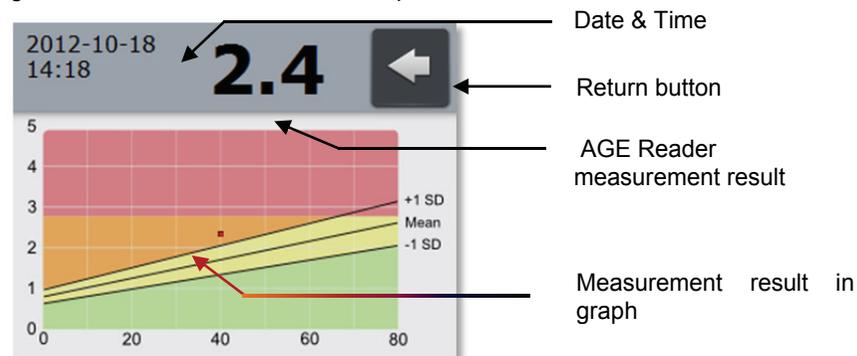


Figure 13. Measurement report

Press the *Return button* to leave the *Measurement report screen* and return to the *Measurement results screen*.

The date and time (*Date & Time*) of the measurement and the numerical representation of the AGE Reader measurement result are displayed at the top of the screen.

The on-screen measurement report is a graph in which the *Measurement result* is drawn as a small black square representing the measured result at the given age. See chapter 7 for more information about AGE Reader measurement results and an explanation of the graph.

6.3.4 Problems during measurement

If the AGE Reader mu is not able to successfully perform the measurement it will abort the measurement and indicate the problem to the user. Three problem indications exist and will be explained subsequently:

- Measurement setup error indication
- Low-signal error indication
- Internal error indication

Measurement setup error indication

If during measurement the measurement mat is not placed properly on the AGE Reader mu or if the subject's arm doesn't completely cover the measurement window ambient light can leak into the measurement window and interfere with the measurement. Although a proper mat and arm position is the responsibility of the user, the AGE Reader mu is capable of detecting light leakage to some extent. When the AGE Reader mu detects any light leakage the measurement will be aborted and the *Measurement setup error screen* will be displayed as an indication to the user (figure 14).



Figure 14. Measurement setup error indication

See section 6.3.1 for instructions and check if both mat and arm are positioned properly before retrying the measurement. Press the *Confirm button* to return to the *Main screen* from where a new measurement can be started.

Low-signal error indication

If the measured fluorescence signal from the arm is too low, the AGE Reader mu is unable to perform a reliable measurement. It will then abort the measurement and raise a low-signal error (figure 15).



Figure 15. Low-signal error indication

In general a low-signal error results from a patient's arm skin that has too much dark pigment. This in turn might be caused e.g. by birth marks, freckles or tinted skin.

See section 6.3.1 Prepare for measurement for instructions on how to position the patient's arm before retrying the measurement. Press the *Confirm button* to return to the *Main screen* from where a new measurement can be started. If the problem persists conclude that the patient's arm has too much pigment, a measurement with the AGE Reader mu is not possible.

External error indication

The External error indication is shown (figure 16) when any of the measurement parameters has an out of bound value that cannot be directly related to the use of the AGE Reader mu.



Figure 16. External error indication

Press the *Confirm button* to return to the *Main screen* from where a new measurement can be started. If the *Internal error indication* remains see section 9.2.

Internal error indication

The Internal error indication is shown (figure 17) in case of an internal system failure that cannot be directly be solved by the user. The device must be returned to the manufacturer, see section 12.1 for contact details.

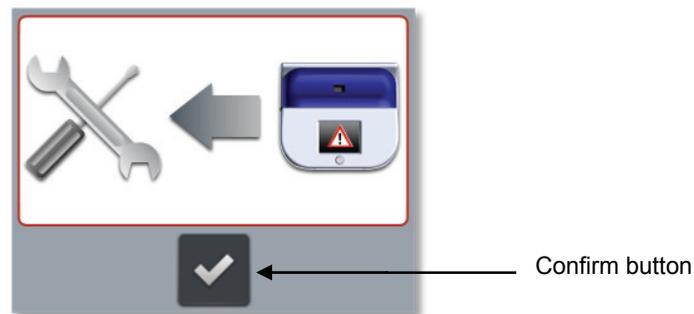


Figure 17. Internal error indication

Press the *Confirm button* to return to the *Main screen*.

6.4 Settings screen

6.4.1 Accessing the settings screen

The *Settings* screen (figure 18) is accessible from the *Main* screen by pressing the *Settings* button on the bottom-left of the *Main* screen.

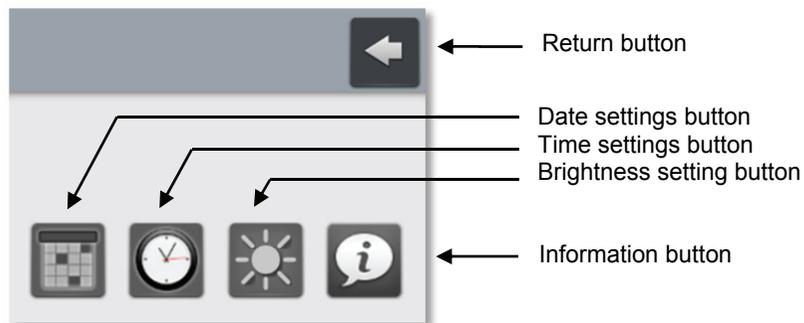


Figure 18. Settings screen

Press the *Return* button to return to the *Main* screen. Four settings buttons are available at the bottom of the *Settings* screen and give access to the following screens and functionality:

- *Date screen:* Change date and date format
- *Time screen:* Change time and time format
- *Brightness screen:* Change the LCD display brightness
- *Information screen:* Show information about the AGE Reader mu

Date screen

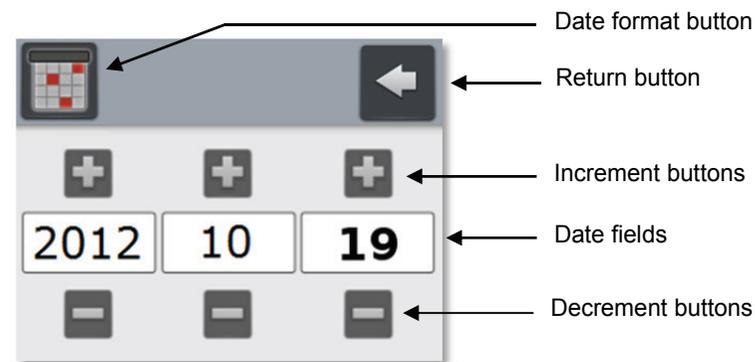


Figure 19. Date screen

The user can return to the *Settings* screen by pressing the *Return* button at the top-right of the screen. The date format can be configured as:

- YYYY-MM-DD (figure 19)
- DD-MM-YYYY
- MM-DD-YYYY

This can be done by pressing the *Date format* button repeatedly until the requested date format is shown in the *Date fields*. In these *Date fields* the individual year, month and day values can be recognized as follows:

- The year (YYYY) is shown as a four digit number
- The day (DD) is shown in bold text.
- The month (MM) is shown is shown a normal (non-bold) text.

The date itself can be changed by pressing the *Increment* button and *Decrement* button of the appropriate *Date field*. Any changes are immediately active.

Time screen

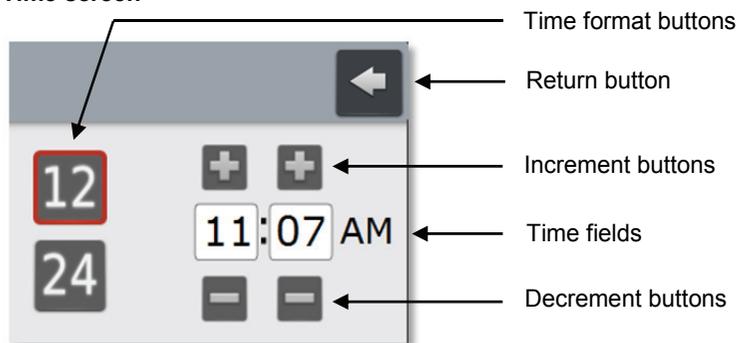


Figure 20. Time screen

The user can return to the *Settings* screen by pressing the *Back button* at the top-right of the screen. Choose between 12-hour (figure 20) or 24-hour time format by pressing the corresponding *Time format button*. With the *Increment button* and *Decrement button* the actual time can be set. Any changes are immediately active.

Brightness screen

The brightness of the LCD display can be set in the *Brightness screen* (figure 21). Using a lower LCD display brightness setting will reduce the power-consumption of the AGE Reader mu and prolongs the operating time of the battery.

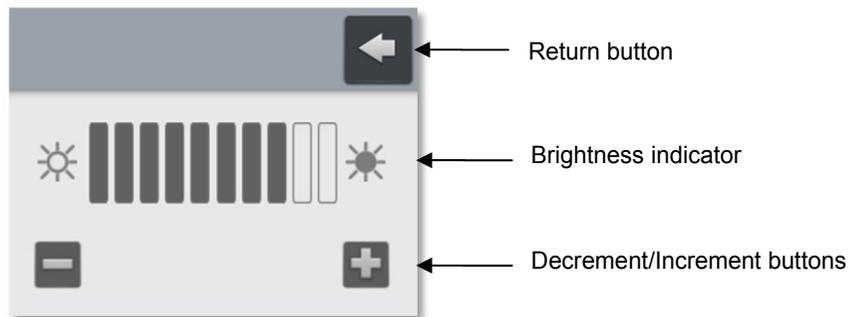


Figure 21. Brightness screen

The user can return to the *Settings* screen by pressing the *Back button* at the top-right of the screen. By using the *Decrement/Increment buttons* the brightness can be changed instantly.

Information screen

The user can select a preferred date format in the *Date format* screen. The *Date format screen* is shown below.

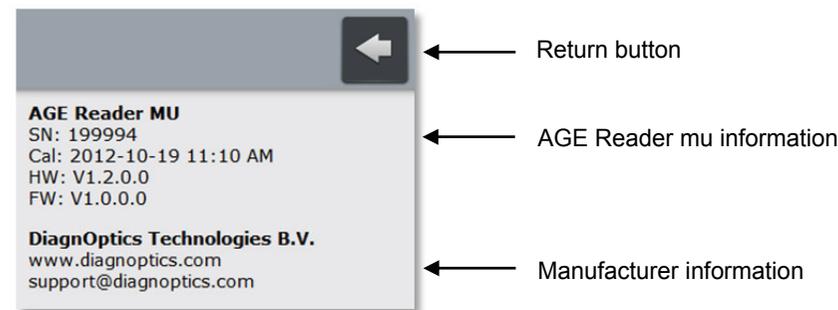


Figure 22. Information screen

Press the return button at the top-right of the screen to return to the *Settings* screen. The upper part of the *Information screen* displays information which is specific for the AGE Reader mu. The fields concerned are:

Abbreviation	Description
SN	AGE Reader mu serial number
Cal	Date and time of last calibration
HW	AGE Reader mu hardware version number
FW	AGE Reader mu firmware version number

The *Manufacturer information* displays the DiagnOptics Technologies B.V. company homepage URL and the email address of the DiagnOptics Technologies B.V. support.

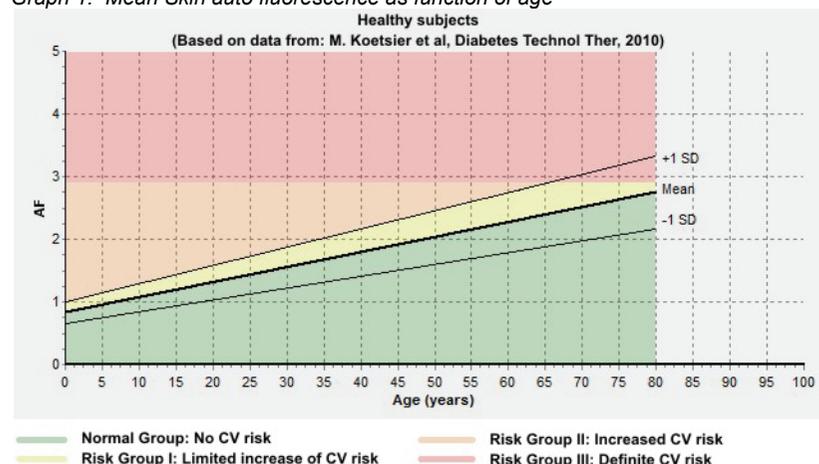
7 Background on AGE values

Age is the most important factor determining the level of Advanced Glycation End-products (AGEs) in tissue. The AGE value as measured by the AGE Reader is also correlated with age. The reference values for AGE values have been based on 456 measurements in Caucasian subjects without cardiovascular disease (smokers and non-smokers) [Lutgers et al., Diabetes Care 2006, and Koetsier et al, Diabetes Technology & Therapeutics, 2010; 12(5):399-403]. Table 2 shows the mean values of the AGE value for several age decades. AGE values are given in arbitrary units \pm 1 standard deviation. N represents the number of subjects in the respective age groups.

Table 2. Mean Skin auto fluorescence per age decades

Age group (years)	AGE Reader measurement result	N
0-10	0.97 \pm 0.17	45
10-20	1.11 \pm 0.20	50
20-30	1.53 \pm 0.30	62
30-40	1.73 \pm 0.42	86
40-50	1.81 \pm 0.36	72
50-60	2.09 \pm 0.36	64
60-70	2.46 \pm 0.57	45
70-80	2.73 \pm 0.55	27
80+	2.71 \pm 0.44	5

Graph 1. Mean Skin auto fluorescence as function of age



Graph 1 shows the mean AGE values as a function of age, together with the lines representing mean \pm 1 standard deviation. The coloured areas indicate the risk classes corresponding to the AGE value combined with age value.

No reliable AGE values can be given with the current AGE Reader mu software if the measured UV reflectance is below 10%. In that case no AGE value is given and the screen shows a message that a reliable measurement is not possible.

Cardiovascular risk interpretation for type 2 diabetes patients based on the AGE Reader measurement.

The AGE Reader measurement result increases considerably with age, both in healthy persons and in those with diabetes or renal disease. Calendar age is in fact the strongest determinant of the AGE Reader measurement. Keep in mind that calendar age itself is also by far the strongest risk indicator in terms of cardiovascular risk (CV risk), as is evident from all known risk scores. Thus, a healthy elderly person may have a higher measurement result than a much younger patient with diabetes. Therefore, age-dependent AGE Reader measurements within levels up to 1 standard deviation (1SD) above the age-corrected mean may serve as reference values for a certain age, but can be considered normal only for the corresponding age group.

AGE Reader measurements should be considered as complementary to, and not a replacement for assessment of conventional cardiovascular risk factors and risk scores. When other risk factors such as blood pressure or cholesterol levels are clearly increased, a low AGE Reader measurement is not a reason to withhold treatment. This especially holds for younger people with extreme values of conventional risk factors.

Always keep in mind that in case of markedly abnormal AGE Reader measurements (high or low) one should make sure that the measurement has been properly performed and that the measured person has not used skin creams, sun blockers or tanning agents.

Normal Group: No increased CV risk

If the AGE Reader measurement is below or equal to the age-related mean, the subject has no calendar age-corrected increase in cardiovascular risk. However if the subject is an elderly person and the result is above 2.5 (even though it is at the age-related mean), the subject may still have increased cardiovascular risk due to his/her calendar age.

Risk Group I: Limited increase of CV risk

If the AGE Reader measurement is above the average but within 1SD of the age-related mean, the subject has a limited increase, corrected for calendar age, in cardiovascular risk.

Risk Group II: Increased CV risk

If the measurement result is above 1SD of the age related mean, the subject has an increased cardiovascular risk. In such case, the advice is to check the levels of other cardiovascular risk factors such as blood pressure and lipid levels. Depending on overall CV risk, lifestyle or even pharmaceutical treatment should be considered.

Risk Group III: Definite CV risk

If the AGE Reader measurement result is 2.9 or above, the subject has a definitely high cardiovascular risk. It is recommended that other cardiovascular risk factors should be assessed and treated, with low threshold and target values for starting or intensifying treatment.

Used in combination with conventional risk scores (UKPDS, SCORE) the following advice applies:

- Normal Group: no risk reclassification to be considered
- Risk Group I: no risk reclassification to be considered
- Risk Group II: consider reclassification to a higher cardiovascular risk class
- Risk Group III: classification as high or very high cardiovascular risk class suggested

8 Cleaning & maintenance

8.1 Cleaning instructions

- **Measurement window.**

The measurement window should always be kept clean!

In the design of the AGE Reader mu, special attention was given to allow cleaning the window by using a removable mat. Place the housing on a horizontal stable surface and carefully remove the mat in order to clean the measurement window. Clean the window with a slightly moistened soft non-fluorescent cleaning wipe (for example the soft reusable cleaning wipes used for spectacles) using a standard 70% alcohol solution. Avoid scratching the window and take care that no textile or paper fibres remain on the window, textiles and paper show fluorescence and may affect the measurement! After cleaning the window, replace the silicone mat in the proper position.

- **Silicone mat.**

The silicone mat can be cleaned with standard mild cleaning agents by removing the silicone mat. If desired, the mat can be disinfected with alcohol or chlorohexidine.

- **Housing & touchscreen.**

The housing and touchscreen can be cleaned with standard mild cleaning agents, for example a slightly moistened cloth. Make sure no fluids enter the housing at the connector inlets and no fluid collects at the bottom of the touchscreen.

8.2 Maintenance instructions

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

The internal battery can only be serviced by DiagnOptics personnel with use of an tool.

The AGE Reader mu is a medical instrument that has been carefully calibrated before use. Small differences exist in the characteristics of the internal optics and the LED spectrum. Albeit small these differences may affect the measurement results of the AGE Reader mu and may impede comparisons of results between individual instruments. Unique calibration files of each individual system are used in the AGE Reader mu Software.

Never make changes in the system on your own!

If damage occurs only to the silicone mat, the power supply or the mains connector set, a replacement can be ordered, see chapter 12.

9 Problems & solutions

9.1 Power supply problems

The AGE Reader mu is either powered by its internal battery or by the supplied external 9-12VDC power supply (part. nr. CFR51000 or CFR52000). When the battery voltage drops below a workable level the AGE Reader mu will automatically be powered down. In this case apply the supplied external 9-12VDC power supply, after which the AGE Reader mu will immediately be functional again.

If the AGE Reader mu cannot be turned on while the external 9-12VDC power supply is applied, it is recommended to contact your local distributor or DiagnOptics Technologies B.V. support.

9.2 Problems during operation

When the AGE Reader mu is turned on, the software will initialize the system. If a fault condition occurs in this start-up phase a fault code is presented by red blinking of the power button with a pattern, see below. If the system successfully passes the start-up phase it enters the operational phase which is reflected by lighting the power-button green continuously.

If a fault condition occurs during the operational phase the AGE Reader mu can no longer guarantee a reliable measurement. Upon a fault the AGE Reader mu will shut-down and the power button will blink red with a pattern that reflects the fault code.

Fault codes can be recognized by the blinking pattern of the power-button. The blinking pattern is repeated continuously with a few seconds pause. The pattern itself consists of long and short blink periods (Represented as **L** and **S** respectively in the blink pattern example below). It is recommended to write down the blink pattern and contact your local distributor or DiagnOptics Technologies B.V. support. Please keep the AGE Reader mu serial number in range if you contact DiagnOptics.

Example error pattern:

Blink pattern: — — — — — —
 L **S** **S** **S** **S** **L**

At any time, the user can press the power-button to shut down the AGE Reader mu.

10 Technical specifications

- Operation: Continuous operation
- Power: 9-12 VDC from external power supply
7,2 VDC from rechargeable Li-Ion battery CFR50200
- Output

UV-A light	$\lambda_p = 375\text{nm}$	$E = 7,81\text{E-}01 \text{ W/m}^2$	@ 0,2m
Blue light	$\lambda_p = 460\text{nm}$	$E = 1,83\text{E-}01 \text{ W/m}^2$	@ 0,2m
Infrared light	$\lambda_p = 880\text{nm}$	$E = 6,26\text{E-}02 \text{ W/m}^2$	@ 0,2m
- Dimensions: Width x depth x Height : 210 x 193 x 81 mm
- Weight: 0,75 kg
- Material (ext.): Enclosure: ASA (V-0 quality)
Mat: Silicone
- Operating Conditions:
 - Temperature range: Lower limit + 10°C - Upper limit + 30°C
 - Relative humidity: 30% to 75% non-condensing
- Storage & Transport Conditions:
 - Temperature range: Lower limit - 40°C - Upper limit + 70°C
 - Relative humidity: 10% to 100% non-condensing

Power Supply (CFR51000):

- Input: 100 - 240 VAC 0,3A 50 – 60 Hz
- Output: 9 VDC 1,1 A

Power Supply (CFR52000):

- Input: 100 - 240 VAC 0,4 - 0,2A 50 – 60 Hz
- Output: 12 VDC 1,1 A

Classifications:

- Classification to 93/42/EEC Class IIa
- Classification to IEC 60601-1 Class II
- Protection against electric shock Type B
- Directive(s): Council Directive 93/42/EEC
- Standard(s): Safety: IEC 60601-1 3rd edition
EMC: IEC 60601-1-2 3rd edition
Risk Analysis: ISO 14971 : 2009

Power Supply (CFR51000 & CFR52000):

- Classification to IEC 60601-1 Class I
- Standard(s): Safety: UL/EN/ IEC 60601-1 3rd edition

Battery:

- Standard(s):
 - UL 1642 Certificate MH12210
 - UL 1642 Certificate MH12566
 - UL 1642 Certificate MH19896

Disposal:

Regulations vary for different countries. Dispose in accordance with local regulations.

11 Marking on the AGE Reader mu

Each device shall be accompanied by all information needed to safely install and use the AGE Reader mu and to identify DiagnOptics as its manufacturer.

This information consists of:

1. Information on the labels, on the device.
2. Information and instructions, on packaging.
3. Information and instructions, in this user manual.

As far as practical and appropriate, the information needed to install the device safely is set out on the labelling on the device itself and/or on the packaging for each unit. Where possible, this information is presented in the form of symbols in conformance with the harmonized standards.

The labelling on the device itself consists of:

1. Rear label: Identification of connector inlets, reset switch and charge LED
2. Serial label: Serial number and contact information of the manufacturer
All necessary information for product identification, product specification, installation, use and warnings.
3. Button label: Power button with symbol and information of power state.
4. Packaging label: Information of content and manufacturer

11.1 The rear label

The rear label is located at the back of the housing of the AGE Reader mu. This label shows all necessary information for installation, use and applicable warnings. The rear label contains two connector inlets (figure 23), one inlet for the accompanying power supply, one connector inlet for the USB connection and will identify them as such. A blue LED will light up when the battery is charging. A reset switch is present to reset the device if necessary.

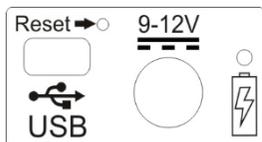


Figure 23. Rear label.

Table 3. Used symbols on rear label

Reset →	Identifies reset-switch
USB	Identifies USB inlet
9-12V	Identifies power supply inlet
 ●	Identifies battery charging indicator, blue light means charging

11.2 The serial label

The serial label (figure 24) is located on the back of the front panel of the AGE Reader mu. This label shows the serial number and contact information of the manufacturer as well as all necessary information for product identification, product specification, installation, use and warnings.



Figure 24. Serial label

Table 4. Used symbols on serial label

AGE Reader mu	Identification of device, device name
Type: CFR00100	Type identification
SN: 100001	Serial number (<i>NEN-EN 980</i>).
 2014-01	Date of manufacture; YYYY-MM (<i>NEN-EN 980</i>).

	CE-Mark & Notified body number (6 mm high)
 DiagnOptics Technologies B.V. Aarhusweg 4-9 9723 JJ Groningen The Netherlands	Identifies DiagnOptics Technologies B.V. as its manufacturer with name and contact information. (NEN-EN 980)
	Read Instructions for use (ISO 7000-1641)
	Caution, read instruction for use for specific warnings (ISO 7000-0434A)
	Type B applied part (IEC 60417-5840)
	Class II equipment (IEC60417-5172)
	Indicating separate collection for electronic equipment (2002-96-EC)
	Polarity symbol, indicates that the centre (tip) of the power plug is Positive (+) and the barrel of the power plug is Negative (-).
	Direct current symbol (IEC60417-5031)
	Barcode for production purposes.

11.3 Power button

The Power button is located at the front of the AGE Reader mu and shows the symbol “Stand-by condition” (figure 25). The condition “ready for use” is indicated by visual means; the symbol will light up green. The conditions “device error” will be indicated by visual means, the symbol will light up by an red flashing indicator light.



Figure 25. Stand-by symbol

11.4 Packaging label

Each AGE Reader mu together with a user manual and power supply will be packed in protective packaging right after production. This packaging should be used for storage and shipment. All packaging materials can be recycled if disposed of separately.



Figure 26. Packaging label

All following information is put on each package by the label as in figure 26:

- Diagnostics logo & address
- Serial number
- Content
- Weight
- Environmental conditions for transport

12 Spare parts & accessories

12.1 Spare Parts

If damage occurs to the silicone mat, the power supply or the mains connector set, a replacement can be purchased via DiagnOptics or its representatives.

Be sure that the damage is limited only to the silicone mat or the power supply. If any doubt exists that damage has been done to the AGE Reader mu itself, please contact DiagnOptics or its representatives. Do not use the device if there is visible damage and/or sharp edges.

Send your request by e-mail or fax and clearly state the serial number of the concerning AGE Reader mu. Also include the article number(s) of the spare parts you would like to order. The article numbers for the spare parts of this device are listed in table 5:

Table 5. Spare parts

Spare part	Article number
Silicone mat	CFR01200
External power supply 9VDC	CFR51000
Mains connector set (9VDC)	CFR51100
External power supply 12VDC	CFR52000
Transport Case	DMU05100

The contact details for technical support are:



DiagnOptics Technologies B.V.
E-mail: support@diagnoptics.com
Tel: +31 50 5890612
Fax: +31 50 5890613

13 Liability & warranty

13.1 Liability

DiagnOptics Technologies and its respective directors, officers, employees and agents and their respective successors, heirs and assigns, are not liable for any damages, losses, obligations, costs and expenses, including attorney's fees that may incur 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 in connection with (a) improper use of the AGE Reader mu, (b) unauthorized modification of the AGE Reader mu, (c) fault or negligence by the user, (d) breach of any warranty or other obligation by the user or (e) invalid or wrong conclusions, and any consequences thereof, drawn by third parties from the measurement results provided by the AGE Reader mu.

13.2 Warranty

The warranty supplied with this AGE Reader mu System is provided separately.

13.3 Declaration of Conformity

The Declaration of Conformity is provided separately.

14 Electromagnetic compatibility

The AGE Reader mu needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this user manual.

14.1 Essential performance

The use of the medical device does not depend on essential performance.

14.2. Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The AGE Reader mu is intended for use in the electromagnetic environment specified below. The customer or the user of the AGE Reader should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The AGE Reader mu uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AGE Reader mu is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

14.3. Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The AGE Reader mu is intended for use in the electromagnetic environment specified below. The customer or the user of the AGE Reader mu should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/-1 kV for input / output lines	+/- 2 kV for power supply lines +/-1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV line(s) to line(s) +/-2 kV line(s) to earth	+/-1 kV line(s) to line(s) +/-2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s <i>U_T is the a.c. mains voltage prior to application of the test level.</i>	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AGE Reader requires continued operation during power mains interruptions, it is recommended that the AGE Reader be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The AGE Reader is intended for use in the electromagnetic environment specified below. The customer or the user of the AGE Reader mu should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the AGE Reader, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ for 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2,5 GHz	3V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AGE Reader is used exceeds the applicable RF compliance level above, the AGE Reader should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AGE Reader.			
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

14.4. Distances between RF equipment

Recommended separation distances between portable and mobile RF communications equipment and the AGE Reader mu			
The AGE Reader mu is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AGE Reader mu can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AGE Reader mu as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



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