

AGE READER^{SU}

User Manual



Contact:

DiagnOptics Technologies BV
Aarhusweg 4-9
9723 JJ Groningen
The Netherlands

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

CE 0344

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1. Introduction

AGEs (Advanced Glycation End products) have a pivotal role in the development of chronic complications of diabetes, renal failure and other common conditions, and 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 SU TM is a proprietary device that can non-invasively assess the tissue accumulation of Advanced Glycation End products (AGEs). This technological breakthrough enables clinicians and scientific researchers to non-invasively measure the AGEs level in 30 seconds. The AGE Reader SU may help in clinical intervention and scientific research on subjects related to AGEs.

The AGE Reader SU is designed, manufactured and commercialized by DiagnOptics Technologies B.V., an innovative life science company based in The Netherlands.

This manual provides the setup and operating procedures as intended for the AGE Reader SU.

DiagnOptics Technologies B.V.

2. Intended use

The AGE Reader SU non-invasively gives, if used as intended, an estimate of (AGE) 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 SU is intended to be used by medical personnel to assess the level of auto fluorescence (AF) 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 homogenous and without exposure to skin care 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 SU .

2.1. Declarations

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 in case the UV reflectance is between 6% and 10%. In case the UV reflectance is below 6%, the AGE Reader SU will give a warning that the reflectance signal is too low for valid results.

UV-Radiation

Using the guidelines of the ICNIRP it is concluded that during AGE Reader SU measurements, as intended and even when repeated up to 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 remains considerably below the maximally allowed values for that period. Radiation exposure to the eyes normally does not occur. Exposures of the eyes longer than 60 seconds per 8-hour period should be avoided.

2.2 Conditions for which the device is not to be used

This device is not intended to be used by patients for which the skin at the measuring area is either:



















- not healthy,
- not homogenous,
- damaged,
- or exposed to skin care creams or any substance that may have fluorescent properties.

The patient will not be harmed by the device, but the measurement can be influenced if situations mentioned above are present.

3. Warnings and precautions

The following warnings and precautions are essential for correct and safe functioning of the AGE Reader SU as is intended by DiagnOptics Technologies B.V., its manufacturer.

Table 1. Warnings & precautions

	This device emits UV-A radiation**.
	The AGE Reader SU 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.
	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.
	No modification of this equipment is allowed.
	Always use the accompanying external power supply (art.nr.: DSU50100)
	The mains plug of the power supply is the separator which connects or disconnects the AGE Reader SU and his power supply from the mains. Avoid positioning the equipment such that access to the coupler, plug, etc. is limited (so that disconnection becomes difficult).
	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 0,5A.
	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 SU.
	Portable and mobile RF communications equipment can affect the AGE Reader SU. 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 AGE Reader SU should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the AGE Reader SU 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.
	Do not open the device. Maintenance and repairs can only be done by DiagnOptics or authorized representatives.
	Do not let fluids ingress. Cleaning should be done with a slightly humidified cloth or alcohol tissues.
	Correct positioning of the arm over the window is essential and should be maintained during the complete measurement process
	Only use an USB 2.0 certified cable with a maximum length of 1,8m.
	AGE Reader SU Software requires Windows 7 or Windows 8 (32 or 64-bit).

4. Description of the AGE Reader SU

4.1. General

The AGE Reader SU is a compact desktop unit designed to non-invasively measure skin auto-fluorescence and thereby to assess skin AGE levels. The unit is operated from a medically approved personal computer or notebook with a Windows operating system using the proprietary AGE Reader SU software (figure 1). Results of the measurements are presented in numerical form on the computer screen and are automatically stored in dedicated folders on the computer.



Figure 1. The AGE Reader SU

Contents of transport box:

- AGE Reader SU
- AGE Reader SU Quick Install Guide
- External power supply article number DSU50100, complying with IEC 60601-1
- Mains supply connector set to comply for use in country of use
- USB-cable
- USB flash drive with AGE Reader SU software and User Manual

4.2. Description of the AGE Reader SU

The AGE Reader SU is a proprietary device used to assist the physician in assessing cardiovascular risk. The AGE Reader uses a non-invasive method based on fluorescence induced by ultraviolet light in human tissue to assess the tissue accumulation of Advanced Glycation End products (AGEs) in the patient. AGEs play a pivotal role in the development of chronic complications of diabetes and other common conditions and are also a marker of oxidative stress. The amount of AGE in tissue can serve as a risk predictor of such complications.

The AGE Reader SU hardware (figure 2) consists of:

- A housing (considered as applied part) with a detachable silicone armrest.
- An external power inlet which is installed in the device. We strongly advise to only use the medically approved power supply accompanying the device, with article number DSU50100.
- A USB port for connection to a computer or notebook (both connectors are located on the rear side).
- A glass measurement window located on top.
- A front panel where all necessary information during use is presented visually for the user.
- The serial number and manufacturer information located on the bottom of the unit.

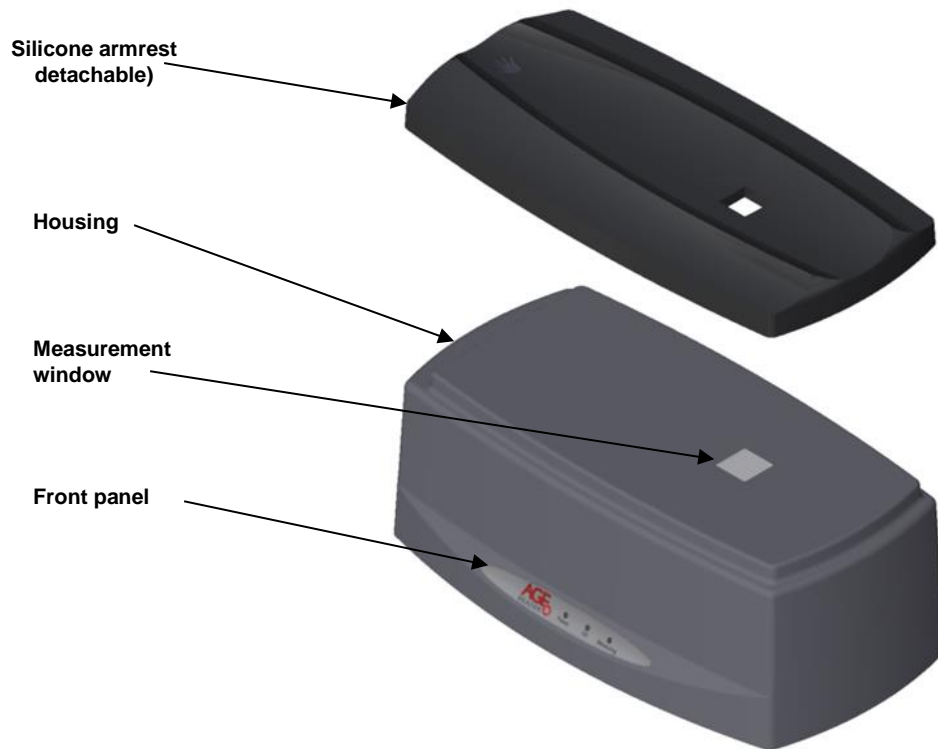


Figure 2. AGE Reader SU components

The AGE Reader SU is powered by a medically approved (IEC 60601-1) 12 VDC external power supply connected to the mains. The AGE Reader SU is connected by means of an USB port to a PC or notebook for device control. The data of the internal spectrometer are relayed to your computer for storage of the auto fluorescence spectrum and calculation of the AF value.

The fluorescence is excited by LED's. A shutter is mounted close to the measurement window to be able to make a dark-reference measurement. Underneath the shutter a white reflection reference standard is mounted.

5. Installing the AGE Reader SU

Before connecting the AGE Reader SU hardware, the software needs to be installed!

5.1. Installation of AGE Reader SU software

1. For installation you need to have administrator rights.
2. Insert the accompanying USB flash drive in the computer or laptop running Windows 7 or Windows 8 (32-64bit).
The installer should start automatically (when auto-run is enabled).
Otherwise run "Setup.exe" from the USB flash drive.
3. The AGE Reader SU program will now self-install the required drivers and software in a new folder "...\\AGE-Reader" in the "Program Files" folder (usually C:\\Program Files\\) of the computer. If preferred this can be changed.

5.2. Installation of the AGE Reader SU hardware

4. Place the AGE Reader SU on a horizontal, flat and stable surface.
5. Select the correct mains plug according to your mains outlet and attach it to the DiagnOptics power supply accompanying the device. Plug the power supply in the mains outlet.
6. Insert the power plug in the power inlet which is located on the rear side of the AGE Reader SU and is labelled "12VDC" (figure 3). A correct power connection will cause the green "Power" indicator LED on the front panel to light up.
7. Connect the USB-cable using the USB-port that is located on the rear side of the AGE Reader SU, labelled as "USB" (figure 3). Connect the other side of the USB cable to the USB port of a computer or notebook.
8. Turn the AGE Reader SU on by the power switch located on the left-rear side of the AGE Reader SU (figure 3).

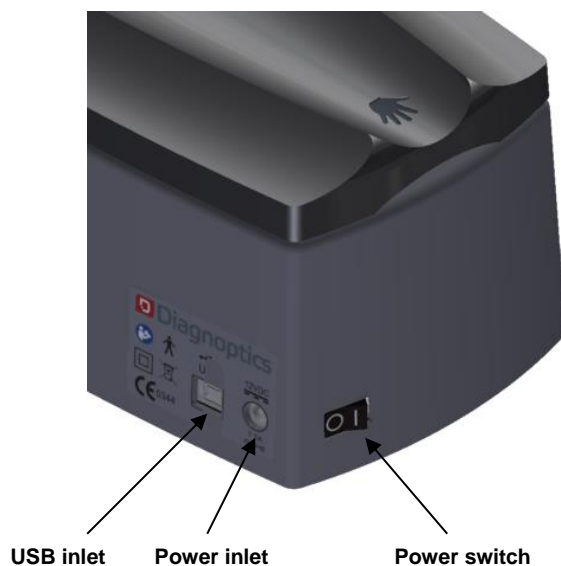


Figure 3. AGE Reader connections & switch

9. Windows should detect the hardware automatically and will display the "Found New Hardware" dialog and starts searching for the driver.
During this process a window can be displayed that the spectrometer board "has not passed Windows Logo testing to verify compatibility": Select "Continue Anyway".
10. The AGE Reader SU software is now ready to be started from the desktop-shortcut "AGE Reader SU" or from the Windows Start Menu where the group "AGE-Reader SU" has been added to the "programs" folder containing the "AGE Reader SU" shortcut.
11. Setup test: You can check the compatibility of the software and the AGE Reader SU unit by performing a first skin AF measurement.

5.3. Uninstalling the AGE Reader SU Software

Remove the program by using:

"Start → Control Panel → Applications → AGE-Reader SU" "change/remove".

Or

Click 'Uninstall' in the AGE Reader SU start menu folder

This will remove all the AGE Reader SU program files.

6. Instructions for use

6.1. Starting the software

Once all the required connections to the AGE Reader SU have been made, the AGE Reader SU can be switched on (section 5.2).

The DiagnOptics software is started from the desktop-shortcut “AGE Reader SU” or from the Windows Start Menu by selecting “Start → programs → AGE-Reader → AGE Reader SU”. The start screen will appear (figure 4).

The green “OK” LED on the front panel of the AGE Reader SU will switch on if the connection is successful and the Main Screen will appear (figure 6).

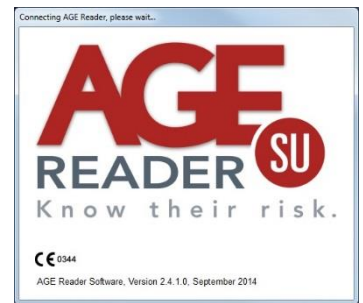


Figure 4. Start screen

If there is no AGE Reader SU connected during start-up, a message will appear (figure 5).

The AGE Reader SU can be connected at a later moment. In that case the user can establish the communication (section 6.3.4.).

NOTE: if no AGE Reader SU is connected; the green LED will not turn on and the text “Connected to device” will not be visible in the chart of the spectrum.

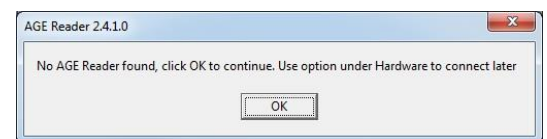


Figure 5. ‘No-AGE Reader found’ message

6.2. Spectrum graph

In the main window a graph is shown of the last acquired AGE Reader SU LED spectrum. The wavelength in nm is on the horizontal axis and the light intensity in counts on the vertical axis. The spectrometer integration time is shown on the left. The spectrum will appear and shows changes in LED intensity during the measurement done by the AGE Reader SU.

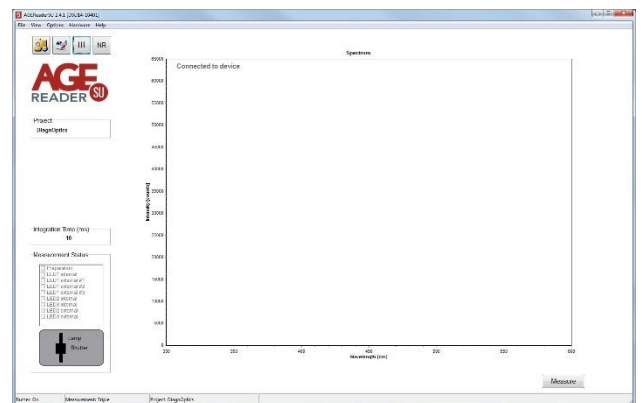


Figure 6. Main screen

6.3. Change settings

The AGE Reader SU Software has several settings and options that can be changed by the user by choosing the options in the main menu or on the optional toolbar at the top of the screen.

The AGE Reader SU settings are stored for the current project in the file “AFRdata.txt”, located in the data folder for that project. Also, the name of the last measurement file is stored in this file.

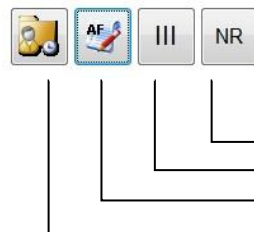
6.3.1. File

- **Exit**
This option will exit the AGE Reader SU Software. Alternatively the normal Windows exit-cross at the right-top of the screen can be selected.

6.3.2. View

- **View Measurement Results**
This will show the summary results which are stored in the file “info.out” located in the selected folder for Data Storage (section 6.3.3.). Double clicking on a result line will produce the corresponding patient report.

- **Toolbar**
Toggle the visibility of the Toolbar. Note that a patient report can always be (re-)generated at a later time regardless of the setting in the menu or toolbar (see “6.5.1 Summary results”).



- Toggle patient report
- Toggle single or triple measurement
- Show measurement results
- Open measurement file

Figure 8. Toolbar

6.3.3. Options

General Settings:

- **Report**
If enabled a full patient report including a chart is produced, otherwise only patient data and a numerical AF value are shown.
- **Print Risk**
If enabled, when printing a full patient report a second page with information about the different risk classes is printed in addition to the full patient report.
- **Buzzer settings**
When selected a buzzer signal is produced at the beginning and end of the patient measurement.
- **Set Project**
The current project can be changed to another existing project or a new project can be created. Each project has its own data folder within the root data folder. For each project the project measurements and project settings are stored in the corresponding project folder. The current project is shown on the main screen.



Figure 9. Set Project

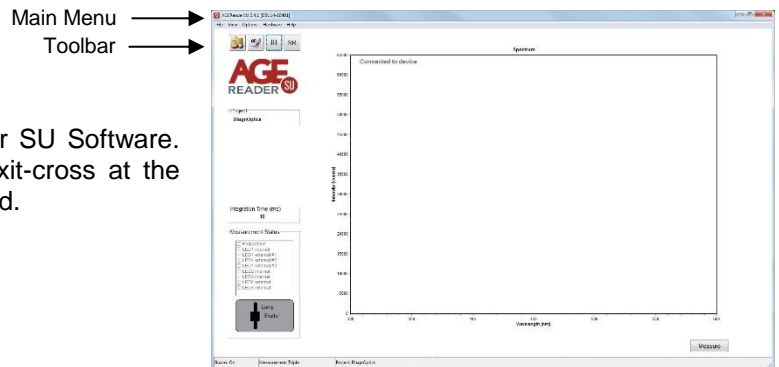


Figure 7. Main Screen & Toolbar

When a new project is created, a folder with the project name is created in the root data folder (figure 9). Initially the project is assigned default user settings (section 6.5.1.). To open the folder in Windows explorer, click the hyperlink on the left-bottom side of the window.

- **Printer settings**

This option opens the Windows Printer Settings Screen where the printer preferences can be changed. The settings affect the print option in the Show Results screen and the print option of the “Patient Report”.

- **Report logo**

This option opens a File Browser where your company logo can be selected to be placed in the head of the “Patient Report”. The advised maximum size of this logo is 200x200 pixels. If no logo is selected the default AGE Reader SU logo will be used instead.

- **Root Data Folder**

The user can set the root data folder. Data of all subsequent new projects will be stored in subfolders of the root data folder. It is recommended to set the root folder only once, on first use (figure 10).

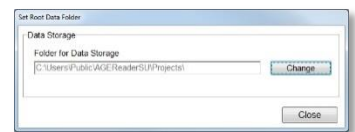


Figure 10. Set root data folder

Measurement settings:

This option lets you choose whether you want to perform a single measurement or a triple measurement. The triple measurement has been included for increased accuracy. The measurement type selected is shown by the corresponding toolbar button, when enabled, and at the bottom of the main screen.

6.3.4. Hardware

- **Connect AGE Reader**

If there is no AGE Reader SU connected and switched on during start-up, the AGE Reader SU can be connected using this option.

If there is an AGE Reader SU connected, the caption of this option will change to “Disconnect AGE Reader” and can be used to disconnect the AGE Reader

First all the required connections to the AGE Reader SU must have been made before the AGE Reader SU can be switched on (section 5.2).

The user can establish the communication by selecting “Connect AGE Reader” under the Hardware Tab. When the connection is established successfully, a message with “Connected to device” is shown in the spectrum graph. The menu item will consequently change in ‘Disconnect AGE Reader’

6.3.5. Help about

This option will open the About screen. This screen provides information regarding the software version and AGE Reader SU serial number and the calibration currently in use. Also the contact information for DiagnOptics Technologies B.V. is presented here.

6.4. Measurements

6.4.1 Preparation of the measurement

To start a measurement, press the “Measure” button on the lower right side of the panel. The ‘Patient Data’ screen will appear.

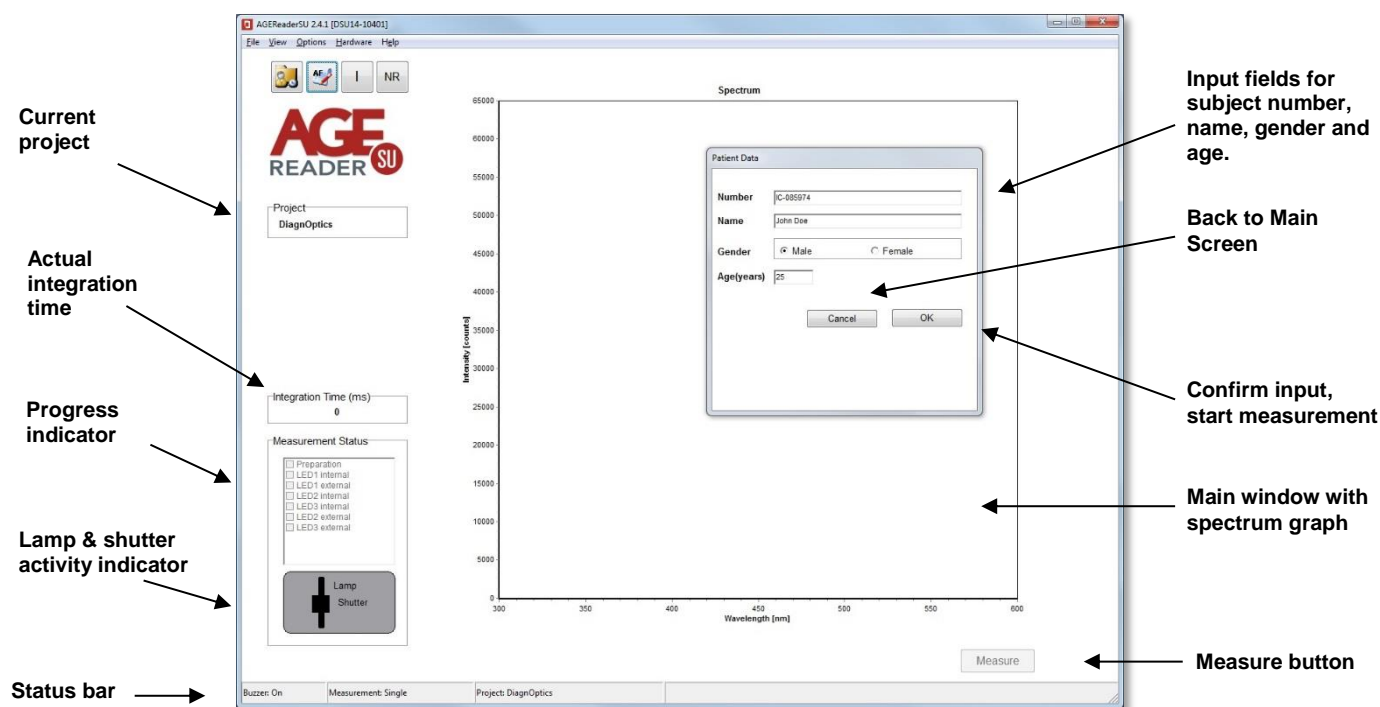


Figure 11. Main screen Layout & Subject Data input screen

The “Patient Data” window (figure 11) allows entering patient number, name, gender and age. (It is also possible to use the first two lines differently, as long as two lines with alpha-numerical characters are used.) If no value, or an invalid value for number or name is given, an error message is produced. Measurements will only start when these fields are valid. If desired, the gender field may be left blank. The lower part of this window shows the folder where the subject data and measurement spectra are stored.

After entering the patient data, select OK.

6.4.2 The measurement

The software now starts the automatic measurement procedure of the AGE Reader SU.

The progress of this procedure is indicated in the progress panel on the left of the main screen. In the left lower panel of the window a symbolic representation informs the user of the activity of the light sources, LED and shutter.

- The violet colour shows that the UV light source is on, and in case the UV light source is off the colour is black.
- The black rectangle shows that the shutter is closed. If the shutter is open, the rectangle will be transparent.
- A white disk indicates that one of the additional measurement LEDs is on.

During measurement the actual integration time may vary during the measurement steps: the integration time is the time that the spectrometer needs to perform a single acquisition of the spectrum. It depends on the light source and for the subject measurement on the reflectivity of the arm.

The measurement can be cancelled during the measurement process by pressing the Cancel button at the right left bottom of the main screen. In that case after completion of the current measurement step the program reverts back to the main screen and no measurement data is stored.

In the following the detailed measurement steps are described. Note that the first two steps are done automatically by the AGE Reader SU Software.

1. Preparation

2. LED1 internal measurement

The AGE Reader SU now detects the UV light intensity reflected from the reference white reflecting sheet within the device. This provides the standard to calculate the reflectance of the skin in the subsequent steps. The UV light source will be switched on and off in this phase for light and dark measurement.

3. LED1 external

During the patient measurement the actual measurement with UV-A light is performed. Before the start of the measurement, optionally a buzzer will be audible to warn the patient that the arm measurement will begin and a screen appears asking to put the forearm on the measurement window (figure 12).

Measurements are preferably performed 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 creams, when used at the forearm at the site of the measurement, can also influence the results and should for that reason be removed before the measurement.

After the patient has put his/her forearm on the measurement window and thereby fully covering it (figure 13) select "OK". The shutter will open after the OK button is clicked. The orange "Measuring" LED on the front of the device will switch on. If the window is not covered by an arm, a violet-blue light can be observed through the measurement window. In case of a triple measurement, the LED1 external steps will be executed three times.



Figure 12. Notification panel for subject measurement start



Figure 13. Positioning of arm on the AGE Reader

4. LED2 internal & LED3 internal

After the measurements with the UV light source, the AGE Reader SU automatically continues to measure using the additional LEDs. The AGE Reader SU now detects the light intensity reflected from the reference white reflecting sheet within the device. This provides the standard to calculate the reflectance of the skin in the subsequent steps. The light sources will be switched on and off in this phase for light and dark measurement.

5. LED2 external & LED3 external

During these measurements, the device will measure on the subject's arm using the additional light sources. The shutter will open in this phase and the light sources will be switched on and off for light and dark measurement.

It is of key importance that the patient puts his/her arm on the armrest such that the elbow rests on the edge of the device and the arm fully covers the measurement window. A measurement usually takes 50-70 seconds. For increased accuracy, the user may use the “Triple Measurement”. With this option three consecutive measurements are performed, with the final measurement result being the average of the three measurements. This option can be selected on the taskbar (under Settings) or on the toolbar (see sections 6.3.2. and 6.3.3). In case of a “Triple Measurement”, it is advised that the patient covers the window with the arm each time at a slightly different position. In this way a natural inhomogeneity in the skin auto-fluorescence is partly averaged out. In the case of a triple measurement the additional LED measurements are performed once after the third UV measurement.

If the subject's skin reflectance is less than 6%, a warning message is given and no result is produced.

6.4.3 Result of the measurement

After successful completion of the measurement, within a few seconds the “Patient Report” is shown. If “Report” is selected, the full report will appear (figure 14). Pressing “Next Page” on this report displays a second page with information about the Risk Classes (section 6.8). This report can be printed. If in addition “Print Risk” is selected, the second page with risk information is also printed. When “Report” is not selected, a brief summary is given (figure 15). The measurement result is automatically stored in the current project folder.

Remark: in patients with darker skin colour (Fitzpatrick class 5-6, dark brown or black) a correction is made to the AF value when the reflectance is between 6 and 10%. When the skin UV reflectance is below 6%, the AGE Reader SU will give a warning that the signal is too low for valid results.

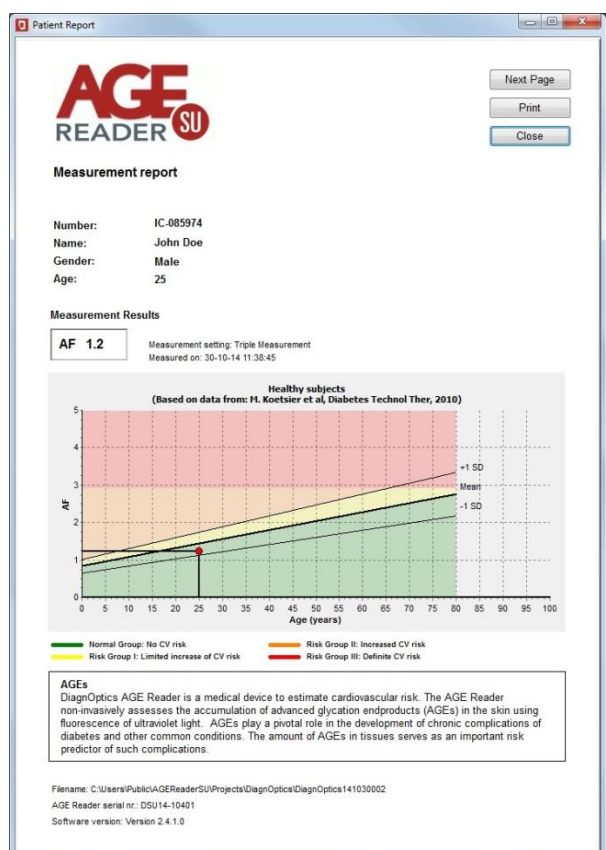


Figure 14. Patient Report example

Figure 15 shows a screenshot of the "Patient Data" window. The window contains input fields for Number (IC-085974), Name (John Doe), Gender (Male selected), Age (years) (25), and AF (1.2). An OK button is located at the bottom right. Below the input fields, it says "Data is saved as :" followed by the file path C:\Users\Public\AGEReaderSU\Projects\DiagnOptics\DiagnOptics14103.

Figure 15. Brief summary measurement result

The measurement is now completed and the AGE Reader SU is ready to be used for the next measurement.

Note that a patient report can always be (re-)generated at a later time (see “6.5.1 Summary results”).

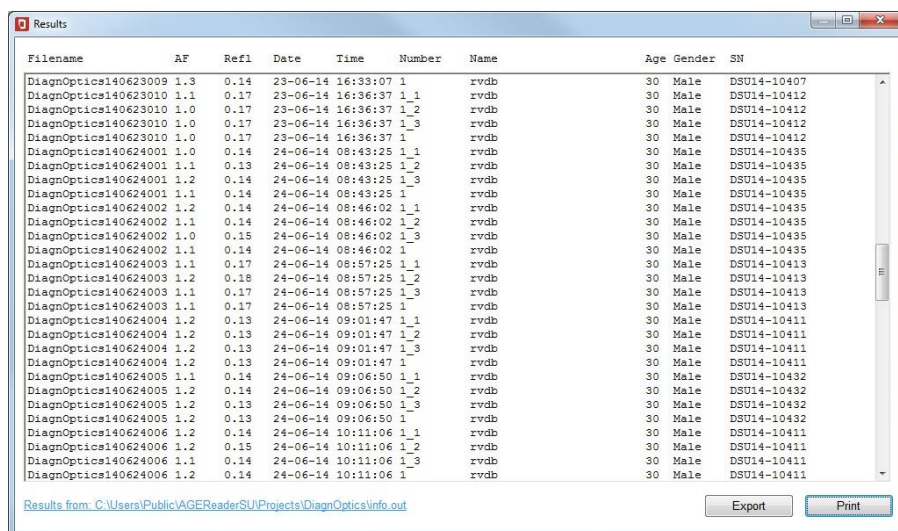
6.5. Data storage and additional information

This section explains and illustrates the type and location of the files of the saved measurements. It also shows the summarising info file which contains the skin AF and reflectance results for each measurement. This section also gives background information on the calculation of AF.

Results are stored in the current project folder. Each time a successful measurement is made with the AGE Reader SU the AF result, reflectance, and the patient data are added to the “info.out” summary file for the current project. This file is located in the project folder, which has the name of the project, situated in the Root Data Folder selected by the user under “Settings” (section 6.3.3.). At the same time the essential results of each measurement are also stored in a “DCF” File in the same folder for backup and future use.

6.5.1. Summary results

The summary results are stored in the file “info-out” for the current project. The summary results can be accessed by the “view” tab in the taskbar or by the toolbar (section 6.3.2). By double-clicking on a line in this window (figure 16), the corresponding patient report will be shown.



Filename	AF	Refl	Date	Time	Number	Name	Age	Gender	SN
DiagnOptics140623009	1.3	0.14	23-06-14	16:33:07	1	rvdb	30	Male	DSU14-10407
DiagnOptics140623010	1.1	0.17	23-06-14	16:36:37	1_1	rvdb	30	Male	DSU14-10412
DiagnOptics140623010	1.0	0.17	23-06-14	16:36:37	1_2	rvdb	30	Male	DSU14-10412
DiagnOptics140623010	1.0	0.17	23-06-14	16:36:37	1_3	rvdb	30	Male	DSU14-10412
DiagnOptics140623010	1.0	0.17	23-06-14	16:36:37	1	rvdb	30	Male	DSU14-10412
DiagnOptics140624001	1.0	0.14	24-06-14	08:43:25	1_1	rvdb	30	Male	DSU14-10435
DiagnOptics140624001	1.1	0.13	24-06-14	08:43:25	1_2	rvdb	30	Male	DSU14-10435
DiagnOptics140624001	1.2	0.14	24-06-14	08:43:25	1_3	rvdb	30	Male	DSU14-10435
DiagnOptics140624001	1.1	0.14	24-06-14	08:43:25	1	rvdb	30	Male	DSU14-10435
DiagnOptics140624002	1.2	0.14	24-06-14	08:46:02	1_1	rvdb	30	Male	DSU14-10435
DiagnOptics140624002	1.1	0.14	24-06-14	08:46:02	1_2	rvdb	30	Male	DSU14-10435
DiagnOptics140624002	1.0	0.15	24-06-14	08:46:02	1_3	rvdb	30	Male	DSU14-10435
DiagnOptics140624002	1.1	0.14	24-06-14	08:46:02	1	rvdb	30	Male	DSU14-10435
DiagnOptics140624003	1.1	0.17	24-06-14	08:57:25	1_1	rvdb	30	Male	DSU14-10413
DiagnOptics140624003	1.2	0.18	24-06-14	08:57:25	1_2	rvdb	30	Male	DSU14-10413
DiagnOptics140624003	1.1	0.17	24-06-14	08:57:25	1_3	rvdb	30	Male	DSU14-10413
DiagnOptics140624003	1.1	0.17	24-06-14	08:57:25	1	rvdb	30	Male	DSU14-10413
DiagnOptics140624004	1.2	0.13	24-06-14	09:01:47	1_1	rvdb	30	Male	DSU14-10411
DiagnOptics140624004	1.2	0.13	24-06-14	09:01:47	1_2	rvdb	30	Male	DSU14-10411
DiagnOptics140624004	1.2	0.13	24-06-14	09:01:47	1_3	rvdb	30	Male	DSU14-10411
DiagnOptics140624004	1.2	0.13	24-06-14	09:01:47	1	rvdb	30	Male	DSU14-10411
DiagnOptics140624005	1.1	0.14	24-06-14	09:06:50	1_1	rvdb	30	Male	DSU14-10432
DiagnOptics140624005	1.2	0.14	24-06-14	09:06:50	1_2	rvdb	30	Male	DSU14-10432
DiagnOptics140624005	1.2	0.13	24-06-14	09:06:50	1_3	rvdb	30	Male	DSU14-10432
DiagnOptics140624005	1.2	0.13	24-06-14	09:06:50	1	rvdb	30	Male	DSU14-10432
DiagnOptics140624006	1.2	0.14	24-06-14	10:11:06	1_1	rvdb	30	Male	DSU14-10411
DiagnOptics140624006	1.2	0.15	24-06-14	10:11:06	1_2	rvdb	30	Male	DSU14-10411
DiagnOptics140624006	1.1	0.14	24-06-14	10:11:06	1_3	rvdb	30	Male	DSU14-10411
DiagnOptics140624006	1.2	0.14	24-06-14	10:11:06	1	rvdb	30	Male	DSU14-10411

Results from: C:\Users\Public\AGEReader\SU\Projects\DiagnOptics\info.out

Export Print

Figure 16. Summary results, Info.out

The file “info.out” contains the AF and reflectance results and the information supplied at the beginning of the measurement, stored as patient number, name, age and gender. To open the folder of the info.out file, click the link in the bottom-left of the window.

The file fields are, from left to right:

- File name: Assigned by the AGE Reader SU (section 6.5.2.)
- AF: The auto fluorescence value as calculated
- Reflectance: The skin reflectance value as calculated
- Date: Date of measurement
- Time: Time of measurement
- Number: Subject number as given before measurement
- Name: Subject name as given before measurement
- Age: Subject age as given before measurement
- Gender: Subject gender as given before measurement
- Serial number: Serial number of the AGE Reader SU used.

The data is stored in a text format and can be exported to Microsoft Excel by clicking the export button. For this, Excel must be properly installed on the system.

6.5.2. DCF Files

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

The DCF filenames are constructed from the project name, that has been given by the user in the File Storage window under Settings (section 6.3.3), as well as from the year, month and date of measurement and a 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 files are stored in a compact DCF file format and also contain time and date of the measurement, spectrometer information and the patient data that was given by the user at the start of the measurement.

The DCF files are intended for back-up of the measurements for future use. When problems with the instrument are detected, the user may send the corresponding files to DiagnOptics for support. Future developments on the software of the AGE Reader SU may lead to further improvements of algorithms that can then be applied to recalculation of AF values on stored results. If you would be interested in this option, it is important to store the measured files for future use!

6.5.3. Storage of settings

For each project, the settings and preferences concerning the AGE Reader SU are stored in the file "AFRdata.txt", located in the current project folder. For a new project, the settings are given default values obtained from the file "DefaultAFRData.txt".

For Windows the DefaultAFRData.txt file is located in the Folder "ProgramData\AGEReaderSU".

The "AFRdata.txt" file for the current project is automatically updated when changes to settings are made in the program and should not be edited by the user.

6.6 Turning off the device

By pressing the red cross in the upper right corner of the screen the AGE Reader SU software can be closed. After the software has closed, the AGE Reader SU can be turned off by the power switch located on the left-rear side of the AGE Reader SU, see figure 3.

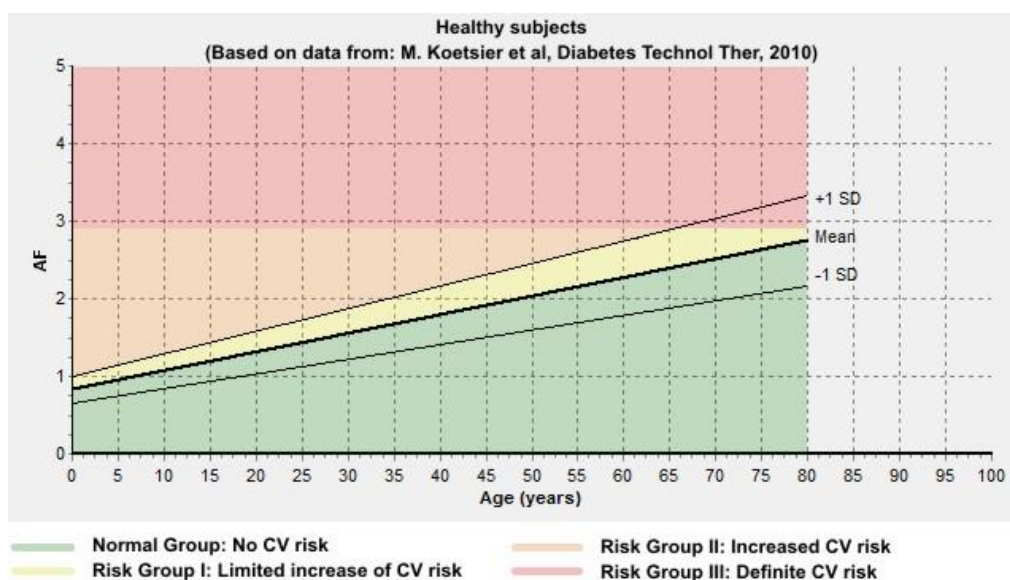
6.6. Background on skin AF

A person's calendar age is usually the most important factor related to the AGE content in different organs. Skin AF as measured by the AGE Reader SU 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	p
0-10	0.97 \pm 0.17	45	< 0.01
10-20	1.11 \pm 0.20	50	< 0.01
20-30	1.53 \pm 0.30	62	< 0.01
30-40	1.73 \pm 0.42	86	0.21
40-50	1.81 \pm 0.36	72	< 0.01
50-60	2.09 \pm 0.36	64	< 0.01
60-70	2.46 \pm 0.57	45	0.12
70-80	2.73 \pm 0.55	27	0.51
80+	2.71 \pm 0.44	5	



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

6.7. Background on the calculation of skin AF

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 SU units are comparable.

When skin reflectance $R < 12\%$, an additional reflection measurement is performed with a white LED to allow for more reliable skin AF values.

Each AGE Reader SU has a unique calibration file that is stored on the internal flash-drive. In this file 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 SU software (version 2.4) if the reflectance is below 6 %. In that case no value is given for the skin AF.

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

The AF value provided by the AGE Reader SU 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. So, 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 (1 SD) 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 SU 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 1 SD 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 1 SD 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 definitely has a 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 Technologies B.V. (info@diagnoptics.com)

7. Cleaning & maintenance

7.1. Cleaning instructions

- **The measurement window**

The measurement window should always be kept clean!

The silicone armrest is designed with an integrated grip for easy removal. This facilitates cleaning of the measurement window (figures 3 and 4).

To clean the window, first hold the housing down on a stable surface and carefully remove the mat. Then 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 parts of textile or paper are remaining on the window, as textiles and paper show fluorescence and so may affect the auto fluorescence measurement!

- **The silicone patient armrest**

The silicone patient armrest can be cleaned with standard cleaning agents by removing it using its integrated grip. The silicone armrest can be disinfected with alcohol or chlorhexidine.

- **The housing**

The housing can be wiped with standard cleaning agents, for example with a slightly humidified cloth or alcohol tissues. Make sure no fluids enter the housing at the connector inlets.

7.2. Maintenance instructions

Frequency of maintenance:

Recalibration of the AGE Reader SU by DiagnOptics is advised after 1000 measurements or 1 year, whatever comes first. The AGE Reader Software keeps track of the total number of measurements and time. If recalibration is advised, the message shown in figure 17 is displayed.

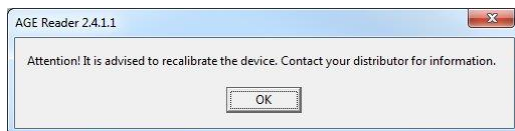


Figure 17. Recalibration advisory

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

The AGE Reader SU is a very sensitive instrument which has been carefully calibrated in the factory. This calibration accounts for small differences in the characteristics of the internal optics, light sources and the individual spectrometers used,. The software takes these differences into account and makes comparisons of auto fluorescence and reflectance results possible for different AGE Reader SU using unique calibration files of each individual system.

Hence, as a first rule never open or make changes to the AGE Reader SU yourself! This voids your warranty and results in an invalid calibration.

Instead, please contact support at the DiagnOptics Technologies B.V. head office in Groningen (The Netherlands) preferably by e-mail or fax, and if necessary by telephone. Always have the serial number of the AGE Reader SU at your disposal.

Our address for support is as follows:

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

If damage is done only to the silicone armrest, the USB cable or the power supply, a replacement can be ordered (chapter 11).

8. Problems & solutions

If a malfunctioning of the AGE Reader SU or the AGE Reader SU software occurs, always make sure that:

- The external power supply (art. Nr.: DSU50100) accompanying the AGE Reader SU is used.
- A computer approved for medical use is used, running 32-, 64bit Windows 7 or Windows 8.
- The power supply and USB-cable are correctly connected.

8.1. 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, please contact DiagnOptics.

Table 3. Software errors

Error	Problem description	Solution
Internal IO Error, restart instrument	The software cannot connect to the AGE Reader.	Restart the device, if the problem persists, return to DiagnOptics Support.
-X Internal IO Error, Y	Hardware communication problems between the PC and the AGE Reader, whereby the number X and Y provide information on which part of the hardware the message relates to.	If the problem persists, return to DiagnOptics Support. By reporting X and Y to DiagnOptics in advance, support can anticipate if necessary.
Hardware error, switch AGE Reader off and on	UV light source is defect	Send back to DiagnOptics Support.
UV lamp error	UV light source is defect	Send back to DiagnOptics Support.
White LED error	White light source is defect	Send back to DiagnOptics Support.
Shutter defect	Shutter is defect	Send back to DiagnOptics Support.
Cannot Determine Integration Time	There can be no correct measurement time determined for the respective arm. The arm in question has a too low reflectance	If the message remains on the same arm, then the user must conclude that the arm is too dark to be measured.
Could not calculate AF	Reliable AF value cannot be determined. This may be because the calculated AF is out of range (e.g. too high / low).	If the message remains on the same arm, then the user must conclude that the arm is too dark to be measured.
IO Error 32	This message is not generated from AGE Reader software, but from Windows itself. The cause may lie in the fact that the result file (info.out) is not accessible to the AGE Reader Software because it is already opened by another program.	Close any programs that use the info.out file except one active AGE Reader Software.

8.2. Hardware errors

Correct functioning of the software and the USB connection are conditions that are checked by the hardware. In case of failure LED's and shutter are turned off after one minute. In this way it is prevented that e.g. the LEDs will remain on when the USB connection is disrupted and the power connection is not disrupted, or that the AGE Reader SU can persist in a condition with the shutter open with the LEDs 'on' even when no measurement takes place.

A separate hardware condition to prevent too high temperatures is given by a thermal switch, checking that the temperature of the AGE Reader SU 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 12 V power is disconnected. It resets itself when the temperature is safe again.

In case the hardware of the AGE Reader SU stops functioning due to an error, the following warning signals will be given:

- Green "Power" LED on
- Green "OK" LED off
- Long audible signal yes

Solutions:

- Software does not function: Close the program and try to start it again.
- Connection problem: Check USB connection. In this case, the software probably has already reported problems earlier.
- AGE Reader SU is too hot: Wait until the green LED is turned on again.

- Green "Power" LED off
- Green "OK" LED off
- Long audible signal no

Solutions:

- Check power switch, power cable and supply connection.
- If not corrected, please contact DiagnOptics.

Support:

For support contact the DiagnOptics Technologies B.V. head office in Groningen (The Netherlands) preferably by e-mail or fax, and if necessary by telephone. Always have the serial number of the AGE Reader SU at your disposal.

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

9. Product specifications

AGE Reader SU:

- Operation Continuous operation
- Power 12 VDC from external power supply (DSU50100)
- Output
 - UV-A light: $\lambda_{\text{peak}} = 375\text{nm}$, $\Delta\lambda = 355\text{nm} - 395\text{nm}$
 - Violet light: $\lambda_{\text{peak}} = 405\text{nm}$, $\Delta\lambda = 385\text{nm} - 425\text{nm}$
 - White light
- Physical
 - Width: 280 mm
 - Depth: 150 mm
 - Height: 115 mm
- Material (ext.)
 - Enclosure: ABS/PMMA
 - Armrest: black Silicone
- Weight: 2,25 kg
- 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
 - Atmospheric pressure: 50KPa – 106KPa

Power Supply (DSU50100):

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

Classifications:

AGE Reader SU:

- Classification to 93/42/EEC Class IIa
- Classification to IEC 60601-1 Class II
- Protection against elec.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
 - Transport: ASTM-D4169-08 distr. Cycle 13 Level

Power Supply (DSU50100):

- Classification to IEC 60601-1 Class I
- Standard(s):
 - Safety: UL/EN/ IEC 60601-1 3rd edition
 - EMC: IEC 60601-1-2

Disposal:

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

10. Marking on the AGE Reader SU

Each device is accompanied by all the information needed to safely install and use the AGE Reader SU 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 practicable and appropriate, the information needed to install the device safely is set out on 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. In areas for which no standards exist, the symbols and colours will be described in the documentation supplied with the device.

The labeling 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 | Information during use. |
| 4. On / off switch | Information regarding position of switch relative to its function. |
| 5. Symbol in mat | Informs the patient the desired direction of the arm |
| 6. Packaging label | Information for transport |
| 7. Packaging sleeve | Marketing information |

10.1 The rear label

The rear label is located at the backside of enclosure of the AGE Reader SU, see figure 18. All necessary information for identification of the manufacturer, product identification, installation, use and applicable warnings are presented visually for the user. The rear label incorporates two connector inlets (see figure 19), One inlet for the accompanying power supply and one connector inlet for the USB connection and identifies them as such. The information presented on the rear label is listed in table 4.













Figure 18. AGE Reader SU backside



Figure 19. Rear Label (scale 1:1)

Table 4. Used symbols on rear label

	Manufacturers logo
	Read Instruction for Use (IEC 601-1 Appendix D table D2- symbol 10 & ISO-7010 - M002)
	Type B applied part (IEC 60417-5840)
	Class II equipment (IEC60417-5172)
	Indicating separate collection for electronic equipment (2002-96-EC)
	CE-Mark & Notified body number (6 mm high)
	Identifying USB inlet
	Identifying power supply inlet
	Power rating (minimal)
	Polarity symbol, indicates that the center (tip) of the output plug is Positive (+) and the barrel of the output plug is Negative (-).

10.2 The serial label

The serial label as shown in figure 20, is located at the bottom of the AGE Reader SU, see figure 21. All necessary information for product identification, product specification and the name address of the manufacturer are presented visually for the user. The information presented on the serial label is listed in table 5.




Figure 20.. Serial label (scale 1:1)



Figure 21. AGE Reader SU bottom

Table 5. Used symbols on serial label

AGE Reader SU	Device name
Type: DSU00100	Type identification
SN: 10000001	Serial number (NEN-EN 980 5.5).

 2014-01

Date of manufacture; YYYY-MM
(NEN-EN 980 5.6).



Barcode for production purposes.



Identifies DiagnOptics Technologies B.V. as its manufacturer with name and contact information. (NEN-EN 980)

10.3 The front label

The front label, figure 23, is located at the front of the AGE Reader SU as seen in figure 22.

All necessary information during use is presented visually for the user. The information presented will inform the user of the state of the device, see table 6.

It will inform that; the power is connected, the device is working as intended and attends the user and patient that the actual patient measurement is in progress, so no movement of the patients arm is tolerable.



Figure 22. AGE-Reader front side



Figure 23. Front label (scale 1:1)

Table 6. Symbols used on front label



Name / Logo of the device

Power

Reference for green LED; on is "power connected"
According to IEC 601-1 sub-clause 6.7: "Ready for action".

OK

Reference for green LED; on is "system O.K."

Measuring

Reference for yellow LED; on is "patient measurement"
According to IEC 601-1 sub-clause 6.7: "Caution or attention required".

10.4 On / off switch

The on / off switch is located at the back of the left side of the AGE Reader SU as shown in figure 24. The different positions of the "power on / off switch" shall be indicated by visual means, see table 7.



Figure 24. On / off switch

Table 7. Symbols used on On / Off switch

O

"Power off" symbol. If pressed, unit is turned off

I

"Power on" symbol. If pressed, unit is turned on

O I

Order of marking

10.5 Symbol on armrest

In the design of the rubber-mat an ergonomically shaped armrest is molded for the patient to rest his underarm in. The direction of the arm is shown by a figure of a hand that is molded in the silicone mat as shown in figure 25.



Figure 25. Applied part with symbols

10.6 Packaging Label

The DiagnOptics logo and address will be placed by the means of a label as is shown in figure 15, which also contains the serial number of the device in the package. This is serial number will be handwritten and is an aid for tracking and recall. Also the weight and content of the package, which is constant, is printed on this same label.

All following information will be placed on each package:

- DiagnOptics logo & address,
- Serial number,
- Content,
- Weight,
- Environmental conditions for transport,
- Receiving party & contact (at shipment)

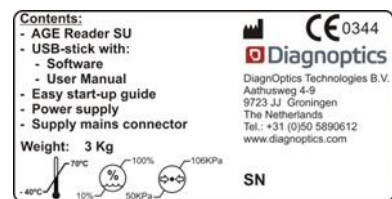


Figure 27. Packaging label (scale 1:2)

10.7 Packaging sleeve

Each packaging will be wrapped with the sleeve in figure 14 for aesthetics and protection.

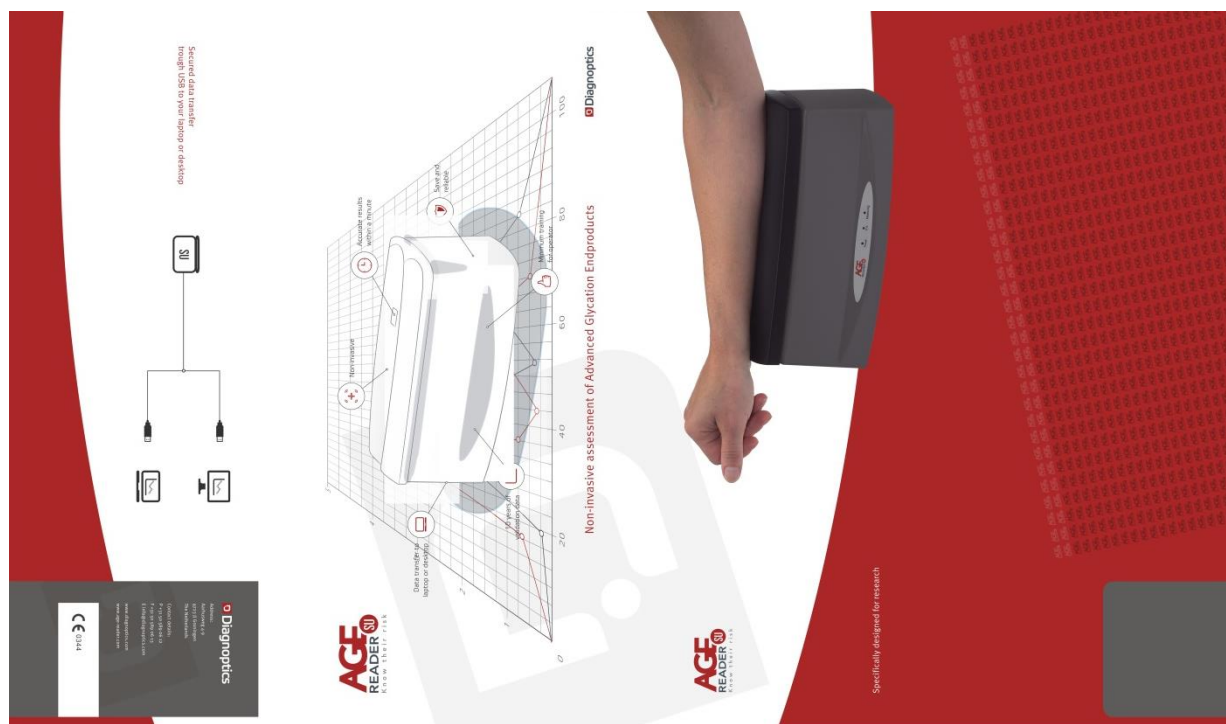


Figure 28. Packaging Sleeve

11. Spare parts

If damage occurs to the silicone armrest or the power supply a replacement can be ordered at our head office in Groningen, The Netherlands.

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

Please send your request by e-mail or fax and clearly state the serial number(s) of the AGE Reader SU (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 9:

Table 4. Spare parts

Spare part	Article number
Silicone patient armrest	DSU10500
External power supply	DSU50100
USB cable	DSU50300

A paper copy of the User Manual can be requested at DiagnOptics at no additional cost and will be delivered within 7 days.

This User Manual can also be downloaded from the DiagnOptics website for registered users. For registration please send a request to: sales@diagnoptics.com.

Our address for support is as follows: DiagnOptics Technologies B.V.
E-mail: support@diagnoptics.com
Fax: +31 50 5890613
Tel.: +31 50 5890612

12. Liability & warranty

12.1. Liability

DiagnOptics Technologies B.V. 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 SU
- (b) unauthorized modification of the AGE Reader SU
- (c) fault or negligence by the user
- (d) breach of any warranty or other obligation by the user
- (e) invalid or wrong conclusions

and any consequences thereof, drawn by third parties from the measurement results provided by the AGE Reader SU.

12.2. Warranty

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

12.3. Declaration of Conformity

The Declaration of Conformity is provided separately.

13. Electromagnetic compatibility

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

13.1. Essential Performance


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

13.2. Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The AGE Reader SU is intended for use in the electromagnetic environment specified below. The customer or the user of the AGE Reader SU 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 SU 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 SU 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	

13.3. Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The AGE Reader SU is intended for use in the electromagnetic environment specified below. The customer or the user of the AGE Reader SU 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	+/- 2 kV for power supply 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)	+/-1 kV line(s) to line(s)	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 SU requires continued operation during power mains interruptions, it is recommended that the AGE Reader SU 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 SU is intended for use in the electromagnetic environment specified below. The customer or the user of the AGE Reader SU 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 SU , 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 SU is used exceeds the applicable RF compliance level above, the AGE Reader SU 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 SU . b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

13.4. Distances between RF equipment

Recommended separation distances between portable and mobile RF communications equipment and the AGE Reader SU			
The AGE Reader SU is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AGE Reader SU can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AGE Reader SU 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.			