CHORUS

OPERATING MANUAL

Release Software N°2.09r10

Multiparametric processor for immunometric assays with ready to use single test devices.

DIESSE

INNOVATIVE CLINICAL DIAGNOSTIC SYSTEMS

MANUFACTURER/AGENT
DIESSE DIAGNOSTICA SENESE SpA
Via delle Rose 10, 53035 Monteriggioni (SI), Italy
Tel. ++39 0577 587111 Fax. ++39 0577 318690
WWW.DIESSE.IT

LEGAL REPRESENTATIVE
MANAGING DIRECTOR
Sig.ra Aurelia Merini Gorini
REGISTERED AND ADMINISTRATIVE OFFICE
Via S. Vittore 36/1, 20123 MILANO, Italy
Tel. ++39 02 4859121 Fax. ++39 02 48008530

SERVICE ASSISTANCE
CUSTOMER CARE
Via del Pozzo 5, 53035 Monteriggioni (SI), Italy
Tel. ++39 0577 319556 Fax. ++39 0577 319020
e-mail: customercare@diesse.it

TECHNICAL ASSISTANCE
Via del Pozzo 5, 53035 Monteriggioni (SI), Italy
Tel. ++39 0577 319572 Fax. ++39 0577 319020
e-mail: **assistenzatecnica@diesse.it**

For the USA
DIESSE INC.
1690 W 38 Place, Unit B1 Hialeah, FL 33012, U.S.A.
Phone: (305) 827-5761 | 1-877-DIESSE-3 | Fax: (305) 827-5762
E-Mail : **salesoffice@diesse.us**

SERVICE ASSISTANCE
DIESSE INC.
1690 W 38 Place, Unit B1 Hialeah, FL 33012, U.S.A.
Phone: 800 582 1937

TECHNICAL ASSISTANCE
DIESSE INC. - CUSTOMER CARE
CUSTOMER CARE
1690 W 38th Place, Unit Bi Hialeah, FL 33012
Tel. 1 (877) 343-7733 Fax. (305) 827-5762
e-mail: **customercare@diesse.us**

This guide is prepared in version 2.09 and corresponds to the CHORUS instrument on which the software program in version 2.09r10 has been installed.
It has been carefully edited and reviewed, and the present version is closely related to the model of the instrument (*which is reported on the instrument number plate*) and to the version of the software program controlling the instrument (*which can be evidenced using a specific procedure*).

Printed in 2006 (Total pages: 97)

ATTENTION this manual is to be use only when complete. If not, DIESSE Diagnostica Senese S.p.A. declines every responsibility. It is possible to request a new copy at Servizio Customer Care - Via del Pozzo 5, 53035 Monteriggioni (SI), Italy. Tel. ++39 0577 319556 Fax. ++39 0577 319020; e-mail: customercare@diesse.it.

DIESSE accepts no responsibility for damage caused directly or indirectly by errors, defects or incidents, due to the use of manual non corresponding to the version of the supplied instrument.

Norms applied to this document:
98/79/CE regarding In-Vitro Medical Diagnostic devices(IVDD)

LIMITATIONS AND WARNINGS

The CHORUS instrument is designed to be used exclusively with the procedures established by DIESSE and stored in the memory of the instrument, and with the components (strips, diluent solution, washing solution etc.) manufactured and supplied by DIESSE.
Any use which differs from that foreseen by the manufacturer may lead to errors in measurements or risk situations, for which the user assumes complete responsibility.
Any violation of the software protections and of the test procedures memorized in the instrument for an unforeseen use, causes the loss of any guarantee regarding the instrument.
Before installing and using the instrument carefully read the warnings contained in the chapters relative to safety and installation and use.
For the use of the CHORUS a brief training is necessary.
All operators that use the instrument have to be trained for its use.
DIESSE accepts no responsibility for damage caused directly or indirectly by errors, defects or incidents, due to the use of the instrument by not trained personnel.

In case of the need of a technical intervention, contact the centre of assistance of your country or, as a second possibility, the DIESSE centre of assistance.

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1 INTRODUCTION

1.1 FIELD OFAPPLICATION

The CHORUS instrument, comprehensive of the installed software, is an automatic system, designed to conduct tests of infectious diseases (with EIA method and complement fixation), autoimmunity(with EIA method) on whole serum samples, using ready to use devices with single doses.

1.2 DESCRIPTION OF THE INSTRUMENT

The CHORUS instrument is constituted by a main “bench-top” type unit, completely autonomous, operating with its installed software already programmed to conduct the foreseen tests (see **fig. 1**).
The high level of automation characterizes it as a real instrument with “walkaway” potentiality.

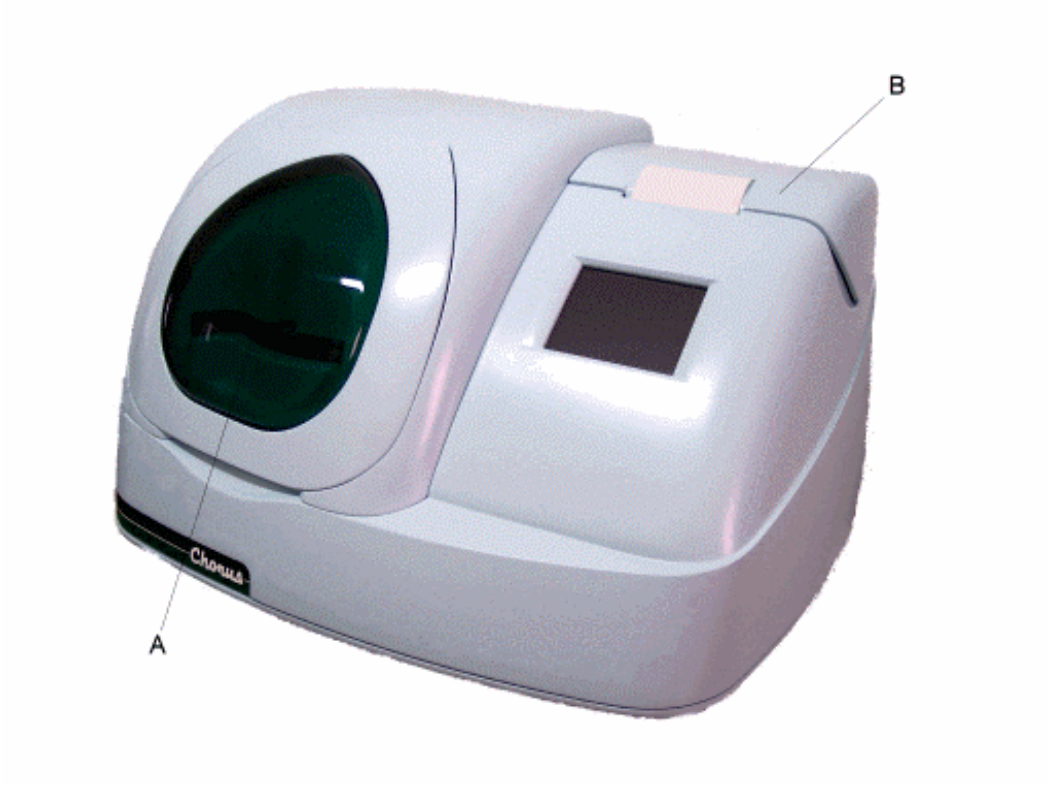


fig. 1

The serum is dispensed manually into the single devices by the user. All other operations (dilution, dispensation, washing steps, optic reading) are executed automatically by the instrument. The results are printed or send to a host computer by the information network of the laboratory (LIS, Laboratory Information System).

Because it is not possible to interrupt the timing of the analysis cycle, no samples can be inserted after the start.

1.2.1 FRONT SIDE

1.2.1.1 Introduction of the strips

Lifting the cover with the green port-hole positioned on the left front side of the instrument (A) **fig. 1**, it is possible to access the zone to insert strips into the tray (see **fig. 2**).

fig. 2

Each position of the carousel has a number and up to 30 strips can be inserted for each testing session.

1.2.1.2 Liquid tanks and printer

Through the opening on the right side of the top of the instrument (B) in **fig. 1**, the internal space is accessible where the tanks are and where the hydraulic and electric connectors to the level sensors of each tanks are planned (see **fig. 3**).

fig. 3

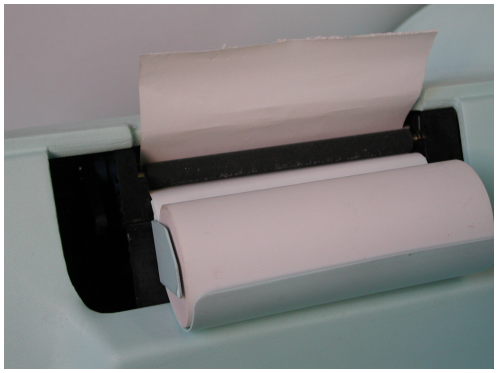


fig. 4

Through the same space the area can be reached that contains the roll of thermal paper and the lever for the introduction into the printing mechanism (see **fig. 4**).

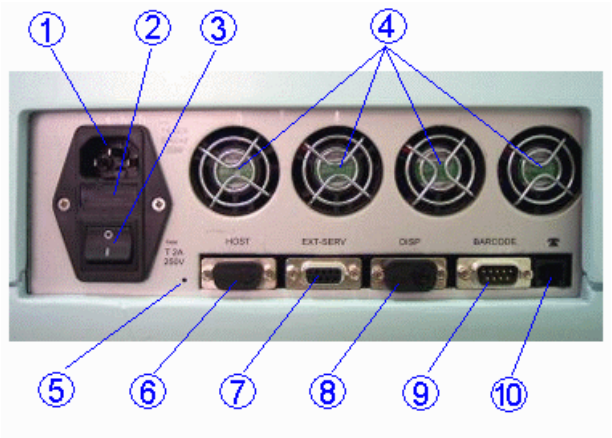
1.2.1.3 Display

On the right side of the instrument a touch-screen colour display with active matrix is positioned. The display is used as a video and as a keyboard.

1.2.2 BACK SIDE

1.2.2.1 Electrical connections

On the back of the instrument on the left the electrical section area is placed as described in **figure 5**



1. *power plug*
2. *protection fuses*
3. *on-off switch*
4. *cooling fan*
5. *switch for initial programming*
6. *serial port for connection to the Host computer*
7. *serial port for connection to PC for technical assistance*
8. *serial port for connection to an external dispensation system*
9. *serial connection to external bar code reader*
10. *phone connector for remote connection through modem*

fig. 5

The following information is reported next to the power plug:

Nominal power tension and frequency

Maximum consumption

Values of the two protection fuses

1.2.2.2 Hydraulic connections

On the back of the instrument on the right the hydraulic section area is placed as described on **figure 6**

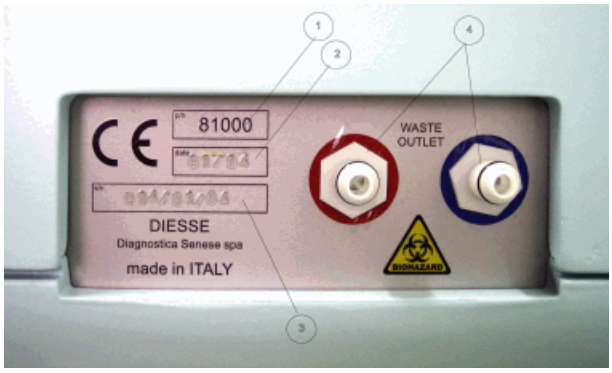


fig. 6

1. *identification code of the CHORUS product*
2. *manufacturing date*
3. *serial number of the instrument*
4. *bayonet joints for the connections to the waste tank*

1.3 SUPPLIED MATERIALS

The instrument is delivered in a box including:

n°1	CHORUS instrument with the software installed
n°1	bar code reader with cable
n°1	separate power cable
n°1	10x concentrated Washing Buffer solution
n°1	50x concentrated autoimmunity buffer solution
n°1	2000x concentrated cleaning solution
n°1	1000x concentrated sanitizing solution
n°2	empty tanks to collect 1 L of Washing Buffer
n°1	empty tank to collect 1 L of cleaning solution
n°1	empty tank to collect 170mL of sanitizing solution
n°1	10 L waste tank
n°1	drainage tube with standard cap
n°1	catching tube for Washing Buffer with level sensor
n°1	catching tube for cleaning solution with level sensor
n°1	roll of thermal paper
n°2	a couple of fuses
n°1	approved power cable
n°1	10 mt telephone cable
n°1	Manual barcode reader with cable
n°1	Operating Manual

1.4 TECHNICAL DATA

Instrument dimensions

Length	17,7 in / 45 cm
Height:	19,7 in / 50 cm
Width :	27,6 in / 70 cm
Weight	approximately : 99 lb / 45 kg charged on 6, 3 cm^2/cad area

Bar code reader

Used for test tube and strip code identification. In connection with the dedicated software procedure installed, it identifies alphanumeric codes with the following characteristics

Max resolution	0,125 mm, 5 mils
Sensor	LCD solid state (2048 pix)
Default codes	code 128, code 39, Interleaved & Codebar 2 of 5
Test tube codes	1-16 alphanumeric characters
Strip and bottle codes	1-20 alphanumeric characters

Communication ports

Serial port (RS 232) for local o remote service
Serial port (RS 232) for local o remote hosting
Phone plug

Display

6” STN color display
320 x 240 pix

Printer

dot thermal type
832 dots/line
Paper size 112 mm (104 usable)
Continuous roll

Central processing Unit

16 bit Microprocessor
Multiple I/O ports
1 Mbyte Internal permanent memory
512 Kb Ram

1.4.1 ENVIRONMENT REQUIREMENTS

Temperature range	18-30°C (64-86°F)
Humidity	< 80%
Altitude	< 2.000 mt (6,562 feet)
Lighting	do not expose to bright lights

No explosive gasses
No dust
No change of air is needed

1.4.2 ELECTRICAL REQUIREMENTS

Current	105 < >240 Vac 50-60 Hz
Absorbed Power	max 350 W
Noise level	< 80 dB
Fuses	2 x 2A T (5x20 mm)

1.5 HOW TO HANDLE THE INSTRUMENT

The present chapter is inserted on the external cover of the transport box as instruction.
It has to be carefully read and the operations described are be executed by specialized personnel of ***DIESSE*** Diagnostica Senese SpA or personnel authorized by DIESSE.

1.5.1 TRANSPORT AND STORAGE

The packaging is formed by a wooden box with the dimensions of 100 x 100 x 100 cm on a pallet
During storage and transportation the indications of TOP and BOTTOM, indicated on the outside, have to be respected. The instrument can be transported in temperature conditions included between 0°C and 50°. Do not leave the boxes in rainy or humid conditions. In case the instrument has been subject to a temperature below 10°C for 24 hours or longer, make sure the installation personnel will check there is no condensation in the encoding systems, in the optical devices and in the moving parts of the instrument, or anyway will not turn it on before leaving the instrument at room temperature for an hour.

1.5.2 UNPACKING

To open the box and the other packaging of the instrument, the following utensils are necessary:

- Two allen keys of 2,5 and 3,0 mm (not provided)
- A big cross screwdriver (not provided).

Once checked that the packing is not ruined and the TOP/BOTTOM positions are correct, proceed as follows:

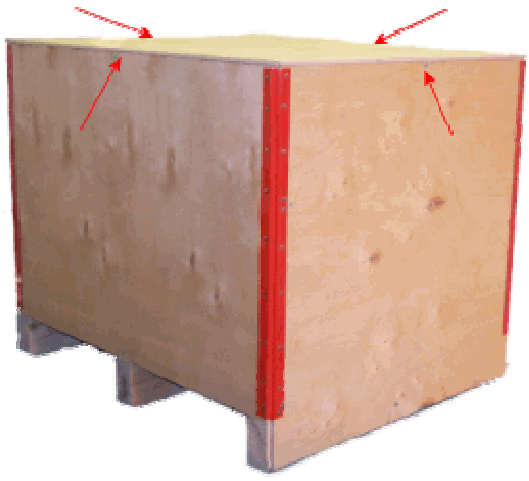


fig. 7

Unscrew the 4 screws on the cover
Remove the cover

fig.8

The open box appears as showed in the figure

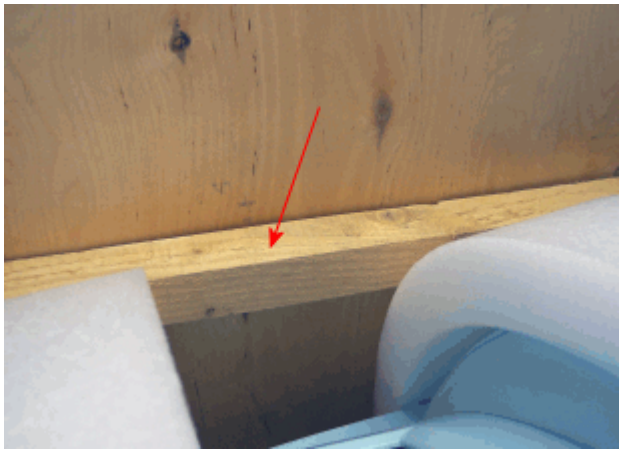


fig. 9

Remove the strip of wood blocking the polyethylene packing, indicated in the figure.

fig. 10

To do this unscrew the two screws blocking the strip of wood, positioned on both sides of the box.

fig. 11

Once removed the strip of wood, the polyethylene protections can be removed as well

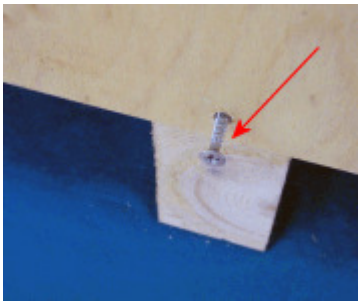


fig.12

At this point the ply-wood box can be taken down, unscrewing the four screws positioned low on the four sides on the bottom.

fig. 13

Once the CHORUS instrument has been taken out of the box, it can be positioned on the working table.

ATTENTION!
The operation has to be executed by two persons, using both hands. The handle positioned on the bottom has to be held with one hand, use the other hand to hold the central part of the instrument. Do not use only one hand, since the instrument might lose its balance.

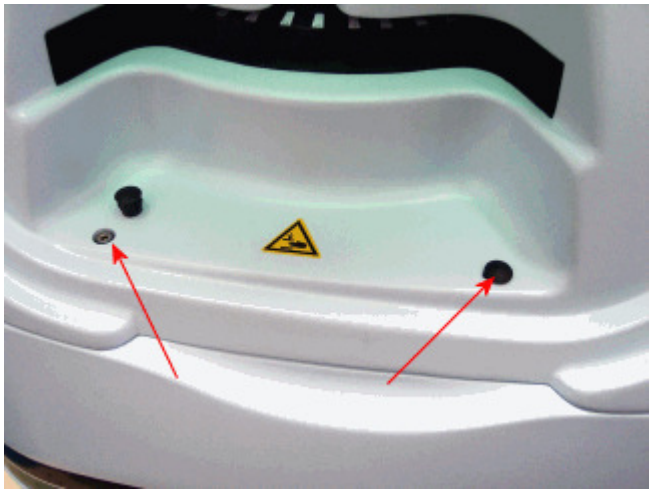


fig. 14

Before turning on the instrument, it is necessary to remove the internal protections blocking the mechanical movements of the washers, of the X trolley and of the dispensers.
For this purpose, remove the superior part of the cover and proceed as follows:
Remove the caps closing the anterior screws, positioned under the loading strips area.
Unscrew the two socket heads (as indicated in the figure) using the 3mm key.
Pay attention to the connector of the lid closure sensor and disconnect it

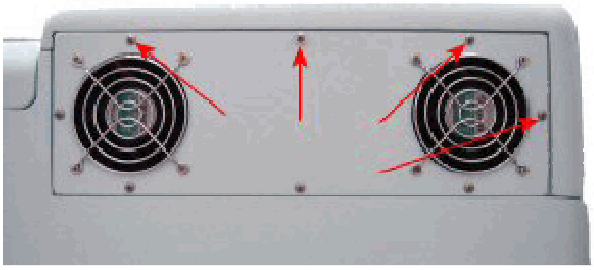


fig. 15

Remove the four allen screws positioned on the back side of the cover around the cooling fans (see the 4 red arrows) using the 2,5mm key.
Lift the top part of the cover to reach the internal part of the instrument

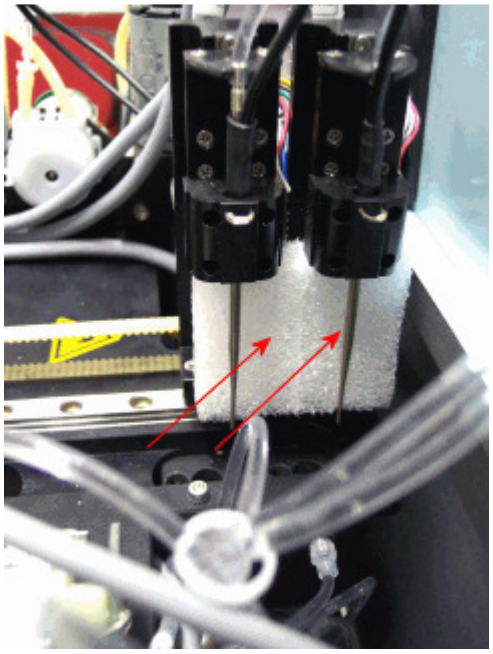


fig. 16

At this point remove the material which vertically block the two dispensers.

Keep all the packing material for later use, in case the instrument has to be moved.

1.5.3 DISCONNECTION AND REINSTALLATION

1.5.3.1 In the same place/building

This type of transport can be carried out by hand or on a trolley, therefore no packaging is necessary and the transport can be executed by personnel not specialized, taking the following precautions:

- disconnect the CHORUS instrument from the power network
- disconnect the two tubes directed to the waste tanks from the instrument
- disconnect and remove the WASHING BUFFER and CLEANING SOLUTION tanks and relative tubes
- two persons are necessary to lift and move the instrument, using both hands: hold the handle on the bottom with one hand and the front part of the casing with the other one to not lose balance during transportation
- move the tanks by themselves, using all the necessary precautions, especially for the waste tank which could drop potentially infectious liquids.

Once the CHORUS instrument has been positioned in its new place it is necessary to:

- reconnect the waste tubes, using all the necessary precautions
- reconnect the tubes to the tanks and insert the probes
- reconnect to the power supply
- turn on the instrument

1.5.3.2 In a different place

If the instrument has to be moved to a different place and therefore a mechanical transport (truck, train, etc…) is necessary, the instrument has to be packed and the assistance of specialized personnel to move it safely, with no risk of damage, is requested.

1.5.4 DEMOLITION

For the demolition of the instrument the assistance of a specialized company is necessary, in order to be guaranteed the correct demolition of all its parts, according to their characteristics.

1.6 INSTALLATION

1.6.1 SET-UP OPERATIONS BY THE USER

The CHORUS has to be installed in an environment suitable for its normal functioning, taking care of the electrical requirements (see par. 1.4) and safety information (see chap. 2) supplied in this manual.
In particular, the laboratory must have a network socket in accordance with relative legislation, fitted out with a correct earth connection and with a line voltage that must be guaranteed in accordance with the specifications, in power as well as in frequency. In the absence of this guarantee, the customer must equip himself with a voltage stabilizer. In fact variations in voltage over a given range of tolerance can cause malfunctioning and/or damage of the instrument.
In the case that the laboratory in which the instrument is placed is subject to frequent current interruptions, it is advisable to connect the instrument to an uninterruptible power supply (UPS) in order not to interrupt the cycle. In this case a 1000 Watt UPS is able to sustain the working system for over 1 hour.
The CHORUS does not need to be connected to centralized gas or liquid supplies, as the liquids required are contained in tanks that are supplied with the system.
Vice versa, a safety tank has to be positioned on the outside of the instrument and connected to a special double tube, to collect the waste liquids. Alternatively, it can be connected to a centralized waste disposal system; requesting the above-mentioned tube with the specifications of the connection.

1.6.2 CONNECTION OF THE INTERNAL TANKS

These operations can be performed even when the instrument is switched on, as long as it is in stand-by, i.e. in the window of the main menu.
In the right-hand frontal cover of the instrument (see **fig. 1**) there is an opening (B), through which the operator can reach the area where the tanks of ***Washing Buffer*** and ***Cleaning Solution*** are located.
Each of the probes that have to be inserted into the tanks (see **fig. 18**), is equipped with two terminals:

- a plastic tube with relative connector, for aspiration of the liquid, identified by a blue (Washing buffer) or white band (Cleaning solution),
- an electric cable with relative connector, for detection of the level of the liquid

which must be connected to the respective plugs as shown in **fig 19**)

ATTENTION!

Each probe must always be used for the same solution to avoid cross-contamination.

Use the probe with the blue band for the thank of Washing Buffer and the one with the white band for the cleaning solution, following the color indicated on the plug connection

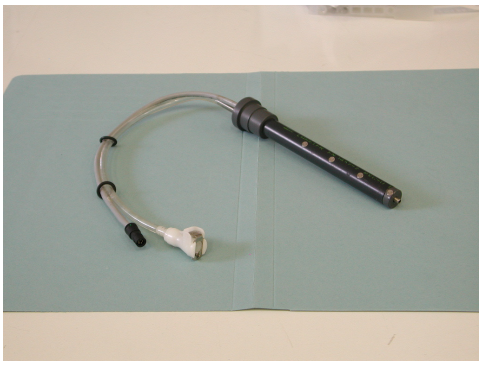


fig. 17

fig. 18

1.6.3 CONNECTION OF DRAINAGE

For correct function of the system, the liquids produced by the instrument must be discarded. These liquids must be collected in suitable, sealed bottles or canalized into a centralized waste disposal system.

There are two attachments on the back of the instrument for the waste tanks(see **fig. 6**)

One has a **red** band and is used for discharge of waste to the tank or the centralized waste collector.

The other has a **blue** band and is used for the return of liquid waste if the bottle is full. In fact the “over-full” sensor is inside the instrument. This control functions correctly only if the cap of the probe which is connected to the waste tank, closes the tank hermetically.

1.6.3.1 Connection to the waste tank

This operation must be performed with the instrument switched off.

a) If the tank supplied with the instrument is used, the probe which is supplied must be used (**fig. 19**); which is equipped with two tubes with connector

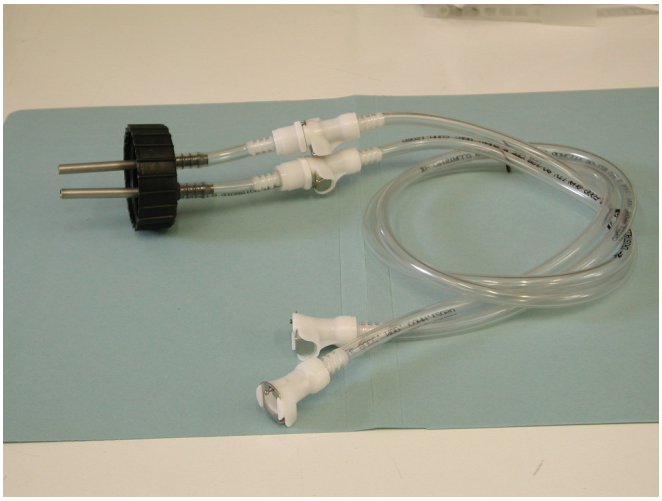


fig. 19

Screw the cap with the two tubes tightly onto the empty 10 L tank and connect the two tubes to the connections on the back of the instrument (*WASTE OUTLET*). Both the red and the blue connector can be used.

ATTENTION!
In order for the “too-full” probe to function properly, the cap must be perfectly screwed on, until compressing the O-ring.

b) If the tank supplied with the instrument is not used, it is advisable to request from the manufacturer a cap suitable for the tank model in use, in order to assure that the connection of the cap to the empty bottle is sealed to guarantee correct function of the “too-full” sensor.

1.6.3.2 Connection to a centralized waste disposal system

This operation must be performed with the instrument switched off.
In this case, only the connection with the red band can be used to connect to the drainage.
If a suitable connection is required, this can be requested from DIESSE Diagnostica Senese SpA, specifying the features of the connection necessary.

1.6.4 WASHING BUFFER REPLACEMENT

The instrument uses two different types of washing buffer, one for the infective disease tests and one for the autoimmunity tests. When its necessary to replace the Washing Buffer tank, the following procedure has to be followed to avoid contamination:

1) Remove the old tank and replace it with the new one. Before putting in the probe absorb carefully all the liquid on the surface of the probe itself. Do not unplug the probe from its connectors. Insert the probe into the new tank.
2) From Check window, press Priming and when asked, type or scan with the barcode reader the code of the Washing Buffer tank that has to be installed
3) The program will start and execute automatically:
   - removing old Buffer from the tubes
   - cleaning of the tubes with new Buffer
   - priming of the tubes with new Buffer.

1.6.5 INTRODUCTION OF PAPER

Through the tank chamber access is also gained to the roll of thermal paper required for the printer. (**fig. 2**0). The paper can be replaced, with the instrument switched on or off, as follows:
Place the roll of paper in the relative slot.
With the instrument switched on :

- Pass the paper through the slot, the printer will advance the paper and then stop automatically
- Pay attention that the heat-sensitive side of the paper faces the operator.
- Switch the instrument off and on again to set the printer error.

With the instrument switched off

- Raise the internal lever pulling it towards the operator (see **fig.21**)
- Pass the paper into the slot until it comes out.
  Pay attention that the heat-sensitive side of the paper faces the operator
- Push down the lever until its mechanical stop
- Start up the instrument again to set the printer error.

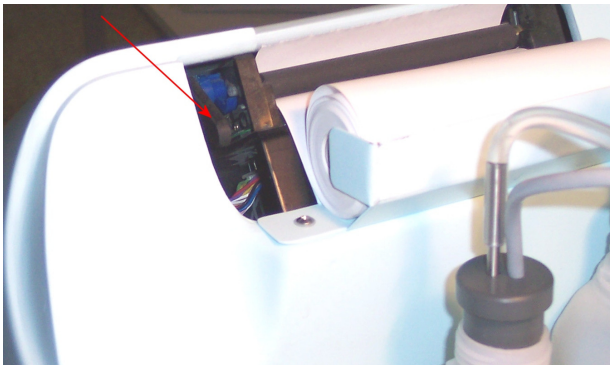


fig. 20

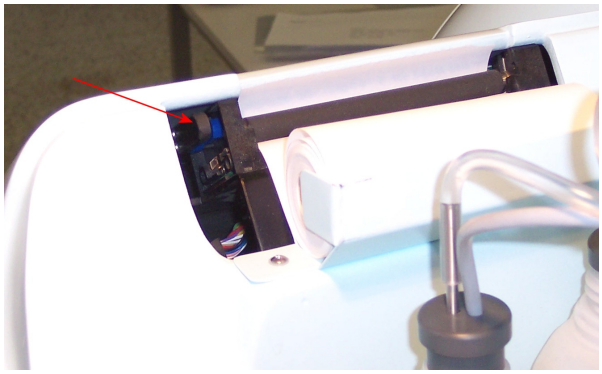


fig. 21

1.6.6 STRIP INTRODUCTION

This operation is not strictly connected to the switching on of the instrument, except for the fact that during the phase of the *initial automatic check* (chap. 4), the operator is requested to insert a strip. When the front cover is opened, the inside appears as shown in **fig. 22**.
The slot where the strip is to be introduced is indicated by a hollow in the carter. Each position on the plate is numbered, and during the guided insertion of the strips, the relative number is shown on the display.

fig. 22

Insert the strips slowly but firmly until resistance of the spring is felt; then push as far as it will go.
To extract the strips, pull hard until the strip is released from the spring which holds it.
Pay attention to not spill the serum.

1.6.7 ELECTRICAL CONNECTIONS

The power supply is situated on the back left hand side of the instrument.
Use only the cable supplied with the instrument for connection to the power supply, without using reducers or extensions which could reduce the protection incorporated in the system against electric shocks.
The cable is first connected to the instrument and then, after checking that it is switched off, the other end of the cable is connected to the power supply.

1.7 SWITCHING THE INSTRUMENT ON

Use the switch on the back of the instrument to switch on. The initial automatic check procedure will begin.
Once the result of procedure is satisfactory, the instrument is ready for use.

1.7.1 WARM-UP

The execution of the cycle is connected to the temperature of the strips indicated in the methods.
Thus, at the switch-on, the instrument will start a warming procedure up to the rest temperature and, whenever this is not yet reached, will signal a thermostation error.
The error signal will stop as soon as the instrument has reached the rest temperature.

1.8 SCREEN SAVER AND STAND-BY STATUS

In case the display is not pressed for more than 6 minutes, the screen saver will activate (whenever it has not been disables); to exit this modality it is sufficient to press the display.
The stand-by status is activated automatically when the instrument does not execute any operational functions; in stand-by the motors are fed in such a way to guarantee a minimum consumption.

1.9 SWITCHING THE INSTRUMENT OFF

Before switching the instrument off, whenever a test cycle has been run, a wash cycle must be performed in order to avoid residual salts containing solutions from crystallizing in the circuits and damaging the instrument and/or invalidating the results.

1.10 CLEANING AND WASHING OF THE INSTRUMENT

The outside of the instrument must be cleaned according to the following precautions:

- switch off and unplug the instrument
- use a damp cloth (alcohol or non corrosive detergents) for the painted parts
- use a dry cloth for the display and plexiglass window
- do not wet the connections on the back of the instrument or the on/off switch.

1.11 SANITIZING CYCLE

A sanitizing cycle exists, which includes of the washing with an antibacterial solution, supplied by Diesse Diagnostica Senese, of all the parts that come in contact with the whole or diluted serum.
This cycle has to be started

- by authorized personnel before accessing the internal parts of the instrument
- when the instrument is expected to remain inactive for a long period of time
- periodically, according to the prescribed using methods.

1.12 EMERGENCY

In case of emergency, switch off the instrument using the general switch or unplug, in order to block all movement of the parts and to interrupt dangerous current.

1.13 ADJUSTMENTS

Three adjustments can be performed using the variable resistor controls foreseen in the instrument's software:

- contrast of the display
- volume of the speaker
- setting of time and date.

The procedure is explained in the relative section (chap. 5.9.1)

1.14 CONNECTION TO A HOST-COMPUTER

The CHORUS is equipped with an RS232 serial interface, through which it can be connected to a Host Computer. This connection allows the instrument to be programmed and the results to be handled by a centralized system.
The connection is of the Query mode type and the protocol is described in the appendix (chap. 8.2)

2 SAFETY

2.1 RISKS OF A MECHANICAL NATURE

2.1.1 TRANSPORTATION

The instrument is packaged and the internal mobile parts are blocked in such a way as to guarantee safe transportation, if the following precautions are observed:
The package, which can be loaded on a pallet, must be moved using a transpallet

- It must not be overturned
- It must not be dropped from a height over 20 cm
- It must not be even partially immersed in liquids
- It must not be stored in an environment with a degree of humidity over 90%.
- It must not be stored at a temperature over 60°c. and below 0°C,

Transportation must therefore always be performed using the original packaging materials and by specialized personnel equipped with adequate safety measures to avoid all incidents which could result in dropping, crushing or breakage.

2.1.2 INSTALLATION OF THE INSTRUMENT

The instrument must be placed on a flat surface which must be:

- Stable, at least 1m x 1m minimum dimensions
- Able to support a weight of 100 kg/mq
- Perfectly horizontal with a maximum slope of 3mm/m
- Smooth and washable.

Moreover:

- The feet of the instrument must all rest on the supporting surface.
- The rear of the instrument must be at least 30 cm away from any obstacle behind it.
- There must be a free area of at least 50 cm around the sides of the instrument.
- There must be free access to the front of the instrument.
- The front cover must be free to open in a position where there is no risk of meeting obstacles (passage of personnel, hanging objects etc.)
- The front cover must not be left open in the absence of the operator.
- The instrument must be placed in a position far from possible sources of knocks (doors, windows, etc) to avoid all accidental bumps during function.
- The protective cabinet must never be removed.

2.1.3 MOVEMENT OF THE SAMPLE TRAY

The only part of the instrument in movement which might come in contact with the operator is the strip tray *(carousel),* which partially extends outside the front opening. The carousel's control system automatically blocks it within a fraction of a second; however, a slight knock could occur with the object blocking it.
The danger is indicated with a signal of the danger of hitting.
The carousel does not begin its movement before the lid is closed.

2.2 ELECTRICAL RISKS

The instrument must be plugged in to the power supply using a regular, well-earthed plug in accordance with regulations. The cable supplied by the manufacturer, which is in accordance with regulations, must be used for connection to the mains.
There is no risk of electric shock for the operator as the instrument is adequately protected.
There is no possibility of causing an electric discharge and interrupting its function, by touching the instrument, because it is adequately protected.
The user must not operate if the cabinet has been removed.
It is advisable not to use an extension to the connecting cable. If this is necessary, the extension used must be in conformity with relative regulations, otherwise it may render ineffective all the safety precautions introduced.

2.3 RISKS DUE TO HIGH TEMPERATURES

The carousel is an exposed part of the instrument and is heated to a temperature that can vary from 25 to 40 °C during the test cycle, depending on the executed test.
Even though a prolonged accidental contact with the plate in the area where the strips are inserted, will not cause burns; however, a label indicates to the operator the danger from heated surfaces.

2.4 BIOLOGICAL RISKS

The material used in the tests is human serum and, as such, potentially infectious. All precautions established by the relative local legislation for laboratories in the countries where the instrument is used, must therefore be followed.
The waste material must also be treated as any other product that can be considered organic hospital waste.
In the areas where contact with serum might occur, there is a label reporting danger of biological contamination.
There is a risk in the following situations:

- When the strips are inserted in the carousel, as the pressure exerted to insert the strip might cause the liquid to spill that was previously dispensed in the first well of the strip.
- During removal of the strip from the carousel, as the force adopted to extract the strip itself might cause liquid to escape, as a little liquid may be left in the well.
- During a cycle with the cover open, if a cycle which includes mixing has been programmed, because the strip well containing the serum protrudes.

- When handling the waste tank and the relative connections to the instrument. There could be drops of waste liquid inside the cap or the tank itself or the connections.

  ATTENTION
  The connections between the instrument and the waste tank must never be detached while the instrument is in operation, because some drops of liquid could spill before the connector on the Chorus closes the waste outlet.

- The waste tank must be closed hermetically by screwing the cap on tightly in order that the rubber gasket seals the tank.

A sanitization cycle is foreseen (see 1.11), using a special liquid which eliminates all harmful microorganisms from the tubes and all the internal surfaces which are in contact with potentially infectious liquids.

2.5 INDIVIDUAL PROTECTION MEASURES

As human serum is handled during the following procedures:

- dispensation of samples in the strips,
- insertion of strips in the carousel,
- removal of strips from the carousel,
- replacement of the waste tank,

it is advisable to use gloves and eye protection; in any case, local regulations in the country of use should be followed.

3 USE OF THE INSTRUMENT

3.1 THE JOB-LIST (J-LIST) AND THE COUPLING-LIST (C-LIST)

The operator who intends to perform a test run will normally have a list in which each sample is associated to one or more tests to be executed. The samples list can be on paper or memorized on the Host Computer of the centralized system.

The **Job List (J-list)** is the list which associates all the **sample codes** to the **test codes.**
In the CHORUS system the sample must be transferred to a ready-to-use device for a specific test, in order to be tested: the strip.
Each strip is provided with a bar code which specifies the type of test (*test-code*) for which it can be used, and a *numeric code* which identifies it unequivocably out of all the strips manufactured by Diesse. The complete code applied to the strip constitutes the *strip-code*.
Before conducting a session, it is possbile to associate each sample code with the strip code of the strip in which it is dispensed.
The **Coupling list (C-List)** is the list which associates all the **sample codes** and the **strip codes**.
The instrument is designed to compile both a **J-list** and a **C-list**.

- ***To reduce errors in performance of the tests*****,**
  i.e. to avoid performing tests on a sample which are not requested, it is preferable that the **J-list** is compiled on the instrument automatically, via a connection to the host computer of the centralized system.
- ***To reduce errors in attribution of results,***
  i.e. to avoid attributing to one sample the result of another sample, it is preferable that the compilation of the **C-list,** in other words dispensation of the sample in the test-strip, take place automatically.

3.2 THE RUNNING-LIST (R-LIST)

The **Running-list (R-list)** is the list of the **thirty** positions in the carousel; the strip code identified in the carousel and the associated patient code (if present) for each position is indicated.
It is compiled by the instrument using the identification procedure which foresees scanning of all the positions on the tray using an internal barcode reader.
After scanning of the carousel, two different cases may arise:
If a C-list has been saved, the patient code is attributed univocally to each of the strips identified, according to the association present in the C-list.
If no C-list has been saved or if the strip code is not associated to any patient-code, the field of the patient code will be filled automatically with a progressive number corresponding with the position number of the sample holder tray.
The **R-list** produced in this way allows the result obtained with each strip to be associated to the relative sample-code, but does not guarantee the lack of errors.

3.2.1 CONNECTION TO HOST COMPUTER NOT AVAILABLE

The following procedure is recommended:

1) On the basis of the paper *J-list*, assemble the strips necessary to perform the tests.
2) Place all the strips in the carousel (it is not necessary to respect the order of insertion from the paper J-list).
3) Start the identification process through the **R-list** command in the Start Window.
4) Get positioned on the first identified position.
5) Dispense the serum in the cuvette #1 of the strip
6) Assign the patient code (if available) to the strip through the bar code reader.
7) Proceed to the next position (strip).
8) Repeat steps 5-7 for all the samples.
9) Once the process is completed, if no errors have been signalled, the cycle can be started.

For more details about the R-list windows see paragraph 5.5

3.2.2 CONNECTION TO THE HOST COMPUTER AVAILABLE

If there is a connection to a host computer, the following procedure is recommended:

1) Enter the **C-list** window from the Start Window.
2) Insert all the patient codes in the table, on the basis of the paper Job-list printed from the Host and using the bar code reader.
3) Request programming by the Host, using the Host command. The system completes the C-list with the compilation of the column of the tests associated to the samples present. The acronyms of the tests are magenta coloured, because they are still temporary codes (test code followed by a series of zeros).
4) Assemble the strips relative to the tests requested by the host and go to position on the first sample of the table.
5) Enable the **MOD** mode of use, to modify.
6) Read the strip code with the bar code reader. If the test code is correct, the strip code is assigned on the table. If the strip code does not correspond to the test code expected by the C-list, no code is assigned.
7) Insert the strip read into an empty position of the tray.
8) Repeat steps 6-7 for all the list.
9) Exit from the **C-list** window and enter the **R-list**.
10) Once the instrument has identified all the strips, dispense the serum into the strips, starting from the strip in the first position until all the samples on the tray are finished.

For more details about the C-list windows see paragraph 5.4

4 START-UP CONTROLS

When switching on the instrument, a series of checks is performed automatically, as reported below, to prepare for correct functioning.

4.1 ELECTRONIC CHECK

The instrument performs a check on the following parts:

- memory: ram, flash, video-ram
- display, printerperipherals: modem, bar-code reader, strip presence sensor
- strip and instrument thermometer, by setting the stand-by temperaturesIf an error is found,

the instrument immediately terminates the controls and visualizes the error doce and description in the errors window.

4.2 CALIBRATION OF THE TOUCH-SCREEN

This is performed on request by the user, by pressing the touch screen within 5 seconds from the moment in which, after the initial blue screen, the blue side bar and the DIESSE logo are shown
(for a complete handling see page 87).

4.3 CONTROL OF THE LID

The control procedure regarding function of the lid, which is necessary for safety reasons (the operator does however have the possibility to skip this check using the "**Skip**" key), consists of the opening and/or closure of the lid to check whether the sensor is working correctly.
In particular:

- If the lid is closed, two consecutive windows (20 seconds apart) request in sequence that the lid be opened (to check the sensor) and then, closed (for safety reasons).
- if it is open, there will be a single request to close the lid (for safety reasons).

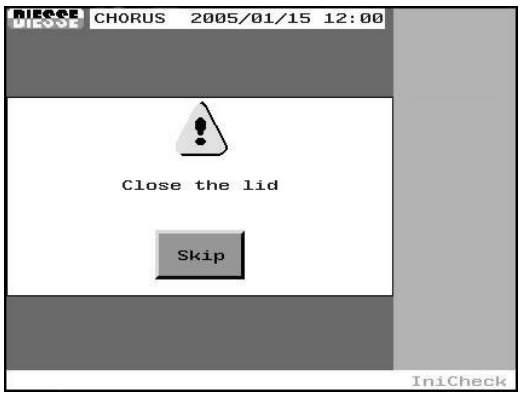


fig. 23

If the operator presses the **Skip** key, the system check will proceed.

- No further controls will be performed on the lid
- An error message (warning) will appear in the first error window, at the end of the check.

If the window should close due to time-up, the system check will proceed.

- ❖ When necessary, opening/closing of the lid will be requested again, to control the error.
- ❖ The error (warning) remains until the lid is correctly positioned in a subsequent control.

Note:
If the **Skip** key is pressed in any part of the program except in the initial check, the error remains until a new initial check is executed.

ATTENTION:
The lid is checked again when the R-List is entered, and if this step should be skipped (using the **Skip** key or due to time-up), the warning signal will remain on the status bar throughout the cycle, indicating the risk for the operator and for the performance of the test itself.

ATTENTION:
It must be stressed that if the operator continues to run the instrument with the lid warning signal on, he does so entirely at his own risk.

4.4 CONTROL OF THE MOTORS

The control procedure for the motors moves each one into its respective working position.
In the case that a motor cannot be positioned correctly, a relative error will appear in the errors window and the instrument check will be interrupted.

4.5 CONTROL OF THE STATE OF THE INSTRUMENT

The instrument check continues with the control of the following pendings:

A) Hydraulic system
   - if the last hydraulic check was not concluded satisfactorily
   - if more than 24 hours have passed since the last check

B) Priming of the wash buffer circuit
   - if the wash buffer is not present in the circuit
   - if more than 6 hours have passed since the last priming check or last cycle

C) Optic system
   - if the last optic calibration check was not concluded satisfactorily
   - if more than 24 hours have passed since the last optic calibration

Note:
The operator has the possibility of not performing the control procedures in as far as:

- - the efficiency of the hydraulic circuit
- - the control of the liquid present in the wash buffer circuit
- - the efficiency of the optic group

are necessary only for performance of the run

Note:
If the operator decides, pressing the Skip button, to skip the initial control, it will not be possible to start a cycle before first re-establishing the state of correct functioning of the instrument.
If the initial control is allowed to continue, the instrument performs:

- The hydraulic check
- Priming of the wash buffer circuit
- Calibration of the optic groups

if the relative controls are outstanding.

Note:
The execution of the hydraulic check foresees priming of the wash buffer circuit, even if this check is not due

4.5.1 PREPARATIONS FOR THE CHECK PROCEDURE

The **Hydraulic Check** requires that the tanks are at least 25% full of the washing solution and the buffer solution and furthermore:

A) Insertion of the check-strip (supplied), in the position 1 on the tray
B) Removal of any strips present in the positions 7 and 11 on the tray
C) Reading of the barcode of the buffer solution.

To perform priming of the wash buffer circuit tubes:
B) Removal of any strips present in the positions 7 and 11 on the tray
C) Reading of the barcode of the buffer solution

To calibrate the optic group
D) Removal of any strips present in positions 10, 20, 30 on the tray
E) The stand-by temperature of the strips must be reached.

For verification of points A), B) and D), a first window appears (see example in **fig. 24**) in which the operator is required to insert and/or remove the strips from the positions indicated.

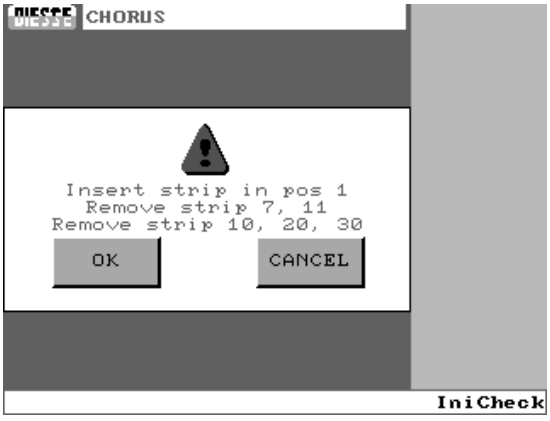


fig. 24

The operator must position and/or remove the strips and press the ***Ok*** key.
If the **Cancel** key is pressed, the check is interrupted (see **fig. 25**).

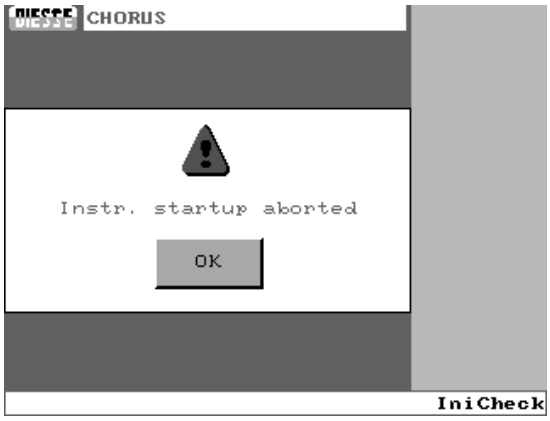


fig. 25

The check continues, and the system controls the position of the strips, and if the insertion/removal operation has not been performed correctly, the window is shown again and another request will be made to the operator. If after the sixth insertion/removal operation of the strips the check is not executed correctly, the procedure is aborted.

For verification of point C) the following window opens up (**fig. 26**), and the operator is requested to read the barcode of the buffer solution to be used.

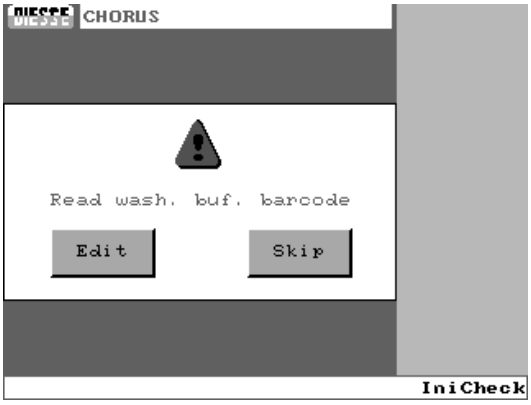


fig. 26

After scanning the code the window closes and the system continues with the check.
If a barcode reader is not available, it is possible to insert the code via manual editing by pressing the **Edit** Key. (code infective diseases buffer = 42461001; code autoimmunity buffer = 42462002).
The **Skip** key can be used to skip this control.

Note:
If the **Skip** key is pressed, the instrument maintains the last type of buffer solution memorized.

Verification of point E) is performed by the instrument before beginning the optic calibration, and if the stand-by temperature has not been reached, a window appears in which the current temperature is indicated, the temperature which must be reached, and the time available (30 minutes), after which the calibration will not be performed.

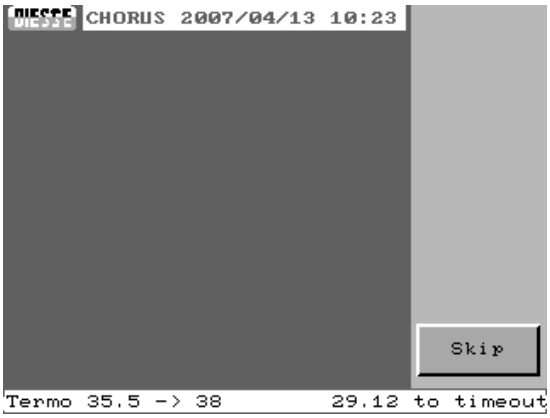


fig. 27

ATTENTION:
If the **Skip** key is pressed, it is possible to skip this waiting period; in this case the optic calibration will also be skipped (in case that it was necessary), as the temperature is an indispensable requisite for correct calibration.

4.5.2 START OF THE CHECK

1) The **Hydraulic check** requires that the tanks contain 25% of buffer solution and wash solution and consists in the following:

- ❖ Control of the level of the liquid present in the tanks
- ❖ Control of the sensors and the function of the drainage well
- ❖ Washing of the dispensers (external and internal)
- ❖ control of the washers, collection wells included
- ❖ priming of the 250 µl syringe (and of the 25 µl syringe if activated)
- ❖ test of the 250 µl syringe (and of the 25 µl syringe if activated)
- ❖ Priming of the buffer solution circuit

2) **Priming** of the buffer solution circuit requires that the tanks contain at least 25% of buffer solution and of washing solution and can be **standard**, in case the selected buffer solution is the same as the one present in the circuit, or **elaborate**, in case the selected buffer solution is different from the one present in the circuit.
Standard priming consists of

- ❖ Emptying of circuit with air
- ❖ Filling with the set buffer solution

Elaborate priming consists of

- ❖ first washing of the circuit, of the dispensers and of the washers
- ❖ first standard priming
- ❖ second washing of the circuit, of the dispensers and of the washers

- second standard priming

3) The **check of the optic group** requires that the stand-by temperature be reached and consists in:
- Calculation of the virtual ramp
- Calculation of the dark offset
- Calculation of the light at 650 nm
- Calculation of the light at 610 nm

If an error is found during any of these phases, the instrument immediately terminates the controls and shows the errors window, where the error found is reported.
In the case that a previous cycle was interrupted, at the end of the controls a warning window allows the archives window to be opened (**View** key **fig. 28**) to verify the run which was interrupted; the print-out of the last run is optional.

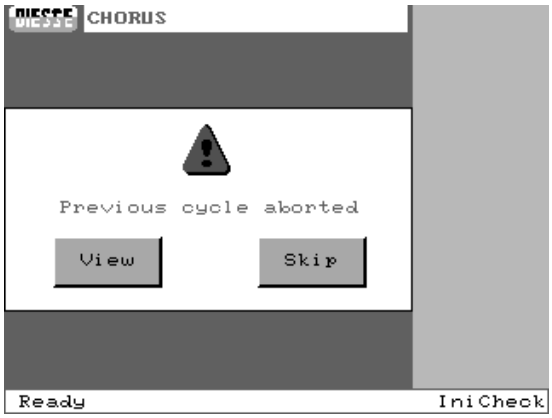


fig. 28

Note:
In this case, before performing a new cycle the instrument automatically performs a quick priming of the washers

Note:
If there are any outstanding controls, the status bar will show the information "**Not ready**". The control window (see 5.10) can be used to visualize the elements requiring an efficiency check.

4.6 ERRORS WINDOW

If errors are found during the *initial check procedure*, the following summary appears:

fig. 29

Print: prints the list of errors found with numeric identification and corresponding string
Silence: disables the sound alarm (*only for recoverable errors of attention*)
Report: prints all the errors with numeric identification, corresponding string and status *(KO for those found)*
Prev/**Next**: moves to the preceding or next page of errors
Exit: returns to the main window

Depending on the types of errors found, the status bar will become a different color and the sound alarm will give out specific signals:

Type of error	***Colour of the status bar***	***Alarm***
Recoverable errors (RE)	Magenta	Acute intermittent signal
Errors of attention or Warnings (WE)	Yellow	
Fatal errors (FE)	Flashing Red	Bitonal signal

ATTENTION!
Not all the User Interface commands will be available in the case that errors are found.

Note:
It is possible to go to the errors window from nearly all the other windows, simply by pressing the central part of the status bar

5 USER INTERFACE

5.1 DESCRIPTION OF THE WINDOWS

All the CHORUS windows are structured as in the following example:

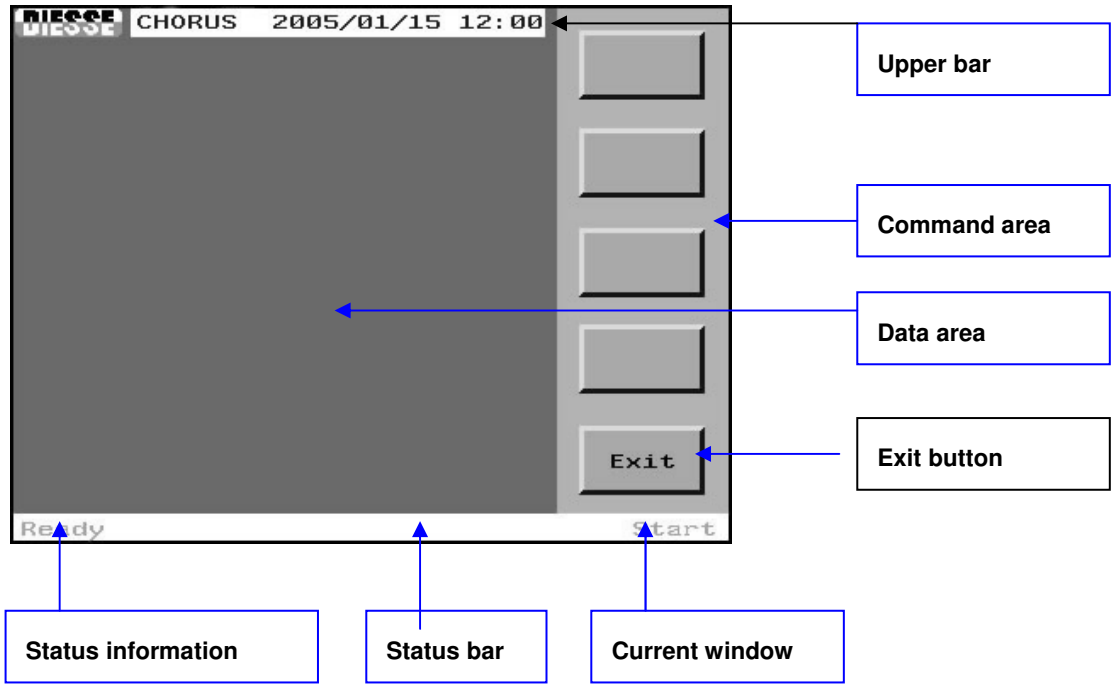
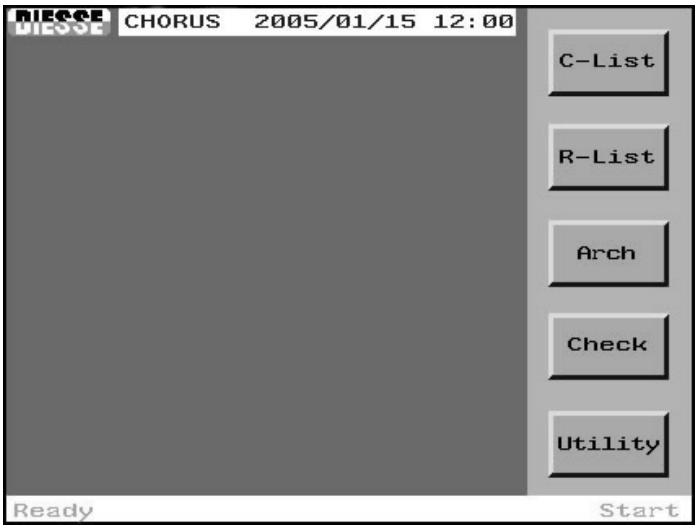


fig. 30

Data area:
This is the part of the screen where all functional data is shown, sample list, tests, editing, results etc.
Command area:
Area dedicated to the command keys (related to the current screen). The only key that appears on all the screens (except the start window) is the ***Exit*** *key, used to return to the previous window.*
Upper Bar
This shows the company logo, the name of the instrument, current time and date.
Status bar:
This shows information on the status of the instrument. The white background shows that the CHORUS instrument is ready and/or running, the red, yellow, or magenta color indicates a problem interfering with normal operation, while the blue color denotes the editing mode.
Status information:
show the indication if the instrument is able to operate or not.
"Ready" indicates that the instrument is ready to execute a cycle
"Not ready" indicates it is not able to execute a cycle, either caused by errors or because one or more checks remained pending on the instrument.
Current window:
Indicates the path of the displayed window. The Start window is considered the main window.

5.2 MAIN WINDOW (START WINDOW)

The *start window* appears at the end of the initial controls, and it is possible to go from this window to all the different functions of the instrument. There is no **Exit** key.



C-List: to access the C-list
R-list: to access the R-list
Arch: to access the archives of the test runs
Check accesses the control window
Pressing the center of the status bar the error window is opened
Utility: to go into the utilities section of the instrument

fig. 31

ATTENTION!
The **R-List** button is disabled if a recoverable or fatal error is found, or if it is necessary to perform a control procedure.

5.3 MANUAL EDITING

Manual editing substituted the barcode reader in the following cases:

- manual introduction of codes which the barcode reader is unable to read
- correction of erroneous codes
- introduction of personalized codes
- introduction of telephone numbers for remote assistance

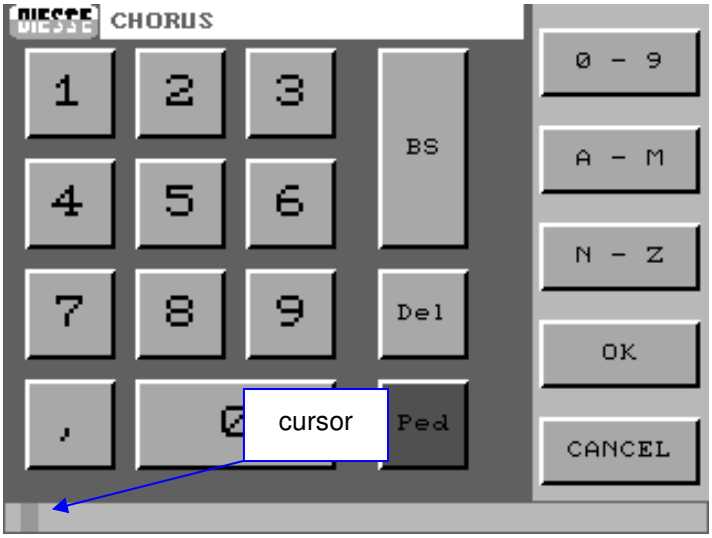
5.3.1 DESCRIPTION OF THE COMMANDS IN EDITING MODE

The **editing** window (**fig. 34**), displaying a numeric keyboard, allows insertion and modification of strip codes without use of the bar code reader.

It also allows the introduction of telephone numbers to connect the instrument via modem to the centers offering assistance.

ATTENTION!

The Ped button is not used at the moment



0-9 : shows the buttons with the numbers from 0 to 9

A-M : shows the buttons with the characters from A to M

N-Z : shows the buttons with the characters from N to Z

BS : backspace

Del : deletes the current code

OK : saves the code and exit the editing window

Cancel : deletes the number selected by the cursor

fig. 32

Even though sample codes generally have a numeric format (they have to be introduced by typing in the exact sequence printed on the label), it is possible to introduce alphanumeric codes simply changing, by means of the appropriate commands, the value of the buttons.

The *strip* codes are also numeric and have to be introduced by reporting the sequence printed on the strip label. Only exiting the editing window, the program will transform the code into the alphabetic acronym of the relative test.

During introduction of a telephone number, the "**Comma**" key can be used, in the case of laboratories with an automatic telephone exchange, to insert a pause between the composition of the first number (generally 0) to obtain the external line, and the telephone number in question.

In the starting window, the *editing* command can be activated in two different ways:

- insert mode (default mode)
- modify mode

When the operator enters the screen in *insert mode*, the editing bar is empty and ready for the new code to be inserted.
In *modify mode* the editing bar shows the code to be modified with the cursor positioned directly after the last character of the code itself.

5.3.2 EDITING IN INSERT MODE

When the operator enters the Insert mode of editing, only the cursor is visualized

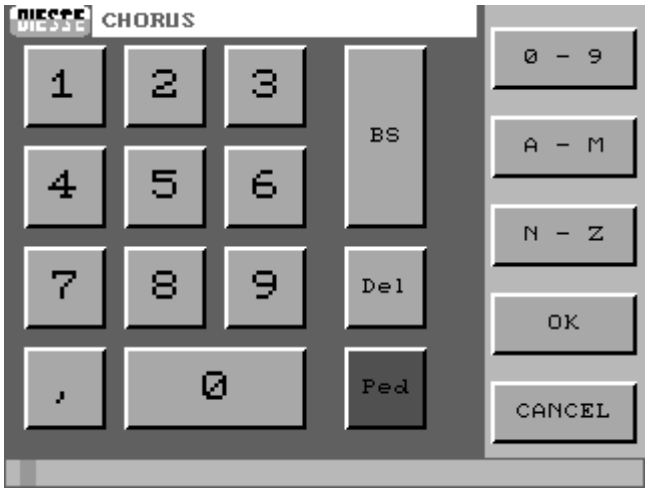


fig. 33

The desired code is inserted by typing the characters on the keyboard.

Press the OK key to save the code and return to the previous window.

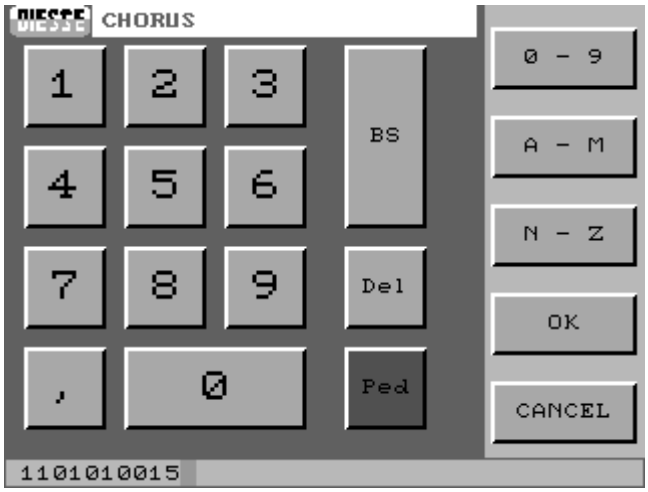


fig. 34

5.3.3 EDITING IN MODIFY MODE

When the operator enters the modify mode of editing, the bar shows the whole code selected, with the cursor positioned after the last character.

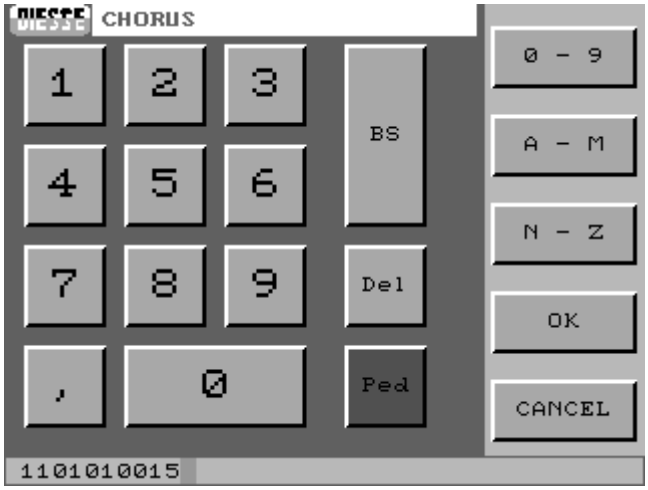


fig. 35

The characters to be modified are cancelled by pressing the BS (*backspace*) key

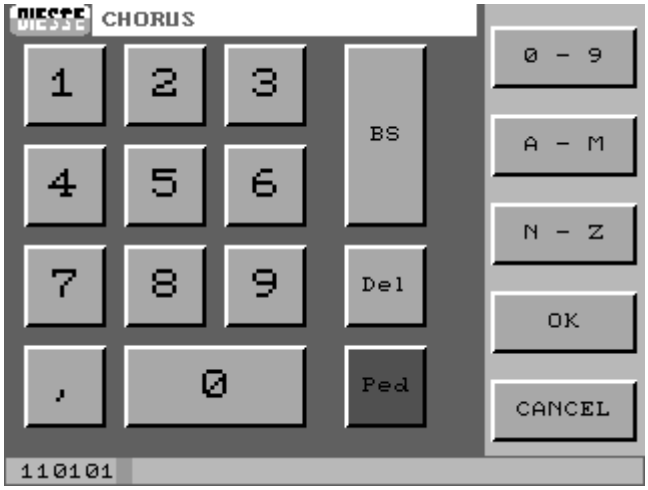


fig. 36

Insert the correct characters and press the OK key to save and exit the window

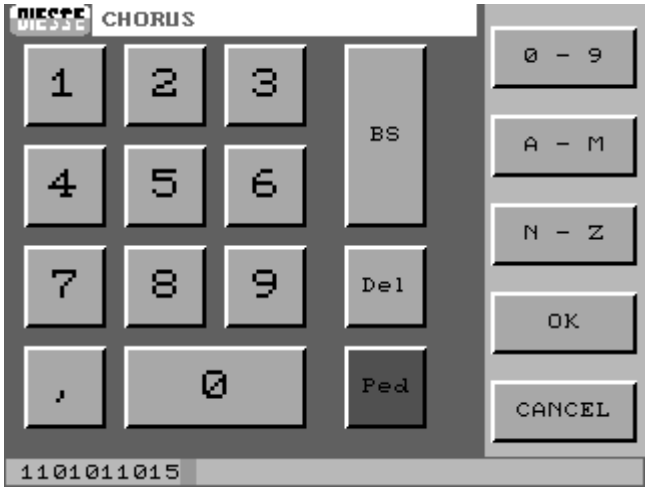
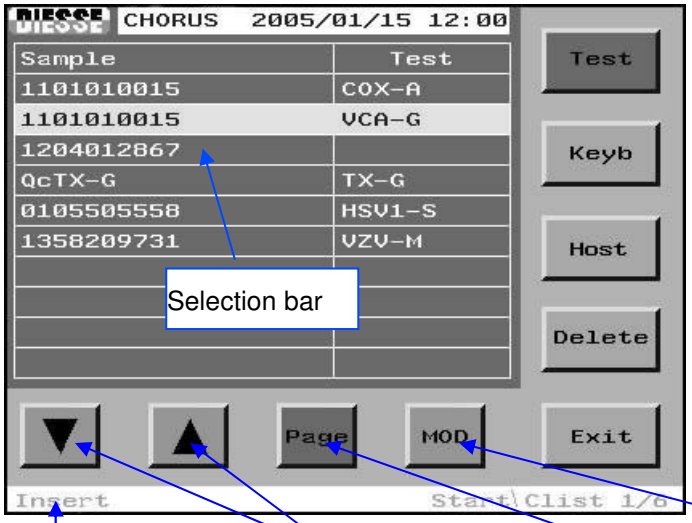


fig. 37

5.4 THE C-LIST WINDOW (COUPLING LIST)

The C-list shows the list of the associations between samples and tests (see 3.1).



Test/Sample: to move the selection bar from the samples column to the test column
Keyb: to access the editing window
Host: to enter the host mode
Delete: cancels the current C-list or the line selected *(a window appears for the choice)*
Exit: returns to the main window
Pressing the center of the status bar **does not** take you back to the errors window

Insert/Modifica-tion: indicates the current mode

▲ ▼: moves the selection bar

Page: passes to the next page

MOD: enables/disables the *modification* mode

fig. 38

Note:
All the keys present in this window, with the exception of the **Keyb** and **Exit** key, can be disabled according to the context

5.4.1 How to use the C-List

When the C-list window is opened, there may be two possible situations:

First case: list empty

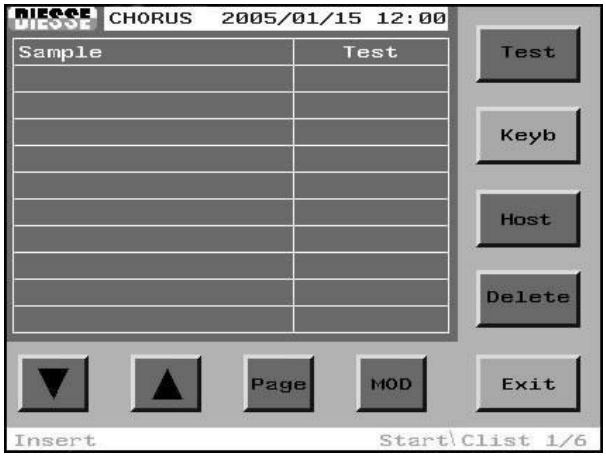


fig. 39

Second case: list compiled

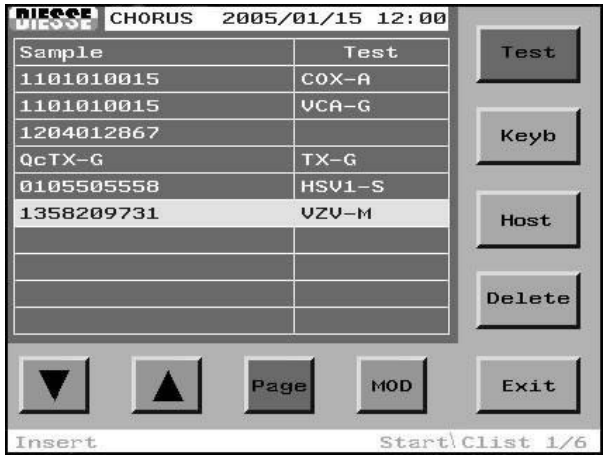


fig. 40

ATTENTION!
It is not possible to start the compilation of a C-list unless at least one sample code has been inserted, because each test must be associated to a sample code already present. In the presence of an empty C-list, therefore, all the keys except the Editing and Exit keys, are disabled.

Apart from the limit reported above, there are no differences in the compilation procedure for an empty list compared to one already compiled.

Note:
To not have to move, once entered into the R-list, any strips inserted during the compilation of the C-list, it is essential to position the strips associated with the calibrators from position 1 onwards, without empty positions.

5.4.1.1 Insertion of the first sample code

ATTENTION!
The Insertion mode must be enabled.

INSERTION BY MEANS OF THE BAR CODE READER

In an empty C-list, the selection bar is not present, and only the **Keyb** and **Exit** keys are enabled.
To start to compile the C-list, the first sample code must be inserted.
It is therefore necessary to proceed with the reading of the bar code of the sample, using the bar code reader.

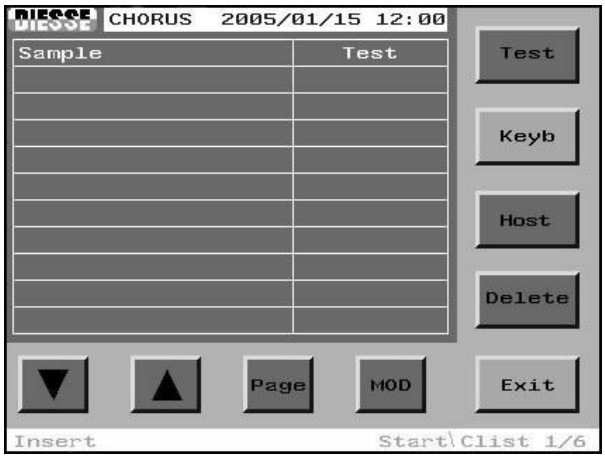


fig. 41

Scanning of the bar code leads to its immediate insertion.
The keys **MOD, Host, Delete** are enabled.

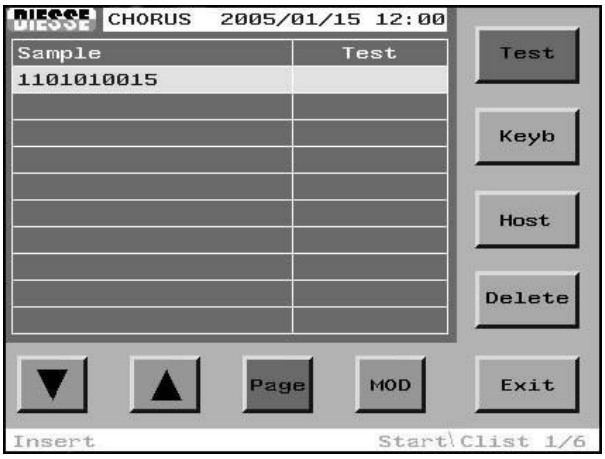


fig. 42

INSERTION THROUGH MANUAL EDITING

In an empty C-list the selection bar is not present and the only keys enabled are the **Keyb** and **Exit** keys.

To insert the first sample code using manual editing, press the **Keyb**

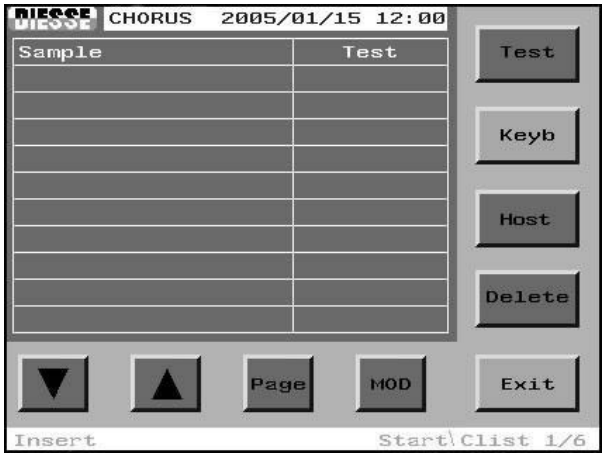


fig. 43

The editing window opens up.
The code is inserted manually.
To save and exit, press the **OK** key (if the **Cancel** key is pressed, the code inserted will not be saved).

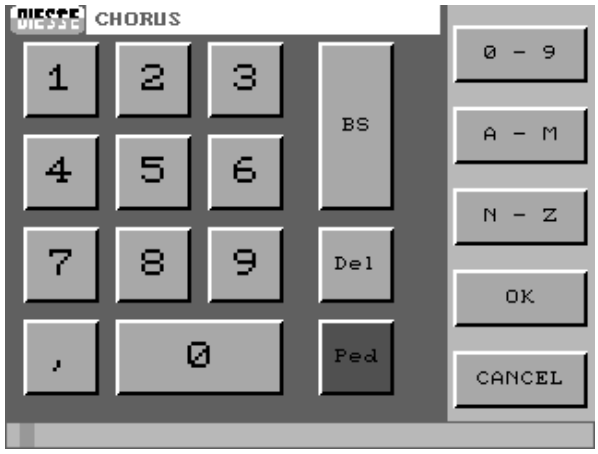


fig. 44

On exiting the editing, the bar will be positioned on the code just inserted.
The keys **MOD, Host, Delete** are enabled.

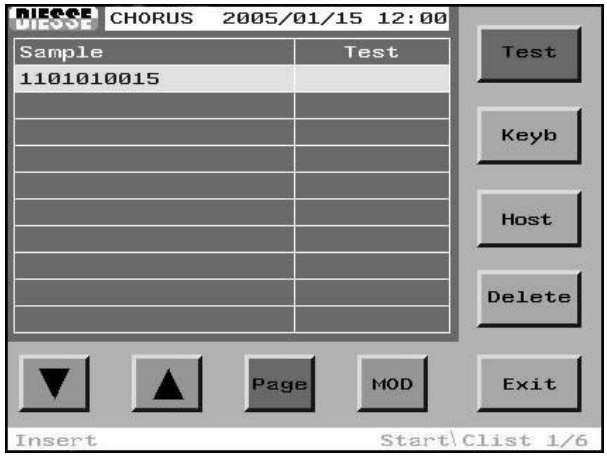


fig. 45

ATTENTION!
Do not insert patient codes with more than 15 characters as these will be considered erroneous strip codes and therefore automatically eliminated by the system.

5.4.1.2 Insertion of the following sample codes

ATTENTION!
The **Insertion** mode must be enabled.

Note:
As the *CHORUS* automatically recognizes the strip codes, the QC codes (quality control) and the calibrator codes, the selection bar may be positioned indifferently either on the "**samples**" column or on the "**test**" column.

Note:
Up to 60 sample codes can be inserted, after which the message "**C-List full!**" will appear**.**

INSERTION USING THE BAR CODE READER

To insert a new code, scan the valid sample code (in the *insertion* mode, the position of the selection bar is not important)

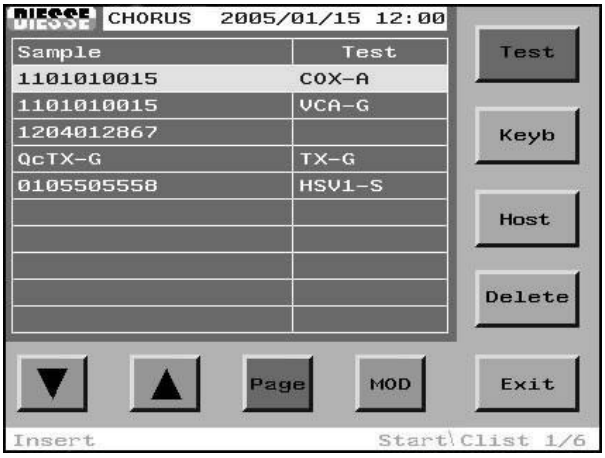


fig. 46

the new code is inserted at the bottom of the list of sample codes already present
the selection bar moves to the new code.

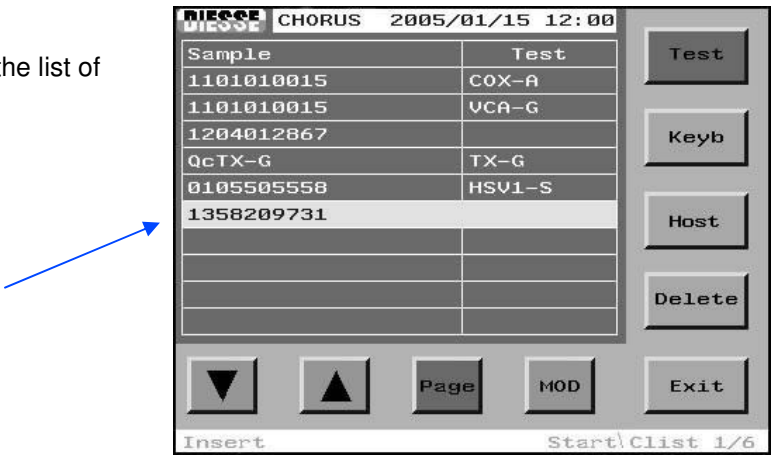


fig. 47

INSERTION OF A SAMPLE CODE WITH MANUAL EDITING

To insert a new sample code manually, press the **Keyb** key (in the insertion mode, the position of the selection bar is not important)

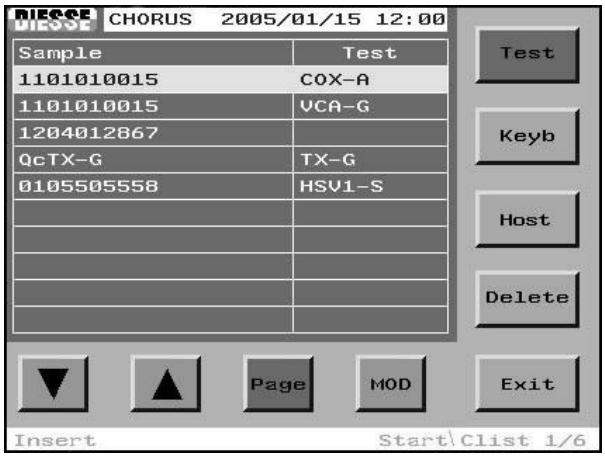


fig. 48

Insert the code manually in the editing window
To save and exit, press the **OK** key (to exit without saving, press **Cancel**).

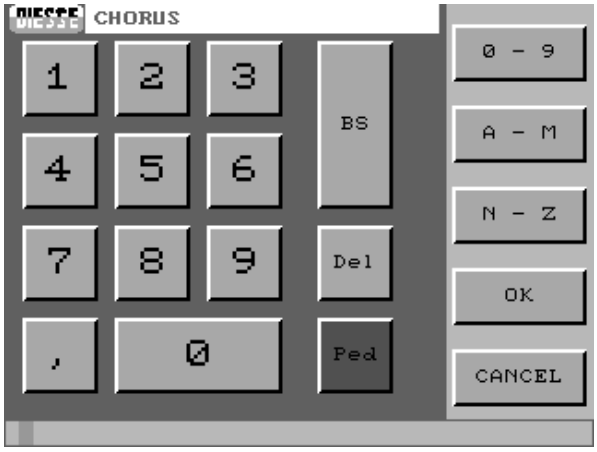


fig. 49

The new code is inserted at the bottom of the list of sample codes already present
The selection bar moves to the new code.

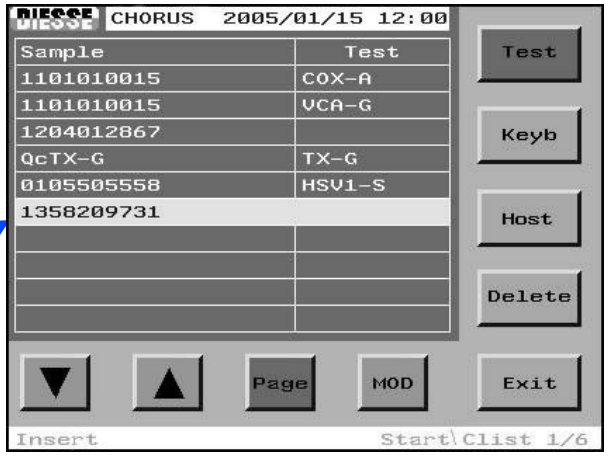


fig. 50

ATTENTION!
Do not insert patient codes with more than 15 characters as they will be considered erroneous strip codes and therefore automatically discarded by the system (a message will appear).

5.4.1.3 Modification of a sample code

ATTENTION!
The **Modification** mode must be enabled.

MODIFICATION USING THE BAR CODE READER

The selection bar must be positioned on the line relative to the sample code to be modified

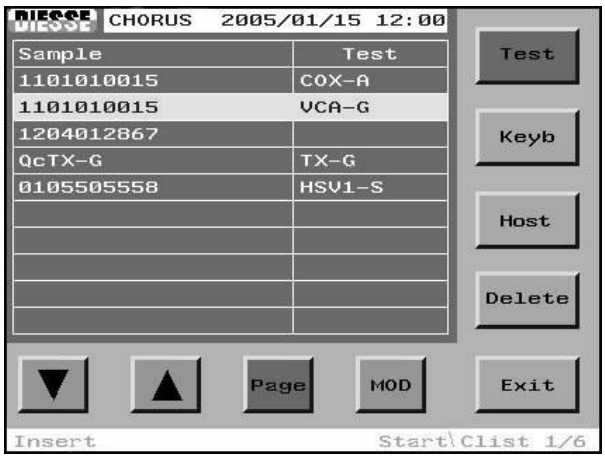


fig. 51

By pressing the **MOD** key, the Modification mode is enabled:
The selection bar moves to the samples column, the change column key is enabled and the status bar will show “Modify”.
The new barcode is scanned using the barcode reader.

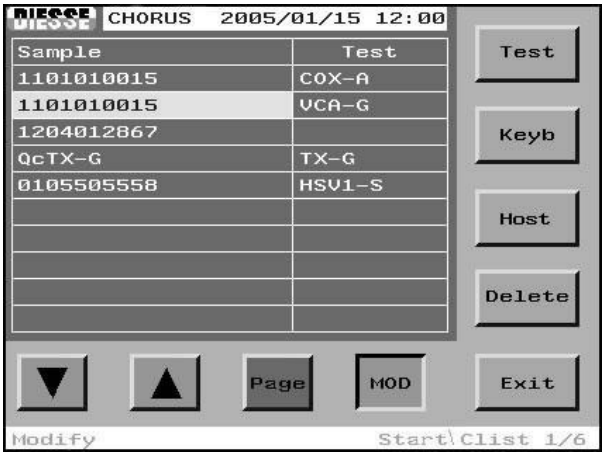


fig. 52

Scanning of the new barcode leads to immediate replacement of the previous one.

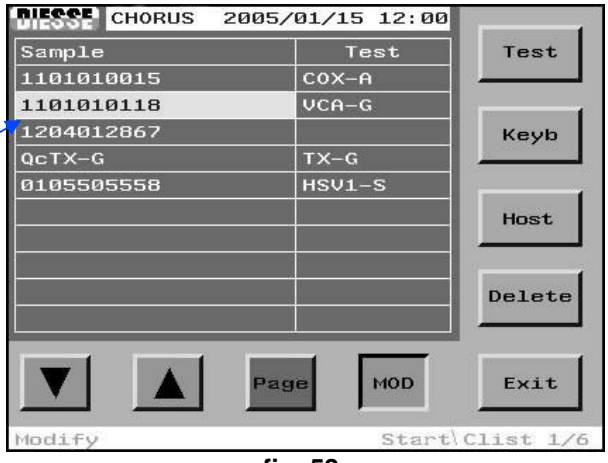


fig. 53

MODIFICATION THROUGH MANUAL EDITING

The selection bar must be positioned on the line relative to the sample code to be modified.

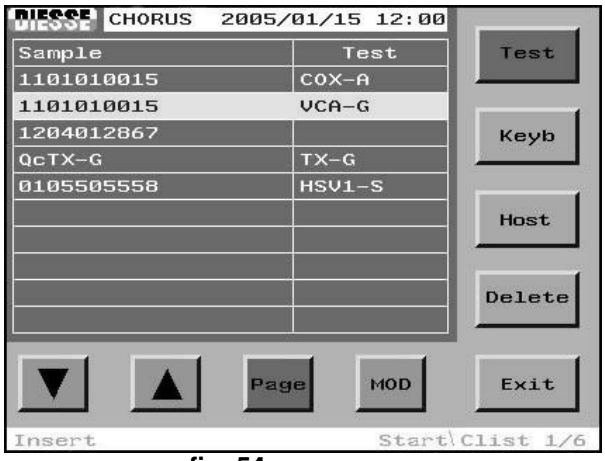


fig. 54

By pressing the **MOD** key, the Modification mode is enabled:
The selection bar moves to the samples column, the change column key is enabled and the status bar will show “Modify”.
Press the Keyboard key to enter the editing mode.

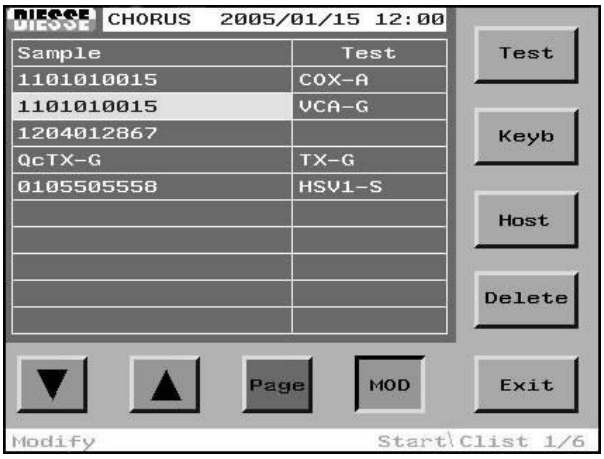


fig. 55

Insert the code manually in the editing window
To save and exit, press the **OK** key (to exit without saving, press **Cancel**)

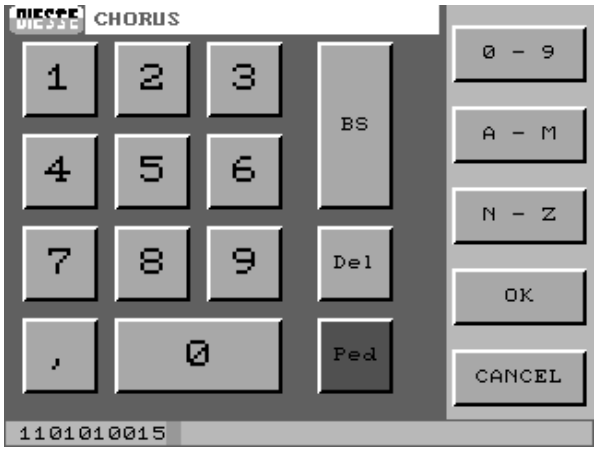


fig. 56

On exiting the editing mode, the selection bar remains positioned on the code which has just been changed.

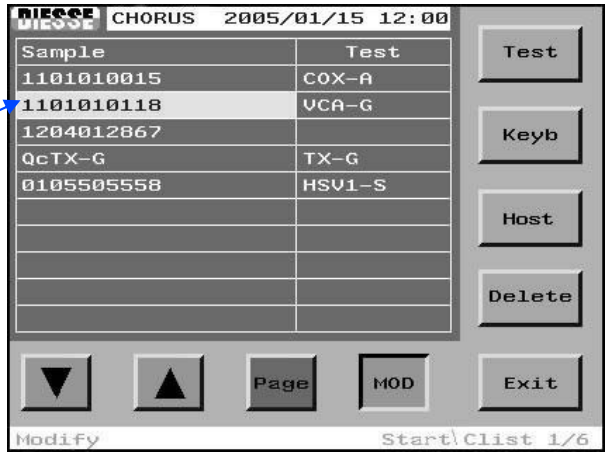


fig. 57

ATTENTION!
Do not insert patients' codes with more than 15 characters as these will be considered erroneous strip codes and automatically eliminated by the system (a warning message will appear).

5.4.1.4 Insertion of a strip code

ATTENTION!
The **Insertion** mode must be enabled.

Note:
As the *CHORUS* automatically recognizes the strip codes, the QC codes (quality control) and the calibrator codes, the selection bar can be positioned either on the "**sample**" column or the "**test**" column.

Note:
Up to 60 associations can be inserted; after this number the message "**C-List full!**" will appear

INSERTION USING THE BARCODE READER

Test not present

In the case that the test is not present in the line selected and a valid strip code is scanned:

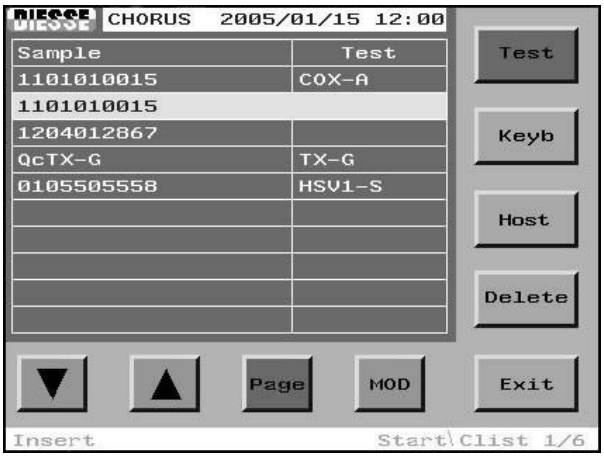


fig. 58

The new code is inserted in the selected field

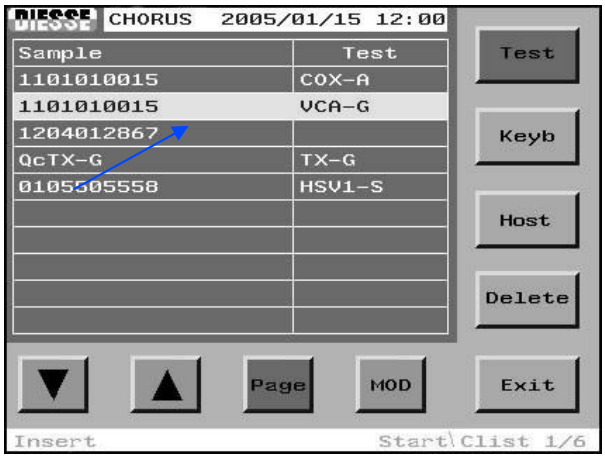


fig. 59

Test already present

In the case that the test is already present in the line selected and a valid strip code is scanned:

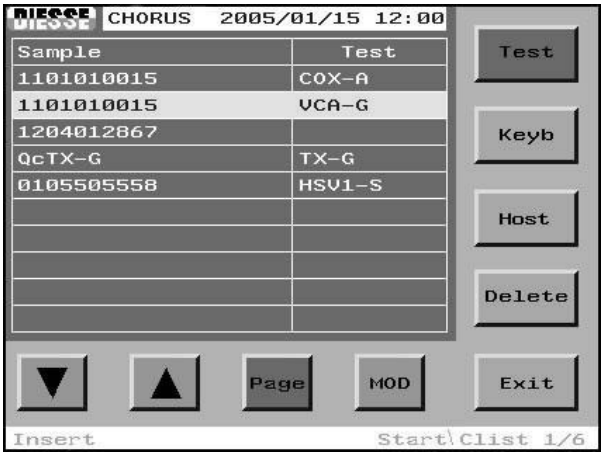


fig. 60

The sample code is duplicated
The new sample/test association is inserted at the bottom of the list of codes already present
The selection bar moves to the new association

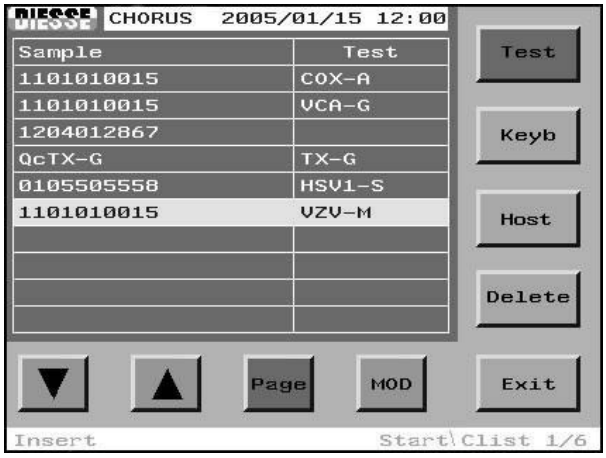


fig. 61

INSERTION THROUGH MANUAL EDITING

ATTENTION!

The **Insertion** mode must be enabled.

Bar positioned on empty test code

When the selection bar is positioned on a line without a test code, and the operator wishes to insert a test manually:

press the **Keyb** key

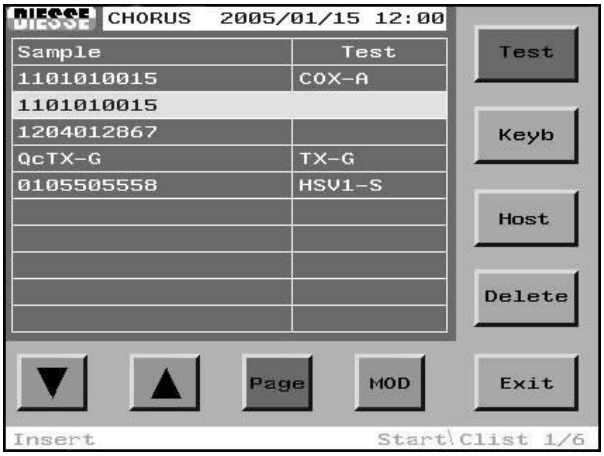


fig. 62

Insert the code manually in the editing window
To save and exit, press the **OK** key (to exit without saving, press **Cancel**)

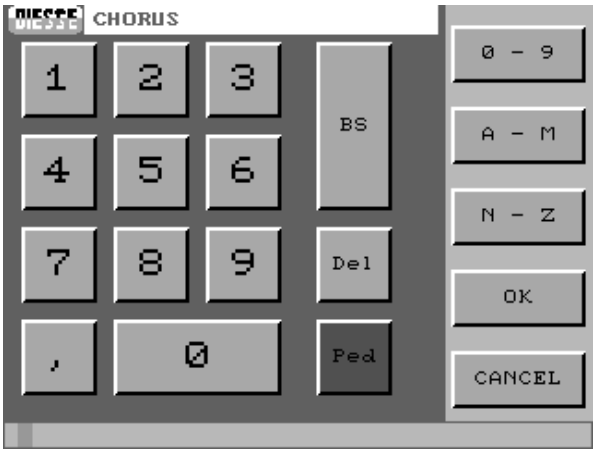


fig. 63

The new test code is thus introduced in the selected position

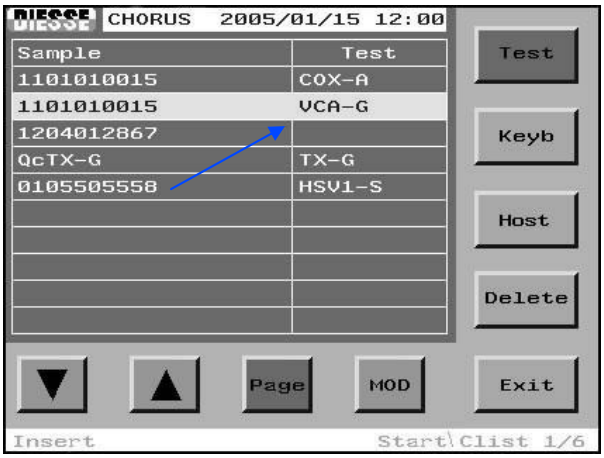


fig. 64

Bar positioned on a test code which is present

When the selection bar is positioned on a line which already contains the test code and the operator wishes to insert manually a new test associated to the same sample code:

press the **Keyb** key

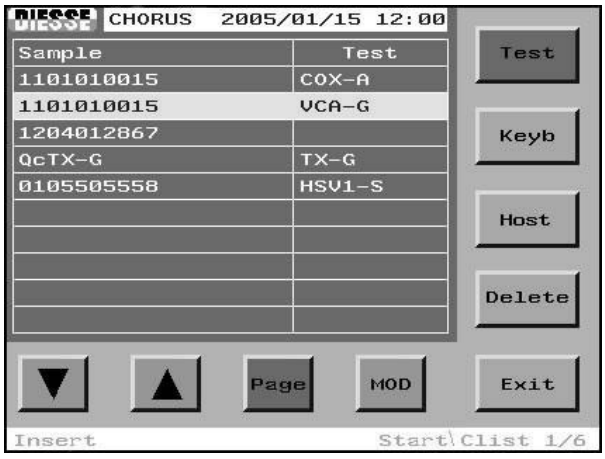


fig. 65

insert the code manually in the editing window

To save and exit, press the **OK** key (to exit without saving, press **Cancel**)

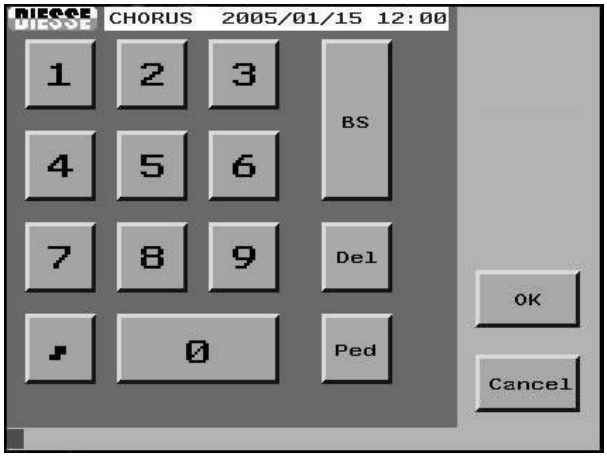


fig. 66

The new association sample/test is thus introduced in the last available position

the selection bar moves to the new association

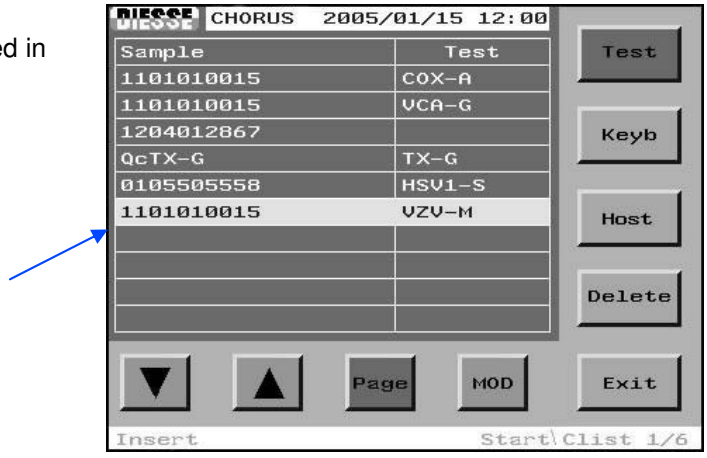


fig. 67

INSERTION OF STRIP CODES IN THE HOST MODE

Open the window of the C-list.
In the example shown in the figure the C-list is completely empty, but some associations could also be present (associations already present will not be considered by the connection to the Host)

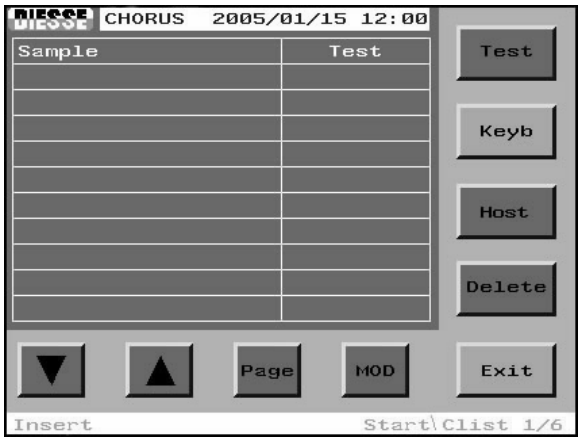


fig. 68

Compile the **C-list** introducing the sample codes (using the barcode reader or manual editing) and then enable the connection to the Host Computer, through the **Host** command.

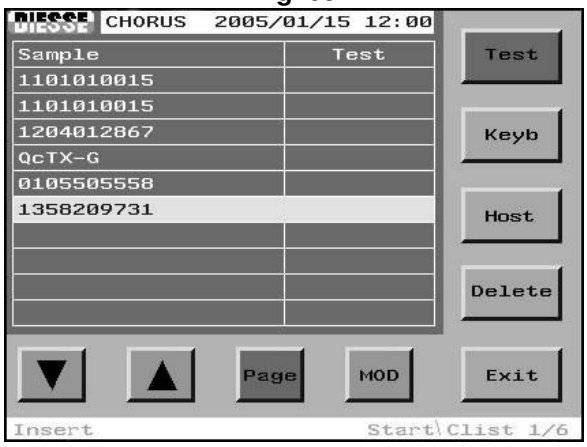


fig. 69

After a few seconds the J-list (Job List) will appear, in which each sample is associated with one or more test codes to be performed.

The magenta colour indicates that the Host has only sent the test codes (temporary codes).

The blue colour indicates that a paediatric sample (this characteristic is not used at the moment, see 5.3.1)

The maximum number of associations allowed in the C-list is 60 (any associations above this number will not be considered by the system).

As the system cannot perform more than 30 tests in a run (as the carousel can contain a maximum of 30 strips), the associations which are not processed in the first run will remain saved in the J-list, to be processed successively; the identification procedure which precedes the RUN in fact individuates the associations and performs the tests, eliminating the tests performed from the J-list. On reopening the J-list, it can be seen that the tests already performed have disappeared, and so on until its complete execution.

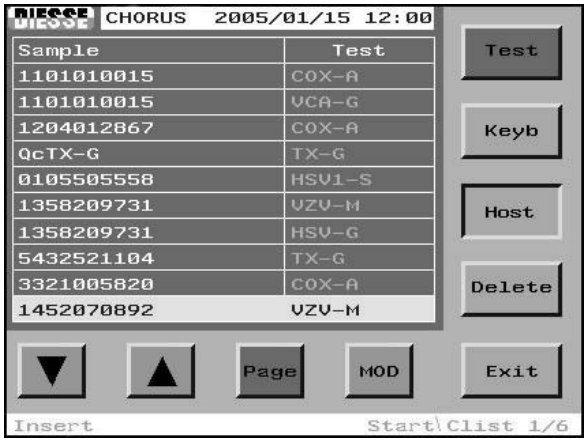


fig. 70

ATTENTION!

It is advisable not to cancel the tests from the Job List because at the end of the RUN, the system automatically cancels those which have been performed, leaving on the list only those still to be executed.

5.4.1.5 Modification of a strip code

ATTENTION!
The **MOD** mode must be enabled.

MODIFICATION USING THE BARCODE READER

The selection bar must be positioned on the line relative to the strip code to be changed.
Press the **MOD** key to enter the modification mode and then the **Test** key to move the selection bar to the test column.

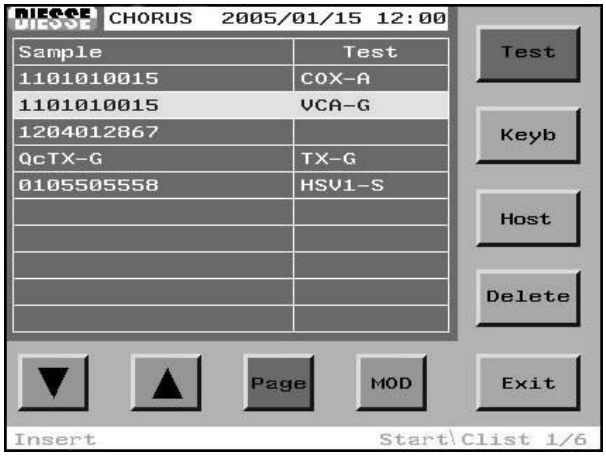


fig. 71

Scan the new barcode using the barcode reader

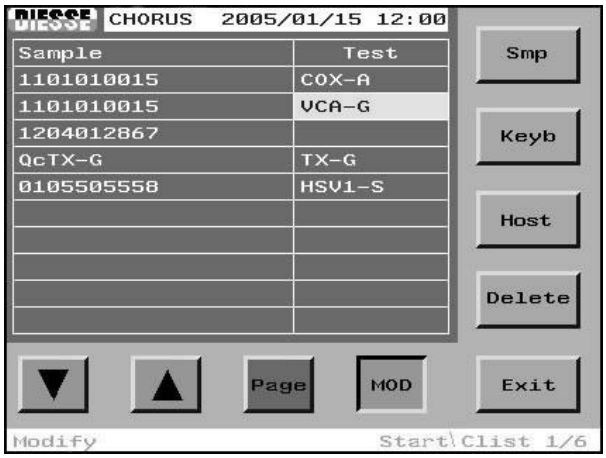


fig. 72

Scanning of the new code leads to immediate replacement of the previous one.

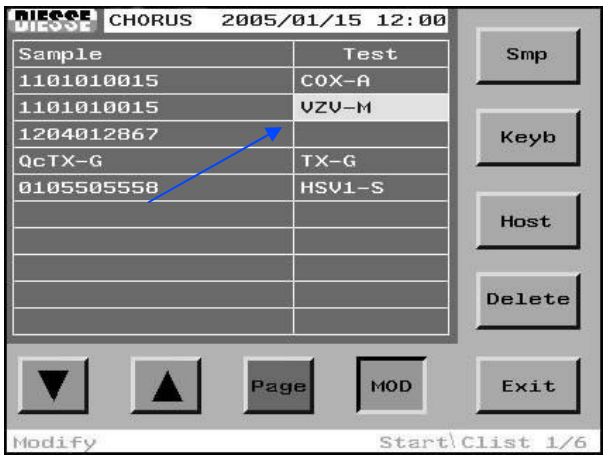


fig. 73

MODIFICATION THROUGH MANUAL EDITING

The selection bar must be positioned on the line relative to the strip code to be changed.

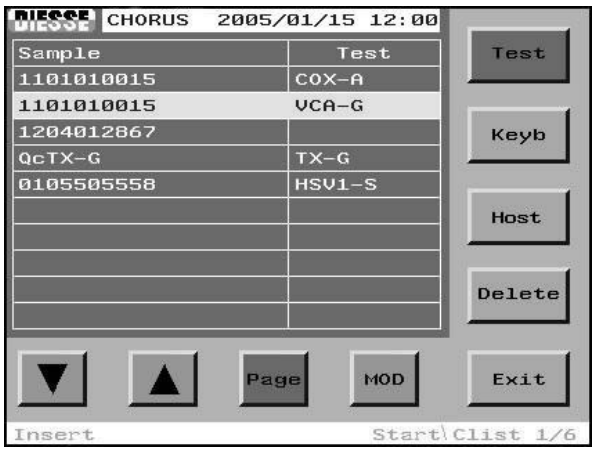


fig. 74

Press the **MOD** key to enter the modification mode, and then the **Test** key to move the selection bar to the test column

To enter the insertion mode, press the **Keyb** key

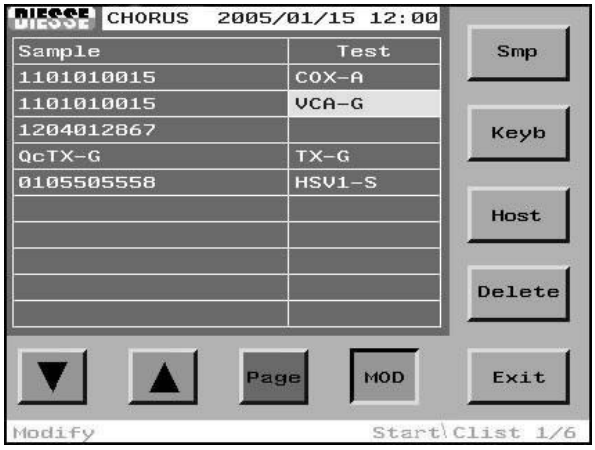


fig. 75

Insert the code manually in the editing window

To save and exit, press the **OK** key (to exit without saving, press **Cancel**)

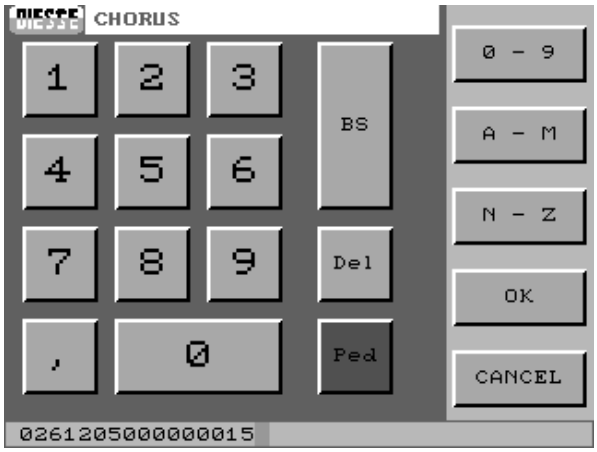


fig. 76

The new code replaces the old one.

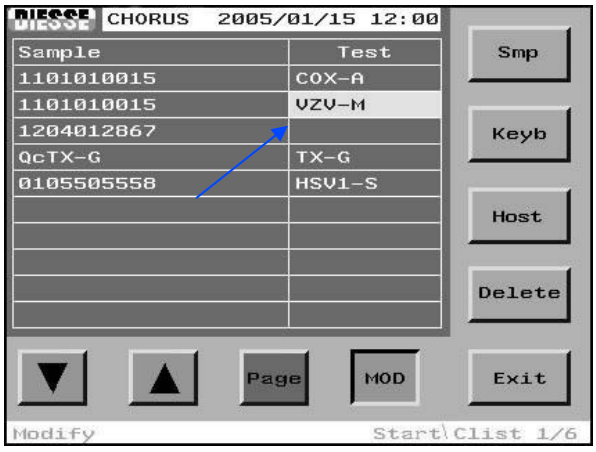


fig. 77

5.4.1.6 Cancellation of codes present in the C-list

To cancel the associations or the single sample codes, press the **Delete** key

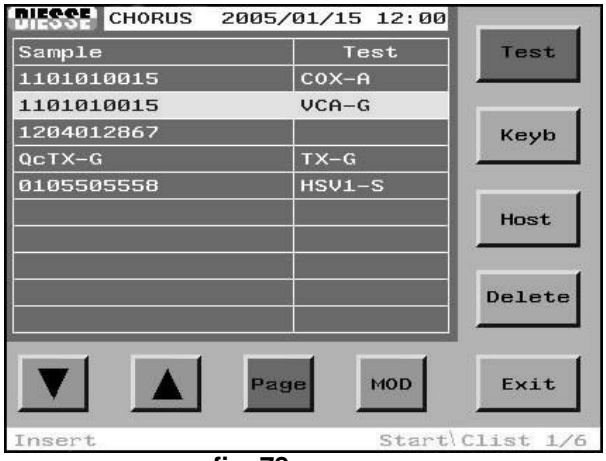


fig. 78

A window will appear for 10 seconds, giving the following choice:

- Delete the whole C-list which is saved (**All** key**)**
- Delete the single line selected by the selection bar (**Current** key)

If the **Cancel** key is pressed, no changes will be made to the C-list.

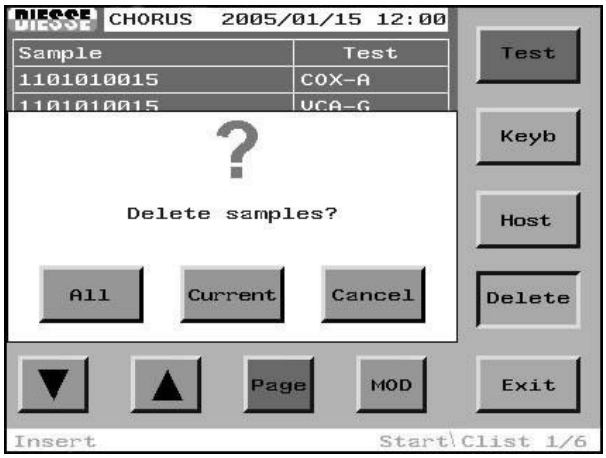


fig. 79

5.5 THE R-LIST (RUNNING LIST) WINDOW

5.5.1 STANDARD USE OF THE R-LIST

The **R-list** contains the list of tests to be performed and may also contain the sample codes associated to these tests. (For information regarding the R-list, see paragraph 3.2.).
Before pressing the **R-list** key in the main window, the strips must be inserted in the tray.

Note
The strips that are intended for the dispensing of the calibrators have to be inserted in the sample holder tray, without leaving empty positions or inserting controls and/or samples between one calibrator and another, from the first position onwards.
In case a calibration of a new product batch is executed the instrument will show, at the end of the scanning of the bar codes of the strips, the error “NO CALIB” on every test of that batch. This error will disappear in the moment the bar code of the calibrator is read; the sample code associated to the strip in which the calibrator is dispensed, will thus be substituted by the text “cal + acronym of the test in execution”
Whenever the association between the calibrator and the strip is already executed in the C-list modality, remember to insert the strips of the calibrators in the first positions of the sample holder tray, one after the other, as specified above.

If a C-list has been compiled, these strips will result already associated to the relative tests. If no C-list has been compiled, it is sufficient to insert all the strips, not yet containing serum, in the tray.
When the **R-list** key is pressed in the main window (*confirmation is required*), an **identification** procedure commences, which identifies all the strips present in the tray, and indicates eventual errors (see 7.2.4).

ATTENTION
During the identification phase, the strips are classified according to “families” of homogeneous tests relative to the execution parameters of the tests themselves. If several families are identified, the run will be divided into sub-sessions, each of which is performed separately, one after the other, without any interruption in the function of the instrument. Each sub-session is stored as an independent session.

After this the R-list window will open, and may appear as follows :

First case: C-list stored

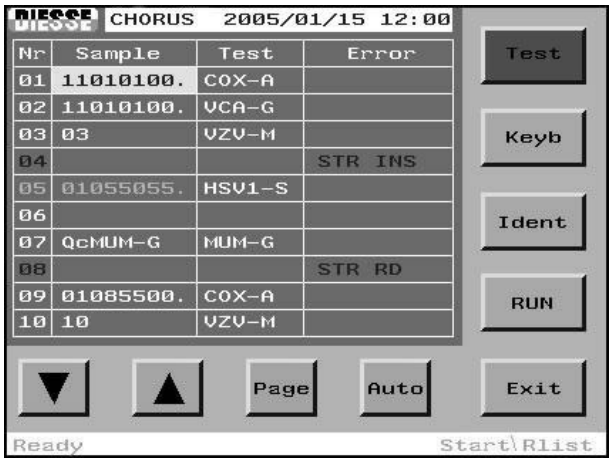


fig. 80

Second case: C-list not stored

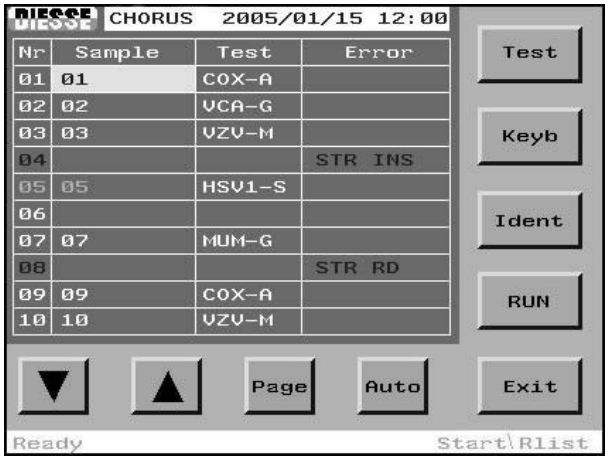


fig. 81

Note:

In case the previous cycle was interrupted, before entering this window, the instrument will execute automatically a quick priming of the washers.

Note:

In the case that the status of the instrument is not compatible with performance of the cycle (i.e. some functions are still pending), or in the case of recoverable or fatal errors, it will not be possible to open this window.

Note:

Access to the errors window by pressing the status bar is disabled from this window

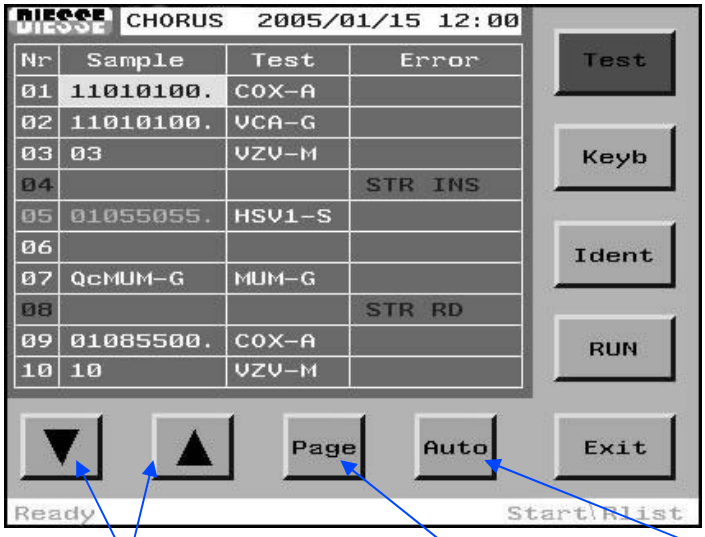
5.5.2 A C-LIST IS STORED

If a **C-list** is stored, the positions in the carousel in which valid strip codes have been identified, are associated with the sample codes present in the C-list itself

The number in blue indicates that the sample is paediatric. (this characteristic is not used at the moment, see 5.3.1)

In the *Err* column, any error strings relative to the strip which has been identified, are shown.

For a complete explanation of the errors, see the specific chapter (7.2.4).



Test: moves the selection bar from the samples column to the test column

Keyb: to access the editing window

Ident: identifies the strips present in the carousel again

Run: starts the cycle

(any strips presenting errors will not be processed)

Exit: returns to the main window

▲ ▼: select the previous/next code and consequently move the carousel

Page: goes to the next page and moves the carousel by 10 positions

Auto: if enabled, allows automatic advancement of the strip tray following insertion of a code via the barcode reader

fig. 82

5.5.3 NO C-LIST IS STORED

In the absence of a **C-list**, the instrument simply indicates the strip codes detected in each of the 30 positions on the carousel and assigns to each one a sample code corresponding to the position of the strip on the plate. If the operator wishes, he can change the sample codes, either by scanning with the barcode reader or by manual editing.

In the *Err* column, eventual error strings are shown regarding the identified strips.

For complete information on the errors, see the specific chapter (7.2.4).

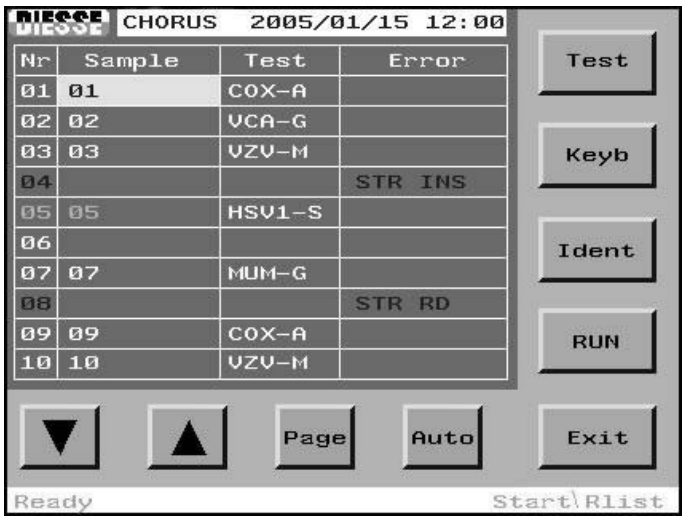


fig. 83

Test: moves the selection bar from the samples column to the test column

Keyb: to access the editing window

Ident: identifies the strips present in the carousel again

Run: starts the cycle

(any strips presenting errors will not be processed)

Exit: returns to the main window

5.5.4 INSERTION OF A SAMPLE CODE

To insert a sample code, place the selection bar on the empty field in the Sample Column, corresponding to the test which has not yet been associated to a sample, and read the sample code with the bar code reader, or press the **Keyb** key to insert it manually.

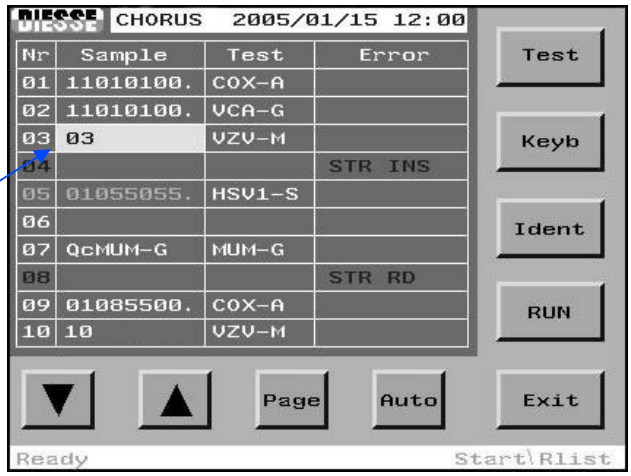


fig. 84

ATTENTION!:

It is possible to insert or modify a sample code only if the strip is present in the tray and there is no corresponding association in the C-list.

If it is necessary to modify or cancel a sample code which is already associated to a test, it is necessary to exit from the R-list window temporarily, go to the C-list, modify the code and return to the R-list.

Note:
To program a paediatric sample, position the selection bar on the corresponding field, enter the editing mode (Keyboard), press the Ped key and save. (this characteristic is not used at the moment, see 5.3.1)

5.5.5 INSERTION OF A STRIP CODE

To insert a strip code, place the selection bar on the empty field in the Test Column, corresponding to the sample which has not yet been associated to a test, and read the strip code with the bar code reader, or press the **Keyb** key to insert it manually.

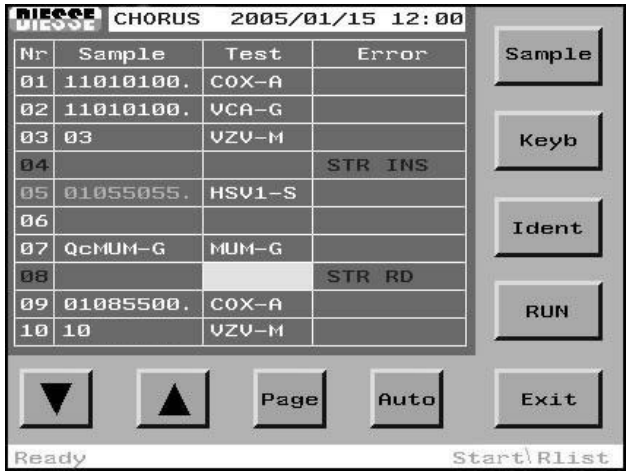


fig. 85

ATTENTION!:
It is possible to insert a strip code only if the strip is present in the tray and the barcode reader has indicated a reading error during the identification phase (**STR RD**). The code inserted will be magenta colored to indicate that it has been inserted manually, and on the test report it will be preceded by a **?**.
If it is necessary to modify or cancel a strip code which has already been associated to a sample, exit the R-list, go to the C-list, modify the association and return to the R-list.

5.6 STARTING THE RUN

At the end of the identification phase, press the **Run** key to start the cycle**.**
If any strips give an error, a message will appear asking for confirmation to start the cycle.
Whenever expired strips are present on the tray, by means of a message box will be requested whether they have to be processed in the cycle too.

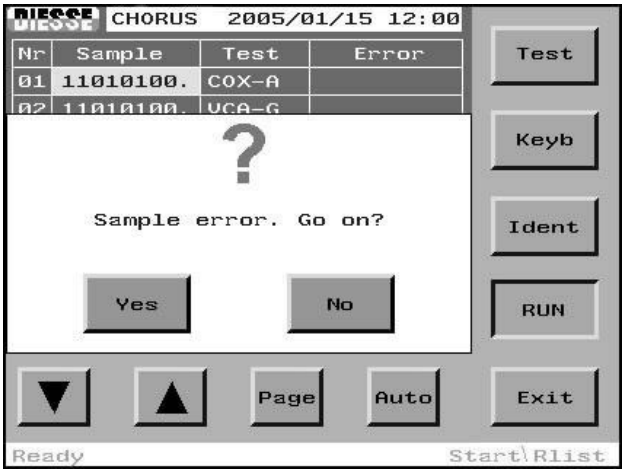


fig. 86

ATTENTION!
The quantity of the buffer solution and of the washing solution depends of the number of tests that has to be executed; in particular:

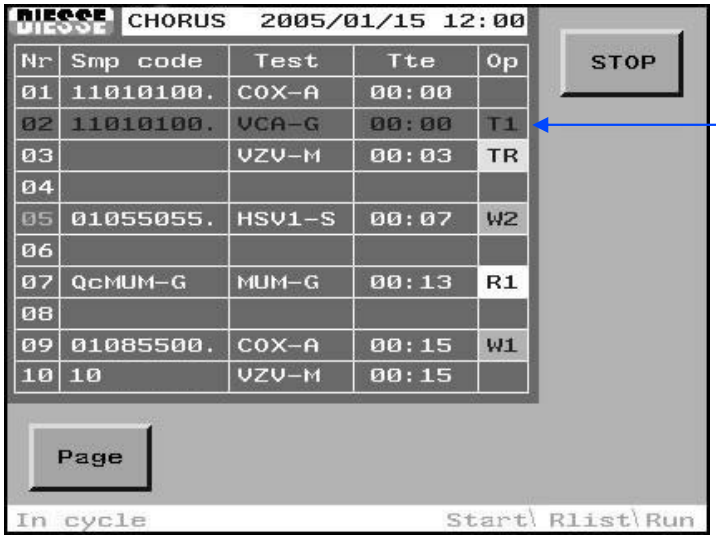
- if there are more than 15 test to be executed:
  it is checked that both tanks contain at least 50% of the liquid
- if there are 15 o less test to be executed:
  it is checked that both tanks contain at least 25% of the liquid

Note:
Strips giving an error will not be processed.
In the case that no strips can be processed, it will be impossible to start the cycle.

5.7 RUNNING THE CYCLE

5.7.1 THE CYCLE WINDOW

When the cycle starts, the system performs the tests programmed and the Run window appears.



STOP: interrupts the cycle

Sample in error

Pag: moves between pages, showing 10 samples on each page

fig. 87

During the cycle, as the results for a sample become available they are displayed, stored and printed.
In the case of a sample error, display and printout take place immediately. The samples with errors will appear in red, with the error code in the OP column.
The RUN session can be interrupted at any time, using the **STOP** key. In this case, the operator is asked to confirm, and when he does so the cycle is stopped. The results of the samples already tested are stored, while the samples still to be processed are not taken into consideration.

The meaning of the columns in the window is as follows:

Nr :
position on the sample plate to be processed; pediatric samples are colored in blue (this characteristic is not used at the moment, see 5.3.1)
Smp code:
alphanumeric code of the sample. This may be the code of a sample, a calibrator or a QC.
Test:
descriptive code of the test to be performed, programmed on a given sample
Tte:
indicates the time, expressed in hours:minutes required to finish the test on the corresponding sample (Time to expiry).
Op:
indicates the code of the operation being performed on the sample.

The possible codes of the operations being performed on the samples are the following:

TR:	*Transfer*
W1 W2 W3:	*Washings in the three stations*
R1 R2 R3:	*Optic readings in the three stations*

For the error codes, see 7.2.5.

At the end of the cycle a message box notifies the operator it is necessary to execute a washing at the end of the working day, to avoid the deposit of molds.

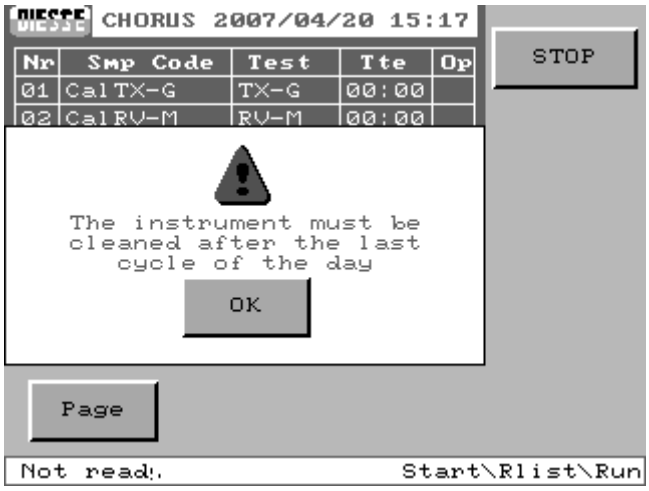


fig. 88

5.7.2 CYCLE RESULTS

At the end of the work cycle the following window appears, reporting the results of the last cycle performed

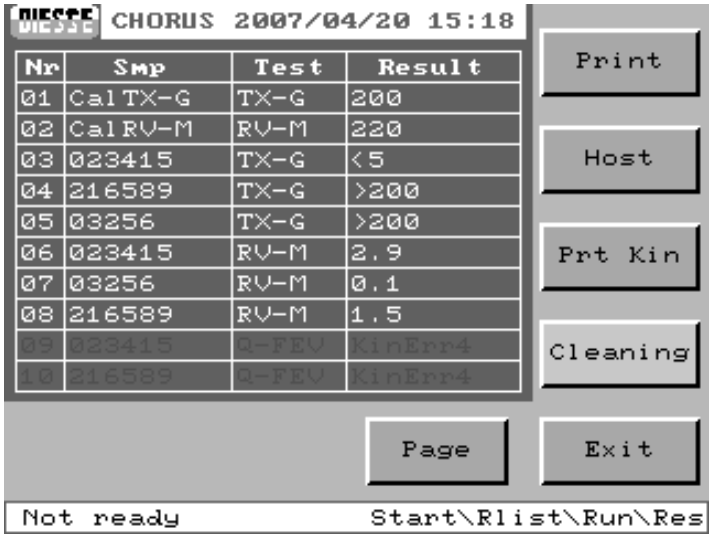


fig. 89

Print: prints the results
Host: sends the results to the Host
PrtKin: prints the kinetics
Cleaning: executes the washing of the circuit of the buffer solution
Pag: visualizes the next page of the results
Exit: returns to the main window

Note:

The lines relative to strips which have not been processed due to error are shown in red
The strip codes inserted manually are shown in magenta

The paediatric codes are shown in blue. (this characteristic is not used at the moment, see 5.3.1)

5.7.3 PRINTED REPORT

Below is an example of the printout of the analysis results:

```
CHORUS     DIESSE Diagnostica Senese SpA
2006/11/01 12:00     Rel. 2.09r10   Meth. 7     S/N: 1000/10/2006

Nr   Smp Code        Test    R  Value         MU    Min   Max   Lot
-------------------------------------------------------------------
01   Qc  TX-av       TX-av   H  50.00         %     40    60    01
02   Qc  TX-av       TX-av   L !25.00         %     40    60    01
03   Cal RV-G        RV-G    -  200                             12
The following sample has been processed with an expired device:
04   Sample #1       TX-av   L  20.00         %                 01
05 T Sample #2      ?TX-av      N.C.          %                 01
06p  Sample #3       TX-av      KinErr0       %                 01
07   Sample #4       TX-av      N.C           %                 01
08   Qc  RV-G        RV-G    N !7.5          IU/ml  10.0  50.0  12
09   Sample #5      ?RV-G    D  10.0         IU/ml              12
10   Sample #6       TX-G       T_ERR                           10
```

fig. 90

The meaning of columns is the following:

Nr:
Position of the strip on the tray. If followed by the letter "p", it is a paediatric sample (this characteristic is not used at the moment, see 5.3.1)

Smp code:
Sample code. If preceded by the letter T, the strip has been processed with a temperature error and the result could therefore not be correct
Possible expired strips will be preceded by the phrase " The following sample is process with a expired strip"

Test:
Test performed. If preceded by the character ? , the strip code was not identified by the barcode reader and was inserted manually (therefore the system cannot guarantee its validity)

R (reference):
This represents the interpretation of the numeric result compared to the cut-off.
Possible values are: P (positive), N(negative), D (doubtful).

Value:
Numeric result. In the QC (quality control) out side the acceptability range this information is proceeded by the character !?
MU:
Units of measure (varies according to the test method used)
Min:
Minimum acceptable limit in the case of QC (quality control)
***Max**:*
Maximum acceptable limit in the case of QC (quality control)
Lot:
Batch number of the strip

Note:
If during a given run, strips that belong to non-homogeneous families of tests have been processed, the results will be printed at the end of each sub-session with a specific report

5.8 THE SESSIONS ARCHIVE

5.8.1 THE ARCHIVES WINDOW

This window presents a list of the runs performed, displaying for each one the date and time of execution. The instrument can store up to 20 runs; the most recent ones overwrite the oldest ones.

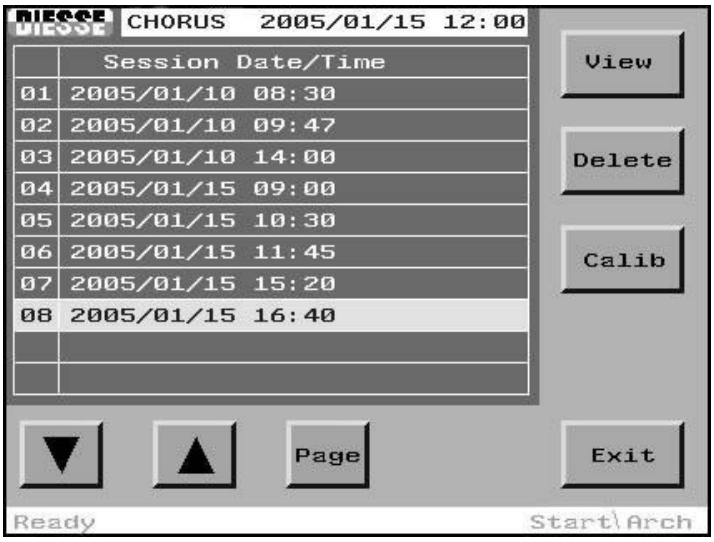


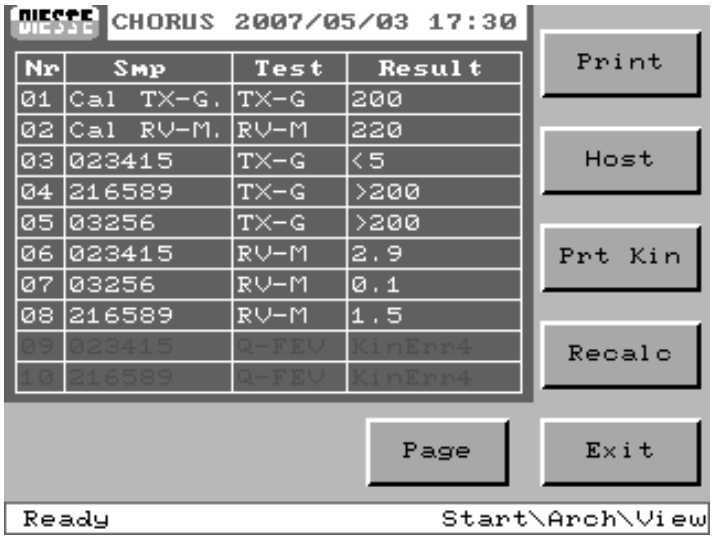
fig. 91

View: enters the session window (displays details of the selected run)
Delete: cancels the entire archive *(a message appears requiring confirmation)*
Calib: prints the calibration list for each test, with the date of run
Pag: visualizes the previous/next page
Exit: returns to the main window

Note:
If during a given run, strips that belong to non-homogeneous families of tests have been processed, the instrument will create an archive for each of the families of tests processed (sub-sessions).

5.8.2 SESSION WINDOW

The session window shows in detail the sessions stored in the archives window. This window shows the samples, the tests performed and the results for each session stored.
It is possible to print from this window and send the results of the session to the Host, view the relative kinetics and recalculate the results using the values of the memorized calibration curve.

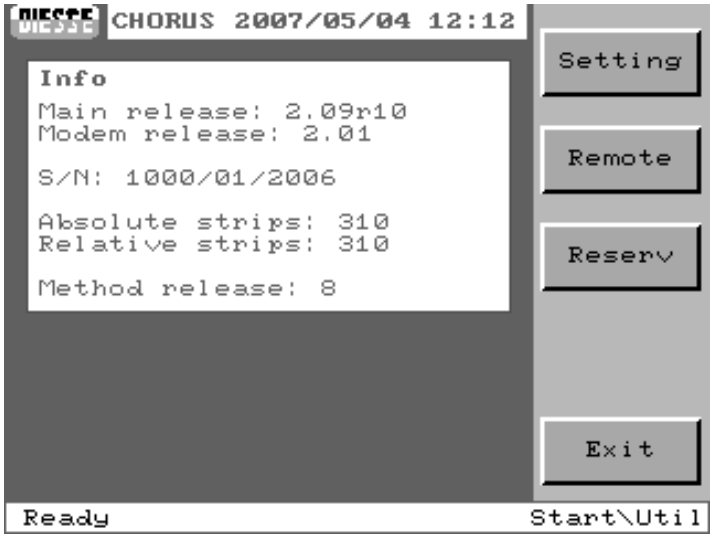


Print: prints the results
Host: sends the results to the host
Prt Kin: prints the kinetics
Recalc: recalculates the results with the new calibration curve
Page: visualizes the previous/next page
Exit: returns to the archives window

fig. 92

5.9 THE UTILITIES WINDOW

The utilities window shows the information identifying the instrument.
It is possible to enter the different utilities functions from here.



Setting: enters the settings window
Remote: enters the window for remote connection
Reserv.: enters the area reserved to technical assistance personnel *(a password is required)*
Exit: returns to the main window

fig. 93

Main Release:
Release firmware of the CHORUS
Modem Release:
Release firmware of the modem
S/N:
Serial number of the CHORUS instrument (serial number/month of production/year of production)
Absolute strips:
Absolute counter of the strips processed by the instrument
Relative strips:
Relative counter of the strips processed (returns to zero after an intervention by technical staff)
Method release :
Release of the test methods stored

5.9.1 SETTINGS WINDOW

Through this window it is possible to reach the instrument settings windows.

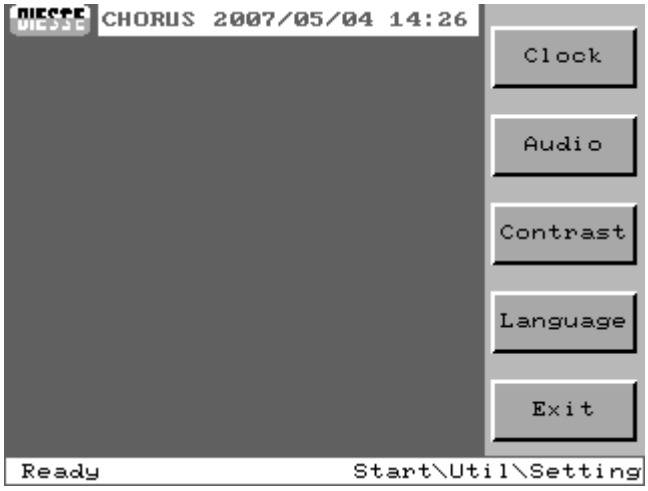


fig. 94

Clock: sets the date and time of the instrument
Audio: sets the volume of the speaker
Contrast: sets the contrast of the monitor
Language: sets the instrument language
Exit: returns to the utilities window

5.9.1.1 Clock setting

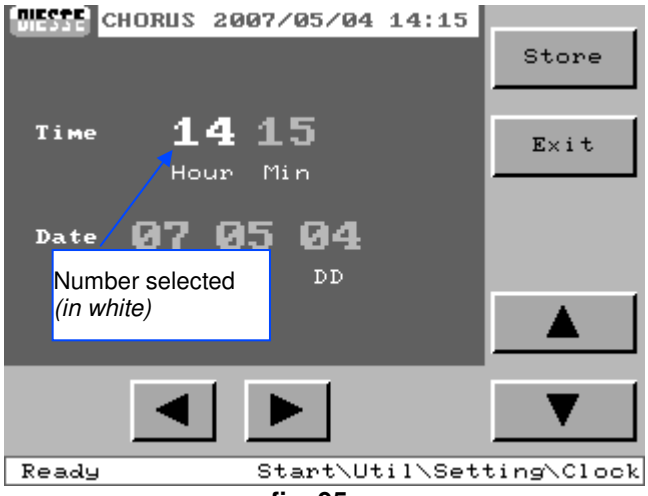


fig. 95

Store: memorizes the date and time that have been set
Exit: returns to the settings window
◄ ►: select the number to be set
▲: increases the number selected
▼: decreases the number selected

5.9.1.2 Audio setting

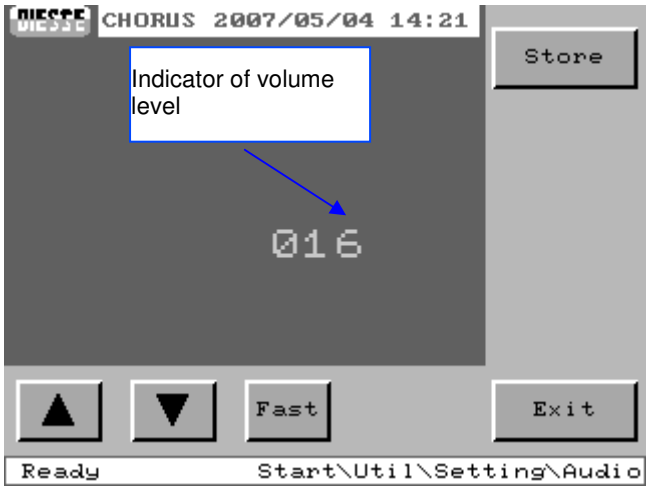


fig. 96

Store: memorizes the volume that has been set
▲ ▼: increases/decreases the volume by one unit at a time
Fast: if activated, allows increases/decreases by ten units at a time
Exit: returns to the settings window

5.9.1.3 Setting of brightness of the monitor

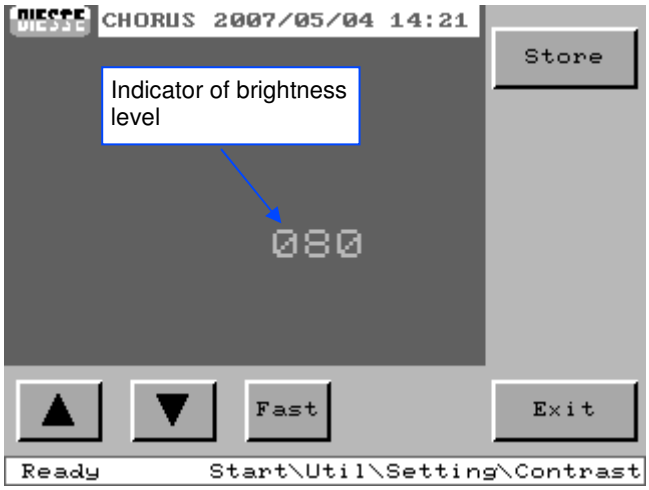


fig. 97

Store: memorizes the level of brightness that has been set
▲ ▼: increases/decreases the level by one unit at a time
Fast: if activated, allows increases/decreases by ten units at a time
Exit: returns to the settings window

5.9.1.4 Language setting

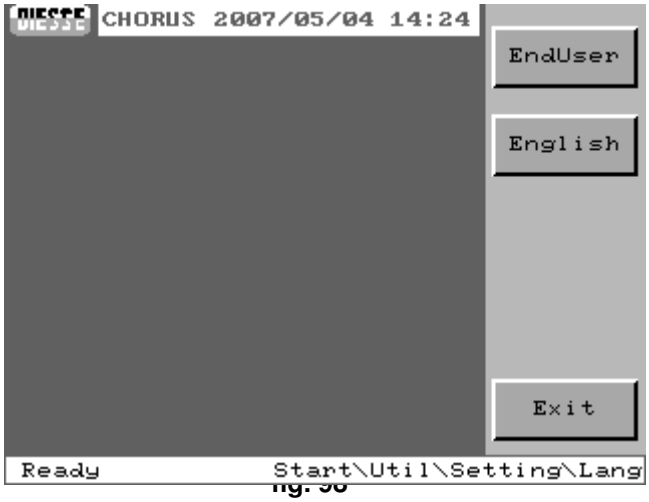


fig. 98

EndUser: sets the language for the user
English: sets the English language

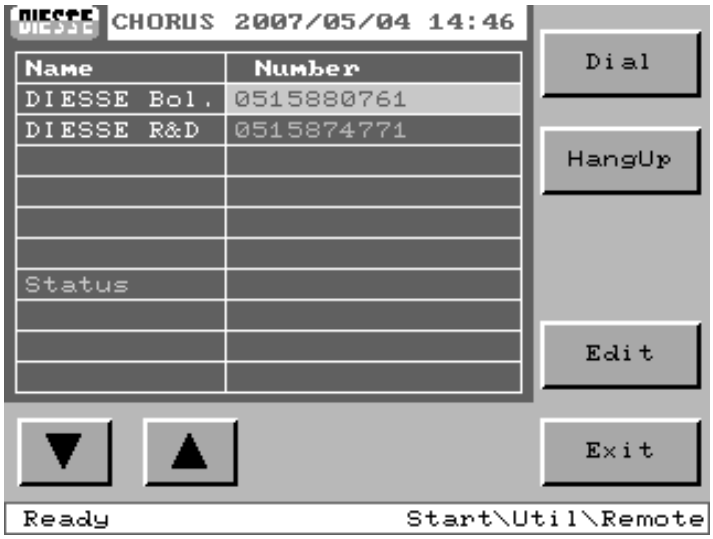
Exit: returns to the settings window

5.9.2 REMOTE CONNECTION WINDOW

Remote connection allows the CHORUS instrument to be connected to the **Diesse** assistance centres for checks and updates.

This window shows a list of telephone numbers which are available for remote connection. The operator can select the desired number and press the **Dial** key. When a connection has been established, an icon showing the connection will appear in place of the logo.

To interrupt the connection, press **Hang up**.



Dial: to connect

Hang Up.: interrupts the connection *(this only appears after connection has been established)*

▲ ▼: to move the selection bar between the numbers displayed

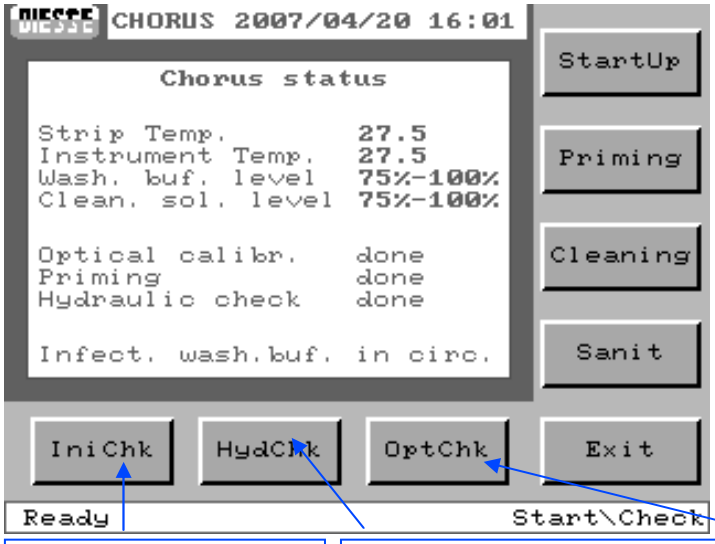
Edit: modifies the telephone number that has been selected

Exit: returns to the utilities window

fig. 99

5.10 CONTROL WINDOW

The control window shows the state of the instrument and allows access to the various controls necessary to re-establish good functioning.



StartUp: checks which controls are due to be performed and starts those necessary automatically

Priming: primes the buffer solution circuit *(requires the type of buffer to be selected)*

Cleaning: washes the buffer solution circuit

Sanit: performs the sanitization cycle on the buffer solution circuit

Exit: returns to the main window

IniChk: performs the initial check (of the electronic part and the motors)

HydrChk: forces the check of the buffer circuit, independently of the necessity (performs priming at the end of the check)

OptChk: forces calibration of the optic group independently of the necessity

fig. 100

Information on the state of the instrument

Strip temp: Temperature measured inside the thermostatic chamber
Instrument temp.: Temperature measured inside the instrument
Wash. buf. level/ Clean. sol. level: Level of liquid in the buffer/cleaning solution tanks.
The values may be:

.	75%-100%	the level is between 75% and 100%
	50%-75%	the level is between 50% and 75%
	25%-50%	the level is between 25% and 50%
	0%-25%	the level is between 0% and 25% (it is not possible to start the run)
	Empty:	the tank is completely empty (it is not possible to start the run)

Optic calibration:
Indicates (in red) when optic calibration is necessary (if more than 24 hours have passed or if the previous calibration was interrupted)
Priming:
Indicates (in red) when priming is necessary (if the circuit contains liquid other than the Buffer or if the previous priming procedure was interrupted, or in case more than 6 hours have passed since the last priming)
Hydraulic Check:
Indicates (in red) when it is necessary to perform a hydraulic check (if more than 24 hours have passed or if the previous check was interrupted)

Liquid in the circuit:
Indicates which liquid is present in the Buffer circuit.
The possible values are:

Air	indicated in red
Infect. Washing buffer	Washing Buffer for infectivology tests
Autoimm. Washing buffer	Washing Buffer for autoimmunity tests
Washing sol.	indicated in red
Sanit. sol.	indicated in red

When these indications are signalled in red, priming is necessary.

6 ORDINARY AND PROGRAMMED MAINTENANCE

6.1 ORDINARY MAINTENANCE

This has to be performed by the user according to needs of the instrument and consists of replacement of the following accessory materials:

The contents of the tanks with buffer and cleaning solution with eventual top-up (see 6.1.1)

The waste tank must be emptied when full.

Paper must be replaced in the printer according to requirements (chap. 1.6.5)

When the instrument is switched on, a control procedure (which can be deactivated by the user) is performed on all the systems (electronic, mechanical, hydraulic).

Particularly, during the initial auto-check phase (chap. **4**), a number of operations is executed to prepare the instrument in optimal working conditions.

These operations can be summarized as follows:

- priming of the Washing Buffer circuit
- washing of the internal parts
- control of the good functioning of the syringes and all the hydraulic parts
- control of the washers and dispensers
- optics calibration

ATTENTION!

The initial automatic control procedure could be avoided using the command available when the instrument is switched on. It is <u>not recommended</u> to use this unless the operator is certain that the instrument is working perfectly

Possible problems or errors are shown in the Error window and some may be resolved by the user, according to the type of error present (See chap. 7)

At the end of the work session it is necessary to start the *cleaning procedure*, to avoid the formation of deposits on needles, tubes and hydraulic parts in general. This procedure is explained in chap. 1.11.

The *sanitization procedure* is a maintenance procedure which can be performed, separately, at the discretion of the operator. This procedure is similar to the cleaning procedure, with the exception that a tank with sanitizing solution is used instead of the cleaning solution.

The aim of this procedure is to avoid the growth of molds in the hydraulic circuit. The frequency with which this procedure is performed is once a week (see chap. 1.11).

6.1.1 REINTEGRATION OF LIQUIDS

The following liquids have to be reintegrated periodically to assure correct use of the instrument:

- **Washing solution:**
  this is contained in a 2-litre tank and has to be reintegrated when the instrument shows that it is lacking.
- **Buffer solution:**
  this is contained in a 1-litre tank and has to be reintegrated when the instrument shows that it is lacking .

ATTENTION!
Do not top up the tank when it is inserted in the instrument.
Do not top up the tank when the instrument is in operation.

6.1.2 REPLACEMENT OF THE WASTE TANK

If the instrument's liquid waste system is connected to the general waste disposal system, no operation is necessary. If on the other hand, the waste liquid is collected in a tank, this must be emptied periodically when requested by the instrument.
To perform this operation:

- wear protective gloves and eye protection
- disconnect the drainage tubes from the instrument
- unscrew the cap of the full tank
- replace the full tank with an empty one
- screw the cap onto the empty tank
- reconnect the tubes to the instrument,
- seal the full tank and deliver for waste disposal in accordance with hospital regulations.

ATTENTION!
It is unadvisable, although possible, to disconnect the waste tank during a cycle, because this increases the risk of potentially infectious liquid being spilt and consequently, the risk of **biological contamination**.

6.2 PROGRAMMED MAINTENANCE

To guarantee correct functioning of the instrument, periodical maintenance must be programmed.
This includes:

- Cleaning of parts,
- replacements,
- calibration controls.

This maintenance must be performed by trained staff.
These timing of these interventions must be programmed with the Technical Assistance service on the basis of the actual use of the instrument, i.e. the average number of tests/month which is performed.
A special counter, described in the utility window (see 5.9), shows the real use of the instrument.
Personnel that performs the maintenance operations is required to fill out a report in which the executed operations are described, with a list of the parts that were replaced, indicating the number of tests performed until the date of the intervention.
A copy of this report has to be consultable for operators

7 TROUBLESHOOTING

A procedure of error detection in background is present on the instrument, to indicate to the operator possible anomalies during functioning with a message on the status-bar,.

This chapter reports the actions that should be taken in case these errors occur.

In order to complete this list it is also necessary to consider the following problems that could appear turning on the system or during its use.

7.1 GENERIC PROBLEMS

Symptom	Probable cause	Solution
Lack of power supply	Switch not activated	Turn the switch ON
	Disconnected cable	Connect the cable to the network and to the instrument
	Lack of network tension	Control the electric system of the room
	Fuses out of order	Replace the fuses with the supplied ones
	Defective power supply feeder	Call for technical assistance

Symptom	Probable cause	Solution
Instrument on and display off	Display out of order	Call for technical assistance
Buttons do not work	Touch screen not calibrated	Restart the instrument running the calibration procedure
	Touch screen out of order	Call for technical assistance

Symptom	Probable cause	Solution
Presence of water in the tray	Washing devices out of order	Dry and start the automatic initial check
Presence of water at the bottom of the instrument	Hydraulic system out of order	Call for technical assistance

7.2 LIST OF ERRORS

7.2.1 WARNINGS

1 Printer paper empty
Description: the paper is lacking in the printer
Corrective action: replace the roll of paper

2 Printer carriage open
Description: the printer carriage is open
Corrective action: lower the lever of the paper carriage

3 Lid unchecked
Description: the lid check was skipped
Corrective action: open/close the door when requested

4 Ext. Barcode-reader
Description: external barcode reader not connected or damaged
Corrective action: control the connection of the barcode reader

5 M-modem found
Description: The micro-modem board is not connected or is damaged

6 Modem timeout
Description: the modem does not respond because not connected or is damaged

7 Modem fault
Description: the modem responds with an error message

8 Strip thermometer
Description: the strip thermometer does not respond

9 Strip temp. adj.
Description: Strip thermostat out of range

10 Instrument thermometer
Description: the instrument thermometer does not respond

11 Instr. Temp adj.
Description: Instrument thermostat out of range

The four temperature errors (8-11) are declassed to warnings only during the cycle, to allow the instrument to process all the strips in any case, and leave to the operator the final decision whether or not to accept the results.
In the printed report, the strips processed with a temperature error will be identified by a “T”

7.2.2 RECOVERABLE ERRORS

33 Clean Sol. 0%
34 Clean Sol. < 25%
35 Clean Sol. < 50%
36 Clean Sol. < 75%
37 Wash buf. 0%
38 Wash buf. < 25%
39 Wash buf. < 50%
40 Wash buf. < 75%
41 Sanit. Sol. 0%
42 Sanit. Sol. < 25%

The errors in the tank levels (33-42) are generated when the tank is checked before using the liquid contained in it. Level 0% indicates that the tank is empty.
The error is corrected by filling the tank .

43 Waste outlet closed
Description: Waste discharge not connected or obstructed.
Corrective action: check the connection of the waste tank outlet
44 Waste tank full
Description: waste tank full (the error of incorrect function of the waste pump can be excluded if the instrument has passed the initial check procedure)
Corrective action: replace the waste tank

7.2.3 FATAL ERRORS

60 FlashROM 0
Description: error in reading/writing the Flash ROM 0 memory.
61 FlashROM 1
Description: error in reading/writing the Flash ROM 1 memory**.**
62 RAM
Description: error in reading/writing the RAM memory.
63 Video RAM
Description: error in reading/writing the Video RAM memory.

As the memories are tested during the initialization phase, when the monitor is not yet active, this error is printed on paper.

64 Clock

Description: error in the system clock.

67 Strip thermometer

Description: the strip thermometer does not respond

68 Strip temp. adj.

Description: Strip thermostat out of range

69 Instr. Thermometer

Description: The instrument thermometer does not respond

70 Instr. Thermo adj.

Description: Instrument thermostat out of range

The four temperature errors (67-70) constitute fatal errors when the instrument is in stand-by.

71 Internal Barcode

Description**:** the internal barcode reader does not respond

72 Simul. Hydr. sens.

Description: error during simulation of the hydraulic sensors.

73 SID

Description: error in the device controlling correct insertion of strips (SID)

74 SPS

Description: error in the sensor controlling presence of strips (SPS)

75 Disp. #1 level sens.

Description: error in the level sensor of dispensator 1

75 Disp. #2 level sens.

Description: error in the level sensor of dispensator 2

77 X carriage assembly
78 Tray assembly
79 Syringe assembly
80 Disp. #1 assembly
81 Disp. #2 assembly
82 Washer #1 assembly
83 Washer #2 assembly
84 Washer #3 assembly
85 OptFilter assembly
86 TSD assembly

The fatal errors (77 - 86) are related to the check of the movement of the relative groups. The error arises in the case that the check of the movement fails.

87 Tray jam

Description: the tray is blocked due to a mechanical hindrance

88 Tray alignment

Description: the synchronizer (TSD) cannot be fitted into the notches on the tray

96 Waste undefined error

Description: a generic error has been found at the start of the hydraulic check, either due to damage in the waste circuit or to defective function of a sensor, or other error. In any case it is not possible to continue with the check procedure.

97 Wast warning sensor

Description: error found at the start of the hydraulic check, due to damaged pre-alarm sensor on the waste well.

98 Output closed sensor

Description: error found at the start of the hydraulic check, due to damaged sensor on the auxiliary well

99 Waste full Sensor

Description: error found at the start of the hydraulic check, due to damage to the “full” sensor on the waste well

100 Waste voiding fault

Description: error activated :

- in background when the waste well has exceeded the filling limit and all functions of the instrument will be blocked
- in the initial check to test partial emptying of the well

101 Aux. Waste well fault

Description: error found at the start of the hydraulic check, due to the fact that the well cannot be emptied

102 Waste pump fault

Description: error found at the start of the hydraulic check, due to damage to the waste pump.

103 Wsh#1 coll.well filling

Description: error due to the collection well of the washing station 1 which was not filled

104 Wsh#2 coll.well filling

Description: error due to the collection well of the washing station 2 which was not filled

105 Wsh#1 coll.well voiding

Description: error found due to the collection well of the washing station 1 which was not emptied

106 Wsh#2 coll.well voiding

Description: error due to the collection well of the washing station 2 which was not emptied

107 Disp#1 ext. washing

Description: error found at the start of the hydraulic check, due to the lack of erogation of the washing liquid from the external washer nozzle of the dispensator 1.

108 Disp#1 int. washing

Description: error found at the start of the hydraulic check, due to the lack of erogation of the washing liquid from the internal washer nozzle from the dispensator 1.

109 Disp#2 ext. washing

Description: error found at the start of the hydraulic check, due to the lack of erogation of the washing liquid from the external washer nozzle from the dispensator 2

110 Int. Washer disp. #2

Description: error found at the start of the hydraulic check, due to the lack of erogation of the washing liquid from the internal washer nozzle of the dispensator 2.

111 Syringe filling

Description: error found at the start of the hydraulic check, due to the impossibility to fill the syringe

112 250 µl syringe disp.

Description: error found at the start of the hydraulic check, due to incorrect erogation of liquid from the 250 ul syringe into the test strip well

113 25 µl syringe disp.

Description: error found at the start of the hydraulic check, due to incorrect erogation of liquid from the 25 ul syringe into the test strip well

114 Washer#1 suct. (well#5)

Description: error found at the start of the hydraulic check, due to incorrect aspiration of washer 1 from well n°5 of the test strip

115 Washer#1 erog. (well#5

Description: error found at the start of the hydraulic check, due to incorrect erogation of washer 1 from well n°5 of the test strip

116 Washer#1 suct. (well#6)

Description: error found at the start of the hydraulic check, due to incorrect aspiration of washer 1 from well n°6 of the test strip

117 Washer#1 erog. (well#6)

Description: error found at the start of the hydraulic check, due to incorrect erogation of washer 1 from well n°6 of the test strip

118 Washer#2 suct. (well#5)

Description: error found at the start of the hydraulic check, due to incorrect aspiration of washer 2 from well n°5 of the test strip

119 Washer#2 erog. (well#5)

Description: error found at the start of the hydraulic check, due to incorrect erogation of washer 2 from well n°5 of the test strip

120 Washer#2 suct. (well#6)

Description: error found at the start of the hydraulic check, due to incorrect aspiration of washer 2 from well n°6 of the test strip

121 Washer#2 erog. (well#6)

Description: error found at the start of the hydraulic check, due to incorrect erogation of washer 2 from well n°6 of the test strip

122 Washer#3 suct. (well#5)

Description: error found during the hydraulic check, due to incorrect aspiration of washer 3 from well n°5 of the test strip

123 Washer#3 suct. (well#6)

Description: error found during the hydraulic check, due to incorrect aspiration of washer 3 from well n°6 of the test strip

129 Error virtual ramp

Description: the determination of the virtual ramp is not been possible due to a hardware error

130 Virtual Ramp < 700

Description: the number of points available for fine regulation of the lamp is < 700.

131 Lamp fault

Description: error found during the optic check, due to loss of luminosity of the lamp

132 Channel #1 receiver
133 Channel #2 receiver
134 Channel #3 receiver
135 Channel #4 receiver
136 Channel #5 receiver
137 Channel #6 receiver

The errors from 132 to 137 may be found during the optic check, and indicate the poor optic emission/reception function in the channel indicated

138 Channel #1 offset
139 Channel #2 offset
140 Channel #3 offset
141 Channel #4 offset
142 Channel #5 offset
143 Channel #6 offset

The errors from 138 to 143 may be found during the optic check, and indicate the poor function of the offset regulation of the channel indicated

144 Channel #1 dark
145 Channel #2 dark
146 Channel #3 dark
147 Channel #4 dark
148 Channel #5 dark
149 Channel #6 dark

The errors from 144 to 149 may be found during the optic check, and indicate the poor function of the Dark reading of the channel indicated

150 Channel #1 air
151 Channel #2 air
152 Channel #3 air
153 Channel #4 air
154 Channel #5 air
155 Channel #6 air

The errors from 150 to 155 may be found during the optic check, and indicate the poor function of the Air reading of the channel indicated.

7.2.4 IDENTIFICATION ERRORS

STR EXP

Description: during the identification procedure, the validity of the strip was found to have expired.

STR CO

Description: during the identification procedure the strip was found to be incompatible with the others present in the tray

STR RD

Description: during the identification procedure the strip barcode was found to be illegible.

STR INS

Description: during the identification procedure the strip was found to be incorrectly inserted in the tray

STR ID

Description: during the identification procedure the test code of the strip was not recognized

CAL POS

Description: during the identification procedure the calibrator was found to be positioned after a strip with the same code. The calibrator must precede the relative strip on the tray

CAL NR

Description: during the identification procedure more than one calibrator was found from the same batch

CAL/STR

Description: during the identification procedure a calibrator was found to be associated to a different test or batch

QC/STR

Description: during the identification procedure the control serum was found to be associated to a different test or batch

STR REP

Description: during the identification procedure the strip was found to have already been processed during the previous run.

STR BUF

Description: during the identification procedure the strip was found to be incompatible with the buffer solution present in the hydraulic circuit

CUV MIS

Description: during the pre-heating procedure, the well 5 or 6 in the strip was not identified. The error code is CM

7.2.5 RUN TIME ERRORS

The RUN TIME errors are found either during the identification phase, and in this case the strip will not be processed, or during the run, in which case the strip is aborted.
If the error is found during the run, it is reported (with a code) in the OP column, in the printed report and is saved in the archives.

SMP QT

Description: the amount of serum dispensed in the reaction well is insufficient. The error code is SQ.

DRILL#1

Description: dispensator 1 has not perforated the strip well correctly. The error code is D1.

DRILL#2

Description: dispensator 2 has not perforated the strip well correctly. The error code is D2.

DISP#1

Description: dispensator 1 has not transferred the correct amount into the measuring well. The error code is T1.

DISP#2

Description: dispensator 2 has not transferred the correct amount into the measuring well. The error code is T2.

LOW CAL

Description: the calibrator is below the minimum acceptable limit

HIGH CAL

Description: the calibrator is above the maximum acceptable limit

CAL OVR

Description: the sample is inserted in a run with its relative calibrator on which the test has failed.

DISPSYR#1

Description: the 250ml syringe did not dispense the correct quantity of liquid because of a loss of steps of the instrument

The error code is S1

DISPSYR#2

Description: the 25ml syringe did not dispense the correct quantity of liquid because of a loss of steps of the instrument.

The error code is S2

KinErr0

Description: Error in the reading of the sample due to a problem occurred during the cycle

KinErr1

Description: the kinetics of the process sample does not correspond to the kinetics expected of the test (initial reading to high)

KinErr2

Description: the kinetics of the process sample does not correspond to the kinetics expected of the test (descending parabola kinetic)

KinErr3

Description: the kinetics of the process sample does not corrispond to the kinetics expected of the test (exponential kinetic)

KinErr4

Description: the kinetics of the process sample does not corrispond to the kinetics expected of the test (initial reading to low- CFT)

ABORTED

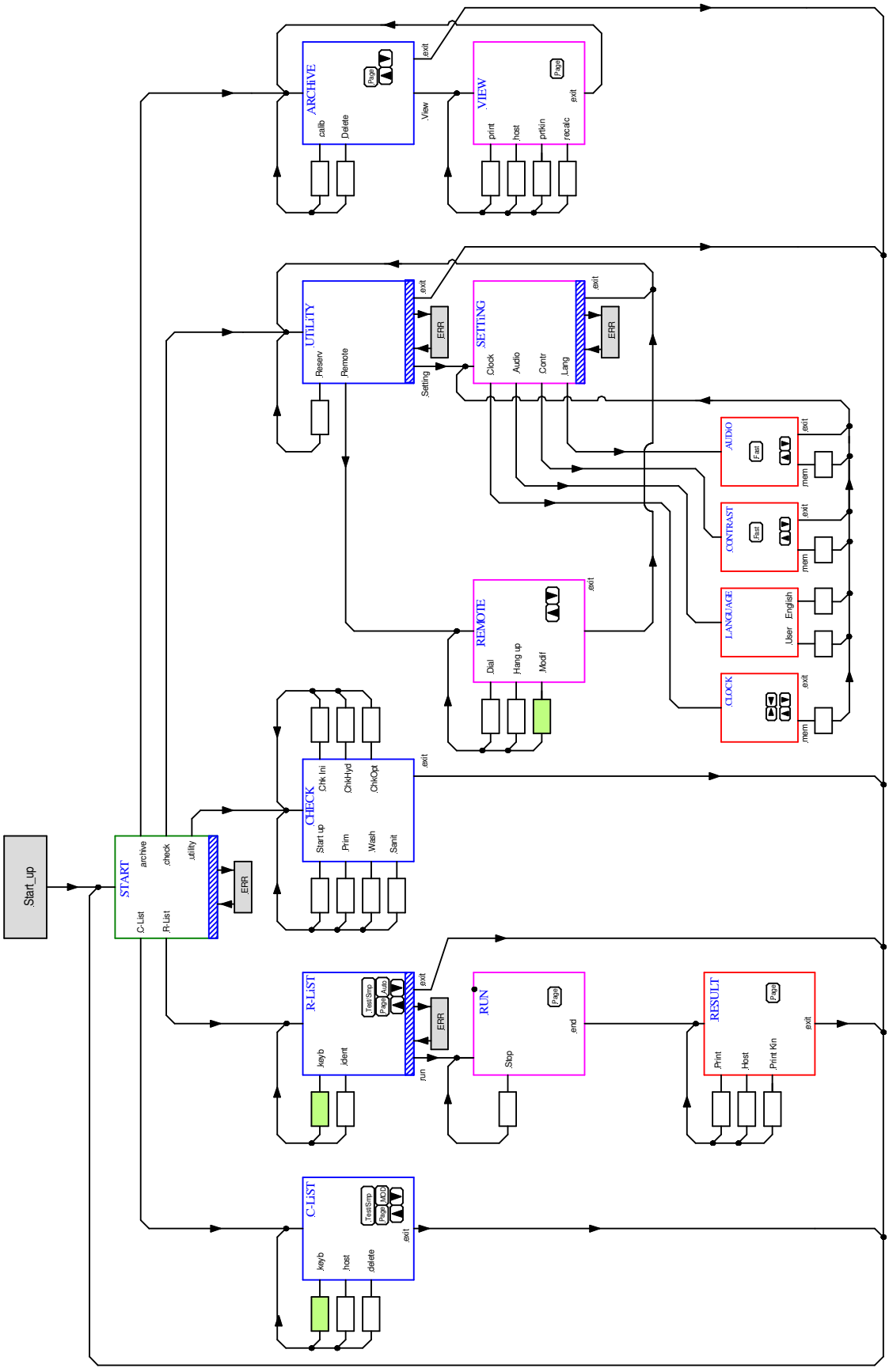
Description: indicates the non execution of the test due to an error of the instrument

T_ERR

Description: indicates the non execution of the test cause by an error in the thermostation during the procedure of pre-heating.

8 APPENDIX

8.1 WINDOWS FLOW-CHART



8.2 TOUCH SCREEN CALIBRATION

La calibrazione del touch screen viene attivata, su scelta dell'operatore, durante la procedura di avvio dello strumento premendo lo schermo entro 5 secondi dal momento in cui si forma la prima finestra vuota (vedi **fig. 101**).

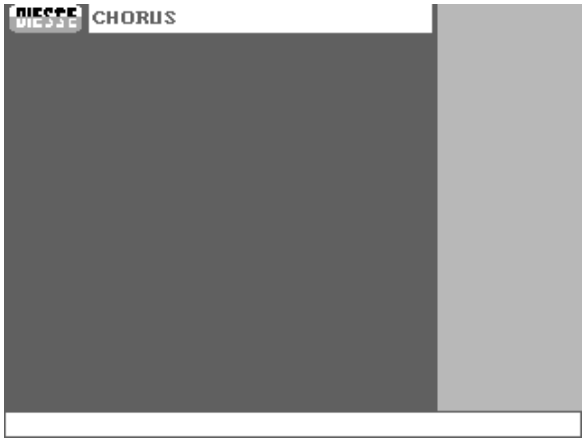


fig. 101

Una volta avviata la procedura di calibrazione, un riquadro rosso si sposta dal centro dello schermo al vertice superiore sinistro e viene visualizzato "Premere vertice".

fig. 102

Per tarare il vertice superiore, premere l'angolo superiore sinistro del riquadro rosso con un oggetto a punta (es. una matita) e mantere la pressione per 5 secondi (viene visualizzato un count-down)

fig. 103

Se la pressione non viene mantenuta per tutti i 5 secondi, oppure il punto di pressione non è stabile, viene richiesto di ripetere l'operazione.

Se, dopo 5 tentativi, viene fallita l'operazione di taratura del vertice, la calibrazione viene interrotta e lo strumento prosegue con la procedura di avvio.

fig. 104

Se l'operazione viene eseguita correttamente, il riquadro rosso si sposta dal centro dello schermo al vertice inferiore destro. Nuovamente compare la richiesta "Premere vertice". Ripetere le operazioni precedentemente descritte sul vertice inferiore, avendo cura di premere l'angolo inferiore destro del riquadro rosso.

fig. 105

Nel caso in cui l'operazione sia stata eseguita correttamente, viene visualizzata la finestra di controllo, tramite la quale è possibile verificare la taratura del touch screen.

Nell'area dati vengono mostrate, di volta in volta, le coordinate dei punti di pressione.

Premendo OK, vengono memorizzati i parametri di calibrazione, la finestra di verifica viene chiusa e lo strumento prosegue nella procedura di avvio.

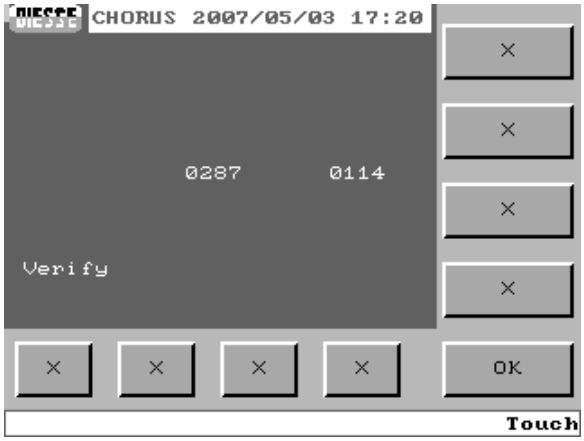
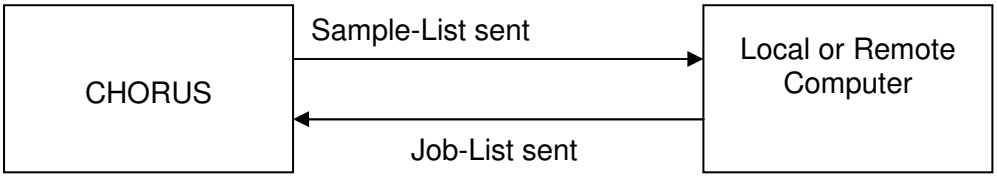


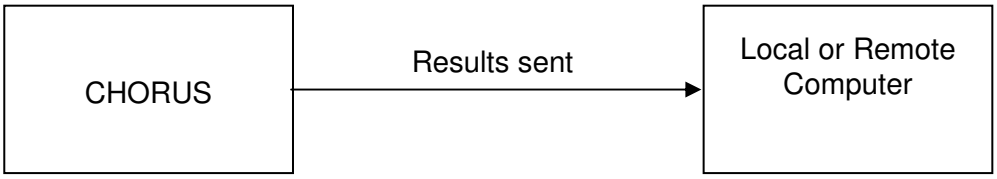
fig. 106

8.3 CHORUS HOSTING

Programming of samples



Filing of results



8.3.1 COMMUNICATION PROTOCOL

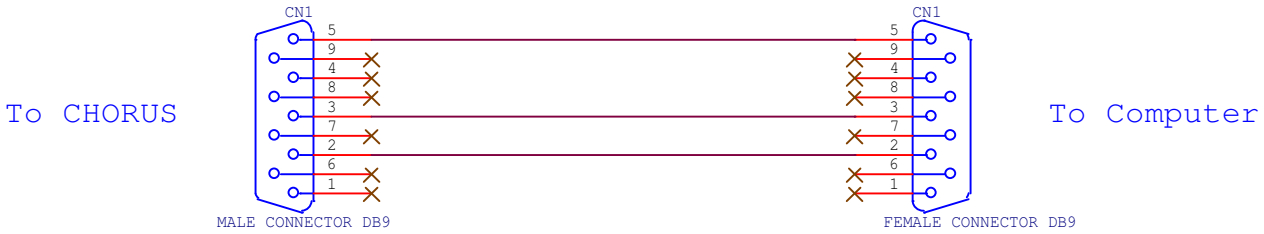
The following document describes the protocol for serial communication between the CHORUS instrument, manufactured by Diesse Diagnostica Senese S.p.A., and a local or remote computer. The term “local Computer” means a Personal Computer positioned near the CHORUS. The term “remote Computer” means a (generally large-scale) computer, the terminals of which are normally placed at the reception, and are able to handle acceptance of patients and most of the computerized instruments in the different laboratories. In this case, the term “Host-Computer” is often used.
In general, the term “***CHORUS Hosting”*** means the interface between the analyzer and the computer, to allow the tests to be programmed on the instrument and corresponding results to be received with the aid of a Computer. In particular, the computer may implament one or bother the following features:

1. receive the sample list from the CHORUS and send back the related Job-list
2. receive sample results

This exchange of data takes place through a serial protocol using a RS-232C connection.

8.3.2 INTERFACE PROGRAMMING

Pinout of the Host connection cable is shown in the following picture (pins shown as unconnected may or may not be connected because not used)



Standard Serial Cable

Data exchage is implemented by a RS232C serial interface that is programmed with the following parameters :

bitrate : settable by WinChorus++ through the hardware parameter *miscellaneous\hosting speed* between the following values:

Bitrate	Parameter
38400 baud	0
19200 baud	1
9600 baud	2
4800 baud	3
2400 baud	4
1200 baud	5
600 baud	6

n bit : 8
stop bit : 1
parity bit : no
Serial port: *set up by WinChorus++* (v 6.43 and following) through the hardware parameter *m*iscellanea\ *hosting serial port between the following values:*

Port	Parameter
HOST	1
EXT-SERV	2

Note:
HOST connector requires firmware version 2.09r10 or above

Note:
Used byte order is little-endian: bytes are stored from the less significant to the most (e.g. a word field of value 258 is coded as 0x0201

8.3.3 SERIAL COMMUNICATION FRAME

Note: variable characters are highlighted in bold inside each frame, frame-specific characters are highlighted in gray

The frame structure used in the serial communication is as follows:

Sender ⟶ *Receiver*

STX	***N***	***CMD***	***D_1***	***D_2***	***…***	***D_{N-1}***	***CS***

Field	Description	Value	Data type	Bytes
STX	Start of Text (frame start character)	0x02	byte	1
N	Frame length (without STX, N, CS character)		byte	1
CMD	Command code		byte	1
$D_1..D_{N-1}$	Potential data characters			N-1
CS	Frame check-sum (without STX, CS character), calculated as a XOR of N+1 frame characters		byte	1

8.3.4 ENQUIRY

Before sending the sample list (see chapter 8.3.5) or session results (see chapter 8.3.6), the CHORUS checks Computer availability with the following frame:

CHORUS ⟶ *Computer*

STX	*2*	*ENQ*	*InstrID*	***CS***

Field	Description	Value	Data type	Bytes
ENQ	Enquiry	0x05	byte	1
InstrID	CHORUS instrument identifier	0x43	byte	1

The Computer must answer with the following frame:

Computer ⟶ *CHORUS*

STX	*1*	*EOT*	***CS***

Field	Description	Value	Data type	Bytes
EOT	End of Text	0x04	byte	1

If, after sending an enquiry frame, the Computer doesn't answer, a time-out error message will be displayed.

8.3.5 SAMPLE PROGRAMMING

After receiving each sample code inserted by the user, the Computer sends the CHORUS the list of tests to be executed on that sample. This is called Job-List (J-List).

After establishing a connection between the Computer and the CHORUS (see chapter 8.3.4), the instrument sends, for each inserted sample, the following frame:

CHORUS ⟶ *Computer*

STX	*21*	*JListCmd*	***StorableRec***	***SampleCode***	***CS***

Field	Description	Value	Data type	Bytes
JLISTCMD	J-List record request command	0xD2	byte	1
STORABLEREC	Remaining test slots		byte	1
SAMPLECODE	Sample code (including trailing 0x00)		string	19

The Computer answers with the following frame:

Computer ⟶ *CHORUS*

STX	***2K + 21***	*EOT*	***SampleCode***	***PedFlag***	***TestID$_1$***	***TestID$_2$***	***…***	***TestID$_K$***	***CS***

Field	Description	Value	Data type	Bytes
PedFlag	Pediatric sample flag (available in firmware version 2.09r10 and above)	0..1	byte	1
TestID$_1$..TestID$_K$	Identifiers of tests to be executed on this sample	1..999	word[]	2K

If, for a certain sample, a single test has to be executed, the frame will contain only one *TestID* record.

Note 1
A table must be created in the Computer of the enabled valid tests, such as Name test / ID Test, in order to be able to send to the instrument the identification of the tests to be performed.
Note 2
The sample code handled by CHORUS must be of 15 characters or less. However, in order to handle also the quality controls (QC), the code must be large enough to contain 18 characters. Therefore the SampleCode field contains 19 characters, including trailing 0x00.
Note 3
Since the total number of storable tests of the CHORUS is limited, the Computer must not send a number of *TestID* records greater than *StorableRec*. There is therefore the possibility that not all the relative ID for a given sample can be sent, for reasons of space. In a subsequent work cycle, the Computer will start to send the data again from the point where it had stopped.

After receiving last sample data, the CHORUS sends the following frame:

CHORUS ⟶ *Computer*

STX	*2*	*JlistEnd*	*InstrID*	***CS***

Field	Description	Value	Data type	Bytes
JlistEnd	J-List end command	0xD3	byte	1

The Computer closes the connection with the following frame:

Computer ⟶ *CHORUS*

STX	*1*	*EOT*	***CS***

8.3.6 RESULT MANAGEMENT

After each cycle, in the result window, or anytime from the session archive, the CHORUS can send the Computer sample results, in order to archive or elaborate them.

After establishing connection between the Computer and the CHORUS (see chapter 8.3.4), the instrument sends the following frame for each sample processed in this session:

CHORUS ⟶ *Computer*

STX	*50*	*ResFrame*	***SampleCode***	***TestDesc***	***Report***	***Titre***	***MeasUnit***	***CS***

Field	Description	Value	Data type	Bytes
ResFrame	Result text sending command	0xD7	byte	1
TestDesc	Test description (with trailing 0x00)		string	7
Report	Reporting (positive, negative, doubtful)		char	1
Titre	Titration (with trailing 0x00)		string	12
MeasUnit	Measure unit (with trailing 0x00)		string	10

The Computer answers with the following frame:

Computer ⟶ *CHORUS*

STX	*1*	*EOT*	***CS***

After sending all result frames, the CHORUS sends the following closing frame:

CHORUS ⟶ *Computer*

STX	*2*	*ResEnd*	*InstrID*	***CS***

Field	Description	Value	Data type	Bytes
ResEnd	Result text sending end command	0xD8	byte	1

The Computer closes the connection with the following frame:

Computer ⟶ *CHORUS*

STX	*1*	*EOT*	***CS***

8.4 EC DECLARATION OF CONFORMITY

EC DECLARATION OF CONFORMITY

In accordance with directive EEC 98/79 relevant the Diagnostic Device CE-IVDD

Diesse Diagnostica Senese S.p.A.

The DIESSE DIAGNOSTICA SENESE S.p.A. with main office in Milano, Via San Vittore 96/1 ITALY

Hereby declares

That the design, type of manufacture of the Diagnostic Device CE-IVDD described here below and the version distributed on the market,

is compliant

to the

" EEC directive 98/79 relevant the Diagnostic Device CE-IVDD"

through the accomplishment to the Annex III (except section 6) and the essential requirements which Annex I.

This declaration shall not be valid if:

- Unauthorised modifications are made to the unit
- The unit is used improperly
- Unauthorised technical operations are made on the unit
- No original spare parts are used.

Product: **Multiparametric processor for immunometric assays**

Type: **CHORUS**

Technical data: **110-220 Vac (50-60 Hz) Pwr:350VA**

Is compliant

In whole and in all its parts to the following standards and related amendments:

EN 61010-1 "Safety for electrical equipment for measurement, control, laboratory use– Part 1: General requirement ".

EN 61326-1 "Electrical equipment for measurement, control, laboratory use – EMC requirements – Part 1: General requirement ".

Corresponds to the requirements of the following EEC directive and related amendments:

Low tension Directive (73/23/EEC)

Electromagnetic compatibility Directive (89/336/EEC) and (93/68/EEC)

Milano, 2005

Signature: General Director

Dr. Francesco Cocola

8.5 WARRANTY CERTIFICATE

WARRANTY CERTIFICATE Chorus

Certificate S/N

DIESSE DIAGNOSTICA SENESE S.p.A., subjects all its products to strict quality controls. However should the instrument show signs of malfunctioning despite these controls, you are invited to contact the authorised Technical Assistance Centre indicated to you at the time of delivery of the instrument.

Limits of liability

DIESSE DIAGNOSTICA SENESE S.p.a. assumes all liability for damages arising from manufacturing defects or malfunctioning of the instrument during the **foreseen use** of the same. It declines any other type of liability.

General guarantee regulations:

DIESSE DIAGNOSTICA SENESE S.p.A. guarantees the Chorus for a period of 12 months from the delivery data (the date on the transport document shall be valid) for defects in the materials or manufacturing.

Should the product prove to be defective during the guarantee period the authorised Assistance Centres will repair it and you will only be charged the transport costs.

General Conditions:

1. The materials and manufacture of this product shall not be considered as defective if the instrument has been adapted, modified or adjusted to comply with national or local standards in force in a country where they differ from those for which the product has originally been designed and constructed. This guarantee shall not cover said adaptations, modifications or adjustments or any attempts at the same, irrespective of whether performed correctly or incorrectly, or any damage deriving from the same.
2. This guarantee shall not cover:
   - periodic checks, maintenance and repairs or replacement of parts due to normal wear and tear,
   - transport costs and risks linked directly or indirectly to the guarantee of this product, including the transfer from the assistance centre to the customer's address,
   - damage deriving from incorrect use, negligence, incorrect installation, impact, falls, insufficient voltage connections, use in environments with extreme conditions, damage caused by liquids dropped inside, etc. or deriving from any other accidental cause.
   - malfunctioning of the instrument due to modifications or repairs carried out on the same by unauthorised third parties.
   - damage caused by the assembly of parts or components not approved by the manufacturer.
3. No interventions carried out under guarantee shall interrupt or prolong the duration of the same for any reason whatsoever.

Copy to be filled out and conserved for the warranty period together with the Operating Manual

DIESSE Diagnostica Senese SpA
Via del Pozzo, 5 - Loc. S. Martino • 53035 Monteriggioni (SI) Italy
Tel.: ++39/0577/31.95.60/61/50 • Fax: ++39/0577/31.87.63
http://www.diesse.it e-mail:salesoffice@diesse.it