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VALAB

Réf. : VAL/31224/MU-08/ERM
Ed./Rév. : 1/A
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USER EXPRESS

VALAB DOCUMENT

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USER

EXPRESS

VALAB-EXPERT 7.01

- Automate connection 4.00
- Expert kernel:
  - Biochemistry: 3.04
  - Coagulation: 2.02
  - Blood gases: 1.05
  - Hematology: 2.05

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SUMMARY

1 INTRODUCTION

Valab is a decision-making expert system for automatic biological validation of reports. Born of active co-operation with research, the system does not consider the problem of biological validation as a machine (algorithmic) but in a global and contextual manner as the biologist does. The tools used to create the product, the partnership implemented for the creation of the knowledge base, and the methods of evaluation make Valab one of the first decision-making expert systems.

Valab is integrated to the laboratory as a PC or compatible microcomputer. It is connected to the LIS (Laboratory Informatic System) as an automated analytical system validating biological reports. When a complete or partial report is to be validated (at least for the parameters involved), the LIS transmits it to VALAB which expertises it in less than a second and immediately sends its answer back to the LIS. In fact we can talk of a dual answer: Firstly a signal indicates whether the analysis / report is medically consistent or not and may be delivered to the prescriber or has to be expertised by the biologist himself. In such a case, Valab sends a comment: A code points out the result(s) that causes the rejection - not necessarily the most pathological one(s). This coded result can be either displayed on the screen by the LIS in case of a human-driven validation session, or directly printed on the result sheet if the validation is carried out on paper. The 5 groups of result making up the code are as follows:

- V: this analysis seems to relate to the context,
- D: the report is globally critical,
- A: the divergence between this parameter and its Anteriority doesn't seem to relate to the context,
- C: this parameter doesn't seem to be Correlated to the context,
- P: panic value. This analysis is outside the validation field that has been specified to me.

The code comprises at least one of these items of information and these items can be combined, for example CP and AP.

Groups A, C and P may carry further information concerning expertise of the parameter (see § 2).

Valab requires minimum maintenance. However you will have to see to it that the units are properly set, and possibly to adapt the limits to your working conditions, but most of all to teach it the specialty of your correspondents (see § 7.2.5).

2 THE COGNITIVE MODEL (REASONING)

2.1 General principles

The construction of human reasoning and the behaviour, which arises from it, are the result of a set of elementary intellectual processes, both conscious (knowledge) and unconscious (experience).

The development of an expert system consists of:

1. Revealing the set of elementary processes,
2. Constructing a model capable of exploiting these processes,
3. Validating the expertise generated.

2.2 Principle

The "intelligent" model, which is the basis of Valab, consists of putting to work all processes linked with the interpretation of a result, using a strategy close to that of human reasoning. Whether or not a result is acceptable depends on a combination of reasonings and not on classification in a pathological model. The latter point makes it difficult to give an exhaustive description of the working of the expert system, because the result never depends on the application of an exclusive rule, but on the contrary, on the application of all the applicable rules.

A simple example should make this clearer: Let us consider a patient for whom we have the clinical information "hepatitis" and who has a very abnormal GOT level at 800 IU 37°: These two items of information are compatible and can be modelled by a simple rule. If, however, this patient also has a normal GPT level, at 20 IU 37°, it becomes evident that if this new element is taken into account, the whole becomes incoherent. Only a "combinatory" approach makes it possible to describe complex models on this mode.

The following categories of information are made use of in the expertise:

- **Demographic**: age, sex,
- **Contextual**: department, emergency, hospitalisation,
- **Medical**: therapeutical and clinical information (TCI),

- **Technical**: complementary information (CI),
- **Inter-parametric**: coherence of the results, taking into account on the one hand the correlations between the various tests, and on the other hand the variation over time of the overall results (inter-parametric kinetics).

2.3 Strategy

The strategy used by the expert system to interpret the acceptability of each parameter is made up of several stages:

1. **Situate** the value observed according to demography (age and sex): normal, low or high value. Hemoglobin at 16 grams does not have the same significance in a man as in a woman or a neonate.
2. **Situate** the present result in relation to a previous result, if there is one: decrease / increase and improvement / worsening.
3. **Trigger** the rules applicable to the situation which has previously been analysed:
   - without anteriority: correlation rules corresponding to a lower or higher tendency,
   - with anteriority: rules of anteriority corresponding to a lower or higher tendency.

   Each set of rules contains on the one hand positive rules, which allow validation of (normally) abnormal results, and on the other hand negative rules which prevent validation of (abnormally) normal results.
4. Establish a synthesis on the acceptability of the result:
   - **V**: validated,
   - **A**: not validated because of "Anteriority",
   - **C**: not validated because of "Correlation",
   - **P**: not validated because of "Panic value",
   - **D**: not validated because of "Domain".

This synthesis may be restricted to the above letters, but it may be completed by:

- adding to **A**, **B** and **C** the symbols < and > which indicate the tendency (lower or higher),

- separating **A** into **a** or **A**, **C** into **c** or **C** indicating the lack of justification (small letter) or the presence of at least one negative rule (capital letter).

These parameters are submitted to expertise in a particular order: this order makes up a "hierarchy".

2.4 Results

The meaning of the results given by Valab is as follows:

- **V**: this normal or pathological result, with or without anteriority, is validated. The value observed is both compatible and coherent with the other information available in the report, and in addition it comes into the field of competence of the system.
- **P**: this result is not validated as its value is outside the competence of the system. This information, called a "panic value" (for example, high potassium at 8 mmol/l) has priority over the notions of "Correlation" and "Anteriority". Each laboratory can define and set the extreme limits, which are suited to its activity.

  Valab can give greater precision to this result by completing **P** by one of the two symbols <, >:

  - **P<**: this result is not validated because its value is below the lower limit.
  - **P>**: this result is not validated because its value is above the upper limit.
- **D**: this code means that the result is not validated because there is at least one element in the report whose presence makes it impossible to validate the report, which is outside the "Domain" of Valab. This type of information is either part of the expertise, for example TCI "malaria", or arises from the way in which the parameters of the system have been set by the user, for example all patients with "infectious diseases".
- **A**: this result is not validated for a reason connected with the "Anteriority" of the parameter. This notion integrates the definition of the delta-check and the dividing point, for the lower ranges, and adds a dynamic dimension by the combination of rules. These rules modulate the acceptability of the variation observed according to the demographic or contextual data, and above all according to the kinetics (direction of change, amplitude, value) of the other parameters.

Valab can give greater precision to this result by replacing **A** by **a** or **A** and by completing it with one of the two symbols < and >:

- **A<**: this result is not validated for a reason related to the "Anteriority" of the parameter. Also, the validation space has been restricted by at least one negative rule (**A**) and the value decreases in relation to the previous value (<).
- **A>**: this result is not validated for a reason related to the "Anteriority" of the parameter. Also, the validation space has been restricted by at least one negative rule (**A**) and the value increases in relation to the previous value (>).
- **a<**: this result is not validated because of lack of justification or inadequate justification accounting for the variation of the parameter in relation to its delta-check (**a**). Also, the value decreases in relation to its anteriority (<).
- **a>**: this result is not validated because of lack of justification or inadequate justification accounting for the variation of the parameter in relation to its delta-check (**a**). Also, the value increases in relation to its anteriority (>).

The intelligence of the system consists on the one hand in its capacity to validate a large variation (greater than the delta-check) if this variation is consistent with the other available data, and on the other hand in its capacity to block a slight or nil variation (less than the delta-check) if this is incompatible with the variations observed in the other parameters.

- **C**: this result is not validated for a reason connected with the "Correlation" of the parameter. Beyond the normal values weighted for age and sex, this concept gives a dynamic definition of the acceptability of the result observed according to the contextual data and the values of the other parameters.

  Valab can give greater precision to this result by replacing C by c or C and by completing it with one of the two symbols < and >:

  - **C<**: this result is not validated for a reason related to the "Correlation" of the parameter. Also, the validation space has been restricted by at least one negative rule (**C**) and the value is low in relation to the median of the correlation limits, corrected according to demography (<).
  - **C>**: this result is not validated for a reason related to the "Correlation" of the parameter. Also, the validation space has

been restricted by at least one negative rule (**C**) and the value is high in relation to the median of the correlation limits, corrected according to demography (>).

- **c<**: this result is not validated because of the lack of justification or inadequate justification accounting for the value of the parameter in relation to its normal levels (**c**). Also, the value is low in relation to the median of the correlation limits, corrected according to demography (<).
- **c>**: this result is not validated because of the lack of justification or inadequate justification accounting for the value of the parameter in relation to its normal levels (**c**). Also, the value is high in relation to the median of the correlation limits, corrected according to demography (>).

As before, the intelligence of the system consists on the one hand in its capacity to validate a pathological result if this result is consistent with the other data (normally abnormal), and on the other hand in its capacity to block a normal result if it is incompatible with other results (abnormally normal).

A "Correlation" error may thus arise from:

- either the existence of a negative correlation between several incompatible elements (**C**),
- or the absence or simply insufficiency of correlations which would make it possible to justify the abnormal result (**c**). The latter case is the more frequent and corresponds, for example, to isolated hyperglycaemia when there is no notion of "endocrinology" in the origin of the report (possible diabetes) and no notion of a reanimation or IC unit (possible glucose infusion).

Flags **V**, **A**, **P**, **C**, **D** are used in version 5.02 and earlier versions. Flags **V**, **A**, **P**, **C**, **D**, **A<**, **A>**, **a<**, **a>**, **P<**, **P>**, **C<**, **C>**, **c<**, **c>** are used in version 7.01 for simulation and are proposed in extended mode for connection. The parameters of all these flags can be set in customized mode (see § 7.2.4). Care should be taken, the set of flags should not be modified if the connection cannot handle it.

Furthermore, the greater the anomaly (i.e. the further the value departs from the normal range), the more validation will require the presence in the report of elements of correlation which by their weight and number will justify the result. For example, extremely high serum potassium cannot be justified by the notion of nephrology alone, but if the serum creatinine, urea, and calcium results are also available...

2.5 Conclusion

These last two groups of results (**A**) (**C**) represent the true expertise of Valab in its ability to reproduce the biologist's reasoning. However, it is realistic to consider that the original configuration is a compromise, whose functioning will put safety before efficiency. The user therefore has to adapt this tool according to the requirements of safety and performance on the one hand, and on the other hand according to the particular context in which he or she works (recruitment population, technique used).

In order to adapt the system, the user has the possibility of setting the parameters of the limits and the delta-check for each test, and the possibility of adjusting the "weight" of the rules by modifying the "Sensitivity" of the system. "Sensitivity" can be modified (neutral value equal to 1) selectively and independently for the "Anteriority" and "Correlation" of each parameter so as to make the system more permissive (value greater than 1) or more restrictive (value less than 1) in accepting an anomaly.

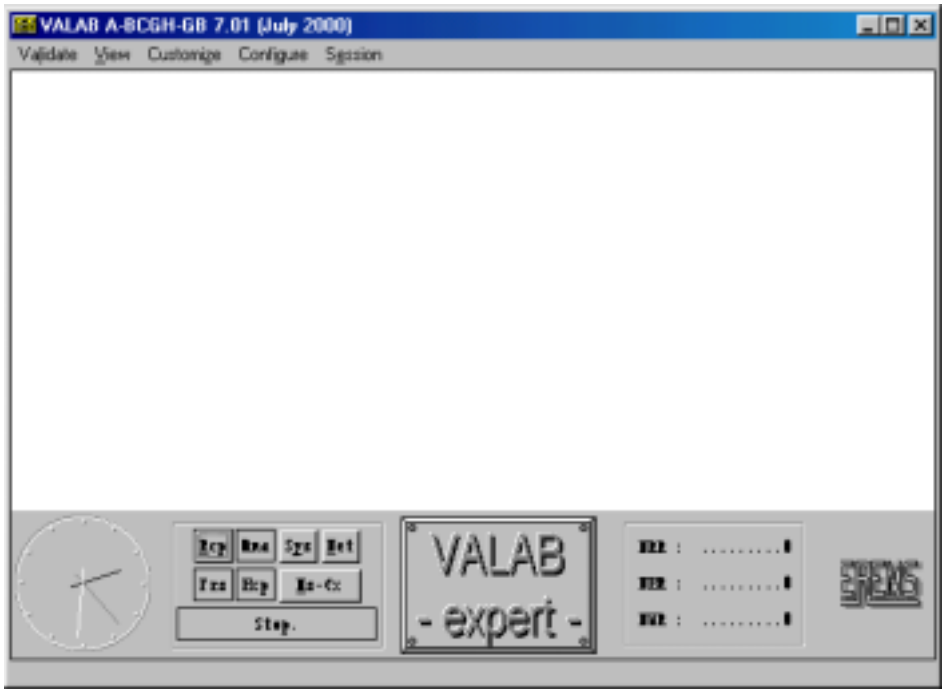
The user is assisted in adapting the system by the general statistics and by the alarms, which indicate the parameters whose settings may require modification.

3 USER EXPRESS: GENERAL INFORMATION

The Valab 7.01 software is a 16-bit Windows® application. For all information concerning the use of such an application (change of dimension, window closure, menus, shortcuts, pointing device...), see the Windows® documentation.

The following paragraphs explain the particularities of the application: composition of the main window of the application, general role of the buttons and indicator lights.

3.1 Main window of the application

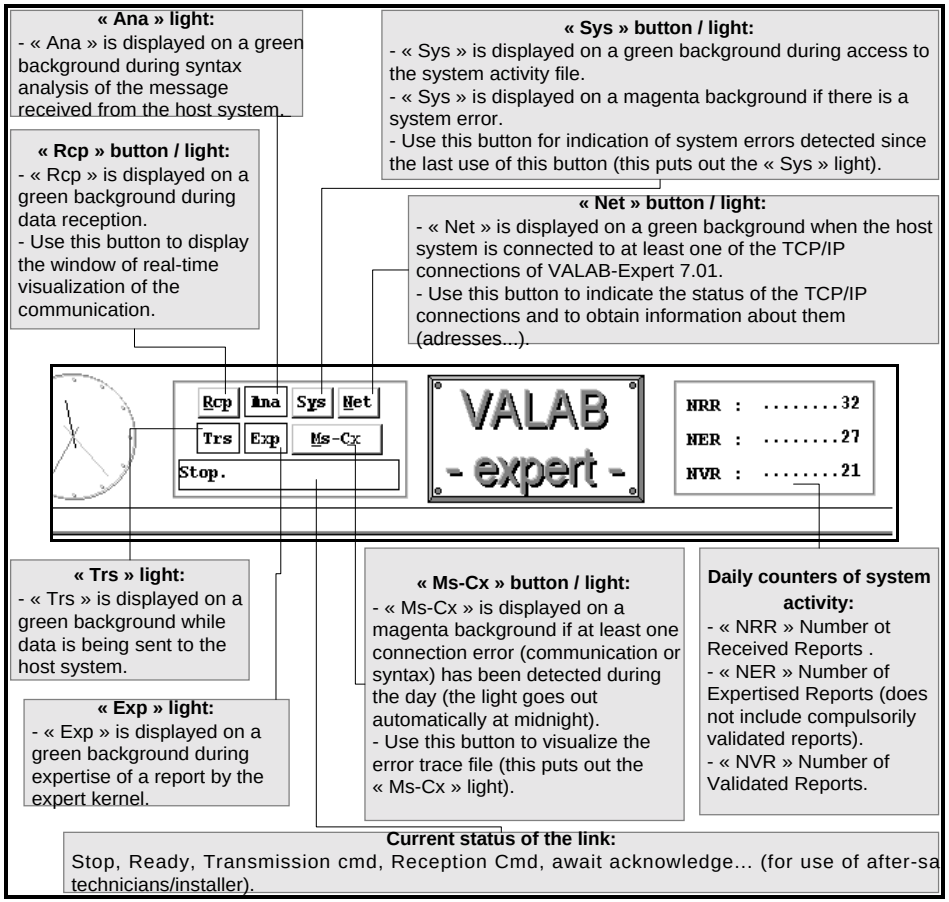


The window of the Valab 7.01 application is made up of 5 zones, which are, from top to bottom:

- the name and the version of the application,
- the main menu,
- the middle zone which is occupied by the current interactive operation (data entry, display...),

- a permanent status panel showing, among others, the clock, the buttons and indicator lights which make it possible to follow the current operations (connection, expertise...), to open certain sessions (real time communication display, error tracing…) and to be informed of the current status of the link and the counters,
- a help chain explaining the role of the current data field.

3.2 Valab status panel



This panel is updated in real time: the clock always indicates the time, the numbers on the counters increase as the reports are received in automatic mode, the indicator lights

change colour according to the operations carried out, and the current status of the link is displayed.

New : a short message of explanation pops up when the cursor is positioned on the various buttons and indicator lights of the status panel.

The status panel buttons are always active if there is no other window in the foreground:

- **"Rcp"**: real-time display of the communication; all data received or transmitted via the connection(s) are displayed in their current state. Characters from 00h to 20h and from 80h to FFh are displayed in hexadecimal numeration and underlined.
- **"Ms-Cx"**: "Error Tracing" file editing. This file stores all errors which occurred during data transfer between Valab and the LIS - CX-ERR - (e.g. max-time or checksum errors...), and all errors in the interpretation of received messages - MS-ERR - (e.g. unknown expressions, incoherent date...). When this button is coloured magenta, an error has occurred since the last consultation of the error tracing file; if not, it is neutral in colour.
- **"Net"**: status of the network connection; no network connection (neutral light) or there is a current network connections (green light). Allows also to obtain information about the current network connections.
- **"Sys"**: access to the statistics file (green light) and system errors (red light); problem with the statistics file, with the error tracing file or lack of space on the disk for backup of reports.

Remark :

If the clock stops, there may be a problem with the functioning of the hardware or software.

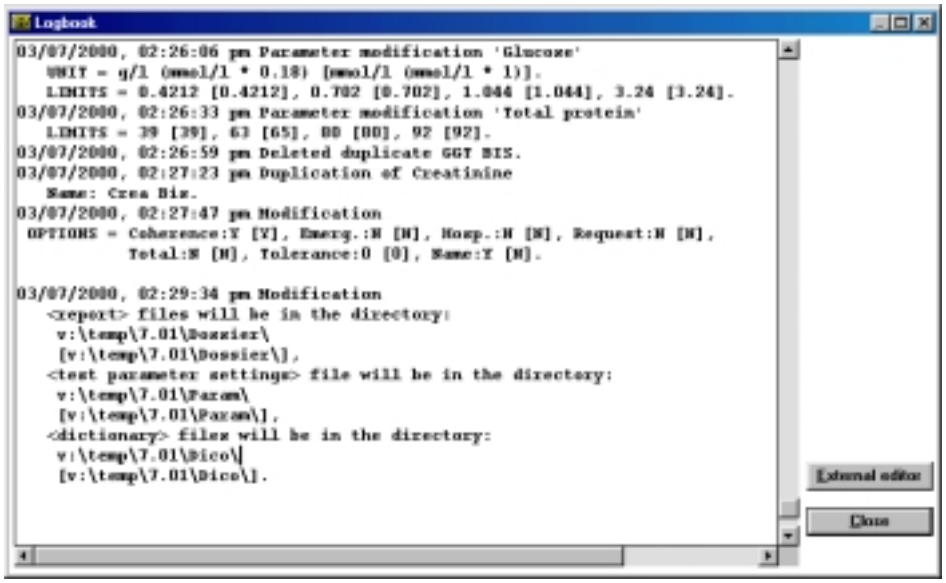
3.3 Logbook

The logbook contains all the modifications carried out by the user in the parameter setting of Valab: parameters of the analyses, expertise options, additions of duplicates, max levels, directories. The values between square brackets [] correspond to the earlier values. It can be consulted in several ways in Valab:

- using the **"Logbook"** button in *View* \ *Tests*,
- using the **"Logbook"** button in *Customize* \ *Tests*,

- using the **"Logbook"** button in *Customize \ Options*.

It is encrypted and may be cut in the Valab editor if it is too large. However, the **"External editor"** button edits the whole of this file and enables it to be printed. When this file is opened under this editor, a "tmp.txt" file is created in text format.

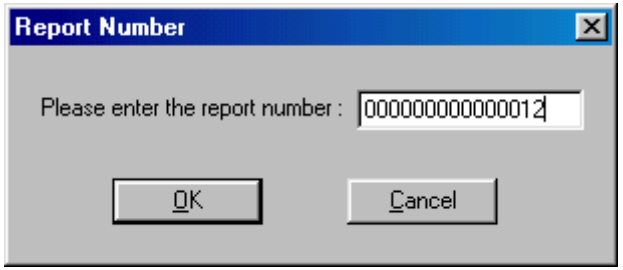


3.4 Connection trace (New)

This function allows to trace a report, through all the frames that have been correctly exchanged, i.e. acknowledged, in automatic mode during the past 48 hours, between the LIS and Valab : date, contents of reports, expertise sent, acknowledgement. This trace can be displayed in the session *Validate/Simulation* :

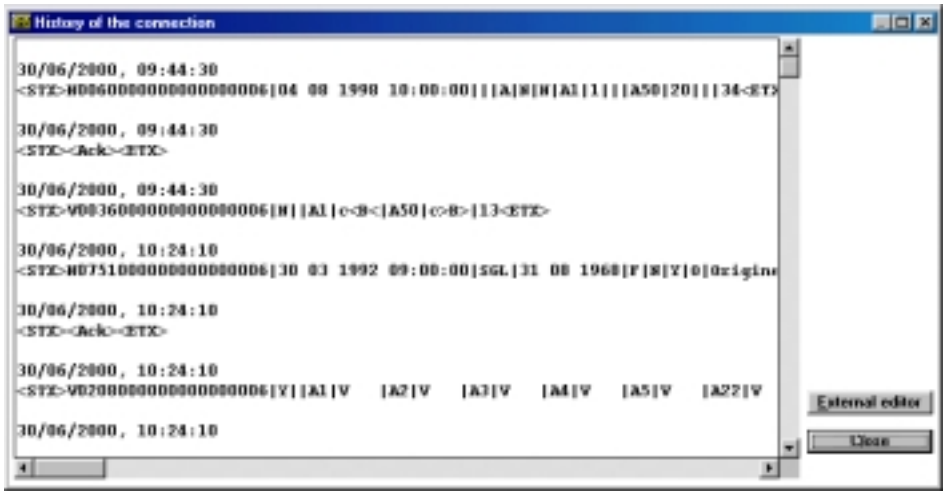
- By clicking on the **"Trace"** button.

It is possible to obtain, either directly the trace of the currently displayed report, or, when no report is displayed, the trace of a saved report, by typing in its report number.



As above, the file is encrypted, and the button **"External Editor"** edits it as a "tmp.txt" file and allows to print it.

This connection trace provides Valab with the complete tracability of the various stages of expertise of a report, especially relevant in the case of successive receptions of reports in partial validation.



Remark :

In order to have this connection trace, the option "Keep a trace of the messages…" in the menu *Configure / Connection / Options* must be set on YES (selection by default).

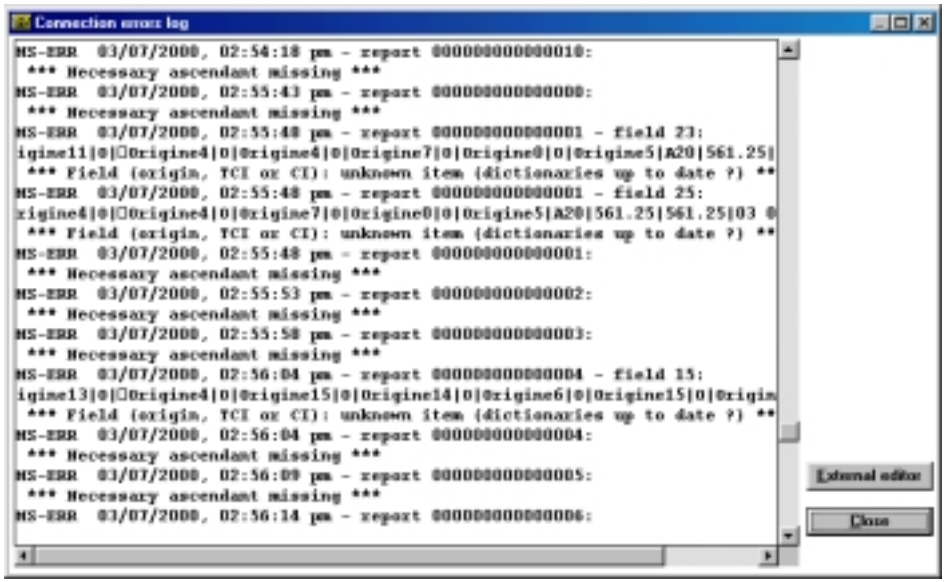
3.5 Error tracing

In this file are stored all anomalies which occurred during the connection or in the syntax. In this case, the message comes after a part of the frame received from the LIS,

a " " showing up before the unknown word or the syntax error. The "Error tracing" file may be read either:

- by the "**Ms-Cx**" button in the status panel when there is no window in the foreground,
- by the "**Error tracing**" button in *View \ Dictionaries*,
- by the "**Error tracing**" button in *Configure \ Connection \ Dictionaries*.

If an error has occurred since the last consultation, the "**Ms-Cx**" button is coloured magenta. The light does not show after the errors have been consulted.



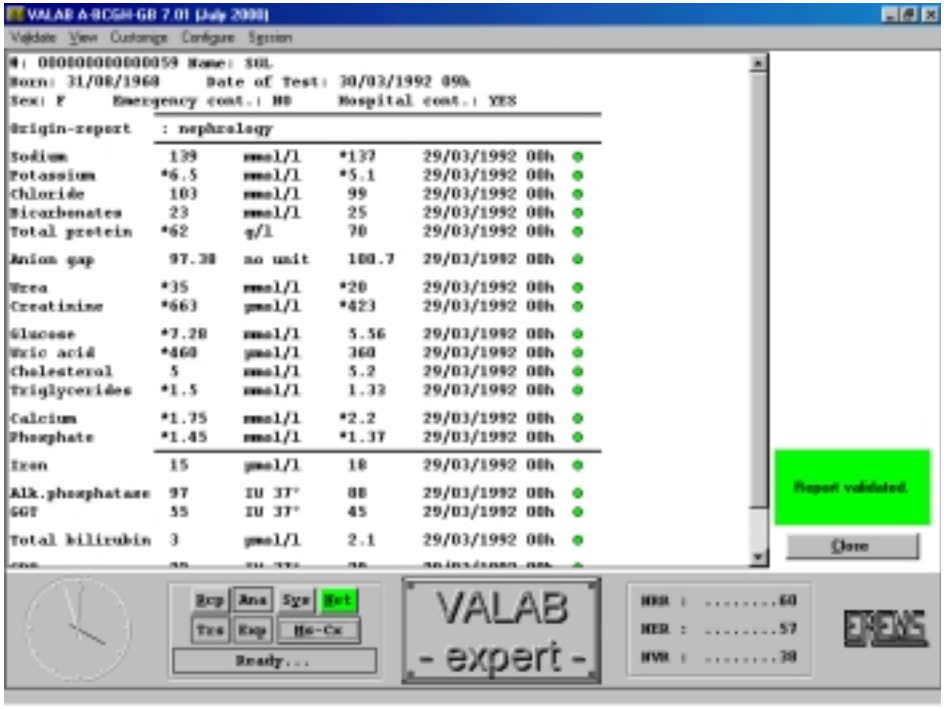
It should be noted that syntax errors due to a symbolic result being transmitted instead of a numerical result can be avoided by entering in the dictionary of complementary information (CI) the symbolic results which appear in the place of the numerical results.

Any logic operator (>, <, =, >=, <=) which comes with the result of a numeric analysis does not induce a syntax error.

4 THE VALIDATE MENU

4.1 Automatic

In *AUTOMATIC*, the report being expertised is displayed as follows:



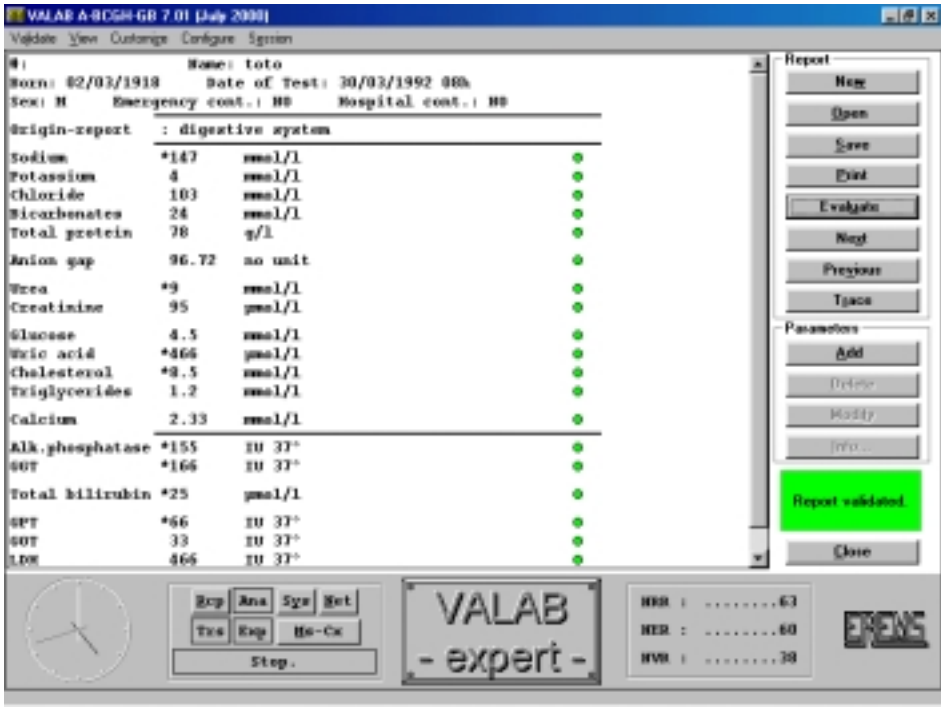
It is the main function of the software. As soon as the option is selected, Valab is connected and can expertise the reports sent to it through the link (Serial or Network). The reports are displayed on the screen in real time, with their expertise which uses extended codes. In order to leave the *Automatic* mode, the operator uses the **"Close"** button and confirms, using the password, whether the current session is closed (no operation during the last 5 minutes or session closed by the user).

When the automated system connection is activated, other options are accessible and can be opened: consultation of analyses, dictionaries, configuration, system activity, configuration of the printer and the password.

Depending on the power of the PC and the influx of reports received by the automated system, other Windows® applications can be used at the same time.

4.2 Simulation

In *Simulation*, the report being expertised appears as follows:



After expertise, tests which are outside normal limits, corrected according to the population (age, sex), are marked by the character "*". The tests not validated by Valab are commented by the extended flags:

- **A**<, **A**>, **a**<, **a**> for Anteriority: this report does not contain sufficient elements to justify the kinetics of this parameter in relation to the previous result, or it contains contradictory information.
- **C**<, **C**>, **c**<, **c**> for Correlation: this report does not contain sufficient elements to justify the difference of this parameter from normal levels, or it contains contradictory information.

- **P<**, **P>** for Panic Value: this parameter is outside the extreme limits, which have been set.
- **D** for Domain: this parameter would have been validated by Valab, but the report must be validated by a biologist. This report is outside Valab's Domain.

(see § 2.4 for more detailed information).

A zone on the right of the report indicates the general status of the report: "Not evaluated" in neutral colour, "Report validated" in green, "Outside extreme limits" or "Report not validated" in magenta. The report is globally validated if all the tests are followed by a green point. On the other hand, it is rejected if one test or more is followed by the flags in red, or if all are followed by a "D".

Please notice that for its reasoning the system computes the anion gap[1], or at least the delta Na-Cl[2] and the immature granulocytes[3]. Moreover, the presence of leukoblasts and / or abnormal lymphocytes is systematically obstructing. In the same way, some symbolic parameters items (therapeutical and / or clinical information, complementary information, red cell morphology, circulating anti coagulant, activated protein C resistance) reject the report with a (**D**)omain error either systematically or if no anteriority is known.

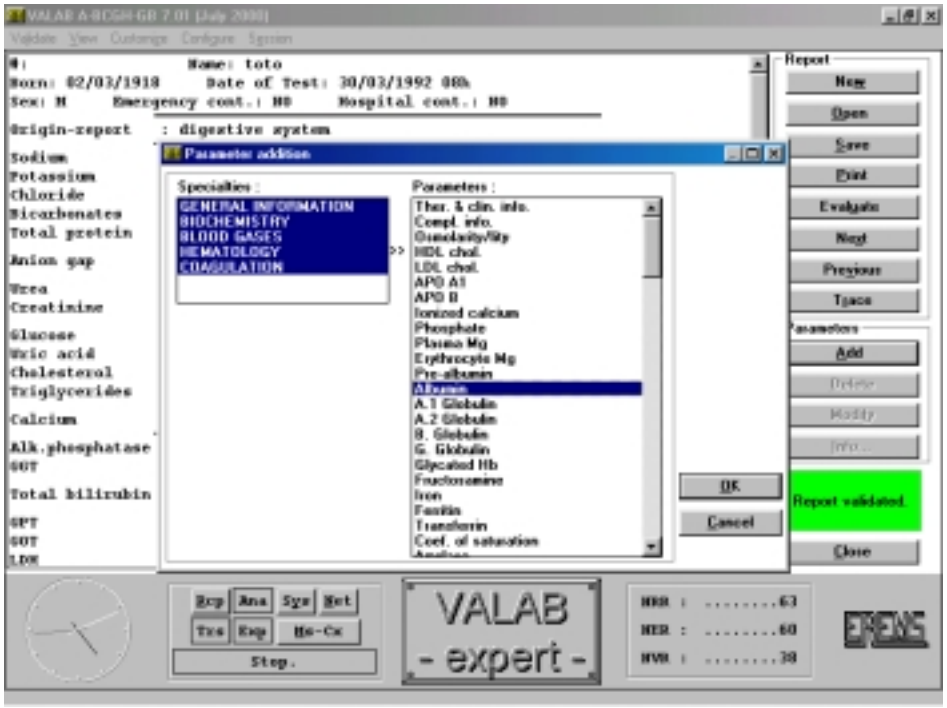
Simulation makes it possible to observe the behaviour of the expert system on a report which is dynamically made up using the buttons or which is loaded from the disk:

- **"New"** deletes the entire content of the current report and initializes the heading by default (dates, emergency and hospital contexts),
- **"Open"** reads a report on the disk,
- **"Save"** saves the current report,
- **"Print"** prints the current report,
- **"Evaluate"** expertises the current report,
- **"Next"** reads another report archived on the disk,
- **"Previous"** allows to display the previous report **(New)**,
- **"Trace"** allows to obtain the trace of the connection for each report **(New :** see § 3.4 for more detailed information),
- **"Add"** adds an item to the current report,
- **"Delete"** deletes the selected item from the report,
- **"Modify"** modifies the values of the selected item,

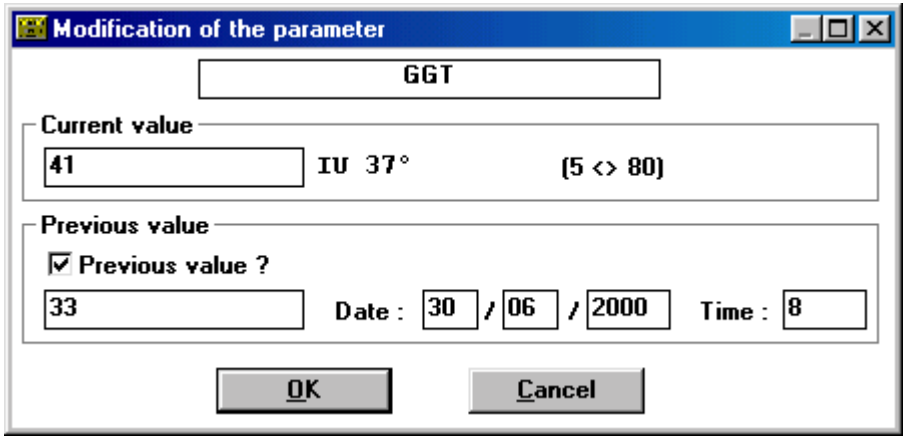
[1] If the electrolyte tests are present (Na, Cl, HCO3, K, Prot).
[2] If Na and Cl are present.
[3] If Promyelocytes and / or Myelocytes and / or Metamyelocytes are present.

- **"Info"** provides information concerning the expertise of the current report,
- **"Close"** leaves *Simulation* mode.

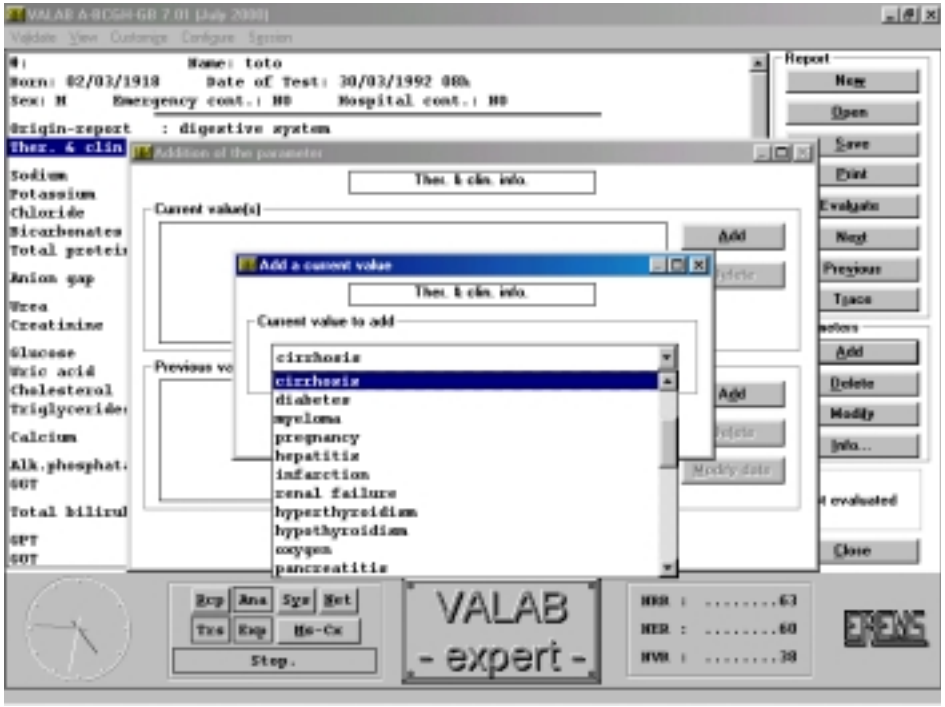
The **"Add"** button opens a window which selects the specialty(ies). It updates the list of parameters, which are not yet included in the report. The user completes the report by selecting one of the parameters of the list (by double clicking or by the **"OK"** button), and he then enters its values. When all the parameters are entered, the **"Cancel"** button returns to the window presenting the report, which has not yet been expertised.



A numerical parameter can be added by entering the present value, the previous value and its date if this result is known. In this case, the box **"Previous value"** must be ticked for it to be taken into account.



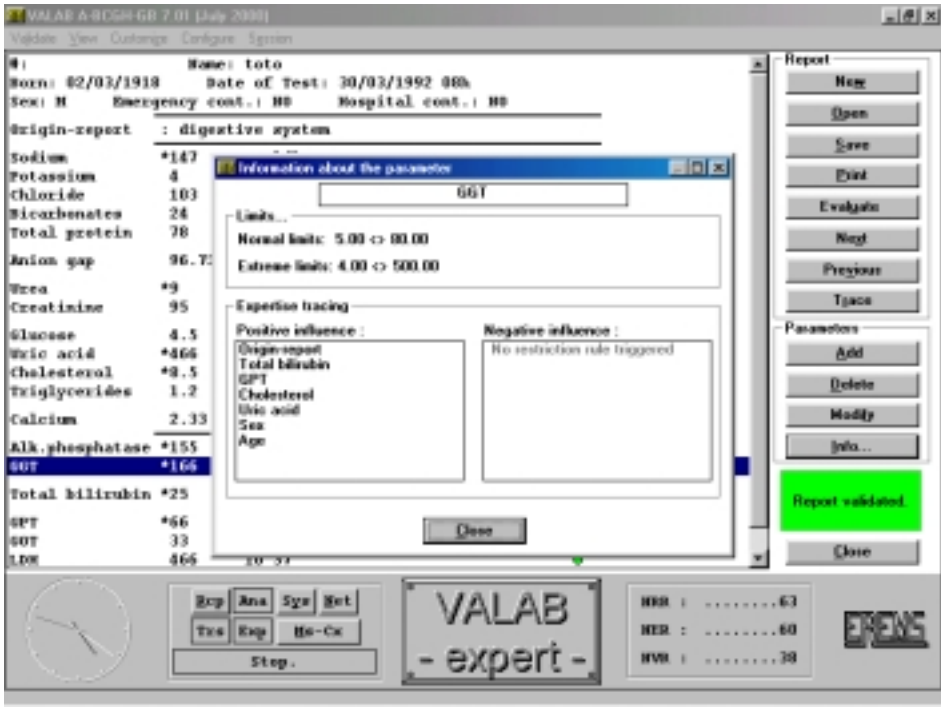
Symbolic information can be added by selecting items of the present value and items of the previous value and by entering its date if these results are known. It is then possible to delete a present value and / or a previous value and modify the date of the previous result selected.



When the report is complete, the expertise is started by the **"Evaluate"** button, and the overall result as well as the results of each parameter are displayed.

The **"Info"** button displays the current limits and traces the expertise by giving the list of all items of information which have influenced acceptance or rejection of the parameter (in decreasing order: the most important at the top of the list).

The **"Next"** button automatically displays a stored report. Sequential scrolling of all the reports in the directory of the *Configure \ System \ Directories* option is obtained by repeated use of the key. **New :** the **"Previous"** button allows previous reports to be displayed, by reverse order scrolling.

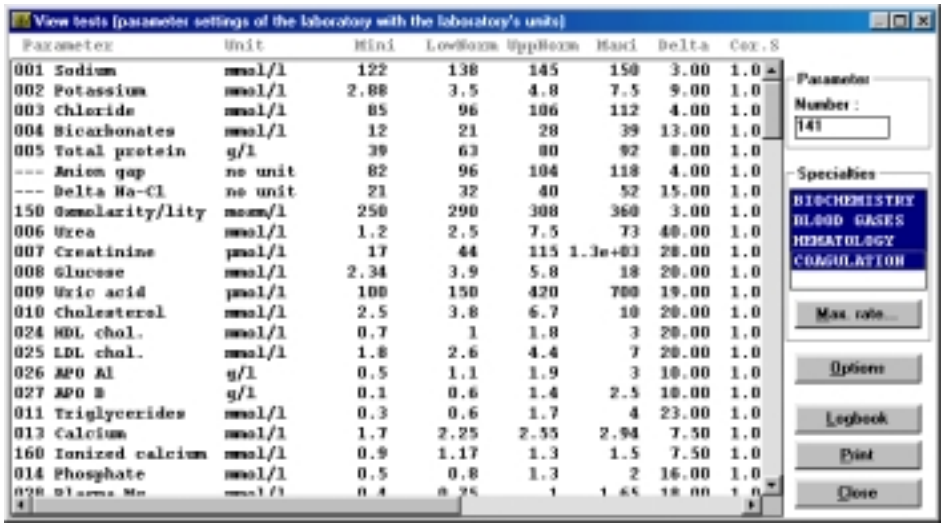


New : After closing and opening again a *Validate / Simulation* session, the current report is automatically re-displayed. This is especially useful while tuning the system using the simulation mode : it is not necessary to save and reload the current report every time the simulation session is closed for changing parameters or options and opened again.

5 THE VIEW MENU

5.1 Tests

The first option in the *View* menu is concerned with parameter settings. It allows display in a single window of all the parameters relating to analyses in one given specialty or more (Biochemistry, Coagulation, Blood Gases, Hematology). It is possible to select a single specialty by clicking on it with the mouse, or several specialties by using the Shift or Ctrl keys when labelling (see the Windows® manual). The analyses and their parameter settings are then displayed in the order in which they are edited. A vertical scroll bar scrolls this list and the number of items it contains is displayed for information. A horizontal scroll bar makes it possible to see the extreme right of the parameters, which does not appear in the window.

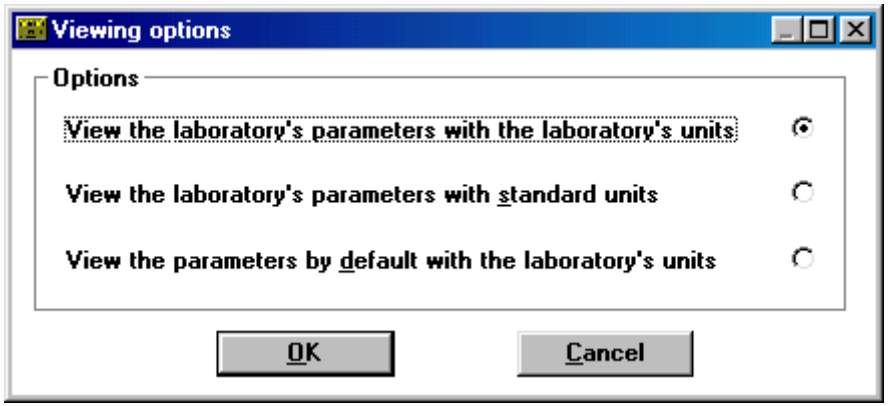


From left to right, the following information is displayed:

- number of the parameter in three characters,
- name of the parameter,
- unit,
- minimal extreme limit,
- lower normal limit,
- upper normal limit,
- maximal extreme limit,
- delta-check,
- correlation sensitivity,
- anteriority sensitivity,
- limit of validity of anteriority,
- a remark (calculated parameter or LIS (Laboratory Information System) unit converted by Valab),
- the conversion factor in a standard unit.

The following buttons can be accessed:

- **"Max. rate..."**, to visualize the max rate by specialty (see § 6.1.1),
- **"Options"**, to view the parameter setting under different formats **(New)**,
- **"Logbook"**, to edit the logbook (see § 3.3),
- **"Print"**, to print the parameter setting of the selected specialty(ies) (see § 7.1.3),
- **"Close"**, to close the window.



New : the **"Options"** button allows viewing the parameter settings under three different formats :

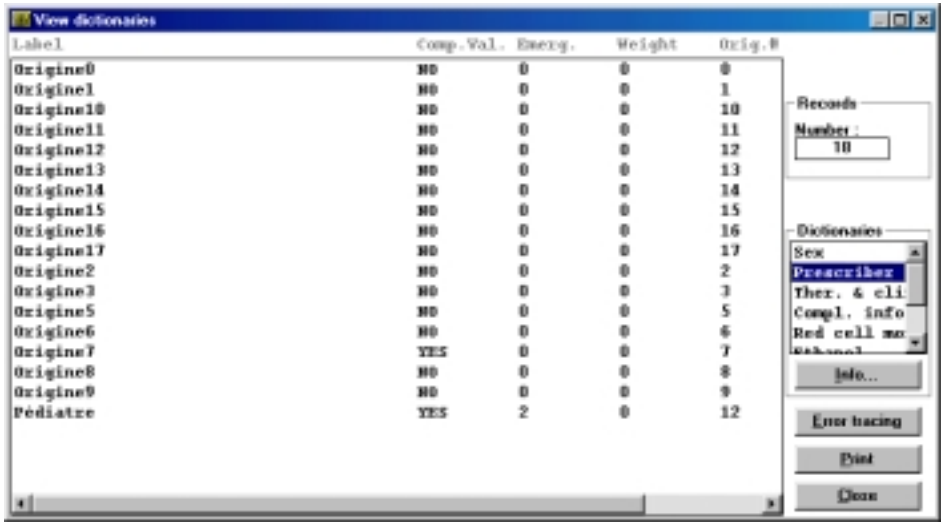
- The laboratory's parameters with the laboratory's units,
- The laboratory's parameters with the standard units (to facilitate assistance and maintenance),
- The parameters by default with the laboratory's units (to evaluate the differences).

5.2 Dictionaries

The *Dictionaries* option of the *View* menu displays the content of the designated dictionary whose labels can be exploited by the system. The number of records displayed corresponds to the single dictionary selected.

The following buttons can be accessed:

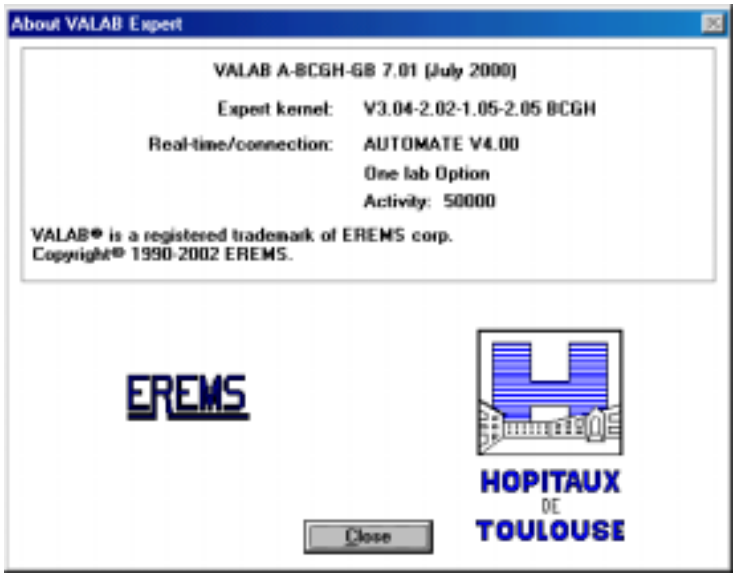
- **"Info..."**, to visualize the items managed by Valab (see § 7.2.5),
- **"Error tracing"**, to edit the error trace file (see § 0),
- **"Print"**, to print the dictionary selected (see § 7.1.3),
- **"Close"**, to close the window.



For more information on the dictionary fields, see § 7.2.5.

5.3 Configuration

In the *View* menu, the *Configuration* option lists the software configuration of Valab: name of the application, version of the application and its expertise modules and connection, option (MonoLabo or MultiLabo), volume of activity, number of duplicates and logos of the partners.

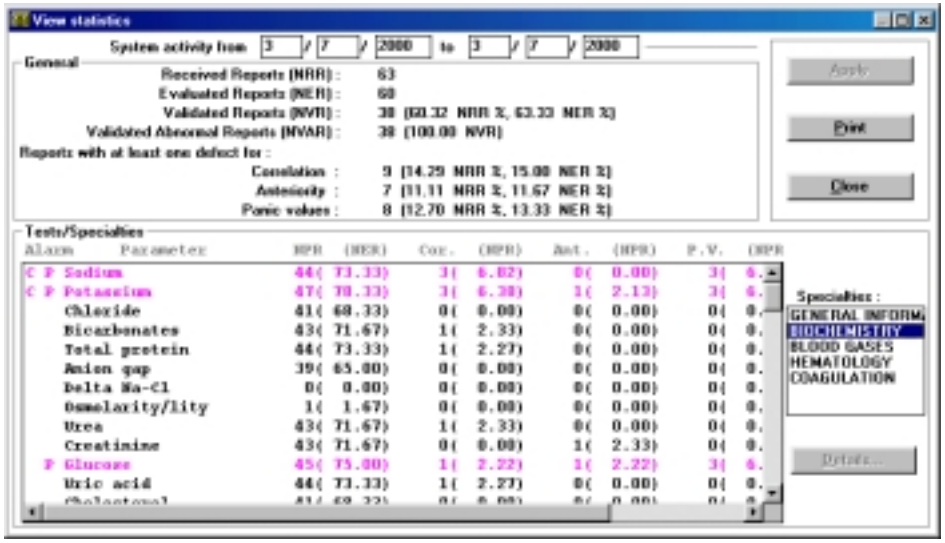


5.4 System Activity

Every day and for every test, Valab archives the number and type of the incoherencies detected in the reports received on the connection(s) of the automated system. *System Activity* is used to operate this database afterwards.

The operator may choose an observation period (default is "from ever" until now), and apply it to obtain the results corresponding to that period using the "**Apply**" button.

The operator can designate the specialty(ies) for which he or she wishes to know the statistics for each parameter (see the Windows® manual for multiple selection).

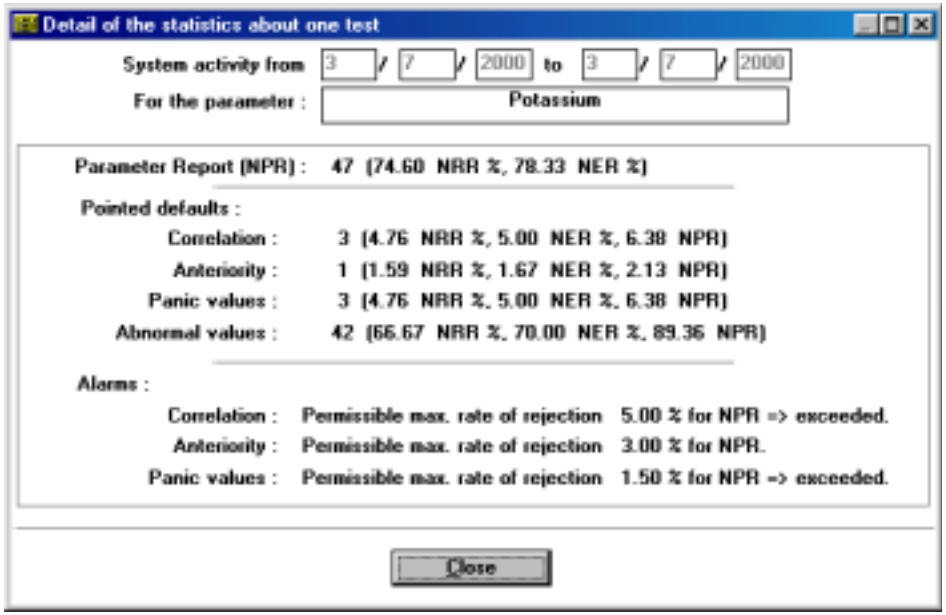


For the designated period, the window supplies the following information:

- NRR: number of received reports,
- NER: number of expertised reports,
- NVR: number of validated reports, its percentage in relation to NRR and NER,
- NVAR: number of validated abnormal reports, its percentage in relation to NVR,
- the number of reports presenting at least one correlation error, its percentage in relation to NRR and NER,
- the number of reports presenting at least one anteriority error, its percentage in relation to NRR and NER,
- the number of reports presenting at least one error outside panic values, its percentage in relation to NRR and NER,
- for each analysis of the specialty(ies) selected: the flags which are displayed when the rate of rejection has been exceeded (alarm concerning statistics); the name of the parameter; the number of reports involving this parameter (NPR) and its percentage in relation to NER; the number of correlation errors involving this parameter and its percentage in relation to NPR; the number of anteriority errors involving this parameter and its percentage in relation to NPR; the number of errors involving exceeded panic values of this parameter and its percentage in relation to NPR. The entire line concerning the parameter is coloured magenta as soon as an alarm is set off.

The following buttons can be accessed:

- "**Apply**", to obtain the statistics corresponding to the period entered,
- "**Print**", to print the statistics of the specialty(ies) selected (see § 7.1.3),
- "**Close**", to close the window,
- "**Details...**", to obtain details of the statistics of the parameter selected.



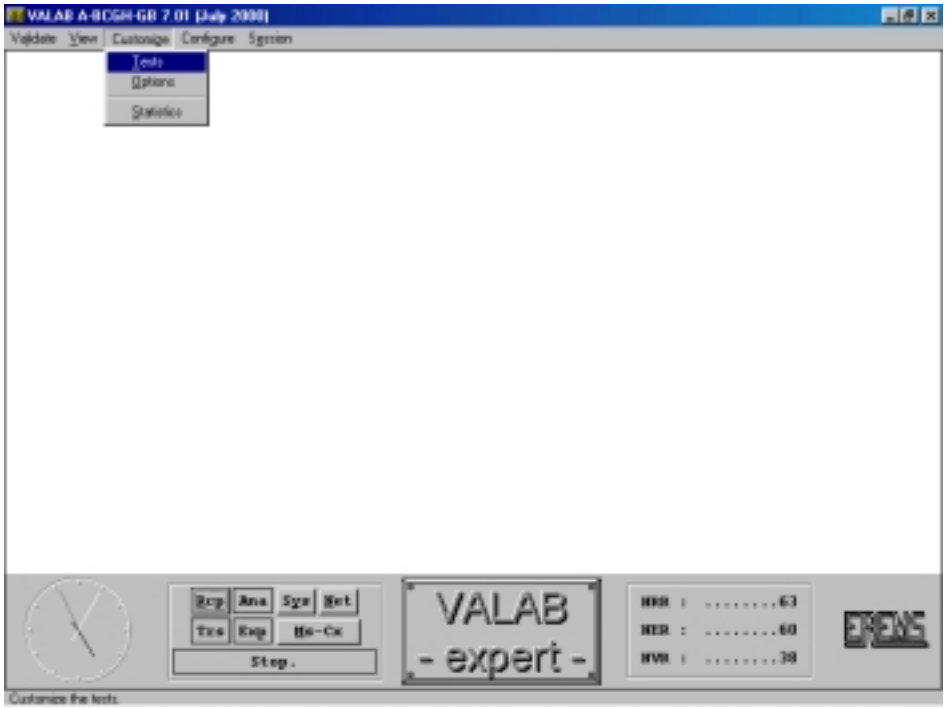
To calculate the extra percentages (in relation to NRR and NER) concerning a parameter as well as its rates of rejection, click twice on the latter or once on the "**Details**" button after selecting it in the list.

New : the file containing the statistical data is regularly saved while the system is in *Automatic* mode, so that it is possible to view nearly in real-time conditions the statistics of the day from a "**Remote Consultation**" version.

6 THE CUSTOMIZE MENU

The *Customize* menu can be accessed if a session is open with at least one operation in the last 5 minutes. Otherwise, a session must be opened in order to access the options again. Care should be taken, irrational programming of panic and normal values or units can make Valab totally inoperative.

Everything under the biologist's responsibility is set through this menu, it gives access to parameter setting of the tests, expertise options and statistics.



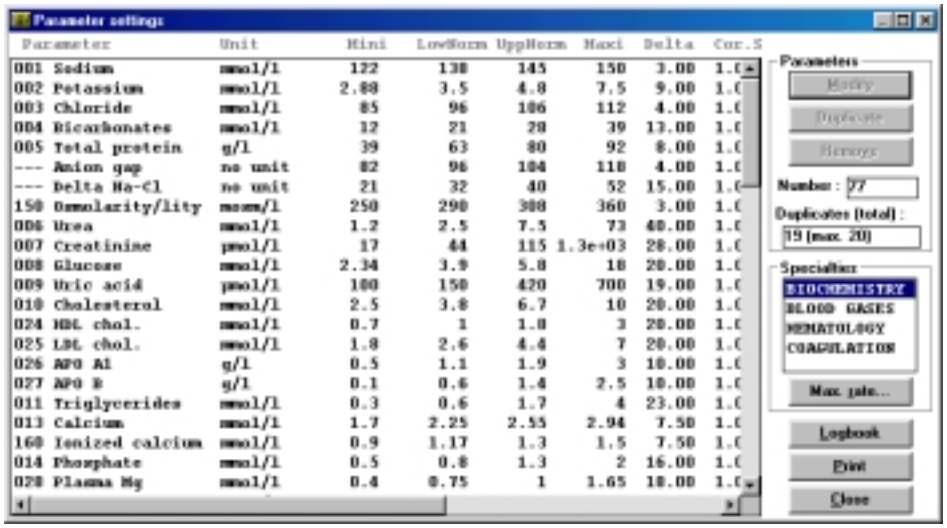
After modification, it is advisable to keep a backup on another medium using the option *Total backup* in the menu *Configure \ System*.

6.1 Tests

This menu accesses parameter setting for the analyses of the specialty(ies) selected (see Windows® manual for multiple selection). The parameter setting of an analysis can be

accessed by a double-click on the parameter in question or by the "**Modify**" button after selecting it.

The number of parameters making up the designated specialties is also displayed. If the complete list is not displayed in the window, the parameters can be scrolled using the vertical scroll bar. A horizontal scroll bar makes it possible to visualize the extreme right-hand part of the parameters, which does not appear in the window.



For more information on the items displayed, see § 5.1.

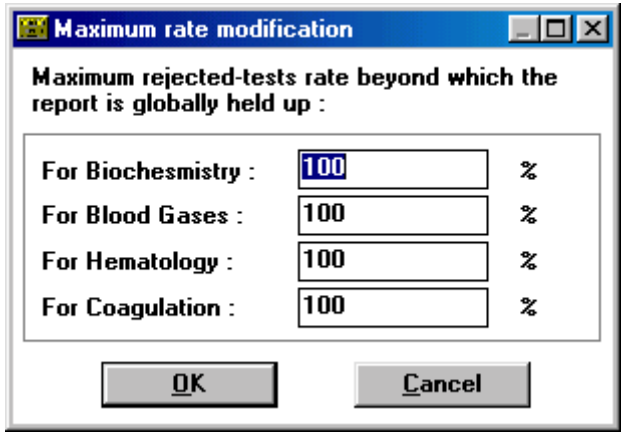
The following buttons can be accessed:

- "**Modify**", to modify the parameter setting of the selected analysis (see § 6.1.2),
- "**Duplicate",** to duplicate the selected analysis **(New :** see § 6.1.3**)**,
- "**Remove**", to remove the selected analysis **(New :** see § 6.1.3**)**,
- "**Max. rate...**", to modify the values of the maximal rates (see § 6.1.1),
- "**Logbook**", to consult the modifications of the parameter settings (see § 3.3),
- "**Print**", to print the parameter setting of the current selection (see § 7.1.3),
- "**Close**", to close the window.

6.1.1 Maximal defect rate

The *Maximal Defect Rate* must be used only if the laboratory partially delivers the reports. More precisely, it answers the tests, as soon they are validated, non-validated ones waiting for the biologist's validation. The *Maximal Defect Rate* blocks the whole report when too many tests are defective (15 - 20 % typically). The report is seen as globally suspect ("D" flag on all tests).

When not used, the Maximal Defect Rate must be set to 100 %.



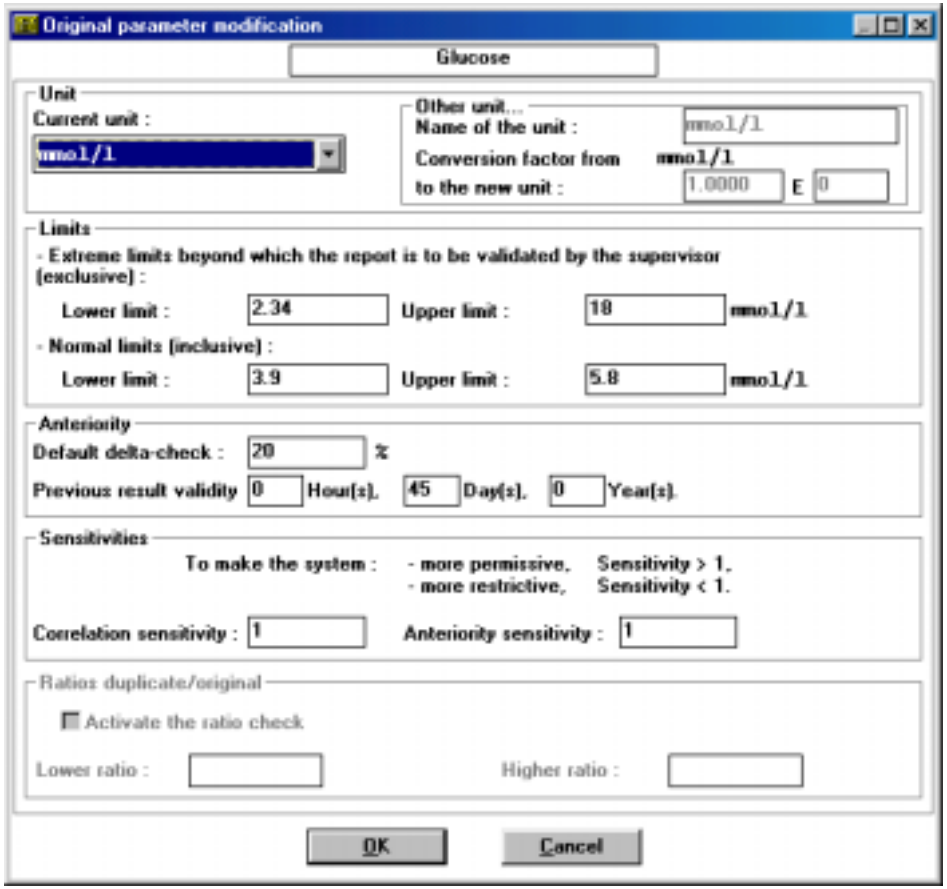
6.1.2 Modifying the parameter settings of a test

The **"OK"** button takes into account the modifications of parameter settings and records them. **"Cancel"** closes the window without recording any changes made.

UNITS:

The "Unit" subwindow programmes both the units in which the tests are received on the link and the units which are displayed.

The system proposes a menu, which scrolls the most frequent units for the current analysis. Nevertheless, choice of "other" accesses the name and conversion factor (mantissa and exponent) of a new unit.



LIMITS:

The system uses a large number of constants - coefficients of stability, of correlation, confidence gaps... All these data were computed from statistical study of the biologist's knowledge, these default settings are supplied with Valab. The expert kernel is validated with these data. However, limits of the different states are programmable, to be adapted to the medical environment and to the working practices of each laboratory:

- normality limits (inclusive), which strictly describe the physiological state of an analysis for a young male adult; the expert system will then add the dynamics relative to age, sex...
- extreme limits (exclusive), above which validation is forbidden.

When data is entered, the software checks the consistent increase of values.

DELTA-CHECKS:

The delta-check acts as the limits do, but it relates to the difference (in percentage) between a test and its previous result. Default values supplied with Valab are derived from statistical study of a large number of reports. The value of the delta-check is one component in interpretation of the variation observed, but actual acceptability of the result by the system is modulated to a considerable extent by the rules of the expertise.

As no numerical criteria nor reliable publication have been released - at this date - Valab does not ponderate the analyses with time. But for every test a maximal validity time for the Previous Result (PR) can be set. Thus, the PR is no longer used during expertise. The operator sets this limit in hours (make sure the LIS sends date and time!) OR in days OR in years. A nil value in each field means "no limit": anteriority is always taken into account. If 2 or 3 fields are not nil, Valab takes into account the first value other than nil by examining first the year, then the days and lastly the hours.

SENSITIVITIES:

Setting of the parameters relating to sensitivities allows the user to modulate the expertise by acting in an overall manner on the "weight" of the rules without modifying the internal logic of the system.

Sensitivity can be adapted (neutral value equal to 1) selectively and independently for the "Anteriority" and "Correlation" of each parameter in order to make the system more permissive (value greater than 1) or more restrictive (value less than 1) concerning the acceptability of an abnormal value.

For example, sensitivity equal to:

- 2.00 makes the system twice as permissive,
- 0.50 makes the system twice as restrictive.

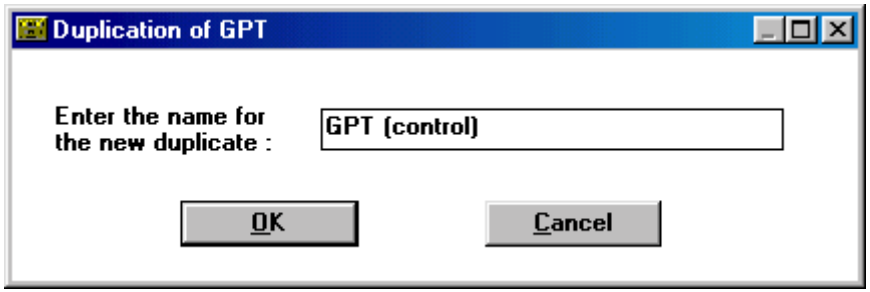
6.1.3 Duplicate Analysis (New)

The concept of duplicate analysis introduces the possibility to use and expertise, possibly in the same report, several times the same biological analysis performed with different techniques : analyzer, unit, reference values, parameter settings…

This function has been developed to respond to the need of some of the laboratories organised with technical wherewithal within which different work methods can be

found (analyzers, units…), to respond to the need of some laboratories performing controls with different techniques (reference value), and also to respond to the use of some specific analyses (e.g. glycaemia cycle).

To create a duplicate, an original analysis must be selected, click on the "**Duplicate**" button and type in the name of the duplicate to be created.



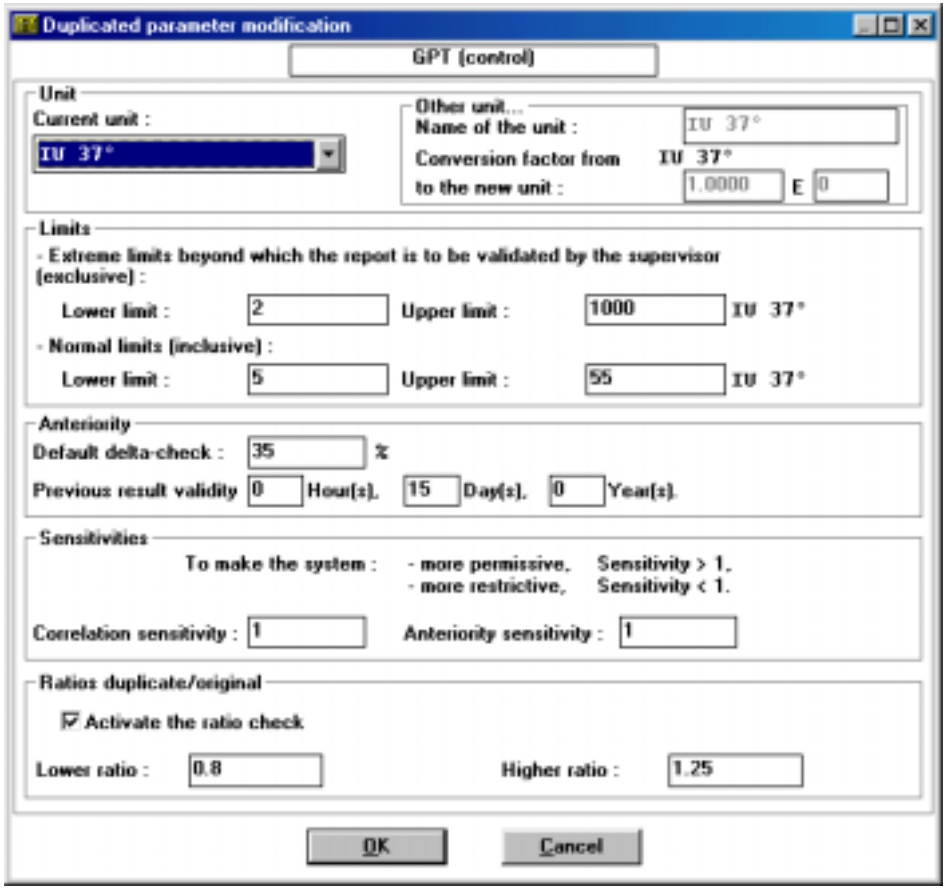
An analysis number, starting from 500, is automatically allocated to the new duplicate. The new duplicate is inserted in the list of duplicates, displayed after the list of the original analyses. In the right part of the screen, a window indicates the total number of duplicates created, as well as the maximum number allowed : 20 in the standard version, 100 if taken as an option.

A duplicate inherits its parameter settings from the original analysis at the moment it is created. From then, modifications can be undertaken in the same way as for an original analysis (see § 6.1.2).

There is an extra option setting for controlling the coherence between the result of the duplicate and the result of its original analysis. The check is expressed in terms of the ratio between the two results, after their automatic conversion into the same reference unit. By default, this option is activated and the acceptable ratios are in the interval [0.8; 1.25].

Please note that several duplicates can be created from a single original analysis, each (e.g. glycaemia cycle) with its own parameter settings (reference values, ratio…).

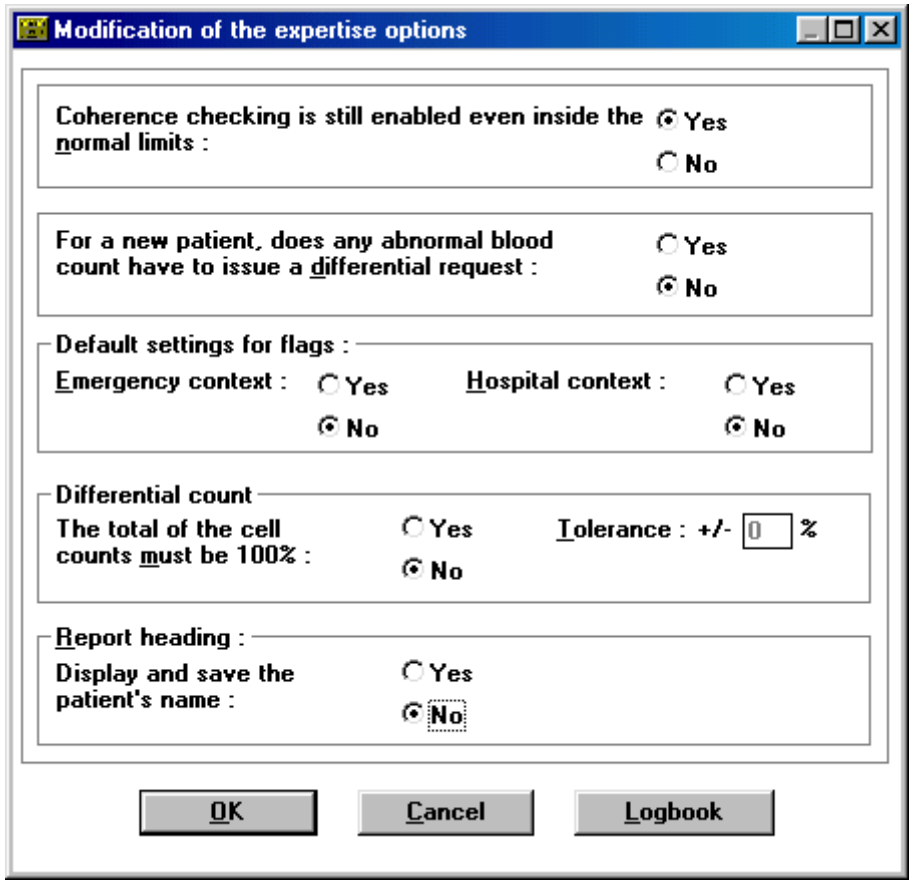
An obsolete or unused duplicate can be deleted by clicking on the "**Remove**" button, after having selected it in the list displayed in the session *Customize / Tests*. The number of the deleted test will be automatically re-used for the next duplicate to be created.



Remark :

A saved report including duplicates cannot be completely loaded in a *Validate / Simulation* session if the configuration (number, identity) of the duplicates has been modified in between the latest saving and the re-loading of the report.

6.2 Options



With *Options*, some of the expertising options can be set:

- The use or not of the consistency check for results relative to anteriority and context, even if all tests are inside normal limits. By default, this option is active.
- Differential request when an abnormal blood count - with age and sex ponderation - is detected for a new patient. By default, this option is inactive.

- Default emergency and hospital context flags if the heading of the report sent by the LIS does not contain these flags or if there is no item in the dictionaries to obtain this information. By default, these flags are set to "No".
- The control on the cell count to check that the total of the counts adds up to 100%, plus or minus a tuneable margin. By default, this option is inactive and no control is performed **(New)**.
- Displaying the patient's name in the reports received and saved in *Automatic* mode. By default, this option is inactive : the patient's name is substituted with "*…LIS…*" **(New)**.

The following buttons can be accessed:

- **"OK"**, to record modifications in the parameter settings,
- **"Cancel"**, to close the window without recording the data entered,
- **"Logbook"**, to consult the modifications in parameter settings (see § 3.3).

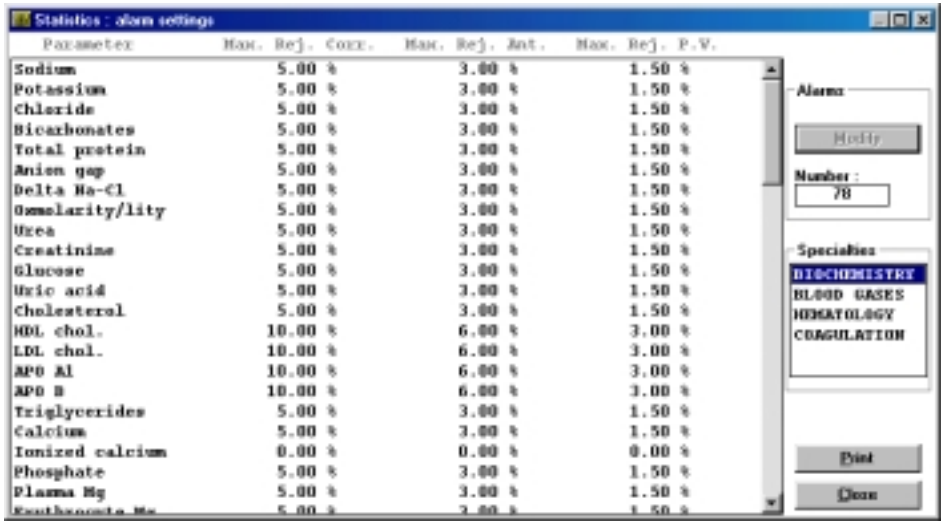
6.3 Statistics

This option defines, for all numerical parameters, the rate of rejection for errors of correlation, anteriority or panic values. When the percentage of errors for a parameter has been exceeded, display of the statistics (see § 5.4) shows the line of the parameter concerned in magenta with the error code on the left. This helps to adjust the system and reveals any problem with parameter setting.

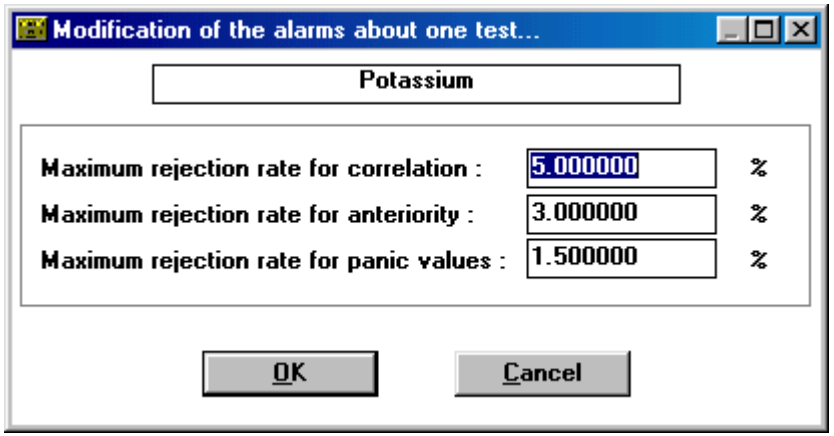
The following buttons can be accessed:

- **"Modify"**, to modify the rates of the parameter selected,
- **"Print"**, to print the parameter setting of the specialty(ies) concerned (see § 7.1.3),
- **"Close"**, to close the window.

The rates concern the specialty(ies) selected, number of corresponding parameters are displayed as an indication.



Modification in the alarms concerning a parameter is presented as follows:



The "**OK**" button validates the data entered, "**Cancel**" closes the window without saving them.

Remark :

The rejection rates cannot be modified for the duplicates, they inherit the rates from the corresponding original analysis.

7 THE CONFIGURE MENU

7.1 System

Each item in this option, except **"Printer"**, is protected by the password to avoid any interference with the system configuration.

7.1.1 Language

The user can change the language used in the software by selecting French, English (USA) or English (GB) to concord with linguistic conventions concerning date and time.

7.1.2 Directories

File management requires the following directories to be set:

- the directory for reports saved and read in Validate / Simulation,
- the directory for the test parameter settings files,
- the directory in which dictionaries are recorded.

If the parameter settings file does not exist in the input directory, a message is displayed but Valab runs with the default parameter settings. It is the same for dictionaries, Valab runs with empty dictionaries.

CAUTION: These directories must exist before being declared in Valab: if they are absent a message is displayed.

As default settings, the files of reports to be used as examples are stored in a "dossier" subdirectory, parameter files in a "param" subdirectory, dictionary files in a "dico" subdirectory. As this configuration can be handled by any computer, the user does not have to set it again.

Remark :

It is not advisable to configure Valab with network paths as Valab will not indicate any error at start-up if the files have not been found (problem linked to the automatic "log

in", see connection manual). The system will use the default parameter settings, which is not necessarily what the user wants.

7.1.3 Printer

This option opens the standard dialogue box for selection and configuration of a Windows® printer.

7.1.4 Laboratory name

This option programmes the heading of the laboratory, which is edited, on all printed documents (reports, dictionaries, parameter settings...).

7.1.5 Password

To protect the system from any interference which would lead to incoherent functioning of Valab, access to certain options (*Customize*, *Configure*) requires an access code which can only be used by the laboratory supervisor. This code is **2110** by default. This option makes it possible to change the password: it is necessary to know the previous access code to have access to this option. Confirmation of the new password is requested to prevent mistakes in keying-in.

It is advisable to customize the password after the system has been set up for everyday use.

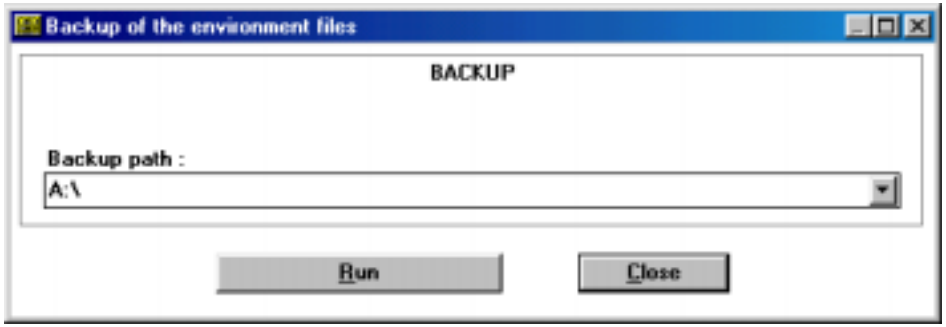
7.1.6 Total backup

This option saves on a diskette or other medium the environment files of your system. It is preferable to use a different medium than that on which Valab is installed, so that if there is a problem with the latter the configuration can be reloaded. If you use diskettes, do not use the installation diskettes but pre-formatted, preferably empty diskettes.

A backup should be done each time a main modification occurs in parameters or dictionaries.

By default, the proposed path is "a:\". The following buttons can be accessed:

- **"Run"**, to backup in the path which is indicated
- **"Close",** to quit the total backup option.



7.2 Connection

Each item in this option is protected by the password to prevent any interference with the configuration of the connection.

7.2.1 Protocol

The communication must comply with a given protocol, which may be adapted by the user by adjusting the following features:

- the message reception delay,
- the acknowledgement waiting delay,
- the delay between XOFF and XON signals,
- answer minimum delay,
- the code for start of frame (STX),
- the code for end of frame (ETX),
- the code for positive acknowledgement (ACK),
- the code for negative acknowledgement (NAK),
- the code for XON (LIS is ready to receive),
- the code for XOFF (LIS is busy),
- a request (optional) enabling search of the LIS' stack of reports. This request is sent every n minutes (n is set through this option) after the latest exchange.

The request mode can be very useful when in network connection, to check from time to time that the TCP/IP link is valid. If the connection between Valab and the LIS is no longer active, Valab will have a problem when the request is sent. It will then close the current connection and automatically await connection on the chosen port. The LIS will then have to reconnect to enable further data exchange.

CAUTION: whatever type of connection is used, the request can be activated only if the LIS also manages it.

Remark:

This protocol is common to both interfaces if they are used simultaneously in the case of the "Multilabo" option.

7.2.2 Interface 1 and 2

The interface between the two systems requires the following parameters to be co-ordinated,

- for serial connection:
  ⇒length of transmitted characters (7 or 8 bits),
  ⇒number of stop bits (1 or 2),
  ⇒parity (even, odd or none),
  ⇒transmission rate in bits/sec, i.e. in Bauds (1200, 2400...),
  ⇒the port used (COM1, COM2...),
- for TCP/IP network connection:
  ⇒the number of the IP port.

The connection can be deactivated by selecting "Inactive".

For the "MultiLabo" option, if both connections used are serial connections, parameter setting must be the same for both paths.

7.2.3 Message format

The various data exchanged via the link can be formatted through this option:

- date and time format with their separators and the indicators of morning and evening,
- real numbers format including the separators for thousands and millions, the decimal mark and the exponent mnemonic,
- ASCII code for field separator,
- age of patients format,
- mnemonic sent by Valab for positive / negative results,
- character set sent by the LIS.

7.2.4 Expertise flags

This option defines:

- the set of characters used to transmit the results of the expertise to the LIS,
- the number of characters used for the overall expertise of the report and of each parameter,
- the characters which enable more detailed interpretation of the expertise.

CAUTION: extended or customized modes should not be used if they cannot be handled by the LIS.

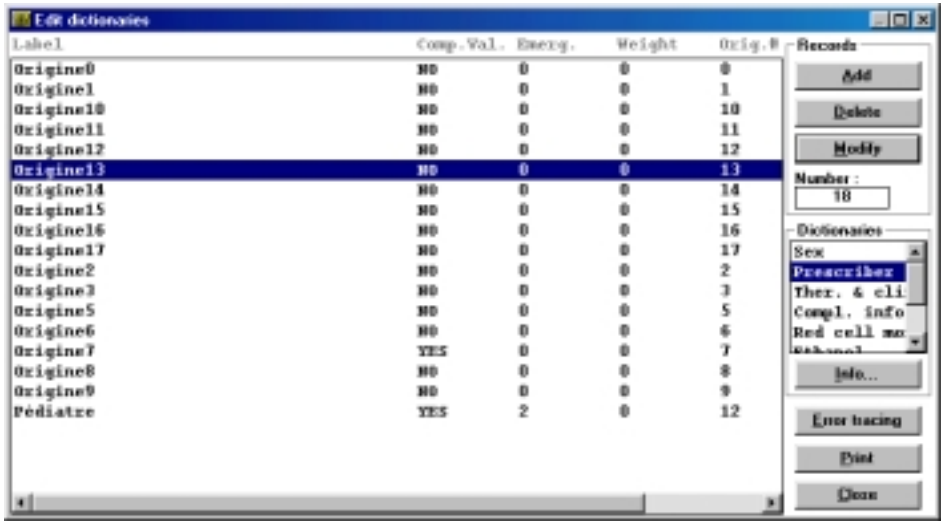
7.2.5 Dictionaries

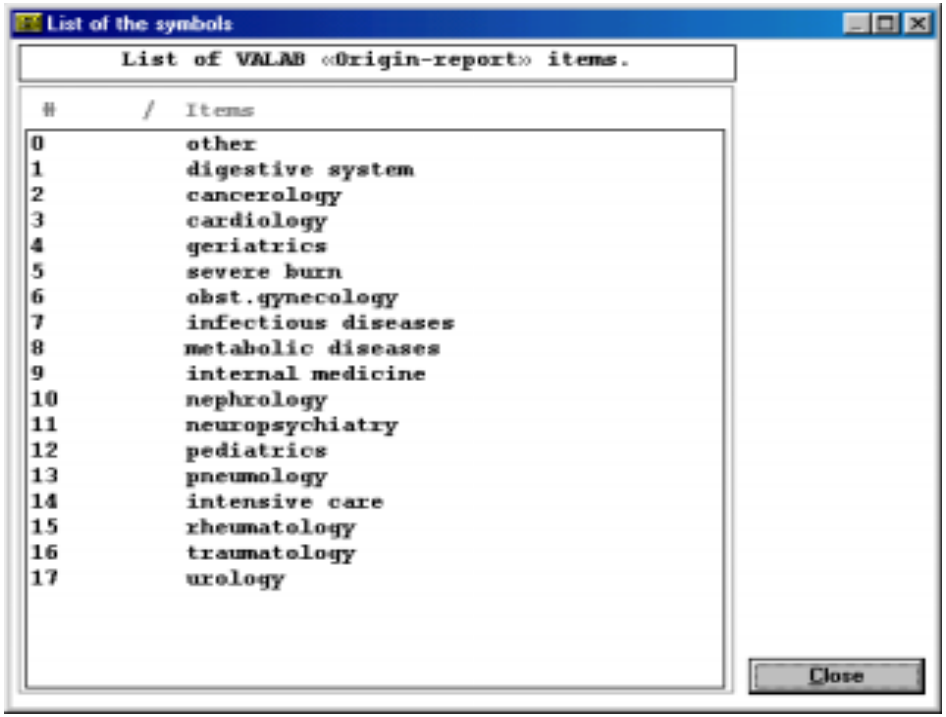
Some items are received from the link as they are in the LIS. This is the case for the prescribers, sexes, complementary information, therapeutical and clinical information, red cell morphology, ethanol gelation test, circulating anti coagulant and activated protein C resistance.

A character conversion table is applied between the LIS message and search in the dictionaries. The Valab editor uses the ANSI character set, the character set used by the LIS is defined in *Configure \ Connection \ Message format*. This table is generated after selecting "**OK**" in the message configuration box (see § 7.2.3). It can then be consulted in the "convtabl.txt" file (for more information, see § 2.5.1 in the Connection Manual).

The following buttons can be accessed:

- **"Add"**, to add an item to the dictionary selected,
- **"Delete"**, to delete the item selected in the current dictionary,
- **"Modify"**, to modify the item,
- **"Info..."**, to list all the items in the current dictionary which are managed by Valab,
- **"Error tracing"**, to consult errors which have occurred during the connection and *"Cut and Paste"* into the dictionaries (see § 0),
- **"Print"**, to print the dictionary selected (see § 7.1.3),
- **"Close"**, to close the window.





Remark:

The link between the numbers of the analyses of Valab and the analyses existing in the LIS takes place on the latter (test dictionary and / or code translation table).

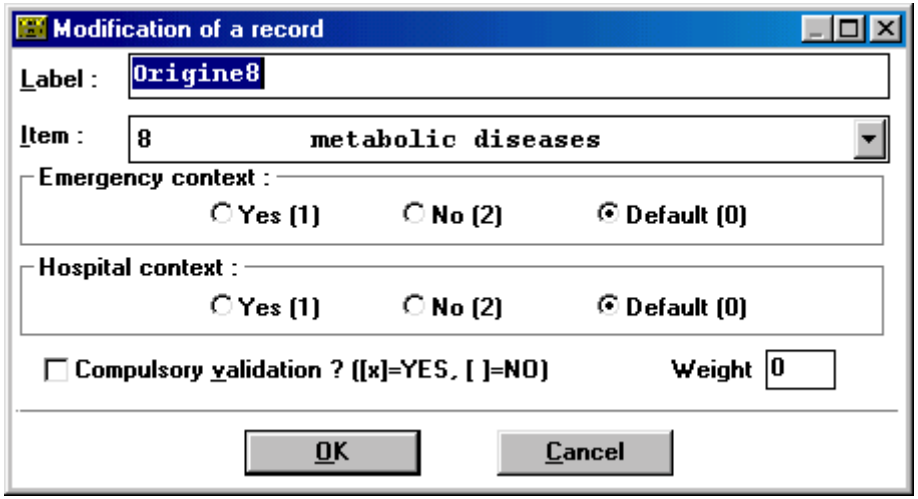
The sex dictionary is selected by default. To change the selection, use the scroll bar if necessary and click on the name of the dictionary. The number of records is then updated and the "**Info**" button displays in a window all the items of the dictionary selected.

To complete the current dictionary, use the "**Add**" button.

The dialogue box for adding or modifying a record contains the following fields:

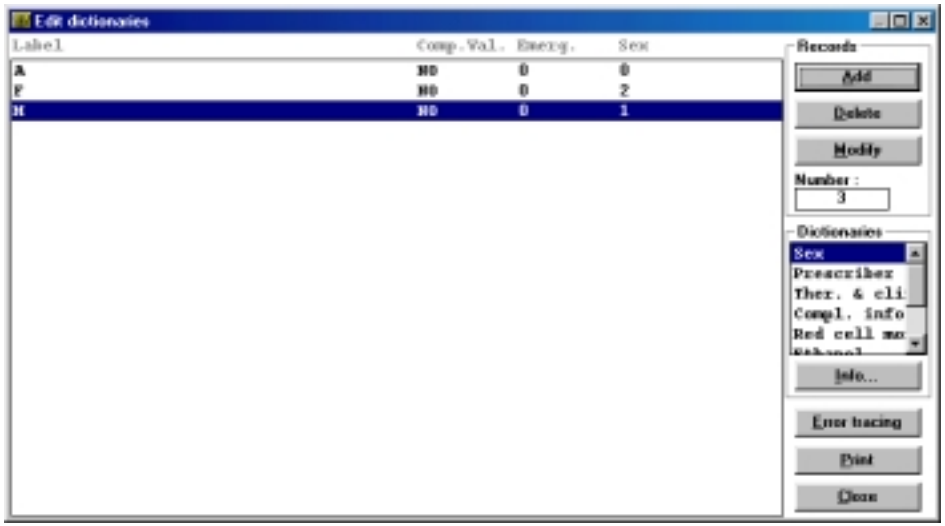
- label used in the LIS,
- number of the associated item in Valab,
- emergency context,
- hospital context,
- field for compulsory validation,
- weight field.

These fields are present but not always accessible in each dictionary.



The label for which the emergency or hospital contexts are initialized at "Default" takes the values defined in the option *Customize \ Options* (see § 6.2).

When a label is selected, the buttons **"Delete"** and **"Modify"** are activated. An identical label cannot be entered twice. The dictionaries have a limited maximal size and a message is displayed when this limit is reached (more than 1000 records. Consult us for further information).



7.2.5.1 Multivaluate mode

This mode enables several items of the same type of information to be retained for the expertise, for example several origins are taken into account in the expertise of a report.

If several items of a report are transmitted, only those, which have the greatest weight, are used for the expertise.

For example: Mrs MacPherson who is in an old people's home (Origin# 4 - geriatrics) is treated by Dr. Smith, a nephrologist, (Origin# 10 - nephrology) and by Dr. Johns, a cardiologist, (Origin# 3 – cardiology). Dr Smith and Dr Johns have a weight field which is greater than that of the old people's home: these first two items give more precise information to the system and are used in expertise of the report.

7.2.5.2 Compulsory manual validation

When an item with a compulsory validation field set at Yes is detected in the report, this report cannot be validated by Valab; all the validated analyses are classified as Domain (D) errors.

7.2.5.3 Emergency and Hospital context

It is recommended that these two criteria should be used as follows:

- select as default option for these 2 options, those which are in the majority in the context of the laboratory (see § 6.2). For example, as most prescribers in a hospital are not junior house physicians, set the default option for Hospital context at Yes.
- when items are entered in the dictionaries, indicate those items which are not part of the default option. In our example, junior house physicians have a Hospital context field set at No, the others have this field at Default (not at Yes).

7.2.5.4 Dictionary of Prescribers

The prescribers' dictionary is used to link the prescriber handle item - sent by the LIS - with the number of origin of the report corresponding in Valab. A prescriber item should start up:

- the compulsory human-driven validation of the report (e.g. vet),
- the emergency context (intensive care, emergency first aid...),
- the hospital context,
- a weight field used in the multivaluate mode described above.

7.2.5.5 Dictionary of Sexes

The dictionary of sexes links the items defined in the LIS with one of the three values of Valab:

- male (#1),
- female (#2),
- unknown (#0).

The item may also enable the human-driven validation for a given report (e.g. animals) or even a criterion of emergency.

7.2.5.6 Dictionary of CI, TCI and symbolic tests

Those dictionaries assign an identification in Valab to each label from the LIS.

Each item:

- launch the manual validation of the report,
- modify the criterion of emergency (default = 0) forcing on YES (1) or NO (2),
- use the multivaluate mode.

7.2.6 Options

Option # 1: enables automatic and continual backup of the day's reports in the "*today*" directory and those of the preceding day in the "*yesterd*" directory. To consult these reports in *Simulation* using the **"Open"** or **"Next"** buttons, the parameters of the option *Configure \ System \ Directories* should be set with the information "*today*" (or "*yesterd*"). By default, this option is active.

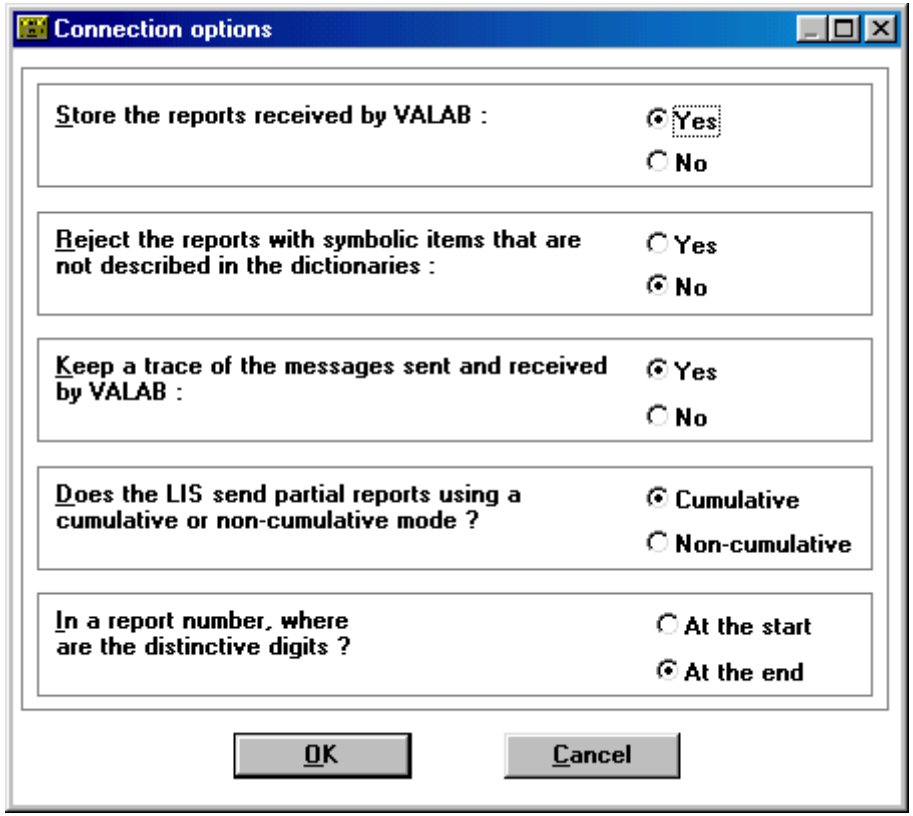
Option # 2: forbids validation of any report with a syntax error, in the communication protocol, on a symbolic item, which is not described in the dictionaries: prescriber, TCI, CI. By default, this option is inactive.

Option # 3 : is concerned with the tracability, on a 48 hour period of time and for each report, of the communication with the LIS. These data are used through the **"Trace"** button in a *Validate / Simulation* session (see § 3.4). By default this option is active **(New)**.

Option # 4 : adapts the calculation of statistics of activity to the strategy along which the partial reports are sent by the LIS. In a cumulative mode, an analysis that is included in a first version of a report, and not included in a later version will be deducted from the statistics, since this should mean it has be removed from the report. In a non-cumulative report, it is not deducted. By default, this option is set to the cumulative mode. The non-cumulative mode should be only used when the LIS sends partial reports containing totally independent groups of analyses **(New)**.

Option # 5 : allows the user to select which part of the report identification numbers, the figures at the beginning or the figures at the end, should be used in the name of the

file in which the report is saved in the *Automatic* mode. By default, the figures at the end of the number are used **(New)**.



8 SESSION

At start-up, all sessions are closed, which limits the use of Valab; the user can access all items in the menu *View*, printer configuration and *Automatic* and *Simulation* modes. However, the user can only leave the *Automatic* mode by keying in the password. A session is opened in *Session \ Open*.

If no operation has taken place after 5 minutes, the session is automatically closed. We advise that the current session should be closed when the system is no longer needed, to prevent unauthorized use during the next 5 minutes. The session is closed using *Session \ Close*.

The option *Session \ Quit* closes the application.

9 INSTALLATION

9.1 Configuration of the hardware and software

In order to be able to use Valab 7.01 comfortably, we advise the following material configuration:

- PC-AT Pentium II / III / Celeron 350 Mhz,
- 32 Mo of RAM,
- 100 Mo free on the hard drive,
- 1 parallel port,
- 1 serial port,
- 1 network card (recommended),
- 1 graphic card (800*600),
- 1 printer.

Valab 7.01 is a 16-bit Windows® application, which runs under the following operating systems:

- Windows 3.11® or later versions,
- Windows 95®, 98®, 2000®,
- Windows NT®,
- other operating systems can be used if Windows® emulation is available...

In order to use a network connection, you require WinSock 1.1 or a later version, which should be installed and configured on the computer on which Valab 7.01 will run.

In order to run under Windows NT®, Valab requires a special installation procedure, which is described on installation disk #1 of Valab 7.01 in the file "WINNT.TXT".

9.2 Installation

The Valab 7.01 installation disk #1 contains the installation and update programme "INSTALL.EXE". Valab 7.01 includes a backup function for all its environment files on various media and supplies a utility programme, "RESTORE.EXE", which recovers these environment files.

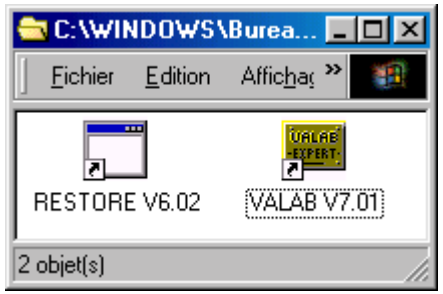
1. Connect the dongle (protection key) supplied with the installation disks to one of the parallel ports of the machine on which Valab 7.01 will run.

2. Insert the Valab 7.01 installation disk #1 in the 3"1/2 drive of the machine, then using the Windows file manager, start the installation programme "INSTALL.EXE".

3. Click on the button "INSTALL: install VALAB V7.01" and follow the instructions on the screen. The installation programme will enable you to select the directory in which Valab 7.01 will be installed, as well as the language in which you wish to use Valab 7.01.

4. At the end of the installation, please note on the installation coupon the code displayed and return it to us as soon as possible.

The installation programme creates a "VALAB" group with two icons: "RESTORE V7.01" starts up the recovery programme for the environment files and "VALAB 7.01" starts up Valab 7.01.



9.3 Restore

If a problem occurs with the hard disk (e.g. hard disk unreadable, loss of a file...) it is possible to retrieve the working environment of Valab 7.01 corresponding to the last total backup via the option *Configure \ System \ Total backup* of Valab 7.01.

1. If necessary, reinstall Valab 7.01,

2. Start up the recovery programme ("RESTORE.EXE") of Valab 7.01 using the icon "RESTORE V7.01" of the "VALAB" group and follow the instructions displayed on the screen. In particular, the recovery programme asks you to indicate the path containing the total backup from which you wish to carry out recovery.