



On Line User Manual

Version 6.0

2021-07-02

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1. On Line



For general and detailed information about the Product environment and the instructions for use of the Control Bar software, see the specific documents of the Product. The knowledge and understanding of these documents is mandatory for an appropriate and safe use of the On Line module, described in this document.

1.1. Introduction

The On Line module manages the large amount of incoming data from the medical devices connected to the patient (monitor, ventilator, BGA etc.) and from the laboratory.

Virtually any medical device equipped with an interface for pc (RS-232, Ethernet or other) and a documented, available communication protocol can be connected to On Line and therefore communicate its data directly to the patient record.

This may bring to a diminished workload of the medical staff, being both instrumental and laboratory data collection, summary and correlation automatized. Moreover, automatic data acquisition may help reducing the manual documentation errors.

1.1.1. Data display

The information managed by the On Line module can be viewed as either tables or charts. The different module's screen are widely configurable: several display windows can be created and configured with the needed items (tables and/or charts). The specific kind of data acquired and the sample rate are configurable. Information acquired by other Product modules (for example Therapy or Infusion) can be automatically displayed.

Specific configuration parameters make it possible to select the colours of the different items displayed on the various screens (i.e. backgrounds, fonts, tables, charts etc...). This feature makes it possible to customize the system according to the preferences and the needs of the specific structures using it. The figures shown in this manual can therefore display different colors from those actually in use in your structure. Refer to your system administrator for further information.

1.1.2. Data acquisition

Data can be acquired in two ways:

- 1) Parameters can be manually entered by the user;
- 2) Data can be automatically acquired by the system.

Automatic acquisition is reserved for parameters generated by interfaceable medical equipment (ventilators, monitors, laboratory instruments), or by a central laboratory.

These data, automatically acquired and inserted in the Product database, can contain "artifacts" (caused, for example, by sudden patient movements, by accidental disconnections etc.). Therefore, the clinical staff has to check, evaluate and accept these

data. Data this way filtered are “validated”. The validation procedure is summarized in paragraph 1.9.

1.2. Module selection

To select the On Line module:

- Click the corresponding icon on the lateral bar.



A screen will appear showing data of the patient currently selected.



The On Line module is widely configurable. The screens shown in this manual can therefore be different from those in use in your Healthcare Structure.

The procedures and the functionalities of the On Line module, described in this manual, remain the same in every configuration. What changes is the way the various screens appear and the specific contents (for instance the kind of data considered).

1.3. Patient selection

To select a patient,

- Click the **Patient** button on Control Bar (Fig 1 A).



Fig 1

The Patient Explorer module opens. See the patient explorer user manual (*USR ENG Patient Explorer*) for instructions.



Other modules can be configured for the patient selection in place of Patient Explorer, depending on the configuration of the Digistat Suite. If this is the case, see the specific documentation for instructions.

When a patient is selected the module displays the data of the selected patient.

1.4. Data display screen structure

The screen shown in Fig 2 displays in chart and tables the data acquired. This is the “Data display” screen of the On Line module. It is widely configurable, i.e. the number and kind of charts and tables displayed depend on the user needs. Nonetheless the structure of the screen is fixed. This section describes the page structure, which is formed of three main parts:

- 1) the list of selectable pages (Fig 2 **A**);
- 2) the “data display” area (displaying the chart and tables - Fig 2 **B**);
- 3) the command bar (Fig 2 **C**).



Fig 2 - Data display screen - Patient selected

1.5. List of selectable pages

The vertical area on the left (Fig 2 **A**, Fig 3) displays the list of all the available pages in the configuration in use. The number and kind of selectable pages is configurable. Many features of each page (as the parameters displayed, the number of charts and tables on it etc...) are decided according to the user needs.



Fig 3 - Selectable pages

Each page is indicated by an icon and a name (the names shown in the figure are “Monitoraggio completo”, “Ventilazione” and “Emogas”). The icon corresponding to the page currently displayed is highlighted. To select a page,

- Click the corresponding icon. The selected page appears on the “data display” area (Fig 2 **A**).

1.6. “Data display” area

The “data display” area is the central part of each screen. Charts and tables are here displayed.

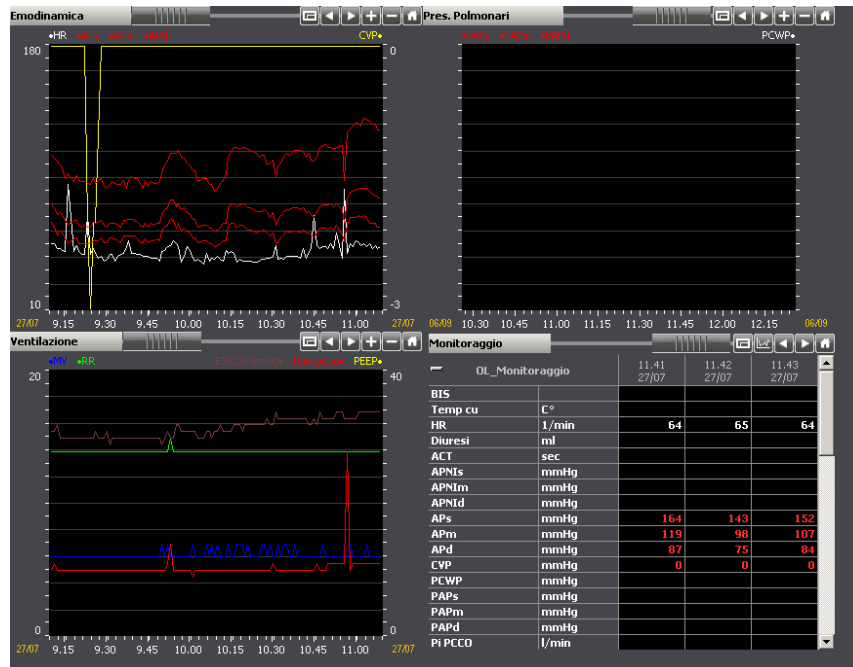


Fig 4 - Data display area

1.6.1. Charts

The On Line module makes it possible to display in charts the trends of selected parameters. This section provides the user with the instructions to read the module's charts.

1.6.1.1. Chart general structure

The horizontal axis of the chart represents time. The time unit of measure (days, minutes, hours) depends on the length of the time span represented on the chart. The vertical axis indicates the value of the represented parameters.

Two scales of values can be used: one on the left (Fig 5 **A**, going from 0 to 20 in the example); one on the right (Fig 5 **B**, from 0 to 40, in the example). The names of the represented parameters are displayed above the chart. On the left are displayed the names of the parameters whose values can be read on the left (in Fig 5 these are “MV” and “RR”). On the right are displayed the names of the parameters whose values can be read on the right (in Fig 5 these are “ETCO2 Ven”, “Paw picco” and “PEEP”).



Fig 5

The color of the parameter name is the color of the corresponding chart. In Fig 6, for example, the charts of the parameters named “MV” and “RR” are drawn in blue and in green.



Fig 6

1.6.1.2. Charts command bar

Above every chart there is a command bar (Fig 7 A, Fig 8).




Fig 7 - Charts

The command bar makes it possible to change the chart display mode. The functions of the different buttons are described below.





Fig 8 - Command bar

Ventilazione - The chart's name is displayed on the left, in the box highlighted in Fig 8 A. The name in the example is "Ventilazione".

 - This object, indicated in Fig 8 B, is named "rollbar". It makes it possible to move back and forth on the time axis. Drag the rollbar to the left to display a chart area referring to a preceding time; drag the rollbar to the right to display a chart area referring to a subsequent time.

The buttons highlighted in Fig 8 C make it possible to perform the following actions:

 - **Full screen display** - Use this button to display the chart in "full screen" mode. A second click brings the chart back to the original proportions.



 - **Back** - Use this button to display a chart portion referring to a time preceding the time currently displayed.



- **Forward** - Use this button to display a chart portion referring to a time following the time currently displayed.



- **Enlarge** - Use this button to select an area to be enlarged on the chart. To do that,

- Click the  button.
- Move the mouse pointer on the chart. The mouse pointer changes to: 
- Click the point corresponding to the left limit of the area to be enlarged. On the chart a vertical bar is displayed, indicating the left limit selected point. The corresponding time is indicated under the bar.
- Click the point corresponding to the right limit of the area to be enlarged. The area comprised between the clicked points is this way enlarged in the chart



- **Minimize** - Use this button to minimize the displayed chart. The time span displayed increases while the chart appears smaller.



- **Original proportions** - Use this button to bring the chart back to the proportions it had before any change was performed in the display mode.

1.6.1.3. Chart cursor

- Click the chart area to display a yellow vertical line (“Chart cursor”, Fig 9).



Fig 9 - Chart cursor

The time corresponding to the point indicated by the cursor can be read below the cursor itself (9:53, 23/06 in Fig 9 **A**; when the point corresponds to a date different from the current date the date is displayed as well).

On the bottom corners (either left or right, depending on the position of the cursor) several boxes appear, displaying the exact chart parameters values at the time indicated by the cursor (in Fig 9 **B**, for example, the parameter named “MV” has a 6 value, the parameter named “RR” has a 14 value etc... This means that those were the parameters values at 9:53 on the 23rd of June).

If the mouse pointer is dragged on the chart area keeping the left button clicked the values indicated by the cursor change with the movement.

- Click any point along the vertical axis to display a horizontal cursor. The values corresponding to the clicked point are displayed at the cursor extremities (Fig 10).
- Move the mouse pointer up or down keeping the left button clicked to drag the horizontal cursor. The values displayed change with the movement.

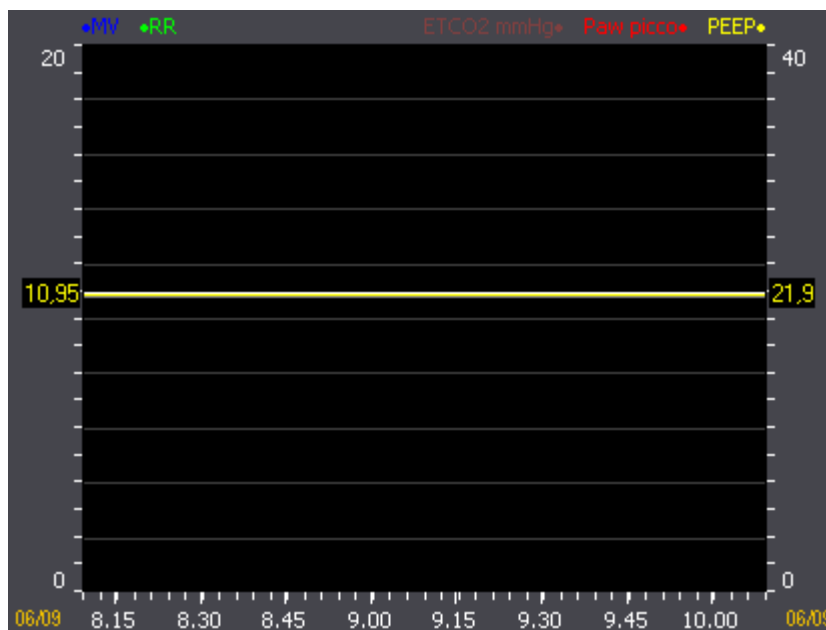


Fig 10 - Horizontal Cursor



When the **Synchro** button on the command bar is selected (Fig 27) one click on one of the charts on the page displays a cursor on all the charts (all cursors indicating the same time). Also, the corresponding column is highlighted on all the tables. See paragraph 1.6.3 for a more detailed description of the synchronization functionalities.

1.6.2. Tables

The tables on the various pages contain textual and/or numeric data. Data can be either manually inserted by the user or automatically acquired by the system and later validated by the physician

Monitoraggio		10.38 23/06	10.39 23/06	10.40 23/06	10.41 23/06	10.42 23/06	10.43 23/06	10.44 23/06	10.45 23/06	10.46 23/06	10.47 23/06	10.48 23/06
OL_Monitoraggio												
BIS												
Temp cu	C°											
HR	1/min	66	74	62	63	66	62	59	58	63	63	73
Diuresi	ml											440
ACT	sec										171	
APNIs	mmHg											
APNIm	mmHg											
APNIId	mmHg											
APs	mmHg	152	157	148	159	154	151	149	146	146	146	195
APm	mmHg	92	86	88	97	92	89	88	85	85	85	124
APd	mmHg	55	52	53	58	55	53	53	51	51	51	73
CVP	mmHg	13	13	13	13	13	12	12	12	12	12	13
PCWP	mmHg											
PAPs	mmHg											
PAPm	mmHg											
PAPd	mmHg											
Pi PCCO	l/min											
Pi SVV	%											
Pi SVR	dyn*s*cm-5											
Pi GEDV mean	ml											
Pi ITBV mean	ml											
Pi EVLW mean	ml											
Vi CO	l/min											
Vi CI	l/min/m2											
Vi SvO2	%											
Vi SVR	dn*s/cm5											
Vi StrokeVolume	ml/beat											
Vi SVV	%											
SvO2	%											
ICP	mmHg											
CPP	mmHg											
SaO2 puls	%	100	100	100	100	100	100	100	100	100	100	100
FiO2	%	48	49	50	50	49	49	48	49	50	50	49
RR	1/min	14	14	14	14	14	14	14	14	14	14	14
TV mL	mL	396	408	395	397	397	396	395	399	398	398	409
Vol min	L/min											
MV	L/min	6	6	6	6	6	6	6	6	6	6	6
PEEP	mbar	0	0	0	0	0	0	1	0	1	1	0
Paw picco	mbar	12	12	12	12	12	12	12	12	12	12	13

Fig 11 - Table

1.6.2.1. Tables general features

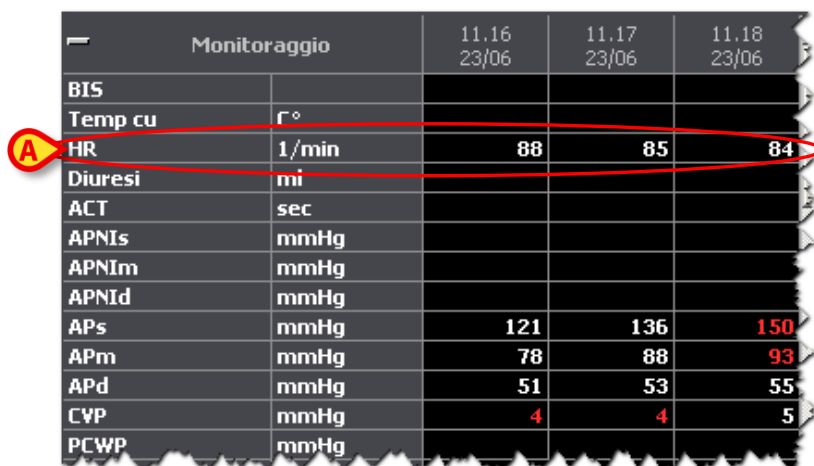
The first column of each table displays, in the first cell on top, the name of the table. In Fig 12 **A** the name is “Mixed parameters”.

<div> <div>A</div> <div>Monitoraggio</div> </div>		11.16 23/06	11.17 23/06	11.18 23/06
BIS				
Temp cu	C°			
HR	1/min	88	85	84
Diuresi	ml			
ACT	sec			
APNIs	mmHg			
APNIm	mmHg			
APNIId	mmHg			
APs	mmHg	121	136	150
APm	mmHg	78	88	93
APd	mmHg	51	53	55
CVP	mmHg	4	4	5
PCWP	mmHg			

Fig 12 - Table name and parameters

The cells placed beneath the title display the names of the relevant parameters considered (“BIS”, “Temp cu”, “HR”, “Diuresi” etc... in Fig 12). The second column specifies, for each parameter, the unit of measure in use.

The values of a specific parameter can be read on the corresponding row. Therefore each row shows the way a specific parameter changes in time. In Fig 13 **A**, for example, the changes in the patient’s heart rate are highlighted.

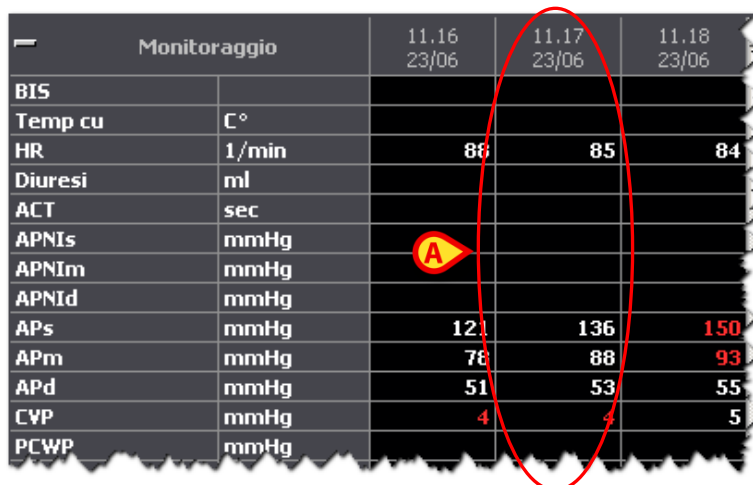


The screenshot shows a table titled "Monitoraggio" with columns for dates 11.16 23/06, 11.17 23/06, and 11.18 23/06. The rows list various parameters: BIS, Temp cu, HR, Diuresi, ACT, APNIs, APNIm, APNId, APs, APm, APd, CVP, and PCWP. A red circle highlights the HR row, which shows values 88, 85, and 84. A yellow circle with the letter 'A' is placed next to the HR row.

Monitoraggio		11.16 23/06	11.17 23/06	11.18 23/06
BIS				
Temp cu	°C			
HR	1/min	88	85	84
Diuresi	ml			
ACT	sec			
APNIs	mmHg			
APNIm	mmHg			
APNId	mmHg			
APs	mmHg	121	136	150
APm	mmHg	78	88	93
APd	mmHg	51	53	55
CVP	mmHg	4	4	5
PCWP	mmHg			

Fig 13

Each column corresponds either to a validation performed by the clinical staff or to a manual data specification. The data specification and the data validation procedures are described in paragraph 1.9.




The screenshot shows the same table as Fig 13, but with a red circle highlighting the column for 11.17 23/06. A yellow circle with the letter 'A' is placed next to the 11.17 23/06 column header.

Monitoraggio		11.16 23/06	11.17 23/06	11.18 23/06
BIS				
Temp cu	°C			
HR	1/min	88	85	84
Diuresi	ml			
ACT	sec			
APNIs	mmHg			
APNIm	mmHg			
APNId	mmHg			
APs	mmHg	121	136	150
APm	mmHg	78	88	93
APd	mmHg	51	53	55
CVP	mmHg	4	4	5
PCWP	mmHg			

Fig 14

The cell on top of each column displays the time of data specification/validation (the date is specified when it’s different from the current date). Each column displays the value of the specified parameters at a certain time. The column highlighted in Fig 14 **A**, for example, displays the values of all the parameters at 11.17 of the 23rd of June.

The button highlighted Fig 15 () minimizes the table.

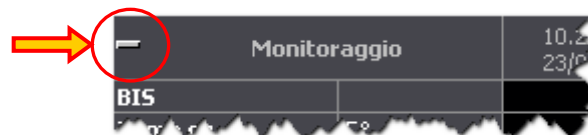


Fig 15


Click the  button to minimize the table (as in Fig 16). Click the  button to bring the table back to the original proportions.



Fig 16

The same table can be divided in different sections. Fig 17 shows a table containing two distinct sections ("Venoso" and "Ventilazione"). The features and the procedures described since apply to each section of the table.

Venoso						
vHCO3	mMol/L					
vCO2	Vol %					
vpCO2	mmHg					
vpH						
vpO2	mmHg					
vSatO2	%					
vSBE	mMol/L					
Ventilazione		10.06 26/08	10.07 26/08	10.08 26/08	10.09 26/08	10.10 26/08
FiO2	%					
SaO2 puls	%	98	99	99	98	98
RR	1/min					
SIMV freq	1/min					
Vol min	L/min					
PEEP	mbar					
ETCO2 mmHg	mmHg					
P5up above PEEP	mbar					

Fig 17 - Two sections

Move the mouse pointer over the values on the table to display a tooltip containing information on the specific value (parameter name, date and time of specification, range of normality - when specified - Fig 18).

10.15 26/08	10.16 26/08
56	56
<div> <div>A</div> <div> HR 26/08/10 10:16 60 ... 90 </div> </div>	
149	155
97	94
60	57

Fig 18

When a small red triangle is displayed on the top-left corner of a cell it means that the value is too long to be displayed entirely (Fig 19). The value is displayed completely in a tooltip when the mouse pointer is moved over the cell.

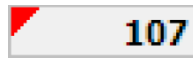


Fig 19 - Partial value

When a small yellow triangle is displayed on the top-left corner of the column heading (Fig 20) it means that there is a textual note associated to the data specified in the column. The note, together with the acronym of the user who added it, is displayed in a tooltip when the mouse pointer is passed over the specific column heading.



Fig 20 - Note

The red values on the table are out of the range of normality set by configuration (Fig 21).



Fig 21

1.6.2.2. Parameter tables' command bar

A command bar is present above each table (Fig 22 A, Fig 23).

Monitoraggio completo		10.04 26/08	10.05 26/08	10.06 26/08	10.07 26/08	10.08 26/08	10.09 26/08	10.10 26/08	10.11 26/08	10.12 26/08	10.13 26/08	10.14 26/08
BIS												
Temp cu	C°											
HR	1/min	58	58	57	59	54	56	59	51	57	51	47
Diuresi	ml											
ACT	ml/h											


Fig 22 - Table

The command bar makes it possible to change the table display mode. The functions of the different buttons on the command bar are described below.






Monitoraggio completo		10.04 26/08	10.05 26/08	10.06 26/08	10.07 26/08	10.08 26/08	10.09 26/08	10.10 26/08	10.11 26/08	10.12 26/08	10.13 26/08	10.14 26/08
BIS												
Temp cu	C°											
HR	1/min	58	58	57	59	54	56	59	51	57	51	47
Diuresi	ml											
ACT	ml/h											

Fig 23 - Command bar


Monitoraggio completo - On the left, in the box highlighted in Fig 23 A, is displayed the name of the table. The name in the example is “Monitoraggio completo” (“Complete monitoring”).

 - This object, indicated in Fig 23 B, is named “rollbar”. It makes it possible to move back and forth on the table. Drag the rollbar to the left to display the columns referring to a time preceding the time currently displayed. Drag the rollbar to the right to display the columns referring to a time following the time currently displayed.

The buttons indicated in Fig 23 C make it possible to perform the following actions:

-  - **Full screen display** - Use this button to display the table in “full screen” mode. A second click brings the table back to the original proportions.
-  - **Back** - Use this button to display a table portion referring to a time preceding the time currently displayed.
-  - **Forward** - Use this button to display a table portion referring to a time following the time currently displayed.
-  - **Original proportions** - Use this button to bring the table back to the proportions it had before any change was performed.
-  - **Chart parameter picker** - Use this button to open a tool making it possible to rapidly create a chart. This tool is described in paragraph 1.6.2.3.

1.6.2.3. Chart popup parameter picker

Click the  button placed above each table to open the tool displayed in Fig 24, named “Chart popup parameter picker”.

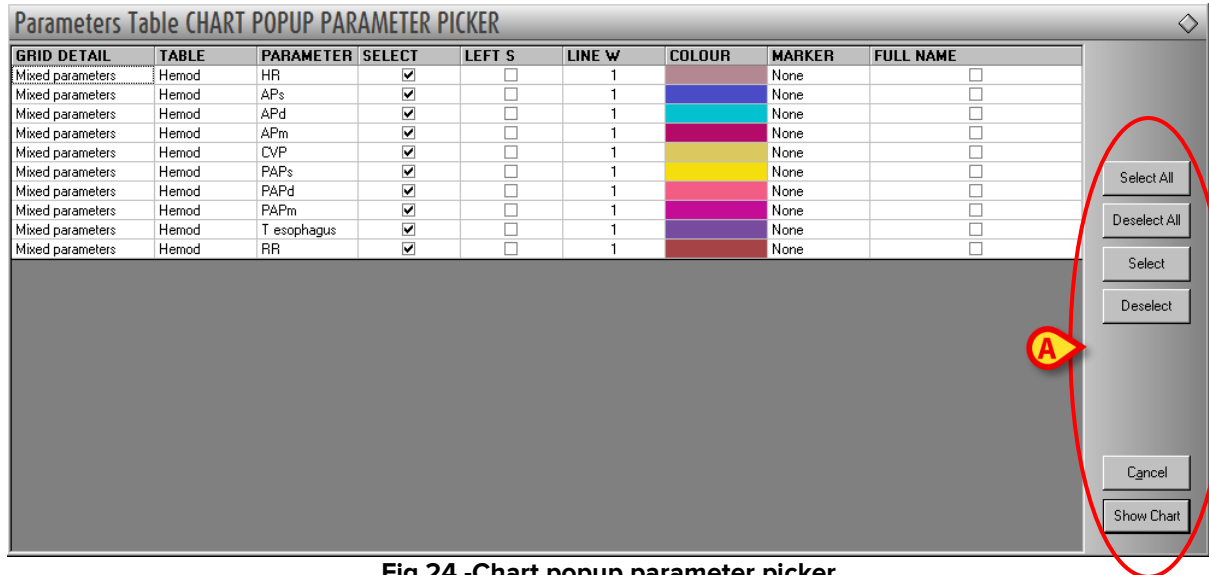


Fig 24 -Chart popup parameter picker


The “parameter picker” makes it possible to display in a separate popup window a chart that is entirely user-defined.

“Parameters picker” description

The “parameters picker” displays a table listing all the relevant parameters (Fig 25).

GRID DETAIL	TABLE	PARAMETER	SELECT	LEFT S	LINE W	COLOUR	MARKER	FULL NAME
Mixed parameters	Hemod	HR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>
Mixed parameters	Hemod	APs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>
Mixed parameters	Hemod	APd	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>
Mixed parameters	Hemod	APm	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>
Mixed parameters	Hemod	CVP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>
Mixed parameters	Hemod	PAs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>
Mixed parameters	Hemod	PAPd	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>
Mixed parameters	Hemod	PAPm	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>
Mixed parameters	Hemod	T esophagus	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>
Mixed parameters	Hemod	RR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1		None	<input type="checkbox"/>

Fig 25 - Parameters table

Each row corresponds to one of the parameters of the original table (i.e. the table on which the  button was clicked).

Grid detail	These three items identify the specific parameter
Table	
Parameter	
Select	Use this checkbox to specify whether representing or not the corresponding parameter on the chart you are creating.
Left S	Check this box if you want to display the specific parameter scale of values on the left of the chart. Do not check it if you want to display it on the right.
Line W	This cell specifies the width of the line drawn in the chart.

Colour	This cell indicates the color of the line.
Marker	This cell specifies whether a marker is drawn or not when the chart line changes direction. It is also possible to select the kind of marker (square, triangle, circle etc...).
Full name	Check this box to display the parameter's full name on the chart.

On the the right of the “Parameters picker” window there are various buttons (Fig 24 **A**). These are their functionalities:

The **Select All** button selects all the parameters on the table.

The **Deselect All** button deselects all the parameters on the table.

The **Select** button makes it possible to select a chosen set of parameters. To do that:

- Click the row corresponding to a parameter.

The row is this way highlighted.

- Move the mouse pointer either upwards or downwards keeping the left button clicked, until you reach a row corresponding to another parameter.

All the rows in between are this way highlighted.

- Click the **Select** button.

All the checkboxes corresponding to the highlighted lines are this way selected in the “Select” column on the table.

The **Deselect** button makes it possible to deselect a chosen set of (previously selected) parameters. To do that:

- Click the row corresponding to a parameter.

The row is this way highlighted.

- Move the mouse pointer either upwards or downwards keeping the left button clicked, until you reach a row corresponding to another parameter.

All the rows in between are this way highlighted.

- Click the **Deselect** button.

All the checkboxes corresponding to the highlighted lines are this way deselected in the “Select” column on the table.

Use the **Cancel** button to abort the chart creation procedure and close the “Parameter picker” window.

Use the **Show Chart** button to display in a popup window the chart having the chosen features.

Chart creation procedure

To create a chart using the “Parameters picker popup window”

- Click the  button.

The “Parameters picker popup window” opens (Fig 24).

- Select, on the parameters table (Fig 25), the parameters to be displayed (and specify their features).
- Click the **Show Chart** button.

A popup window containing the defined chart shows up. In the example shown in Fig 26 two parameters are displayed (“APs” in magenta and “HR” in green; two different markers were chosen).



Fig 26 - Pop-up chart

The chart’s command bar is described in paragraph 1.6.1.2.

1.6.3. Charts and tables synchronization

It is possible to synchronize charts and tables.

The synchronization functionality is active when the **Synchro** button on the command bar is selected (Fig 27).



Fig 27 - Command Bar

It is an ON/OFF button. When selected the button is highlighted. Click it again to deactivate the charts and tables synchronization.

When the synchronization functionality is active, one click on one of the charts displays the chart cursor (the vertical yellow cursor, see Fig 9) on all the charts on the page. The cursors all indicate the same time. The column corresponding to the same time is highlighted on the possible tables on the same page.

If no data is available on the table at the time corresponding to the cursor position on the chart, then no column is selected.

Similarly, the selection of a column on a table displays the yellow cursor on all the charts on the page, in the position corresponding to the time specified on the column heading. To select a column on a table,

- click the column to be selected. The column is this way highlighted (Fig 28).



OL_Monitoraggio		09.40 23/06	09.41 23/06	09.42 23/06
BIS				
Temp cu	C°			
HR	1/min	73	69	71
Diuresi	ml			
ACT	sec			
APNIs	mmHg			
APNIm	mmHg			
APNIId	mmHg			
APs	mmHg	163	156	178
APm	mmHg	103	97	114
APd	mmHg	64	58	69
CVP	mmHg	7	7	7
PCWP	mmHg			
PAPs	mmHg			
PAPm	mmHg			
PAPd	mmHg			
Pi PCCO	l/min			

Fig 28 - Selected column

Fig 29 shows the synchronization between a chart and a table: the highlighted column, referring to the 09:41 of the 23rd of June, corresponds to the cursors in the charts.














Fig 29 - Synchronization between charts and tables

1.7. Main page command bar

The command bar of the On Line module main page (Fig 30) is formed of several buttons. Each button makes it possible to perform a specific action. The various functionalities are listed in this paragraph. They are described in detail in the paragraphs indicated.



Fig 30 - Command bar

	Use this button to access the “Data entry” screen (Fig 32), used both for manual data entry and data validation purposes. The validation procedure makes it possible to control the data automatically acquired and to filter the possible artifacts. The validation procedure is described in paragraph 1.9.
	Use this button to double the time span displayed on the charts. If, for instance, 8 hours are displayed, one click on this button displays 16 hours. This kind of change in the display mode is temporary. The chart goes back to the normal display mode if another page is accessed or another patient is selected.
	Use this button to halve the time span displayed on the charts. If, for instance, 8 hours are displayed, one click on this button displays 4 hours. This kind of change in the display mode is temporary. The chart goes back to the normal display mode if another page is accessed or another patient is selected.
	Use this button to scroll back all the tables and the charts displayed on screen.
	Use this button to scroll forward all the tables and the charts displayed on screen.
	Use this button to bring the page back to its original display mode (scale, values). The page displays the latest values acquired (either manually or automatically).
 	Use this button to activate the charts and tables synchronization functionality. It is an ON/OFF button that remains selected once clicked. The synchronization functionality is described in paragraph 1.6.3.
	Use this button to access the system’s print functionalities. See paragraph 1.10 for a description of these functionalities.
	This button opens a tool making it possible to either design new pages or to modify the structure of the existing ones. These functionalities are reserved to the system administrators (or person with an equivalent permissions level). If the logged user is not allowed to access these functionalities the button is either absent or disabled.
	Use this button to suspend the automatic data acquisition from the medical devices connected to the patient. See paragraph 1.11.

1.8. Manual data entry and data validation

The data automatically acquired from the medical devices can contain “artifacts” (caused, for example, by sudden patient movements, by accidental disconnections etc.). These data are called “raw data”. The clinical staff has to evaluate these “raw data” in order to either accept or refuse them. This paragraph describes the validation procedure.

Click the **Data Entry** button on the main screen command bar (Fig 31) to access the data entry and validation functionalities.



Fig 31 - Command bar

The following screen opens (Fig 32):

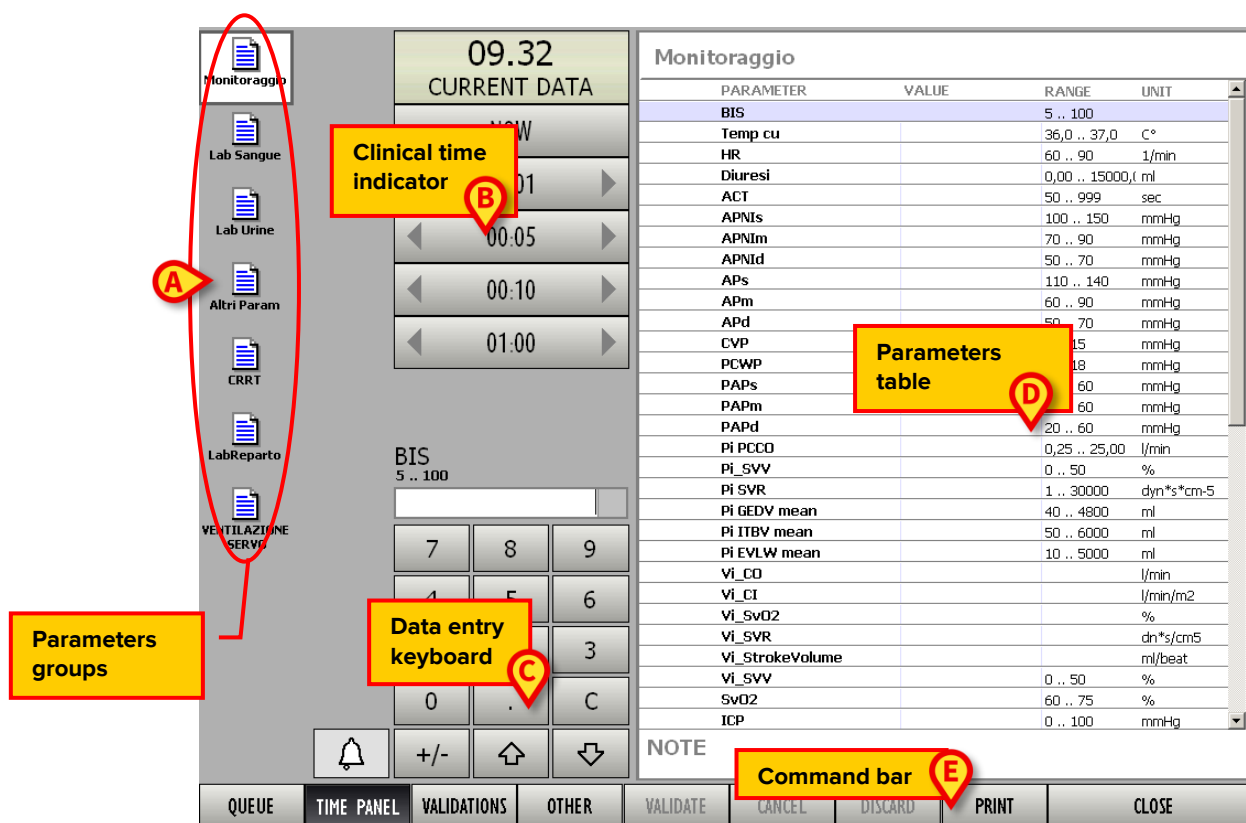


Fig 32 - Data entry screen

This screen is formed of five main parts:

- 1) the list of parameters groups (described in paragraph 1.8.1);
- 2) the clinical time indicator (described in paragraph 1.8.2);
- 3) the data entry keyboard (described in paragraph 1.8.4);
- 4) the parameters table (described in paragraph 1.8.3);
- 5) the command bar (described in paragraph 1.8.6).

The data validation procedure is summarized in paragraph 1.9.

1.8.1. Parameters groups

The icons on the left (Fig 32 **A**, Fig 33) represent the existing groups of parameters.

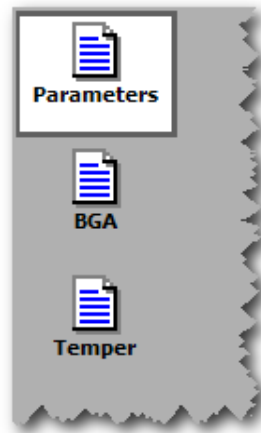


Fig 33 - Parameters groups

Each icon refers to a different group of parameters. The number of groups and their type are set by configuration. To display the data of a specific group

- click the corresponding icon. The clicked icon appears as highlighted (it is the group named “Parameters” in Fig 33).

On the right of the screen, the parameters table (Fig 32 **D**) displays the values of the selected group.

1.8.2. Clinical time indicator

The panel indicated in Fig 32 **C** and enlarged in Fig 34 makes it possible to read and set the clinical time. The data displayed on the table on the right refer to the time here displayed (Fig 32 **D**, Fig 37). The buttons on the panel can be used to change the time displayed and show this way the data referring to a different time.

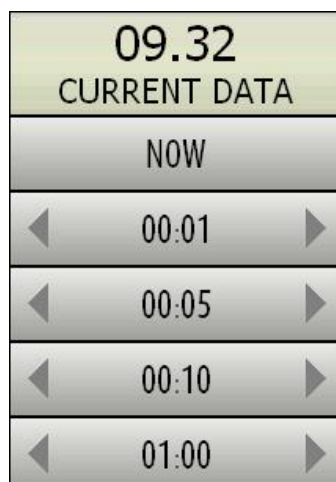


Fig 34 - Clinical time indicator

On top the time is displayed (it is 09:32 in the figure). When the time displayed is the current time the indication “CURRENT DATA” appears in the panel (as in Fig 34).

The buttons placed below the time indication make it possible to change the clinical time.

Use the **00:01** button to move back and forward on the time-line one minute per click (left arrow is the back button).

Use the **00:10** button to move back and forward on the time-line ten minutes per click (left arrow is the back button).

Use the **24:00** button to move back and forward on the time-line one day per click (left arrow is the back button).

Use the **Now** button to display the current time.



The data displayed on screen refer to the time displayed on the clinical time indicator.

The data displayed on screen refer to the time displayed on the clinical time indicator. Therefore the changes in the time displayed on the time indicator change the data displayed on the table on the right (Fig 32 **D**, Fig 37). That is, for example: if the clinical time displayed is 09:30 the data displayed on the table are those acquired at 09:30; if the clinical time displayed is 08:30 the data displayed on the table are those acquired at 08:30. This feature makes it possible, if necessary, to validate past data.



For instance: in case the results of a laboratory exam referring to a sample taken hours before the current time are delivered to the system, it is better to set the clinical time to the time of the sample.

If, before accessing the validation screen, a cursor is activated either on a table or a chart, when accessing the validation screen an additional button is displayed on the time panel, referring to the time indicated by the cursor. This makes it possible to rapidly edit any value already existing on the tables.

1.8.2.1. Previous validations list

It is possible to display the list of all the previous validations under the clinical time indicator. To do that

- Click the **Validations** button on the command bar (Fig 35).



Fig 35 - Command bar

The list of all the previous validations appears under the clinical time indicator (Fig 36).

10.32	
08/09/10 10:32	Monitoraggio
08/09/10 09:32	Lab Sangue
08/09/10 09:32	Altri Param
08/09/10 09:32	CRRT
08/09/10 09:32	Monitoraggio

Fig 36 - Validations list

Each row corresponds to a validation. For each validation are specified the date, the time and the group.

- Click the line corresponding to a past validation to display the corresponding data on the table on the right (Fig 32 **D**).

1.8.3. Parameters table description

The table indicated in Fig 32 **D** and highlighted in Fig 37 displays all the parameters configured in the system belonging to the selected group.

Monitoraggio			
PARAMETER	VALUE	RANGE	UNIT
BIS	78	5 .. 100	
Temp cu	36,8	36,0 .. 37,0	C°
HR	89	60 .. 90	1/min
Diuresi	7800,00	0,00 .. 15000,0	ml
ACT		50 .. 999	sec
APNis		100 .. 150	mmHg
APNim	88	70 .. 90	mmHg
APNid	75	50 .. 70	mmHg
APs		110 .. 140	mmHg
APm		60 .. 90	mmHg
APd	56	50 .. 70	mmHg
CVP	8	5 .. 15	mmHg
PCWP	20	6 .. 18	mmHg
PAPs		20 .. 60	mmHg
PAPm		20 .. 60	mmHg
PAPd	36	20 .. 60	mmHg
Pi PCCO	16,80	0,25 .. 25,00	l/min
Pi_SVV	45	0 .. 50	%
Pi SVR		1 .. 30000	dyn*s*cm-5
Pi GEDV mean		40 .. 4800	ml
Pi ITBV mean		50 .. 6000	ml
Pi EVLW mean		10 .. 5000	ml
Vi_CO			l/min
Vi_CI			l/min/m2
Vi_SvO2			%
Vi_SVR			dyn*s/cm5
Vi_StrokeVolume			ml/beat
Vi_SVV	48	0 .. 50	%
SvO2		60 .. 75	%
ICP	85	0 .. 100	mmHg
NOTE			

Fig 37 - Parameters table

Each row corresponds to a parameter. There are four columns on the table:

- The “Parameter” column displays the name of the parameter;
- The “Value” column displays, when specified, the parameter value;

- The “Range” column displays, when specified, the range of normality for the values of the corresponding parameter;
- The “Unit” column displays the unit of measure of the corresponding parameter.

The “Note” area placed below the table makes it possible to add a note about a specific data set validation. To add a note

- click the “Note” area. A blinking cursor appears.
- Type the note (Fig 38).

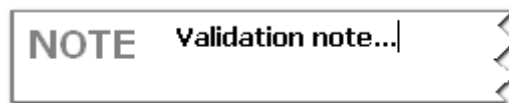


Fig 38

When a textual note is associated to a validation, a specific yellow marker is displayed on the corresponding column on the “Data display” table (Fig 39).

	10.48
	78
	36,8
	89
	7800
	88
	75

Fig 39

The data entry procedure is described in paragraph 1.8.5. The validation procedure is described in paragraph 1.9.

1.8.4. Data entry keyboard

The keyboard indicated in Fig 32 **C** and enlarged in Fig 40 makes it possible to insert numeric and textual (depending on the parameter) data in the parameters table (Fig 32 **D**, Fig 37).

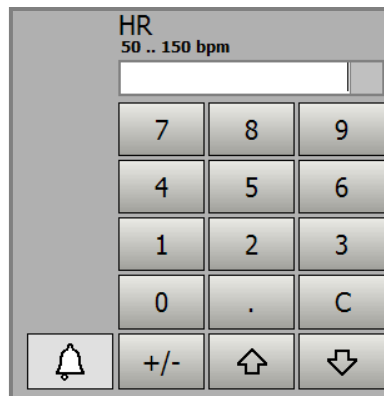



Fig 40 - Data entry keyboard

- Click the buttons on the keyboard to insert numeric data.

Textual data are usually selected on a menu containing a list of pre-defined options. When this is the case the  button is displayed alongside the field. This button opens the list of options (Fig 41).

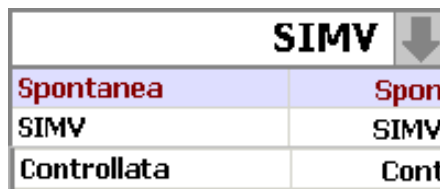


Fig 41 - Options

- Click the relevant option to select it and add it to the table.

1.8.5. How to enter data

To enter data

- Set the clinical time that you want to associate to the data you are entering (see paragraph 1.8.2 for the clinical time selection procedure).



The table on the right displays the values acquired at the selected time. When the clinical time displayed is the current time the table displays the current data (Fig 42).

The screenshot shows a software interface for data entry. On the left is a sidebar with icons for 'Monitoraggio', 'Lab Sanguine', 'Lab Urine', 'Altri Param', 'CRRT', 'Lab Reparto', and 'VENTILAZIONE SERVO'. The main area is divided into three sections. The top section shows a time display '10.48' and a 'NOW' button. Below this are four time selection buttons: '00:01', '00:05', '00:10', and '01:00'. The bottom section is a numeric keypad with buttons for digits 0-9, a decimal point, a 'C' (clear) button, and arrow buttons for up and down. A red circle labeled 'B' highlights the '89' value in the keypad. The right section is a table titled 'Monitoraggio' with columns 'PARAMETER', 'VALUE', 'RANGE', and 'UNIT'. The 'HR' row is highlighted in blue, and a red circle labeled 'A' highlights the value '89' in the 'VALUE' column. Below the table is a 'NOTE' section with the text 'Validation note...'. At the bottom of the interface are several buttons: 'QUEUE', 'TIME PANEL', 'VALIDATIONS', 'OTHER', 'VALIDATE', 'CANCEL', 'DISCARD', 'PRINT', and 'CLOSE'.

PARAMETER	VALUE	RANGE	UNIT
BIS	78	5 .. 100	
Temp cu	36,0	36,0 .. 37,0	C°
HR	89	60 .. 90	1/min
Diuresi	7800,00	0,00 .. 15000,0	ml
ACT		50 .. 999	sec
APNis		100 .. 150	mmHg
APNim	88	70 .. 90	mmHg
APNid	75	50 .. 70	mmHg
APs		110 .. 140	mmHg
APm		60 .. 90	mmHg
APd	56	50 .. 70	mmHg
CVP	8	5 .. 15	mmHg
PCWP	20	6 .. 18	mmHg
PAPs		20 .. 60	mmHg
PAPm		20 .. 60	mmHg
PAPd	36	20 .. 60	mmHg
Pi PCCO	16,80	0,25 .. 25,00	l/min
Pi SVV	45	0 .. 50	%
Pi SVR		1 .. 30000	dyn*s*cm-5
Pi GEDV mean		40 .. 4800	ml
Pi ITBV mean		50 .. 6000	ml
Pi EVLW mean	678	10 .. 5000	ml
Vi CO			l/min
Vi CI			l/min/m2
Vi SvO2			%
Vi SVR			dn*s/cm5
Vi StrokeVolume			ml/beat
Vi SVV	48	0 .. 50	%
SvO2		60 .. 75	%
ICP	85	0 .. 100	mmHg

Fig 42 - Data entry

One of the rows is highlighted, corresponding to one of the parameters. The value specified on the highlighted row (if a value is specified - Fig 42 **A**) is displayed in the data entry field, above the numeric keyboard (Fig 42 **B**).

- Use the arrow buttons on the keyboard ( and ) to select the row corresponding to the parameter to be specified. Otherwise click the relevant row.

The parameter value (if present) is displayed in the data entry field, otherwise no value appears in the field.

- Use the data entry keyboard to enter the new value (Fig 43)

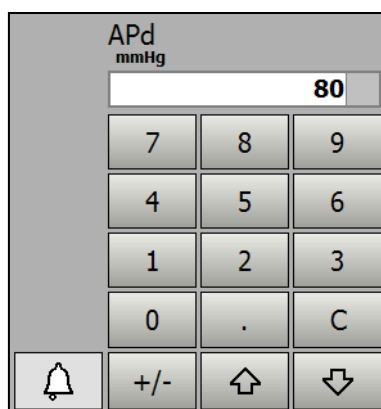




Fig 43 - New value added

- Use the arrow buttons on the keyboard ( and ) to select either the previous or the following row. Otherwise click the **Return** key on the PC keyboard. The new value is displayed (Fig 44).

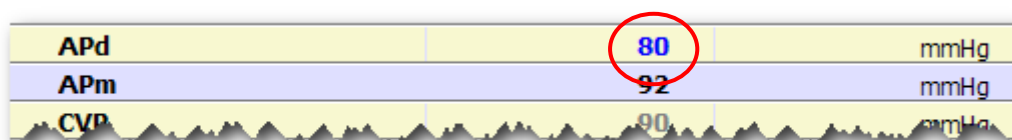




Fig 44

For some parameters a “Normality” range is specified. When the value, either acquired by the system or specified by the user, is out of the normality range the  icon appears alongside the value. See for instance Fig 45, in which the value of the parameter “NBPD” is 58 mmHg when the normality range specified is 60 to 160 mmHg. In this case the  icon appears alongside the value.

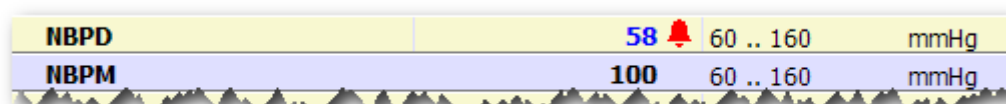






Fig 45

When a row corresponding to a value that is out of the normality range is selected, the  button placed alongside the numeric keyboard becomes red. In Fig 46 the “NBPD” value is selected and the button is red.

T esophagus	37,0	C°
T bladder		°C
Glycemie		
Diuresis		ml
ACT		U
NBPS	126	60 .. 160 mmHg
NBPD	58	60 .. 160 mmHg
NBPM	100	60 .. 160 mmHg
T1		10,0 .. 40,0 C°
RR	22 (1/m)	rpm

Fig 46

The values that are out of the normality range, after the validation, are displayed in red on the “data display” table on the main screen (Fig 47) unless the  button is clicked before the validation. If the  button is clicked it turns grey again - . The corresponding value is consequently displayed in black on all the module’s screens.

NBPS	mmHg	134	136
NBPD	mmHg	70	58
NBPM	mmHg	102	100
T1	C°		
RR	rpm	22	22

Fig 47

When an impossible value is specified (a value that is out of specific plausibility criteria) the On Line module inhibit the operation and informs the user with a specific pop-up message.














1.8.6. The command bar of the data entry screen

The command bar of the data entry screen is formed of various buttons making it possible to perform specific procedures.

The different functionalities of the buttons are listed in the present paragraph and, when necessary, explained in more detail in the indicated paragraphs.



Fig 48 - Command bar

 	<p>This button displays the list of items that are part of the validation queue. See paragraph 1.8.7 for a description of the validation queue. When the button is grey there is no queue</p> <p>When the button is yellow there is a queue. Click the button to display the items in the queue.</p>
 	<p>When this button is selected the area indicated in Fig 34 and Fig 32 B (the “Clinical time” area) displays the buttons making it possible to edit the clinical time (see paragraph 1.8.2 for the procedure). The selection of this button excludes the possibility to select the “Validations” and “Other” buttons.</p>
 	<p>When this button is selected the area indicated in Fig 34 e Fig 32 B (the “Clinical time” area) displays the list of all the past validations (see paragraph 1.8.2.1 for the procedure). The selection of this button excludes the possibility to select the “Time panel” and “Other” buttons.</p>
 	<p>This button has the general purpose to display any list that the Healthcare Structure using the On Line module may find useful. The list is displayed in the area indicated in Fig 34 and Fig 32 B (the “Clinical time” area). For instance, the system administrators can define a <i>Query</i> identifying a certain kind of validations and use the “Other” button to immediately display the query results.</p> <p>The selection of this button excludes the possibility to select the “Time panel” and “Validations” buttons.</p>
	<p>Use this button to validate the data displayed on screen. See paragraph 1.9 for the data validation procedure.</p>
	<p>Use this button to bring the values of the parameters displayed on screen to their original values. All the changes possibly performed are annulled.</p>
	<p>This button is only enabled when the validation queue is displayed. Use this button to discard one of the data sets on the queue. See paragraph 1.8.7 for the detailed procedure.</p>
	<p>Use this button to print the parameters’ values.</p>
	<p>Use this button to close the “Data entry” screen.</p>

1.8.7. Validation queue

Some parameters can be configured to be stored in a validation queue as soon as they are acquired. These are the cases of data whose acquisition must be immediately communicated to the medical staff (as, for instance, the laboratory exams or the emogas analysis) .

If there are data in the validation queue the **Queue** button on the command bar turns yellow.

- Click the button to display the the validation queue.

These data can be either analyzed, edited, validated or discarded. In all cases this kind of data must be viewed by a physician. The validation procedure is the same used for the other parameters, described in paragraph 1.9.

To display and validate the data in the “validation queue”

- click the **Queue** button.

A list of icons is displayed on screen (Fig 49 **A**). Each icon corresponds to a set of data waiting for validation (“queued” data).

When the validation queue is displayed the **Queue** button is highlighted (Fig 49 **B**).

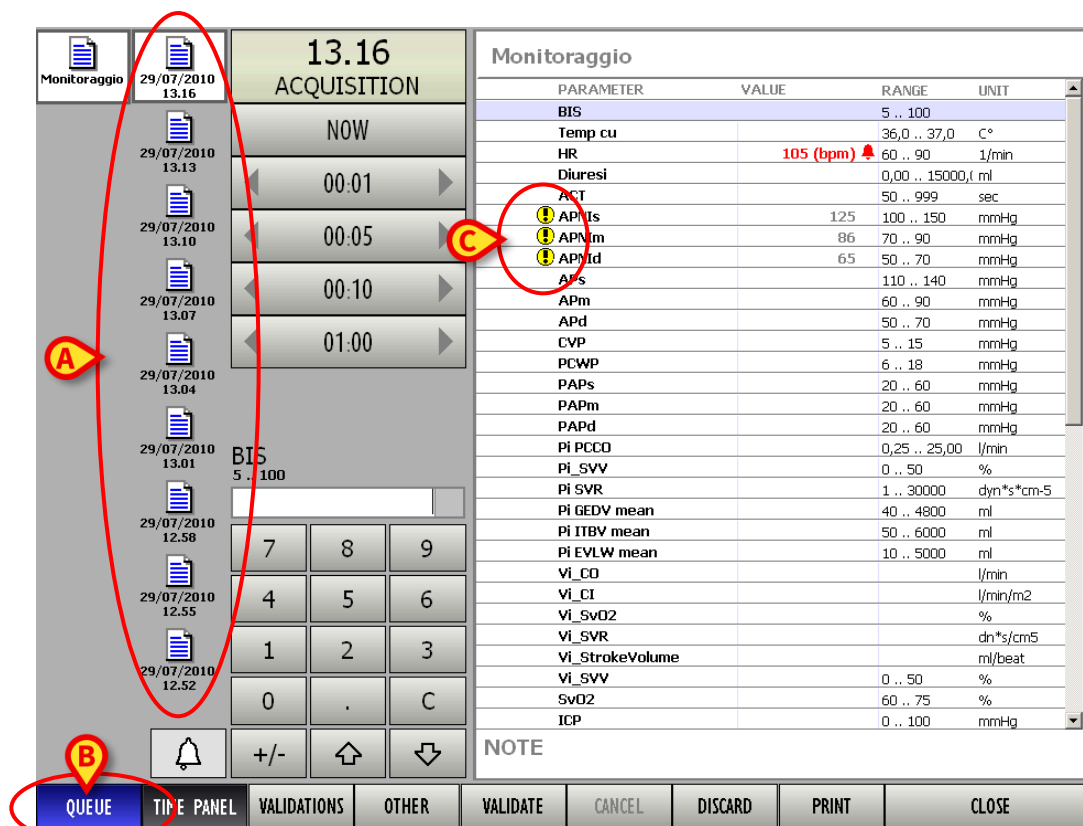


Fig 49 - Validation queue displayed

The time of acquisition of the corresponding data is specified beneath each icon.

- Click the icon corresponding to the data to be validated. The icon is this way highlighted (Fig 50).

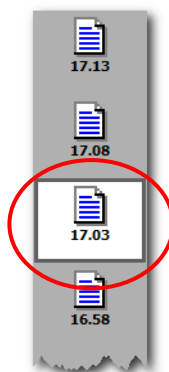


Fig 50


The parameters table on the right displays the parameters and the values corresponding to the clicked icon.


- Review and (in case) edit the data on the table (the procedure is described in paragraph 1.8.5).
- Click the **Validate** button to validate the data and add them to the patient documentation.

Otherwise,

- click the **Discard** button to reject the data and cancel them definitively. In both cases the icon corresponding to the set of data disappears from the validation queue.



When the  icon is displayed alongside the parameter name (as, for instance, in Fig 49 C) it means that the corresponding parameter was acquired before the acquisition time indicated under the icon.

For example: there are ten parameters, 6 of them are acquired at 10:30 and the remaining 4 parameters are acquired at 11:00. When the 11:00 o'clock acquisition is displayed the  icon is displayed alongside the 6 parameters acquired at 10:30.

1.9. Data validation procedure

This paragraph summarizes the data validation procedure. On the On Line module data display screen (Fig 51),

1. Click the **Data Entry** button on the command bar (Fig 51 **A**).

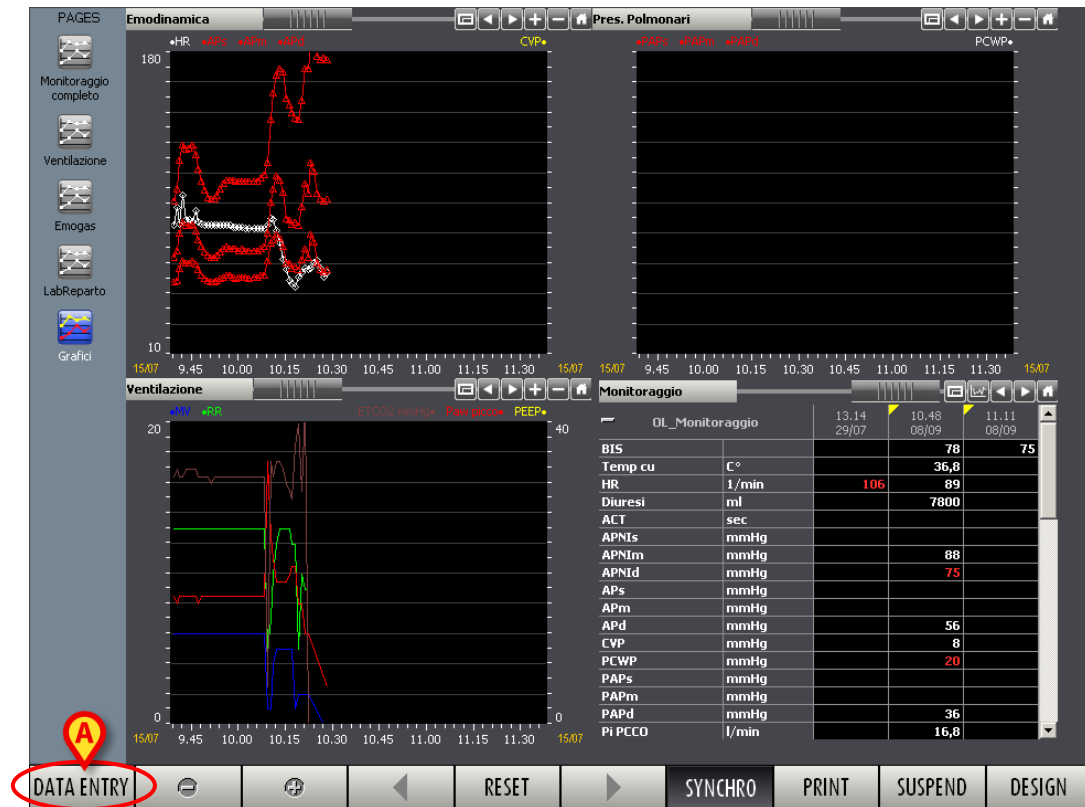


Fig 51 - Data display screen

The “Data entry” screen opens (Fig 52).

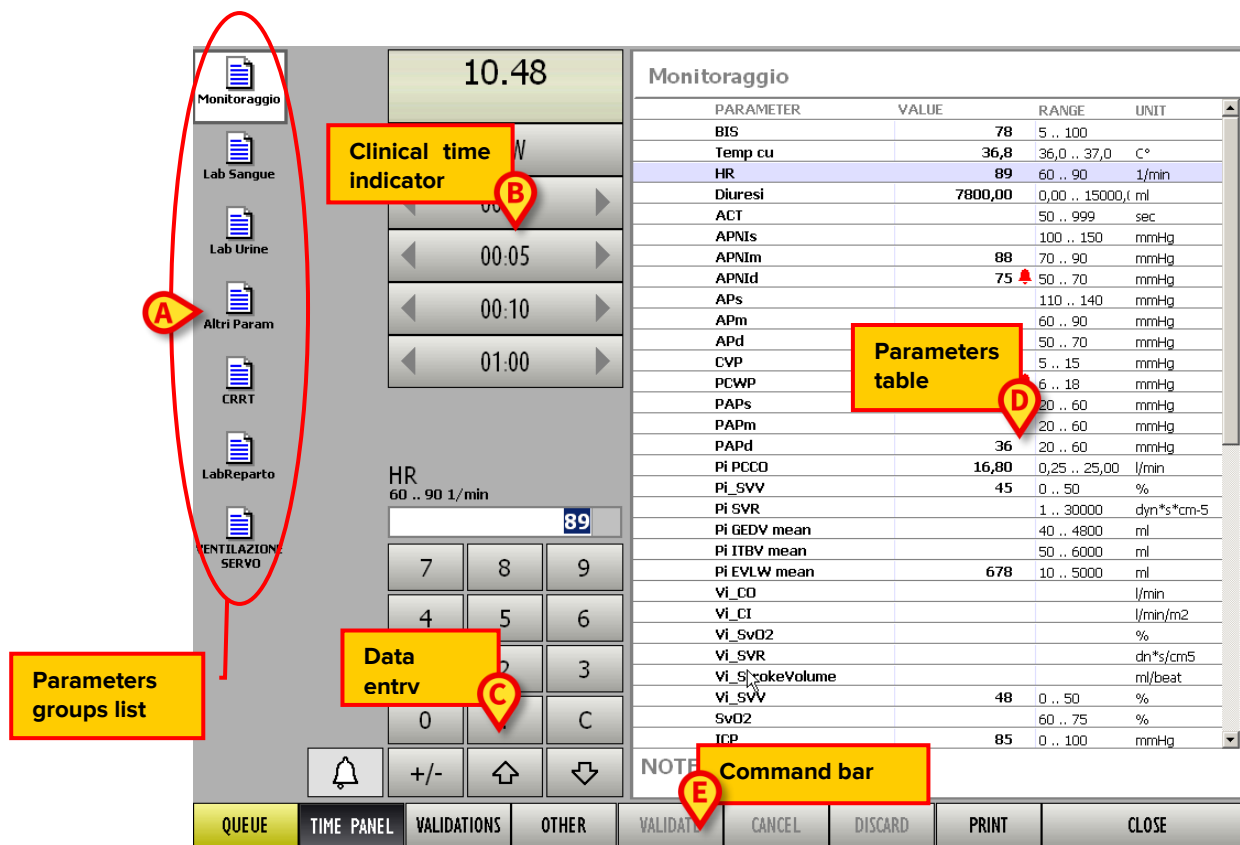


Fig 52 - Data entry screen

- Click the icon corresponding to the group of parameters to be validated (Fig 52 A).

The icon is this way highlighted. The parameters and values of the selected group at the time indicated by the clinical time indicator appear on the parameters table (Fig 52 D). See paragraph 1.8.1 for a detailed description of the parameters group selection procedure.

- Set the clinical time (using the appropriate buttons - Fig 52 B) in case you need to validate data referring to a time preceding the current time.

The parameters table displays the values corresponding to the selected time. See paragraph 1.8.2 for a description of the time setting procedure.

- Enter data using the data entry keyboard (Fig 52 C). See paragraph 1.8.5 for a description of the data entry procedure.
- Click the **Validate** button on the command bar (Fig 52 E) to confirm the data entered.

Otherwise, to abort the procedure,

- click the **Cancel** button.
- Repeat steps 1 to 5 for each group of parameters to be validated.
- Click the **Close** button to go back to the On Line data display screen (Fig 51).

See paragraph 1.8.7 for the queue validation procedure.

1.10. Print functionalities

To access the On Line module's print functionalities.

- Click the **Print** button on the command bar (Fig 53).



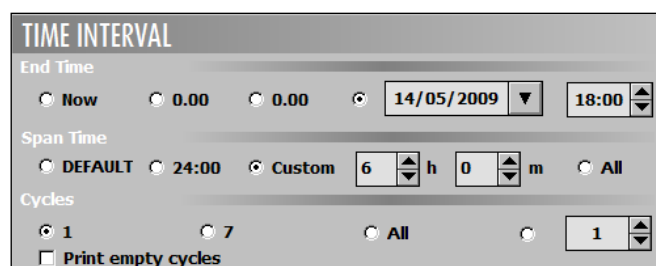
Fig 53 - Command bar

A specific window opens, making it possible to define the features of the report to be printed (Fig 54).

A screenshot of the 'PRINT REPORT' window. At the top, there are tabs for 'Yesterday' and 'Today'. Below these are buttons for 'Shift 1 6.00', 'Shift 2 12.00', and 'Shift 3 20.00'. A horizontal timeline with numbers 0, 3, 6, 9, 12, 15, 18, 21 is shown, with a green triangle pointing to 12. Below the timeline is the 'TIME INTERVAL' section, which includes 'End Time' (Now, 0.00, 0.00, 15/05/2009, 23:59), 'Span Time' (DEFAULT, 24:00, Custom, 24 h 0 m, All), 'Cycles' (1, 7, All, 1), and a checkbox for 'Print empty cycles'. The 'REPORTS SELECTION' section has a sub-section 'Available Reports' with a checkbox for 'Foglio Giornaliero'. At the bottom, there is a 'PATIENTS' section with radio buttons for 'Selected Patient only' and 'All Patients at this location'. A 'PRINT' button and a 'CANCEL' button are located at the bottom right.

Fig 54 - Print reports definition

- Use the **Yesterday** and **Today** buttons to print either yesterday's or today's data (Fig 54 **A**).
- Use the **Shift 1**, **Shift 2**, etc. buttons to select the shift to which the print reports refer (Fig 54 **B**).
- The bar indicated in Fig 54 **C** indicates the current time (in the figure it is 12:00 o'clock approximately).
- The area shown in Fig 55 makes it possible to select the time interval to which the print reports refer.



TIME INTERVAL

End Time
☒ Now ☐ 0.00 ☐ 0.00 ☒ 14/05/2009 ▼ 18:00 ▲▼

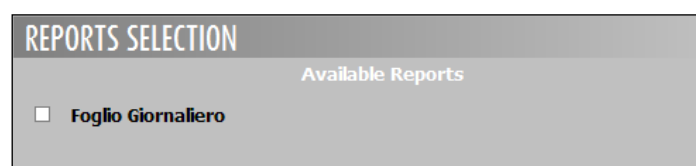
Span Time
☐ DEFAULT ☐ 24:00 ☒ Custom 6 ▲▼ h 0 ▲▼ m ☐ All

Cycles
☒ 1 ☐ 7 ☐ All ☐ ▲▼

☐ Print empty cycles

Fig 55 - Time interval selection

The area shown in Fig 56 makes it possible to select one of the available reports. The number and kind of available reports is defined by configuration through the integrated “On Line reports maker” editor (to access this tool enter the Clinical Configuration functionalities on the Product main menu).




REPORTS SELECTION

Available Reports

☐ Foglio Giornaliero

Fig 56 - Available reports selection

The area shown in Fig 57 makes it possible to decide whether printing the data of a single patient or the data of all the patients in the location.



PATIENTS

☒ Selected Patient only ☐ All Patients at this location

Fig 57 - Patient selection

After report definition,

- Click the **Print** button to create the report.

A print preview can be displayed.

1.11. Data acquisition suspension

The **Suspend** button on the command bar of the data display screen (Fig 58) makes it possible to either suspend or stop the direct data acquisition from the medical devices.



Fig 58 - Command bar

To either suspend or stop the data acquisition

- click the **Suspend** button. Different options are available (Fig 59).



Fig 59

The **10 Minutes** button suspends the data acquisition for 10 minutes.
The **30 Minutes** button suspends the data acquisition for 30 minutes.
The **60 Minutes** button suspends the data acquisition for 60 minutes.
The **Stop** button suspends the data acquisition for an undetermined time.

When one of the three temporary suspension options (10, 30 and 60 minutes) is selected, a popup window appears to remind the user of the acquisition restart time (Fig 60).



Fig 60 - Acquisition suspended

The **Stop** button (Fig 59 **A**) displays a different popup window (Fig 61).

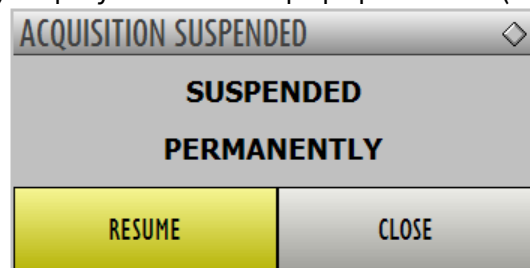


Fig 61 - Acquisition suspended permanently

On both windows,

The **Resume** button (Fig 60 **A**) makes data acquisition start again;

The **Close** button (Fig 60 **B**) closes the acquisition suspension confirmation window.

When data acquisition is suspended the **Suspend** button is red.

- Click the red button to display the following options:

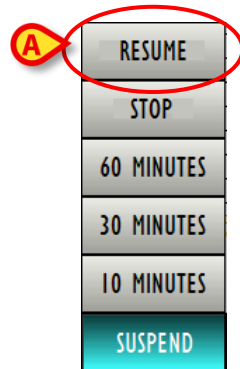


Fig 62

The **Resume** option (Fig 62 **A**) is added to the options displayed in Fig 59.

- Click the **Resume** button to start data acquisition again.