Eye & Health Care
NIDEK TECHNOLOGIES S.R.L.

NAVIS - EyeBank

version 3.7.3

Operator's manual

Revision 8

2024-04-08

 Before using this software, we recommend to read carefully this manual. Keep this document in a safe place for future reference.

Manufacturer

For any request, encountered problem or question, please contact us at:

Eye & Health Care
NIDEK TECHNOLOGIES

Nidek Technologies Srl

Via dell'Artigianato, 6/A

35020 Albignasego (PD) – ITALY

Phone: +39-049-86 29 200

Email: nidektechnologies@nidektechnologies.it

Web: www.nidektechnologies.it

Contents

1. INTRODUCTION

1.1 Classification and intended purpose

According to directive 98/79/EC for in vitro diagnostic medical devices, the NAVIS - *EyeBank* software is classified as General/Other IVD. The conformity assessment route is Annex III. It shall be used by a physician or a properly licensed practitioner, in the interpretation of corneal endothelium density measurements.

The NAVIS - *EyeBank* software has been developed to automatically estimate endothelial cell density by processing images of explanted corneas, acquired with optical microscopes. It is therefore possible to acquire and store such images in a digital format and then process them and store and/or print the results of such analysis.

The measurement is fully automatic and yields estimates of cell density from images featuring such a magnification factor that manual counting results to be quite complicate and subject to errors.

The analysis consists in the estimate of the cell density [cells/mm^2] of an endothelium, by processing an entire endothelial image, i.e. it is not regions-based. Additionally information on mean and standard deviation of densities derived from several images of the same endothelium can be retrieved through the statistics panel.

It is the operator's responsibility to check the information produced by the automatic analysis: results are meaningful only for images of corneal endothelium acquired with a calibrated microscope.

It is the operator's responsibility to decide how to value and use the results yielded by the automatic analysis.

1.2 Restriction in use

The *Eyebank* software is exclusively aimed at processing images showing a magnification factor in the range 1.5 - 2.0 micron/pixel (typical of images taken with a 10x magnification): Nidek Technologies does not guarantee any reliability for measurements performed on images showing significantly different magnification factors.

1.3 Composition of the system

The *Eyebank* system includes:

- NAVIS installation CD;
- USB dongles containing the activation keys respectively for NAVIS, the corneal microscopy application, the cell analysis software itself;
- this operator's manual;
- the NAVIS PC, including the frame-grabber board;
- camera connection cable and footswitch.

The following items are also required and not included:

- optical microscope with accessories, including C-mount adapter for the camera;
- PAL color camera;

1.4 SYMBOLS

Symbol	Description
	Model
 yyyy-mm-dd	Manufacturing date and device version
	Manufacturer name and address
	In vitro diagnostic device

Symbol	Description
	Consult operator’s manual
	CE mark Directive 98/79/EC

1.5 Serious incident reporting

Any serious incident occurring in relation to the device must be reported to the manufacturer:

Nidek Technologies Srl
Via Dell'Artigianato, 6/A 35020 Albignasego (PD) – Italy
tel. +39 049 8629200 email: service @nidektechnologies.it

and the competent authority of the Member State where the user and/or patient is established.

The list can be accessed from the European Union website at the following link:
https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

A «**serious accident**» means any incident that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person,

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

(c) a serious public health threat;

«**Incident**» means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any harm as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device.

2. INSTALLATION

The installation, especially as far as microscope calibration is concerned, shall be performed by Nidek Technologies' authorized personnel. An erroneous installation can directly affect the software performance.

Find here below some general indications.

2.1 Hardware installation procedure

1. Install the NAVIS PC;
2. Mount the camera and connect it to the power supply;
3. Connect the video cable to the camera and to the frame grabber board;
4. Connect the footswitch to the serial port COM1 (or to a USB port, depending on the supplied cable);
5. Turn on the microscope, the camera and the PC

2.2 Software installation procedure

The EyeBank software comes with the NAVIS installation CD and is automatically installed when installing the NAVIS software. As for most NAVIS applications, activation keys shall be installed before first use.

To install the activation keys, proceed as follows:

1. Insert USB Dongle #1;
2. Run the license installation tool by selecting C:\NAVIS\mainbody\Nat\NAT.exe;
3. Drag the corresponding license from the uppermost window and drop it onto the lowermost one;
4. Repeat for all USB dongles;
5. Select *Done*, then Yes.

2.3 Microscope calibration

The calibration procedure is described by the Microscope calibration manual which is part of the product documentation.

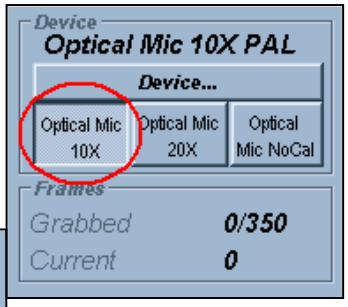
3. IMAGE ACQUISITION

Once the microscope has been calibrated, to acquire images proceed this way:

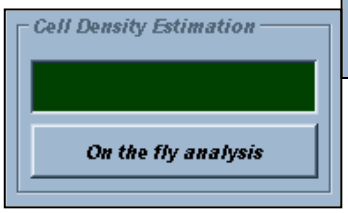
1. Run the *Corneal microscopy* application from the NAVIS initial screen;

2. Select a patient in the *Patient list* panel (or create a new one, by specifying last and first name and date of birth);

3. Check that the correct magnification factor is selected in the acquisition screen (and that the corresponding objective is used on the microscope).



4. Check the *On the fly analysis* button status: if it is pressed the analysis will be performed immediately after the image acquisition. If you want to perform the analysis later, de-check the button.



5. Place the corneal sample on the microscope and press the footswitch (or the *Acquire* button) when the live image looks fine in terms of focusing, framed field and illumination.

In case the *on the fly* analysis is active, the *Cell Density Estimate* box will show the estimated density value, expressed in cells/mm², or *NP* (Not Processable) if the image reveals to be not suitable for the analysis.

For a successful automatic analysis it is necessary that images are well in focus, i.e. it should be possible to identify clearly cell contours in a sufficiently wide portion of the image. Consider figure 1 and 2 as a reference.

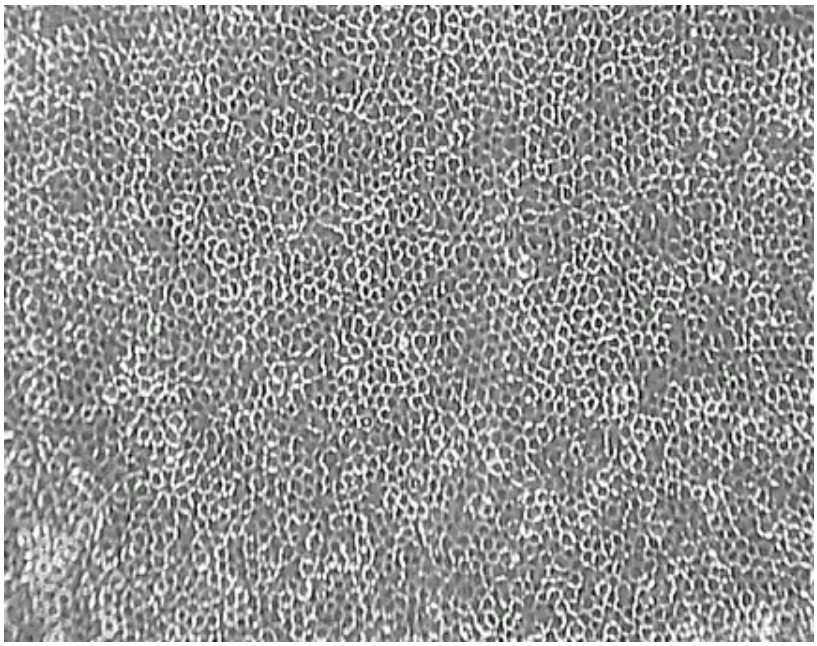


Figure 1 – Example of an image suitable for the automatic analysis.

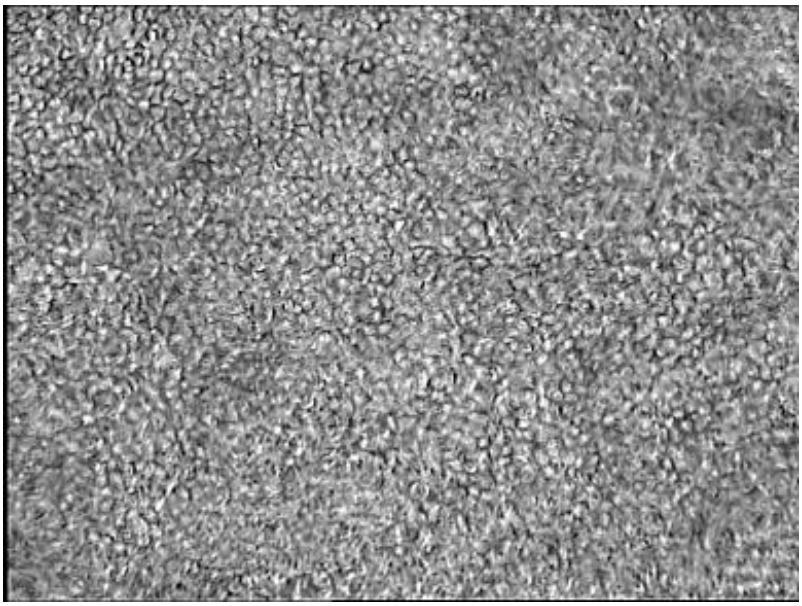


Figure 2 – Example of an image not suitable for the analysis

4. DENSITY EVALUATION

In order to process a previously stored image, there are two options:

- quick analysis;
- full analysis.

4.1 Quick analysis

In case one wants to just get the estimated density for a certain image, one can use the quick analysis. Proceed as follows:

1. from the main window of the Corneal Microscopy application, right click on any image acquired with a 10X magnification factor;
2. from the context menu, select the *Analysis* item.

After few seconds, a message box will display the analysis results. By pressing the OK button, the results will be automatically saved to disk and displayed in a label under the image thumbnail.

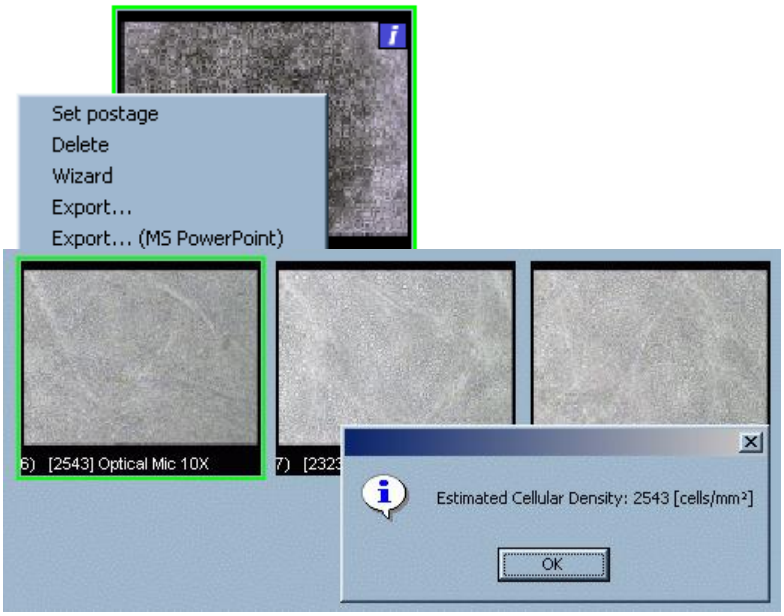


Figure 3 – Sequence for quick analysis

4.2 Full analysis

In order to open the complete processing screen, proceed as follows:

1. from the main window, select the image to be processed
2. press the *Automatic Cell Count* button:

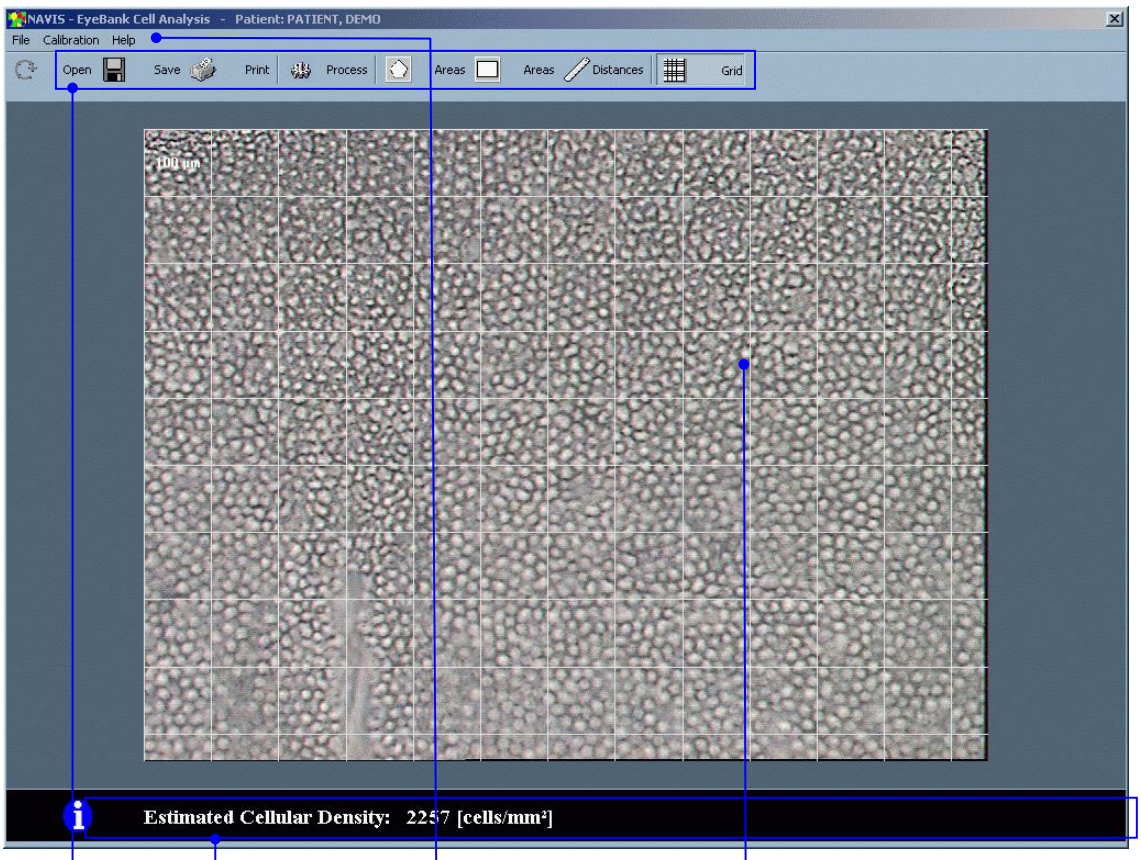
If the button is disabled (grayed), it means that the activation key of the Eyebank software has not been correctly installed.

The message *No calibration data available for this examination* refers to an image which was not acquired with a calibrated microscope and therefore for which no analysis is possible.

4.2.1 Interface

The graphical interface of the EyeBank processing screen consists of four main elements:

- the image under analysis;
- the window menu;
- the toolbar;
- the information bar.



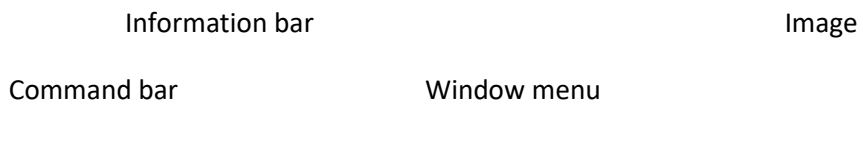


Figure 4 – graphical interface

4.2.1.1 Image

It is the image to which the results refer. A light gray grid, with a fixed pitch of 10 μm, can be superimposed on it.

4.2.1.2 Toolbar

Integrates the application menu, supplying an immediate approach to the most important functionalities. In particular, the following commands are present:

- **Load**

  Loads data from disk, if previously saved, related to density results and to other measurements

  (distances and areas) done on the image;

- **Save**

  Saves the density result and any other measurement done on the image;

- **Print**

  Opens the print preview panel;

- **Process**

  Processes the image and shows the value of the estimated cell density in the information bar;

- **Areas**

  To measure polygonal/rectangular areas;

- **Distances**

  To measure distances between two points;

- **Grid**

  To show / hide the micrometric grid.

4.2.1.3 Application menu

In addition to the commands already present on the toolbar, it contains the following:

- **Exit**

  Closes the current window;

- **Calibration**

  Shows an informative panel concerning the metric data associated to the image;

- **About**

  Shows an informative panel concerning the software version.

4.2.1.4 Information bar

Shows, depending on the context, information concerning:

- the estimated cell density value for the current image;
- the rectangular or polygonal area currently selected, expressed in mm^2;
- the length of the segment currently selected, expressed in μm.

4.2.1.5 Loading and saving

In order to load stored measurements of areas and distances, press the button *Load* from the command toolbar or select the menu items *File* and *Load*. Likewise, in order to save new measurements, press the *Save* button from the command toolbar or select the menu items *File* and *Save*.

4.2.1.6 Automatic analysis of the image

In order to run the cell density estimate algorithm, press the button *Process* in the command toolbar. After few seconds, the estimated density value will be shown in the information bar. If the image is not suitable for the analysis, instead of the above-mentioned information, the words “Not processable image!” will be printed. In that case, it is recommended to acquire new images and repeat the analysis.

4.2.1.7 Area measurement

By clicking on one of the two buttons, the application will enter the *Area measurement* mode. This functionality permits to measure the area of regions inside the image. It is possible to choose between rectangular and polygonal regions.

It is not possible to obtain cell density estimates inside regions. Even when a region is highlighted, the analysis will be performed on the whole image.

4.2.1.8 Rectangular regions

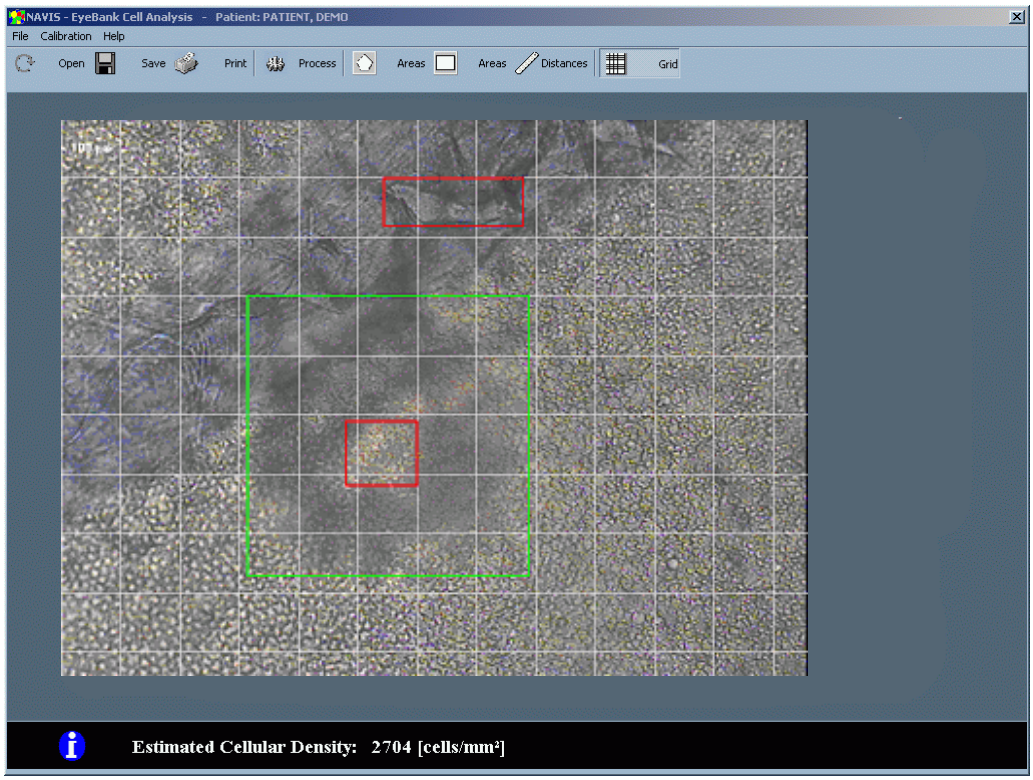


Figure 5 – Area measurement of rectangular regions.

- **Creation**

  Move the mouse pointer inside the image and left click on any point. Move the mouse, keeping the mouse button pressed, and release: a green rectangle, having the two selected points as opposite vertexes, will be drawn. In the information bar the value of the corresponding area will appear, expressed in mm².

- **Selection**

  In order to select an existing rectangle, left lick on its interior. The selected rectangle border will be green, while unselected ones will stay red and the corresponding area will appear in the information bar, expressed in mm².

  If two or more rectangles are partially overlapped, the first one in order of creation will be selected.

  Moving

  In order to move a rectangle inside the image, left click on its interior and move the mouse, keeping the mouse button pressed.

- **Resizing**

  In order to modify width and height of a rectangle, left click on any sides or vertexes.

- **Deletion**

  In order to delete a rectangle, right click on its interior. A context menu will appear: select *Delete* to delete the current rectangle or *Delete all* to delete all rectangles present on the image. It is also possible to delete the currently selected rectangle by simply pressing the *Cancel* or *Backspace* keys of the keyboard.

4.2.1.9 Generic polygonal regions

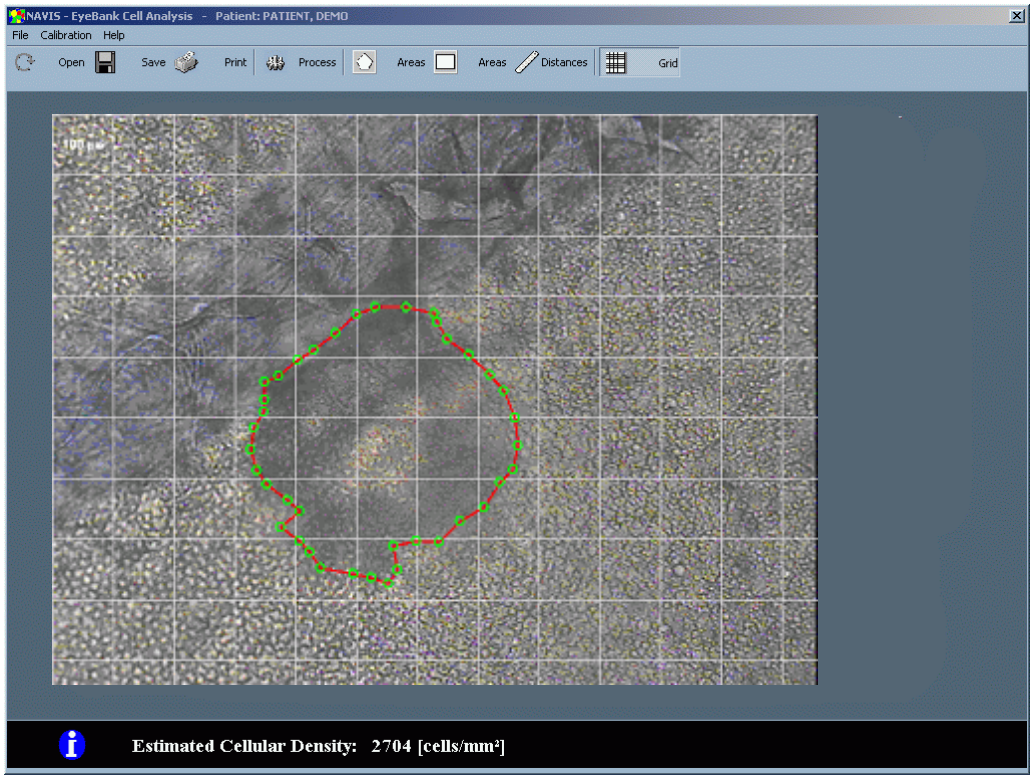


Figure 6 – Area measurement of a polygonal region.

- **Creation**

  Move the mouse pointer inside the image and click on any point. Repeat this procedure many times until all vertexes of the polygon will be drawn. To close the polygon, click on the first drawn vertex. Only one polygon at a time can be drawn and measured.

- **Deletion**

It is possible to delete any vertex of a polygon, by right clicking on the corresponding circlet. To delete the entire polygon left simply click on any point of the image external to the polygon.

4.2.1.10 Distance measurement

- Distance values are obtained by clicking on any point of the image and then dragging e mouse to the other ending of the segment: a green line will highlight the measured segment and the length will appear in the information bar.

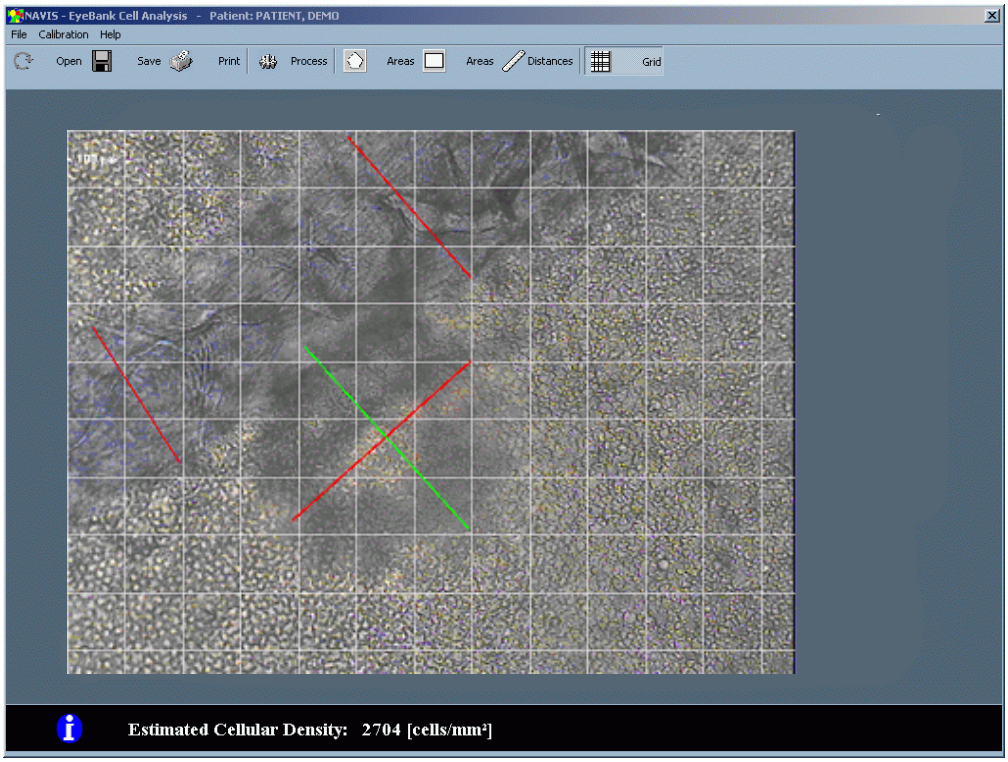


Figure 7 – Distance measurement.

In order to delete a segment, select it and right click on any point of it: select *Delete* or *Delete all* to delete all segments on the image.

4.3 Printing results

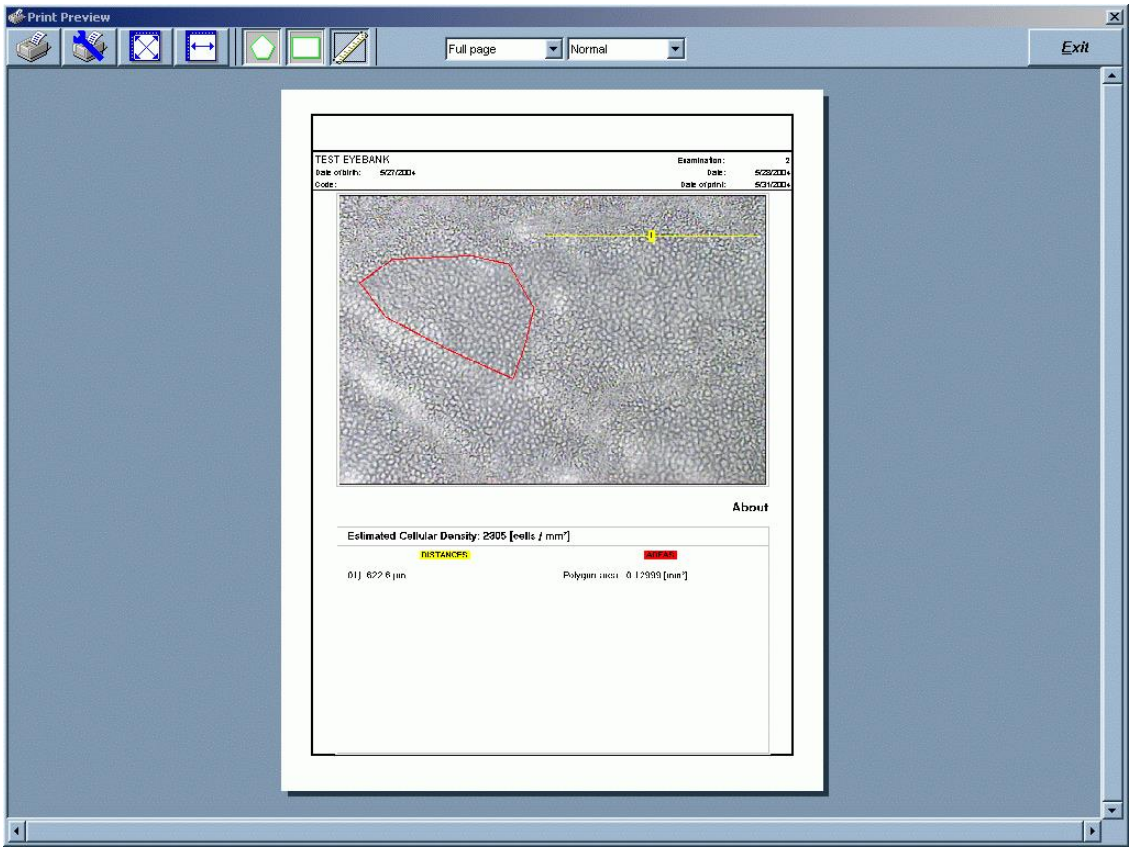


Figure 8 – Results print preview.

When the *Print* button is pressed, a print preview window opens. This window shows:

- patient's data;
- exam's data;
- the endothelial image;
- the value of the estimated cell density, in cells / mm²;
- indications on areas and distances measurements.

As a default setting, all graphical elements, drawn in the different measurement modes, are superimposed on the endothelial image. If you want to change this behaviour, click on the three buttons in the toolbar.

4.4 Statistics

It is possible to obtain some useful statistical information, related to different images of the same cornea. To do that:

1. close the *EyeBank* panel (if active);
2. select one or more processed images. Right click on any of the selected images and select *Statistics* from the context menu (see fig 10).

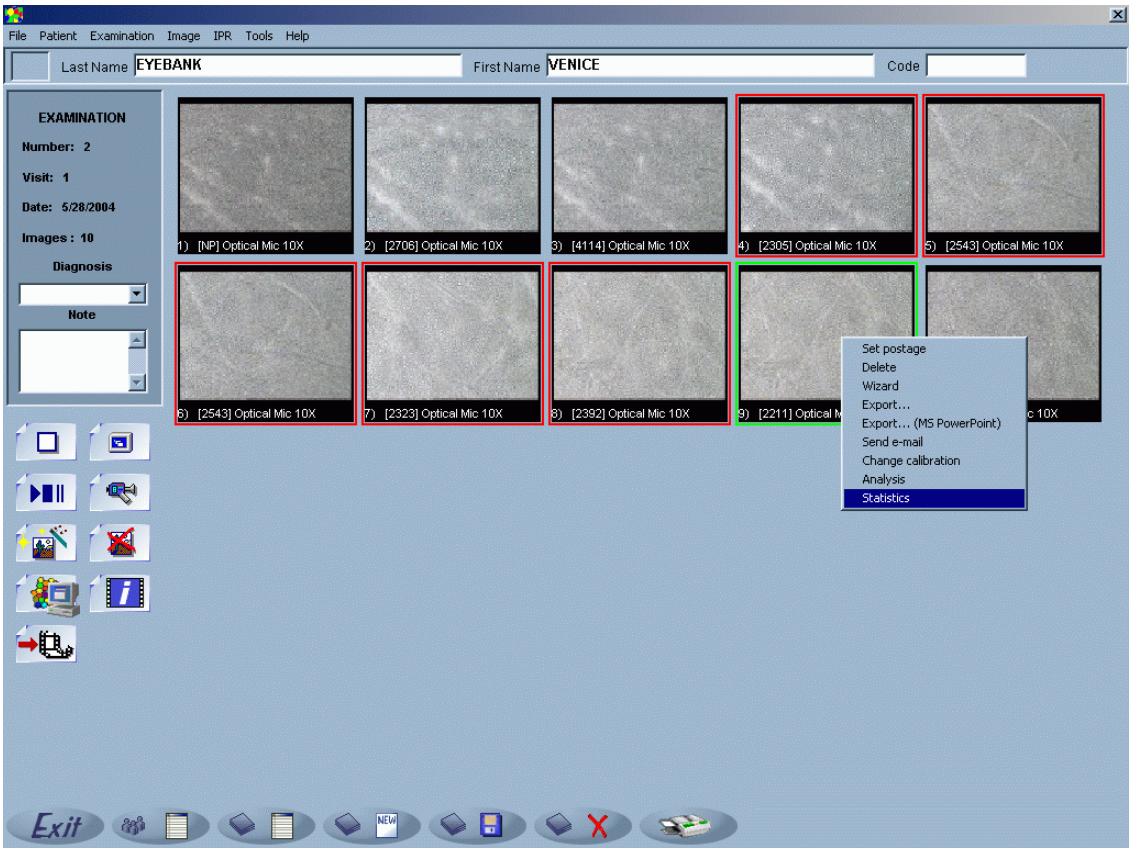


Figure 9 – Opening of the statistics panel.

The statistics panel (figure 10) shows information on:

- data related to the selected sample (source image and density value);
- statistical data (mean and standard deviation of densities, number of samples).

In order to select a sample, click inside the corresponding red square: this will also load the corresponding image in the background. By clicking again on the same square the display will get back to thumbnails-view mode.

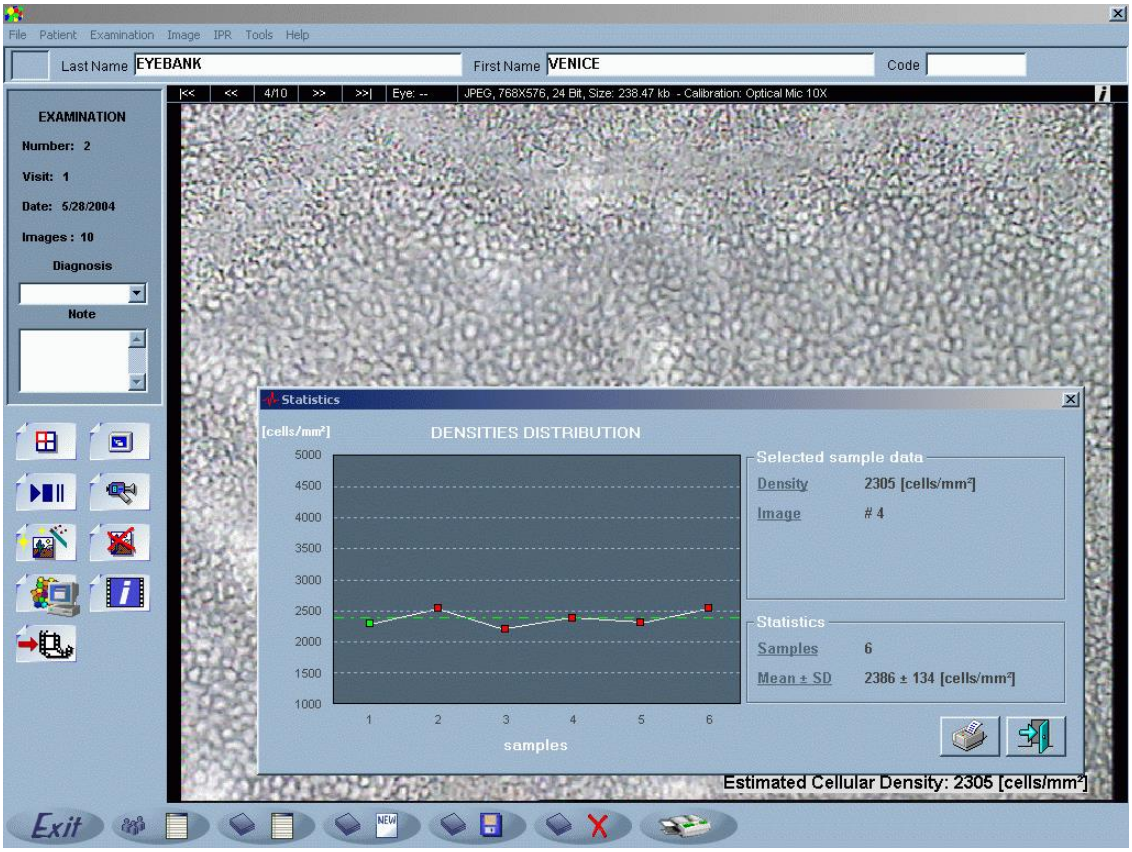


Figure 10 – Statistics panel

5. APPENDIX

5.1 EC declaration of Conformity

According to the Directive 98/79/EC Annex III concerning in vitro diagnostic medical device.

Application of Council Directives

In vitro diagnostic Medical Device Directive 98/79/EC and following amendments

Manufacturer

Nidek Technologies S.r.l.

Manufacturer address

Via dell'Artigianato, 6/A – 35020 Albignasego (Padova) – Italy

Type of equipment

Ophthalmic software

Class

General/Other IVD

Model

NAVIS - EyeBank

Versions

3.7.x