Instructions for Use

DiagnOptics

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Contents

1 Introduction

Advanced glycation end products (AGEs) play a key role in the development of diabetes and its complications. The level of AGEs in tissues with slow turnover serves as a memory of glycometabolic stress and is a valuable predictor of (pre-)diabetes and cardiovascular complications.
Intermittent periods of (post-meal) hyperglycemia result in persistent increases in (tissue) AGE levels. This makes the measurement of tissue AGE levels a useful tool to detect IGT and diabetes in such periods of still intermittent hyperglycemia.
AGEs normally accumulate over a person's lifetime, but this process occurs more rapidly in patients with (pre-)diabetes. Tissue AGEs correlate closely with and are predictors of early kidney, eye and nerve disease in patients with diabetes mellitus. Moreover they are valuable predictors of future cardiovascular morbidity and mortality. AGEs are considered to be a major target in the treatment of diabetes and cardiovascular disease.

Diab-spot
DiagnOptics was the first to introduce the technology to noninvasively measure the tissue accumulation of AGEs by means of fluorescence techniques. Diab-spot features this AGE measurement and combines this with a small number of characteristics to calculate the Diab-spot test result. These simple characteristics include questions about the person's length, weight, age and family history of diabetes, which can be easily answered on the touch screen. Diab-spot yields an immediate screening result on the spot.
The detection of (pre-)diabetes patients by Diab-spot is superior to FPG and HbA1c. In a multi-center clinical study in the Netherlands, both sensitivity and specificity of Diab-spot were significantly better than FPG and HbA1c.

The Diab-spot 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 Diab-spot.

DiagnOptics Technologies B.V

2 Intended use

The Diab-spot is indicated for non-invasive screening of individuals who are at risk for (pre)diabetes to determine whether diagnostic testing is necessary. Clinical evidence shows that the Diab-spot risk prediction may assist to identify people with (pre)diabetes.

The Diab-spot is a proprietary device to assist in assessing the risk of having (pre)diabetes. The Diab-spot non-invasively assesses the risk of having (pre)diabetes by combining the optical assessment of the accumulation of advanced glycation end products (AGEs) in a person and a small number of clinical characteristics to be obtained by answering simple questions. Diab-spot measurements are performed directly on intact healthy skin on the volar side of the forearm. The skin at the measuring area should be homogeneous and without exposure to skin creams or any substance that may have fluorescent properties.

The Diab-spot is intended to be operated under the supervision of someone who is familiar with the Diab-spot user manual.

UV-Radiation
Using the guidelines of the ICNIRP it is concluded that during Diab-spot 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 subjects, and to the eyes of subjects 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.

2.1 Conditions for which the device is not to be used

This device is not intended to be used by patients whereby the skin at the measuring area is:
- not healthy,
- not homogenous,
- damaged,
- 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 precaution are essential for correct and safe functioning of the Diab-spot as is intended by DiagnOptics, its manufacturer.

Table 1. Warnings & precautions

	The Diab-spot 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.: SAR52801)
	The mains plug of the power supply is the separator which connects or disconnects the Diab-spot 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)
	To avoid risk of electric shock, this equipment must only be connected to a Class 1 supply mains with protective earth
	This device meets all requirements for electromagnetic compatibility of IEC 60601-1-2. If the user however notes unusual device behaviour, particularity if such behaviour is intermittent and associated with nearby usage of portable and mobile RF communications equipment, this could be an indication of electromagnetic interference. If such behaviour occurs, the user should try moving the interfering equipment further from this device. Failure to do so could result in the equipment not functioning properly.
	The use of accessories, transducers and cables other than those specified, with the exception of replacements parts sold by DiagnOptics, may result in increased emissions or decreased immunity of the AGE Reader CU.
	The Diab-spot should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Diab-spot should be observed to verify normal operation in the configuration in which it will be used.
	Do not use excessive force or sharp objects on the touch panel
	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. Opening the device will void the warranty.
	Correct positioning of the arm over the window is essential and should be maintained steady during the measurement process
	Do not let fluids ingress
	Do not use the device if there is visible damage and/or sharp edges.

4 Description of the Diab-spot

4.1 General

The Diab-spot is a small, desktop unit (figure 1).

The Diab-spot is a proprietary device to assist in assessing the risk of having (pre)diabetes. The Diab-spot non-invasively assesses the risk of having (pre)diabetes by combining the optical assessment of the accumulation of advanced glycation end products (AGEs) in a person and a small number of clinical characteristics to be obtained by answering simple questions. Diab-spot measurements are performed directly on intact healthy skin on the volar side of the forearm. The skin at the measuring area should be homogeneous and without exposure to skin creams or any substance that may have fluorescent properties.

Figure 1. The Diab-spot

4.2 Description of the Diab-spot

The Diab-spot consists of a small desktop housing with a detachable silicone-mat for the subject to rest his forearm on for the measurement.

The Diab-spot is powered by an accompanying medically approved external power supply connected to the mains and can also be powered from the internal rechargeable Lithium Ion battery.
The Diab-spot 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 Diab-spot software. This user-friendly software allows the user to change his preferences and assesses the risk of having (pre-) diabetes. The test results are presented on screen and can be graphically displayed by printing the measurement report. The test results are automatically stored on the internal flash drive in dedicated folders.

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. 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.

The Diab-spot has the following external features (figure 2):

- A detachable silicone mat.
- Power inlet. Only use the medically approved power supply accompanying the device, with article number SAR52801.
- A USB port for external storage device.
- A measuring window of special glass is located on the top of the Diab-spot.
- 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.

Figure 2. Diab-spot components

Contents of transport box:

- Diab-spot
- This user manual
- External power supply article number SAR52801, complying to IEC 60601-1
- Mains supply cable with mains plug to comply with regulations for use in country of usage
- USB-Storage device

5 Installing the Diab-spot

1. Place the Diab-spot on a horizontal, flat and stable surface.
2. Connect the mains supply cord with the DiagnOptics power supply with part number SAR52801 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 Diab-spot and is labeled as “Power in” (figure 3). A blue LED will light up when the battery is recharging.
4. The Diab-spot can now be turned on by the power button located on the label on the front side of the Diab-spot (figure 4). A green LED above the button will light up if the device is in its ‘power on’ state.
5. The Diab-spot software will start-up automatically.

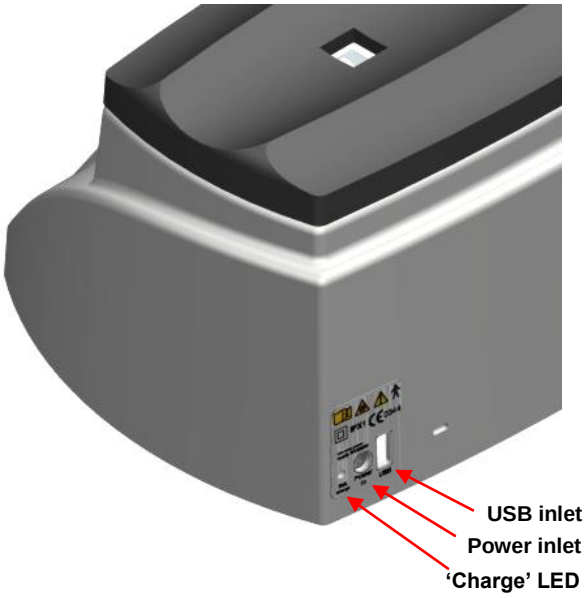

Figure 3. Diab-spot connections

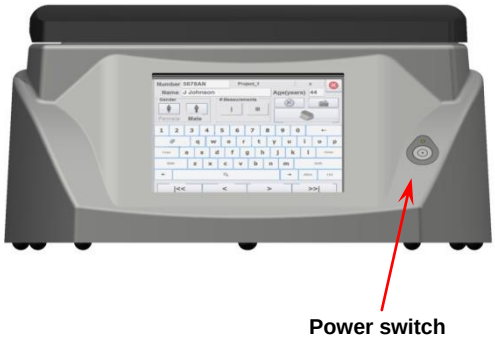

Figure 4. Diab-spot front side with power switch

6 Instructions for use

6.1 Starting the Diab-spot

When starting the Diab-spot 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 Diab-spot and is labeled as “Power in” (figure 3). A blue LED will light up when the battery is recharging.

Turn the Diab-spot on by pressing the ‘power button’ located on the label on the front side of the Diab-spot (figure 4). A green LED above the button will light up if the device is in its ‘power on’ state.

The dedicated Diab-spot software is preinstalled and will start-up automatically. When the device is ready for use the ‘main-screen’ will appear (figure 5).

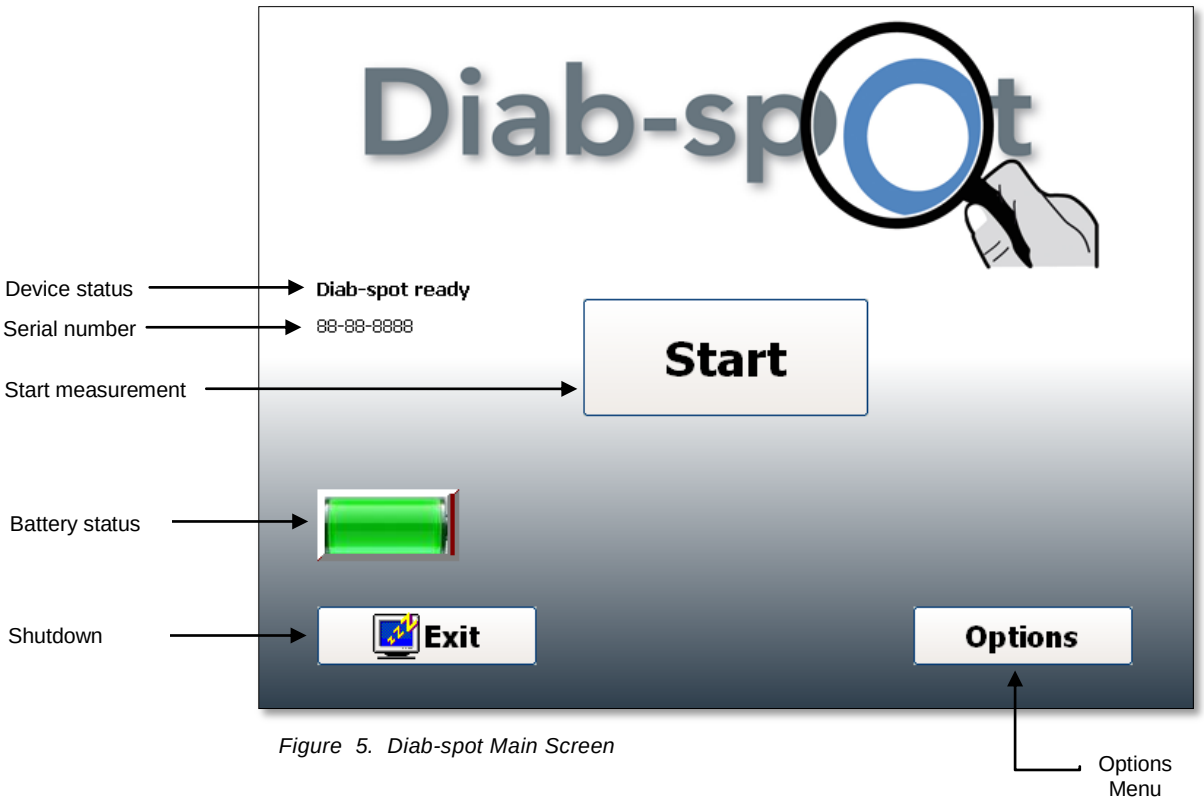

Figure 5. Diab-spot Main Screen

6.2 Warming-up

During start-up, the device state is presented 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 subjects during one session no further warming up time for the lamp is needed. If no measurement is taken within 10 minutes, the Diab-spot 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 Diab-spot is not used for a long time, 3 minutes warming up as described above is required before measurements can be done.

6.3 Options menu

By choosing the 'Options' button in the main menu (figure 5) the 'Diab-Spot Options' menu will be opened where several settings can be changed. The 'Diab-Spot Options' menu is shown (figure 6). To exit this menu press the button with the cross in the upper right corner at the top of the screen, to return to the 'main screen'.

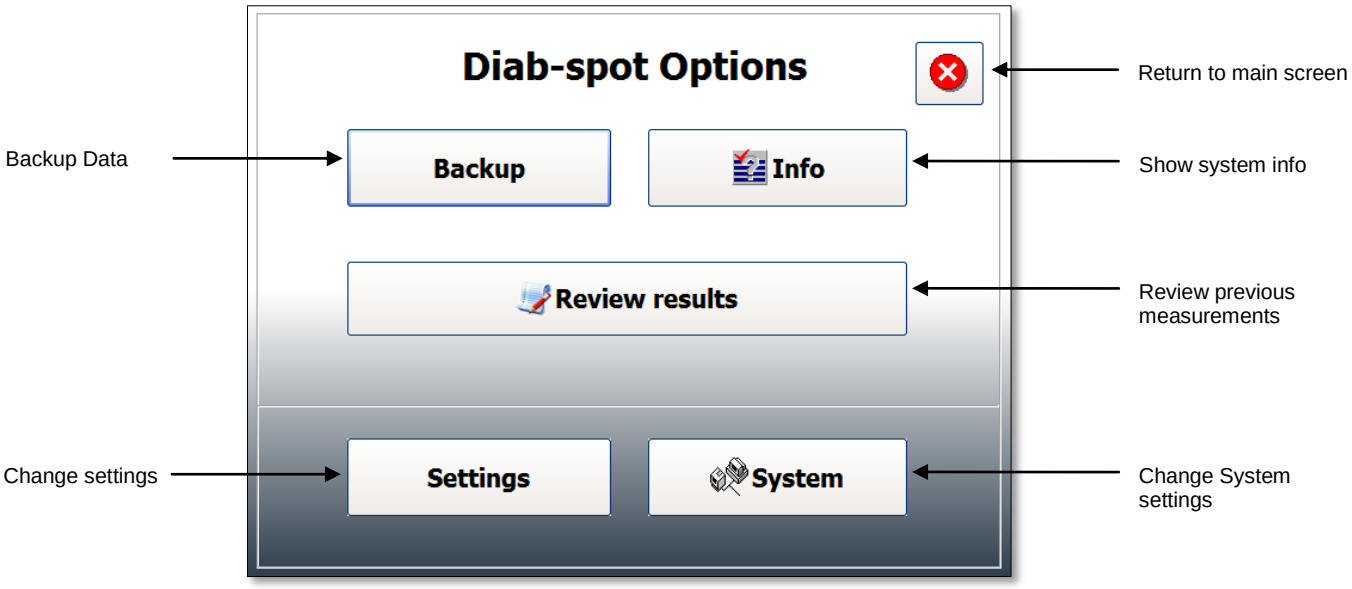

Figure 6. Diab-spot Options Menu

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 (figure 3), and press the 'Backup Data' button. A window to confirm that a USB storage device is inserted will appear. 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 Diab-spot.
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 Info screen

By choosing the 'Info' button in the 'Options menu' (figure 6) the 'Info' screen (figure 7), will be opened.
This screen provides information regarding the user software version, windows embedded software version, Diab-spot 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 'Options menu'.

Figure 7. Diab-spot Info Screen

6.3.3 Review of previous measurements

By selecting the 'Review Measurement' button, the user can recall previous measurements. Browsing through stored measurements can be done by means of the arrow buttons at the bottom of the screen (figure 8). The measurement currently reviewed is shown at the top of the screen, the result of this measurement is displayed in the center. To print the results in form of a report (figure 22), press the button with the printer symbol. To return to the 'Options screen' press the button with the cross.

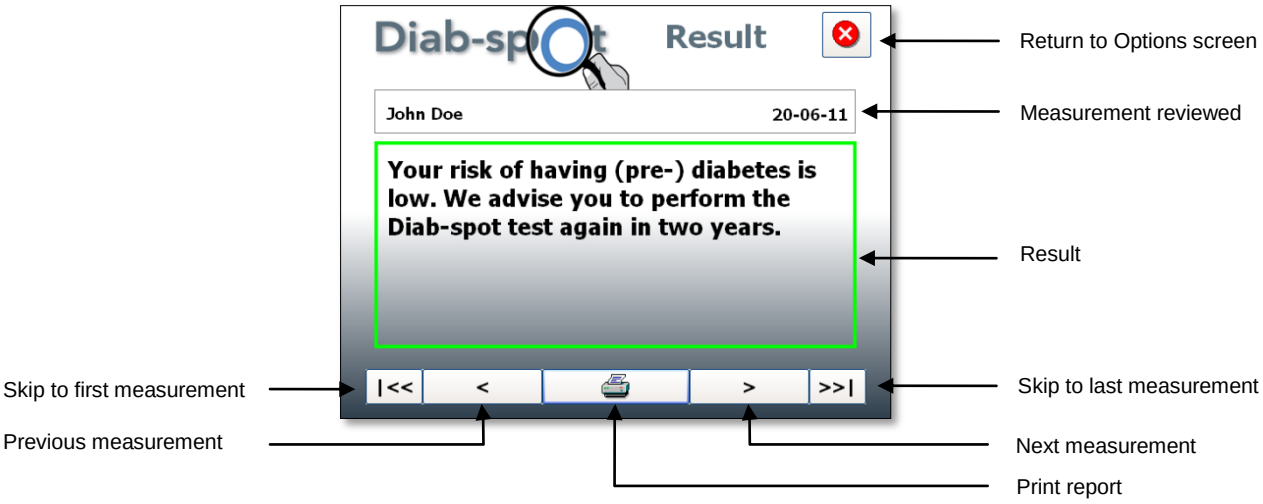

Figure 8. Diab-spot Review Measurements screen

6.3.4 Settings

By choosing the 'settings' button in the options menu (figure 6), the 'Diab-spot settings' menu will be opened where settings can be changed. The 'Diab-spot settings' menu is shown in figures 9 & 10. 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.
The Diab-spot software distinguishes three types of settings

1. *Project settings*, these settings affect the desired measurement preferences (figure 9).
2. *General settings*, these set the date, time, printer and language (figure 10).
3. *More settings*, these set the system of measurement and the printer (figure 11).

Project Settings

By selecting the 'Project settings' tab, the menu will appear (figure 9).

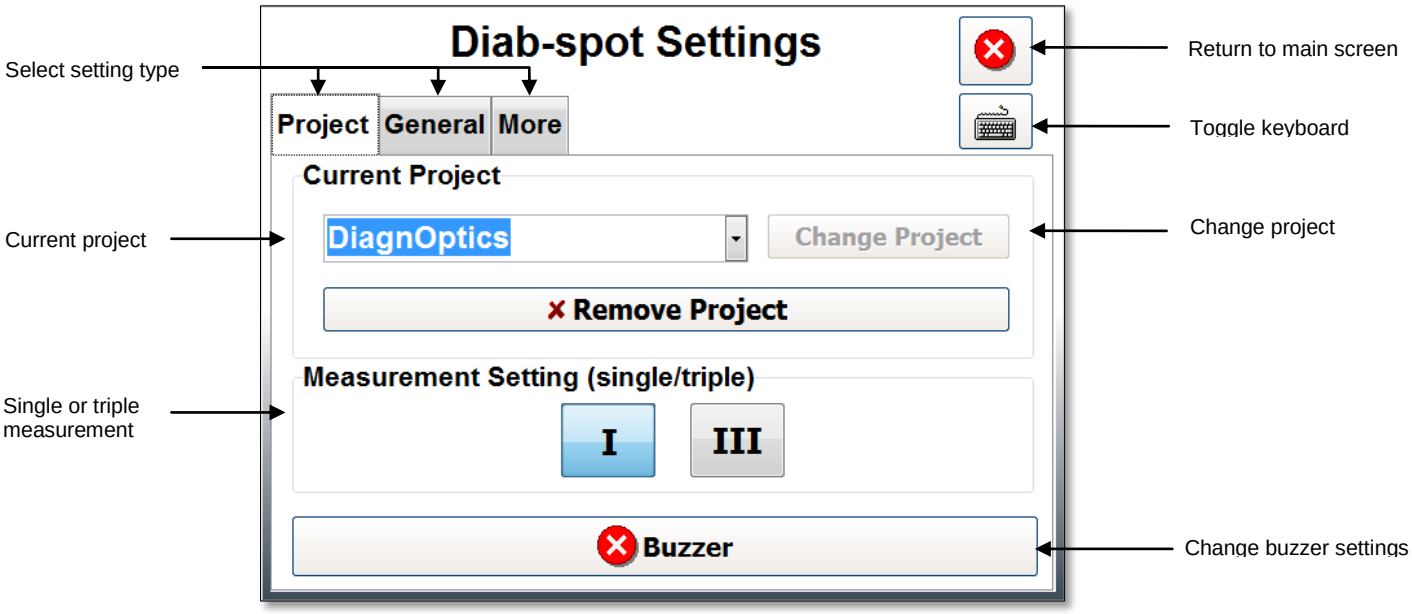

Figure 9. Diab-spot Project settings screen

Change project
Here the current project can be changed. 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.

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

Measurement #
Here 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.

General Settings
By selecting the 'general settings' tab, the menu will appear (figure 10).

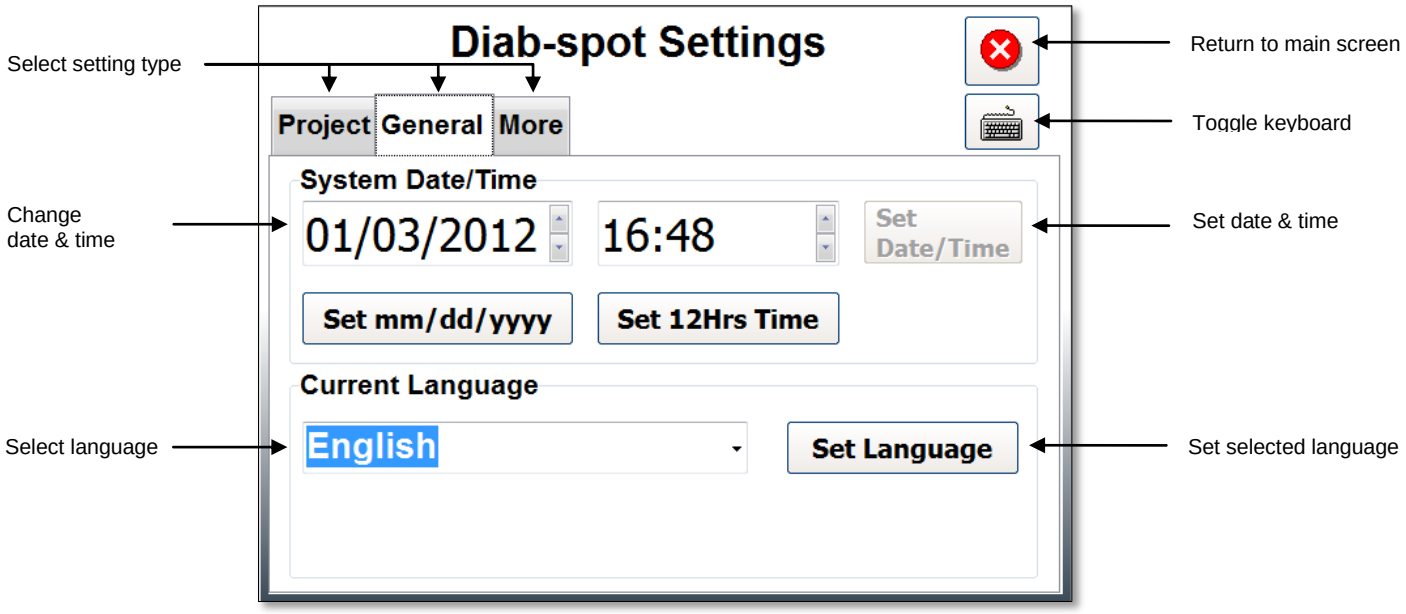

Figure 10. Diab-spot General settings screen

Set date / time
The current date and time can be changed by the arrowed buttons in the corresponding fields. The new time and date are made active by pressing the 'Set Date/Time' button.

Set language
The current language be changed by the pull-down-menu. The selected language is made active by pressing the 'Set language' button.

More Settings
By selecting the 'More Settings' tab, the menu will appear (figure 11).

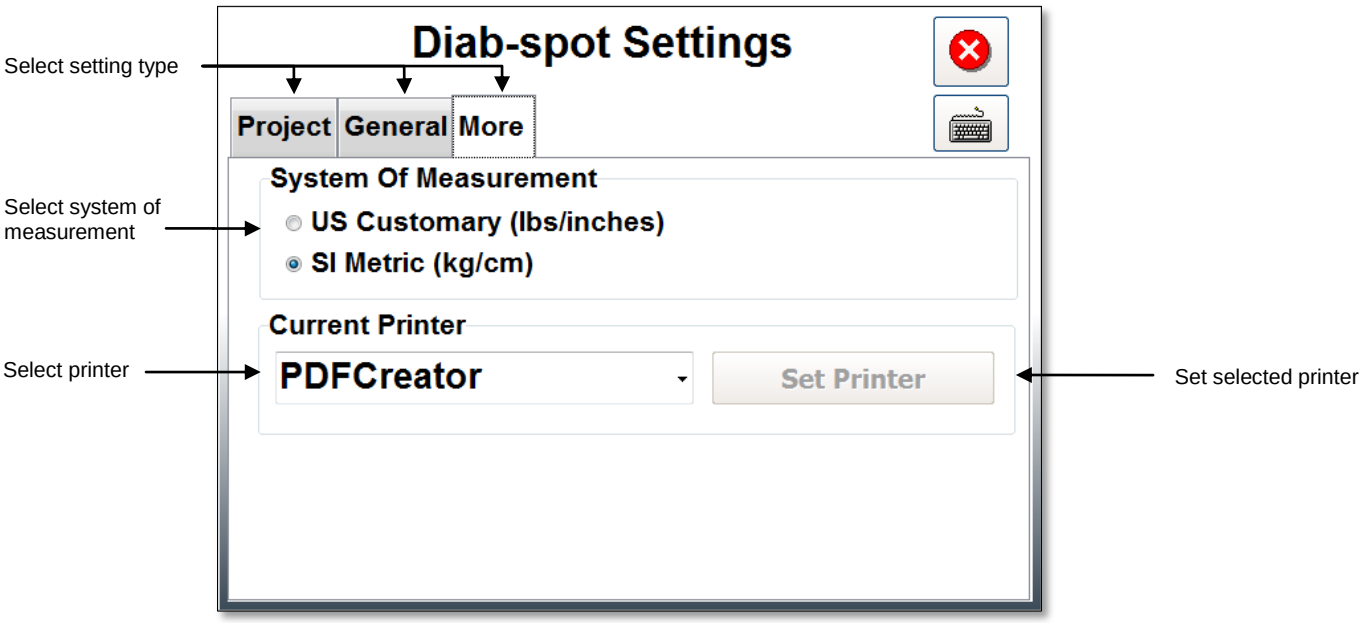

Figure 11. Diab-spot More settings screen

Set system of measurement
This selects the measurement system to be used. This setting is immediately active.

Set printer
This selects the default printer. The current printer can be changed by the pull-down-menu. The selection is made active by pressing the 'Set as default Printer' button. More information of the printers that can be used with the Diab-spot is provided in chapter 6.8.

6.3.5 System settings

By choosing the 'System' button in the 'Options menu' (figure 6) the 'System Settings' menu will be opened (figure 12).
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'.

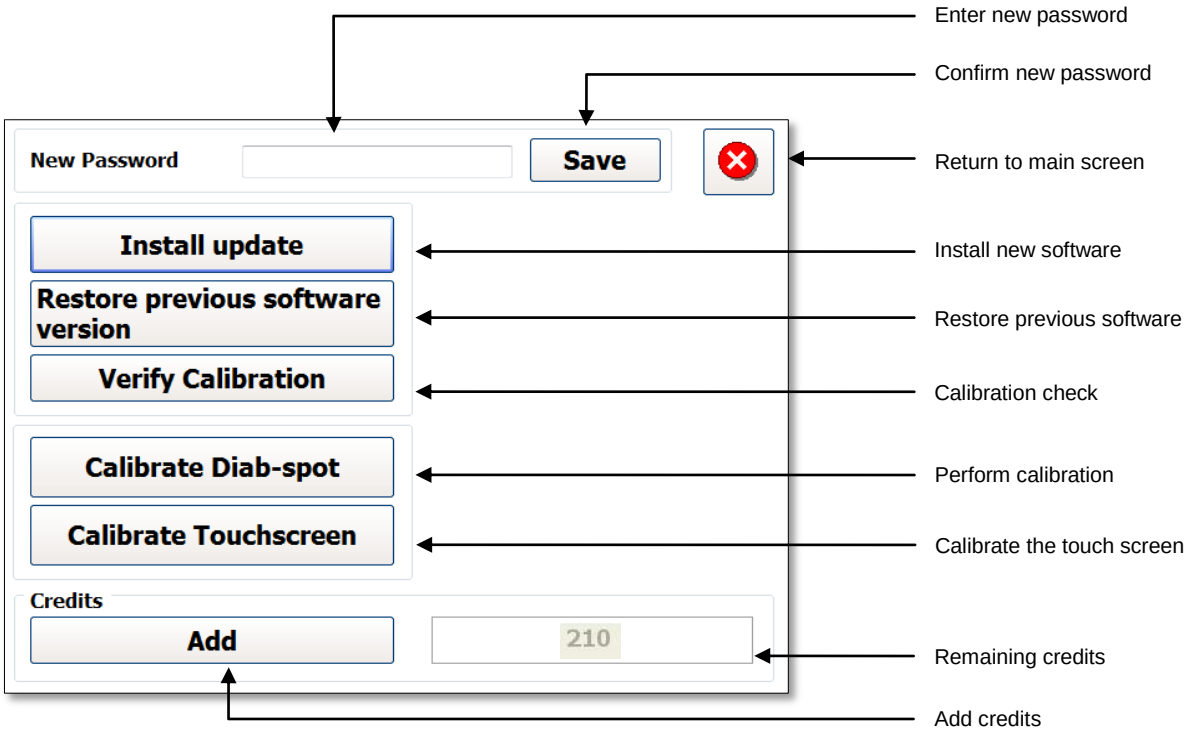

Figure 12. Diab-spot System settings screen

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 'Diab-spot 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 (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 'Diab-spot 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 in section 6.3.1.

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 Diab-spot has a limited number of measurements (Credits) installed.
In the field in the lower left corner of the screen the number of remaining Credits is displayed (figure 12). The remaining credits are also displayed in the 'Subject 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 (figure 3) and press the 'Update credits' button. The credits-update process will be performed automatically.

Calibrate
This option is only accessible for DiagnOptics and its representatives to perform a calibration of the Diab-spot.

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 will start again.

6.4 Measurements

To start a measurement, press the “Measure” button in the main menu (figure 5).
The ‘Subject Data’ screen will appear (figure 13).

Figure 13. Subject Data screen

6.4.1 Subject data screen

The ‘Subject data’ screen (figure 13) has several fields where, subject name, gender and year of birth 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.

After filling in the subject data, the arm measurement can be started. Press the ‘Next’ button to start the measurement. To return to the ‘Main screen’, press the ‘Previous’ button.

The automatic arm measurement procedure of the Diab-spot will now be started.

6.4.2 Arm measurement procedure

During the measurement, the progress screen is displayed, as shown in figure 14.

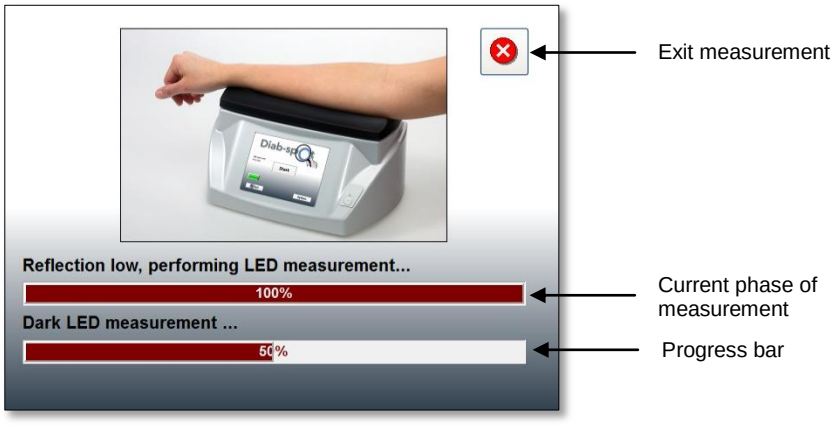

Figure 14. Measurement progress screen

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

The Diab-spot software does the first three steps automatically:

1. **Preparation**
2. **Reference white UV measurement**
   The Diab-spot now measures the intensity of the UV light which is used as a reference.
3. **Reference dark UV measurement**
   The Diab-spot 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. **Subject measurement**
   During the subject measurement, the skin auto fluorescence measurement with UV-A light is performed. Before the start of the measurement, optionally a buzzer will be audible to warn the user and subject that the measurement will begin, and a window appears asking for the forearm to be put on the measurement window (figure 15). After the subject has put the forearm on the window and thereby fully covering it, select 'Next', the subject measurement will start.

   The subject measurement usually takes 20-30 seconds.

Figure 15. Notification for subject to place the arm

   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.

5. **Subject dark measurement**
   The subject 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 Diab-spot during the UV measurement. Therefore, it is important that the subject keeps the forearm 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 subject covers the window with the arm each time at a slightly different position.

If the UV reflectance of the forearm is less than 12%, steps 2-5 are repeated with a white 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. If the reflectance is less than 6%, the Diab-spot will give a warning that the signal is too low. In that case no result is produced and no credit is deducted.

The measurement is completed when the screen shown in figure 16 and an optional second audible signal (double beep) from the buzzer.

Figure 16. End of measurement

6.5 Clinical characteristics

After completing the Diab-spot measurement and pressing the “next” button a number of questions will be asked. The displayed questions can differ from one person to another. Only the questions relevant for the respective person will be asked.

The questions which can be asked are:

- Has a direct family member been diagnosed with diabetes?
- Do you use any drug against high blood pressure?
- Do you have an autoimmune disease?
- Have you been hospitalized the last 6 months for; heart attack, stroke or severe infections?
- Do you have kidney disease?

NOTE: *Not all questions will be asked, the software decides which question is relevant for the assessment.*

These questions will be asked on the Diab-spot display and can be easily answered on the touch screen, an example of an question is shown in figure 17.
By pressing the ‘next’ button on the bottom-right on the screen the next question will appear. To return to a previous question, press the ‘previous’ button. To cancel the assessment, press the button with the cross in the upper right corner at the top of the screen, the software will return to the ‘main screen’.

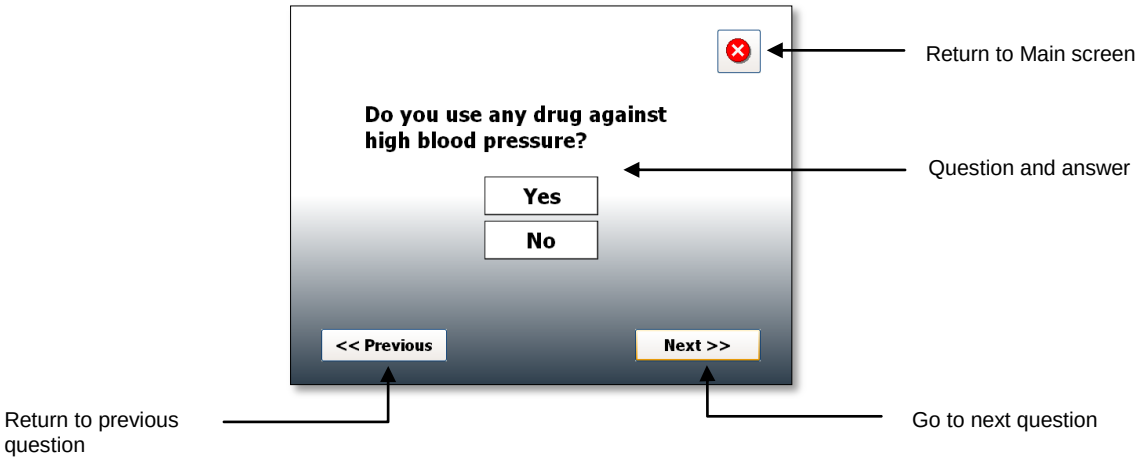

Figure 17. Example of a question screen.

Besides the questions, the “Weight & Height” screen (figure 18) could be displayed where subject’s weight and height can be entered to calculate BMI (Body Mass Index).
The ‘Weight & Height” screen, has two fields where, subjects weight and the height can be entered. These fields must be filled in. To erase the input of the fields, press the button with the blue cross.

Figure 18. Weight & Height screen

After filling in the subjects weight and the height, the assessment can be started. Press the ‘Next’ button to start the assessment. To return to the ‘Main screen’, press the ‘Previous’ button.

6.6 Test results

After evaluation of the Diab-spot measurement and the clinical characteristics, the software calculates the risk of having (pre-) diabetes.

There are three possibilities for the Diab-spot test result:

1. The risk of having (pre-) diabetes is low repeat Diab-spot test in 2 years (figure 19).
2. The risk for heart and blood vessel disease is increased, diabetes cannot be excluded. Advised to visit doctor for additional testing, repeat Diab-spot test again in 1 year (figure 20).
3. The risk of having (pre-) diabetes is increased. Advised to visit doctor for official diagnostic test (figure 21).

6.6.1 Negative result

If, after evaluation of the Diab-spot measurement and the clinical characteristics, a low risk of having (pre-) diabetes is determined the negative test result will be displayed. This negative test result will be shown on the display (figure 17).
The result can also be printed as a measurement report (figure 22) by pressing the button with the printer symbol. To start a new assessment, press the button with the green tick mark and the software return to the 'Main Screen'.

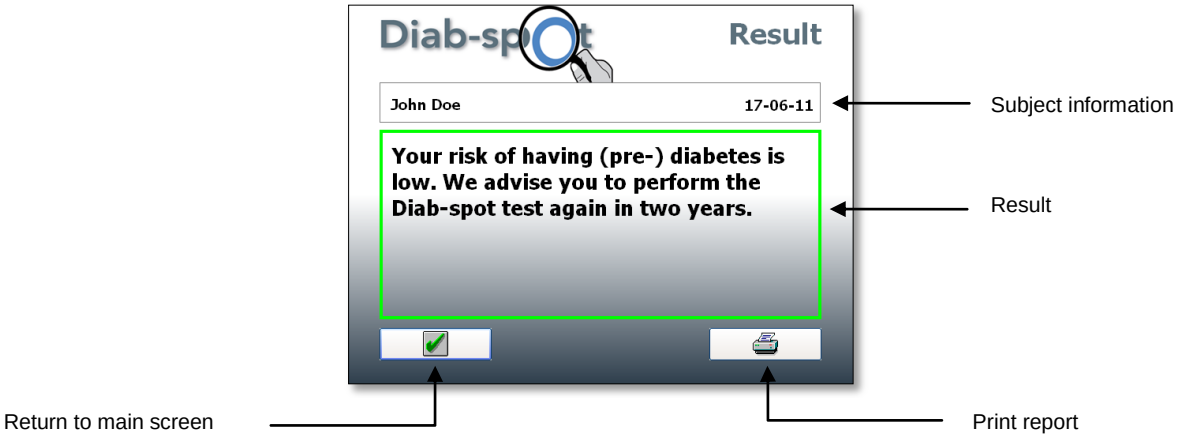

Figure 19. Negative result screen

6.6.2 Positive results

If, after evaluation of the Diab-spot measurement and the clinical characteristics, an increased risk for having (pre-) diabetes is determined a positive test result will be shown. This positive test results will be shown on the display (figure 20 and 21).
The result can also be printed as a measurement report (figure 22) by pressing the button with the printer symbol. To start a new assessment, press the button with the green tick mark and the software return to the 'Main Screen'.

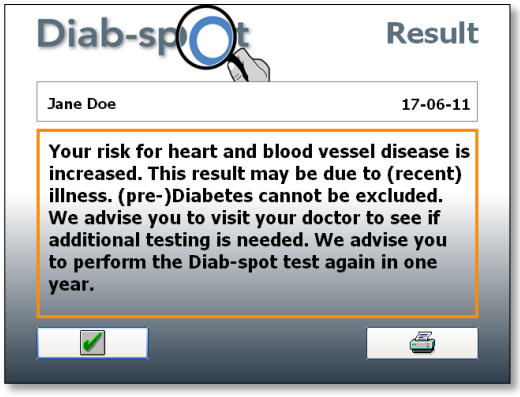

Figure 20. High CV risk result screen

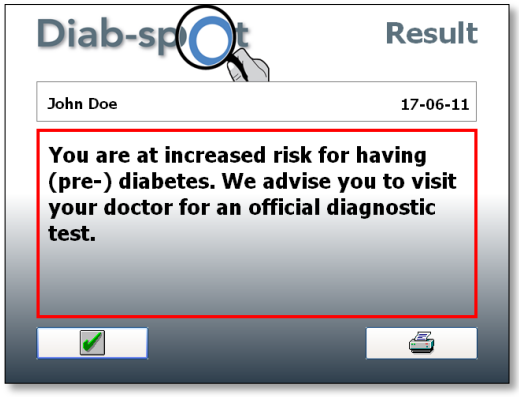

Figure 21. Positive result screen

6.7 Test report

The Diab-spot test results can be printed if a printer is connected. On the measurement report, the Diab-spot test result, the Diab-spot measurement and all relevant clinical characteristics are shown. The size of the printout depends on the print settings, see chapter 6.3.4.

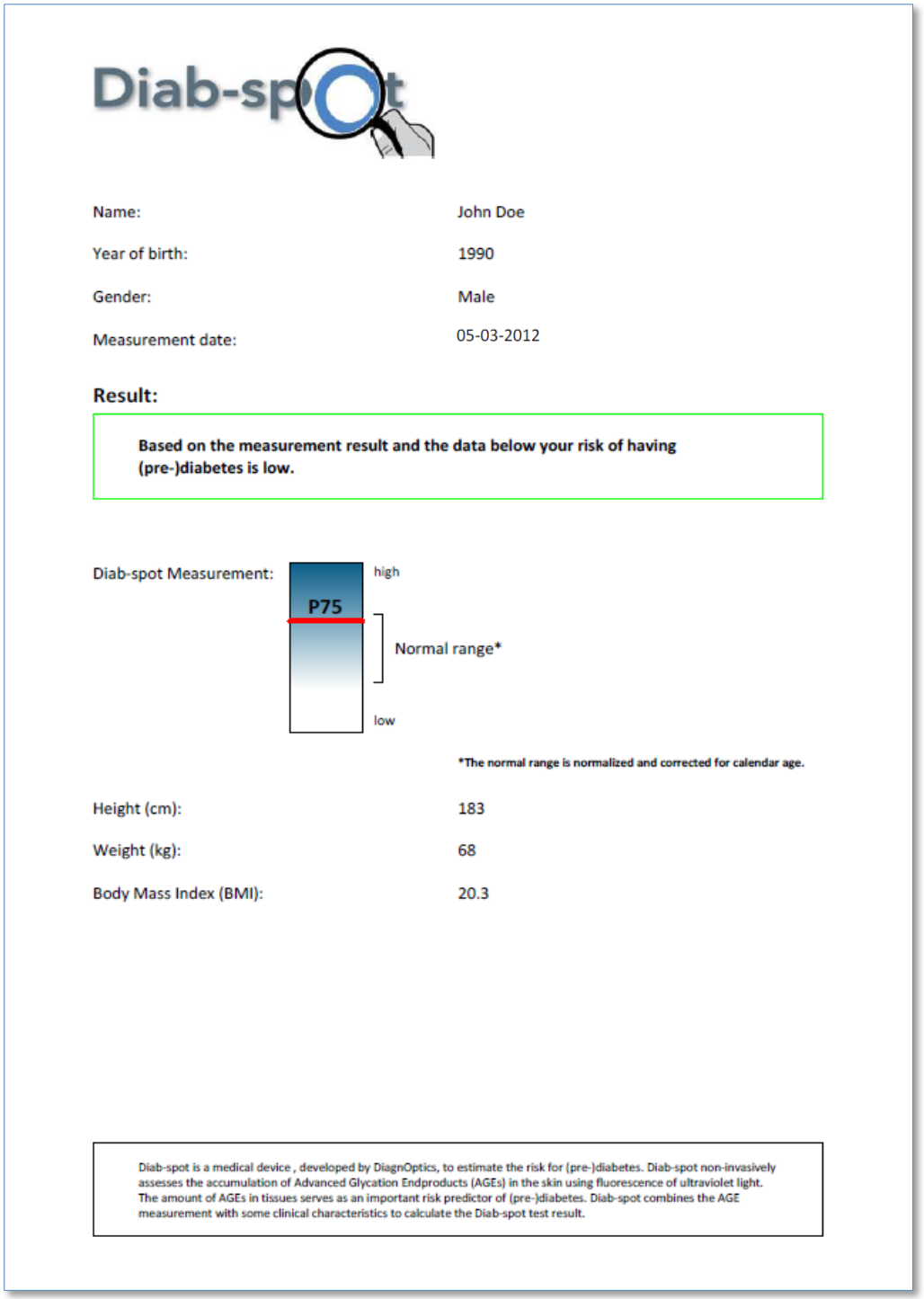

Figure 22. Full report on A4 size

6.8 Connecting a printer

To print a report, a PCL 3 compatible color printer can be connected to the Diab-spot'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 Diab-spot and wait until the message 'Diab-spot ready' appears on the left side of the screen.
3. Connect the printer cable to the USB port, located on the back of the Diab-spot.
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***
• *6000* • *7000* • *8000* • *4500* • *6500* • *8500* • *H470* • *K8600*	• 111 • 130 • 510 • T620 • T770 • Z2100 • Z3200	• F4400 • F4480 • 6940	• *Plus* • *Premium* • *D110* • *B209* • *C309* • *C410* • *A646* • *B8550* • *C3100 series* • *C4600 series* • *C4700 series*	• *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 Diab-spot.

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 6.3.2. Previous images only support the HP Officejet H470.

6.9 Turning off the device

By choosing the 'Exit' button in the main menu (figure 5) the 'Diab-Spot' can be turned off.
A window to confirm that the user wants to turn of the device will appear. After this confirmation the device is preparing to be turned off, when the device is ready to be turned off the screen is displayed (figure 23). The Diab-spot can now be turned off by pressing the power button located on the label on the front side of the Diab-spot, see figure 4.

NOTE: Press the power button ONLY when the screen shown in figure 23 is displayed !!!

Figure 23. Diab-spot turn off screen

6.10 Background information

6.10.1 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 Diab-spot 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!

6.10.2 Skin color

The device and its software have been validated in subjects with skin UV reflection ≥6% (Fitzpatrick class 1-4). In subjects with darker skin color (Fitzpatrick class 5-6, dark brown or black) a correction is made to the Diab-spot measurement result if the UV reflectance is between 6% and 10%. If the UV reflectance is below 6%, the Diab-spot will give a warning that the signal is too low for valid results. In that case no result is produced and no credit is deducted.

7 Cleaning & maintenance

7.1 Cleaning instructions

- **The measurement window.**
  The measurement window should always be kept clean!
  In the design of the Diab-spot, 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. 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 fibers remain on the window. Textile and paper fibers show fluorescence and so may affect the auto-fluorescence measurement!
- **The silicone subject mat.**
  The silicone subject 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.

7.2 Maintenance instructions

This system does not contain parts that can be serviced by the user!
The Diab-spot is a very sensitive instrument that has been carefully calibrated before use. Small differences exist in the internal optics characteristics 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 Diab-spot. This may impede comparisons of results between individual instruments. Therefore, unique calibration files of each individual system are used in the Diab-spot software. The software will detect which spectrometer is contained in the Diab-spot 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 Diab-spot 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

8 Problems & solutions

If a malfunctioning of the Diab-spot or the Diab-spot software occurs, always make sure that the external power supply (part. nr.: SAR52801) accompanying the Diab-spot is used.

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, contact DiagnOptics.

Table 2. 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 Diab-spot dealer.
Shutter defect, contact manufacturer.	Contact your Diab-spot dealer.
UV lamp hardware error, contact manufacturer.	Contact your Diab-spot dealer.
White LED hardware error, contact manufacturer.	Contact your Diab-spot dealer.
<Directory name> could not be created. Contact DiagnOptics Technologies B.V.	Likely problem with internal storage medium. Contact your Diab-spot dealer.
<Filename> could not be created.	Likely problem with internal storage medium. Contact your Diab-spot dealer.
C:\Agereader_SA\DefaultAFRdata.txt not found.	This file contains the default settings. Likely problem with internal storage medium. Contact your Diab-spot dealer.
Incompatible Calibration file. Contact DiagnOptics Technologies B.V.	Problem reading calibration file. Likely problem with internal storage medium. Contact your Diab-spot 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 Diab-spot 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 Diab-spot dealer.
No license found. Contact DiagnOptics Technologies B.V.	Problem with license file. Please contact your Diab-spot 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 Diab-spot 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 Diab-spot 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 Diab-spot 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 Diab-spot dealer.
ERROR : No Calibration Software found ...	No valid USB stick with calibration program present. Contact your Diab-spot dealer.
AgeReaderActions.exe not found.	Missing program. Contact your Diab-spot dealer.

8.2 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 Diab-spot 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 Diab-spot 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 19V 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 Diab-spot 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.
- Diab-spot 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 Diab-spot 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 Technical specifications

Diab-spot:

- Operation: Continuous operation
- Power: - 19 VDC from external power supply SAR52801
  - 14,4 VDC from rechargeable Li-ion battery SAR52300
- Output: UV-A light $\Delta\lambda$ = 345nm – 410nm
  Peak wavelength λ = 365nm
  Irradiance E = 123 W m^{-2}
- Physical: Width: 299.3 mm
  Depth: 213.5 mm
  Height: 150 mm
- Material (ext.): Enclosure: ABS/PMMA
  Subject-mat: black Silicone
- Weight: 4.8 kg
- Operating Conditions:
  - temperature range: Lower limit + 10ºC - Upper limit + 40°C
  - Relative humidity: 30% to 75% non-condensing
- Storage & Transport Conditions:
  - temperature range: Lower limit - 40ºC - Upper limit + 70°C
  - Relative humidity: 10% to 100% non-condensing

Power Supply (SAR52801):

- Input: 100 - 240 VAC 47 – 63 Hz
  2A - 1A
- Output: 19 VDC 150W

Battery (SAR52300):

- Type: Lithium Ion rechargeable battery
- Output: 14.4 VDC
- Capacity: 6.6 Ah

Classifications:

Diab-spot:

- 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: 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 (SAR52801):

- 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.

10 Marking on the Diab-spot

Each device shall be accompanied by all the information needed to safely install and use the Diab-spot 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 subject 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.

10.1 The rear label

The rear label is located on the backside of housing of the Diab-spot (figure 24). All necessary information for installation, use and applicable warnings are presented visually for the user. The rear label contains two connector inlets (figure 25), 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 24. Diab-spot rear

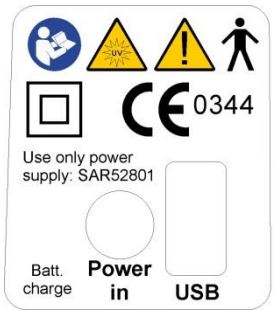

Figure 25. Rear label

Table 3. Used symbols on rear label

	Read Instruction for Use (*IEC 601-1 Appendix D table D2- symbol 10 &* ISO-7010 - M002
	Warning for UV emissions *(IEC 60417)*
	General mandatory action sign *(IEC 601-1 Appendix D table D2- symbol 9 & NEN-EN 980 4.10)*
	Type B symbol for protection against electric shock *(IEC 601-1 Appendix D table D1- symbol 19)*
	Class II symbol, double isolated *(IEC 601-1 Appendix D table DI- symbol 9)*
CE 0344	CE-Mark & Notified body number (6 mm high)
Use only power supply: SAR52801	Instruction to use only the certified power supply accompanying the device.
○ / ●	Reference for condition “Charging” When active, device is charging.
Batt. charge	Notification if battery is charging when (blue) LED is activated
USB	Identifies the USB connector
Power in	Identifies the power-in connector

10.2 The serial label

The serial label (figure 27), is located on the bottom of the Diab-spot, (figure 26). All necessary information for product identification, product specification and the name address of the manufacturer are presented visually for the user, see table 4.

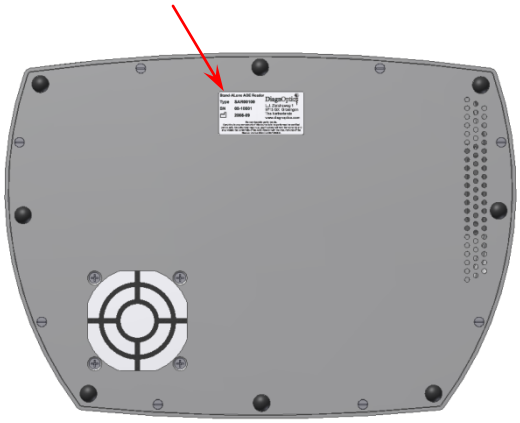

Figure 26. Diab-spot bottom

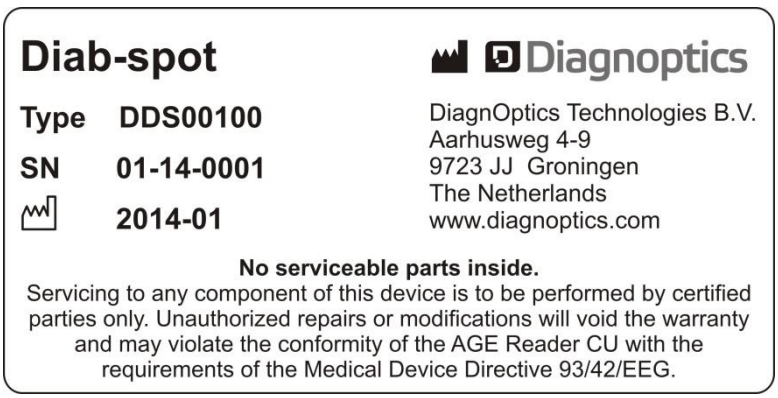

Figure 27. Serial label

Table 4. Used symbols on serial label

Diab-spot	Identification of device, device name
Type DDS00100	Type identification
SN 01-14-0001	Serial number *(NEN-EN 980 4.5).*
2014-01	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 Diab-spot with the requirements of the Medical Device Directive 93/42/EEG.	Warning not to service the device yourself
Diagnoptics DiagnOptics Technologies B.V. Aarhusweg 4-9 9723 JJ Groningen The Netherlands www.diagnoptics.com	Identifies DiagnOptics Technologies B.V. as its manufacturer with name / logo and contact information

10.3 The front label

The front label (figure 29) is located at the front of the Diab-spot (figure 28).
The power on / standby switch is located at the bottom of the front label (figure 29). 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 5.

Figure 28. Diab-spot front label location

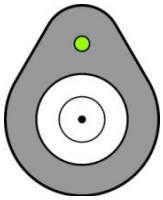

Figure 29. Front label

Table 5. 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.

10.4 Symbol in applied part

In the design of the silicone-mat an ergonomically shaped armrest is molded for the subject to rest the forearm in. The direction of the arm is shown by a figure of a hand that is molded in the silicone-mat (figure 30).

Figure 30. Applied part with symbol

10.5 Power supply label

The medical approved power supply accompanying the Diab-spot is labeled as in figure 31.
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 31. Power supply label

10.6 Packaging

Each Diab-spot, 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 separately disposed.

Figure 32. DiagnOptics packaging label

All following information is put on each package by the label (figure 32):

- Contents
- Weight
- Size
- Serial number
- DiagnOptics logo & address

11 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 Diab-spot itself, please contact DiagnOptics or its representatives.

Send your request by e-mail or fax and clearly state the serial number(s) of the Diab-spot(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 6. Spare parts

Spare part	Article number
Silicone subject mat	SAR02500
USB storage device	SAR07400
External power supply	SAR52801

Our address for support is as follows:

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

12 Liability & warranty

12.1 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 Diab-spot
b - unauthorized modification of the Diab-spot
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 Diab-spot

12.2 Warranty

The warranty supplied with this Diab-spot System is provided separately.

12.3 Declaration of Conformity

The Declaration of Conformity is provided separately.

13. Electromagnetic compatibility

The AGE Reader CU 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 is intended for use in the electromagnetic environment specified below. The customer or the user of the AGE Reader should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The AGE Reader 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 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	

16.3. Electromagnetic immunity

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

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

13.4. Distances between RF equipment

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