

AGE READER^{CU}

Know their risk.



Instructions for Use



Contact:

DiagnOptics Technologies BV
Meditech Center
L.J. Zielstraweg 1
9713 GX Groningen
The Netherlands

Tel.: +31 50 5890612
Fax: +31 50 5890613
E-mail: info@diagnoptics.com
Web: www.diagnoptics.com

CE 0344

Contents

| | | |
|------|--|----|
| 1 | Introduction | 2 |
| 2 | Intended use | 3 |
| 3 | Warnings and precautions | 4 |
| 4 | Description of the AGE Reader CU | 5 |
| 4.1 | General | 5 |
| 4.2 | Description of the AGE Reader CU | 5 |
| 5 | Installing the AGE Reader CU | 7 |
| 6 | Instructions for use | 8 |
| 6.1 | Starting the AGE Reader CU | 8 |
| 6.2 | Warming-up | 8 |
| 6.3 | Main menu | 9 |
| 6.4 | Measurements | 13 |
| 6.5 | Data Storage | 17 |
| 6.5 | Connecting a printer | 18 |
| 7 | Background on Skin AF | 19 |
| 8 | Calibration Verification | 21 |
| 9 | AGE Reader CU Dataview | 23 |
| 9.1 | Installation instructions | 23 |
| 9.2 | Starting the software | 23 |
| 9.3 | The Main screen | 24 |
| 9.4 | Importing CU data | 24 |
| 9.5 | Sorting and browsing data | 25 |
| 9.6 | Data operations | 25 |
| 9.7 | Options | 26 |
| 10 | Cleaning & maintenance | 27 |
| 10.1 | Cleaning instructions | 27 |
| 10.2 | Maintenance instructions | 27 |
| 11 | Problems & solutions | 28 |
| 11.1 | Software errors | 28 |
| 11.2 | Hardware errors | 29 |
| 12 | Technical specifications | 30 |
| 13 | Marking on the AGE Reader CU | 31 |
| 13.1 | The rear label | 31 |
| 13.2 | The serial label | 32 |
| 13.3 | The front label | 33 |
| 13.4 | Symbol in applied part | 34 |
| 13.5 | Power supply label | 34 |
| 13.6 | Packaging | 34 |
| 14 | Spare parts | 35 |
| 15 | Liability & warranty | 36 |
| 15.1 | Liability | 36 |
| 15.2 | Warranty | 36 |
| 15.3 | Declaration of Conformity | 36 |

1 Introduction

AGEs have a pivotal role in the development of chronic complications of diabetes, renal failure and other common conditions, but are also a marker of oxidative stress. The amount of AGE in tissue can serve as a risk predictor of cardiovascular risk in such complications.

The AGE Reader CU™ is a proprietary device that can non-invasively assess the tissue accumulation of Advanced Glycation Endproducts (AGEs). This technological breakthrough enables clinicians and scientific researchers to non-invasively measure the level of AGEs within a minute. The AGE Reader CU may help in clinical intervention and scientific research on patients related to AGEs.

The AGE Reader CU was developed and is being commercialized by DiagnOptics Technologies B.V, an innovative life science company based in the Netherlands.

This manual provides the instructions for use for the AGE Reader CU.

DiagnOptics Technologies B.V

2 Intended use

The AGE Reader CU non-invasively gives, if used as intended an estimate 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 on cardiovascular disease.

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

AGE measurements should be performed directly on intact healthy skin on the lower forearm. The skin at the measuring area should be homogeneous and without exposure to skin creams or any substance that may have fluorescent properties.

All instructions, procedures and information in this user manual and on the labelling on the device is 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 CU.

Pigmented skin

The device and its software have been validated in patients with skin reflection $\geq 6\%$ (Fitzpatrick class 1-4). In patients with darker skin colour (Fitzpatrick class 5-6, dark brown or black) a correction is made to the AF value if the UV reflectance is between 6% and 10%. If the UV reflectance is below 6%, the AGE Reader CU will give a warning that the signal is too low for valid results.















UV-Radiation

Using the guidelines of the ICNIRP it is concluded that during AGE Reader CU measurements, as intended, even when repeated up to a 100 times on the same skin site within an 8-hour period, the local radiation exposure on the skin of the patients, and to the eyes of patients and operators remain considerably below the maximum allowed values for that period. Radiation exposure to the eyes normally does not occur. Exposure of the eyes longer than 60 seconds per 8-hour period should be avoided.

3 Warnings and precautions

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

Table 1. Warnings & precautions

| | |
|---|--|
|  | The AGE Reader CU is intended for static use! It is not intended to be a portable device, transportation of the device must be done with great care and at your own risk. |
|  | Protect against falls and mechanical shocks. |
|  | This device emits UV-A radiation** |
|  | Measurements should be done on the dominant arm on healthy undamaged skin without birthmarks or excessive hair growth. Self tanning agents must not be used for at least 2 days. Sun-blockers and other skin care products should be removed before measurement. |
|  | Only use the accompanying external power supply (part.nr.: SAR52800). |
|  | The mains plug of the power supply is the separator which connects or disconnects the AGE Reader CU and his power supply from the mains. |
|  | Do not use excessive force on the touch panel. |
|  | Do not use sharp objects on the touch panel. |
|  | This device meets all requirements for electromagnetic compatibility per International Electro-technical Commission (IEC) 60601-1-2 and the Medical Device Directive and has been fully tested to such requirements. It is unlikely that the user will encounter problems with this device because of inadequate electromagnetic immunity. However, electromagnetic immunity is always relative and standards are based on anticipated environments of usage. If the user notes unusual device behaviour particularly if such behaviour is intermittent and associated with nearby usage of radio or TV transmitters, cell phones or electrosurgical 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 measurement window should always be kept clean |
|  | Never place anything on top of the device other than intended |
|  | Maintenance and repairs should only be done by DiagnOptics or authorized representatives. |
|  | Correct positioning of the arm over the window is essential and should be maintained steady during the measurement process. |
|  | Do not let fluids ingress. |

**** UV-Radiation**

Using the guidelines of the ICNIRP it is concluded that during AGE Reader CU measurements, as intended, even when repeated up to 100 times on the same skin site within an 8-h period, the local radiation exposure on the skin of the patients, and to the eyes of patients and operators remains considerably below the maximally allowed values for that period. Radiation exposure to the eyes normally does not occur.

Exposures to the eyes longer than 60 seconds per 8-h period should be avoided.

4 Description of the AGE Reader CU

4.1 General

The AGE Reader CU is a small, desktop unit, see figure 1, designed to measure non-invasively skin auto fluorescence and thereby to assess skin AGE levels.

The AGE Reader CU consists of a small desktop housing with a detachable silicone-mat. The AGE Reader CU is completely operated from an touch-panel on a 5,7" TFT-screen with LED backlight which is connected to an internal computer running dedicated AGE Reader CU Software. This user-friendly software allows the user to change his preferences and calculates the AF value by using algorithms. Results of the measurements are presented numerically and can be graphical displayed on the screen, and are automatically stored on the internal flash drive in dedicated folders.

The AGE Reader CU is powered by an accompanying medically approved external power supply connected to the mains. The device can also be powered from the internal rechargeable Lithium Ion battery.

Contents of transport box:

- AGE Reader CU
- This user manual
- External power supply article number SAR52800, complying to IEC 60601-1
- Mains supply cable with mains plug to comply with regulations for use in country of usage
- USB-Storage device
- CD with Dataview Software



Figure 1. The AGE Reader CU

4.2 Description of the AGE Reader CU

The AGE Reader CU is a proprietary device to assist a physician in assessing cardiovascular risk. This new way of non-invasive monitoring uses autofluorescence of ultraviolet light in human tissue.

The AGE Reader CU assesses the tissue accumulation of Advanced Glycation Endproducts (AGEs) in the patient. AGEs play a pivotal role in the development of chronic complications of diabetes and other common conditions, but are also a marker of oxidative stress. The amount of AGEs in tissue can serve as a risk predictor of such complications.

The AGE Reader CU (as shown in figure 2) has the following external features:

- A detachable silicone mat.
- Power inlet. Only use the medically approved power supply accompanying the device, with article number SAR52800.
- A USB port for external storage device.
- A measuring window of special glass is located on the top of the AGE Reader CU.
- A 5,7" TFT- & Touch screen from where the device is operated and all necessary information during use is presented visually for the user.
- The serial number is located on the bottom of the unit. It contains information about the spectrometer and lamp characteristics of the specific unit for the manufacturer.

The AGE Reader CU consists of a small desktop housing with a detachable silicone-mat for the patient to rest his arm on for the measurement, shown in figure 2.

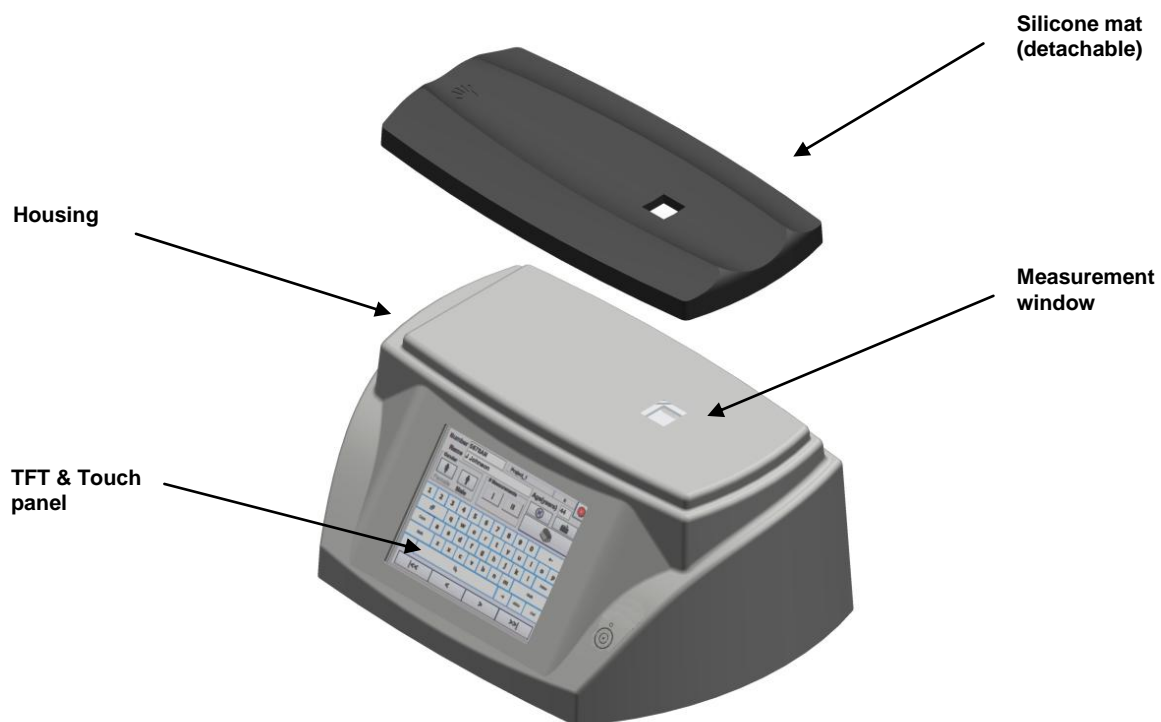


Figure 2. AGE Reader CU components

A back-up of the results can be made by means of the accompanying USB storage device that can be inserted at the rear of the device. Using the specific Dataview Software that is accompanying the device, the user can reopen this back-upped data on his/her own PC. The user is also able to perform updates and upgrades by means of the accompanying USB storage device.

The fluorescence is excited by a 4 Watt UV-A fluorescent tube that is driven by an electronic starter. A shutter is capable to close the measurement window, to be able to make a dark-reference measurement and a reflection measurement on the white reference standard mounted under it.

5 Installing the AGE Reader CU

1. Place the AGE Reader CU on a horizontal, flat and stable surface.
2. Connect the mains supply cord with the DiagnOptics power supply with part number SAR52800 accompanying the device and connect it to the mains.
3. Insert the power plug in the power inlet which is located on the rear side of the AGE Reader CU and is labelled as "Power in", see figure 3. A blue LED will light up when the battery is recharging.
4. The AGE Reader CU can now be turned on by the power button located on the label on the front side of the AGE Reader CU, see figure 4. A green LED above the button will light up if the device is in its 'power on' state.

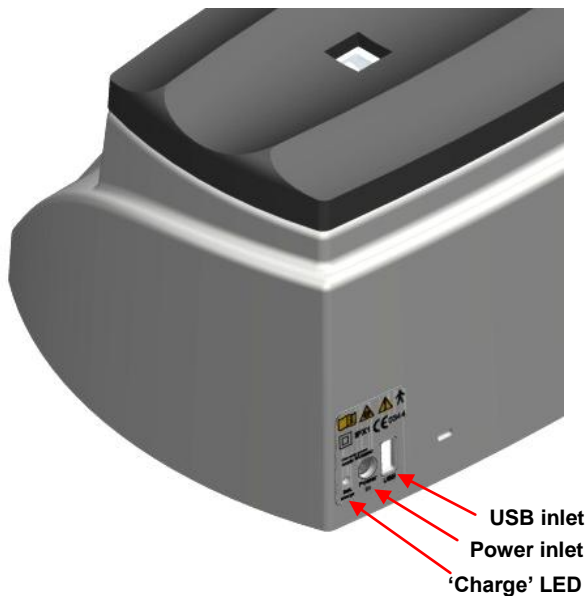


Figure 3. AGE Reader CU connections



Figure 4. AGE Reader CU front side with power switch

5. The dedicated AGE Reader CU Software is preinstalled and will start-up automatically.

6 Instructions for use

6.1 Starting the AGE Reader CU

When starting the AGE Reader CU for the first time it is recommended to charge the internal battery. Although the battery will not be completely empty from the factory, it is best to charge it completely. This will extend the battery life. Insert the power plug into the power inlet that is located on the rear side of the AGE Reader CU and is labelled as “Power in”, see figure 3. A blue LED will light up when the battery is recharging.

Turn the AGE Reader CU on by pressing the ‘power button’ located on the label on the front side of the AGE Reader CU, see figure 4. A green LED above the button will light up if the device is in its ‘power on’ state.

The dedicated AGE Reader CU Software is preinstalled and will start-up automatically. When the device is ready for use the ‘main-screen’ as shown in figure 5 will appear.

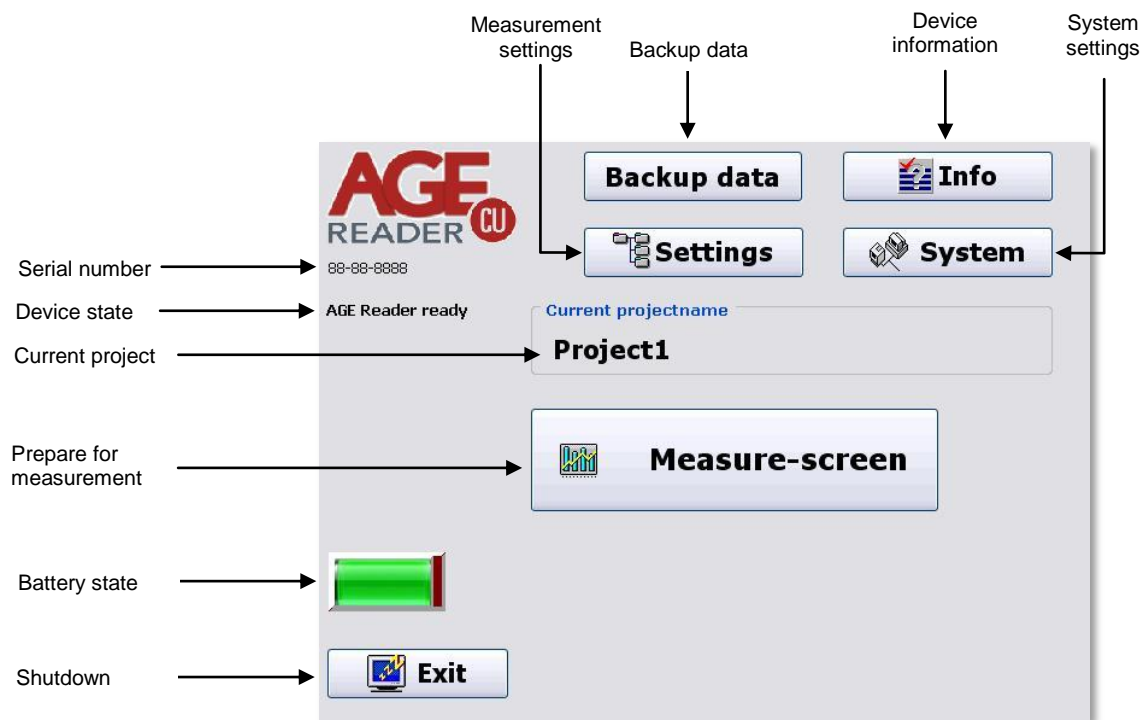


Figure 5. Main Screen

6.2 Warming-up

During start-up, the device state is presented under the ‘AGE Reader’ logo in the ‘main-screen’. Under the Measure Screen button the following message appears:

“Recommendation: 3 minutes warming up before measurement”.

This recommendation is given to allow the lamp output to stabilize. When consecutive measurements are made on different patients during one session no further warming up time for the lamp is needed. If no measurement is taken within 10 minutes, the AGE Reader CU Software will turn off the lamp to reduce lamp wear and to reduce system heating up. When a new measurement is started by pressing the ‘measure’ button, the lamp will turn on again. This will take about 15 seconds during which time no input can be done. If the AGE Reader CU is not used for a long time, 3 minutes warming up as described above is required before measurements can be done.

6.3 Main menu

6.3.1 Backup Data

The user has the option to backup all measurements on an USB storage device. Insert the accompanying USB storage device in the USB-inlet, as shown in figure 3, and press the 'Backup data to USB-stick' button. At the end of the backup procedure the connection with the USB Memory device is closed, and the user needs to remove the USB memory device from the Reader.

After that the measurements can be opened or backed up on a PC or laptop running the 'AGE Reader CU Dataview' software as described in chapter 9.

NOTE: When the USB storage device is inserted for the first time, wait 30 seconds before continuing. The system needs to install the correct drivers.

6.3.2 System settings

By choosing the 'system' button in the main menu (see figure 5) the 'AGE Reader system settings' menu will be opened where system settings can be changed. The 'AGE Reader system settings' menu is shown in figure 6.

This menu is password protected and can only be opened and changed by the user with full rights. The default password, set by DiagnOptics, is "0000". It is strongly advised to change this password at first use.

After making the desired changes, pressing the button with the cross in the upper right corner at the top of the screen returns to the 'main screen'.

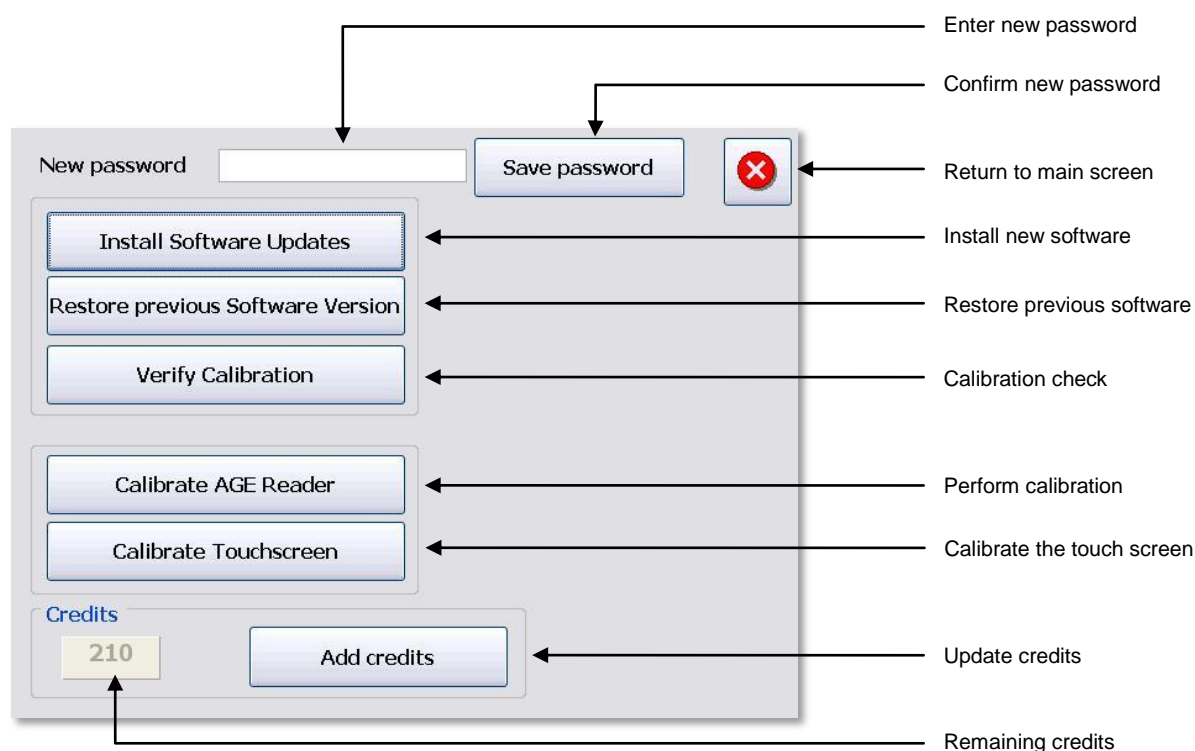


Figure 6. AGE Reader CU System Settings menu

Change password

A new password can be set by tapping in the blank field behind the text "new password". After tapping, a keyboard will appear where the new password can be entered. After pressing the 'Save password' button the new password is saved.

Install Software Updates

The 'AGE Reader CU Software' can be updated. Software updates are occasionally available from DiagnOptics. These will be supplied on a USB storage device. Please contact DiagnOptics or your local distributor about how to obtain the updates.

The software can be updated by inserting the USB storage device with the update in the USB-inlet, as shown in figure 3, and press the 'Install software updates' button. The update process will be performed automatically. The previous version will be automatically backed-up on the internal flash drive.

NOTE: Before a software update is performed, create a backup of your data by the procedure described in section 6.3.1.

Restore previous software

The 'AGE Reader CU Software' can be restored to the previous version if desired.

Press the 'Restore previous software' button and the restore process will be performed automatically and the previous version of the software is installed again.

NOTE: Before software downgrade is performed, create a backup of your data by the procedure described above.

Verify Calibration

This option can be used to verify the calibration of the instrument. This can only be performed if the calibration verification kit has been purchased. See chapter 8 for information about this option.

Credits

The AGE Reader CU has a limited number of measurements (Credits) installed unless you have an AGE Reader CU with unlimited measurements. In that case the field 'Credits' will be blank and the button will be disabled.

In the field in the lower left corner of the screen the number of remaining Credits is displayed. The remaining credits are also displayed in the 'Patient data screen'.

To update the number of Credits, insert the USB storage device supplied by DiagnOptics containing the credit upgrade for the instrument in the USB-inlet, shown in figure 3, and press the 'Update credits' button. The credits-update process will be performed automatically.

Calibrate AGE Reader

This option is only accessible for DiagnOptics and its representatives to perform a calibration test of the AGE Reader CU.

Calibrate Touch screen

Please only use this option when necessary. This calibration needs to be done with care.

The user has the option to re-calibrate the touch screen. By pressing this button the touch screen calibration procedure will be started. The procedure will show a dot in the upper left corner of the touch screen. After pressing that dot with a pointed but not sharp object, the next dot will be displayed. After pressing all the four dots that will be displayed in each corner of the screen the touch screen is calibrated.

If the OK button is not pressed within 10 seconds after this calibration, it is assumed that the calibration was not successful, and the touch-screen calibration program is started again.

6.3.3 Info screen

By choosing the 'Info' button in the main menu (see figure 5) the 'Info' screen will be opened. The 'Info' screen is shown in figure 7. This screen provides information regarding the user software version, windows embedded software version, AGE Reader CU serial number, calibration file and version number currently used. Also the contact information of the manufacturer DiagnOptics is presented here. From this screen the user can also display the "Declaration of Conformity" and the "CE Certificate".

Pressing the button with the cross in the upper right corner at the top of the screen returns to the 'main screen'.



Figure 7. AGE Reader CU Info screen

6.3.4 Settings

By choosing the 'settings' button in the main menu (see figure 5), the 'AGE Reader settings' menu will be opened where these settings can be changed. The 'AGE Reader settings' menu is shown in figure 8. After making the desired changes, pressing the button with the cross in the upper right corner at the top of the screen returns to the 'main screen'.

The settings are stored in the selected project, so that each project can have its own settings.

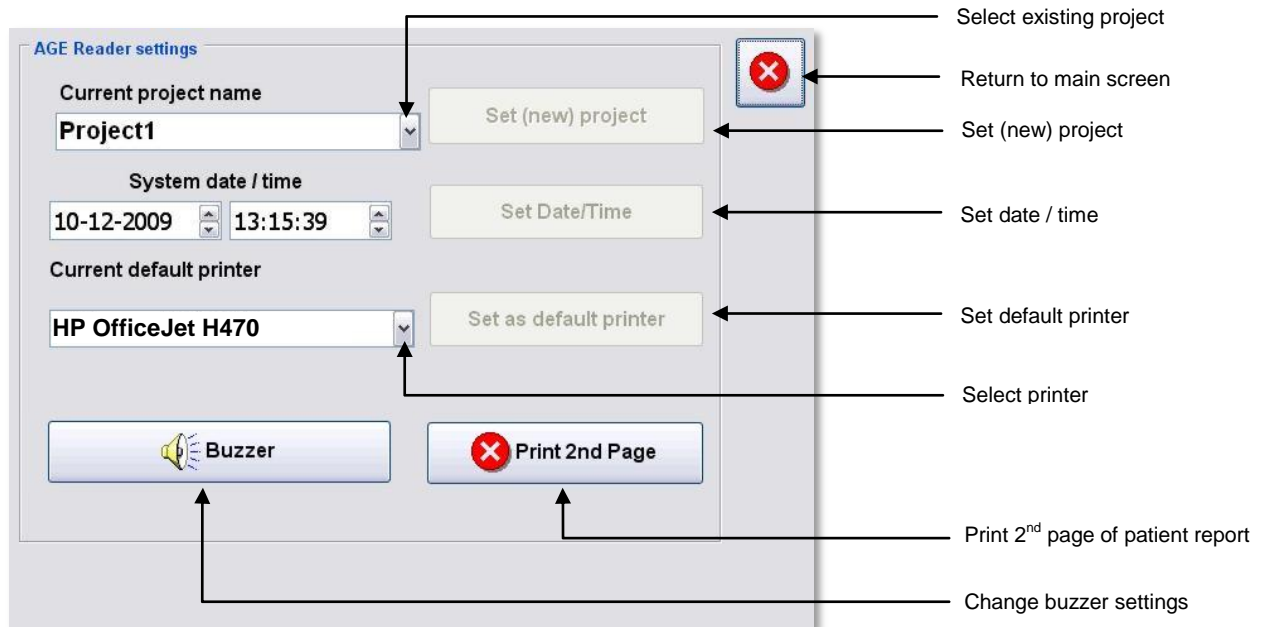


Figure 8. AGE Reader Settings menu

Set (new) project

Here the current project can be selected. By using the pull-down menu an existing project can be selected, or a new project created. When the pull-down menu is selected the keyboard will be displayed to enable entry of a new project name. The selected project is made active by pressing the 'Set (new) project' button. A number of characters are not allowed in the project name, such as '.', '/', '\'. If entered an error message is given.

All measurements made within the selected project will be saved in the same directory on the internal flash drive.

Set date / time

The current date and time can be set by pressing the 'Set Date / Time' button. When pressed, a keyboard will be displayed where the new date and time can be entered. The new Time and Date are made active by pressing the Set Date/Time button.

Set as default printer

This option enables selection of the default printer. The selection is made active by pressing the 'Set as default Printer' button. The setting affects the print option in the 'Measurement results' screen. More information of the printers that can be used with the AGE Reader is provided in chapter 6.5.

Buzzer

The buzzer signal that is produced at the beginning and end of the patient measurement can be turned 'on' or 'off' by the user.

Print 2nd Page

Printing of the second page of the Patient Report, with information about the different risk classes, can be enabled or disabled.

6.4 Measurements

To start a measurement, press the “Measure-screen” button in the main menu (see figure 5).
The ‘Patient Data’ screen as shown in figure 9 will appear.

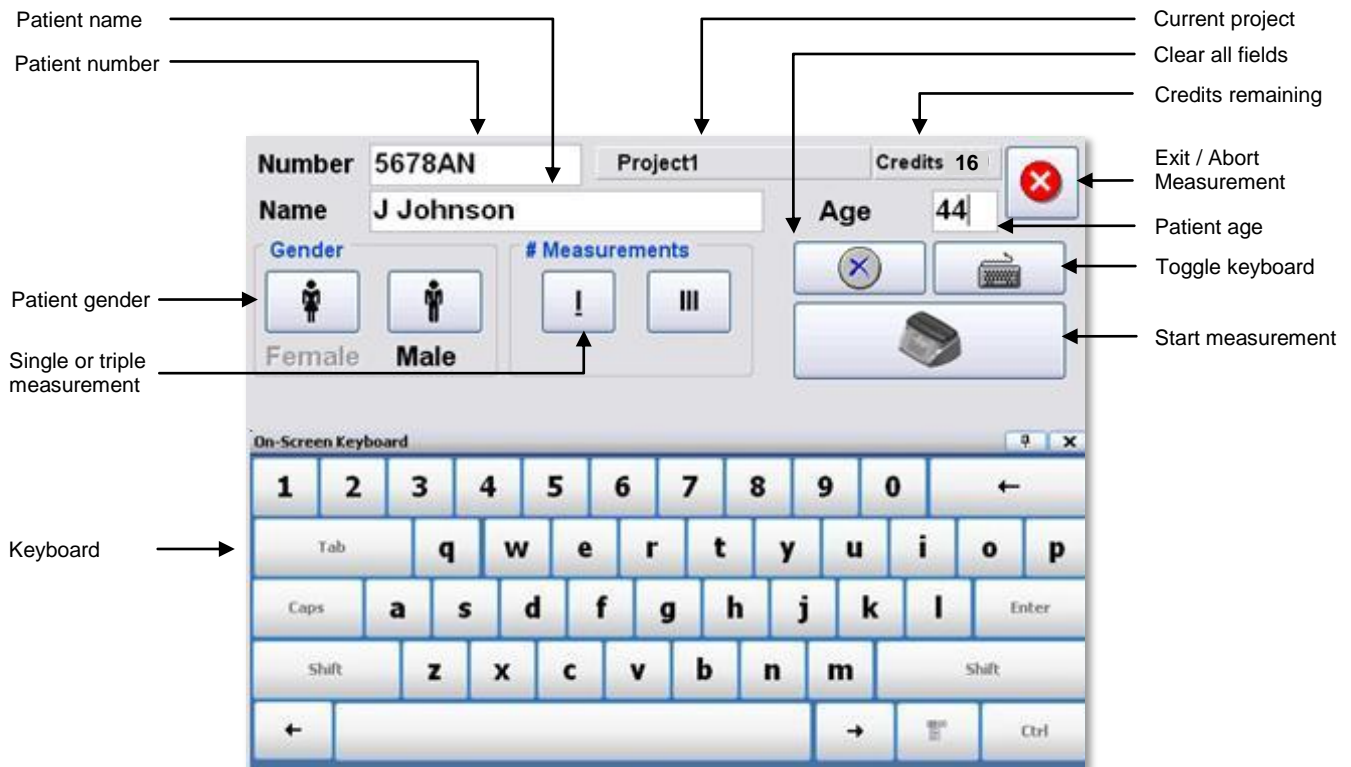


Figure 9. Patient Data

6.4.1 Measure screen

The ‘Measure screen’ as shown in figure 9, has several fields where patient number, patient name, gender and age can be entered. These fields must be filled in before a measurement can be performed! To erase all input of the fields, press the button with the blue cross.

In this screen the option is given to perform a single measurement or a triple measurement. The triple measurement has been included for improved accuracy by reducing the effect of skin inhomogeneity. The measurement type selected is shown in green, and by an underscore under the selected option. The current project, under which the measurements are stored, is shown in the field right of the patient number. On the right of this field the number of remaining credits (measurements) is displayed. If you have an AGE Reader CU with unlimited measurements this field will be blank.

After filling in the patient data, press the button with the AGE Reader CU icon to start the measurement.

The automatic measurement procedure of the AGE Reader CU will be started.

6.4.2 Measurement procedure

During the measurement, the keyboard will disappear and a progress bar is displayed, as shown in figure 10. The patient data entered in the previous step will remain visible.



Figure 10. Measure Screen

The measurement consists of several steps. The current step of the measurement is displayed above the progress bar.

The AGE Reader CU Software does the first three steps automatically:

1. **Preparation**
2. **Reference white UV measurement**
The AGE Reader CU now measures the intensity of the UV light which is used as a reference.
3. **Reference dark UV measurement**
The AGE Reader CU now measures the dark-current of the spectrometer which is used as a reference.

These first 3 phases should take no more than app. 30 seconds.

4. **Patient measurement**
During the patient measurement the skin autofluorescence measurement with UV-A light is performed. Before the start of the measurement, optionally a buzzer will be audible to warn the user and patient that the measurement will begin, and a window appears asking for the lower arm to be put on the measurement window, see figure 11. After the patient has put the arm on the window as in figure 12 and thereby fully covering it, select OK. The patient measurement will start after the OK button is pressed. The patient measurement usually takes 20-30 seconds.
Measurements are preferably taken on the dominant arm on healthy undamaged skin without birthmarks or excessive hair growth. Self tanning agents must not have been used for at least 2 days. Sun blockers and other skin care products can also influence the results and should for that reason be removed before the measurement.



Figure 11. Notification for patient measurement start



Figure 12. Positioning of arm on the AGE Reader CU

5. Patient dark measurement

The patient dark measurement is the next step in the measurement procedure. This step is taken to be able to correct for possible leakage of surrounding light between the skin and the upper surface of the AGE Reader CU during the UV measurement. Therefore, it is important that the patient keeps the arm in the same position during this part of the measurement.

If the “Triple Measurement” option is selected, steps 4 & 5 will be repeated 3 times. It is advised that the patient covers the window with the arm each time at a slightly different position.

If the UV reflectance of the arm is less than 12%, steps 2-5 are repeated with a white LED light source. In that case a second progress bar for the LED measurements is displayed underneath the main progress bar. In the case of a triple measurement this LED measurement is only performed once.

The measurement can be aborted by pressing the ‘Exit’ button in the top right corner. In that case no results are stored and no credit is deducted

If the reflectance is less than 6%, no result is produced and no credit is deducted.

The measurement is completed when the progress bar is filled and an optional second audible signal (double beep) from the buzzer.

Within a few seconds the “Patient Results” screen as shown in figure 13 is displayed. The AF results are presented numerically as an AF-value. The patient data entered will remain visible.

6.4.3 Review of previous measurements

The user has the option to recall previous measurements by means of the buttons at the bottom of the screen, see figure 13. To return to the ‘main screen’ press the red cross. To start a new measurement press the button with the tick mark.

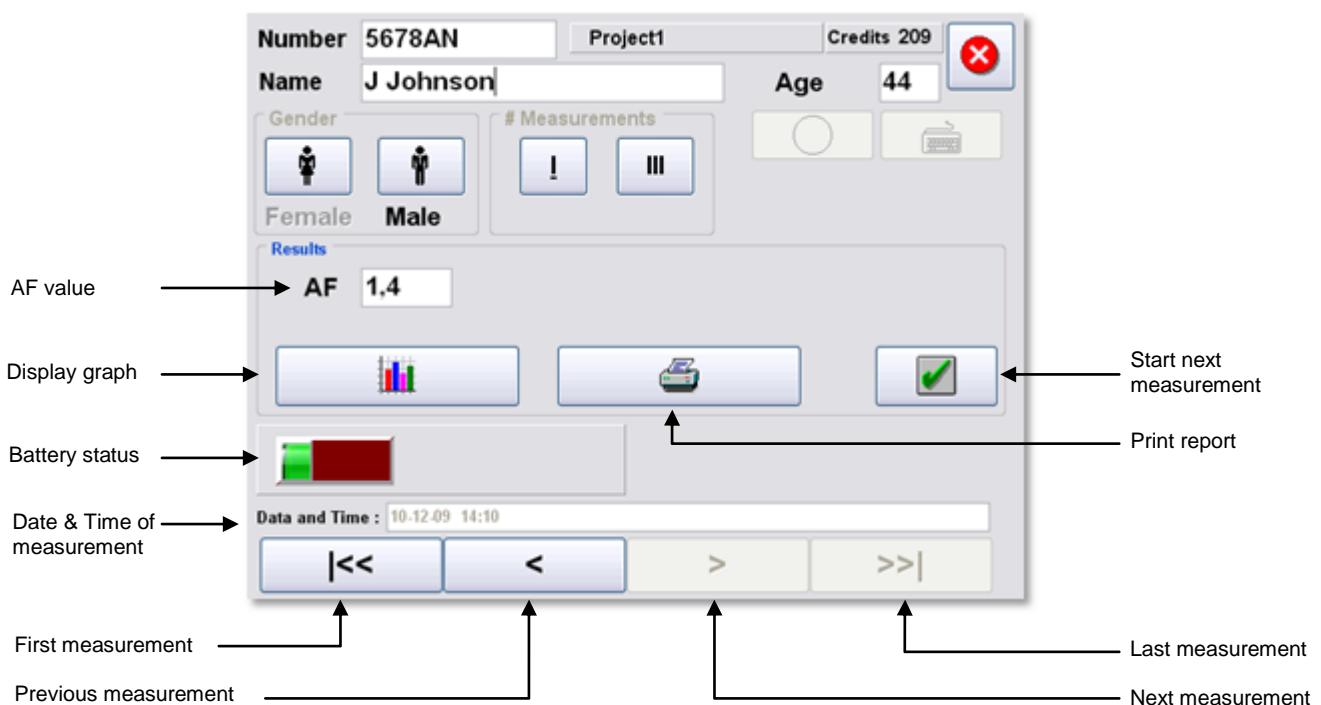


Figure 13. Patient results

Remark: The device and its software have been validated in patients with skin reflection $\geq 6\%$ (Fitzpatrick class 1-4). In patients with darker skin colour (Fitzpatrick class 5-6, dark brown or black) a correction is made to the AF value if the UV reflectance is between 6% and 10%. If the UV reflectance is below 6%, the AGE Reader CU will give a warning that the signal is too low for valid results.

If desired the “results graph” can be displayed by pressing the button with the graph-symbol. This will open a screen as shown in figure 14, which displays the measured AF-value against the age of the patient. This allows for a comparison with the average AF-value of healthy control patients. Risk classes are

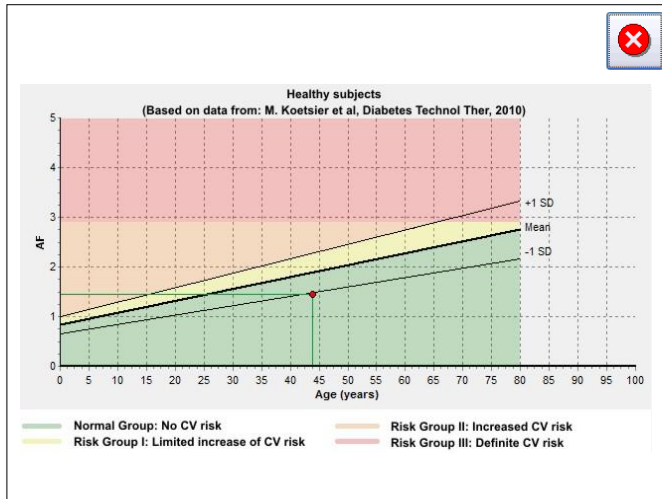
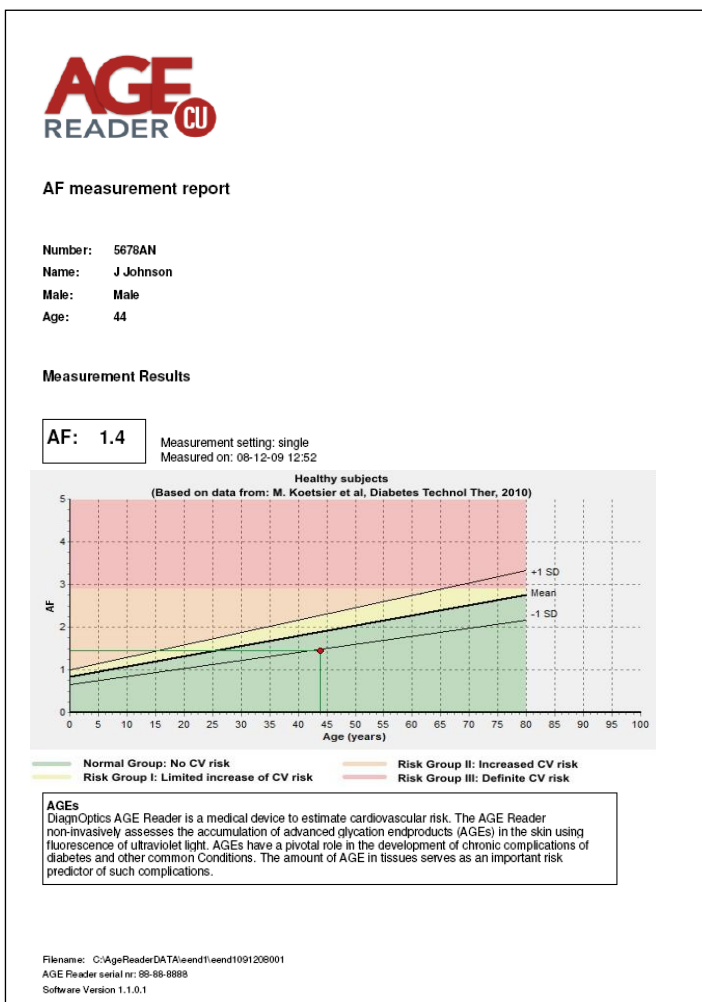


Figure 14. Results graph

When the button with the printer symbol is pressed, a patient-report, as shown in figure 15, will be printed. For this function a printer needs to be connected.



If the Print 2nd Page option is enabled, see chapter 6.3.4 'Settings', a second page will be printed which shows information about the different risk classes for cardiovascular risk interpretation, see section 7.

6.5 Data Storage

A separate folder is created on the internal flash drive for each project that has been created by the user under Settings (see section 6.3.3). This folder has the same name as the project. Each time the AGE Reader has performed a measurement; the raw data of each measurement are stored in a "DCF" file in the dedicated folder of the project for backup and future use. At the same time the AF result, Reflectance, and the patient data are added to the "info.out" file. This file is located in the same project folder.

6.5.1 Info.out file.

The summary results are stored in the file "info.out" in the dedicated project folder. The summary results can be accessed on an external PC from the backed up data, see 6.3.1. The data are stored in a Notepad text format, and can be exported to other file formats like Excel or Word in a conventional manner.

The file fields are, from left to right:

- | | |
|-----------------|--|
| • File name | Designated by the AGE Reader CU |
| • AF | The auto fluorescence value as calculated |
| • Reflectance | The skin reflectance value as calculated |
| • Date | Date of measurement |
| • Time | Time of measurement |
| • Number | Patient number as given before measurement |
| • Name | Patient name as given before measurement |
| • Age | Patient age as given before measurement |
| • Gender | Patient gender as given before measurement |
| • Serial number | Serial number of the AGE Reader CU used |

6.5.2 DCF Files

All the data from a measurement are stored in a DCF-file containing the raw spectra per measurement. This file is in a proprietary format and can only be read by the manufacturer.

The DCF filenames are designated by the current project name, to which are added year, month and date of measurement and the consecutive number of the measurement made during this calendar day. When a new day has started, the numbering of files starts again with 001. In this way, all filenames remain unique.

The DCF files are intended for back-up of the measurements and for future use. When problems with the instrument are detected, the user may send the corresponding file to DiagnOptics for support. Future developments on the software of the AGE Reader CU may lead to further improvements of algorithms that can then be applied to recalculation of AF values on stored results. We suggest to store the measured files for future use!

6.5 Connecting a printer

To print a report, a PCL 3 compatible color printer can be connected to the AGE Reader's USB port.

We strongly advise to use a good quality USB cable with a maximum length of 1,8m.

When connecting a printer for the first time the printer driver will be installed by the software. In order to install the printer driver please follow the steps listed below:

1. Make sure printer cable is disconnected.
2. Switch on AGE Reader and wait until the message 'AGE Reader ready' appears on the left side of the screen.
3. Connect the printer cable to the USB port, located on the back of the AGE Reader.
4. The printer is installed automatically. Allow two minutes for printer installation.
5. Select 'Settings' and check under 'Current default printer' that the printer is listed.
6. Select the printer and press 'Set as default printer'.
7. Printer is now ready for use.

Below is a list of PCL 3 compatible printers from HP:

| Officejet series | Designjet series | Deskjet series | Photosmart series | Other |
|---|---|--|--|--|
| <ul style="list-style-type: none"> • 6000 • 7000 • 8000 • 4500 • 6500 • 8500 • H470 • K8600 | <ul style="list-style-type: none"> • 111 • 130 • 510 • T620 • T770 • Z2100 • Z3200 | <ul style="list-style-type: none"> • F4400 • F4480 • 6940 | <ul style="list-style-type: none"> • Plus • Premium • D110 • B209 • C309 • C410 • A646 • B8550 • C3100 series • C4600 series • C4700 series | <ul style="list-style-type: none"> • PSC2100 series |

Please note that this list is provided by HP, the listed printers are not tested by DiagnOptics. Therefore DiagnOptics cannot be held responsible for correct functioning of the printers in combination with the AGE Reader.

The following printers are successfully tested by DiagnOptics:.

- HP Officejet H470,
- HP PSC2110
- HP Photosmart 3180.

*This list of compatible printers only works with Windows Embedded image version 1.2.1 or higher, the image version on your device is displayed in the 'Info' screen, see 6.3.3.
Previous images only support the HP Officejet H470.*

7 Background on Skin AF

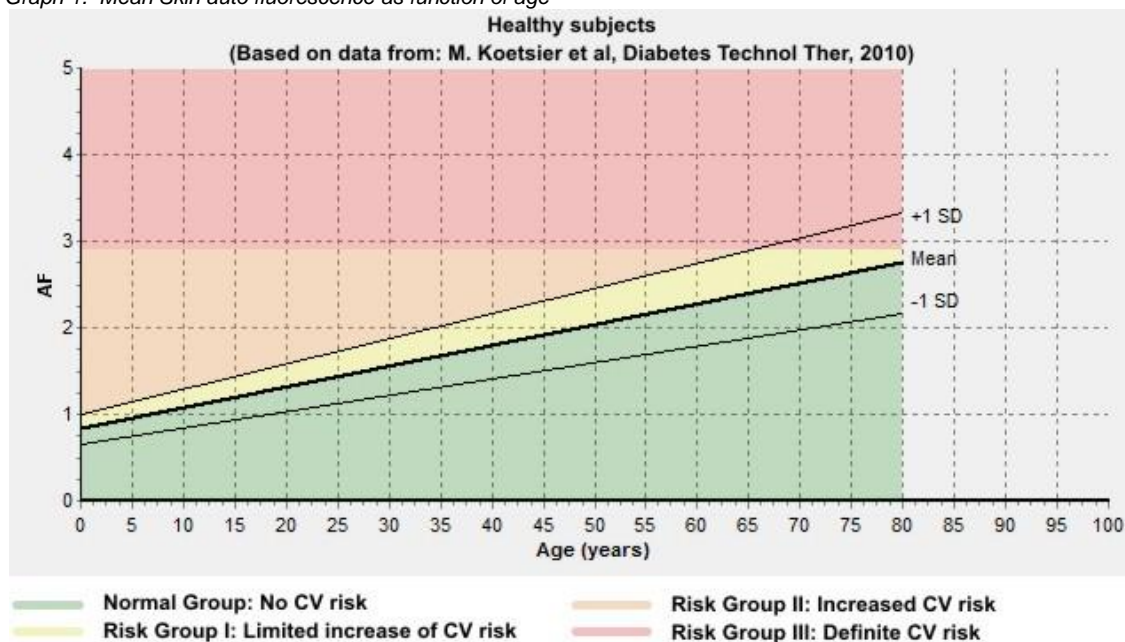
Age is usually the most important factor determining AGE content in different organs. Skin AF as measured by the AGE Reader is also influenced by age. The reference values for skin AF have been based on 456 measurements in Caucasian subjects without cardiovascular disease (smokers and non-smokers) [Lutgers 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 AF for several age decades. Values of skin AF are in arbitrary units ± 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) | AF | 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 values of skin AF as a function of age, together with the lines representing mean ± 1 standard deviation. The coloured areas indicate the risk classes corresponding to skin AF combined with age value.

Background on calculation of skin AF and reflectance

Skin AF is calculated as the ratio of the light intensity reflected by the skin in the 420-600 nm wavelength range, and the light intensity in the 300-420 nm wavelength range. By using calibrated spectrometers, the results obtained by different AGE Reader CUs are comparable. When skin reflectance $R < 12\%$, an additional measurement is performed with a white LED to allow for more reliable skin AF values.

Each AGE Reader CU has a unique calibration file that is stored on the internal flash-drive. In this an individual correction factor for each wavelength, corrections for reflectance and several other parameters are stored.

No reliable skin AF results are possible with the current AGE Reader CU software (version 1.2) if the reflectance is below 6 %. In that case no value is given for the skin AF.

Cardiovascular risk interpretation for Type 2 diabetes patients based on the measured AF value.

The AF value provided by the AGE Reader 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 AF values. 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 AF value than a much younger patient with diabetes.

Therefore, age-dependent AF values 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.

AF values provided by the AGE Reader 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 AF level 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 AF values (high or low) one should make sure that the AF measurement has been properly performed and that the measured person has not used skin creams, sun blockers or tanning agents.

Normal group: No CV risk

If the AF value is below or equal to the age-related mean, the subject has no calendar age-corrected increase in risk of diabetes or cardiovascular disease. However if the subject is an elderly person and the AF value 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 AF measurement value is above the average but within 1SD of the age-related mean, the subject has a limited increase, corrected for calendar age, in his/her risk of diabetes or cardiovascular disease.

Risk Group II: Increased CV risk

If the AF measurement value is above 1SD of the age related mean, the subject has increased risk in comparison to his/her age group. In such a 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 AF measurement value is 2.9 or above, the subject has a definitely high risk of cardiovascular disease or diabetes. 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 CV risk class
- **Risk Group III:** classification as high or very high CV risk class suggested

For further information please contact DiagnOptics at info@diagnoptics.com.

8 Calibration Verification

The calibration of the instrument can only be verified with the help of a calibration verification kit, part number Cal-Kit-01, which can be ordered at DiagnOptics (see fig. 16 screen shot with calibration kit dialog)

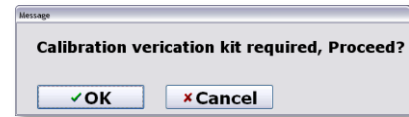


Figure 16. Calibration kit required dialog

The verification needs to be performed between 10 and 15 minutes after the instrument is switched on from cold. **Prepare for the verification before switching on the instrument:**

- Clean the AGE Reader window.
- Ensure the Calibration standard is clean. (Note: do not use solvents or water to clean the standard)
- Place the calibration mat and the calibration standard on the AGE Reader.

After starting the verification option, the 10 minute wait time is indicated by the progress bar at the bottom of the screen, see figure 17. On the first screen information is provided about the current calibration filename, calibration date and time and calibration version number. In addition the date and time of the last verification, if available, is shown.

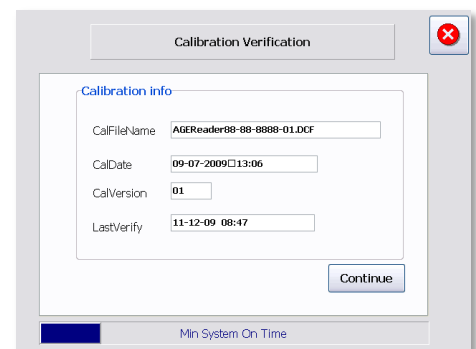


Figure 17. Calibration verification screen

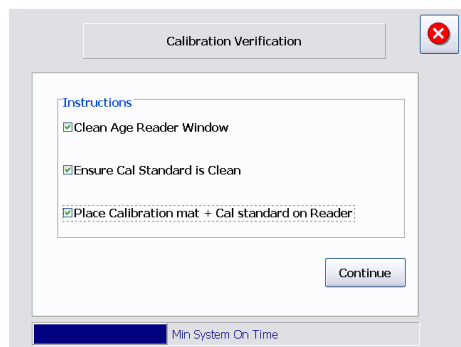


Figure 18. Prepare verification

Press continue to proceed to the next screen. This contains the instructions for use as listed above, see figure 18. When the instructions have been followed, check the tick boxes and proceed by pressing 'Continue'.

In the screen presented (figure 19), the serial number and AF value of the calibration standard needs to be entered. The serial number needs to be entered with the right format, with letters and digits in the correct place. The AF value needs to be entered with two significant digits. Both values are noted at the bottom of the calibration standard. After pressing the OK button, the keyboard for data entry disappears.



Figure 19. Verification data input

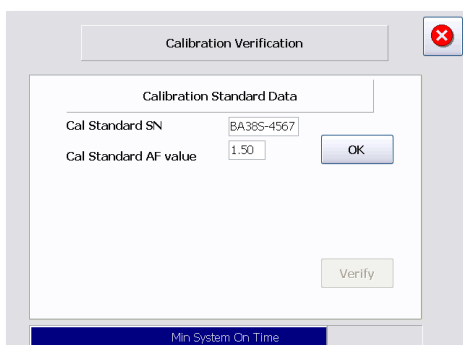


Figure 20. Verification start

The 'Verify' button is not enabled until the 10 minute wait minimum wait time has been exceeded. See figure 20. When the minimum time of 10 minutes has passed, as indicated by the progress bar, the 'Verify' button is enabled, see figure 20. Pressing this button starts the actual verification measurement. If the elapsed time since switch-on exceeds 15 minutes, the message 'System on time > 15 minutes, please switch off instrument and allow to cool down'. In that case the reader needs to be switched off for at least 2 hours.

During the calibration verification measurement progress is shown (figure 21). The measurement can be aborted by pressing the 'Quit Verify' button.

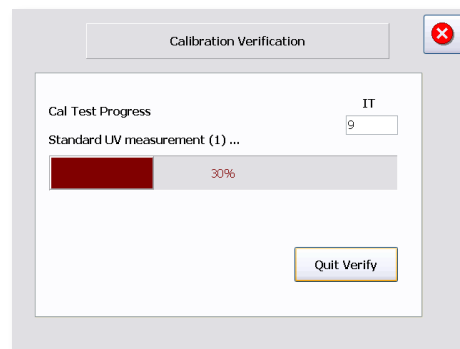


Figure 21. Verification process

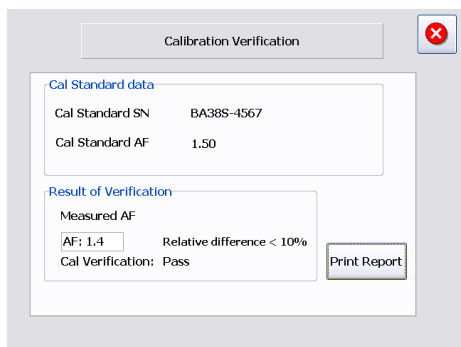


Figure 22. Verification results

After successful completion of the verification measurement the result of the verification is shown, see figure 22. The measured AF value of the standard is shown. If the relative difference between the specified and the measured value is less than 10%, the result of the verification is 'Pass', otherwise the result is indicated as 'Fail'. In the latter case the instrument needs to be re-calibrated.

The result of the verification measurement is stored in the instrument. This data is saved to an external USB memory device by the 'Backup Data' option on the main screen.

A calibration verification report can be printed by pressing the 'Print Report' button. This will print the report to the printer selected under 'Settings'. See figure 23.

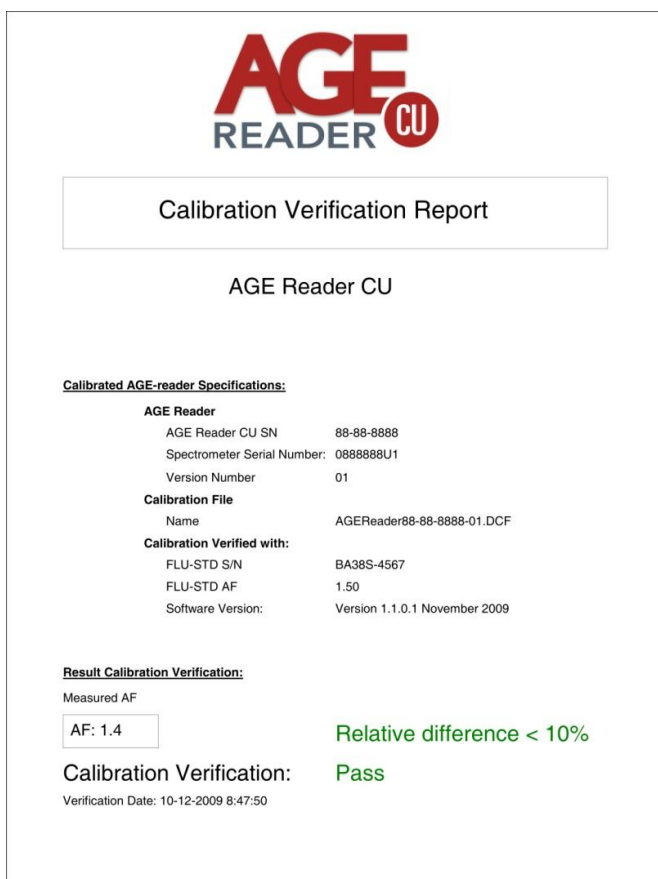


Figure 23. Calibration verification report

9 AGE Reader CU Dataview

The purpose of the software is to store the data that has been backed up on an USB-stick on a PC, to easily view and analyse that data, produce and print reports, to sort and filter the data and to export the filtered data.

9.1 Installation instructions

To install you need to have administrator rights.

Insert the AGE-Reader CD in the CD/DVD-drive of a computer running Windows 2000 or later.

The installer should start automatically, otherwise run "Setup CU Datviewer.exe" from the CD.

The AGE Reader CU Dataview program will now self-install the software in a new folder "\AGE-Reader" in the "Program files" folder (usually C:\Program Files\) of the computer. This can be changed if preferred.

Uninstalling the Dataview software

Remove the program by using: "Start->Control Panel->Applications->AGE Reader CU Dataview" 'change/remove'.

This will remove all the program files. The backup data will be untouched.

9.2 Starting the software

The DiagnOptics AGEReader CU Dataview program can be started from the desktop-shortcut 'AGE Reader CU Dataview' or from the Windows Start Menu, by selecting Start -> Programs -> AGE-Reader->AGE Reader CU Dataview.

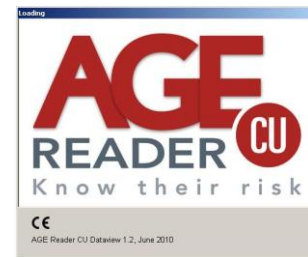


Figure 24. Dataview splashscreen

When starting the software for the first time, the user is asked to choose a folder to store the measurement data, see figure 25. If the user decides not to choose a folder the default folder will be used: 'C:\AGEReaderBKData'.



Figure 25. Define Dataview data folder

If the user chooses to manually select a storage folder, the message dialog in figure 26 will be shown: (The chosen data storage directory will be displayed in the status bar at the bottom of the screen. To figure caption) When there is no data in the data storage folder, the user is asked to import data from the USB storage device by selecting the 'Import data' button as shown in figure 27.

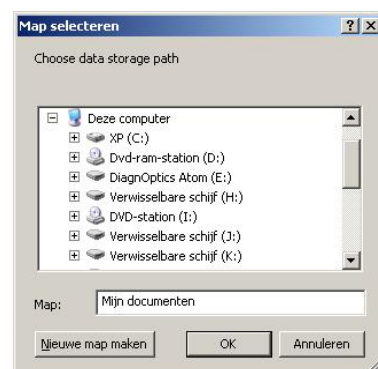
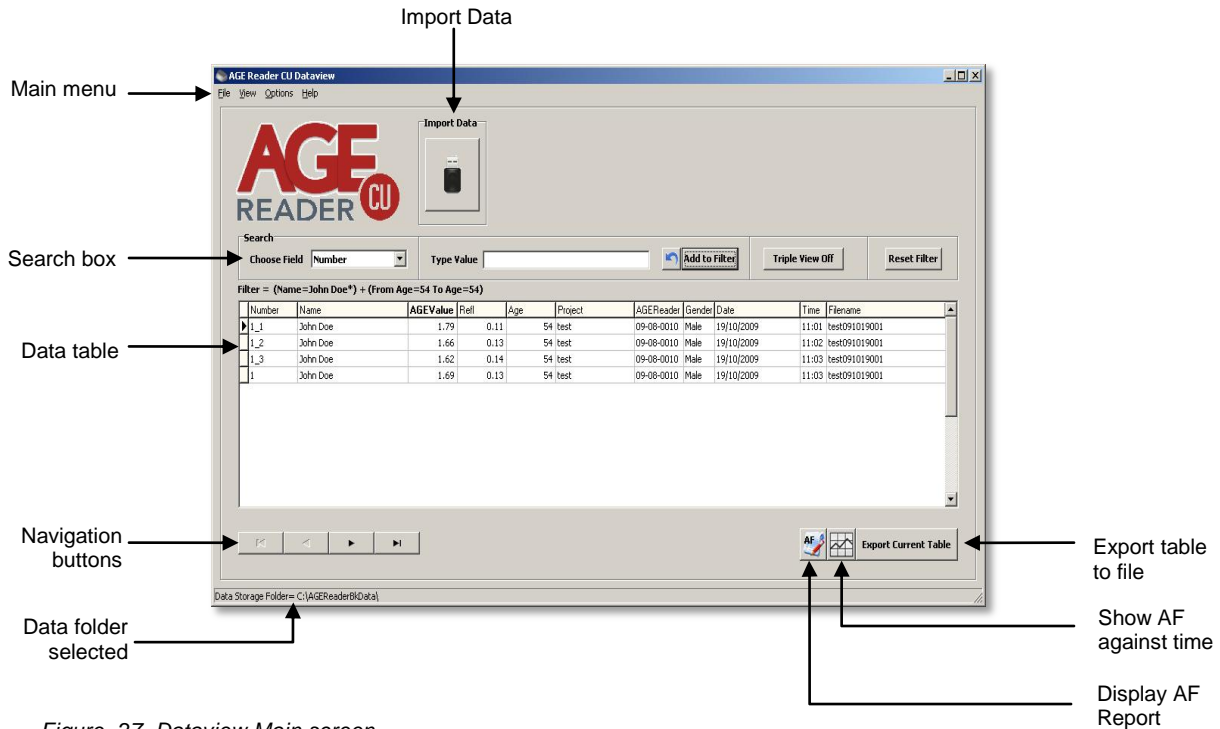


Figure 26. Select Dataview data folder 23

9.3 The Main screen

After setting the storage folder, the main screen as shown in figure 27 will appear. It consists of 6 fields, the main menu, the import data button, the search box, the data table, the navigate button, and the extra buttons



9.4 Importing CU data

To import CU measurement data, that has been backed up on an USB-stick, as described in chapter 6.3.1 follow the next steps:

- Connect the data backup USB stick to the PC
- Click on the USB-Button
- Choose the USB Drive with the Backed up CU measurements as shown in figure 28.

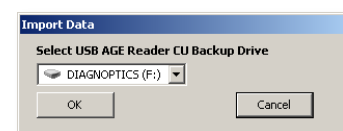


Figure 28. Select USB Device.

The data will be automatically stored into the data storage folder and the data will be displayed in the data table, figure 27.

9.5 Sorting and browsing data

With the navigate buttons (see figure 27) or by scrolling, the user can navigate through the data. By clicking on the fieldname in the data table, the data will be sorted alphabetically or numerically. By holding the fieldname in the data table and dragging it, the user is able to change the field order.

9.6 Data operations

This section includes the operations that can be performed on the imported data in the AGE Reader CU data view: filtering, showing/printing an AF report or a chart of AF against time, and exporting.

9.6.1 Filtering

With the AGE Reader CU Dataview the user is able to filter CU data with the filters available in the search box, see figure 27. Data can be filtered by specifying one or more fields, by using the following steps:

- Choose a field: **AGE Value, Age, AGE Reader, Refl, Filename, Gender, Name, Number, Date or time**
- Enter a value, the value type depends on the chosen field (for the date field, a from- and to-date needs to be entered, and when choosing the AGE Reader Field an AGE Reader Serial number needs to be entered and so on). The software will generate a message when the value is incorrect.

While entering the value, the data will be filtered. If the user wants to filter on more fields, the user needs to click the 'Add to Filter' button (see figure 29) before choosing the next field and entering the next value.

The current filter is displayed underneath the search box (see figure 29)

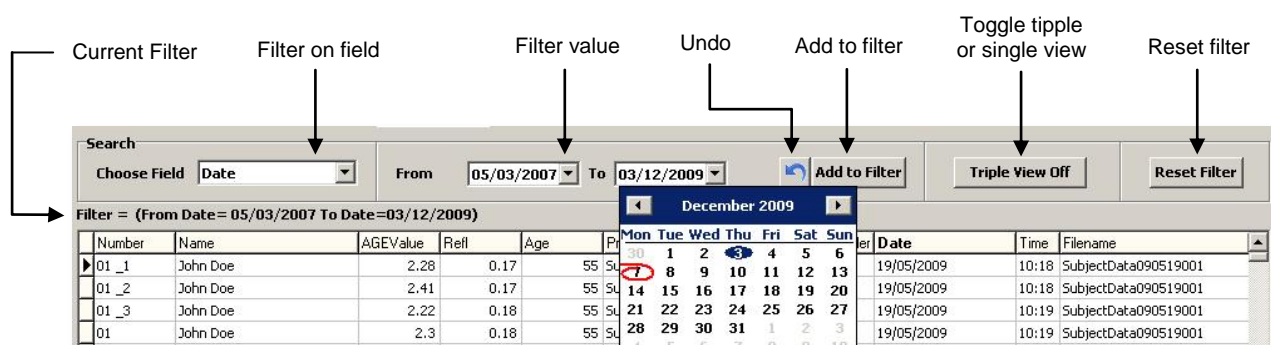


Figure 29. Search Box.

To clear the filter, click the 'Reset Filter' button (see figure 29).
To remove the last added field, click the undo button (see figure 29).

9.6.2 Triple view mode

There is a standard filter button in the search box, called 'triple view on/off'. With this button all results are shown of a triple measurement, or just the mean values of a triple measurement. The button shows which filter will be executed when the button is clicked.

9.6.3 Exporting to a file

The current selected data (filtered, sorted) can be exported to a text file by clicking the 'Export current table' button.

9.6.4 AF Report

The user is able to view an AF report of a selected measurement by double clicking the record in the table or by clicking the 'AF Report' button see figure 27.

The AF Report will look like figure 30. The user is able to print this report by clicking the print button. The user can get more information on the risk classes, by clicking on the 'Next Page' button.

To print the report, click 'Print'.

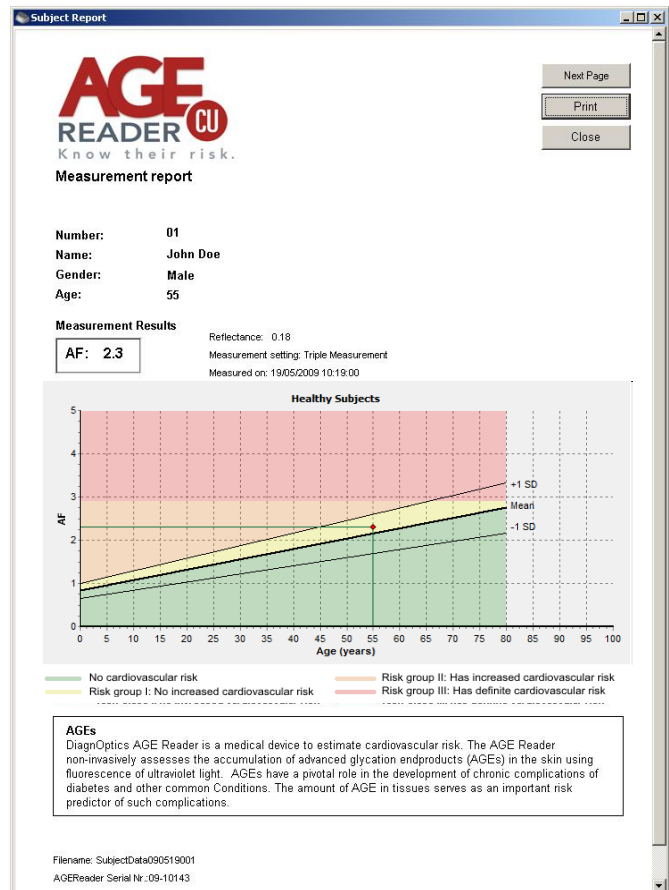


Figure 30. AF Report.

9.6.5 View the AF against time

The user is able to produce a chart of the AF against the time. This will be based on the data in the table. To produce this chart click on the 'AF against time' button see figure 27. The graph shown in figure 31 will be displayed. This graph can be printed.

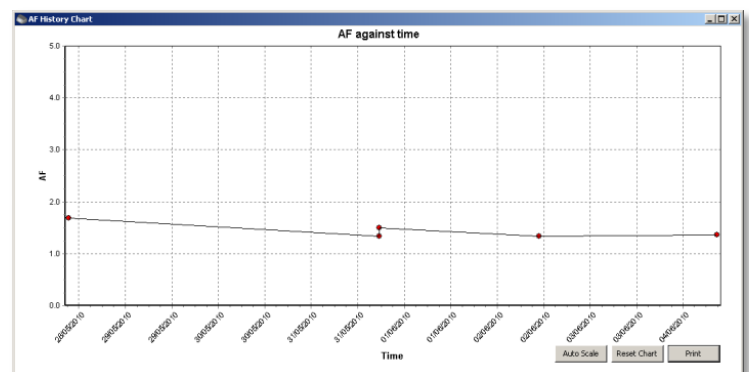


Figure 31. AF against time chart.

9.7 Options

9.7.1 Change data storage folder

To change the data storage folder go to the main menu->Options->Settings->Change data storage Folder. A dialog is presented like in figure 26, choose/create directory for data storage. When the directory is successfully assigned, the user is asked to copy existing data into the new folder.

9.7.2 Setting the printer

To set the printer go to the main menu->Options->Settings->Set Printer, a dialog will appear with a list of available printers to choose from. When no printer has been set the default directory will be used.

10 Cleaning & maintenance

10.1 Cleaning instructions

- **The measurement window.**

The measurement window should always be kept clean!

In the design of the AGE Reader CU, special attention is given to make cleaning of the window easy by removing the silicone-mat, which is designed with an integrated grip for easy removal, see figure 2. Hold the housing down on a stable surface and carefully remove the mat.

Clean the window with a slightly humidified soft non-fluorescent cleaning wipe (for example the soft reusable cleaning wipes used for spectacles) using a standard 70% alcohol solution. Avoid scratches on the window and take care that no textile or paper fibres remain on the window, as textiles and paper show fluorescence and so may affect the auto-fluorescence measurement!

- **The silicone patient mat.**

The silicone patient mat can be cleaned with standard mild cleaning agents by removing the silicone mat by its integrated grip for easy removal. If desired, the silicone mat can be disinfected with alcohol or chlorhexidine.

- **The housing & touch screen.**

The housing and touch screen can be cleaned with standard mild cleaning agents; for example a slightly humidified cloth or alcohol tissues. Make sure no fluids enter the housing at the connector inlets or fluid is collected at the bottom of the touch panel.

10.2 Maintenance instructions

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

The AGE Reader CU is a very sensitive instrument that has been carefully calibrated before use. Small differences exist in the characteristics of the internal optics of the individual spectrometers used. The same holds for differences in lamp spectrum characteristics. Albeit small, such differences may affect the measurement results of the AGE Reader CU, and may impede comparisons of results between individual instruments. Therefore, unique calibration files of each individual system are used in the AGE Reader CU software. The software will detect which spectrometer is contained in the AGE Reader CU, and will only function after recognition of the correct spectrometer.

So, never make changes in the system on your own!

If damage occurs only to the silicone mat or the power supply, a replacement can be ordered, see chapter 13.

Frequency of maintenance:

Replacement of lamp by DiagnOptics after +/- 2000 measurements.

Contact:

Contact your local distributor or the DiagnOptics head office in Groningen (The Netherlands) preferably by e-mail or fax, if necessary by telephone. Always have the serial number of the AGE Reader CU at your disposal.

Our address for support is as follows:

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

11 Problems & solutions

If a malfunctioning of the AGE Reader CU or the AGE Reader CU software occurs, always make sure that the external power supply (part. nr.: SAR52800) accompanying the AGE Reader CU is used.

11.1 Software errors

The following software errors and their corresponding error message can occur. The possible solution for each error is stated. If the problem is persistent, contact DiagnOptics.

Table 3. Software errors

| ERROR MESSAGE | POSSIBLE SOLUTIONS |
|---|--|
| -<nn> Internal IO error. Switch AGE Reader off and on. | Hardware problem. Switch machine off and on. If problem persists, contact your AGE Reader CU dealer. |
| Shutter defect, Contact manufacturer. | Contact your AGE Reader CU dealer |
| UV lamp hardware error, Contact manufacturer. | Contact your AGE Reader CU dealer |
| White LED hardware error, Contact manufacturer. | Contact your AGE Reader CU dealer |
| <Directory name> could not be created. Contact DiagnOptics Technologies B.V. | Likely problem with internal storage medium. Contact your AGE Reader CU dealer. |
| <Filename> could not be created | Likely problem with internal storage medium. Contact your AGE Reader CU dealer. |
| C:\Agereader_SA\DefaultAFRdata.txt not found | This file contains the default settings. Likely problem with internal storage medium. Contact your AGE Reader CU dealer. |
| Incompatible Calibration file. Contact DiagnOptics Technologies B.V. | Problem reading calibration file. Likely problem with internal storage medium. Contact your AGE Reader CU dealer. |
| Error in reading Calibration file. Contact DiagnOptics Technologies B.V. | |
| Calibration file has incorrect EEPROM nr. Contact DiagnOptics Technologies B.V. | |
| More than 25 Calibration files present. Contact DiagnOptics Technologies B.V. | |
| Calibration file not found. Contact DiagnOptics Technologies B.V. | Device needs to be calibrated. Contact your AGE Reader CU dealer. |
| You exceeded 999 measurements in current project on this day. | Set new Project Name under Settings / Current Project name |
| Project name not valid, Project set to DiagnOptics, please set Project under Settings | Set Project name under Settings / Current Project name |
| Filename already exists. Please change Project Name in the Settings menu. | Choose new Project Name under Settings - Current Project Name |
| Wrong password | Password for system settings not valid. Check documentation or contact your AGE Reader CU dealer |
| No licence found. Contact DiagnOptics Technologies B.V. | Problem with license file. Please contact your AGE Reader CU dealer |
| | |
| Illegal license. Contact DiagnOptics Technologies B.V. | |
| No more measurement credits. Please upgrade | Purchase and install new credits |
| ERROR : No new measurement credits found ... | No USB stick with valid credits found. Contact your AGE Reader CU dealer |
| No default printer installed. | Select default printer under Setting, Current default printer. |
| Language file not found | Missing language file for selected language. Contact your AGE Reader CU dealer. |
| ERROR : Backup directory not created ... | Check working USB stick is inserted in USB port |

| | |
|---|---|
| ERROR : No updates found ... | No valid USB stick with program update available. Contact your AGE Reader CU dealer |
| ERROR: Update directory not found. | |
| Upgrade file corrupt. Upgrade aborted. | |
| ERRORS detected. Update aborted. | Check correct USB stick with program update is inserted. If problem persists, contact your AGE Reader CU dealer |
| ERROR : No Calibration Software found ... | No valid USB stick with calibration program present. Contact your AGE Reader CU dealer |
| AgeReaderActions.exe not found | Missing program. Contact your AGE Reader CU dealer. |

11.2 Hardware errors

Correct functioning of the software and internal communication status are checked by the hardware. In case of failure of the internal communication, the lamp and shutter are turned off after one minute. This prevents the situation in which e.g. the lamp will remain on when the software is not responding, or that the AGE Reader CU can persist in a condition with the shutter open with the lamp “on” even when no measurement takes place.

A separate hardware condition to prevent too high temperatures is given by thermal switches, checking that the temperature of the AGE Reader CU will not be too high, such as under the exceptional conditions that the lamp and/or shutter are ON during an exceptionally long period. In those situations the 24V from the power supply and the power from the internal battery are disconnected. It resets itself when the temperature is safe again.

In case the hardware of the AGE Reader CU stops functioning due to an error, the following solutions are given:

- Software does not function: Switch the instrument off and restart.
- Connection problem: Check external USB device
- AGE Reader CU is too hot: Wait until the green LED is turned on again.

Contact:

Contact your local distributor or the DiagnOptics head office in Groningen (The Netherlands) preferably by e-mail or fax, if necessary by telephone. Always have the serial number of the AGE Reader CU at your disposal.

Our address for support is:

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

12 Technical specifications

AGE Reader CU:

- Operation
 - Continuous operation
 - 24 VDC from external power supply SAR52800
 - 14,4 VDC from rechargeable Li-ion battery SAR52300
- Power
 - UV-A light $\Delta\lambda = 345\text{nm} - 410\text{nm}$
 - Peak wavelength $\lambda = 365\text{nm}$
 - Irradiance $E = 123 \text{ W m}^{-2}$
- Output
- Physical
 - Width: 299,3 mm
 - Depth: 213,5 mm
 - Height: 150 mm
 - Enclosure: ABS/PMMA
 - Patient-mat: black Silicone
 - 4,8 kg
- Material (ext.)
- Weight:
- Operating Conditions:
 - temperature range: Lower limit + 10°C - Upper limit + 40°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 (SAR52800):

- Input
 - 100 - 240 VAC 47 – 63 Hz
 - 1,4A - 0,6A
- Output
 - 24 VDC 120W

Battery (SAR52300):

- Type
 - Lithium Ion rechargeable battery
- Output
 - 14,4 VDC
- Capacity
 - 6,6 Ah

Classifications:

AGE Reader CU:

- Classification to 93/42/EEC
 - Class IIa
- Classification to IEC 60601-1
 - Class II
- Protection against elec.shock
 - Type B
- Protection against ingress water
 - IPX1
- Directive(s):
 - Council Directive 93/42/EEC
- Standard(s):
 - Safety: International Standard IEC 60601-1
 - EMC: International Standard IEC 60601-1-2
 - Risk Analysis: International Standard ISO 14971
 - Transport: ASTM-D4169-08 distr. Cycle 13 Level I

Power Supply (SAR52800):

- Classification to IEC 60601-1
 - Class I
- Standard(s):
 - Safety: International Standard IEC 60601-1
 - EMC: International Standard IEC 60601-1-2

Battery (SAR52300):

- Standard(s):
 - EMC: EMC Directive 89/336/EEC
 - UL recognized: NWGQ2.MH25771
 - UL1642 recognized nr. MH13806

Disposal:

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

13 Marking on the AGE Reader CU

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

This information is given by the manufacturer by taking account of the training and knowledge of the potential users in the forms of:

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

As far as practical and appropriate, the information needed to install the device safely is set out on the labeling 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 labeling on the device itself consists of:

- | | |
|--------------------|--|
| 1. Rear label | All necessary information for product identification, product specification, installation, use and warnings. |
| 2. Serial label | Serial number and contact information of manufacturer |
| 3. Front label | Incorporated power switch & shows information relative to power state. |
| 4. Symbol in mat | Informs the patient about the desired direction of the arm |
| 5. Power supply | Information of part number and relation to device |
| 6. Packaging Label | Information of content and manufacturer |

13.1 The rear label

The rear label is located on the backside of housing of the AGE Reader CU, see figure 33. All necessary information for installation, use and applicable warnings are presented visually for the user. The rear label contains two connector inlets (see figure 34), one inlet for the accompanying power supply and one connector inlet for the USB connection and identifies them as such. A blue LED will light up if the battery is charging

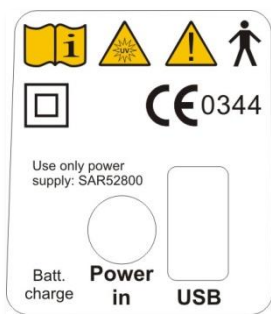









Figure 34. Rear label (scale 1:1)



Figure 33. AGE Reader CU rear

Table 4. Used symbols on rear label

| | |
|---|---|
|  | Read Instruction for Use |
|  | Warning for UV emissions |
|  | Attention, consult accompanying documents |
|  | Type B symbol for protection against electric shock |
|  | Class II symbol, double isolated |
|  | CE-Mark & Notified body number |
| Use only power supply: SAR52800 | Instruction to use only the certified power supply accompanying the device. |
|  | Reference for condition "Charging" When active, device is charging. |
| Batt. charge | Notification that battery is charging when (blue) LED is activated |
| USB | Identifies the USB connector |
| Power in | Identifies the power-in connector |

13.2 The serial label

The serial label as shown in figure 36, is located on the bottom of the AGE Reader CU, see figure 35. All necessary information for product identification, product specification and the name address of the manufacturer are presented visually for the user.

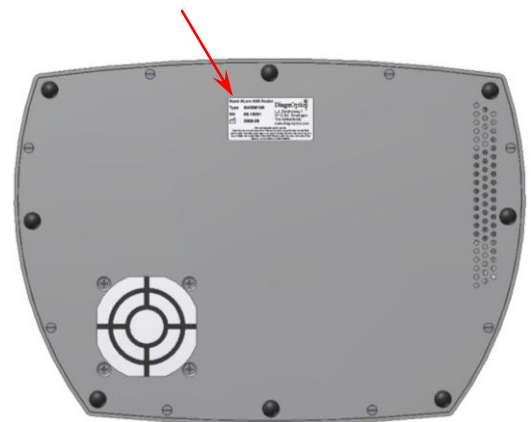




Figure 35. AGE Reader CU bottom

AGE Reader CU

Type DCU00100

SN 08-12-0001

 **2008-12**

 **DiagnOptics**



DiagnOptics Technologies B.V.
L.J. Zielstraweg 1
9713 GX Groningen
The Netherlands
www.diagnoptics.com

No serviceable parts inside.

Servicing to any component of this device is to be performed by certified parties only. Unauthorized repairs or modifications will void the warranty and may violate the conformity of the AGE Reader CU with the requirements of the Medical Device Directive 93/42/EEG.

Figure 36. Serial label (scale 1:1)

Table 5. Used symbols on serial label

| | |
|--|---|
| AGE Reader CU | Identification of device, device name |
| Type DCU00100 | Type identification |
| SN 08-12-0001 | Serial number (NEN-EN 980 4.5). |
|  2008-12 | Date of manufacture; YYYY-MM (NEN-EN 980 4.6). |
| No serviceable parts inside. Servicing to any component of this device is to be performed by certified parties only. Unauthorized repairs or modifications will void the warranty and may violate the conformity of the AGE Reader CU with the requirements of the Medical Device Directive 93/42/EEG. | Warning not to service the device yourself |
|  DiagnOptics Technologies B.V. L.J. Zielstraweg 1 9713 GX Groningen The Netherlands www.diagnoptics.com | Identifies DiagnOptics Technologies B.V. as its manufacturer with name / logo and contact information |

13.3 The front label

The front label, figure 38, is located at the front of the AGE Reader CU as seen in figure 37.
The power on / standby switch is located at the bottom of the front label as shown in figure 38. The information presented will inform the user of the state of the device.
The conditions “ready for use” shall be indicated by visual means by a green adjacent indicator light, as listed in table 6.



Figure 37. AGE Reader CU front side

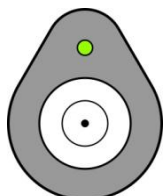





Figure 38. Front label (scale 1:1)

Table 6. Symbols used on front label

| | |
|---|---|
|  /  | Reference for condition “ready for use”. When active, device is ready for use. |
|  | Reference for “Power on for part of the equipment” symbol. If pressed, unit is turned on or off. |

13.4 Symbol in applied part

In the design of the silicone-mat an ergonomically shaped armrest is moulded for the patient to rest the underarm in. The direction of the arm is shown by a figure of a hand that is moulded in the silicone-mat as shown in figure 39.



Figure 39. Applied part with symbol

13.5 Power supply label

The medical approved power supply accompanying the AGE Reader CU is labelled as in figure 40. The label is placed on the bottom of the power supply.

The label shows the DiagnOptics identification number of the power supply as is referred to on the rear label. This will identify this power supply as the only correct part in order to obtain a safe combination.



Figure 40. Power supply label

13.6 Packaging

Each AGE Reader CU, together with its user manual, CD with software and its power supply will be packed in protective packaging right after production for storage and shipment. All packaging materials can be recycled if disposed of separately.



Figure 41. DiagnOptics packaging label (scale 2:1)

All following information is put on each package by the label as in figure 41:

- DiagnOptics logo & address,
- Serial number,
- Content,
- Weight.

14 Spare parts & Accessories

14.1 Spare Parts

If damage occurs to the silicone mat or the power supply, a replacement can be ordered at DiagnOptics or its representatives.

Be sure that the damage is limited only to the silicone mat or the power supply. If any doubt should exist that damage has been done to the AGE Reader CU itself, please contact DiagnOptics or its representatives.

Send your request by e-mail or fax and clearly state the serial number(s) of the AGE Reader CU(s) concerning. 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 7:

Table 7. Spare parts

| Spare part | Article number |
|-----------------------|----------------|
| Silicone patient mat | SAR02500 |
| USB storage device | SAR07400 |
| External power supply | SAR52800 |

14.2 Accessories

The calibration of the instrument can only be verified with the help of a calibration verification kit, part number Cal-Kit-01, which can be ordered at DiagnOptics

Our address for support is as follows:

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

15 Liability & warranty

15.1 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 CU, (b) unauthorized modification of the AGE Reader CU, (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 CU.

15.2 Warranty

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

15.3 Declaration of Conformity

The Declaration of Conformity is provided separately.