

sebia

NEUROSOFT SEBIA

Ref. 1115

INSTRUCTION MANUAL

2007/03

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1. FOREWORD

In order to provide maximum performance at all times, users of this software must become acquainted with the warnings given in this instructions for use.

Responsibilities of SEBIA:

SEBIA may only be deemed responsible for consequences on the software's reliability and specifications if the software is operated in accordance with the instructions herein.

The suggestions provided by the software are designed to help the interpretation, and are dedicated to the laboratory. These suggestions are only indicative.

WINDOWS® is trademark of Microsoft Corporation.

This software program and the present instruction manual are protected by Copyright Law and International Treaties.

Instructions for use printed on paper are available from SEBIA Technical Service.

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In an instruction for use, every modification from the previous version is written in red.

IMPORTANT: every previous version must be cancelled.

2. PRINCIPLE

NEUROSOFT SEBIA software is based on neural network which aims to provide help to the operator when interpreting migration patterns analysed in PROTEIN(6) program with CAPILLARYS automated system.

CAUTION: NEUROSOFT SEBIA is not intended to confirm the interpretation of patterns. NEUROSOFT SEBIA is designed as a support tool to provide the physician additional information in classifying patterns as normal or pathologic.

The neural network allows the software to « learn » to discriminate a normal fraction from an abnormal fraction, according to fractions from the reference database.

PLEASE NOTE: the interpretation algorithm was developed for migration patterns containing 6 fractions, therefore NEUROSOFT SEBIA cannot make interpretations for patterns with a different number of fractions.

NEUROSOFT SEBIA is designed to provide automatic discrimination of morphologically normal patterns from abnormal ones.

Automatic prediction allowed by NEUROSOFT SEBIA software is designed to:

- automatically analyze and classify the migration patterns (2 clusters are available: normal and abnormal),
- standardize the validation process in order to reduce the subjectivity factor of human analysis,
- drastically reduce the time took by the analysis (more than 200 analysis in less than 2 minutes),
- provide help to the operator when analyzing profiles.

3. INSTALLATION

Contact the SEBIA Technical Department.

4. DESCRIPTION OF THE « INTERPRETATIVE AID » MENU

Before running PHORESIS software, insert the USB key provided by SEBIA. This will add the menu « Interpretative aid » to the PHORESIS software which can be seen only from PROTEIN(6) analysis technique.

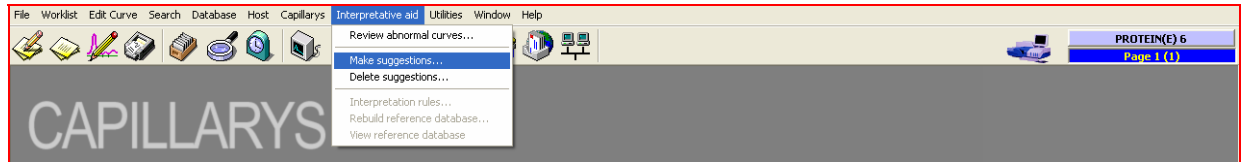


4.1. FUNCTION REVIEW ABNORMAL CURVES

This function allows the operator to visualize the curves labeled as « abnormal » by NEUROSOFT SEBIA.

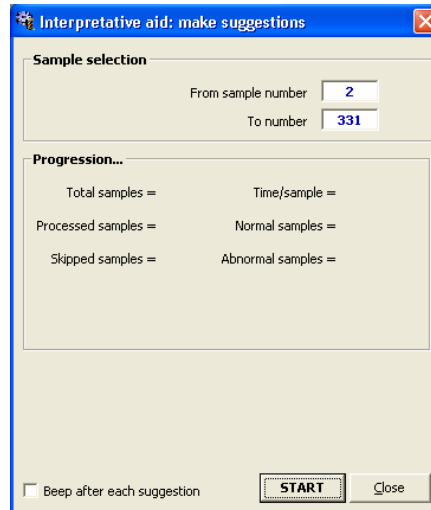


4.2. FUNCTION MAKE SUGGESTIONS

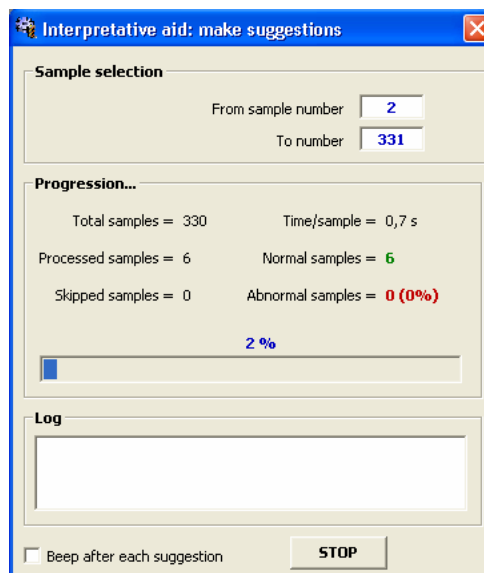


The function “Make Suggestions” results in the analysis of curves that have been selected by the operator

When selecting this function, the following dialog box will be displayed:



After the sample range has been selected, in the field “Sample Selection”, click on the “START” button. The analysis of the selected curves begins and a new section (Log) is displayed in the same dialog window.



Section « Sample selection »:

Data range to analyze.

Section « Progression »:

Progression of the interpretations.

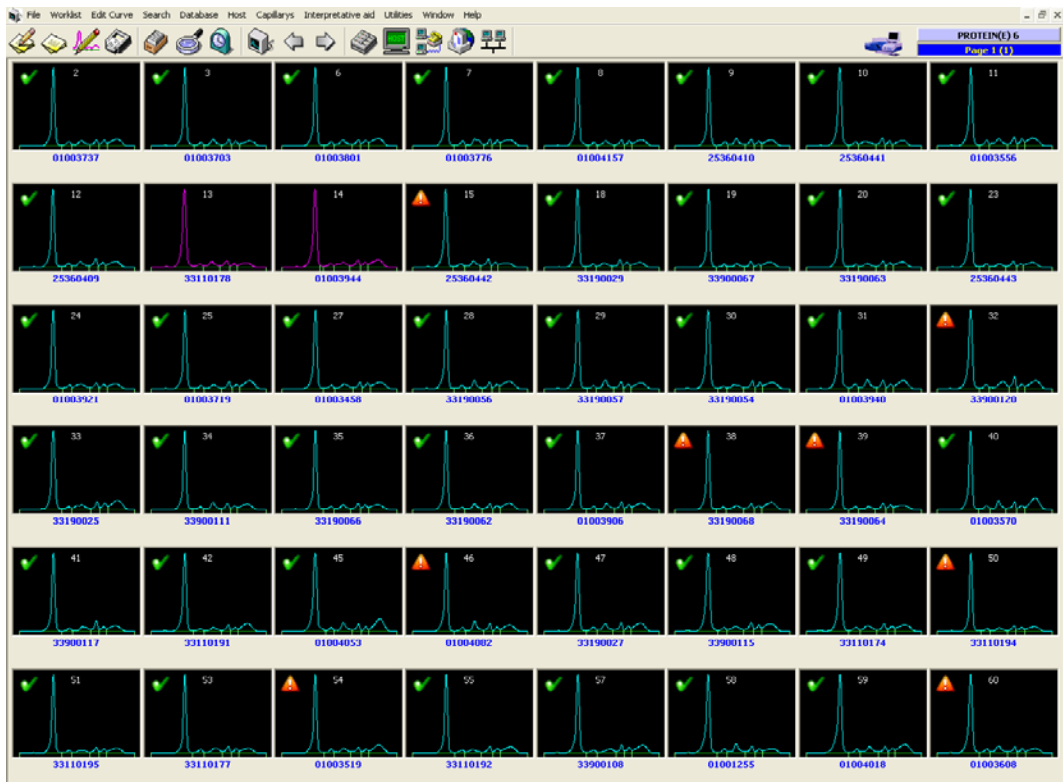
Section « Log »:


In this section possible warnings after analyzing the curves are displayed.


Icon « Beep after each suggestion »:

A beep will be emitted after each suggestion.

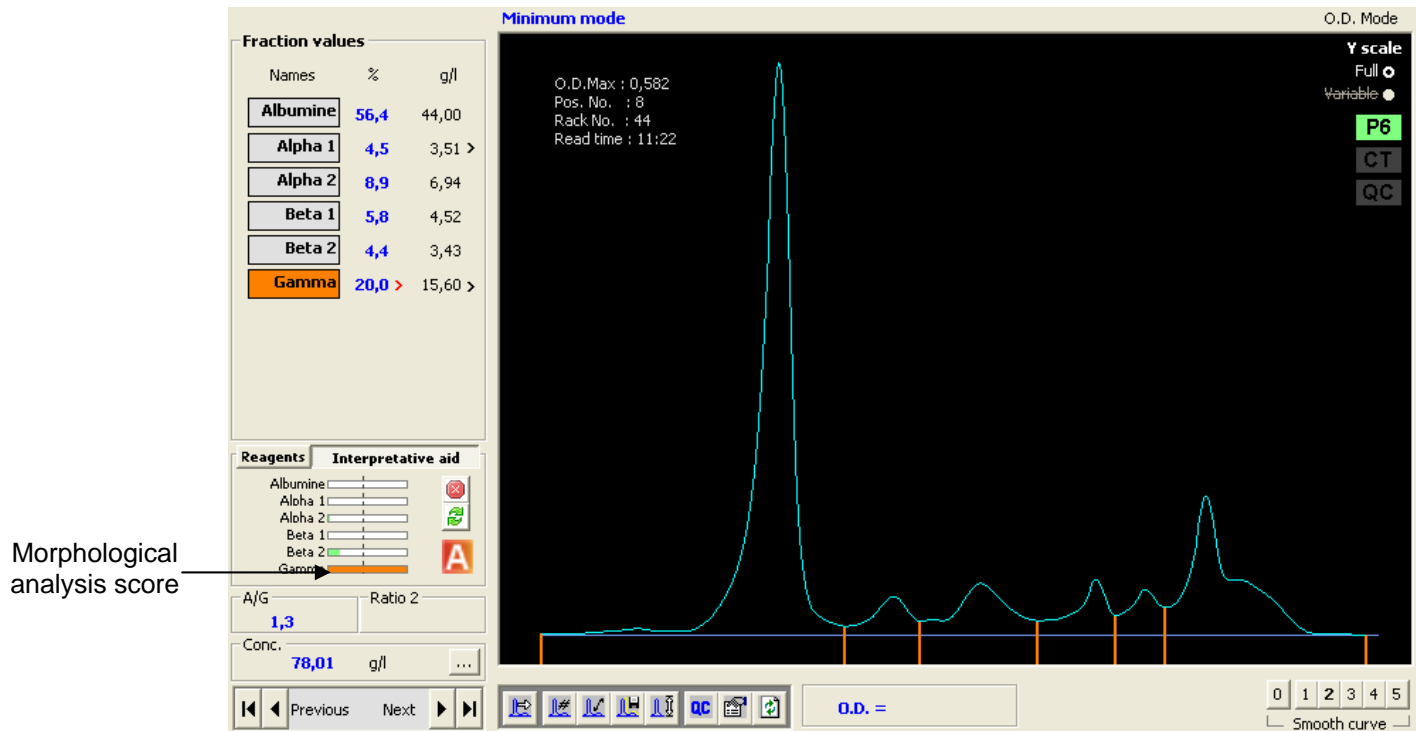
When the analysis is finished, an icon will be displayed on the curve mosaic window to show the suggestion:



The icon  means that the curve does not show any abnormal fraction.

The icon  means that the curve shows at least one abnormal fraction.


To open the curve review window, click on the curve:



In the “Fraction values” section, fractions displayed with an orange background are identified by NEUROSOFTE SEBIA as abnormal (in this example the Gamma fraction).

The “Interpretative aid” section displays a measure of the “abnormality” of a fraction in orange. The longer the orange area (bar) appears, the more the morphology of the fraction is different from the morphology of a normal fraction. **As long as this measure is lower than a threshold defined in the software, the fraction is deemed to be normal and the measure is displayed in green. If the measure is higher than this threshold the measure is displayed in orange and the fraction is deemed to be abnormal.**

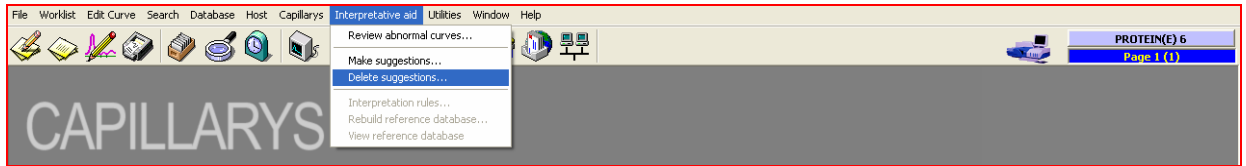
PLEASE NOTE: a pattern is deemed to be abnormal if at least one of its fraction is abnormal.

The icon  allows to remove the measure and to cancel the interpretation of the curve.

The icon  allows to run a new interpretation of the curve.

PLEASE NOTE: the « Interpretative aid » section now covers the area that previously displayed the reagents lot numbers. To see the lot numbers, click on “Reagents”.

4.3. FUNCTION DELETE SUGGESTIONS



When selecting this function, 2 consecutive dialog windows will be displayed allowing the operator to enter the range of curves where suggestions made by NEUROSOFT SEBIA are to be deleted.

5. TROUBLESHOOTING

The message « The input file collects a wrong number of minima » may appear when NEUROSOFT SEBIA is making suggestions, in the “Log” section, if the pattern has not identified exactly 6 fractions. Insert minima in the pattern in order to have exactly 6 fractions.

6. REGULATORY INFORMATION

SEBIA satisfies the following requirements:

- With regard to European Directives the following applies:
 - 98/79/EC on in vitro diagnostic medical devices (IVDMD).

- With regard to quality management standards the following applies:
 - EN ISO 9001 : 2000 - "Quality Management Systems - Requirements",
 - EN ISO 13485: 2003 - "Medical Devices - Quality management systems - Requirements for regulatory purposes".

- With regard to harmonized standards for EC marking (98/79/EC) of in vitro diagnostic medical devices (IVDMD) the following applies:
 - EN 591: 2001 - "Instructions for use for in vitro diagnostic instruments for professional use",
 - EN 980: 2004 - "Graphical symbols for use in the labeling of medical devices",
 - EN ISO 14971: 2001 - "Medical devices - Application of risk management to medical devices".

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