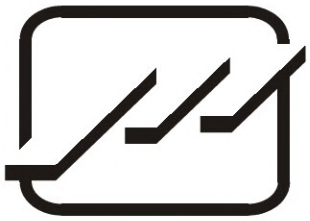
# POOYANDEGAN RAH SAADAT

## OPERATOR'S MANUAL

**S1600 Patient Monitor**
**S1800 Patient Monitor**
**ZAGROS Patient Monitor**
**ALBORZ B5 Patient Monitor**
**ALBORZ B9 Patient Monitor**
**ZAGROS s Patient Monitor**



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**D00200-2**

# Chapter 2 System Configuration

Patient care monitor has a flexible configuration. Press HOME/MENU key on the front panel or the rotary switch in Header area to enter HOME WINDOW and set configuration (Figure 2-1).

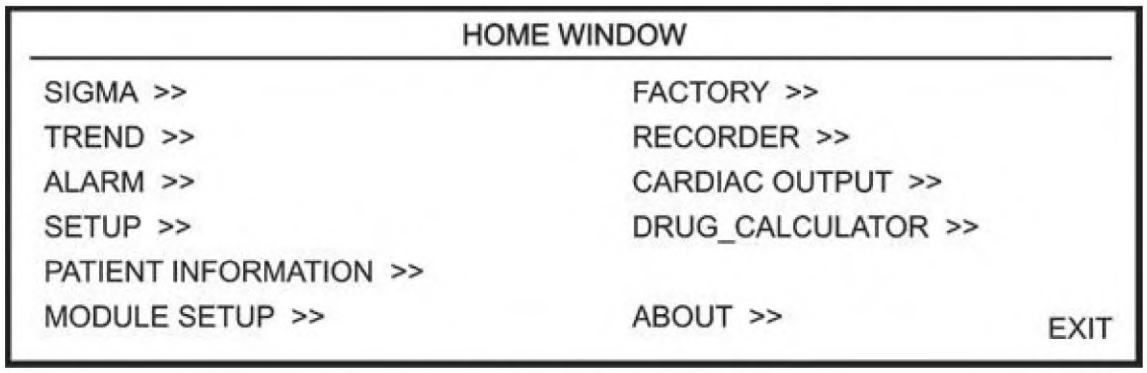



**Figure 2-1 HOME WINDOW**

**NOTE:**

**If power failure occurs and the battery cannot be used, the system settings will be maintained.**

- For the latest saved ECG signals, please refer to **2.1 SIGMA**.
- For previous values of numeric parameters, please refer to **2.2 TREND**.
- For alarm setting (e.g. volume adjustment), please refer to **2.3 ALARM**.
- For date and time setting please refer to **2.4 SETUP**.
- For patient setting please refer to **2.5 PATIENT INFORMATION**.
- For color setting and checking the modules version please refer to **2.6 MODULE SETUP**.
- For internal recorder setting please refer to **2.7 RECORDER**.
- For CARDIAC OUTPUT setting please refer to **2-8 CARDIAC OUTPUT**.
- For DRUG CALCULATION setting please refer to **2-9 DRUG CALCULATOR**.

## 2.1 SIGMA

Patient care monitor is able to save and display 10 traces of ECG signal in SIGMA WINDOW. Time of displaying ECG signal is 170 sec in S1600 monitor, 200 sec in S1800 and ZAGROS S monitors and 260 sec in ALBORZ monitors.
Pick "SIGMA" in HOME WINDOW to call up the following window:

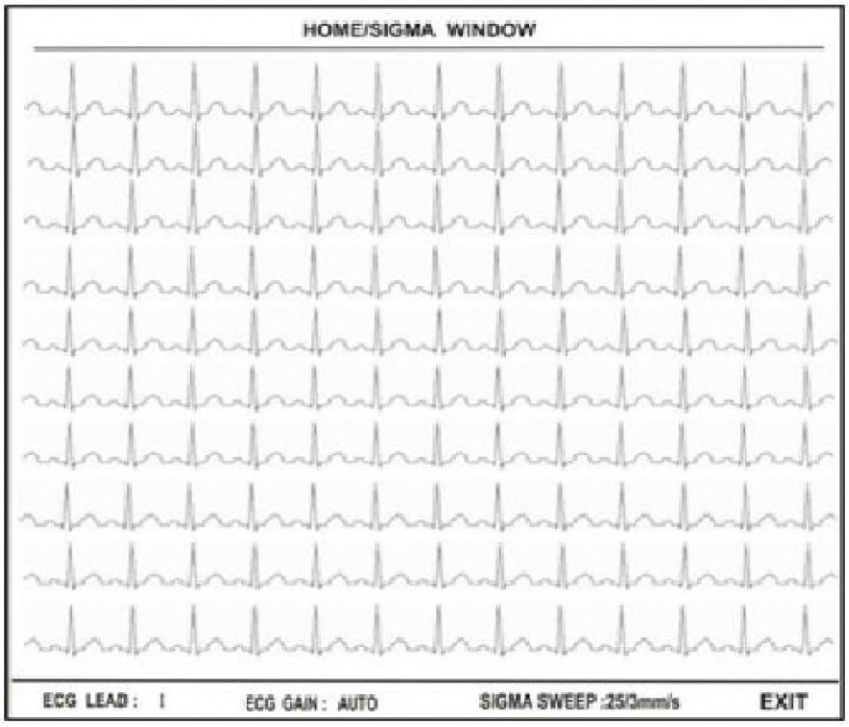



**Figure 2-2 HOME/SIGMA WINDOW**

You can view ECG settings including ECG LEAD, ECG GAIN and SIGMA SWEEP SPEED in this window. Refer to Chapter 4 -ECG MONITORING for details.

## 2.2 TREND

The latest 96 hours of parameters values are recorded every second in Trend Window. Pick "TREND" in the HOME WINDOW to call up the following menu:

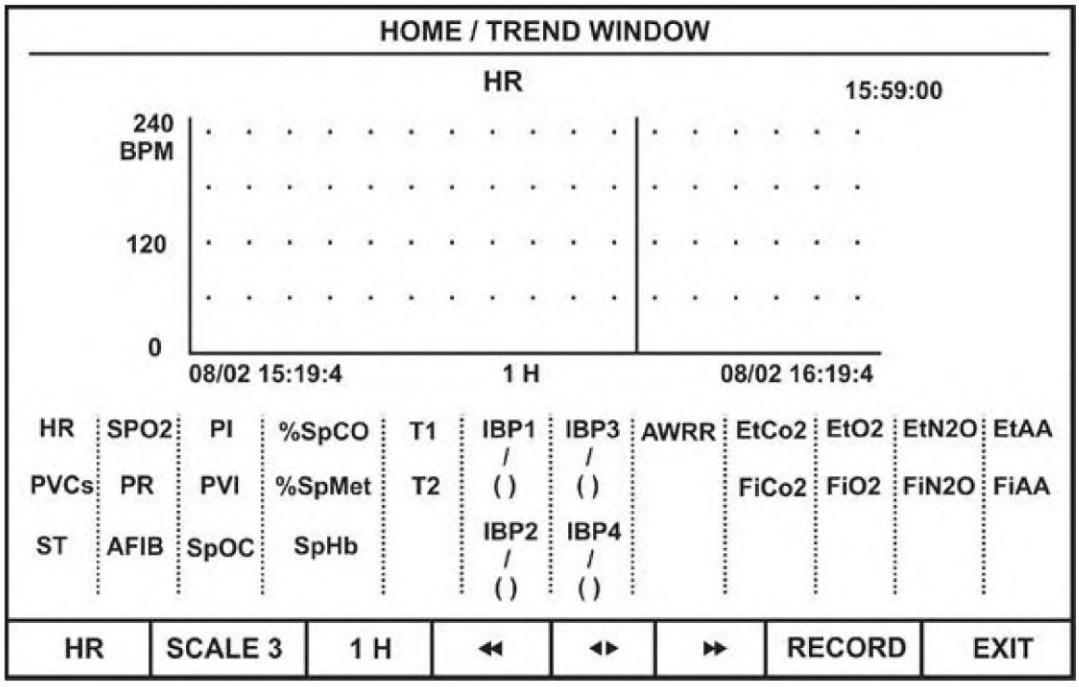



**Figure 2-3 HOME/TREND WINDOW**

Y-axis stands for related parameter value and X-axis for time.

■ **To select trend graph of a specific parameter:**

Pick parameter name (the most left item) and select your intended parameter by turning the knob. Available options are HR, SPO2, RESP, T1, T2, IBP1, IBP2, AWRR, CO2, N2O, O2, AA, PVCs, ST, AFIB, PR, PI, PVI, SPOC,%SpCo,%SpMet, SpHb, 6PARAMS and OXY_CRG (IBP3 and IBP4 parameters are also available in P6).

■ **To change the display scale:**

Pick "SCALE" (the second left item) to adjust the Y-axis scale and thus change the trend curve in proportion.

| PARAMETER | SCALE1 | | SCALE2 | | SCALE3 | | SCALE4 | | SCALE5 | | SCALE6 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MIN | MAX | MIN | MIN | MIN | MAX | MIN | MAX | MIN | MAX | MIN | MAX |
| HR | 0 | 60 | 0 | 120 | 0 | 240 | - | - | - | - | - | - |
| SPO2 | 80 | 100 | 60 | 100 | 0 | 100 | - | - | - | - | - | - |
| T1 | 30 | 42 | 24 | 48 | 0 | 48 | - | - | - | - | - | - |
| T2 | 30 | 42 | 24 | 48 | 0 | 48 | - | - | - | - | - | - |
| IBP1/IBP2/ IBP3/IBP4 | -20 | 50 | -20 | 100 | -20 | 200 | -50 | 300 | 50 | 250 | - | - |
| RESP | 0 | 60 | 0 | 120 | 0 | 240 | - | - | - | - | - | - |
| AWRR | 0 | 60 | 0 | 120 | 0 | 240 | - | - | - | - | - | - |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CO2 | 0 | 50 | 0 | 100 | - | - | - | - | - | - | - | - |
| O2 | 0 | 50 | 0 | 100 | - | - | - | - | - | - | - | - |
| N2O | 0 | 50 | 0 | 100 | - | - | - | - | - | - | - | - |
| AA | 0 | 1.0 | 0 | 2.0 | 0 | 3.0 | 0 | 5.0 | 0 | 10.0 | 0 | 20.0 |
| PVCs | 0 | 20 | 0 | 50 | 0 | 100 | - | - | - | - | - | - |
| ST | -0.2 | 0.2 | -0.5 | 0.5 | -1 | +1 | -2 | 2 | - | - | - | - |
| AFIB | 0 | 1 | - | - | - | - | - | - | - | - | - | - |
| PR | 0 | 60 | 0 | 120 | 0 | 240 | - | - | - | - | - | - |
| PI | 0 | 20 | 0 | 10 | 0 | 5 | - | - | - | - | - | - |
| PVI | 0 | 100 | 0 | 30 | - | - | - | - | - | - | - | - |
| SpOC | 0 | 36 | 8 | 20 | - | - | - | - | - | - | - | - |
| SpCo | 0 | 60 | 0 | 42 | 0 | 12 | - | - | - | - | - | - |
| SpMet | 0 | 70 | 0 | 16 | - | - | - | - | - | - | - | - |
| SpHb | 0 | 25 | 5 | 17 | - | - | - | - | - | - | - | - |

**■ To select time interval of displaying the trend graph:**
Pick the third left item, available options are 15 min, 30 min and 45 min, 1, 2 and 4 hours.

**■ To select time interval of trend in x-axis**
Select ⏮ or ⏭ to change time intervals in the X-axis and to adjust start and end time of this axis. By every click on these buttons, you can change the time interval of x-axis to the extent of the specified time in the third left item.

**■ To obtain trend data of a specific time:**
Select ◄► to view trend values of a specific time. By clicking on this button and turning rotary, you can move the cursor line through the graphic trend that points to specific times. This time is displayed on the right side of the TREND WINDOW and numeric value related to this time is displayed below the parameter. You can do this only for 15, 30, 45 min and 1, 2 hr intervals (set in the third left item).

**TREND 6PARAMS**
Select 6PARAMS in the first left item of HOME/TREND WINDOW to access the following window in which you can monitor TREND graph of six parameters simultaneously.

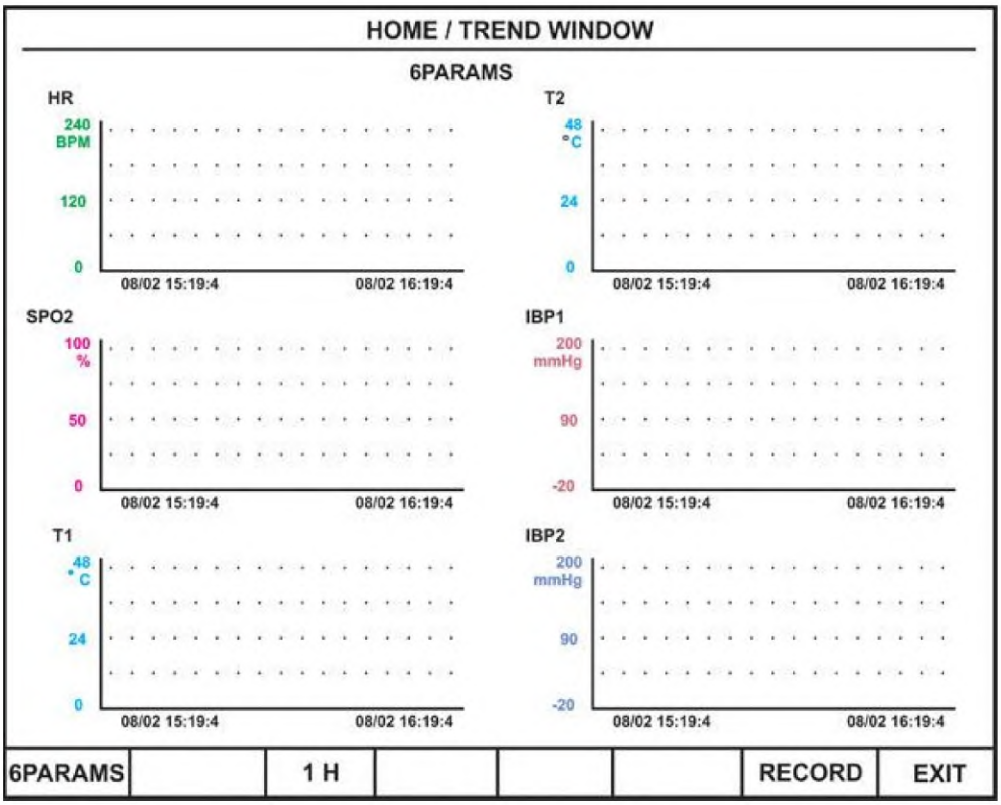



**Figure 2-4- HOME/ ALARM WINDOW**

To select time interval of displaying the trend graph, pick the third left item. Available options are 15 min, 30 min and 45 min, 1, 2 and 4 hours.

Select “RECORD” in this window to record all six trend graphs.

By turning the rotary in this window and clicking it on a parameter, you can select your desired parameter and view its trend graph. Available options are HR, SPO2, RESP, T1, T2, IBP1, IBP2, AWRR, CO2, N2O, O2, AA, PVCs, ST, AFIB, PR, PI, PVI, SPOC, %SpCo, %SpMet, SpHb and OFF.

- **TREND OXY_CRG**

Select OXY_CRG in the first left item of HOME/TREND WINDOW to access the following window in which you can monitor HR, SPO2 and RESP signals simultaneously. OXY_CRG aids clinician to detect and evaluate patient critical conditions e.g. apnea and breathing disorder especially in neonates.

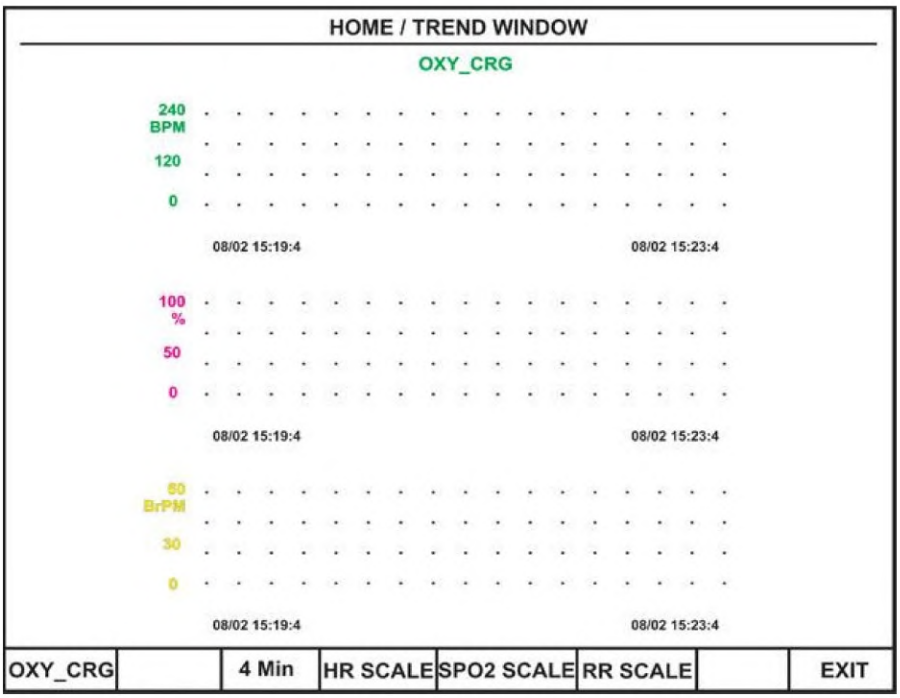



**Figure 2-5- HOME/ ALARM WINDOW**

To select time interval of displaying the trend graph, pick the third left item. Available options are 2, 4 and 8 minutes.

To change the display scale of each of three trend curves, click on HR SCALE, SPO2 SCALE or RR SCALE.

## 2-3 ALARM

Pick "ALARM" in HOME MENU to call up the following window:

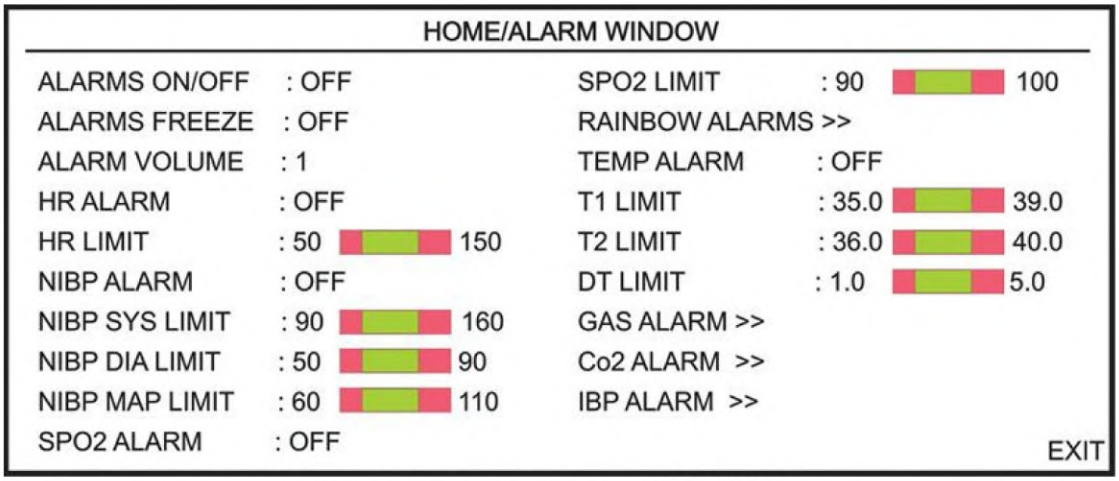



**Figure 2-6 HOME/ALARM WINDOW**

**■ ALARMS ON/OFF**

Pick "ON" to enable the alarm functions.

Pick "OFF" to disable the alarm functions such as audio alarm, parameters blinking and alarm light indicator. In "OFF" mode there will be ⚠ symbol beside all parameters. This function changes alarm settings of all parameters, but you are able to turn on/off alarm of a specific parameter in its own window.

**■ ALARM FREEZE**

Pick "ON" to freeze all the related signals when parameter's value violates adjusted alarm limits. In freeze mode, press "Freeze" button on the front panel to release the waveform refreshing.

Pick "OFF" to disable ALARM FREEZE.

**■ ALARM VOLUME**

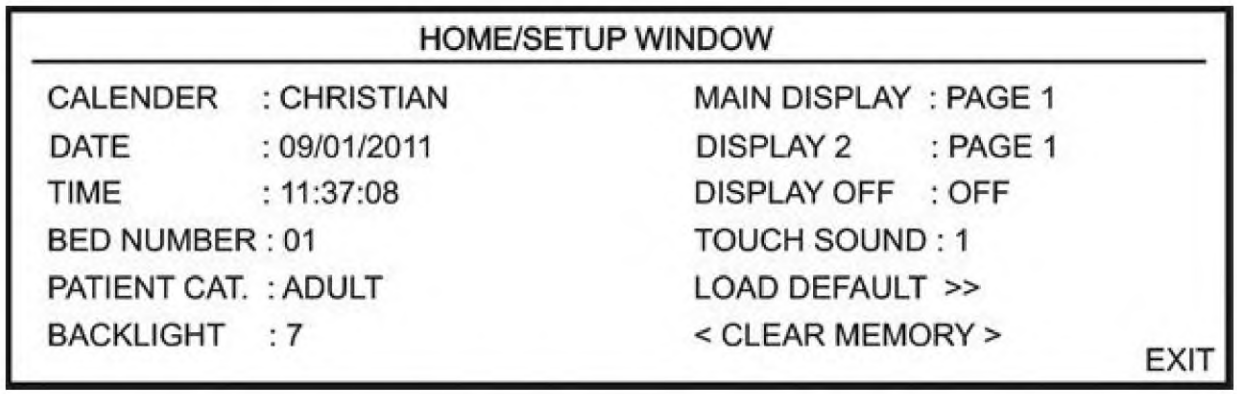
Pick "ALARM VOLUME" to set the volume of alarm sound. The selection ranges from 1 to 7. 1 represents minimum volume, while 7 represents maximum volume.

**NOTE:**

**All other settings in this menu are about alarm ON/OFF and alarm high/low limit of measurable parameters. You are able to set these items in the related parameters menu. Refer to each module's chapter for details.**

## 2.4 SETUP

Choose "SETUP" in HOME WINDOW to call up the following menu:




**2-7 HOME / SETUP WINDOW**

| | |
|---|---|
| **CALENDAR** | available options are "SOLAR" and "CHRISTIAN". |
| **DATE** | current date of monitoring. |
| **TIME** | current time of monitoring. |
| **BED NUMBER** | patient bed number (1-150). |

| | |
|---|---|
| **PATIENT CAT.** | available options are "ADULT", "NEONATE " and "PEDIATRIC' |
| **BACKLIGHT** | ranges from 1 to 8 for B9 monitor and from 1 to 6 for other monitors |
| **MAIN DISPLAY** | available options for when IBP is set OFF are "PAGE1", "PAGE 2" and "PAGE 3"and for IBP : ON are "PAGE 1" to "PAGE 6" and "PUMP PAGE" |

## Different page configurations

There are pages with different configurations to display parameters and waveforms:

- If IBP module is OFF:

**P1:** You can monitor ECG (two traces), SPO2 and RESP/GAS signals as well as numeric parameters HR, SPO2%, PR, RESP/GAS, NIBP and TEMP (MAIN DISPLAY= PAGE 1 mode)

(When Display Format is set to 4 Traces, four traces of ECG signal as well as SPO2 and RESP/GAS signals are displayed in this page.
When Display Format is set to7 Traces, seven traces of ECG signal are displayed).

**P2:** You can monitor same parameters and signals as P1, but arrangement of parameters windows differ slightly from P1. (MAIN DISPLAY= PAGE 2 mode)

(When Display Format is set to 4 Traces, four traces of ECG signal as well as SPO2 and RESP/GAS signals are displayed in this page.
When Display Format is set to7 Traces, seven traces of ECG signal are displayed).

**P3 :**You can monitor ECG (2 traces), CO2(RESP) and SPO2 signals as well as all numeric parameters (special page for Rainbow parameters) (MAIN DISPLAY= PAGE 3 mode)

**P4:** You can monitor ECG signal (12 traces) and numeric parameters of P1.

(Only with settings of CABLE TYPE: 10WIRES and DISPLAY FORMAT: 12 TRACES, you can access this page)

- If IBP module is ON:

**P1:** The following signals will be displayed in this page for different Display Formats:

a) CASCADE/2 TRACES: ECG signal (two traces), SPO2, IBP1,IBP2 and RESP/CO2
b) 4 TRACES: ECG (four traces) and IBP1/2 signals
c) 7 TRACES: Seven traces of ECG signal
Numeric parameters HR, PVCs, ST, SPO2%, PR, IBP1, IBP2, RESP/CO2, NIBP and TEMP are also displayed in this page. (MAIN DISPLAY= PAGE 1 mode)

**P2:** You can monitor parameters and signals of P1 (except ECG signal), but Parameter area of different modules is larger. (MAIN DISPLAY= PAGE 2 mode)

**P3 :**You can monitor ECG (2 traces), CO2(RESP), IBP1,IBP2 and SPO2 signals as well as all numeric parameters (special page for Rainbow parameters) (MAIN DISPLAY= PAGE 3 mode)

**P4 :** You can monitor ECG, IBP1 and IBP2 signals (in a larger scale) as well as numeric parameters HR, PVCs, ST, SPO2%, PR, IBP1,IBP2, NIBP and TEMP (special page for large scale IBP) (MAIN DISPLAY= PAGE 4 mode)

**P5:** You can monitor ECG (two traces), IBP1, SPO2 and RESP signals as well as all numeric parameters of P1 except IBP2 (MAIN DISPLAY= PAGE 5 mode).

**P6:** You can monitor ECG, SPO2, RESP/CO2 and two IBP (IBP1,2 or IBP 3,4) signals as well as all numeric parameters of P1 and IBP3,4 parameters. (special page for 4 channel IBP) (MAIN DISPLAY= PAGE 6 mode)

**P7:** You can monitor ECG, SPO2, IBP1 and IBP2 signals as well as all numeric parameters HR, PVCs, ST, SPO2%, PR, IBP1,IBP2, NIBP and TEMP (MAIN DISPLAY= PUMP PAGE mode)

In this page the word "PUMP" is shown on ECG signal and <AUTO SCALE> appears on IBP signals that by turning the rotary and selecting it, IBP scales are adjusted automatically.

When ASYSTOLE condition is generated, the message "ECG ASYSTOLE" is shown that by pressing Alarm Silence key, you can disable audio alarm.

**P8:** You can monitor ECG signal (12 traces) and numeric parameters of P1.

(Only with settings of CABLE TYPE: 10WIRES and DISPLAY FORMAT: 12 TRACES, you can access this page)

**DISPLAY 2** available options for when IBP is set OFF are PAGE 1 to PAGE 7 and for IBP: ON are PAGE 1 to PAGE 19 (except PAGE 8)

## Different page configurations on the second display

There are pages with different configurations to display parameters and waveforms:

- If IBP module is OFF:

**P1:** You can monitor ECG (two traces),SPO2 and RESP/GAS signals as well as all numeric parameters .

**P2:** You can monitor same parameters and signals as P1, but Parameter area of different modules is larger.

**P3 :**You can monitor ECG (four traces), SPO2, RESP/GAS signals as well as all numeric parameters.

**P4:** You can monitor parameters and signals of P3, but Parameter area of different modules is larger.

**P5 :**You can monitor ECG signal (seven traces) and all numeric parameters.

**P6:** You can monitor parameters and signals of P5, but Parameter area of different modules is larger.

**P7 :**You can monitor parameters and signals of P1 as well as Rainbow parameters (special page for Rainbow parameters)

- If IBP module is ON:

Configuration of P1 to P8 is the same as IBP OFF mode.

**P9:** You can monitor ECG (two traces), SPO2, RESP/GAS and IBP1,IBP2 signals as well as all numeric parameters.

**P10:** You can monitor parameters and signals of P9, but Parameter area of different modules is larger.

**P11 :** You can monitor ECG (four traces), IBP1 and IBP2 signals as well as all numeric parameters.

**P12:** You can monitor parameters and signals of P12, but Parameter area of different modules is larger.

**P13:** You can monitor ECG signal (seven traces) and all numeric parameters.

**P14 :**You can monitor parameters and signals of P15, but Parameter area of different modules is larger.

**P15:** You can monitor parameters and signals of P9 as well as Rainbow parameters (special page for Rainbow parameters)

**P16:** You can monitor ECG, IBP1 and IBP2 signals (in a larger scale) as well as numeric parameters HR, PVCs, ST, SPO2%, PR, IBP1,IBP2, NIBP and TEMP (special page for large scale IBP)

**P17 :**You can monitor ECG (two traces), SPO2, IBP1 and RESP signals as well as all numeric parameters of P9 except IBP2.

**P18 :** You can monitor ECG, SPO2, RESP/CO2 and two IBP (IBP1,2 or IBP 3,4) signals as well as all numeric parameters of P9 and IBP3,4 parameters. (Special page for 4-channel IBP).

**P19:** You can monitor ECG, SPO2, IBP1 and IBP2 signals as well as numeric parameters HR, PVCs, ST, SPO2%, PR, IBP1, IBP2, NIBP and TEMP (PUMP PAGE).

**DISPLAY OFF** the display screen is turned off, until a button is pressed or an alarm occurs. If Alarm Silence is activated, the display will not be turned off.

**TOUCH SOUND** available options are 1-3 and OFF.

**LOAD DEFAULT** pick it to call up the following window:

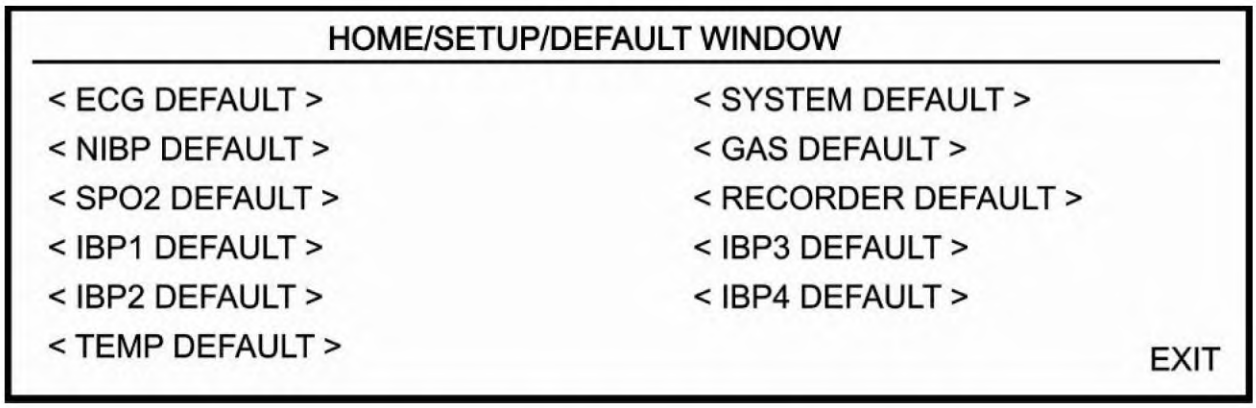



**Figure 2- 8 HOME/SETUP/DEFAULT WINDOW**

If you choose any options in this window, the system will load the factory settings of related parameter. (Refer to appendix I for factory settings of parameters). Because of changing all your previous settings, the system asks if you are sure to change all by this message:

**ECG SETTING WILL BE DEFAULT, ARE YOU SURE?**
**YES NO**

**CLEAR MEMORY** To delete stored parameters in system such as parameters saved in TREND window, NIBP LIST window, CSM TREND window and ARR EVENT LIST window.

For each separate window, a message will appear on the screen which asks you whether to clear that item or not. These messages are as a follow:

**TREND WILL BE CLEARED, ARE YOU SURE?**
**YES NO"**

**NIBP LIST WILL BE CLEARED, ARE YOU SURE?**
**YES NO"**

**CSM TREND WILL BE CLEARED, ARE YOU SURE?**
**YES NO"**

**ARR LIST WILL BE CLEARED, ARE YOU SURE?**
**YES NO"**

## 2.5 PATIENT INFORMATION

Choose "PATIENT INFORMATION" in HOME WINDOW to call up the following window:

**Figure 2-9 HOME/PATIENT INFORMATION WINDOW**

Press "NEW" to enter new patient information.
Press "EDIT" to edit current patient information.
The information menu is as a follow:

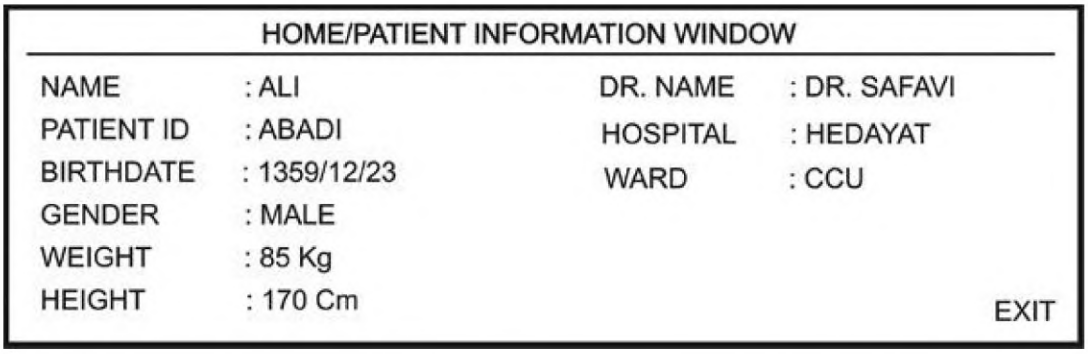



**Figure 2-10 HOME/PATIENT INFORMATION WINDOW**

Pick an item to call up the following window in which you can input data:

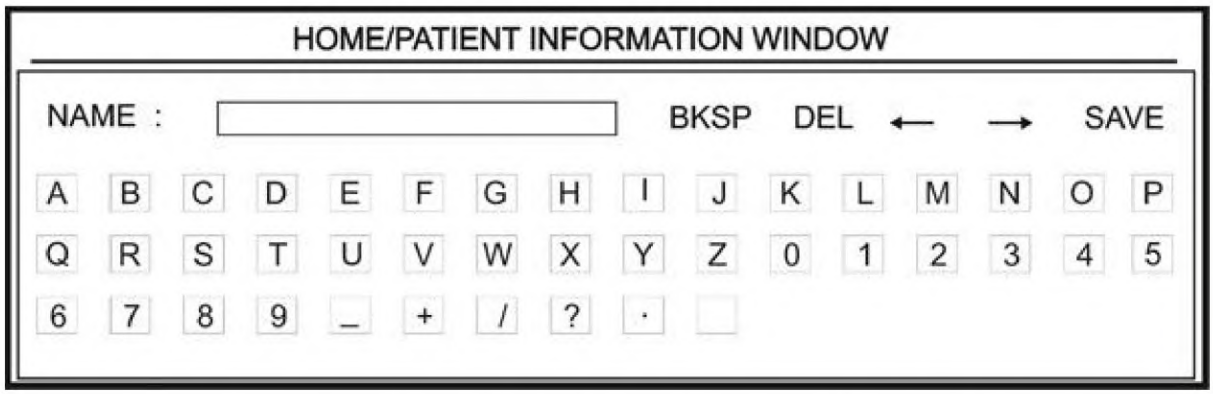



**Figure 2-11 HOME/PATIENT INFORMATION WINDOW**

| | |
|---|---|
| NAME | Patient name (length: 18 characters) |
| PATIENT ID | Hospital ID for patient (length: 18 characters) |
| BIRTH DATE | Date of the birth |
| GENDER | Available options are MALE and FEMALE |
| WEIGHT | Available between 0.5 to 300 Kg |
| HEIGHT | Available between 20 to 250 cm |
| DR. NAME | Physician name (length: 16 characters) |
| HOSPITAL | Hospital name (length: 16 characters) |
| WARD | Hospital ward name (length: 16 characters) |

## 2.6 MODULE SETUP

Choose "MODULE SETUP" in HOME WINDOW to call up the following window:

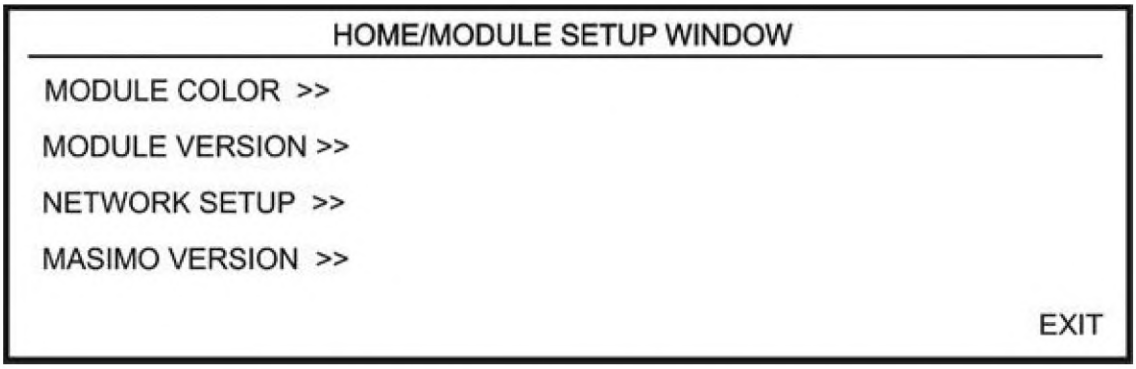



**Figure 2-12 HOME/ MODULE SETUP WINDOW**

Pick "MODULE COLOR" in MODULE SETUP window to call up the following window. You can set color of all parameters except ECG in this window. Select <DEFAULT COLOR> to restore default color of all modules.

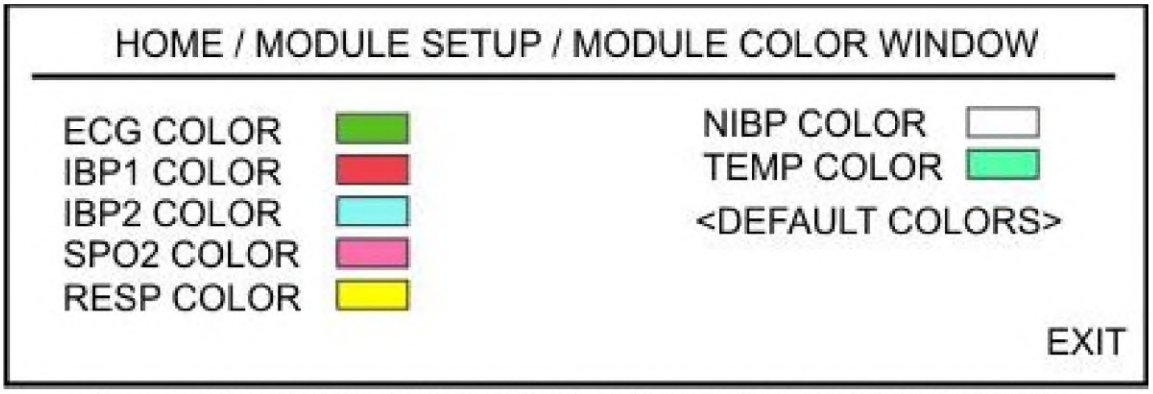


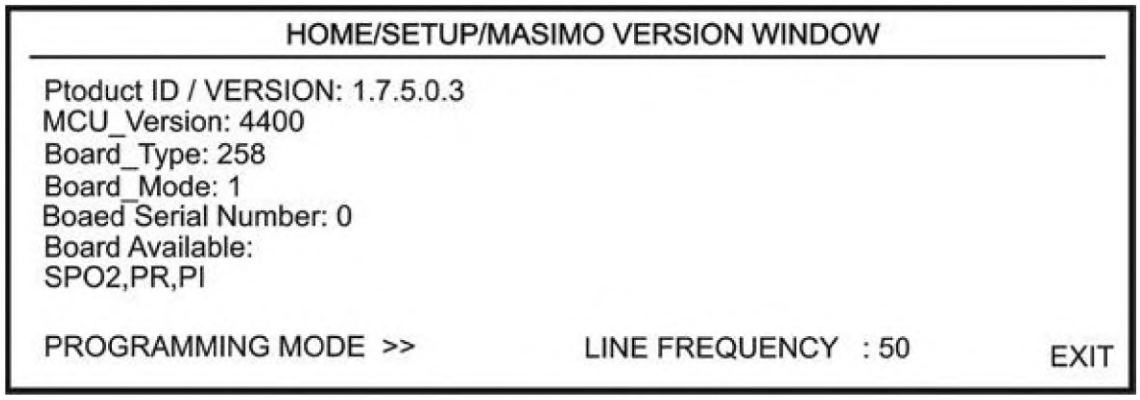

**Figure 2-13 HOME/ MODULE SETUP / MODULE COLOR WINDOW**

For each change in parameters color, the following message will appear on the screen which asks you whether to change color or not.

**COLOR WILL BE CHANGED, ARE YOU SURE?**

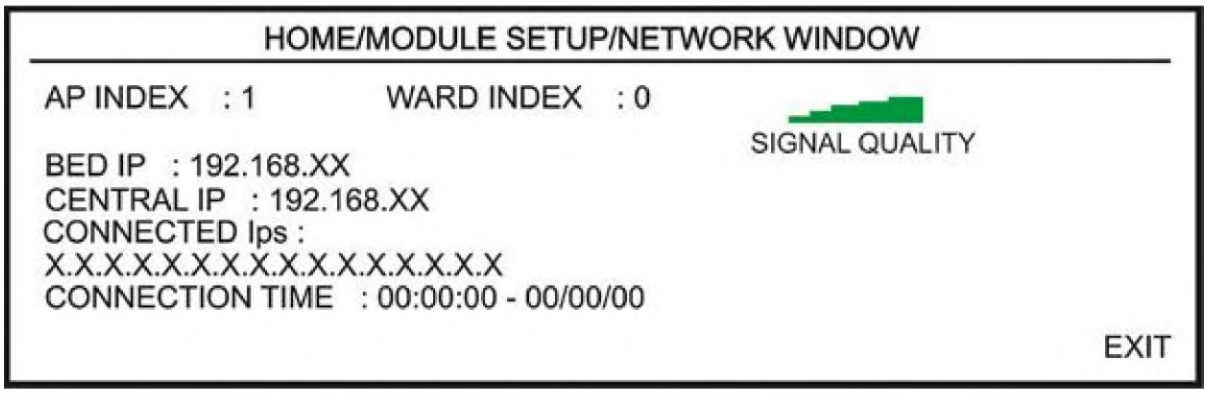
**YES NO**

Choose "MODULE VERSION" in MODULE SETUP window to call up the following window and see version of all modules:



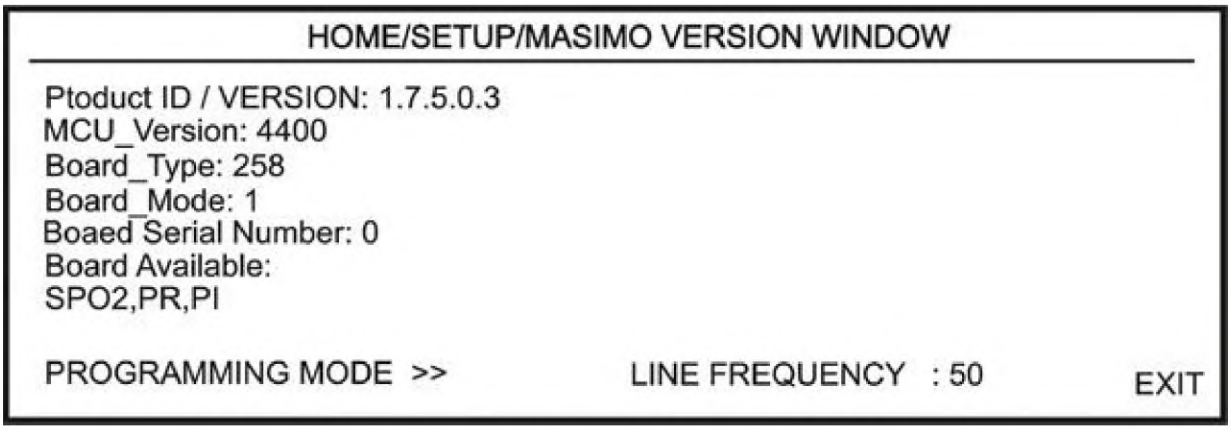

**2-14 HOME/ SETUP/ MODULE VERSION WINDOW**

Choose "NETWORK SETUP" in MODULE SETUP window to call up the following window in which you can perform settings of Central system and observe some information like bedside and Central IP addresses, time of network connection, etc.




**2-15 HOME/ MODULE SETUP/ NETWORK WINDOW**

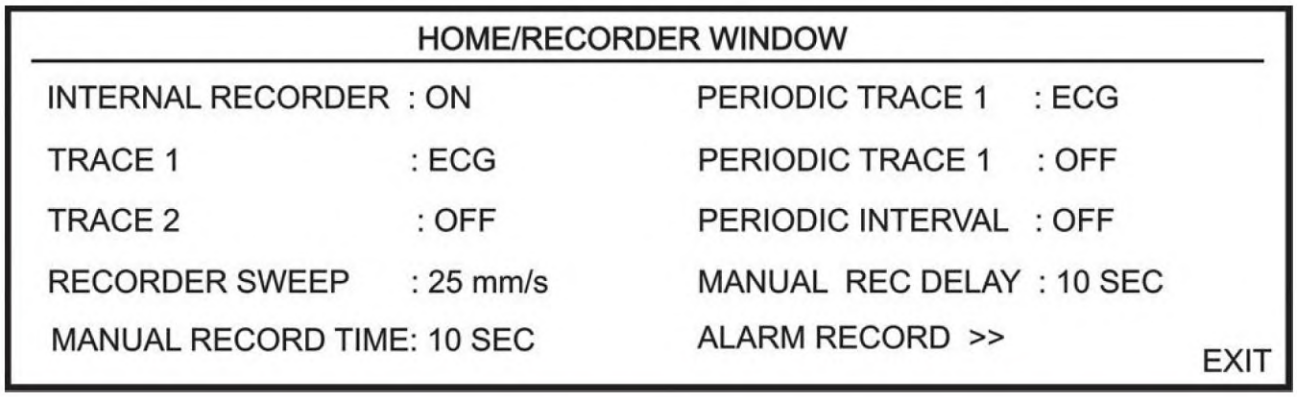
Choose "MASIMO VERSION" in MODULE SETUP window to call up the following window in which you can observe MASIMO module information, set frequency and connect programmer to enable the intended MASIMO parameter.




**2-16 HOME/ SETUP/ MASIMO VERSION WINDOW**

## 2.7 RECORDER

Choose "RECORDER" in HOME WINDOW menu to call up the following window:




**2-17 HOME/RECORDER WINDOW**

- **INTERNAL RECORDER**
  Pick "ON" to enable internal recorder and record via it.
  Pick "OFF" to disable the internal recorder and record via central system.

- **TRACE1**
  To choose the first trace of print out record in manual recording.
  Available options are ECG, SPO2, IBP1, IBP2, RESP and OFF.

- **TRACE2**
  To choose the second trace of print out record in manual recording.
  Available options are ECG, SPO2, IBP1, IBP2, RESP and OFF.

- **RECORDER SWEEP**
  Available options for RECORDER SWEEP are 6, 12.5, 25 and 50 mm/s.

- **MANUAL RECORD TIME**
  Available options for MANUAL RECORD TIME are "MANUAL" and "CONTINUOUS".

- **PERIODIC TRACE 1**
  To choose the first channel trace of print out record in automatic recording.
  Available options are ECG, SPO2, IBP1, IBP2, RESP and OFF.

- **PERIODIC TRACE2**
  To choose the second channel trace of print out record in automatic recording.
  Available options are ECG, SPO2, IBP1, IBP2, RESP and OFF.

- **PERIODIC INTERVAL**
  To choose time interval in periodic recording mode. Available selections are 15min, 30min,1h,2h,4h,8h,12h,24h and OFF.

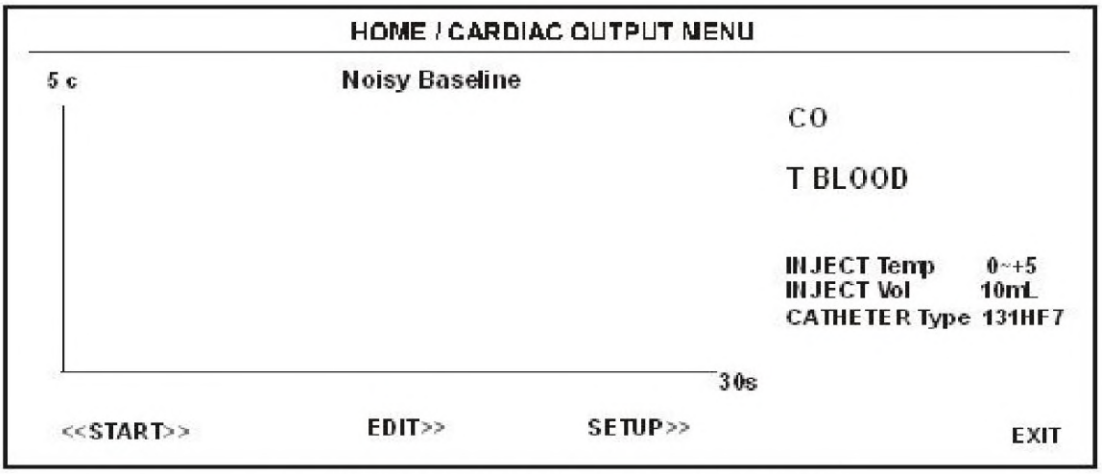
- **MANUAL REC DELAY**

  To create delay in manual recording. For example if you set this item to 10 seconds and press Record button, data of the latest 10 seconds will be recorded.
  Available options are 5 sec to 15 sec by step of 1 sec.

- **ALARM RECORD**
  If alarm recording for each parameter is set ON, it automatically starts recording when alarms happen.

## 2. 8 CARDIAC OUTPUT

Choose “CARDIAC OUTPUT” in HOME WINDOW to access the following window.

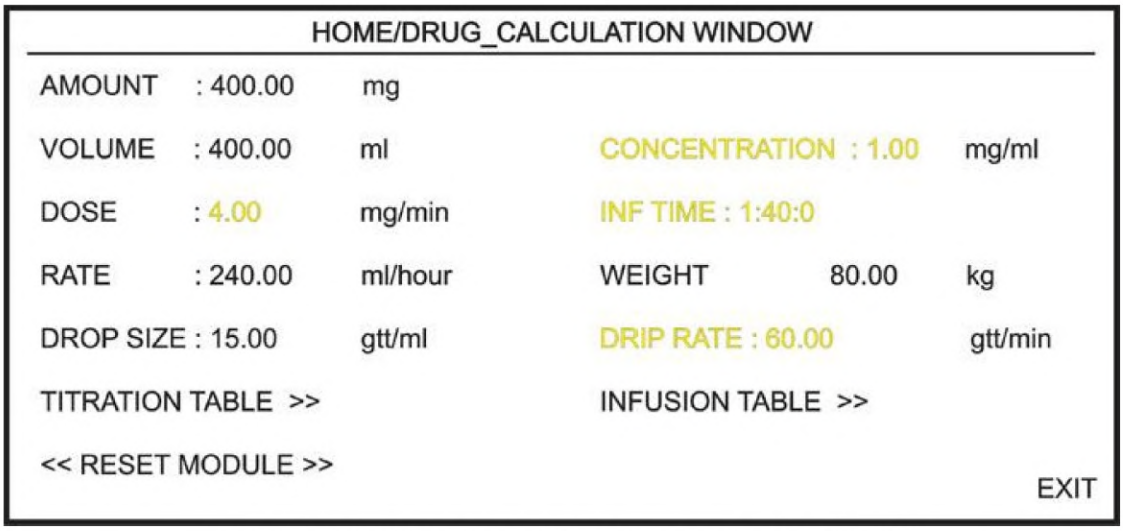



**2-18 HOME/ CARDIAC OUTPUT MENU**

Please refer to Chapter 15- CO Monitoring for details.

## 2. 9 DRUG_CALCULATOR

Choose “DRUG_CALCULATOR” in HOME WINDOW to access the following window.




**2-19 HOME/ DRUG_CALCULATION WINDOW**

This window is used to calculate rate, dosage, amount or volume, capacity and time of drug infusion. Infusion rate based on Drop Size is defined as Drip Rate.

- Three of parameters AMOUNT, VOLUME, DOSE and RATE are entered by user as input, and output values are automatically calculated and displayed in yellow color.

- Measurement unit of AMOUNT and DOSE can be selected by user.
  Available units for AMOUNT and DOSE are as follows:
  AMOUNT: mg ,mcg
  DOSE: mg/min , mg/kg//min ,mcg/min and mcg/kg/min

- Weight is adjustable by user, but weight value adjusted in PATIENT INFORMATION menu is displayed in this window by default.

- User can select << RRESET MODULE>> to delete all input values and calculations for new input data and calculations.

- Calculation is automatically performed as user changes inputs.

- DRIP RATE is automatically calculated as user defines DROP SIZE.

Choose TITRATION TABLE >> to access the following window in which you can review the relation between rate and dosage of drug infusion.

HOME/DRUG/TITRATION TABLE

AMOUNT : 400.00 mg VOLUME: 400.00 ml WEIGHT:80.00 kg DOSE UNIT: mg/min

| DOSE | INF RATE | DOSE | INF RATE | DOSE | INF RATE | DOSE | INF RATE |
|---|---|---|---|---|---|---|---|
| 0.50 | 30.00 | 5.50 | 330.00 | 10.50 | 630.00 | 15.50 | 930.00 |
| 1.00 | 60.00 | 6.00 | 360.00 | 11.00 | 660.00 | 16.00 | 960.00 |
| 1.50 | 90.00 | 6.50 | 390.00 | 11.50 | 690.00 | 16.50 | 990.00 |
| 2.00 | 120.00 | 7.00 | 420.00 | 12.00 | 720.00 | 17.00 | 1020.00 |
| 2.50 | 150.00 | 7.50 | 450.00 | 12.50 | 750.00 | 17.50 | 1050.00 |
| 3.00 | 180.00 | 8.00 | 480.00 | 13.00 | 780.00 | 18.00 | 1080.00 |
| 3.50 | 210.00 | 8.50 | 510.00 | 13.50 | 810.00 | 18.50 | 1110.00 |
| 4.00 | 240.00 | 9.00 | 540.00 | 14.00 | 840.00 | 19.00 | 1140.00 |
| 4.50 | 270.00 | 9.50 | 570.00 | 14.50 | 870.00 | 19.50 | 1170.00 |
| 5.00 | 300.00 | 10.00 | 600.00 | 15.00 | 900.00 | 20.00 | 1200.00 |

EXIT

**2-20 HOME/ DRUG/ TITRATION TABLE**

- To review the relation between different doses of drug and time of their infusion, INF RATE for doses 0.5 to 20 (according to adjusted unit in HOME/DRUG_CALCULATION WINDOW) is displayed in this window.
- Adjusted AMOUNT, VOLUME and WEIGHT values and DOSE UNIT in HOME / DRUG_CALCULATION WINDOW are automatically displayed in this window.

Choose INFUSION TABLE >> in HOME/ DRUG_CALCULATION WINDOW to access the following window in which you can observe the relation between amount and volume of infused drug and infusion time.

HOME/DRUG/INFUSION TABLE

DOSE : 4.00 mg/min RATE : 240.00 ml/hour AMOUNT : 400.00 mg

VOLUME : 400.00 ml WEIGHT : 80.00 kg INF TIME : 1:40:0

| AMOUNT | VOLUME | INFUSION TIME |
|---|---|---|
| 10.00 | 10.00 | 0:2:30 |
| 53.33 | 53.33 | 0:13:20 |
| 96.67 | 96.67 | 0:24:10 |
| 140.00 | 140.00 | 0:35:0 |
| 183.33 | 183.33 | 0:45:50 |
| 226.67 | 226.67 | 0:56:39 |
| 270.00 | 270.00 | 1:7:30 |
| 313.33 | 313.33 | 1:18:19 |
| 356.67 | 356.67 | 1:29:10 |
| 400.00 | 400.00 | 1:40:0 |

EXIT

**2-21 HOME/ DRUG/ INFUSION TABLE**

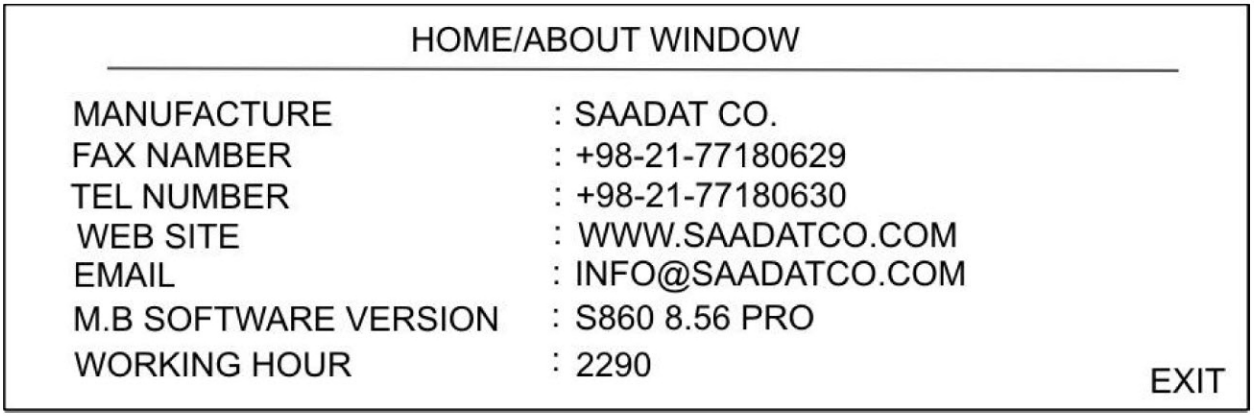
- To review the relation between different values of AMOUNT and VOLUME and their corresponding INFUSION TIME, you can observe this window.

- Adjusted DOSE ، RATE ، AMOUNT ، VOLUME ، WEIGHT and INF TIME in HOME/ DRUG_CALCULATION WINDOW are automatically displayed in this window.

- More clearly displaying user selection and calculations of HOME/ DRUG_CALCULATION WINDOW, AMOUNT value as well as VOLUME and INFUSION TIME are displayed yellow in the last row of the table.

## 2. 10 ABOUT

Choose "ABOUT" in HOME WINDOW to call up the following window in which you can observe the system and manufacturer information.




**2-22 HOME/ABOUT WINDOW**

# Chapter 3 Alarm

This chapter gives general information about alarm and related functions.

⚠ **Warning** ⚠
**Always verify the audible and visible alarms when monitor is powered on.**

## 3.1 Alarm Categories

Alarms can be classified into three categories: Physiological, Technical and Prompt messages.

### 3.1.1 Physiological alarms

Physiological alarms also called patient status alarms are triggered by a parameter value that violates adjusted alarm limits or an abnormal patient condition.

### 3.1.2 Technical alarms

Technical alarms also called system status alarms are triggered by a device malfunction or a patient data distortion due to improper operation or mechanical problems.

### 3.1.3 Prompt messages

In fact, prompt messages are not alarm messages. In addition to physiological and technical alarm messages, the patient monitor displays some messages indicating the system status. All messages are displayed in the **Message Area**.

## 3.2 Alarm Modes

### 3.2.1 Alarm Level and Setup

Portable Patient Monitor offers three levels of alarm.

Level I alarm indicates the patient's life is in danger or the monitor under use has serious problems. It is the most serious alarm.
Level II alarm means serious warning.
Level III alarm is a general warning.

Patient monitor has preset the alarm level for the parameters. You can also modify alarm level of each module in its own window.

## 3.2.2 Alarm Modes

Alarm messages, LEDs and sounds are designed in such a manner that can be recognizable by the operator from a distance of 1 m.

**Display Screen**

When an alarm is triggered by a parameter, the parameter value will blink on the screen and alarm message with regard to its level will be displayed in different backgrounds.

Level I alarm message: Red background – Black text

Level II alarm message: Yellow background – Black text

Level V alarm message: Cyan background – Black text

If the monitor displays an informative message (or if Alarm silence key is pressed), the background will change to gray.

**Alarm Indicator**

Alarm indicator flashes red for Level I alarm and yellow for Level II alarm and lights yellow for Level III alarm.

**Alarm Sound**

Corresponding alarm sound will be activated, if the alarm is not silent (i.e., the SILENCE button has not been pressed). The sounds of the alarm for the three levels are different:
Level I alarm sounds "DO-DO-DO--DO-DO" every 10 seconds;
Level II alarm sounds "DO- DO-DO" every 20 seconds;
Level III alarm sounds "DO-" every 30 seconds.

Alarm volume is adjustable in the range of 1 to 7. The sound pressure in front of the monitor and at the distance of 1m is in the range of 54 dB(A) to 75dB(A) depending on the selected volume.

**NOTE:**

**When alarms of different levels occur at the same time, the alarm LED prompts the alarm of the highest level.**

### 3.2.3 Alarm verification when the system is powered on

During the monitor is being powered on, audible and visible (yellow and red indicators) alarms will be self tested.
The monitor beeps every time it is powered on and yellow and red indicators light concurrently. The indicators turn off after the monitor powers on completely. If no beep sound is heard or no alarm indicator lights, do not use the monitoring system on any patient and notify After Sales Service.

## 3.3 Alarm Causes

Alarms are triggered by a parameter or by technical problems of the patient monitor. The delay time from an alarm occurrence to alarm manifestation (parameter blinking, alarm message, alarm sound) is less than 1 second (Delay time of APNEA alarm is corresponding to APNEA LIMIT setting in RESP menu)

**Condition activating alarm of a parameter:**
When the measurement value exceeds the adjusted alarm limits and the alarm is in "ON" mode.
If the monitor detects situations like ASYSTOLE or APNEA, alarm will be activated even when it is in "OFF" mode.

## 3.4 Alarm Silence Button Function

Pressing the "Alarm Silence" button once can suspend all alarm sounds for 2 minutes. Message "ALARM SILENCE" prompts in the Header Area for 120 seconds. During the 2 minutes if new alarm occurs, the Silence status will be terminated and both audible and visible alarms are triggered. If within the 2 minutes of alarm suspension the operator presses "Alarm Silence" button, the alarm suspension status will be ended and the normal alarm status resumed immediately.

## 3.5 Parameter Alarm

Alarm setting of each parameter can be found in its specific window. You can observe and set the alarm limits and alarm features of each parameter in its specific window.

When a parameter alarm is 'OFF', this symbol " " is displayed beside the parameter.

When parameter alarm is 'ON', alarm limits are displayed beside the parameter. If parameter value exceeds the adjusted alarm limits, the alarm will be triggered and the following actions will take place:

1. Alarm message is displayed on the screen.
2. The monitor beeps in its corresponding alarm level and volume.
3. Alarm indicator flashes.

⚠ **Warning** ⚠

**Alarm settings including priorities, limits and alarm sound should be set with regard to patient conditions in a way that occurrence of repetitive alarm is prevented and the patient life is not threatened.**

## 3.6 When an alarm occurs

User will be informed of alarm occurrence through visual and audible alarm indications. It is needed to identify the alarm and act appropriately according to the cause of the alarm.

1. Check the patient's condition.
2. Identify the module in alarm.
3. Identify the cause of alarm.
4. Silence the alarm, if necessary.
5. When cause of alarm has been over, check that the alarm is working properly.

You will find the alarm messages of the individual parameters in each module's chapter.

# Chapter 6 SPO2 and Rainbow Parameters Monitoring

## 6.1 GENERAL

SPO2 Rainbow module is the only technology which measures multiple blood parameters as well as common pulse oximetry parameters (SPO2 and Pulse Rate) in a continuous and non-invasive method that traditionally measured through the invasive and time-consuming methods. This module is designed by Masimo Company and submitted to its approved companies.

### Measurable physiological parameters by Masimo Rainbow module

SpO2
Pulse Rate
Perfusion Index (PI)
and optional parameters such as:
SpHb
SpOC
SpCo
SpMet
Pleth Variability Index (PVI)

## % SPO2

Extent of oxygen saturation in hemoglobin of arterial blood can be detected from the SPO2 waveform. For example, if 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has an oxygen saturation of 97%. The SPO2 value on the monitor will be 97%. The SPO2 value shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin.

$$SPO_2 = \frac{O_2Hb}{O_2Hb + HHb} \times 100$$

## Pulse rate

PR indicates the Heart Rate per minute which SpO2 module extracts from the pulse oximetry signal.

## Perfusion Index

Perfusion index (PI) indicates arterial pulse signal strength as a ratio of pulsatile blood flow to the non-pulsatile blood.

Perfusion Index enables you to choose the best position for sensor placement.

$$\mathbf{PI} = \frac{\overline{\mathbf{AC}}}{\mathbf{DC}} \times \mathbf{100\%}$$

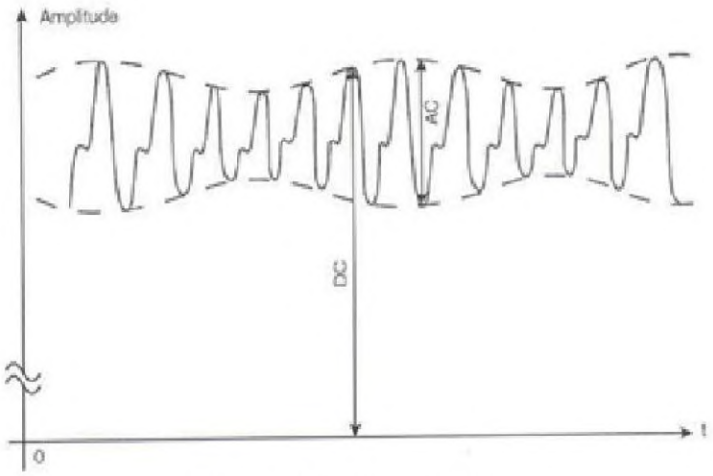



**Figure 6-1 PI definition**

**PI greater than 1% is preferable.**

## SpHb

SpHb indicates the level of total hemoglobin in the arterial blood. The unit of measurement is grams per decilitre (g/dL).

## SpOC

SpOC indicates oxygen content in the blood. Neither SpO2 nor Hb parameter by itself can indicate the actual amount of oxygen in the blood. A patient with normal SpO2 or Hb may have low levels of oxygen. In fact, both SpO2 and Hb are considered by SpOC parameter. The unit of measurement is ml/dL (milliliters of oxygen per deciliter of blood).

## SpCO

This parameter indicates the level of carbon monoxide concentration in arterial blood. It is expressed as a percentage of hemoglobin bound with carbon monoxide.

## SpMet

This parameter indicates the level of methemoglobin concentration in arterial blood. The amount is expressed as percentage (ratio of methemoglobin to total hemoglobin in blood)

## Pleth Variability Index

This parameter is to measure dynamic changes in PI during the respiratory cycle which can be extremely associated with intrathoracic pressure changes.

PVI can be a useful noninvasive monitoring method or an advanced indicator to detect physiological changes of intrathoracic pressure. During one or two complete respiratory cycle, PVI is calculated as follows:

$$PVI = \frac{PI_{Max} - PI_{Min}}{PI_{Max}} \times 100\%$$

PVI can help clinicians predict fluid responsiveness in patients.

■ The %SPO2, PR, PI, PVI, SPOC, %SpMet, %SpCo and SpHb values can be displayed on the main screen. The Pleth waveform is displayed as normalized waveform and its amplitude does not comply with real blood volume variations.

■ User can be informed of inadequacy of signal and physiological parameters values by various messages and alarms in necessary situations.

**Operating Principals**

1.Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxhygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).

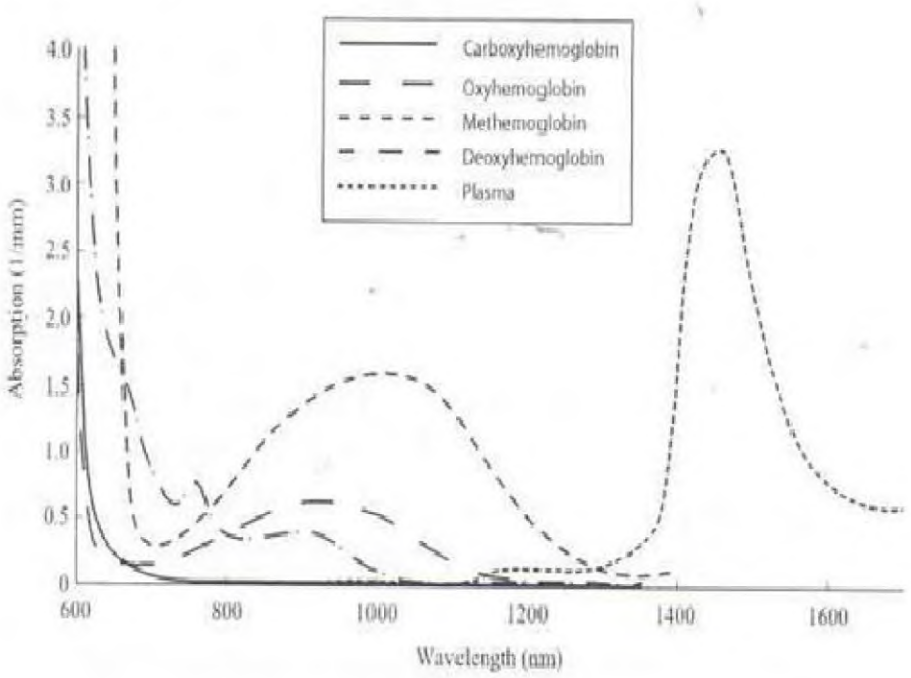



**Figure 6-2 Absorption Spectra**

2. The amount of arterial blood in the tissues changes with your pulse (photoplethysography).Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

A multi-wavelength sensor is used to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma. This sensor is utilized with various light-emitting diodes (LEDs) that pass light through the site to a photodiode (detector). Signal data is obtained by passing various visible and infrared lights (LED's, 500 to 1400 nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful for

clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the module for calculation.

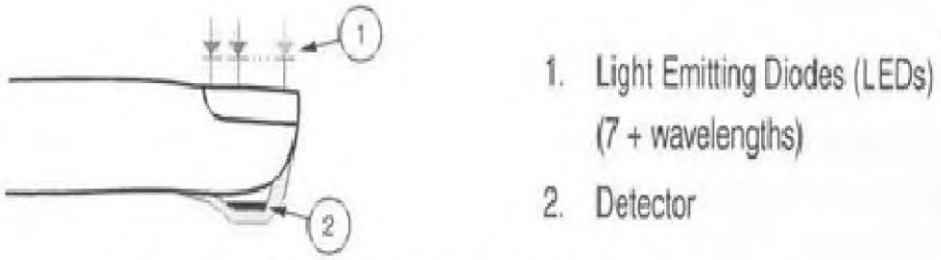



**Figure 6-3 Light Emitting Diodes and Detector**

Once the signal is received from the sensor, it utilizes Masimo Rainbow SET signal extraction technology to calculate the patient's functional oxygen saturation (SPO2 (%)), blood levels of carboxy hemoglobin (SpCO (%)), methemoglobin (SpMet (%)), Total Hemoglobin concentration (SpHb g/dl) and pulse rate (PR (PPM)).

**Signal Extraction Technology (SET)**

Masimo (SET) signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise).

Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform (DST), readily identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

**NOTE:**

**For more information about Masimo Rainbow module, please refer to APPENDIX III.**

**NOTE:**

**A pulseoximetry is an early warning device .Use lab co-oximeter to understand the patient's condition completely.**

**NOTE:**

**Assessment of pulse oximeter probe or pulse oximeter monitor accuracy cannot be done using simulators and functional testers.**

**⚠Warning⚠**

**Use only the recommended manufacturer SPO2 sensor for monitoring. Other SPO2 sensors may cause monitor malfunction, thus operator is responsible to select an appropriate sensor before use.**

**⚠Warning⚠**

**Regarding the selected module, use accessories specified for each spo2 module (refer to chapter 20)**

**⚠Warning⚠**

**While choosing sensor, consider sensor direction for use, written on the package such as patient's age and weight or if the sensor is reusable or disposable.**

**⚠Warning⚠**

**Pulseoximetry can overestimate the SPO2 value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.**

**⚠Warning ⚠**

**ESU wire and SPO2 cable must not be tangled up.**

**⚠Warning⚠**

**Do not use the sensor on extremities with arterial catheter or venous syringe.**

**⚠Warning⚠**

**High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps and direct sunlight can interfere with the performance of an SPO2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied and cover the sensor site with opaque**

**material. Failure to take this action in high ambient light conditions may result in inaccurate measurements.**

**NOTE:**

**SPO2 module updates SPO2 and pulse rate values every 1 sec.**

**NOTE:**

**Do not perform SPO2 and NIBP measuring in same arm simultaneously; because obstruction of blood flow during NIBP measuring may adversely affect the SPO2 value.**

Measurement range of SPO2 and PR parameters in SPO2 MASIMO module is as follows:

| Parameter | Measurement Range |
|---|---|
| SpO2 | 0 – 100% |
| Pulse Rate | 0 – 240 bpm |

Measurement range of MASIMO Rainbow set is as follows:

| Parameter | Measurement Range |
|---|---|
| SpMet | 0.0 – 99.9% |
| SpCO | 0.0 – 99.9% |
| SpHb | 0.0 – 25.0 g/dL |
| SpOC | 0.0 – 35.0 ml /dL |
| Perfusion Index | 0.0 – 20% |
| PVI | 0 – 100% |

Materials used in our SPO2 sensors are innoxious.

**SPO2 measurement:**

1. Turn on the monitor.
2. Attach the sensor to the appropriate site of the patient finger (Refer to Figure 6-4 for the proper method)
3. Plug the connector of the sensor extension cable into the SPO2 socket on the left side of the device.

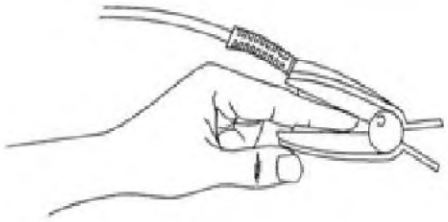


**Figure 6-4 SPO2 sensor placement**

**NOTE:**

- **Make sure the nail covers the light window.**
- **The wire should be on the backside of the hand.**

**NOTE:**

**SPO2 value is always displayed in a fixed position of SPO2 window and Pulse Rate is displayed beside it, but if "HR SOURCE" is set to "SPO2", PR value will be eliminated from SPO2 window and displayed instead of HR value in the ECG WINDOW.**

⚠**Warning**⚠

**Verify sensor cable fault detection before monitoring. Unplug the SPO2 sensor cable from its socket, the screen will display the error message "SPO2 NO PROBE"**

⚠**Warning** ⚠

**Do not use the sterile supplied SPO2 sensors if the packaging or the sensor is damaged and return them to the vendor.**

⚠**Warning** ⚠

**Measurement limitations**

**In operation, the accuracy of oximetry measurement can be affected by:**

- **Electroshock and electrosurgical interference**
- **Excessive patient movement.**
- **Injection of intravascular dye such as indocyanine green or methylen blue.**
- **Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin**
- **Sensor temperature (maintain between 28° C and 42° C for best operation)**
- **External illumination more than 5,000 lumens/square meter (typical office lighting)**
- **Improper sensor application.**
- **Venous pulsations**

- **Cabling entanglement or strangulation**
- **Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line**
- **Do not use oximeters and oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.**

⚠**Warning**⚠

**Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion. Check per 2-3 hours the sensor placement and move it when the skin deteriorates. More frequent examinations may be required for different patients.**

⚠**Warning**⚠

**Tissue damage or inaccurate measurement can be caused by incorrect application or use of an SPO2 sensor, for example by wrapping the sensor too tightly or by applying supplemental tape.**

⚠**Warning**⚠

**Do not immerse sensor and patient cable completely in water, solvents, or cleaning solutions because the sensor and patient cable are not waterproof.**

⚠**Warning**⚠

**Loss of pulse signal can occur when**

- **The patient is in cardiac arrest or in shock.**
- **The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.**
- **There is arterial occlusion proximal to the sensor.**

## 6.2 SPO2 WINDOW

The following items are displayed in SPO2 parameter window:

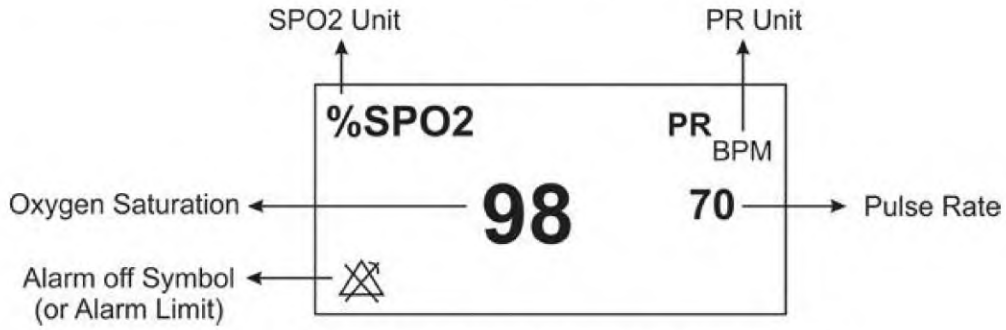



**Figure 6-5 SPO2 PARAMETER WINDOW**

SPO2 parameter window in P3 (special page for Rainbow parameters) is as follows:

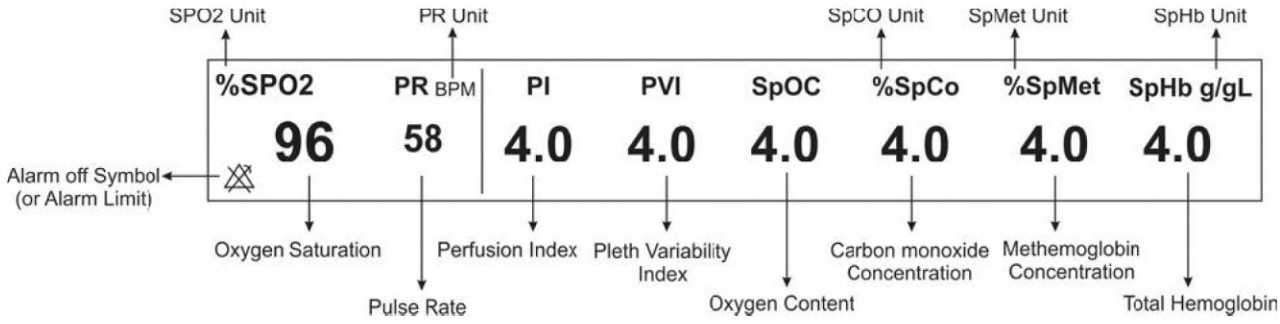



**Figure 6-6 RAINBOW PARAMETERS WINDOW**

The SPO2 WINDOW is as follows:

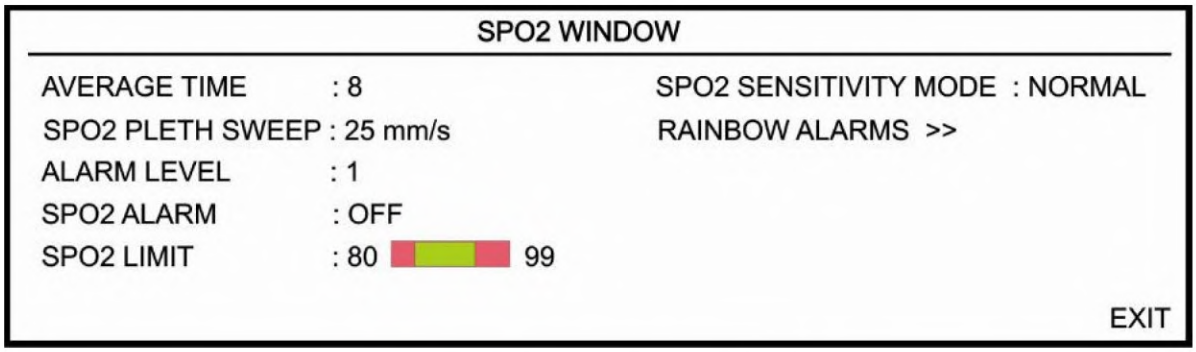



**Figure 6-7 SPO2 WINDOW**

- **AVERAGE TIME**

Available options are 2-4, 4-6, 8, 10, 12, 14 and 16.

- **SPO2 PLETH SWEEP**

Available options for SPO2 PLETH SWEEP are 12.5 mm/s and 25 mm/s.

- **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

■ **SPO2 ALARM**

Pick "ON" to enable SPO2 alarm functions such as parameters blinking, audio alarm, and light indicator. Pick "OFF" to disable the alarm functions and there will be a"⚠"symbol in the Parameter Area.

■ **SPO2 LIMIT**

SPO2 alarm is activated when the SPO2 exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (min: 1 and max: 100, by step 1)

■ **SPO2 SENSITIVITY MODE**

It is only applicable to Masimo module. Available options for SPO2 SENSITIVITY are NORMAL, MAX and APOD.

**NORMAL:** The perfusion threshold has different limits as the perfusion calculation is data dependent .Specially; there is an intelligent algorithm which adjusts the low perfusion limit in accordance with the quality of the incoming plethysmography waveform between 0.5% and 0.02%. This mode provides the best combination of sensitivity and probe-off detection performance. This mode is recommended for the majority of patients.

**MAX:** Recognizing that some clinicians may want the absolute low perfusion performance (0.02%) all of the time and may be willing to sacrifice sensor off detection, Masimo provides a maximized sensitivity mode. This mode should be used for the sickest patients, where obtaining a reading is most difficult. Maximum Sensitivity is designed to interpret and display data for even the weakest of signals. This mode is recommended during procedures and when clinician and patient contact is continuous.
In MAX mode, the message "SPO2 MAX SENS." displays on the screen with yellow colour.

**APOD (Adaptive Probe Off Detection):** This mode is not advisable for patients with low perfusion because the system has the least sensitivity to signal changes in this mode. It is used in situations having risk of probe detachment (e.g. children or uneasy patients).
By selecting this mode, “SPO2 APOD MODE” appears on the screen with yellow colour.

■ **RAINBOW ALARMS**

You can change alarm limits of PI, PVI, SpOC, SpCO, SpMet and SpHb parameters in SPO2/MASIMO ALARMS window (Figure 6-6).

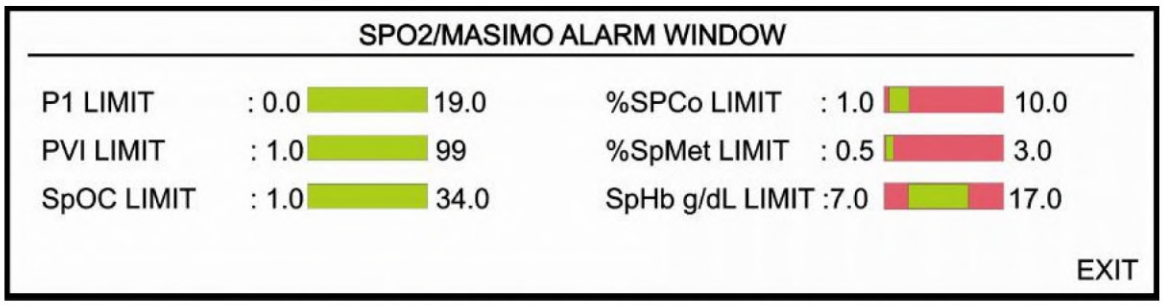



**Figure 6-8 SPO2/ MASIMO ALARM WINDOW**

Alarm limit of Rainbow parameters is as follows:

| Parameter | | Alarm Limit |
|---|---|---|
| PI | HIGH Alarm | PI LOW Alarm +0.1 to 19.0 |
| | LOW Alarm | 0.0 to PI HIGH Alarm -0.1 |
| PVI | HIGH Alarm | PVI LOW Alarm +1 to 99 |
| | LOW Alarm | 1 to PVI HIGH Alarm -1 |
| SpCO | HIGH Alarm | SpCO LOW Alarm +1 to 99 |
| | LOW Alarm | 1 to SpCO HIGH Alarm -1 |
| SpMet | HIGH Alarm | SpMet LOW Alarm +0.5 to 99.5 |
| | LOW Alarm | 0.5 to SpMet HIGH Alarm -0.5 |
| SpHb | HIGH Alarm | SpHb LOW Alarm +0.1 to 24.5 |
| | LOW Alarm | 0.5 to SpHb HIGH Alarm -0.1 |
| SpOC | HIGH Alarm | SpOC LOW Alarm +1 to 34 |
| | LOW Alarm | 1 to SpOC HIGH Alarm -1 |

# 6.3 SPO2 and Rainbow Parameters Alarm Messages

**a) Physiological alarms**

Alarm occurs when SPO2 and PR values exceed adjusted alarm limits.

| Alarm | Situation | Visual alarm | Audio alarm |
|---|---|---|---|
| %SPO2 HIGH | SPO2 violates adjusted high limit | ●SPO2 value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| % SPO2 LOW | SPO2 violates adjusted low limit | ●SPO2 value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| PR HIGH | PR value violates adjusted high limit. | ● PR value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| PR LOW | PR value violates adjusted low limit. | ●PR value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

If MASIMO Rainbow module is used, alarm occurs when each of Rainbow parameters exceed the adjusted alarm limits.

| Alarm | Situation | Visual alarm | Audio alarm |
|---|---|---|---|
| PI HIGH | PI violates adjusted high alarm limit | ● PI value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| Alarm | Situation | Visual alarm | Audio alarm |
| PI LOW | PI violates adjusted low alarm limit | ● PI value blinks.<br>●Alarm indicator flashes. | Activated |

| | | | |
|---|---|---|---|
| | | ● Alarm message is displayed in a background corresponding to its level. | |
| PVI HIGH | PVI value violates adjusted high alarm limit. | ● PVI value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| PVI LOW | PVI value violates adjusted low alarm limit. | ● PVI value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| SpOC HIGH | SpOC violates adjusted high alarm limit | ● SpOC value blinks.<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| SpOC Low | SpOC violates adjusted low alarm limit | ● SpOC value blinks.<br>●Alarm indicator flashes<br>● The message is displayed in a background corresponding to its level. | Activated |
| SpCO HIGH | SpCO violates adjusted high alarm limit | ● SpCO value blinks.<br>●Alarm indicator flashes<br>● The message is displayed in a background corresponding to its level. | Activated |
| SpCO LOW | SpCO violates adjusted low alarm limit | ● SpCO value blinks.<br>●Alarm indicator flashes<br>● The message is displayed in a background corresponding to its level. | Activated |
| SpMet HIGH | SpMet violates adjusted high alarm limit | ● SpMet value blinks.<br>●Alarm indicator flashes<br>● The message is displayed in a background corresponding to its level. | Activated |
| Alarm | Situation | Visual alarm | Audio alarm |

| | | | |
|---|---|---|---|
| SpMet LOW | SpMet violates adjusted low alarm limit | ● SpMet value blinks.<br>●Alarm indicator flashes<br>● The message is displayed in a background corresponding to its level. | Activated |
| SpHb HIGH | SpHb violates adjusted high alarm limit | ● SpHb value blinks.<br>●Alarm indicator flashes<br>● The message is displayed in a background corresponding to its level. | Activated |
| SpHb LOW | SpHb violates adjusted low alarm limit | ● SpHb value blinks.<br>●Alarm indicator flashes<br>● The message is displayed in a background corresponding to its level. | Activated |

**b) Technical alarms**

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| SPO2 NO PROBE | SPO2 probe is disconnected from the monitor. | Make sure that the probe is correctly connected to the monitor. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| SPO2 PROBE DEFECT | The SPO2 probe is damaged | Change the SPO2 probe. | Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| SPO2 PROBE OFF | SPO2 probe may be detached from the patient. | Make sure that SPO2 probe is properly attached to the patient | Alarm level 2- The message is displayed in yellow background. By Pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| SPO2 CHECK PROBE | SPO2 probe is not properly positioned to the patient | Make sure that SPO2 probe is properly connected to the patient (refer to figure 6-1). | Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is suspended for at least 120s. Alarm is activated when SPO2 ALARM is "ON". |
| SPO2 HIGH | This may be caused by entering | Make sure that SPO2 probe is | Alarm level 2- The message is displayed |

| | | | |
|---|---|---|---|
| AMBIENT LIGHT | environmental light into the probe | properly connected to the patient (refer to figure 6-1). | by yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is suspended for at least 120s. Alarm is activated when SPO2 ALARM is "ON". |
| SPO2 DEFECT | SPO2 module failure | Power off and then on the system. If this message is displayed again, the user should contact local After Sale Service. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

After taking the mentioned actions if above messages are displayed again, the SPO2 probe may be damaged and you should contact with local After Sales Services.

**c) Messages**

| Message | Cause | Solution | Explanation |
|---|---|---|---|
| SPO2 SEARCH | SPO2 is not calculable due to some reasons such as long time motions. | Connect the sensor to other finger, provoke blood recycle, and calm the patient. | In this condition SPO2 value is displayed blank. |
| SPO2 SIGNAL WEAK | The SPO2 signal amplitude is too weak or undetectable. | Change the probe position. | In this condition SPO2 value is displayed. |

## 6.4 SPO2 PROBE CLEANING

To clean the sensor, first remove it from the patient and disconnect it from the monitor. You may then clean the probe by wiping it with a 70% isopropyl alcohol pad. Allow the probe to dry prior to placement on a patient.

⚠**Warning**⚠
**Do not sterilize the patient cable and probes by autoclave, irradiation, steam or ethylene oxide.**

⚠**Warning**⚠
**To prevent damage, do not immerse the probe in any liquid solution.**

⚠**Warning**⚠
**Do not use any probe or cable that may be damaged or deteriorated.**

# Chapter 7 NIBP Monitoring

## 7.1 GENERAL

NIBP (Non-invasive Blood Pressure) measurement is based on the oscillometric technique. Initially, cuff is inflated to a pressure greater than systolic pressure as blood flow in the extremity occludes effectively. Then the pressure in the cuff is gradually reduced until the patient pressure is detected and the cuff is deflated completely. Systolic, Diastolic and Mean Arterial pressures can be calculated using pressure pulses detected during pressure drop. Oscillation amplitude increases to a maximum peak and then decreases. If the process of the cuff pressure reduction is done appropriately and pulses detected between systolic and diastolic pressures are collected, the profile curve can be obtained using pulses' pressure and amplitude. The peak oscillation amplitude is defined as the Mean Arterial Pressure (MAP). Systolic and diastolic pressures can be obtained from suitable thresholds before and after MAP pressure.

- NIBP module is designed according to standard EN 1060-1.
- Blood pressure measurement according to this method is equivalent to the cuff-Stethoscope Method.
- It is applicable for adults, pediatrics and neonates.
- There are three modes of measurement: manual, automatic and STAT
    - In the MANUAL mode, only one measurement is performed.
    - In the AUTO mode, the measurement is cycled. You can set the interval time to 1,2,3,5,10,15,20,30,45,60,90 minutes and 2, 4, 8,12,16,20 and 24 hours.
    - In STAT mode, measurement is performed up to ten times in 5 minutes and with 30s interval between measurements. If an error occurs, NIBP measurement is suspended.
- NIBP measurements can be performed adjacent to electrosurgical unit.

**⚠Warning⚠**

**1. You must not perform NIBP measurements on patients under any condition which the skin is damaged or expected to be damaged.**

**2. Ensure that the correct setting is selected when performing measurements on children. It may be dangerous for the children to use an over pressure level.**

**⚠Warning⚠**

**Before starting a measurement, verify that you have selected a setting appropriate for your patient (Neonate, Adult or Pediatric)**

⚠Warning⚠

**Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.**

⚠Warning⚠

**Do not wrap the cuff around the arm on the same side as mastectomy surgery has been performed.**

⚠Warning⚠

**Use only recommended manufacturer Blood Pressure Cuffs and Hose. Using other cuffs or hoses may result in inaccuracies.**

⚠Warning⚠

**Blood pressure measurement can be affected by the position of the cuff and patient's physiological condition.**

⚠Warning⚠

**According to general requirement for safety, Luer lock connectors are not used .Don't use NIBP cuff with Luer lock connector because if Luer lock connector is used, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into blood vessel.**

⚠Warning⚠

**Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.**

⚠Warning⚠

**The maximum cuff inflation pressure is 290 mmHg in adult mode, 240mmHg in pediatric mode and 145 mmHg in neonate mode. Furthermore independent maximum pressure control preservative is forecasted inside the system.**
**Also the blood flow occlusion time during measurement has been limited to 2 minutes in adult and pediatric modes and 90 seconds in neonate mode, however it is necessary that operators pay attention that long-time and continuous measurements can lead to muscular and neurotic harms, skinny injuries or circulatory system failure. Therefore when monitoring a patient, examine the limb wearing cuff frequently.**

**Preparatory steps for pressure measurement:**

1. Plug in the air hose and switch on the system.
2. Apply the blood pressure cuff to the patient's arm or leg following the instructions below (Figure 7-1).

- Ensure that the cuff is completely deflated.
- Apply the appropriate size cuff to the patient. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia.

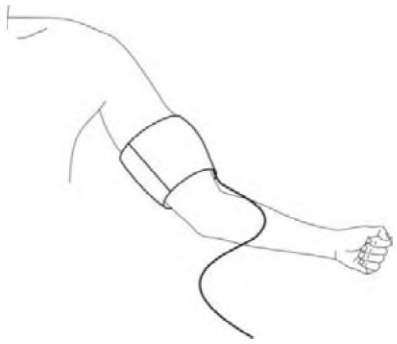


**Figure 7-1 Applying Cuff**

**NOTE:**

**The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous measurement. If the cuff size is in question, then use a larger cuff. (Refer to chapter 20 for more detail about size of cuff.)**

3. Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart.

4. Check whether the patient mode is appropriately selected. To change the patient mode, choose PATIENT CAT. from the HOME/SETUP WINDOW.

5. Select a measurement mode (Automatic or Manual) in the NIBP WINDOW.

6. Press the START/STOP button on the front panel to start a NIBP measurement.

**⚠Warning⚠**

**Please take into account the following items as you perform blood pressure measurement particularly in patients with hypertension.**

**- The patient is placed in a comfortable position.**

**- The patient's feet are not on each other.**

**- The feet should be on a flat floor.**

**- The back and arm of the patient have a good support (for example a chair with back and arms)**

**-The cuff is placed at the same level as heart.**

**- Keep patient calm and silent during measurement.**

- **Keep patient calm for 5 minutes before measurement is performed.**

**Operation Hints**

1. To start a MANUAL measuring:
   Press the START/STOP button on the front panel.

2. To stop a MANUAL measuring
   Repress the START/STOP button on the front panel.

3. To start AUTO measuring:
   Select NIBP WINDOW menu and pick AUTO for measuring interval setting, then
   Press START/STOP button on the front panel.

⚠**Warning**⚠

**Prolonged non-invasive blood pressure measurements in Auto mode may be associated with ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.**

4. To start a MANUAL measuring during the AUTO mode:
   Press START/STOP button on the front panel.

5. To stop AUTO measuring:
   Select the NIBP WINDOW and set MANUAL mode.

6. To start STAT measuring:
   Press START/STOP button on the front panel.

⚠**Warning**⚠

**Prolonged non-invasive blood pressure measurements in STAT mode may be associated with ischemia, neuropathy or dermal injuries in the limb wearing the cuff.**

**NOTE:**

**If you are in doubt about the accuracy of any measurement(s), check the patient's vital signs by an alternative method before checking the functionality of the monitor.**

**Measurement Limitations**

In different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances, when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could

interfere the measurement and make the measurement unreliable or longer. In some cases, the patient's condition will make a measurement impossible.

- **Patient Movement**

Measurements will be unreliable or may not be possible if the patient is moving, shivering or having convulsions. These motions may interfere the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

- **Cardiac Arrhythmias**

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia causes an irregular heart beat. Thus the measuring time will be prolonged.

- **Heart-lung Machine**

Measurements will not be possible if the patient is connected to a heart-lung machine.

- **Pressure Changes**

Measurements will be unreliable and may not be possible if the patient's blood pressure changes rapidly over a short period of time.

- **Severe Shock**

If the patient is in severe shock or hypothermia, measurements will be unreliable because of reduced pulsation of the arteries.

- **Heart Rate limits**

Measurements can not perform at a heart rate of less than 40 bpm and greater than 240 bpm.

- **Pregnant**

Measurements will be unreliable and may not be possible for patients who are pregnant, including pre-eclampic.

## 7.2 NIBP WINDOW

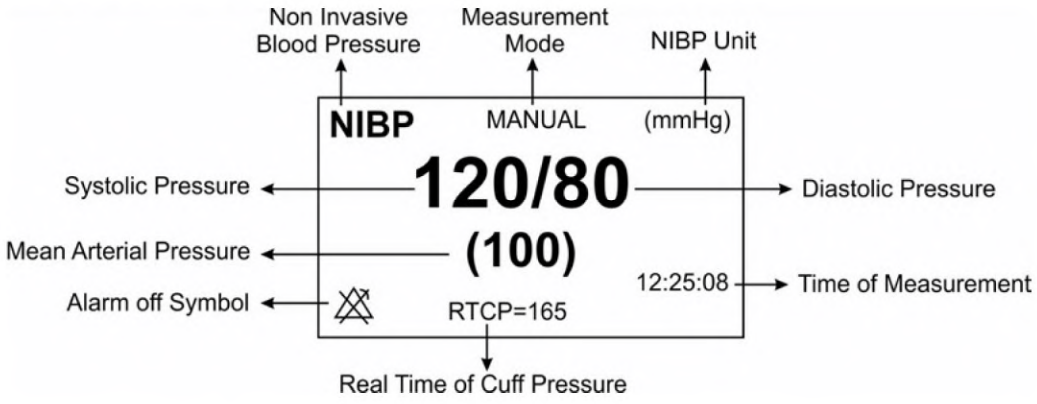



**Figure 7-2 NIBP PARAMETER WINDOW**

In pages which IBP parameter is not displayed (RESP mode), PR value will also be displayed in this window, Figure 7-3.

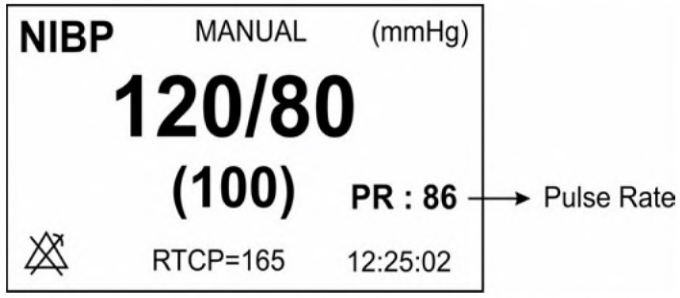



**Figure 7-3 NIBP PARAMETER WINDOW (Pages without IBP)**

Heart rate measured by NIBP module is in the range of 40 to 240 BPM.

NIBP window is as follows:

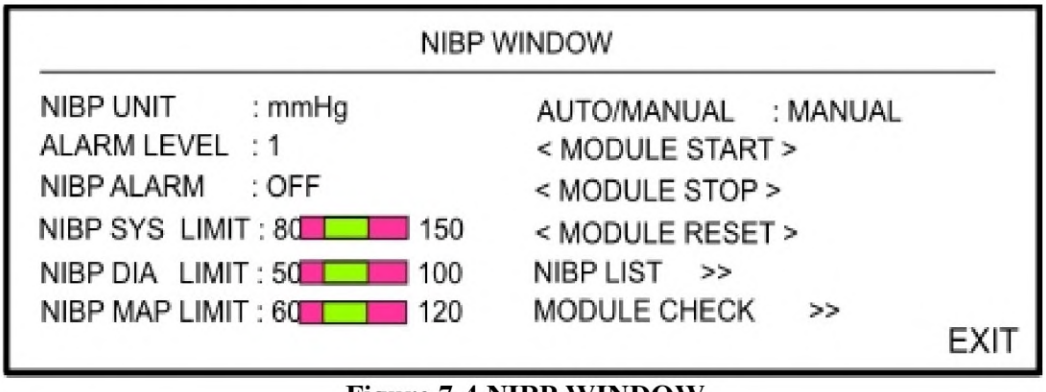



**Figure 7-4 NIBP WINDOW**

- **NIBP UNIT**

Pick this item to adjust measurement unit. (Options: mmHg or KPa)

■ **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

■ **NIBP ALARM**

Pick "ON" to enable NIBP alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the alarm functions and there will be a " "symbol in the Parameter Area.

■ **NIBP SYS LIMIT**

SYS alarm is activated when the systolic pressure exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.

Adult → Max: 255, Min: 30

Pediatric → Max: 240, Min: 30

Neonate → Max: 135, Min: 30

■ **NIBP DIA LIMIT**

DIA alarm is activated when the diastolic pressure exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.

Adult → Max: 220, Min: 15

Pediatric → Max: 220, Min: 15

Neonate → Max: 110, Min: 15

■ **NIBP MAP LIMIT**

MAP alarm is activated when the mean arterial pressure exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.(min:25 and max:200)

Adult → Max: 235, Min: 20

Pediatric → Max: 230, Min: 20

Neonate → Max: 125, Min: 20

■ **AUTO/MANUAL/STAT**

There are three modes of measurement available: MANUAL, AUTO and STAT. In the MANUAL mode, only one measurement is performed. In the AUTO mode, measurement is repeated over a specified period of time ; available intervals are 1,2,3,5,10,15,20,30,45, 60, 90 minutes and 2, 4, 8, 12,16,20,24 hours. In STAT mode, measurement is performed up to ten times in 5 minutes and with 30s interval between measurements. If an error occurs, NIBP measurement is suspended.

**<MODULE START>**

To start measurement

**<MODULE STOP>**

To stop measurement

**<MODULE RESET>**
To set maximum inflation pressure of cuff to 150 mmHg for adult, 140 mmHg for pediatric and 85 mmHg for neonate.

■ **NIBP LIST**
Patient monitor can store the latest 500 NIBP measurement data.
Pick "NIBP LIST" in the NIBP WINDOW to view the result and time of the latest NIBP measurements, as shown in Figure 7-3.

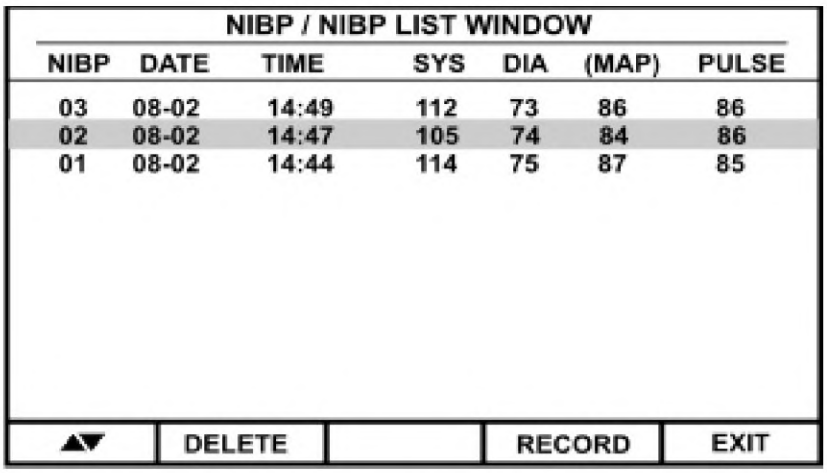



**Figure 7-5 HOME/NIBP LIST WINDOW**

By clicking on the first left item you can select a line of NIBP measured data.
By clicking on "UP-DOWN" you can access previous and next pages of NIBP LIST.
By clicking on "DELETE" you can delete selected data in NIBP LIST.
By clicking on "RECORD" you can record NIBP LIST data.

■ **MODULE CHECK**
Available options are "NIBP MANOMETER","NIBP LEAKAGE","MODULE SELF TEST" and "MODULE STOP".

**NOTE:**

**Below tests must only be done by personnel trained and authorized by manufacturer.**

**NIBP MANOMETER**
Wrap the cuff around a rigid cylinder. Connect a calibrated reference manometer and a ball pump by means of a T-piece connector and hoses to the monitor. Set the monitor in" NIBP

MANOMETER" mode. Inflate the pneumatic system to 0, 50 and 200 mmHg by ball pump separately. The difference between the indicated pressure of the reference manometer and the indicated pressure of the monitor should not exceed ±3 mmHg.

**NIBP LEAKAGE**

Wrap the cuff around a cylinder of an appropriate size, and the circumference of the applied cuff does not exceed that of the cylinder more than 7%.Set the monitor in "NIBP LEAKAGE" mode.

The monitor inflates the cuff up to 200mmHg and keeps it constant for 15 sec .If air leakage result is satisfactory, "NIBP LEAKAGE OK" message is displayed; otherwise you will receive "PNUMATIC LEAK" message.

## 7.3 NIBP Alarm Messages

**a) Physiological alarms**

Alarm occurs when the pressure (SYS. DIA or MAP) exceeds the alarm limit.

| Alarm | Situation | Visual prompt | Audio sound |
|---|---|---|---|
| NIBP SYS HIGH | SYS violates adjusted high limit | ● SYS value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP SYS LOW | SYS violates adjusted low limit | ● SYS value blinks<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP DIA HIGH | DIA violates adjusted high limit | ● DIA value blinks.<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP DIA LOW | DIA violates adjusted low limit | ● DIA value blinks<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP MAP HIGH | MAP violates adjusted high limit | ● MAP value blinks.<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP MAP LOW | MAP violates adjusted high limit | ● MAP value blinks.<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |

**a) Technical alarms**

| Alarm | Cause |
|---|---|
| SELF-TEST FAILED | NIBP hardware module failure |
| NIBP LOOSE CUFF | Cuff is completely unwrapped, no cuff attached |
| NIBP MODE ERROR | Adult mode instead of neonate mode (while neonate cuff is applied) or occlusion happened in air way |
| NIBP AIR LEAK | Air leak in cuff, hose or connector |
| NIBP AIR PRESSURE ERROR | Unstable pressure value (e.g. kinked hoses) |
| NIBP SIGNAL WEAK | Very weak patient signal due to a loosely wrapped cuff or extremely weak pulse from patient. |
| NIBP RANGE EXCEED | Measuring pressure is more than upper limit (255mmHg) for adult or (135mmHg) for neonate. |
| NIBP EXCESSIVE MOTION | Arm movement, noisy signal or irregular pulse(e.g. arrhythmia) |
| NIBP OVER PRESSURE SENSED | Measured pressure exceeds safe software limit, 290 mmHg for adult, 240 mmHg for pediatric and 145 mmHg for neonate. |
| NIBP SIGNAL SATURATED | Large motion artifact that saturates the amplifier's amplitude handling capability |
| NIBP PNEUMATIC LEAK | Air leakage during leak test |
| NIBP TIME OUT | Measurement time exceeds 3 minutes (2 minutes for CAS Medical module) in adult and pediatric mode or 90 seconds in neonate mode. |
| SYSTEM FAILURE | Error occurs in pump, A/D sampling, pressure transducer or software. |
| NIBP NO MODULE | No NIBP module is installed. |
| NIBP LOW BATTERY | The battery charge is not enough to measure NIBP. |
| NIBP MODULE ERROR | Some errors occur during measurement. |

Alarm level of above messages is set in NIBP WINDOW. By pressing ALARM SILENCE, alarm will be disabled and ignores this fault and message background will change to gray.

**c) Messages**

| Alarm | Cause |
|---|---|
| NIBP STOP PRESSED | NIBP stop key is pressed during measurement. |
| NIBP LEAKAGE O.K | Successful leakage test. |

## 7.4 NIBP CUFF CLEANING

- **Cleaning**

  Durable one-piece cuffs may be safely cleaned with a damp cloth (70% alcohol or 0.5% bleach solution may be used) or washed in water (60ºC maximum) with soap or detergent.

- **Sterilization**

  Do not use steam or heat to sterilize the cuff. Gas sterilization may be used if necessary.

- **Disinfection**

  Glutaraldehyde type liquid disinfectants may be used on durable cuffs. Prolonged use of these disinfectants at full strength may cause discoloration of the white cuff marking.

# CHAPTER 8 TEMP Monitoring

## 8.1 GENERAL

Measurement of patient temperature is accomplished by processing the signal from a probe containing temperature dependent resistor called thermistor .Value of this resistor is measured by the monitor continuously and displayed on screen. Patient monitor has two different kinds of temperature probe, a probe for esophageal /rectal temperature measurement and other for skin temperature measurement.

**Specification:**

| | | |
|---|---|---|
| Measuring and Alarm Range | | 0~50 ºC |
| Accuracy | | ± 0.2 º C |
| Delay time | For rectal/esophageal probe | 50sec |
| | For skin probe | 20sec |

Two TEMP probes can be used together to obtain 2 temperature data and compare them to determine the temperature difference.
Accuracy of measured temperature is checked per minute by an internal reference resistor calibrated on temperature 37.1˚C.

TEMP monitoring setup:

- Plug TEMP probe directly into the monitor.
- Attach the TEMP probe(s) properly to the patient.
- Switch on the system.

**Inspection and recalibration**

Visually inspect the probe for cracks, holes, crazing etc, prior to each use. If any such degradation in the cable jacket is discovered, discard probe according to your hospital's procedure for medical waste. When using temperature probe, the user must determine that a probe style is suitable and sufficiently flexible for esophageal or rectal use.
Probe cannot be "recalibrated" per se, but should be inspected monthly by the hospital Biomedical Equipment group to ensure they are working properly. Probes can be tested by plugging into a patient monitor and looking for an electrical open or short–circuit, Intermittent reading or extremely inaccurate readings which would indicate probe wire damage. The sensor stability is well-documented; Probe accuracy should not drift out of tolerance over the normal life of probe.

⚠WARNING⚠

**Use only the recommended manufacturer TEMP probe for monitoring, other probes may cause system malfunction.**

**NOTE:**

**Please be noted that the metal side of probe should be used for making measurements.**

⚠WARNING⚠

**Using ESU with temperature measurement simultaneously may cause patient burn. If possible, remove the probe from patient contact before activating the surgical unit or other RF source. If probe must be used simultaneously with electrosurgical apparatus, hazards can be reduced by selecting a temperature monitoring point which is remote from the expected RF current path to the ground return pad.**

⚠WARNING⚠

**Over straining will result in mechanical damage of the probes.**

⚠WARNING⚠

**The temp probes should be calibrated every two years or according to hospital calibration schedule. Contact After Sale Service to perform probe calibration.**

⚠WARNING⚠

**The temperature probes carry a one-year warranty on workmanship, components and accuracy tolerances. Probe life with normal use should exceed one year.**

## 8.2 TEMP WINDOW

The following items are displayed in TEMP parameter window.

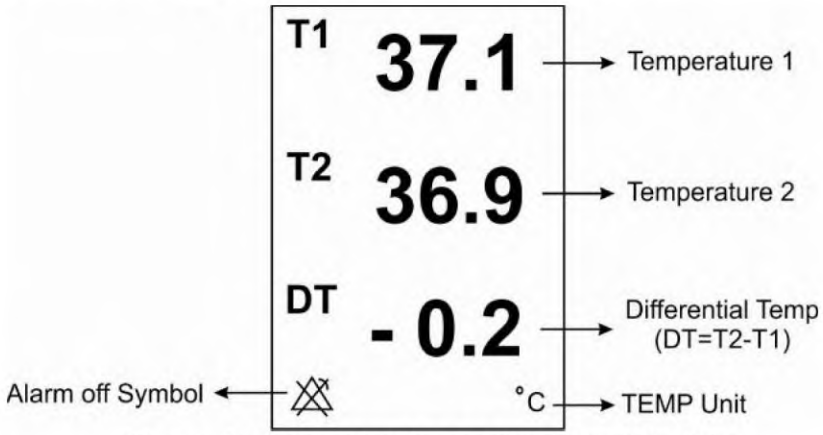



**Figure 8-1 TEMP PARAMETER WINDOW**

The TEMP WINDOW is as follows:

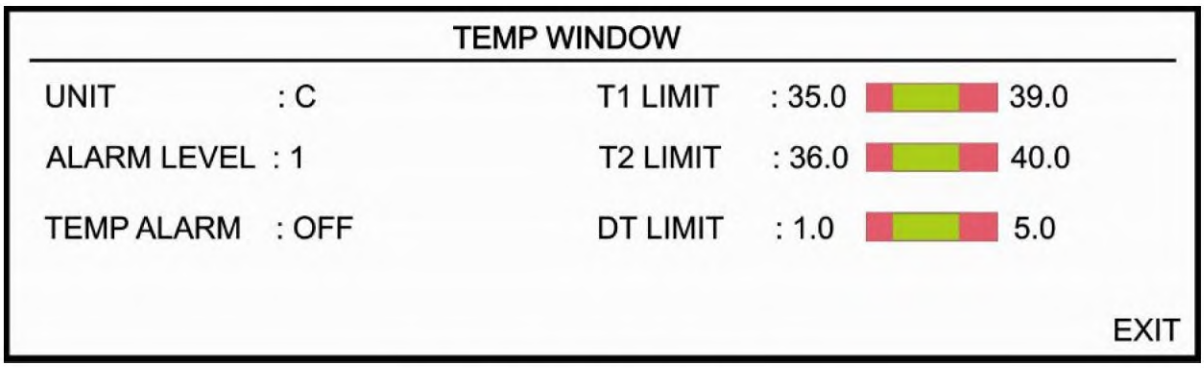



**Figure 8-2 TEMP WINDOW**

- **UNIT**

Pick this item to set measurement unit. (options: ºC or ºF)

- **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

- **TEMP ALARM**

Pick "ON" to enable TEMP alarm functions such as parameters blinking, audio alarm, and light indicator.Pick "OFF" to disable the alarm functions and there will be a "⚠" symbol in the Parameter Area.

- **T1 LIMIT**

T1 alarm is activated when the channel-1 temperature exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.(min:0.0 and max:50.0)

- **T2 LIMIT**

T2 alarm is activated when the channel-2 temperature exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.(min:0.0 and max:50.0)

- **DT LIMIT**

DT alarm is activated when the difference between channel-1 and channel-2 exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (min:0.0 and max:50.0).

T1 is Channel-1 of temperature.
T2 is Channel-2 of temperature
DT is the temperature difference between the above two.

## 8.3 TEMP ALARM MESSAGES

Alarm occurs when the alarm function is "ON" and temperature exceeds adjusted alarm limit.

| Alarm | Situation | Visual prompt | Audio sound |
|---|---|---|---|
| T1 HIGH | The temperature (T1) violates adjusted high limit | ● T1 value blinks<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| T1 LOW | The temperature (T1) violates adjusted low limit | ● T1 value blinks<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| Alarm | Situation | Visual prompt | Audio sound |
| T2 HIGH | The temperature (T2) violates adjusted high limit | ● T2 value blinks.<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| T2 LOW | The temperature (T2) violates adjusted low limit | ● T2 value blinks<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| DT HIGH | Difference between two channels temperature (DT) violates adjusted high limit | ● DT value blinks.<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |
| DT LOW | Difference between two channels temperature (DT) violates adjusted low limit | ● DT value blinks.<br>●Alarm indicator flashes.<br>●Alarm message is displayed in a background corresponding to its level. | Activated |

# 8.4 TEMP SENSOR CLEANING AND MAINTENANCE

To clean the temp sensor, first remove it from the patient and disconnect it from the monitor.

**NOTE:**

**Reusable temperature probes are sold non- sterile.**

■ **Cleaning**

Probe should be cleaned prior to disinfection or sterilization to improve the effectiveness (as recommended in ANSI/AAMI ST35: Good Hospital Practice: Handling and Biological Decontamination of Reusable Medical Device,1991)

When wiping clean, hold the probe in one hand at the sensing tip and wipe the probe and lead wire toward the plug. Excessive pressure could stretch the cable jacket and break the internal wires, destroying the probe .Continued flexing of lead wires in use and cleaning can also break the internal wire.

Avoid contact with materials such as ketone, ether or ester solvents. Prolonged immersion in alcohols or mild organic solvents, detergent solutions or highly alkaline solutions will cause the vinyl to lose flexibility. The probe plugs should not be immersed.

⚠**Warning**⚠

**Never immerse the probe plug in any liquid.**

■ **Sterilization**

Ethylene oxide is the preferred sterilization method. After sterilization, probes must be safely and thoroughly ventilated before handling or use. Using a generic EtO sterilizing procedure, an aeration time of minimum 12 hours is recommended to dissipate residual EtO in probe.

■ **Disinfection**

Probes may be disinfected by washing with 70% isopropanol, activated dialdehyde (Cidex) or sodium hypochlorite (bleach diluted 1:10 minimum in water.) After washing, probes should be rinsed thoroughly with water. Brief immersion of the probe in detergent solutions is not harmful. Manufacturer does not make any claim as to the efficacy of these chemicals for infection control. Please consult your hospital's Infection Control Officer for the applicable disinfection policies.

⚠**Warning**⚠

**Never boil the temperature probes.**

**Storage and Handling**

When not in use, probes and leads should be loosely coiled and stored at room temperature .Do not wrap probes around equipment cases to avoid damaging internal wires.

# Chapter 13 ST Monitoring

## 13.1 GENERAL

ST segment deviation is defined as the displacement above or below the isoelectric level. The measurement of deviation compares the isoelectric point to the ST measurement point.
The isoelectric point defines the point of zero voltage (no electrical activity) with a default position of 80ms from R wave as 0msec in the horizontal (time) axis. The ST point occurs in the ST segment between J-point and the T wave, at a default position of 110 ms after R wave. The following figure illustrates a typical QRS complex.

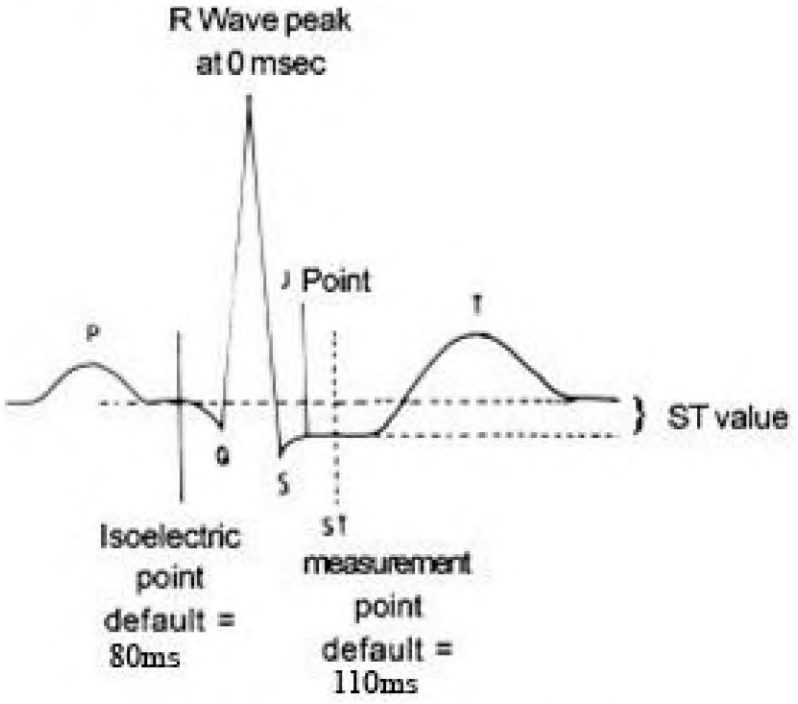



**Figure 13-1 ST Measurement Algorithm**

The ST measurement for each beat complex is vertical difference between the two measurement points, ST and ISO.

The ST analysis examines QRS complexes classified as normal beats (beat detection and classification information provided by the arrhythmia algorithm are used to eliminate beat that are ventricular in origin). The monitor combines the measurements and features of normal beats into a composite (or average) QRS complex. It derives the ST segment deviation from this average.

The ST segment algorithm documents changes in ST segment in adult patients that can be indicative of the severity and duration of myocardial ischemia. Since many ischemic episodes are

silent or painless, continuous monitoring of ST segment changes can provide the earliest warning of ischemic events.

**NOTE:**

**ST monitoring is available for adult and pediatric patient and it is not recommended for neonates.**

**NOTE:**

**If there are not at least 5 normal complexes in the last 50 beats of ECG signal, the ST value will not be displayed.**

**NOTE:**

**Applied lead for ST, ARR, Pace and HR is reference lead that is displayed in the first trace and can be adjusted in ECG menu.**

**NOTE:**

**To ensure proper analysis of ST segment deviation, it is recommended to use Extended filter.**

ST monitoring function is "OFF" as a default. You can switch it "ON", when this monitoring is necessary.

When ST monitoring is enabled, current ST values are trended and can be reviewed on the TREND window.

**NOTE:**

**Measurement unit of ST segment is "mV".**

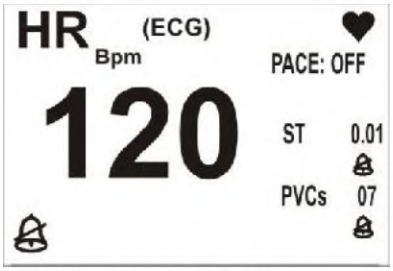



**Figure 13-2 ST value in ECG parameters area**

Measurement range of ST segment is between -2.0 mV to +2.0 mV.

Measurement symbol of ST segment "+" means elevating and "-"means depressing.

## 13.2 ST ANALYSIS WINDOW

Pick "ST ANALYSIS "in the ECG WINDOW to call up the following menu:

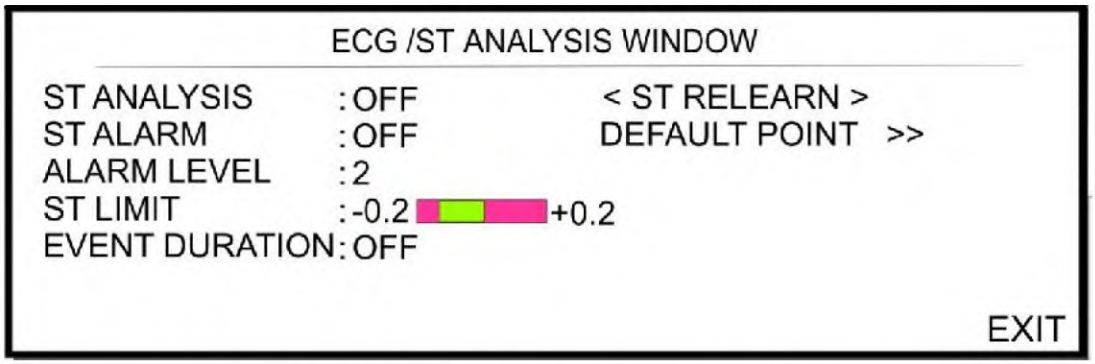



**Figure 13-3 ECG/ ST ANALYSIS WINDOW**

■ **ST ANALYSIS**

Pick this item to enable or disable ST monitoring. The default is OFF. When the ST monitoring is disabled "ST OFF" is displayed in ECG parameter area.

■ **ST ALARM**

Pick "ON" to enable alarm functions such as parameters blinking, audio alarm and light indicator.Pick "OFF" to disable the alarm functions and there will be a "⚠" symbol in the Parameter Area.

■ **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

■ **ST LIMIT**

ST alarm is activated when the ST segment value exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (Range: -2.0 ~ +2.0 step 0.1)
Default for upper limit is +0.2 and for lower limit is -0.2.

■ **EVENT DURATION**

Pick this item to determine the time that a potential ST alarm condition must persist on ECG waveform before the monitor classifies it as a valid alarm condition.
Available options for EVENT DURATION are OFF, 15s, 30s, 45s and 60s.The default is OFF and alarm will be activated immediately if alarm condition happens.

■ **ST REALERN**

Pick to start a learning procedure. The "RELEARN" message is displayed in the ECG waveform area of the screen. It takes usually about 20 seconds.

During relearn procedure the following actions will be taken:

- Blanks average stored dominant QRS complex currently displayed on the DEFAULT POINT Window.
- Learns and identifies the new dominant QRS complex template.
- New complex is displayed on DEFAULT POINT Window.

**NOTE:**

**You can do relearn procedure by selecting <ARR RELEARN> in ECG/ARR ANALYSIS window.**

**NOTE:**

**The monitor automatically begins to learn a reference template whenever you execute any of the following tasks (If ST ANALYSIS is ON and there is no technical ECG alarm active, like CHECK LEAD):**

- **Turning on the monitor**
- **Connecting ECG cable.**
- **Changing an ECG lead configuration.**
- **Choosing "NEW" in HOME / PATIENT INFORMATION**

**NOTE:**

**A yellow vertical marker with "LRN" label On ST in TREND window shows the time in which the learning procedure has been done.**

### ■ DEFAULT POINT

Pick "DEFAULT POINT" in the ST ANALYSIS WINDOW to adjust the position of both ISO and ST measurement points. When you change the ST and ISO measuring points on the DEFAULT POINT Window, the monitor recomputes the ST deviation value accordingly.

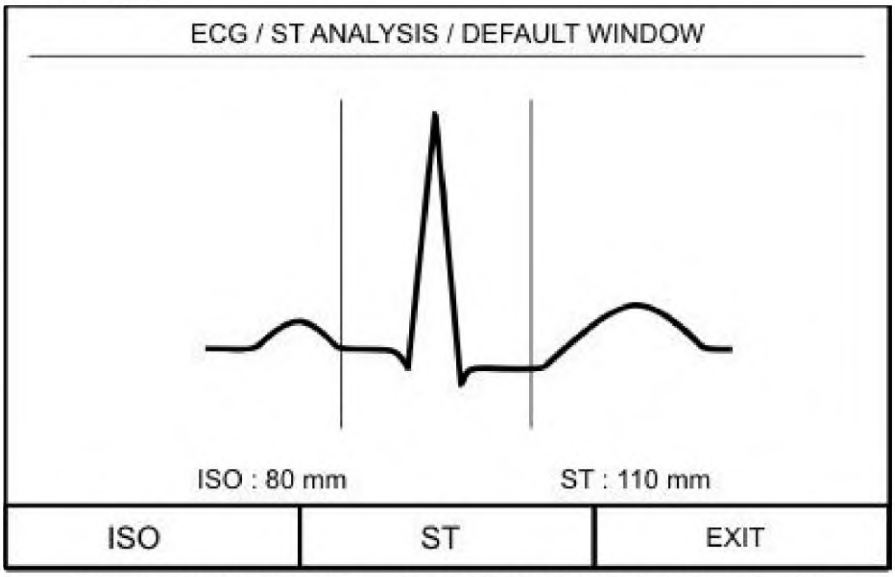



**Figure 13-4 ECG/ST ANALYSIS/DEFAULT WINDOW**

As shown above, the DEFAULT POINT WINDOW shows the dominant QRS complex template. Two vertical lines indicate the positions of the ISO and ST points.

ISO: It is the base point, used to indicate the baseline point of the ST analysis. The default is 80ms.

ST: It is the ST measurement point. The default is 110ms.

(Selectable between 5 to 400 ms by step of 5ms)

The reference point is the position where the peak of R-wave locates.

**NOTE:**

**It is good clinical practice to check the position of ISO and ST measuring points before starting ST monitoring and finishing learning procedure.**

**NOTE:**

**In practice, the accurate determination of ISO and ST measuring points requires careful clinical evaluation**.

**NOTE:**

**The ST measurement point should be adjusted if patient's HR or ECG morphology changes significantly.**

If the template is not established, a horizontal line will be displayed and if the ST ANALYSIS is "OFF", the message "ST ANALYSIS KEY IS OFF" appears in this window.

You may select ISO or ST, and then switch the knob left or right to move the cursor line. When the cursor is at the intended position, you may select the base point or the measurement point.

**NOTE:**

**Abnormal QRS complex is not considered in ST segment analysis.**

**NOTE:**

**If pace is ON (for patient with pacemaker) or while learning procedure, there is no waveform in DEFAULT POINT Window and you can see just ISO and ST lines. In this condition, ST value will not be measured.**

**NOTE:**

**A red vertical marker with "CHG" label on ST in TREND window shows the time in which the measuring point has been changed.**

## 13.3 ST Alarm Messages

Alarm occurs when ST value exceeds adjusted alarm limits:

| Alarm | Situation | Visual prompt | Audio sound |
|---|---|---|---|
| ST HIGH | ST segment value violates adjusted high limit | ●ST value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| ST LOW | ST segment value violates adjusted low limit | ●ST value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

ST messages include:

| Message | Cause | Solution |
|---|---|---|
| ST OUT OF RANGE HIGH | The ST algorithm has calculated value +1mV outside the high end of the ST measurement range. | ●Check the ISO and ST measuring points.<br>●Observe the patient and treat if clinically indicated. |
| ST OUT OF RANGE LOW | The ST algorithm has calculated value -1mV outside the low end of the ST measurement range. | ●Check the ISO and ST measuring points.<br>●Observe the patient and treat if clinically indicated. |

Alarm level of above messages is set in ST WINDOW. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled for 120S.

# 14 Arrhythmia Monitoring

## 14.1 GENERAL

Arrhythmia means any disturbance or irregularity of cardiac rhythm. Stability of the cardiac rhythm is essential for sufficient pumping function of the heart and adequate cardiac output. Maintaining adequate cardiac output is vital for organ perfusion and survival. Arrhythmia can cause a decrease in cardiac output. Therefore fast and accurate detection of arrhythmia is critical.

The medical professionals can use the arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and give proper treatment.

**NOTE:**

**If arrhythmia monitoring is "ON", the heart rate is calculated by the arrhythmia software.**

**NOTE:**

**This monitor can detect up to 13 types of arrhythmias.**

**NOTE:**

**Arrhythmia monitoring is available for adult and pediatric patients and it is not recommended for neonates.**

**NOTE:**

**Applied lead for ST, ARR, Pace and HR is reference lead that is displayed in the first trace and can be adjusted in ECG menu.**

⚠**Warning**⚠

**The ARR monitor can only be operated by personnel who have passed professional training and are familiar with this manual.**

⚠ **Warning** ⚠

**The ARR monitor is intended for use only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**

**NOTE:**

**It is recommended to use ECG lead I or II to have the best accuracy of ARR software.**

## Arrhythmia detection algorithm principle

The arrhythmia algorithm is based on template matching. (A template is a group of beats matching the same morphology). The algorithm detects QRS complexes, generates QRS templates and performs beat labelling. This algorithm is divided into three parts: detector, classifier and labelling.

**The detector** algorithm detects waves in ECG signal that could be QRS complexes.

**The classifier** algorithm forms templates of similar QRS complexes. During the learning phase an initial set of QRS template is built. Then the monitor creates a reference template based on its identification of the patient's dominant QRS pattern. When a new true QRS complex is detected, it is compared with the existing templates. If no match is found, a new QRS template is added to the template set.

**The labelling** algorithm analyses all templates. Each template and the beats belonging to it are labelled with one of the following names: normal beats, ventricular beats and questionable beats. Through this process, the monitor can verify an arrhythmia event's occurrence.

Parallel to this process there is an algorithm for detection of ventricular fibrillation.

Detection of ventricular fibrillation is based on waveform analysis. AFIB arrhythmia is detected through obtained parameters in the previous parts and analysis of R-R intervals. Maximum one minute after occurring AFIB arrhythmia, related alarm will be activated and time of arrhythmia occurrence will be recorded in the Trend window.

## Beat and rhythm classification

Beat classification refers to the analysis of individual beats. If the new beat's features do not match those of the normal template, the new beat is classified as premature or questionable.

The monitor uses all detected beats to calculate the heart rate, eliminating questionable beats from arrhythmia classification.

Rhythm classification refers to analysis of sequences of beats. The monitor compares the sequence of the last twelve beats with the sequences stored in the monitor's memory. If it detects two or more events simultaneously, the monitor alarms in order of event priority.

The following table describes available beat classifications:

| Arrhythmia | Event and Beat Classification |
|---|---|
| ECG ASYSTOLE | 5 seconds pass without the detection of valid QRS complex. |
| VFIB ARRHYTHMIA | Ventricular Fibrillation: The monitor identifies a sinusoidal waveform with fibrillation characteristics. (Certain ventricular tachycardias have sinusoidal waveforms closely resembling those of ventricular fibrillation. Because of the similarity of these waveforms, the monitor may classify such types of ventricular tachycardia as ventricular fibrillation) . |
| VTAC ARRHYTHMIA | Ventricular Tachycardia: N or more PVC's are detected in a time interval T= (60*(N-1))/R, where N is defined as the VTAC count and R is defined as the VTAC rate. |
| RUN ARRHYTHMIA | Ventricular Run: Series of 3 to N-1 consecutive PVCs with a beat to beat rate ≥ the VTAC rate. |

| | |
|---|---|
| AIVR ARRHYTHMIA | Accelerated Idioventricular Rhythm: Series of 3 or more PVCs with a beat rate less than the VTAC rate. |
| BIGEMINY ARRHYTHMIA | Ventricular Bigeminy: Sequence of beats with the pattern : normal, PVC, normal, PVC, normal, PVC |
| TRIGEMINYARRHYTHMIA | Ventricular Trigeminy: Sequence of beats with the pattern : normal, normal, PVC, normal, normal, PVC |
| COUPLET ARRHYTHMIA | Ventricular Couplet: Sequence of beats with the pattern : normal, PVC, PVC, normal, PVC, PVC |
| TACHY ARRHYTHMIA | Sinus Tachycardia: HR ≥ TACHY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis. |
| BRADY ARRHYTHMIA | Sinus Bradycardia: HR≤ BRADY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis. |
| AFIB ARRHYTHMIA | Atrial Fibrillation: Formation of QRS complexes in irregular intervals |
| PAUS ARRHYTHMIA | Actual R-R interval more than 2.1 times of the average R-R interval. |
| FREQUENT PVCs | More than N (event count set in the ARR SETUP WINDOW) PVC per minute. |

Premature Ventricular Contraction (PVC) is ectopic impulse originating from ventricles, before the normal electrical activation sequence of the heart has occurred.

The PVC value is shown in ECG parameter window and updated every 5 seconds.

When ARR analysis is enabled, current PVC values are trended every 20 seconds and can be reviewed on the TREND window.

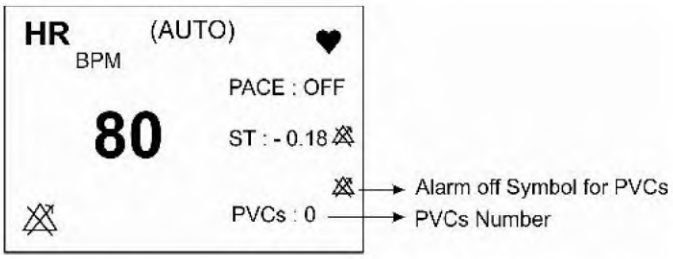



**Figure 14-1 PVC value in ECG parameters area**

**NOTE:**

**When PACE is turned ON, for patient with pacemaker, the system will not detect the arrhythmia relating to premature ventricular beats.**

## 14.2 ARR ANALYSIS WINDOW

Pick "ARR ANALYSIS"in the ECG WINDOW to call up the following menu:

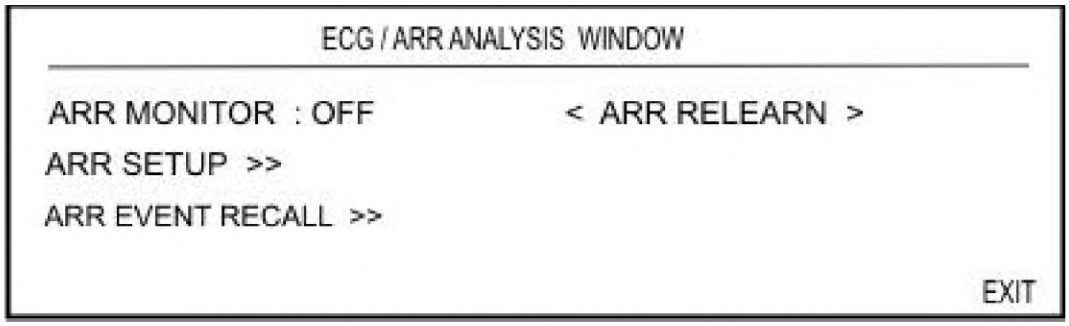



**Figure 14-2 ECG/ARR ANALYSIS WINDOW**

■ **ARR MONITOR**

Pick this item to enable or disable arrhythmia monitoring. The default is "OFF". When the Arrhythmia monitoring is disabled "PVCs OFF" is displayed in ECG parameters area.

■ **ARR SETUP**

Pick "ARR SETUP" in ARR ANALYSIS Window to call up the following menu:

ECG/ARR ANALYSIS/ARR SETUP WINDOW

| | ALARM LEVEL | RATE | COUNT | ARCHIVE |
|---|---|---|---|---|
| ASYSTOLE | 1 | - | - | STR |
| VFIB | 1 | - | - | STR |
| VTAC | 1 | >=120 | >=5 | STR |
| RUN | 1 | >=120 | >=3 | STR |
| AIVR | 2 | >=119 | >=3 | STR |
| COUPLET | 2 | - | - | STR |
| BIGEMINY | 2 | - | - | STR |
| TRIGEMINY | 2 | - | - | STR |
| TACHY | 2 | >=120 | - | OFF |
| BRADY | 2 | <=50 | - | OFF |
| AFIB | 1 | - | - | STR |
| PAUSE | 2 | - | - | OFF |
| FREQUENT PVCs | OFF | - | >=10 | - |

ALL ALARM LEVEL:NONE ALL ARCHIVE:NONE

EXIT

**Figure 14-3 ECG/ARR ANALYSIS /ARR SETUP WINDOW**

The ARR SETUP table allows you to configure arrhythmia monitoring accordingly to your patient's needs. All detectable arrhythmia events listed in the first column of the table .Using the remaining columns, you can modify the attributes of each event. Fields that are not applicable for certain event category are shown with dash symbol, while those that cannot be modified are ghosted. Arrhythmia default settings are shown in figure 14-3

Modifying arrhythmia settings:
1. Scroll the cursor frame to parameters whose arrhythmia functions you wish to configure and click.
2. Scroll to the function you wish to modify. (The first column, "ALARM LEVEL ", is highlighted when you first click on a parameter.)
3. Click to access settings of the selected arrhythmia function.
4. Dial through settings and click to confirm your selection.
5. Repeat step 1-4 to configure additional arrhythmia functions or parameters.

- **ALARM LEVEL**

Available options are 1, 2 and OFF to set the level of alarm for every arrhythmia event. (For more detail about alarm levels refer to chapter 3.)
ALARM LEVEL for "ASYSTOLE" cannot be modified and always is in level 1.

- **RATE**

With count, you can determine the point at which an event call is triggered.
You can't modify the rate for "ASYSTOLE", "VFIB", "COUPLET", "BIGEMINY", "TRIGEMINY", "PAUS", " AFIB" and "FREQUENT PVCs" .
"RUN" and "AIVR" derive their rate settings from "VTAC" and cannot be modified.

| Arrhythmia event | Rate setting |
|---|---|
| VTAC | 100-200 step by 10 |
| RUN | Same as VTAC rate |
| AIVR | <VTAC rate-1 |
| TACHY | 100-200 step by 10 |
| BRADY | 30-105 step by 5 |

- **COUNT**

With rate, you can determine the point at which an event call is triggered.
You can't modify the count for "ASYSTOLE", "VFIB", "COUPLET", "BIGEMINY", "TRIGEMINY","TACHY","BRADY", "AFIB" and "PAUS".
Count of "AIVR" is ≥3 and cannot be modified.

| Arrhythmia event | Count setting |
|---|---|
| VTAC | 5-12 step by 1 |
| RUN | ($VTAC_{count}$ -1) ~3 step by 1 |
| FREQUENT PVCs | 1-15 step by 1 |

- **ARCHIVE**

You can determine whether the selected event is stored, recorded automatically or both. You can view stored events on ARR EVENT RECALL Window.

**STR:** Stores selected arrhythmia event.
**REC:** Automatically generates a recording of selected event.
**STR/REC**: Event is stored and recorded simultaneously.
**OFF**: No action if arrhythmia event activates.

- **ALL ALARM LEVEL**

Press to set the level of all arrhythmia alarms to the same value or to disable all of them.

- **ALL ARCHIVE**

Press to set all arrhythmia ARCHIVE condition to the same state.

■ **ARR EVENT RECALL**

Pick " ARR EVENT RECALL" in ARR ANALYSIS WINDOW to call up the following menu:

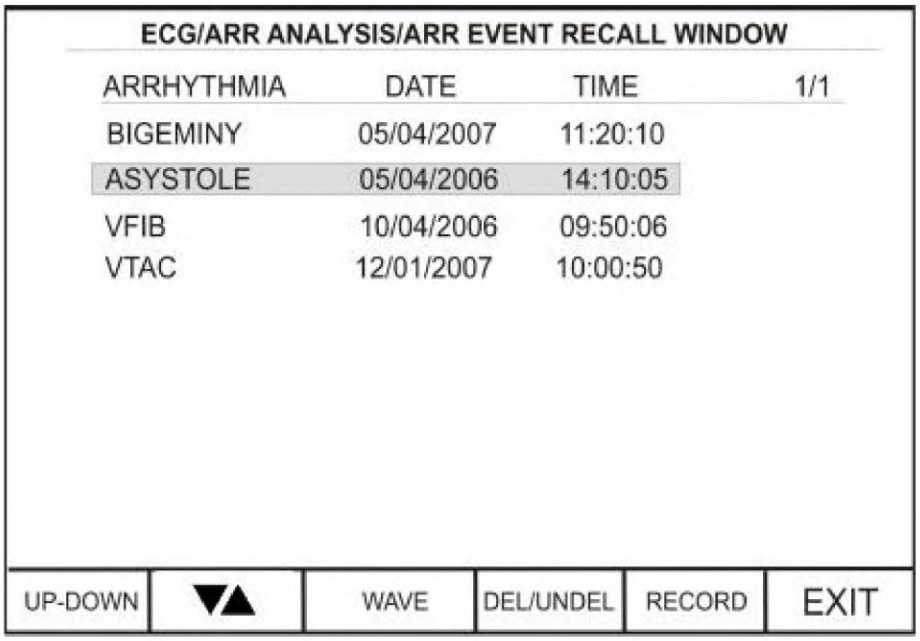



**Figure 14-4 ECG/ARR ANALYSIS / ARR EVENT RECALL WINDOW**

You can review any stored arrhythmia event (maximum 150 events) in this window.

**NOTE:**

**If an arrhythmia event occurs and persists, it will be stored in ECG/ARR ANALISIS/ARR EVENT RECALL WINDOW for one time, but if this event is removed and then occurs again, it will be stored twice.**

■ **To review different event pages:**

Maximum of 8 arrhythmia events can be displayed in each page of "ARR EVENT RECALL" window simultaneously. When there is more than 8 events, different pages are available. Pick "UP-DOWN" (the most left item) to review different pages.

■ **To select an arrhythmia event:**

Pick the second left item to select an arrhythmia event displayed in the window.

■ **To delete an arrhythmia event:**

Pick the forth left item to choose an arrhythmia event for removing from the list. When you click on "DEL/UNDEL" button, the selected event will be highlighted and removed if you exit the window.

**NOTE:**

**To ignore deleting a selected item, click on the "DEL/UNDEL" key one more time before exiting from the window.**

■ **To see detail information of arrhythmia event:**

Pick the third left item to call up the following window:

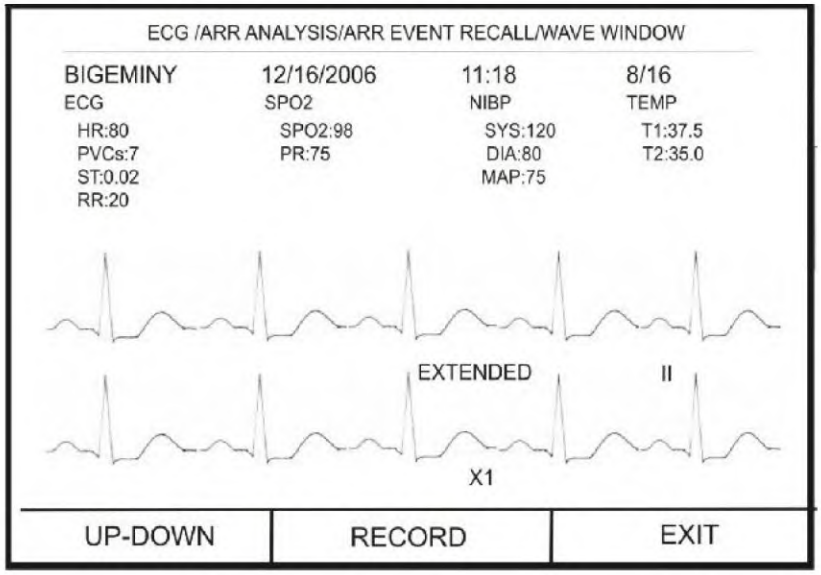



**Figure 14-5 ECG/ARR ANALYSIS /ARR EVENT RECALL/WAVE WINDOW**

In this window, waveform and time of selected arrhythmia event as well as other vital sign parameters values at the event time are displayed.

- **UP-DOWN**

  This option allows you to page up and down to review the waveform and the parameters of other arrhythmia events.

- **RECORD**

  This option allows you to record the arrhythmia signal. If settings of RECORDER SWEEP: 25mm/s and MANUAL RECORD TIME:10 sec are selected in HOME /RECORDER WINDOW, arrhythmia signal will be recorded for about 20 seconds. This record starts from10 seconds before arrhythmia occurrence and will continue until 10 seconds after that.

■ **ARR RELEARN**

Pick to start a learning procedure. The "RELEARN" message is displayed in the ECG waveform area.

**NOTE:**

**You can do relearn procedure by selecting <ST RELEARN> in ECG/ST ANALYSIS window.**

**NOTE:**

**In most situations the learning phase takes about 20 seconds.**

**NOTE:**

**If the monitor couldn't find 6 matching beats after 20 seconds, the relearn procedure continues and the "RELEARN" message remains on the display, till acceptable condition happens.**

**NOTE:**

**While the monitor is in learning phase, all arrhythmia alarms and trend collection are suspended.**

**NOTE:**

**Before starting learning procedure, verify the quality of the ECG signal and ensure that the patient's ECG displays a normal reference pattern.**

**NOTE:**

**The monitor automatically begins to learn a reference template whenever you execute any of the following tasks (If ARR ANALYSIS is ON and there is no technical ECG alarm active, like CHECK LEAD):**

- **Turning on the monitor**

- **Connecting ECG cable.**
- **Changing ECG lead configuration.**
- **Choosing "NEW" in HOME / PATIENT INFORMATION**

**NOTE:**

**It is recommended to perform relearn procedure under the following conditions:**

- **A lead is reconnected or electrodes are repositioned.**
- **Eight hours have passed since last reference complex learned.**
- **Other significant changes appear on the morphology of the patient's ECG.**

# Chapter 15 C.O. Monitoring

## 15.1 GENERAL

Cardiac Output (C.O.) is the volume of blood pumped by the heart ventricle per minute. The measurement unit is litres per minute (L/min).

To understand the clinical importance of measuring cardiac output, consider that the primary function of the heart is to deliver sufficient oxygenated blood to meet the metabolic needs of the body tissues. The cardiac output measurement invasively measures cardiac output and other hemodynamic parameters using a technique called thermodilution. C.O. measurements in SAADAT monitors are carried out using the right heart thermodilution method. This method is known as "gold standard" of C.O. measurement.

## C.O. Measurement using the Right Heart Thermodilution Method

In the right heart thermodilution method, a cold fluid of known volume and temperature is injected into the right atrium thought a pulmonary artery catheter (PAC). The injected fluid mixes with the blood in the right ventricle and the change in blood temperature is measured with a thermostat situated in the distal end of the catheter in the pulmonary artery.

After injection, the blood temperature descends and then rises smoothly to reach its initial state. The lower cardiac output value, the colder temperature of injectate solution. Cardiac output is inversely proportional to the area under the thermodilution curve (Refer to figure 15-1).

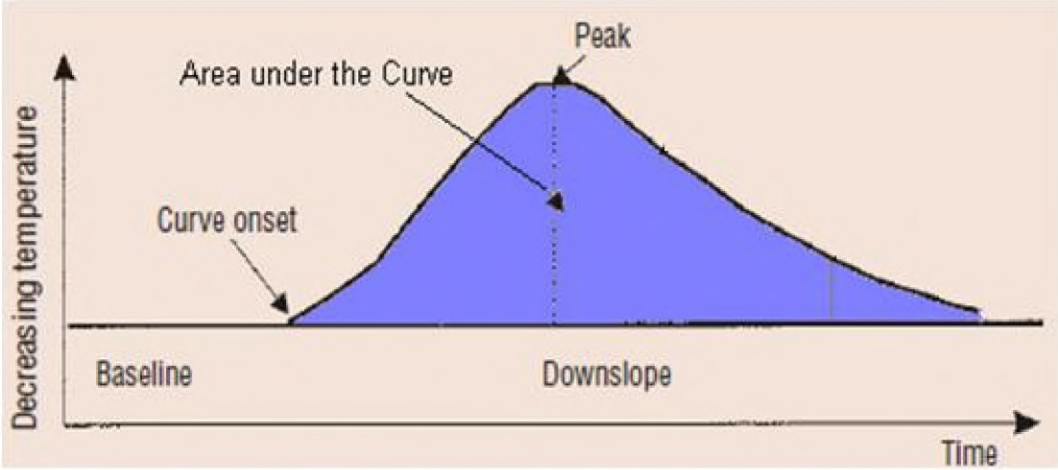



**Figure 15-1- Thermodilution curve after injecting injectate (Note that the curve peak indicates the lowest temperature).**

**NOTE:**

**Fluid injection must be carried out smoothly.**

⚠**Warning**⚠

**C.O. measurement must be carried out by trained and qualified individuals.**

C.O. value is influenced by injection technique. As mentioned above, the curve should have a steep rise and gradual return to baseline (See figure 15-2). Other curves are samples of high cardiac output, low cardiac output and prolonged injection. A series of measurements must be carried out to achieve a reliable C.O. value and average of multiple thermodilution measurements is used for therapy decisions.

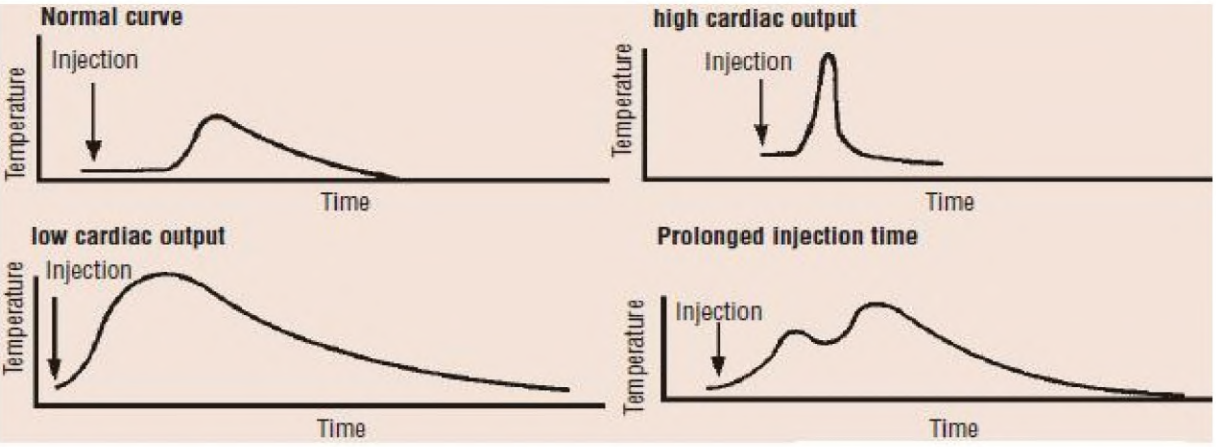



**Figure 15-2 Sample curves of temperature change in C.O. measurement**

## Setting up RH C.O. Measurements

1. Enter the catheter into the heart and place it in proper position (Follow your hospital standards to avoid unintentional extraction of C.O. catheter).
2. Connect the other side of the catheter to SAADAT C.O. cable.
3. Connect C.O. cable to the respective connector on the side panel of SAADAT monitor.
4. Prepare ice bath (water) and injected solution (0 °C).

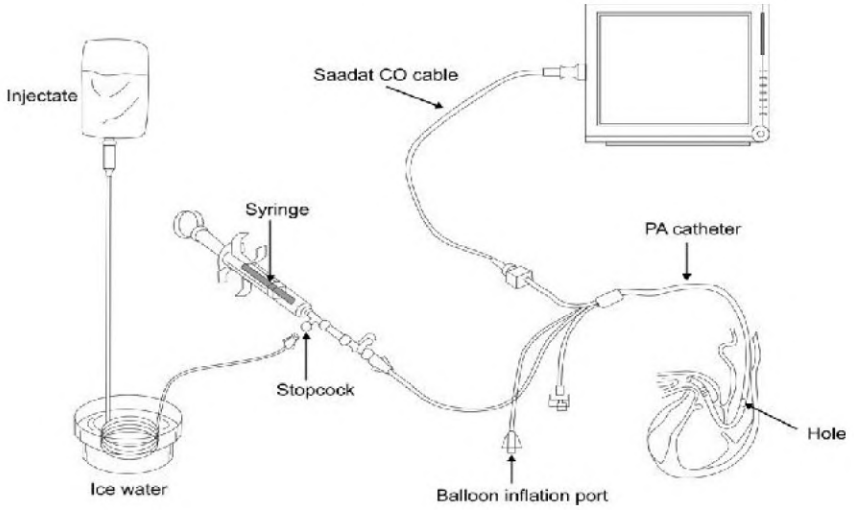



**Figure 15-3 Setting up RH C.O. Measurement**

**⚠Warning⚠**

**C.O. module calculates cardiac output based on injectate temperature of 0 °C. There will be measurement error if the temperature of injectate solution is not zero.**

**⚠Warning⚠**

**Use only the accessories specified in this manual.**

**⚠Warning⚠**

**Make sure that no part of accessories is in contact with any other conductive parts.**

**NOTE:**

**If the patient condition is unstable, the measurement cannot be done or is unreliable.**

**⚠Warning⚠**

**Don't use electrosurgical equipment during C.O. measurement.**

**⚠Warning⚠**

**Disposable catheter should not be reused.**

**NOTE:**

**Do not use the catheter if its package is damaged.**

**NOTE:**

**Before using catheter, inflate the balloon to make sure that it is not damaged.**

**NOTE:**

**Before using catheter, inject the solution by syringe to check path of injectate.**

# 15-2 CARDIAC OUTPUT MENU

Pick "CARDIAC OUTPUT" in HOME MENU to call up the following menu:

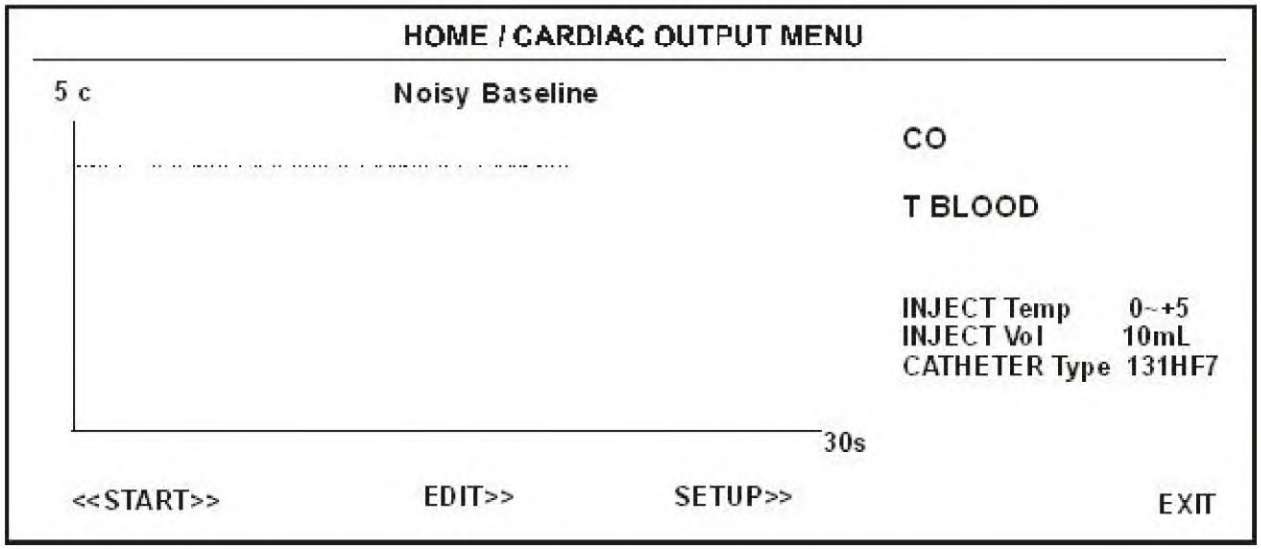



**Figure 15-4 HOME/CARDIAC OUTPUT MENU**

If C.O. cable and catheter are not firmly connected to the monitor, the message "No Cable" will appear on the screen. If after connecting C.O. cable, "Noisy Baseline" appears, the monitor can not start measurement. If the message does not disappear after a while, possible causes can be improper placement of the catheter or interference of other devices such as electrosurgical unit in the vicinity of the monitor. When you see the message "Ready For Measurement", start measurement by selecting **Start** key.

The blood temperature is displayed in front of **TBlood** in this window. If the temperature is out of the range 25 – 45 °C, the message "Out Of Range" appears on the screen. In this condition C.O. measurement is impossible.

- **START**

When you see the message "**Ready for Measurement**", press the Start key and then when you see the message "**Inject Now**", inject the solution.

During measurement, the thermodilution curve is displayed and the message "**CALCULATING**" will appear above the curve when C.O. value is calculated by the system.

At the end of the measurement C.O. value will be displayed on the screen. After each measurement if the curve appears abnormal (due to noise or inappropriate injection), a

question mark symbol ("?") will appear next to the calculated C.O. value. The thermodilution curve, cardiac output numeric value and measurement time are stored in one of five EDIT windows. Press STOP key during measurement to stop it.

**NOTE:**

**Sudden variations in pulmonary artery blood temperature resulted from e.g. patient movement or drug injection may cause C.O calculation. To avoid incorrect curve detection, immediately after "Inject Now" appears, inject the solution.**

## ▪ EDIT

Pick "EDIT" in HOME/CARDIAC OUTPUT MENU to call up the following window:

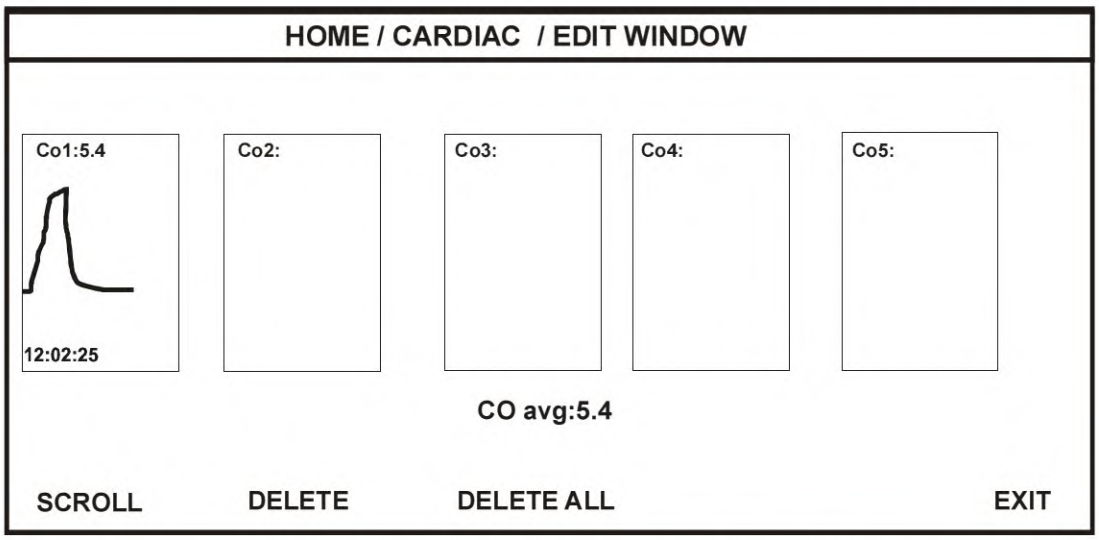



**Figure 15-5 HOME/CARDIAC/EDIT WINDOW**

Numeric value, curve and time of the last five C.O. measurements are displayed in this window. Averaged C.O. value is displayed below the window. User can identify and delete erroneous measurements and then average value of other measurements will be recalculated by the system.

If you perform more than five measurements without rejecting any, the first measurement will automatically be deleted when sixth curve is stored.

## □ SCROLL

Press SCROLL to move red frame between curves and press ENTER to select one curve.

### DELETE

Press to delete the selected curve.

### DELETE ALL

Press to delete all stored C.O. curves.

## SETUP

C.O. settings can be changed in the Setup menu. Pick SETUP in HOME/CARDIAC OUTPUT MENU to call up the following menu (Figure 15-6):

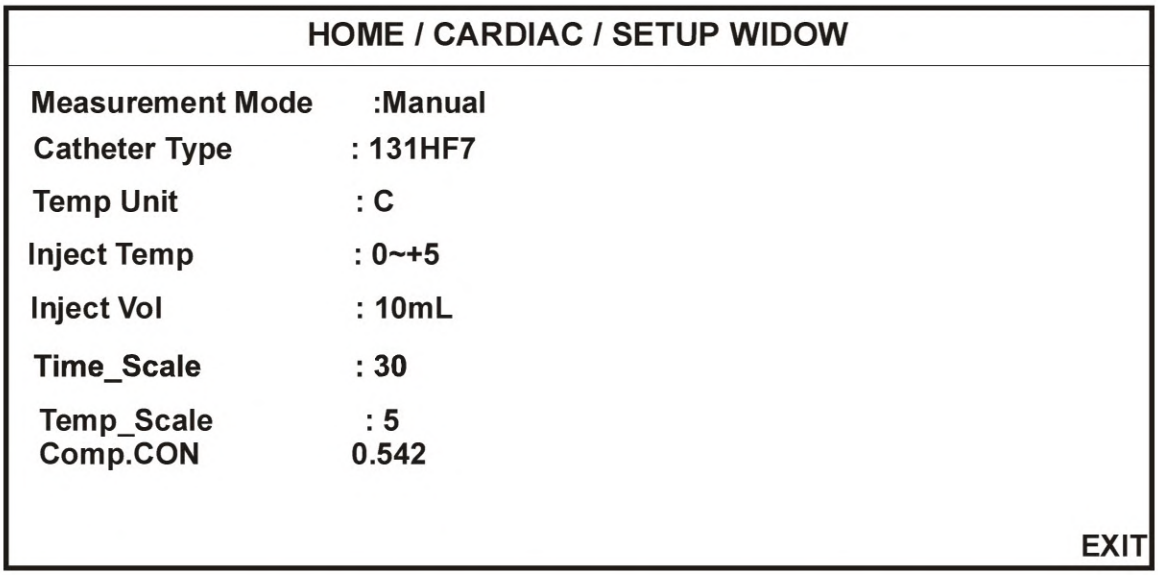



**Figure 15-6 HOME/CARDIAC/SETUP WINDOW**

### Measurement Mode

To start measurement in MANUAL mode, press START key in CARDIAC OUTPUT MENU after you prepared injectate solution.

### Catheter Type

To select catheter type. Available options are “131HF7” and “139HF75P” Edwards catheters and “Simulator”. The last option is intended to use simulator with Comp.Con. of 0.542.

### Comp. Con.

The computation constant changes based on catheter type. Make sure that appropriate catheter is selected, because computation constant directly influences C.O. measurement.

C.O. settings in SETUP menu can be monitored in CARDIAC OUTPUT MENU to check and modify any possible error occurred in data input.

## 15-3 C.O. Alarm Messages

| Message | Explanation |
|---|---|
| **No Cable** | C.O. cable is not connected to the monitor. |
| **Ready for measurement** | The system alerts user to start measurement |
| **Noisy Baseline** | The system is not ready for measurement.<br>(If the message does not disappear after a while, possible cause can be improper placement of the catheter. Make sure that the catheter is placed properly in the patient body). |
| **Start pressed when not ready please wait** | If Start button is pressed before the message "Ready for measurement" appears, the measurement will not be started and this message will appear. To start measurement, wait until "Ready for measurement" is displayed. |
| **Inject now** | Start injection procedure. |
| **Not injected in the expected time** | Injection is not performed long time after Start C.O. is selected. |
| **Minimum not detected in the expected time** | The curve peak has not been detected in the expected time. |
| **Calculating** | C.O. is being calculated. |
| **Curve end not detected!** | The curve end has not been detected in the expected time. |
| **Minimum and End Not Confirmed-Noisy Curve** | C.O. calculation is stopped due to noisy curve |
| **Done! Check edit menu or oldest curve is replaced!** | All five C.O. measurement windows are filled. In order to observe average value and deleting/selecting measurements, refer to Edit window, otherwise start a new measurement the oldest measurement data will be replaced by new one. |

## 15-4 C.O. Cable Cleaning

Disconnect the cable from monitor. Use a soft cloth moistened with 70% isopropyl alcohol to clean the cable and then dry it with a clean cloth.

**⚠Warning⚠**

**Do not sterilize the C.O. cable by autoclave, irradiation or ethylene oxide.**

**⚠Warning⚠**

**To prevent damage, do not immerse the cable in any liquid solution.**

**⚠Warning⚠**

**To avoid environment pollution, catheters shall be disposed in accordance with hospital regulations.**

# Chapter 18 Getting Started

## 18.1 Open the Package and Check

Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage.

- Check for any mechanical damage.
- Check for the existence of the power cable and accessories.

If there is any problem, contact the distributor immediately.

## 18.2 Place the battery fuse

When you use the system for the fist time, you should place the fuse on the rear panel.

## 18.3 Connect the Power Cables

Connection procedure of the AC power line:

- Make sure the AC power supply complies with following specification: 100-240 VAC, 50 /60Hz
- Plug the power cable to power supply socket of the monitor. Connect the other end of the power cable to a grounded power receptacle.

**NOTE:**

**Make sure that the battery indicator lights. If it does not light, check your local power supply and power cable connection. If the problem still exists, contact the local After Sale Service.**

**NOTE:**

**The battery needs to be charged after transportation or storage. If the power supply is not properly connected before turning on the monitor, it may not work properly because of insufficient power. Connect the power supply to charge the battery for about 24 hours.**

## 18.4 Power on the Monitor

Press POWER key to power on the monitor. At the same time a beep sound will be heard and yellow and red indicators light simultaneously. After 30 seconds or more that the system self-tests are performed, the main screen will be displayed and you can start monitoring.

Perform the following settings before monitoring:

- New patient information (For details, please refer to chapter 2, PATIENT INFORMATION )
- Patient mode (Adult/Neonate/ Pediatric) before NIBP measurement
- Alarm sound
- Alarm limits
- Zeroing before IBP measurement
- Pulse oximetry
- RESP

**NOTE:**

**Check all the functions of modules that may be used and make sure that the monitor is in good connection.**

**NOTE:**

**The battery must be recharged after each use to ensure adequate electricity reserve. To do so, you only connect the system to AC INPUT.**

⚠**Warning**⚠

**If any sign of damage is detected, or the monitor displays any error messages, do not use it on any patient. Contact biomedical engineer in the hospital or local After Sale Service immediately.**

## 18.5 Connect Patient Sensors

Connect all the necessary accessories between the monitor and the patient.

**NOTE:**

**For any information about correct connection of accessories, refer to each module's chapter.**

SAADAT Monitors Technical specifications:

| APPLICABLE STANDARDS | |
|---|---|
| EN 60601-1 (1995), EN 60601-1 (2006), EN 601-1-1 (2001), EN 60601-1-2 (2007), EN 60601-1-8 (2007), EN 60601-2-26 (2003), IEC 60601-2-26 (2012), EN 60601-2-27 (2006), IEC 60601-2-27 (2011), EN 60601-2-30 (2000), IEC 80601-2-30 (2009), EN 60601-2-34 (2000), IEC 60601-2-34 (2011), EN 60601-2-49 (2001), IEC 60601-2-49 (2011), EN 1041 (2008), EN 980 (2008), EN 1060-1 (2009), EN 1060-3 (2009), EN 12470-4 (2009), AAMI ISO 81060-2 (2009), ISO 9919 (2005), ISO 80601-2-61 (2011), ISO 21647 (2004), ISO 80601-2-55 (2011), ISO 10993-1 (2003), ISTA 1A (2001) | |
| **CLASSIFICATION** | |
| Protection against electroshock | Class I, Type CF for all modules (except Multi-gas, NIBP and CSM/BFA modules that are BF) (based on IEC 60601-1). |
| Mode of operation | Continues operation equipment |
| Harmful Liquid Proof Degree | IPX1 |
| Method of sterilization and disinfection | Refer to each module's chapters and chapter 21 for detail. |
| Safety of anesthetic mixture | Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. |
| **DISPLAY** | |
| S1600 | TFT COLOR 800 × 600, 10.4” |
| S1800 | TFT COLOR 800 × 600, 12” |
| Zagros | TFT COLOR 800 × 600, 12” |
| Alborz B5 | TFT COLOR 1024 × 768, 15” |
| Alborz B9 | LED COLOR 1366 × 768, 18.5” |
| ZAGROS S | LED COLOR 800 × 600, 12” |
| Waveforms | ECG, SPO2, IBP1, IBP2, RESP/GAS,EEG (Freezable), C.O. |
| Numeric Parameters | HR,PVCs,ST,SPO2, PR, NIBP (SYS, DIA, MAP), IBP1(SYS,DIA,MAP), IBP2(SYS,DIA,MAP), RR, T1, T2, DT, EtCo2, FiCo2, AWRR, EtN2O, FiN2O, EtO2, FiO2, EtAA, FiAA, CSI/BFI, BS%, EMG%, SQI%, C.O, Alarm Limits. |
| Operation Method | Membrane/Keys and rotary knob, Touch Screen(Optional) |
| **ECG** | |
| Leads | Selectable 3 ,5 or 10 Wires<br>For 3 wire: I, II, III<br>For 5 wire :I,II,III,V,aVR,aVF,aVL<br>For 10 wire : I,II,III,V,aVR,aVF,aVL ,C2, C3, C4, C5. C6 |
| Dynamic Range | ± 5 mV |
| Lead Off Current | < 90 nA |
| Gain | 4, 2, 1, 1/2, 1/4, Auto |
| Calibration | 1mV, 0.5 sec |
| Filters | “MONITOR” ( 0.5 - 24 Hz )<br>“NORMAL” ( 0.5 - 40 Hz )<br>“EXTENDED” ( 0.05-100 Hz) |
| CMRR | > 98 dB |
| Internal Noise | < 30 µV RTI |
| Input Impedance | > 5 MΩ |

| | |
|---|---|
| QRS Detection | Duration : 40 to 120 msec<br>Amplitude : 0.25 to 5 mV for Adult/Pediatric<br>0.2 to 5 mV for Neonate |
| Heart Rate Range | 15 - 300 BPM for adult/Pediatric<br>15 - 350 BPM for neonate |
| Accuracy | ±1% or 2 BPM |
| Tall T-Wave | Reject up to 1.2 mV Amp. |
| Pacer Detection/Rejection | Duration : 0.1 - 2 msec<br>Amp: ±2 to ± 700 mV (Without over/undershoot)<br>Reject from heart rate counter<br>Re-insert into ECG to display on screen<br>Ineffective pace rejection: HR:0, Pace: 60<br>HR:60, Pace:60<br>HR:30, Pace:80<br>Beside rejection of atrial paces preceed ventricular paces by 150 or 250 ms |
| Protection | Defibrillator and Electrosurgery |
| Standards | ANSI/AAMI EC-13, EN 60601-2-27 |
| **ANALOG OUTPUT** | |
| Signals | ECG |
| Maximum delay | ≤30 ms |
| Output range | ± 5 V |
| Signal gain | 1000 (1V/mV) |
| Gain accuracy | ± 20 mV |
| Maximum offset | ± 50 mV |
| ECG bandwidth | "MONITOR" ( 0.5 - 24 Hz )<br>"NORMAL" ( 0.5 - 40 Hz )<br>"EXTENDED" ( 0.05-100 Hz) |
| Pacemaker pulses | Amplitude: 5 V (nominal)<br>Duration: 5 ms |
| ECG range | -5 to 5 mV |
| Output impedance | 249 Ω ± 5% |
| Data rate | 400 samples/sec |
| Standards | ANSI/AAMI EC-13 |
| **ARRHYTHMIA ANALYSIS** | |
| Type | ASYS, VFIB, VTAC, RUN, AIVR, COUPLET, BIGEMINY, TRIGEMINY, TACHY, BRADY, AFIB, PAUS, FREQUENT PVCs |
| Learning | Rapid Learning: only 20 seconds required for recognition of dominant rhythm. |
| Method | Real time arrhythmia detection with innovative feature. |
| Memory | Capability of storing the latest 150 ARR event. (waveform and Parameters) |
| **ST ANALYSIS** | |
| Display resolution: | 0.01 mV |
| Measurement Range | -2mv to +2mv |
| Alarm Range: | -2mv to +2mv |

| | |
|---|---|
| **Features:** | **User Adjustable Isoelectric and ST point trending of ST values** |
| **Update period:** | **5 Sec.** |
| **NIBP** | |
| **Measurement method** | **Oscillometric** |
| **Measurement mode** | **Manual/Automatic/Stat** |
| **Measurement time** | **20-25 sec (excluding cuff pressurization time)** |
| **Measurement Range** | **Adult: SYS 30 ~ 255 mmHg<br>DIA 15 ~ 220 mmHg<br>MAP 20 ~ 235 mmHg<br><br>Neonate: SYS 30 ~ 135 mmHg<br>DIA 15 ~ 110 mmHg<br>MAP 20 ~ 125 mmHg<br><br>Pediatric: SYS 30 ~ 240 mmHg<br>DIA 15 ~ 220 mmHg<br>MAP 20 ~ 230 mmHg** |
| **Pressure Transducer accuracy** | **±3 mmHg full range** |
| **Initial Inflation Target** | **Adult 150 mmHg, Pediatric 140mmHg, Neonate 85 mmHg** |
| **Overall System Efficacy** | **Meet ANSI/AAMI SP-10/2002** |
| **Memory** | **500 Records** |
| **SPO2 (Masimo Rainbow Set)** | |
| **Method** | **2 Wave length pulse wave type** |
| **Range** | **SpO2 0 – 100 %<br>SpMet 0 – 99.9 %<br>SpCO 0 – 99 %<br>SpHb 0 – 25.0 g/dL<br>SpOC 0 – 35.0 ml/dL<br>PR 25 – 240 bpm<br>PI 0 – 20.0 %<br>PVI 0 – 100 %** |

| | |
|---|---|
| Accuracy | **Oxygen Saturation**<br>During no motion conditions:<br>Adult/Pediatric: ±2% (SPO2 70 ~ 100%)<br>Neonate: ±3%(SPO2 70 ~ 100%)<br>During motion conditions:<br>Adult/Pediatric/Neonate: ±3% (SPO2 70 ~ 100%)<br>During low perfusion conditions:<br>Adult/Pediatric/Neonate: ±2% (SPO2 70 ~ 100%)<br><br>**Pulse Rate**<br>During no motion conditions:<br>Adult/Pediatric/Neonate: ±3bpm (PR 25 ~ 240)<br>During motion conditions:<br>Adult/Pediatric/Neonate: ±5bpm (PR 25 ~ 240)<br>During low perfusion conditions:<br>Adult/Pediatric/Neonate: ±5bpm (PR 25 ~ 240)<br><br>**Carboxyhemoglobin Saturation**<br>Adult/Pediatric: ±3% (1 - 40)<br><br>**Methemoglobin Saturation**<br>Adult/Pediatric/Neonate: ±1% (1 – 15)<br><br>**Total Hemoglobin**<br>Adult/Pediatric: ±1g/dL (8 – 17) g/dL |
| Resolution | SpO2 1 %<br>SpCO 1.0 %<br>SpMet 0.1 %<br>SpHb 0.1 g/dL<br>PI 0.1%<br>PVI 1%<br>SpOC 0.1 ml/dL<br>PR 1 BPM |
| Please note that pulse-oximetry method (SPO2) is compared to laboratory spectroscopy of sample blood (SaO2). This method measures precision of SPO2 measurement using statistical analysis. Therefore, measurement precision is reliable for at least two third of measurements. | |
| **TEMPERATURE** | |
| Probe Type | YSI 400 Compatible |
| Range | 0 - 50 °C |
| Accuracy | ± 0.2 °C |
| **RESPIRATION** | |
| Method | Impedance |
| Base Resistance | 250 -1250 Ohm |
| Dynamic Range | 0.2 - 2 Ohm |
| Breath Rate Range | 0 - 253 BrPM |
| Accuracy | ±2% or 2 BrPM |
| **IBP** | |
| Channel | 2 (Up to 4) |

| | |
|---|---|
| Measurement Range | SYS -50 ~ 300 mmHg<br>DIA -50 ~ 300 mmHg<br>MAP -50 ~ 300 mmHg |
| Pressure Filter | 8Hz, 16Hz,22Hz selectable |
| Press Sensor Sensitivity | 5 μV / V / mmHg |
| Press Sensor Impedance | 300 ~ 2500 Ohm |
| Resolution | 1 mmHg |
| Accuracy | 2 % or 2mmHg (each one is greater) without transducer |

## Multi-gas (Mainstream)

| | |
|---|---|
| Power supply | 4.5-5.5 VDC, max 1.4W |
| Method | Infrared absorption |
| Measuring mode | Mainstream |
| IRMA Harmful Liquid Proof Degree | IPX1 |
| Et and Fi Parameters | |

Fi and ET are displayed after one breath and have a continually updated breath average.

| | |
|---|---|
| IRMA CO2 | CO2, CO2 waveform |
| IRMA ICU | CO2,O2, 2 selectable waveform |
| IRMA OR | CO2,O2,N2O, Anaesthesia Agent (HAL, ISO, ENF, SEV, DES), 5 selectable waveform, MAC |
| IRMA OR+ | CO2,O2,N2O, Anaesthesia Agent (HAL, ISO, ENF, SEV, DES), 5 selectable waveform, Automatic identification, MAC |

| | |
|---|---|
| Sensor head | 3-10 channel NDIR type gas analyzer measuring at 4-10μm. pressure, temperature and full spectral interference correction. |
| Sensor Dimension (W×D×H) | IRMA CO2/AX+: 38×37×34mm<br>IRMA OR/OR+ (including O2 sensor XL): 38×29×39mm |
| Sensor weight | <25g(cable excluded)<br><38g(O2 sensor XL included, cable excluded) |
| Oxygen sensor | integrated ultra-fast response time galvanic oxygen sensor.<br>>100000 oxygen hours |
| Calibration | No routine calibration required<br>Room air calibration of O2 sensor performed automatically when changing airway adapter (<5sec) |
| Warm-up time | concentrations reported in less than 10s,<br>full accuracy with in 10s for IRMA CO2, 20s for IRMA AX+ and 1 minute for IRMA OR/OR+.<br>(IRMA OR HAL measurement: Full accuracy within 3 minutes) |
| Operating temperature | IRMA CO2: 0 to 40°C<br>IRMA OR /OR+: 10 to 35°C<br>IRMA AX+: 10 to 40°C |
| Storage and transportation temperature | IRMA CO2: -40 to 75°C<br>IRMA OR /OR+: -20 to 50°C<br>IRMA AX+: -20 to 75°C<br>IRMA oxygen sensor XL: -20 to 50°C |
| Operating humidity | 10 to 95% RH, non-condensing |

| | |
|---|---|
| Storage and transportation humidity | 5 to 100% RH, condensing |
| Operating atmospheric pressure | IRMA CO2/AX+: 525 to 1200hPa<br>IRMA OR/OR+: 700 to 1200hPa |
| Storage and transportation pressure | 500 to 1200hPa |
| Surface temperature | max 50°C / 122°F |
| Rise time (@10 l/min) | CO2≤ 90ms<br>O2≤300ms<br>N2O≤300ms<br>HAL,ISO,SEV,ENF,DES≤300ms |
| Delay time | ≤ 140ms |
| Primary agent threshold | 0.15% V |
| Secondary agent threshold | 0.2% +10% of total agent concentration |
| Agent identification time | <20 seconds |
| Total system response time | < 1 second |
| Respiration rate | 0~150BrPM |

Accuracy specifications-during standard conditions

| Gas | Measuring range | | | Accuracy |
|---|---|---|---|---|
| | CO2 | OR | AX+/OR+ | |
| CO2 | 0-15% | 0-10% | 0-10% | ±(0.2%$_{ABS}$+2%$_{REL}$) |
| | | | 10-15% | ±(0.3%$_{ABS}$+2%$_{REL}$) |
| | 15-25% | 10-20% | 15-25% | Unspecified |
| N2O | - | 0-100% | 0-100% | ±(0.2%$_{ABS}$+2%$_{REL}$) |
| HAL,ISO,ENF | - | 0-5% | 0-8% | ±(0.15%$_{ABS}$+5%$_{REL}$) |
| | | 5-12% | 8-25% | Unspecified |
| SEV | - | 0-8% | 0-10% | ±(0.15%$_{ABS}$+5%$_{REL}$) |
| | | 8-15% | 10-25% | Unspecified |
| DES | - | 0-18% | 0-22% | ±(0.15%$_{ABS}$+5%$_{REL}$) |
| | | 18-25% | 22-25% | Unspecified |
| O2 | - | 0-100% | 0-100% | ±(1%$_{ABS}$+2%$_{REL}$) |

Accuracy specification-during all condition

| | |
|---|---|
| CO2 | ±(0.3%$_{ABS}$ or ±4%$_{REL}$) |
| N2O | ±(2%$_{ABS}$ or ±5%$_{REL}$) |
| Single agent | ±(0.2%$_{ABS}$ or ±10%$_{REL}$) |
| Dual agent | ±(0.2%$_{ABS}$ or ±10% of total agent concentration) |
| O2 | ±(2%$_{ABS}$+2%$_{REL}$) |

Note 1 : The accuracy specification is valid for all specified environment conditions, and includes effects from the following interfering gases : N2O, O2, HAL, ISO, ENF, SEV, DES, Ethanol, Isopropyl alcohol, Acetone, Methane, He. See Appendix IV for effects from water vapour partial pressure on gas reading.

**Note 2: The accuracy specification is not valid if more than one gas for IRMA OR and more than two gas for IRMA OR+/AX+ are in the gas mixture.**

**Interfering gas and vapour effects**

| Gas or vapour | Gas level | CO2 | | Agents | N2O |
|---|---|---|---|---|---|
| | | IRMA CO2, OR | IRMA AX+/OR+ | | |
| N2O [4] | 60 vol% | - [1 & 2] | - [1 & 2] | - [1] | - [1] |
| HAL [4] | 4 vol% | - [1] | - [1] | - [1] | - [1] |
| ENF, ISO, SEV [4] | 5 vol% | +8% of reading [3] | - [1] | - [1] | - [1] |
| DES [4] | 15 vol% | +12% of reading [3] | - [1] | - [1] | - [1] |
| Xe (Xenon) [4] | 80 vol% | -10% of reading [3] | | - [1] | - [1] |
| He (Helium) [4] | 50 vol% | -6% of reading [3] | | - [1] | - [1] |
| Metered does inhaler propellants [4] | Not for use with metered dose inhaler propellants | | | | |
| C2H5OH (Ethanol) [4] | 0.3 vol% | - [1] | - [1] | - [1] | - [1] |
| C3H7OH (Isopropanol) [4] | 0.5 vol% | - [1] | - [1] | - [1] | - [1] |
| CH3COCH3 (Acetone) [4] | 1 vol% | - [1] | - [1] | - [1] | - [1] |
| CH4 (Methane) [4] | 3 vol% | - [1] | - [1] | - [1] | - [1] |
| CO (Carbon monoxide) [5] | 1 vol% | - [1] | - [1] | - [1] | - [1] |
| NO (Nitrogen monoxide) [5] | 0.02 vol% | - [1] | - [1] | - [1] | - [1] |
| O2 [5] | 100 vol% | - [1 & 2] | - [1 & 2] | - [1] | - [1] |

**Note 1 : Negligible interference, effect included in the specification " Accuracy all conditions" above.**

**Note 2 : For probes not measuring N2O and/or O2 the concentrations shall be set from host according to the instructions. (IRMA CO2 measures neither N2O, nor O2. IRMA AX+ dose not measure O2.)**

**Note 3 : Interference at indicated gas level. for example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture contaning 5.0 vol% CO2 and 50 vol% Helium, the measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.**

**Note 4 : According to the EN ISO 21647:2004 standard.**

**Note 5 : In addition to the EN ISO 21647:2004 standard.**

| | |
|---|---|
| **Sample Rate** | **20 Hz / channel** |

## Multi-gas (Sidestream)

| | |
|---|---|
| **Power supply** | **4.5-5.5 VDC**<br>**ISA CO2: <1.4 W (normal op.), <1.8 W (peak @ 5 VDC)**<br>**ISA AX+: <1.6 W (normal op.), <2.0 W (peak @ 5 VDC)**<br>**ISA OR+: <2.0 W (normal op.), <2.4 W (peak @ 5 VDC)** |
| **Method** | **Infrared absorption** |
| **Measuring mode** | **Sidestream** |

**Et and Fi Parameters**

**Fi and ET are displayed after one breath and have a continually updated breath average.**

| | |
|---|---|
| **ISA CO2** | **CO2, CO2 waveform** |
| **ISA OR+/AX+** | **CO2,O2, N2O, primary and secondary Agents (HAL, ISO, ENF, SEV, DES)** |

| | |
|---|---|
| Automatic agent identification | ISA OR+/AX+: primary and secondary agent. |
| Sensor head | 2-9 channel NDIR type gas analyzer measuring at 4-10μm. |
| Sensor Dimension (W×D×H) | ISA CO2/AX+: 33x78×49mm<br>ISA OR+: 49×90×100mm |
| Sensor weight | ISA CO2/AX+: 130g (including cable)<br>ISA OR+: 400g (including cable) |
| Calibration | No span calibration is required for the IR bench. An automatic zero reference calibration is performed at startup and then every 24 hours. |
| Compensation | |
| ISA CO2 | Automatic compensation for pressure and temperature.<br>Manual compensation for broadening effects on CO2. |
| ISA OR+/AX+ | Automatic compensation for pressure, temperature and broadening effects on CO2. |
| Warm-up time | |
| ISA CO2 | <10 seconds (concentrations reported and full accuracy) |
| ISA OR+/AX+ | <20 seconds (concentrations reported, automatic agent identification enabled and full accuracy) |
| Operating temperature | ISA CO2: 0 to 50°C<br>ISAOR+ /AX+: 5 to 50°C |
| Storage temperature | -40 to 70°C |
| Operating humidity | <4 kPa H2O (non-condensing)<br>(95 %RH at 40°C) |
| Storage humidity | 5 to 100 %RH (condensing)<br>(100 %RH at 40°C) |
| Operating atmospheric pressure | 52.5 to 120 kPa<br>(Corresponding to a max altitude of 4572 m/15000 feet) |
| Storage atmospheric | 20 to 120 kPa |
| Typical rise time at 50 l/min sample flow | |
| CO2 | ≤ 200 ms (≤ 250 ms for ISA OR+/AX+) |
| N2O | ≤ 350ms |
| Agents | ≤ 350ms |
| O2 | ≤ 450ms |
| Primary agent threshold (ISA OR+/AX+) | 0.15 V%. When an agent is identified, concentrations will be reported even below 0.15 V% |
| Secondary agent threshold (ISA OR+/AX+) | 0.2 V% +10% of total agent concentration |
| Agent identification time (ISA OR+/AX+) | <20 seconds (Typically <10 seconds) |
| Total system response time | < 3 second (with 2m sampling line) |
| Sampling flow rate | 50 ± 10 ml/min |
| Respiration rate | 0~150BrPM |
| Accuracy specifications-during standard conditions | |

| Gas | Measuring Range | Accuracy |
|---|---|---|
| CO2 | 0~15% | ±(0.2 V% +2% of reading) |
| | 15~25% | Unspecified |
| N2O | 0-100% | ±(2 V% +2% of reading) |
| HAL,ISO,ENF | 0-8% | ±(0.15 V%+5% of reading) |
| | 8-25% | Unspecified |
| SEV | 0-10% | ±(0.15 V% +5% of reading) |
| | 10-25% | Unspecified |
| DES | 0-22% | ±(0.15 V% +5% of reading) |
| | 22-25% | Unspecified |
| O2 | 0-100% | ±(1 V% +2% of reading) |

**Accuracy specification-during all condition**

| | |
|---|---|
| CO2 | ±(0.3 kPa + 4% of reading) |
| N2O | ±(2 kPa + 5% of reading) |
| Agents | ±(0.2 kPa + 10% of reading) |
| O2 | ±(2 kPa + 2% of reading) |

**Note 1: The accuracy specification is valid for all specified environment conditions.**

**Note 2: The accuracy specification is not valid if more than tow agents are present in the gas mixture. If more than tow agents are present, an alarm will be set.**

**Interfering gas and vapour effects**

| Gas or vapour | Gas level | CO2 | | Agents | N2O |
|---|---|---|---|---|---|
| | | IRMA CO2, OR | IRMA AX+/OR+ | | |
| N2O [4] | 60 vol% | - [2] | - [1] | - [1] | - [1] |
| HAL [4] | 4 vol% | - [1] | - [1] | - [1] | - [1] |
| ENF, ISO, SEV [4] | 5 vol% | +8% of reading [3] | - [1] | - [1] | - [1] |
| DES [4] | 15 vol% | +12% of reading [3] | - [1] | - [1] | - [1] |
| Xe (Xenon) [4] | 80 vol% | -10% of reading [3] | | - [1] | - [1] |
| He (Helium) [4] | 50 vol% | -6% of reading [3] | | - [1] | - [1] |
| Metered does inhaler propellants [4] | Not for use with metered dose inhaler propellants | | | | |
| C2H5OH (Ethanol) [4] | 0.3 vol% | - [1] | - [1] | - [1] | - [1] |
| C3H7OH (Isopropanol) [4] | 0.5 vol% | - [1] | - [1] | - [1] | - [1] |
| CH3COCH3 (Acetone) [4] | 1 vol% | - [1] | - [1] | - [1] | - [1] |
| CH4 (Methane) [4] | 3 vol% | - [1] | - [1] | - [1] | - [1] |
| CO (Carbon monoxide) [5] | 1 vol% | - [1] | - [1] | - [1] | - [1] |
| NO (Nitrogen monoxide) [5] | 0.02 vol% | - [1] | - [1] | - [1] | - [1] |
| O2 [5] | 100 vol% | - [2] | - [2] | - [1] | - [1] |

| | |
|---|---|
| **Note 1 : Negligible interference, effect included in the specification " Accuracy all conditions" above.** | |
| **Note 2 : Negligible interference with N2O/O2 concentrations correctly set, effect included in the specification " Accuracy all conditions" above.** | |
| **Note 3 : Interference at indicated gas level. for example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture contaning 5.0 vol% CO2 and 50 vol% Helium, the measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.** | |
| **Note 4 : According to the EN ISO 21647:2004 standard.** | |
| **Note 5 : In addition to the EN ISO 21647:2004 standard.** | |
| **Sample Rate** | **20 Hz / channel** |
| **CSM** | |
| **EEG sensitivity** | **±400µV** |
| **Noise** | **<2µVp-p <0.4µV RMS, 1-250 Hz** |
| **CMRR** | **>140dB** |
| **Input impedance** | **>50MΩ** |
| **Sample rate** | **2000 samples/sec(14 bits equivalent)** |
| **CSI and update** | **0-100. Filter 6-42Hz, 1sec. update** |
| **EMG** | **0-100 logarithmic. Filter 75-85 Hz,1 sec. update** |
| **BS%** | **0-100%. Filter 2-42 Hz, 1 sec. update** |
| **Digital output** | **Wireless to CSM card in monitor (ISM 2.4GHz)** |
| **Wireless range** | **Up to 10 meters** |
| **Display size** | **1.3" x 0.7"** |
| **Alarms** | **High/low with user selectable limit** |
| **Artifact rejection** | **Automatic** |
| **Sensor impedance range** | **0-10kOhm I measurement current 0.01µA** |
| **Battery** | **Rechargeable NiMH or 9V Alkaline (6AM6/IEC: 6LR61/ANSI: 1604A)** |
| **Supply current** | **30mA(typical)** |
| **Max. battery lifetime-Alkaline** | **30h(stand alone)**<br>**18h(transmitting wireless)** |
| **Battery recharge time** | **4 Hours (CSMX04 Only)** |
| **Weight** | **4.6 ounces (130 g) with battery** |
| **Dimensions** | **4.6×2.7×1.2"** |
| **Classification** | **Internal power supply Class II, type BF, continuous use Sensors Danmeter Neuro Sensors** |
| **Cable length** | **77" with 14" split** |
| **Mounting options** | **Velcro strip l.7x0.9"** |
| **Memory** | **Data recording 18 hours** |
| **CSM module Environment - Operation** | **Temperature 50-104°F**<br>**Rel humidity 30~75%**<br>**Air pressure 700-1060 hPa** |
| **CSM module Environment-Transport and storage** | **Temperature 50-104°F ***<br>**Rel. humidity 30-95%**<br>**Air pressure 700-1060hPa**<br><br>***If transport without sensors:-4-158°F** |

| BFA | |
|---|---|
| EEG sensitivity | ±450μV |
| Noise | <2μVp-p <0.4μV RMS, 0.25-250 Hz |
| CMRR | >140dB |
| Input impedance | >50MΩ |
| Sample rate | 1000 samples/sec(16 bits equivalent) |
| Brain Function Index (BFI) | 0-100. Filter 1-47Hz, 1sec. update |
| EMG | 0-100. Filter 30-47 Hz,1 sec. update |
| BSR | 0-100. Filter 2-47 Hz, 1 sec. update |
| Signal Quality Index (SQI) | 0-100. 1 sec. update |
| EEG Waveform | ±250μV, user-adjustable, 5 sec |
| Alarms | Auditory and visual, user-adjustable limits |
| Artifact rejection | Automatic |
| Sensor impedance measurement | 0-30kOhm / Manual-Automatic/ measurement current 0.06μA |
| Power supply | 5 VDC |
| Power Consumption | Less than 0.5 W |
| Weight | 100 gr |
| Dimensions | 111×64×25 mm |
| Classification | Class I, type BF, continuous use |
| Sensors | Ambu Neuro Sensors |
| Cable length | 195 cm/ 77" with 35 cm/ 14" split |
| Memory | Data recording (96 hours) |
| Trend | BFI/EMG/SQI/BS, 10 sec. update |
| Environment - Operation | Temperature 5-40°C<br>Rel humidity 20~96%<br>Altitude -200~3000m |
| **Cardiac Output** | |
| Method | Right Heart Thermodilution |
| Range | 0.5-18 l/min |
| Resolution | 0.01l/min |
| Reproducibility | ±3% |
| **RECORDER** | |
| Model | SAADAT Thermal Printer |
| Printing Speed | 6, 12.5, 25, 50 mm/sec |
| Paper | 58mm by 100 foot roll |
| **ALARM** | |
| Sources | Error messages, All other parameter limits |
| Alarm On/Off | Selectable for all parameters |
| Alert | Blinking on Display, Volume Selectable Audio Alarms, Light indicator |

<table>
<tr><td colspan="2">TREND</td></tr>
<tr><td>Sources</td><td>HR,PVCs,ST,AFIB,SPO2, RR, T1, T2, IBP1(SYS,DIA,MAP), IBP2(SYS,DIA,MAP), IBP3(SYS,DIA,MAP), IBP4(SYS,DIA,MAP), EtCo2,FiCo2,AWRR(sidestream, mainstream), EtN20,FiN2O,EtO2,FiO2,EtAA,FiAA(ISO, DES, ENF, HAL, SEV)</td></tr>
<tr><td>Trend Time Save</td><td>96 Hours</td></tr>
<tr><td>Trend Time Interval</td><td>15, 30, 45 Min, 1, 2 and 4 Hours</td></tr>
<tr><td>Resolution</td><td>1 sec</td></tr>
<tr><td colspan="2">INPUT/OUTPUT</td></tr>
<tr><td>Network</td><td>Reliable TCP/IP Protocol Ethernet LAN with RJ45 Interface and WIFI5</td></tr>
<tr><td>Connection</td><td>VGA connector, External Alarm, Wired Remote Control</td></tr>
<tr><td colspan="2">GENERAL</td></tr>
<tr><td>Safety</td><td>Based on IEC 60601-1, Class I</td></tr>
<tr><td>Protection</td><td>Against Electro surgery and Defibrillator (Except BFA/CSM)</td></tr>
<tr><td>AC Power</td><td>100 - 240 VAC, 50/60 Hz , Ip: 0.9 – 0.4 A</td></tr>
<tr><td>Internal Battery</td><td>
<table>
<tr><td></td><td>Sealed Lead Acid, Rechargeable, 12 V, 3.3 AH</td><td>Lithium Polymer 11.1V,4.3AH (Optional)</td></tr>
<tr><td>Charge Time</td><td>16 Hours</td><td>Maximum 8 Hours</td></tr>
<tr><td rowspan="3">Usage</td><td>NOVIN: More than 120 min (Full Charge)</td><td rowspan="3">More than 3.5 Hours</td></tr>
<tr><td>B5: More than 60 min (Full Charge)</td></tr>
<tr><td>B9: More than 1:45 Hours (Full Charge)</td></tr>
</table>
<table>
<tr><td></td><td>Sealed Lead Acid, Rechargeable, 12 V, 1.2 AH</td><td>Lithium Polymer 11.1V,4.3AH</td></tr>
<tr><td>Charge Time</td><td>Maximum 2 Hours</td><td>Maximum 8 Hours</td></tr>
<tr><td>Usage</td><td>ZAGROS S: More than 1 Hour 1</td><td>More than 6 Hours</td></tr>
</table>
</td></tr>
<tr><td>DC Power Plug</td><td>12-14 V DC, Maximum 3 A (Without Recorder)<br>Maximum 6 A (With Recorder)</td></tr>
<tr><td colspan="2">Physical Specification</td></tr>
</table>

| Model | Dimension | Weight (approximately) | |
|---|---|---|---|
| | | with Lithium Polymer Battery | with Sealed Lead Acid Battery |
| NOVIN S1600 | 26(W) × 21(H) × 18(D) | 4 Kg | 5 Kg |
| NOVIN S1800 | 31(W) × 28(H) × 19(D) | 4.5 Kg | 5.5 Kg |
| Zagros | 32(W) × 30(H) × 19(D) | 5 Kg | 6 Kg |
| ALBORZ B5 | 42(W) × 36(H) × 17(D) | 6 Kg | 7 Kg |
| ALBORZ B9 | 45(W) × 36(H) × 17(D) | 7 Kg | 8 Kg |
| ZAGROS S | 347 (W) ×309 (H) ×142 (D) | 4.2 Kg | --- |

## ENVIRONMENTAL

| | |
|---|---|
| Temperature | Operating: 5 to 40 °C<br>Storage & Transport: -20 to 60 °C |
| Humidity | Operating: 20-90 % (Noncondensing)<br>Storage & Transport: 10-95 % (Noncondensing) |
| Altitude | -200 to 3000 m |

# Chapter 20 Accessories

## Information

This chapter lists the recommended accessories used for patient monitor and their part codes.

⚠ **Warning** ⚠

**The accessories listed below are specified to be used for bedside monitor. Manufacturer does not take responsibility for any possible hazard to the patient or monitor if other accessories are used.**

⚠ **Warning** ⚠

**Patient protection against defibrillator effects requires using accessories specified in this chapter.**

## 20.1 ECG Accessories

| | |
|---|---|
| •ECG PATIENT CABLE 3 WIRES | PART. #:10-003 |
| •ECG PATIENT CABLE 5 WIRES | PART. #:10-038 |
| •ECG PATIENT CABLE 10 WIRES | PART. #:10-066 |
| •ECG PATIENT CABLE - Neonate - FMT (E201-3000) | PART. #:10-055 |
| •ECG Lead Wire - Neonate | PART. #:03-122 |

## 20.2 SPO2 (MASIMO & RAINBOW) Accessories

| | |
|---|---|
| • Adult Reusable Sensor, > 30 Kg, (LNCS DCI) | PART.#:18-045 |
| • SPO2 Disposable Sensor, <1 Kg, (LNCS NeoPt) | PART.#:18-046 |
| • SPO2 Disposable Sensor, <3 Kg or >40 Kg, (LNCS Neo) | PART.#:18-047 |
| • SPO2 Reusable Y- Sensor, > 1 Kg (LNCS) | PART.#:18-049 |
| • SPO2 Extension Cable, (Red LNC-10) | PART.#:18-060 |
| •SPO2 Reuseable Sensor,Finger/Toe, Adulat > 30 Kg, Red DCI-dc12 | PART.#:18-055 |
| •SPO2 Extension Cable | PART.#:18-056 |
| •Rainbow R25 Sensor, Adult, Adhesive, >30Kg, (SPO2,SPCo,SPMet) | PART.#:18-062 |
| •Rainbow Resposable R2-25a Sensor, Disposable, Adult, >30Kg, (SPO2,SPHb,SPMet) | PART.#:18-063 |
| •Rainbow Resposable R2-25r Sensor, Reusable, Adult, >30Kg, (SPO2,SPHb,SPMet) | PART.#:18-064 |
| •Rainbow Resposable R2-20a Sensor, Disposable, Pediatric, 10-50KG, (SPO2,SPHb,SPMet) | PART.#:18-065 |
| •Rainbow Resposable R2-20r Sensor, Reusable, Pediatric, 10-50KG, (SPO2,SPHb,SPMet) | PART.#:18-066 |
| •Rainbow DC-3 SC 360, Reuseable, Adult, (SpO2,SpMet,SpHb) | PART.#:18-068 |
| •Rainbow DCI, Reuseable, Adult, (SpO2,SpCO,SpMet) | PART.#:18-069 |
| •M-LNCS DCI, Reuseable, Adult, (SpO2) | PART.#:18-070 |
| •Rainbow R1-20L Pulse Co-Oximeter Sensor, Disposable, Pediatric, ( SPHb ,SPO2,SPMet) | PART.#:18-072 |
| • SPO2 Disposable Sensor, 3-20 Kg, (LNCS Inf) | PART.#:18-075 |

## 20.3 TEMP Accessories

| | |
|---|---|
| • TEMP Probe, Skin, LAUNCH (98ME04GA634) | PART.#:10-083 |
| • TEMP Probe, Rectal, LAUNCH (98ME04GA635) | PART.#:10-084 |

## 20.4 NIBP Accessories

| | |
|---|---|
| • NIBP Infant Cuff, Tuff-Cuff (TCS0813) | PART.#:13-033 |
| • NIBP Infant Cuff, Ultra Check (US0814) | PART.#:13-051 |
| • NIBP Child Cuff, Tuff-Cuff (TCS1219) | PART.#:13-034 |
| • NIBP Child Cuff, Ultra Check (US1320) | PART.#:13-052 |
| • NIBP Small Adult Cuff, Tuff-Cuff (TCS1725) | PART.#:13-035 |
| • NIBP Adult Cuff, Ultra Check (US2635HP) | PART.#:13-050 |
| • NIBP Cuff Reusable – Neonate – Single M5301 Bladderless, Tube Length 20Cm | PART.#:13-077 |
| • NIBP Cuff Reusable – Infant – Single M5302 Bladderless, Tube Length 20Cm | PART.#:13-078 |
| • NIBP Cuff Reusable – Pediatric – Single M5303 Bladderless, Tube Length 20Cm | PART.#:13-079 |
| • NIBP Cuff Reusable – Adult – Single M5304 Bladderless, Tube Length 20Cm | PART.#:13-080 |
| • NIBP Cuff Reusable – Large Adult – Single M5305 Bladderless, Tube Length 20Cm | PART.#:13-081 |
| • NIBP Cuff Reusable – Thigh – Single M5306 Bladderless, Tube Length 20Cm | PART.#:13-082 |
| • NIBP Disposable Cuff, Neonate, 3-5.5cm, PRS (M5541-1# | PART.#:13-085 |
| • NIBP Disposable Cuff, Neonate, 4-8cm, PRS (M5541-2#) | PART.#:13-086 |
| • NIBP Disposable Cuff, Neonate, 6-11cm, PRS (M5541-3#) | PART.#:13-087 |
| • NIBP Disposable Cuff, Neonate, 7-13cm, PRS (M5541-4#) | PART.#:13-088 |
| • PU Helical Bourdon Tube | PART. #:13-073 |
| • PU Legthing Tube | PART. #:13-075 |
| • NIBP Hose 2.5m | PART. #:13-097 |

## 20.5 IBP Accessories

| | |
|---|---|
| • IBP Transducer , MEDEX - .MX860/866 Novatrans | PART.#:16-00 1 |
| • IBP Disposable Dome – MEDEX - MX860/866 Novatrans Dome | PART.#:16-031 |
| • IBP Extension Cable – MEDEX - MX860/866 Novatrans Extension | PART. #:16-032 |
| • IBP Transducer, MEDEX (MX960P1 LogiCal) | PART. #:16-002 |
| • IBP Transducer, Dome, MEDEX (MX960XXP1) | PART. #:16-033 |
| • IBP Extension Cable – MEDEX - MX960 Logical Extension | PART. #:16-034 |
| • IBP Transducer Cable – TRUWAVE | PART.#: 16-037 |
| • IBP Transducer , Disposable – RX only –PX260 | PART.#: 16-036 |
| • IBP Holder | PART.#:16-030 |
| • IBP Extension Cable, for MX960 | PART. #:16-050 |

## 20.6 GAS Accessories (Mainstream)

| | |
|---|---|
| • IRMA CO2 only probe (2++) | PART. # 20-053 |
| • IRMA ICU probe | PART. # 20-021 |
| • IRMA OR probe | PART. # 20-022 |
| • IRMA OR+ probe | PART. # 20-023 |
| • IRMA AX probe | PART. # 20-038 |
| • IRMA AX+ probe | PART. # 20-039 |
| • IRMA Disposable Airway Adapter without O2 port | PART. # 20-025 |
| • IRMA Disposable Airway Adapter with O2 port | PART. # 20-026 |
| • IRMA Disposable Airway Adapter for infant | PART. # 20-035 |
| • IRMA Adapter Cable | PART. # 20-027 |
| • IRMA O2 sensor | PART. # 20-024 |

| | |
|---|---|
| ● Probe Holder for IRMA sensor | PART. # 20-043 |
| ● IRMA & BFA Extension to IRMA Connector | PART. # 19-145 |

## 20.7 GAS Accessories (Sidestream)

| | |
|---|---|
| ● ISA CO2 only probe . | PART. # 20-046 |
| ● ISA AX+ probe | PART. # 20-049 |
| ● ISA OR+ probe | PART. # 20-052 |
| ● Nomoline with luer lock connector. 2 m. Box of 25 | PART. # 20-045 |
| ● Clamp of ISA Module Holder | PART. # 20-055 |

## 20.8 CSM Accessories

| | |
|---|---|
| ● CSM1 Complete Module SET | PART. # 22- 001 |
| ● CSM2 Complete Module SET | PART. # 22-002 |
| ● CSM rechargeable battery-CMX04 | PART. # 22-003 |
| ● CSM power/charger-CSMX05 | PART. # 22-004 |
| ● CSM patient cable-CSMX06 | PART. # 22-005 |
| ● CSM carrying case-CSMX09 | PART. # 22-006 |
| ● CSM procedure pack-CSMX005- Neuro Sensor | PART. # 22-009 |
| ● CSM Neuro Sensors (25pc/bag) -DMX001 | PART. # 22-010 |
| ● CSM clip for patient cable-CSMX007 | PART. # 22-011 |
| ● CSM2 module-CSM004 | PART. # 22-012 |

## 20.9 BFA Accessories

| | |
|---|---|
| ● CSM Accessory Patient Cable, SAADAT | PART. # 22- 028 |

## 20.10 C.O. Accessories

| | |
|---|---|
| ● SAADAT CO Cable | PART. # 19-069 |
| ● Intro-Flex , Percutaneous sheath Introducer – EDWARDS Lifesciences | PART. # 19-061 |
| ● Swan-Ganz CCO/VIP , Thermodilution Catheter , EDWARDS Lifesciences | PART. # 19-062 |

## 20.11 Power Cable

| | |
|---|---|
| ● AC Power Cable | PART. # 03-018 |

# APPENDIX I

## LIST OF MONITOR PARAMETERS (SELECTIONS AND DEFAULTS)

| Menu item | selection | Default |
|---|---|---|
| **The parameters in ECG menu** | | |
| **ECG LEAD** | I,II,III,aVR,aVF,aVL,V,C2,C3,C4,C5,C6 | II |
| **CABLE TYPE** | 3 Wires,5 Wires, 10 Wires | 3 Wires |
| **DISPLAY FORMAT** | Cascade, 2Traces, 4Traces, 7Traces, 12Traces | Cascade |
| **ECG GAIN** | ×0.25,×0.5,×1,×2,×4,AUTO | AUTO |
| **ECG SWEEP** | 12.5,25,50mm/s | 25 |
| **ECG FILTER** | MONITOR,NORMAL,EXTENDED | NORMAL |
| **HR AVERAGE** | 4,8,16SEC | 8SEC |
| **HR SOURCE** | ECG,SPO2,IBP1,IBP2,AUTO | AUTO |
| **BEAT VOLUME** | 1,2,3,4,5,6,7,OFF | 1 |
| **PACE DETECT** | ON,OFF | OFF |
| **ECG CALIB** | ON,OFF | OFF |
| **ALARM LEVEL** | 1,2 | 1 |
| **HR ALARM** | ON,OFF | OFF |
| **HR HIGH ALARM** | HR LOW ALARM +5 to 250 | 150Bpm |
| **HR LOW ALARM** | 30 to HR HIGH ALARM -5 | 50Bpm |
| **The parameters in RESP menu** | | |
| **RESP LEAD.** | RA-LA,RA-LL | RA-LA |
| **RESP GAIN** | ×0.25,×0.5,×1,×2,×4 | ×1 |
| **RESP SWEEP** | 3,6,12.5,25mm/s | 6mm/s |
| **ALARM LEVEL** | 1,2 | 1 |
| **RR ALARM** | ON ,OFF | OFF |
| **RR HIGH ALARM** | RR LOW ALARM +1 to 150 | 25Brpm |
| **RR LOW ALARM** | 5 to RR HIGH ALARM -1 | 5Brpm |
| **APNEA LIMIT** | 10 to 40S, OFF | 10S |
| **The parameters in SPO2 menu** | | |
| **AVERAGE TIME** | 2-4,4-6,8,10,12,14,16 | 8 |
| **SPO2 PLETH SWEEP** | 12.5,25mm/s | 25mm/s |
| **ALARM LEVEL** | 1,2 | 1 |
| **SPO2 ALARM** | ON,OFF | OFF |
| **SPO2 HIGH ALARM** | SPO2 LOW ALARM +1 to 100 (with step 1) | 100 |
| **SPO2 LOW ALARM** | 1 to SPO2 HIGH ALARM -1 (with step 1) | 90 |
| **SPO2 SENSITVITY MODE** | NORMAL , MAX , APOD | NORMAL |
| **PI HIGH ALARM** | PI LOW ALARM +0.1 to 19.0 (with step 0.1) | 19.0 |
| **PI LOW ALARM** | 0.0 to PI HIGH ALARM -0.1 (with step 0.1) | 0.0 |
| **PVI HIGH ALARM** | PVI LOW ALARM +1 to 99 (with step 1) | 99 |
| **PVI LOW ALARM** | 1 to PVI HIGH ALARM -1 (with step 1) | 1 |
| **SpOC HIGH ALARM** | SpOC LOW ALARM +1 to 34.0 (with step 1) | 34.0 |
| **SpOC LOW ALARM** | 1.0 to SpOC HIGH ALARM -1 (with step 1) | 1.0 |
| **SpCO HIGH ALARM** | SpCO LOW ALARM +1 to 99.0 (with step 1) | 10.0 |
| **SpCO LOW ALARM** | 1.0 to SpCO HIGH ALARM -1 (with step 1) | 1.0 |
| **SpMet HIGH ALARM** | SpMet LOW ALARM +0.5 to 99.5 (with step 0.5) | 3.0 |
| **SpMet LOW ALARM** | 0.5 to SpMet HIGH ALARM -0.5 (with step 0.5) | 0.5 |
| **SpHb HIGH ALARM** | SpHb LOW ALARM +0.1 to 24.5 (with step 0.1) | 17.0 |
| **SpHb LOW ALARM** | 0.5 to SpHb HIGH ALARM -0.1 (with step 0.1) | 7.0 |

| The parameters in NIBP menu | | |
|---|---|---|
| **NIBP UNIT** | mmHg , KPa | mmHg |
| **ALARM LEVEL** | 1,2 | 1 |
| **NIBP ALARM** | ON,OFF | OFF |
| **SYS HIGH ALARM** | Adult: SYS LOW ALARM +5 to 255<br>Neonate: SYS LOW ALARM +5 to 135<br>Pediatric: SYS LOW ALARM +5 to 170<br>(with step 5) | Adult: 160mmHg<br>Neonate: 90mmHg<br>Pediatric: 120mmHg |
| **SYS LOW ALARM** | Adult: 30 to SYS HIGH ALARM -5<br>Neonate: 30 to SYS HIGH ALARM -5<br>Pediatric: 40 to SYS HIGH ALARM -5<br>(with step 5) | Adult: 90mmHg<br>Neonate: 40mmHg<br>Pediatric: 70mmHg |
| **DIA HIGH ALARM** | Adult: DIA LOW ALARM +5 to 220<br>Neonate: DIA LOW ALARM +5 to 110<br>Pediatric: DIA LOW ALARM +5 to 150<br>(with step 5) | Adult: 90mmHg<br>Neonate: 60mmHg<br>Pediatric: 70mmHg |
| **DIA LOW ALARM** | Adult: 15 to DIA HIGH ALARM -5<br>Neonate: 15 to DIA HIGH ALARM -5<br>Pediatric: 10 to DIA HIGH ALARM -5<br>(with step 5) | Adult: 50mmHg<br>Neonate: 20mmHg<br>Pediatric: 40mmHg |
| **MAP HIGH ALARM** | Adult: MAP LOW ALARM +5 to 235<br>Neonate: MAP LOW ALARM +5 to 125<br>Pediatric: MAP LOW ALARM +5 to 165<br>(with step 5) | Adult: 110mmHg<br>Neonate: 70mmHg<br>Pediatric: 90mmHg |
| **MAP LOW ALARM** | Adult: 20 to MAP HIGH ALARM -5<br>Neonate: 20 to MAP HIGH ALARM -5<br>Pediatric: 20 to MAP HIGH ALARM -5<br>(with step 5) | Adult: 60mmHg<br>Neonate: 25mmHg<br>Pediatric: 50mmHg |
| **AUTO/MANUAL** | 1min, 2min, 3min,5min,10min,15min,20min,<br>30min,45min, 60min, 90min,<br>2hr,4hr, 6hr, 8hr, 12hr, 16hr, 20hr, 24hr,MANUAL,<br>STAT | MANUAL |
| **The parameters in TEMP menu** | | |
| **TEMP UNIT** | ℃,℉ | ℃ |
| **ALARM LEVEL** | 1,2 | 1 |
| **TEMP ALARM** | ON ,OFF | OFF |
| **T1 HIGH ALARM** | T1 LOW ALARM +1 to 50 | 39 |
| **T1 LOW ALARM** | 0 to T1 HIGH ALARM -1 | 35 |
| **T2 HIGH ALARM** | T2 LOW ALARM +1 to 50 | 40 |
| **T2 LOW ALARM** | 0 to T2 HIGH ALARM -1 | 36 |
| **DT HIGH ALARM** | DT LOW ALARM +1 to 50 | 5 |
| **DT LOW ALARM** | 0 to DT HIGH ALARM -1 | 1.0 |

| The parameters in IBP menu | | |
|---|---|---|
| **IBP UNIT** | mmHg , KPa,cmH2O | mmHg |
| **IBP LABEL** | IBP, ART, PAP, CVP, LAP, RAP, LVP, RVP,ICP | IBP |
| **IBP SWEEP** | 3,6,12.5,25 mm/s | 12.5 mm/s |
| **IBP GRID** | ON, OFF | OFF |
| **IBP FILTER** | 8, 16, 22 Hz | 16 Hz |
| **IBP ALARM** | ON,OFF | OFF |
| **ALARM LEVEL** | 1,2 | 1 |
| **IBP HIGH ALARM** | IBP LOW ALARM +5 to 300 | SYS: 150 mmHg<br>DIA: 100 mmHg<br>MEAN: 115 mmHg |
| **IBP LOW ALARM** | -50to IBP HIGH ALARM -5 | SYS: 80 mmHg<br>DIA: 50 mmHg<br>MEAN: 60 mmHg |
| **ART HIGH ALARM** | ART LOW ALARM +5 to 300 | SYS: 150 mmHg<br>DIA: 100 mmHg<br>MEAN: 115 mmHg |
| **ART LOW ALARM** | -50to ART HIGH ALARM -5 | SYS: 80 mmHg<br>DIA: 50 mmHg<br>MEAN: 60 mmHg |
| **LVP HIGH ALARM** | LVP LOW ALARM +5 to 300 | SYS: 150 mmHg<br>DIA: 20 mmHg<br>MEAN: 80 mmHg |
| **LVP LOW ALARM** | -50 to LVP HIGH ALARM -5 | SYS: 80 mmHg<br>DIA: -5 mmHg<br>MEAN: 20 mmHg |
| **PAP HIGH ALARM** | PAP LOW ALARM +1 to 120 | SYS: 40 mmHg<br>DIA: 20 mmHg<br>MEAN: 30 mmHg |
| **PAP LOW ALARM** | -50 to PAP HIGH ALARM -1 | SYS: 5 mmHg<br>DIA: -5 mmHg<br>MEAN: 0 mmHg |
| **RVP HIGH ALARM** | RVP LOW ALARM +1 to 100 | SYS: 40 mmHg<br>DIA: 15 mmHg<br>MEAN: 30 mmHg |
| **RVP LOW ALARM** | -50 to RVP HIGH ALARM -1 | SYS: 5mmHg<br>DIA: -5 mmHg<br>MEAN: 0 mmHg |
| **CVP HIGH ALARM** | CVP LOW ALARM +1 to 100 | 15 mmHg |
| **CVP LOW ALARM** | -50 to CVP HIGH ALARM -1 | -5 mmHg |
| **LAP HIGH ALARM** | LAP LOW ALARM +1 to 100 | 20 mmHg |
| **LAP LOW ALARM** | -50 to LAP HIGH ALARM -1 | -5 mmHg |
| **RAP HIGH ALARM** | RAP LOW ALARM +1 to 100 | 15 mmHg |
| **RAP LOW ALARM** | -50 to RAP HIGH ALARM -1 | -5 mmHg |
| **ICP HIGH ALARM** | ICP LOW ALARM +1 to 100 | Adult: 10mmHg<br>Neonate: 4mmHg<br>Pediatric: 4mmHg |
| **ICP LOW ALARM** | -40 to ICP HIGH ALARM -1 | 0 mmHg |

| IBP SCALE | | | |
|---|---|---|---|
| IBP | HIGH | LOW +10 TO 300 (with step 10) | 200 |
| | LOW | -50 TO HIGH-10 | -20 |
| | SIGN | (HIGH+LOW )/2 | 90 |
| ART | HIGH | LOW +10 TO 300 (with step 10) | 200 |
| | LOW | -50 TO HIGH-10 | 40 |
| | SIGN | (HIGH+LOW )/2 | 120 |
| PAP | HIGH | LOW +5 TO 300 (with step 5) | 80 |
| | LOW | -50 TO HIGH-5 | -10 |
| | SIGN | (HIGH+LOW )/2 | 35 |
| CVP | HIGH | LOW +5 TO 300 (with step 5) | 30 |
| | LOW | -50 TO HIGH-5 | -10 |
| | SIGN | (HIGH+LOW )/2 | 10 |
| LAP | HIGH | LOW +5 TO 300 (with step 5) | 40 |
| | LOW | -50 TO HIGH-5 | -10 |
| | SIGN | (HIGH+LOW )/2 | 15 |
| RAP | HIGH | LOW +5 TO 300 (with step 5) | 30 |
| | LOW | -50 TO HIGH-5 | -10 |
| | SIGN | (HIGH+LOW )/2 | 10 |
| LVP | HIGH | LOW +10 TO 300 (with step 10) | 200 |
| | LOW | -50 TO HIGH-10 | -20 |
| | SIGN | (HIGH+LOW )/2 | 90 |
| RVP | HIGH | LOW +5 TO 300 (with step 5) | 80 |
| | LOW | -50 TO HIGH-5 | -10 |
| | SIGN | (HIGH+LOW )/2 | 35 |
| ICP | HIGH | LOW +5 TO 100 (with step 5) | 40 |
| | LOW | -40 TO HIGH-5 | -10 |
| | SIGN | (HIGH+LOW )/2 | 15 |

| The parameters in ARR menu | | | |
|---|---|---|---|
| **ARR MONITOR** | | ON, OFF | OFF |
| **ALARM LEVEL** | ASYSTOLE | 1 | 1 |
| | VFIB | 1 | 1 |
| | VTAC | 1 | 1 |
| | RUN | 1, 2, OFF | 1 |
| | AIVR | 1, 2, OFF | 2 |
| | COUPLET | 1, 2, OFF | 2 |
| | BIGEMINY | 1, 2, OFF | 2 |
| | TRIGEMINY | 1, 2, OFF | 2 |
| | TACHY | 1, 2, OFF | 2 |
| | BRADY | 1, 2, OFF | 2 |
| | AFIB | 1, 2, OFF | 1 |
| | PAUS | 1, 2, OFF | 2 |
| | FREQUENT PVCs | 1, 2, OFF | OFF |
| **RATE** | VTAC | 100 to 200 (with step 10) | >=120 |
| | RUN | $VTAC_{rate}$ | >=120 |
| | AIVR | $<VTAC_{rate}-1$ | >=119 |
| | TACHY | 100 to 200 (with step 10) | >=120 |
| | BRADY | 30 to 105 (with step 5) | <=50 |
| **COUNT** | VTAC | 5 to 12 (with step 1) | >=5 |
| | RUN | 3 to $VTAC_{count}-1$ (with step 1) | >=3 |
| | AIVR | - | >=3 |
| | FREQUENT PVCs | 1 to 15 (with step 5) | >=10 |
| **ARCHIVE** | ASYSTOLE | STR, STR/REC, OFF, REC | STR |
| | VFIB | STR, STR/REC, OFF, REC | STR |
| | VTAC | STR, STR/REC, OFF, REC | STR |
| | RUN | STR, STR/REC, OFF, REC | STR |
| | AIVR | STR, STR/REC, OFF, REC | STR |
| | COUPLET | STR, STR/REC, OFF, REC | STR |
| | BIGEMINY | STR, STR/REC, OFF, REC | STR |
| | TRIGEMINY | STR, STR/REC, OFF, REC | STR |
| | TACHY | STR, STR/REC, OFF, REC | OFF |
| | BRADY | STR, STR/REC, OFF, REC | OFF |
| | AFIB | STR, STR/REC, OFF, REC | STR |
| | PAUS | STR, STR/REC, OFF, REC | OFF |
| | FREQUENT PVCs | - | - |
| **The parameters in ST menu** | | | |
| **ST ANALYSIS** | | ON, OFF | OFF |
| **ST ALARM** | | ON, OFF | OFF |
| **ALARM LEVEL** | | 1, 2 | 1 |
| **ST LOW ALARM** | | -2 to ST HIGH ALARM -0.1 | -0.2 |
| **ST HIGH ALARM** | | ST LOW ALARM +0.1 to 2 | 0.2 |
| **EVENT DURATION** | | 15S, 30S, 45S, 60S, OFF | OFF |

| The Parameters in GAS WINDOW(Mainstream & Sidestream) | | | | |
|---|---|---|---|---|
| **CO2 UNIT** | KPa ,%V ,mmHg | | mmHg | |
| **SIGNAL SWEEP** | 3mm/s, 6mm/s, 12.5mm/s, 25mm/s | | 12.5mm/s | |
| **SIGNAL SCALE** | **CO2** | 6%,10%,Auto scale | 10% | |
| | **O2/N2O** | 0-50%,0-100%, Auto scale | 100% | |
| | **AA** | 1,2,3,5,10,20%, Auto scale | 20% | |
| **WAVEFORM** | CO2, O2, N2O, AA | | CO2 | |
| **O2 COMPENSATE** | 1-100 vol%, OFF | | 21% , AUTO | |
| **N2O COMPENSATE** | 0-100 vol% ( ONLY FOR ISA CO2, IRMA2 CO2 ) | | 0% | |
| **GAS UNIT** | KPa ,%V | | %V | |
| **AGENT** | ISO,ENF,HAL,DES,SEV<br>For IRMA(OR+) & IRMA(AX+) & ISA(OR+) & ISA(AX+): AUTO | | HAL<br><br>AUTO | |
| **WORK MODE** | MEASURE, STANDBY | | MEASURE | |
| **GAS/RESP** | GAS, RESP | | GAS | |
| **FIIL SIGNAL** | ON,OFF | | OFF | |
| **CO2 ALARM** | ON,OFF | | OFF | |
| **N2O ALARM** | ON,OFF | | OFF | |
| **AA ALARM** | ON,OFF | | OFF | |
| **O2 ALARM** | ON,OFF | | OFF | |
| **ALARM LEVEL** | 1,2 | | 2 | |
| **APNEA ALARM** | 10s,15s,20s,25s,30s,35s,40s,OFF | | ADULT | NEONATE |
| | | | 30S | 15S |
| **AWRR LOW** | 1~(HIGH-1) | | 5 BrPM | 15 BrPM |
| **AWRR HIGH** | (LOW+1) ~120 | | 30 BrPM | 60 BrPM |
| **EtCo2 LOW** | 0.4~(HIGH-0.1) (%V) | | 2.6%V | |
| **EtCo2 HIGH** | (LOW+0.1)~13(%V) | | 6.5%V | |
| **FiCo2 HIGH** | 0.4~ 13(%V) | | 1.3%V | |
| **EtO2,FiO2 LOW** | 18~(HIGH-1) (%V) | | 50% - ( For IRMA ICU: 25 ) | |
| **EtO2,FiO2 HIGH** | (LOW+1)~105(%V) | | 100% | |
| **EtN2O ,FiN2O LOW** | 1~(HIGH-1) (%V) | | 35% | |
| **EtN2O ,FiN2O HIGH** | (LOW+1)~100(%V) | | 75% | |
| **EtDES ,FiDES LOW** | 0.1~(HIGH-0.1) (%V) | | 5% | |
| **EtDES ,FiDES HIGH** | (LOW+0.1)~18(%V) | | 10% | |
| **EtISO ,FiISO LOW** | 0.1~(HIGH-0.1) (%V) | | 0.8% | |
| **EtISO ,FiISO HIGH** | (LOW+0.1)~5(%V) | | 2% | |
| **EtENF ,FiENF LOW** | 0.1~(HIGH-0.1) (%V) | | 0.5% | |
| **EtENF ,FiENF HIGH** | (LOW+0.1)~5(%V) | | 1.5% | |
| **EtSEV ,FiSEV LOW** | 0.1~(HIGH-0.1) (%V) | | 1% | |
| **EtSEV ,FiSEV HIGH** | (LOW+0.1)~8(%V) | | 3% | |
| **EtHAL ,FiHAL LOW** | 0.1~(HIGH-0.1) (%V) | | 0.5% | |
| **EtHAL ,FiHAL HIGH** | (LOW+0.1)~5(%V) | | 1.5% | |
| **ZERO** | Only for Mainstream | | | |

| The Parameters in CSM/BFA WINDOW | | |
|---|---|---|
| **EEG Gain** | 25uV,50-250uV | 100uV |
| **CSM/BFA ALARM** | ON,OFF | OFF |
| **CSI/BFI LOW** | 1~(HIGH-1) | 35% |
| **CSI/BFI HIGH** | (LOW+1)~100 | 60% |
| **The Parameters in Cardiac Output WINDOW** | | |
| **Catheter Type** | 131HF7,139HF75P,Simulator | 131HF7 |
| **Temp_Scale** | 1,2,4 | 1 |
| **SYSTEM DEFUALT** | | |
| **ALARM VOLUME** | 1,2,3,4,5,6,7 | 1 |
| **CALENDAR** | SOLAR, CHRISTIAN | CHRISTIAN |
| **PATIENT CAT.** | ADUL,NEONATE,PEDIATRIC | ADULT |
| **BED NUMBER** | 1..150 | 01 |
| **TOUCH SOUND** | 1, 2, 3, OFF | 1 |
| **BACK LIGHT** | 1 to 6 ( 1 to 8 for ALBORZ B9 ) | 10” Monitor: 3<br>12” Monitor: 5<br>15” Monitor: 2<br>18.5” Monitor: 7 |

# APPENDIX II
## Messages and Alarms

## Technical Alarms

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **SYSTEM ALARMS** | | | |
| **LOW BATTERY** | insufficient battery charge | Connect the power cable to the system. | When the battery is running out of power, level III alarm is activated. If user does not apply AC power to the monitor, level II and I alarms are displayed respectively as the charge level decreases. |
| **ECG ALARMS** | | | |
| **ECG NO CABLE** | ECG cable is not connected to the system | Connect ECG cable | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ECG NOISE** | ECG signal is noisy or saturated. | Check for any possible sources of signal noise in the area around the cable and electrode, and check the patient for great motion and also check the lead wires. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ECG CHECK LA,RA,LL** | Mentioned leads are not properly connected. | Make sure that mentioned electrode is properly connected | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ECG DEFECT** | ECG module failure | Power off and then on the system .If this message is displayed again the user should contact local After Sale Service. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **ECG CHECK RL OR ALL** | RL or other leads are not properly connected when ECG lead is V, aVR, aVF or aVR. | Make sure that all electrodes and patient cable are properly connected | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ECG CHECK LL OR ALL** | LL or other leads are not properly connected when ECG lead is I | Make sure that all electrodes and patient cable are properly connected | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ECG CHECK LA OR ALL** | LA or other leads are not properly connected when ECG lead is II | Make sure that all electrodes and patient cable are properly connected | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ECG CHECK RA OR ALL** | RA or other leads are not properly connected when ECG lead is III | Make sure that all electrodes and patient cable are properly connected | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ECG CHECK C (C2, C3, C4, C5, C6 )** | C lead is not properly connected to the patient. | Make sure that all electrodes esp. C and ECG cable are properly connected. | Alarm level 2-the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **RESP ERROR MESSAGES** | | | |
| **RESP CHECK LEADS** | The RESP leads are not properly connected. | Make sure that all electrodes, lead are properly connected | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault .Alarm is activated when RR ALARM is "ON". |
| **SPO2 ALARMS** | | | |
| **SPO2 NO PROBE** | SPO2 probe is not connected to the monitor. | Make sure that the probe is correctly connected to the monitor. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **SPO2 PROBE DEFECT** | The SPO2 probe is damaged | Change the SPO2 probe. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **SPO2 PROBE OFF** | SPO2 probe may be detached from the patient. | Make sure that SPO2 probe is properly attached to the patient | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **SPO2 CHECK PROBE** | SPO2 probe is not properly positioned to the patient | Make sure that SPO2 probe is properly connected to the patient (refer to page 6-2). | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. Alarm is activated when SPO2 ALARM is "ON". |
| **SPO2 HIGH AMBIENT LIGHT** | This may be caused by entering environmental light into the probe | Make sure that SPO2 probe is properly connected to the patient (refer to page 6-2). | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. Alarm is activated when SPO2 ALARM is "ON". |
| **SPO2 DEFECT** | SPO2 module failure | Power off and then on the system .If this message is displayed again, the user should contact local After Sale Service. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP ALARMS** | | | |
| **SELF-TEST FAILED** | NIBP hardware module failure | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP LOOSE CUFF** | Cuff is completely unwrapped or no cuff attached. | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **NIBP MODE ERROR** | Adult mode is used instead of neonate mode (while neonate cuff is applied) or an occlusion happens in air way | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP AIR LEAK** | Air leak in cuff, tube or connector | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP AIR PRESSURE ERROR** | Unstable pressure value (e.g. kinked hoses) | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP SIGNAL WEAK** | Very weak patient signal due to a loosely wrapped cuff or extremely weak pulse from patient. | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP RANGE EXCEEDED** | Measuring pressure is more than upper limit (255mmHg)for adult or (135mmHg) for neonate | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP EXCESSIVE MOTION** | Arm movement, noisy signal or irregular pulse(e.g. arrhythmia) | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP OVER PRESSURE SENSED** | Measured pressure exceeds safe software limit, 290 mmHg for adult, 240 mmHg for pediatric and 145mmHg for neonate. (NIBP SAADAT: measured pressure exceeds safe software limit, 290 mmHg for adult and 150 mmHg for neonate) | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **NIBP SIGNAL SATURATED** | Large motion artifact that saturates the amplifier's amplitude handling capability. (This message is not displayed for SAADAT NIBP module). | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP PNEUMATIC LEAK** | Leakage during leak test | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP TIME OUT** | Measurement time exceeds 120 seconds for adult and pediatric or 90 seconds for neonate (SAADAT NIBP: Measurement time exceeds 176 seconds for adult or 90 seconds for neonate) | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **SYSTEM FAILURE** | Error occurs in pump, A/D sampling, pressure transducer or software. | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP NO MODULE** | No NIBP module is installed. | | Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP LOW BATTERY** | The battery charge is not enough to measure NIBP. | | Alarm level is set in NIBP ALARM MENU. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **NIBP MODULE ERROR** | Some errors occur during measurement. | | Alarm level is set in NIBP ALARM MENU. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault. |
| **IBP ALARMS** | | | |

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **IBP1/IBP2 NO SENSOR** | Channel 1 or 2 transducer is not connected. | Check the transducer connection. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **IBP1/IBP2 STATIC PRESSURE** | This condition occurs when the maximum and minimum values of a pulsatile pressure signal (Just for IBP, ART, PAP, RVP and LVP labels) differ by less than 3mmHg.In this case, only Mean pressure is displayed in this state.<br>This message can be caused by the following reason:<br>● A physiological condition e.g. asystole<br>● Transducer turned off to the patient.<br>● A catheter tip lodged against a vessel wall.<br>● A clot on the catheter tip. | ●Check patient and do necessary treatment<br>●Turn on the stopcock to patient and turn it off to the atmospheric pressure.<br>●Follow hospital procedure for dislodging catheter.<br>●Follow hospital procedures for clotted catheters. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

| GAS (Mainstream) ALARMS | | | |
|---|---|---|---|
| **Alarm** | **Cause** | **Solution** | **Explanation** |
| **CO2 SYSTEM FAULT # 1,2,3,4** | Sensor error | Turn the system off and on and if problem still exists, contact the manufacturer service department. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **CO2 REPLACE ADAPTOR** | IR signal low | Change the adaptor | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **CO2 NO ADAPTOR** | There is no adaptor connected to the sensor. | Connect the adaptor | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **CO2 INVALID** | CO2 outside specified accuracy range. | Zero the sensor, if the problem still exists, contact after sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **O2 INVALID** | O2 outside specified accuracy range. | Zero the sensor, if the problem still exists, contact After sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **N2O INVALID** | N2O outside specified accuracy range. | Zero the sensor, if the problem still exists, contact After sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **AGENT INVALID** | Agent outside specified accuracy range. | Zero the sensor, if the problem still exists, contact After sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ACCURACY INVALID, PLEASE ZERO.** | Anesthesia agents are out of accuracy range except O2 | Zero the sensor, if the problem still exists, contact After sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **CO2 INVALID AMBIENT PRES** | Ambient pressure outside operating range. | Turn the system off and on and if problem still exists, contact after sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **CO2 INVALID AMBIENT TEMP** | Internal temperature outside operation range. | Turn the system off and on and if problem still exists, contact after sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **O2 PORT FAILURE** | Adapter O2 port Clogged or plugged. | Connect the adaptor | Alarm level 2- the message is displayed in yellow background. By Pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **REPLACE O2 SENSOR** | O2 sensor lifetime is passed. | Replace O2 sensor by a new one. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

| Message | Cause | Solution | Explanation |
|---|---|---|---|
| **ROOM AIR O2 CALIB REQUIRED** | If the sensor operate for a long time period without being disconnected from the sampling line or the operating temperature for oxygen sensor changes significantly. | Perform room air calibration. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **CO2 NO SENSOR** | Sensor is disconnected from system. | Connect sensor if problem exist again, Contact after sales service of manufacturer. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

| GAS (SIDESTREAM) ALARMS | | | |
|---|---|---|---|
| **Alarm** | **Cause** | **Solution** | **Explanation** |
| **CO2 SYSTEM FAULT #1,2,3,4** | Sensor error | Turn the system off and on and if problem still exists, contact the manufacturer service department. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **CHECK SAMPLING LINE** | IR signal low | Change sampling line | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **SAMPLING LINE CLOGGED** | Sampling line occlusion | Remove obstruction otherwise change the sampling line by a correct one. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **CO2 INVALID** | CO2 outside specified accuracy range. | Zero the sensor, if the problem still exists, turn off and on the system and if again this message appears contact after sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **O2 INVALID** | O2 outside specified accuracy range. | Zero the sensor, if the problem still exists, contact After sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **N2O INVALID** | N2O outside specified accuracy range. | Zero the sensor, if the problem still exists, contact After sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **AGENT INVALID** | Agent outside specified accuracy range. | Zero the sensor, if the problem still exists, contact After sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ACCURACY INVALID, PLEASE ZERO.** | Anesthesia agents are out of accuracy range except O2 | Zero the sensor, if the problem still exists, contact the manufacturer service department. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **CO2 INVALID AMBIENT PRES** | Ambient pressure outside operating range. | Turn the system off and on and if problem still exists, contact after sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **CO2 INVALID AMBIENT TEMP** | Internal temperature outside operation range. | Turn the system off and on and if problem still exists, contact after sales service of manufacturer. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **REPLACE O2 SENSOR** | O2 sensor lifetime is passed. | Replace O2 sensor by a new one. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **O2 SENSOR ERROR** | Sensor failure | Replace O2 sensor by a new one. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **O2 SPAN CALIB REQUIRED** | If the sensor operate for a long time period without being disconnected from the sampling line or the operating temperature for oxygen sensor changes significantly. | Perform room air calibration. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **CO2 ZERO REFERENCE CALIB** | CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low. | Perform automatic zeroing procedure in an environment with CO2 less than 0.80%V. | Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec. |
| **CO2 NO SENSOR** | Sensor is disconnected from system. | Connect sensor if problem exist again, Contact after sales service of manufacturer. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

| CSM ALARMS | | | |
|---|---|---|---|
| **Alarm** | **Cause** | **Solution** | **Explanation** |
| **CSM ELECTROD ALARM** | Placement of neuro sensors and their connections might be in problem. This alarm can also be caused by high frequency instrument. | ●Check all neuro sensors and their connections.<br>●Check the patient cable. If not connected, then connect it. If faulty, replace patient cable.<br>●Check if either of the neuro sensors are disconnected or badly connected.<br>●Replace faulty sensor. | Alarm level 3- the message is displayed in cyan background. By Pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **CSM SQI LOW** | If the impedance of the white or black sensors exceeds 1kΩ, the SQI will fall gradually. Poor impedance conditions may cause the SQI to fall to 50%. Artefacts can have many causes: high frequency instrument, EMG, etc. are typical causes. If SQI falls because of extensive use of high frequency instrument, it will rise as soon as the high frequency instrument is stopped. | ●Check that all neuro sensors and cable connections are correctly connected.<br>●Has the use of any mechanical device that could generate high frequency activity (e.g. patient warmer) been initiated or is any such device in close proximity to the CSM neuro sensors?<br>If possible move disturbing device away from the neuro sensors.<br>●Check grounding of disturbing device.<br>●Reduce the influence from disturbing device by disconnecting CSM Power to let the CSM module run from the battery. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **CSM IMPEDANCE HIGH** | If sensor impedance is > 5kΩ the CSI, BS and EMG will be blanked | ●Check that neuro sensors are not dry.<br>●Check that the skin has been cleaned properly.<br>●Clean and prepare skin as described in this manual and attach new neuro sensors. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault . |
| **CSM LINK OFF** | CSM module is off or it is on but wireless communication is not established. | ●Try to establish wireless communication. Refer to section 12-2-2 | |

| BFA ALARMS | | | |
|---|---|---|---|
| **Alarm** | **Cause** | **Solution** | **Explanation** |
| **BFA ELECTRODE ALARM** | Placement of neuro sensors or their connections might be faulty or the impedance of the sensors may exceed 10k Ω. This alarm can also be caused by high frequency instrument. | ●Check all neuro sensors and their connections.<br>●Check the patient cable. If it is not connected or is faulty, please connect it or replace it.<br>● Check if either of the neuro sensors is disconnected or wrongly connected.<br>●Replace faulty sensor.<br>●Follow the procedure explained in the section "Skin Preparation and Sensor Placement" to clean the skin. | Alarm level 3- the message is displayed in cyan background. By Pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **BFA SQI LOW** | If the impedance of the white or black sensors exceeds 1kΩ, the SQI will fall gradually. Artefacts can have many causes including high -frequency instruments, EMG, etc. | ●Check that all neuro sensors and cables are correctly connected.<br>●Has the use of any mechanical device that could generate high frequency activity (e.g. patient warmer) been initiated or is any such device in close proximity to the CSM neuro sensors?<br>If possible move disturbing device away from the neuro sensors.<br>●Check grounding of disturbing device. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **BFA IMPEDANCE HIGH** | If sensor impedance is > 5kΩ the BFI, %BS and %EMG will be blanked. | ●Check that neuro sensors are not dry.<br>●Check that the skin has been cleaned properly.<br>●Follow the procedure explained in the section "Skin Preparation and Sensor Placement" to clean the skin. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **BFA LINK OFF** | BFA module is off. | ●Connect the module to the monitor through interface cable. | Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. |
| **ST ALARMS** | | | |
| **ST OUT OF RANGE HIGHT** | The ST algorithm has calculated value +1mV outside the high end of the ST measurement range. | ●Check the ISO and ST measuring points.<br>●Observe the patient and treat if clinically indicated. | |
| **ST OUT OF RANGE LOW** | The ST algorithm has calculated value -1mV outside the low end of the ST measurement range. | ●Check the ISO and ST measuring points.<br>●Observe the patient and treat if clinically indicated. | |
| **RECORDER ALARMS** | | | |
| **Rec. Software Error** | Software error | Turn the system off and on .If the problem persists, contact after sales service department of the manufacturer. | |
| **Recorder Fault** | Hardware error | Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer. | |

| Alarm | Cause | Solution | Explanation |
|---|---|---|---|
| **Rec Door Open** | The recorder door is open | Close the recorder door. | |
| **Rec Paper Out** | Recorder paper has been finished. | Insert a new paper roll. | |
| **Printhead Hight Temp** | The thermal head is too hot. | Stop operation for a few minutes. | |
| **Printhead Hight Vol** | Print head voltage is high. | Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer. | |
| **Printhead Low Vol** | Print head voltage is low. | Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer. | |
| **Time out Error** | The recorder can not record. | Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer. | |

# MESSAGES

| Message | Cause | Solution | Explanation |
|---|---|---|---|
| **ECG MESSAGES** | | | |
| **ECG SIGNAL WEAK** | ECG amplitude is lower than standard limit | Check the situation of the chest leads | |
| **SPO2 MESSAGES** | | | |
| **SPO2 SEARCH** | SPO2 is not calculable due to some reasons such as long time motions. | - Connect the sensor to other finger of the patient<br>- Provoke blood recycle<br>- Calm the patient. | In this condition SPO2 parameter is displayed blank. |
| **SPO2 SIGNAL WEAK** | The SPO2 signal amplitude is too weak or undetectable. | Change the place of the probe. | In this condition SPO2 parameter is displayed. |
| **NIBP MESSAGES** | | | |
| **NIBP STOP PRESSED** | NIBP stop key is pressed during measurement. | | |
| **NIBP LEAKAGE O.K** | Successful leakage test | | |
| **IBP MESSAGES** | | | |
| **IBP1/IBP2 ADJUST SCALE** | IBP1 or IBP2 signal is out of display range for about 5 seconds. | Press <AUTO SCALE> in IBP WINDOW. | |
| **IBP1/IBP2 SEARCH** | IBP signal can't be processed by the software because the signal is weak or less pulsatile. | ●Check all IBP measurement setup is suitable or not.<br>●Check patient status and treat him, if necessary | |

| GAS MESSAGES | | | |
|---|---|---|---|
| **Message** | **Cause** | **Solution** | **Explanation** |
| **CO2 SENSOR STANDBY MODE** | Manual setting and if no breath is detected for 30 min and ETCO2 is less than 4 mmHg for more than 30 min or when the monitor does not detect adapter of IRMA sensor for 10 min. | Enter GAS window and set WORK MODE on MEASURE. | |
| **AGENT ID UNRELIABLE**[1] | - The accuracy of the agent identification and measurement could not be guaranteed.<br>-More than 2 aesthetic agents are present in the breathing circuit<br>-High concentrations of solvents, cleaning agents or other interfering gases are present in the breathing circuit | | |
| **C.O. MESSAGES** | | | |
| **No Cable** | C.O. cable is not connected to the monitor. | ●Check that catheter cable is connected to the monitor firmly. | |
| **Ready for measurement** | The system alerts user to start measurement | | |
| **Noisy Baseline** | The system is not ready for measurement.<br>(If the message does not disappear after a while, possible cause can be improper placement of the catheter. Make sure that the catheter is placed properly in the patient body). | ● Make sure that the catheter is placed properly in the patient body. | |

| Message | Cause | Solution | Explanation |
|---|---|---|---|
| **Start pressed when not ready please wait** | If Start button is pressed before the message "Ready for measurement" appears, the measurement will not be started and this message will appear. To start measurement, wait until "Ready for measurement" is displayed. | | |
| **Inject now** | Start injection procedure. | | |
| **Not injected in the expected time** | Injection is not performed long time after Start C.O. is selected. | | |
| **Minimum not detected in the expected time** | The curve peak has not been detected in the expected time. | | |
| **calculating** | C.O. is being calculated. | | |
| **Curve end not detected!** | The curve end has not been detected in the expected time. | | |
| **Minimum and End Not Confirmed-Noisy Curve** | C.O. calculation is stopped due to noisy curve | | |
| **Done! Check edit menu or oldest curve is replaced!** | All five C.O. measurement windows are filled. In order to observe average value and deleting/selecting measurements, refer to Edit window, otherwise start a new measurement the oldest measurement data will be replaced by new one. | | |

# PHYSIOLOGICAL ALARM

| ALARM | SITUATION | VISUAL PROMPTS | AUDIO SOUND |
|---|---|---|---|
| **ECG ALARMS** | | | |
| HR HIGH | Heart rate violates adjusted high limit | ●HR value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| HR LOW | Heart rate violates adjusted low limit | ●HR value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| ECG ASYSTOLE | Heart beat is not detected in last 10 seconds. | ●HR is "00" and blinks<br>●Alarm indicator flashes.<br>● Message "ECG ASYSTOLE" is displayed in red background. | Activated |
| **RESP ALARMS** | | | |
| RR HIGH | Respiration rate violates adjusted high limit | ●RESP value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| RR LOW | Respiration rate violates adjusted low limit | ●RESP value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| APNEA | Non-respiration condition overruns adjusted time | ●Alarm indicator flashes<br>●"RESP APNEA" is displayed in red background. | Activated |
| **SPO2 ALARMS** | | | |

| ALARM | SITUATION | VISUAL PROMPTS | AUDIO SOUND |
|---|---|---|---|
| %SPO2 HIGH | SPO2 violates adjusted high limit | ●SPO2 value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| % SPO2 LOW | SPO2 violates adjusted low limit | ●SPO2 value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| PR HIGH | Pulse rate violates adjusted high limit | ●PR value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| PR LOW | Pulse rate violates adjusted low limit | ●PR value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| PI HIGH | PI violates adjusted high limit | ●PI value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| PI LOW | PI violates adjusted low limit | ●PI value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| PVI HIGH | PVI violates adjusted high limit | ●PVI value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

| ALARM | SITUATION | VISUAL PROMPTS | AUDIO SOUND |
|---|---|---|---|
| PVI LOW | PVI violates adjusted low limit | ●PVI value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| SpOC HIGH | SpOC violates adjusted high limit | ● SpOC value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| SpOC LOW | SpOC violates adjusted low limit | ● SpOC value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| SpCO HIGH | SpCO violates adjusted high limit | ● SpCO value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| SpCO LOW | SpCO violates adjusted low limit | ● SpCO value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| SpMet HIGH | SpMet violates adjusted high limit | ● SpMet value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| SpMet LOW | SpMet violates adjusted low limit | ● SpMet value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| SpHb HIGH | SpHb violates adjusted high limit | ● SpHb value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

| ALARM | SITUATION | VISUAL PROMPTS | AUDIO SOUND |
|---|---|---|---|
| SpHb LOW | SpHb violates adjusted low limit | ● SpHb value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| **NIBP ALARMS** | | | |
| NIBP SYS HIGH | SYS violates adjusted high limit | ● SYS value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP SYS LOW | SYS violates adjusted low limit | ● SYS value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP DIA HIGH | DIA violates adjusted high limit | ● DIA value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP DIA LOW | DIA violates adjusted low limit | ● DIA value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP MAP HIGH | MAP violates adjusted high limit | ● MAP value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| NIBP MAP LOW | MAP violates adjusted low limit | ● MAP value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

| TEMP ALARMS | | | |
|---|---|---|---|
| **ALARM** | **SITUATION** | **VISUAL PROMPTS** | **AUDIO SOUND** |
| T1 HIGH | The temperature (T1) violates adjusted high limit | ● T1 value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| T1 LOW | The temperature (T1) violates adjusted low limit | ● T1 value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| T2 HIGH | The temperature (T2) violates adjusted high limit | ● T2 value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| T2 LOW | The temperature (T2) violates adjusted low limit | ● T2 value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

| ALARM | SITUATION | VISUAL PROMPTS | AUDIO SOUND |
|---|---|---|---|
| DT HIGH | Difference between two channels temperature (DT) violates adjusted high limit | ● DT value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| DT LOW | Difference between two channels temperature (DT) violates adjusted low limit | ● DT value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| **IBP ALARMS** | | | |
| IBP SYS HIGH | SYS violates adjusted high limit | ● SYS value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| IBP SYS LOW | SYS violates adjusted low limit | ● SYS value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| IBP DIA HIGH | DIA violates adjusted high limit | ● DIA value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

| ALARM | SITUATION | VISUAL PROMPTS | AUDIO SOUND |
|---|---|---|---|
| IBP DIA LOW | DIA violates adjusted low limit | ● DIA value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| IBP MEAN HIGH | MEAN violates adjusted high limit | ● MEAN value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| IBP MEAN LOW | MEAN violates adjusted low limit | ● MEAN value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | |
| **GAS ( sidestream & Mainstream ) ALARMS** | | | |
| AWRR HIGH | Respiration rate violates adjusted high limit | ●AWRR value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| AWRR LOW | Respiration rate violates adjusted low limit | ●AWRR value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| EtCo2 HIGH | End Tidal CO2 violates adjusted high limit | ●EtCo2 value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| EtCo2 LOW | End Tidal CO2 violates adjusted low limit | ●EtCo2 value blinks<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

| ALARM | SITUATION | VISUAL PROMPTS | AUDIO SOUND |
|---|---|---|---|
| FiCo2 HIGH | FiCo2 violates adjusted high alarm limits | ●FiCo2 value blinks<br>●Alarm indicator flashes<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| CO2 RESP APNEA | Non-respiration condition overruns in adjusted time | ●Alarm indicator flashes<br>●"CO2 RESP APNEA" blinks in red background. | Activated |
| EtN2O HIGH | End Tidal N2O violates adjusted high limit | ●EtN2O value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| EtN2O LOW | End Tidal N2O violates adjusted low limit | ●EtN2O value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| FiN2O HIGH | FiN2O violates adjusted high limit | ●FiN2O value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| FiN2O LOW | FiN2O violates adjusted low limit | ●FiN2O value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| EtAA HIGH | End Tidal AA violates adjusted high limit | ●EtAA value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

| ALARM | SITUATION | VISUAL PROMPTS | AUDIO SOUND |
|---|---|---|---|
| EtAA LOW | End Tidal AA violates adjusted low limit | ●EtAA value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| FiAA HIGH | FiAA violates adjusted high limit | ●FiAA value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| FiAA LOW | FiAA violates adjusted low limit | ●FiAA value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| EtO2 HIGH | End Tidal O2 violates adjusted high limit | ●EtO2 value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| EtO2 LOW | End Tidal O2 violates adjusted low limit | ●EtO2 value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| FiO2 HIGH | FiO2 violates adjusted high limit | ●FiO2 value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| FiO2 LOW | FiO2 violates adjusted low limit | ●FiO2 value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| **CSM/BFA ALARMS** | | | |

| ALARM | SITUATION | VISUAL PROMPTS | AUDIO SOUND |
|---|---|---|---|
| CSI/BFI HIGH | Cerebral state index violates adjusted high limit | ●CSI/BFI value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in yellow background. | Activated |
| CSI/BFI LOW | Cerebral state index violates adjusted low limit | ●CSI/BFI value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in yellow background. | Activated |
| **ST ALARMS** | | | |
| ST HIGH | ST segment value violates adjusted high limit | ●ST value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |
| ST LOW | ST segment value violates adjusted low limit | ●ST value blinks.<br>●Alarm indicator flashes.<br>● Alarm message is displayed in a background corresponding to its level. | Activated |

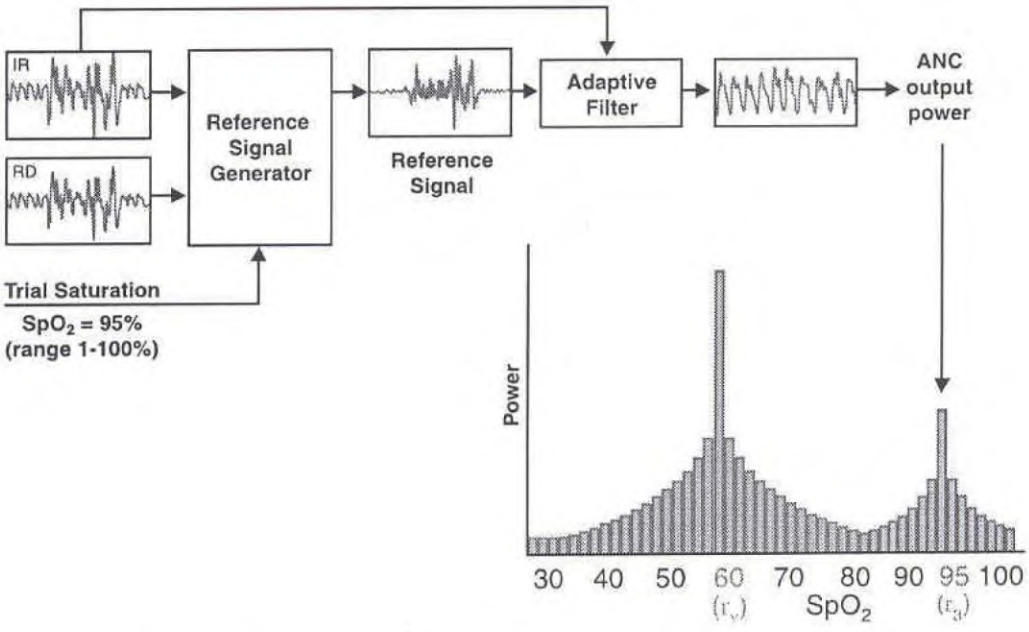
# APPENDIX III
## MASIMO MODULE

### Signal Extraction Technology

### INTRODUCTION

Masimo SET® pulse oximetry is a new and fundamentally distinct method of acquiring, processing and reporting arterial oxygen saturation and pulse rate. As illustrated below, Masimo SET technology enables the power of adaptive filters to be applied to real-time physiologic monitoring by utilizing proprietary techniques to accurately establish a "noise reference" in the detected physiologic signal, thus enabling the direct calculation of arterial oxygen saturation and pulse rate. Because it is not bound by a conventional "red over infrared" ratio approach, the Masimo SET system substantially eliminates the problems of motion artifact, low peripheral perfusion and most low signal-to-noise situations. This greatly extends the utility of SpO2 in high motion, low signal and noise intensive environments.

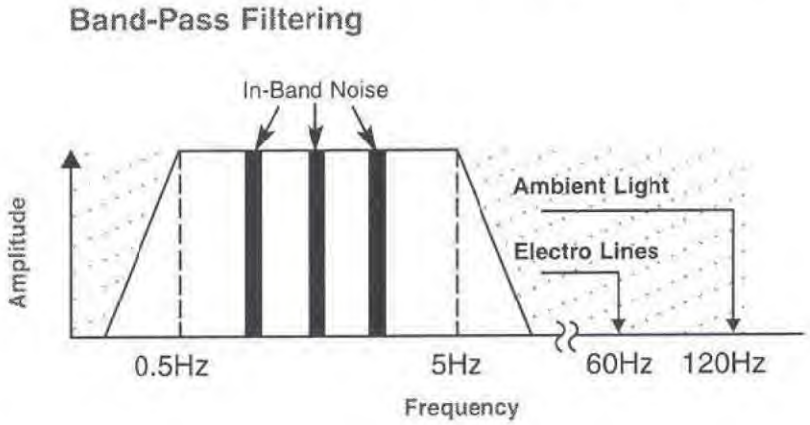
### Discrete Saturation Transformation (DST®) Algorithm




Masimo SET's most powerful algorithm is DST. All algorithms depend upon assumptions. The more assumptions, the weaker the algorithm. DST makes only one assumption - that arterial blood has a higher oxygenation than venous – making it the most powerful pulse oximetry algorithm.

## CONVENTIONAL FILTERS

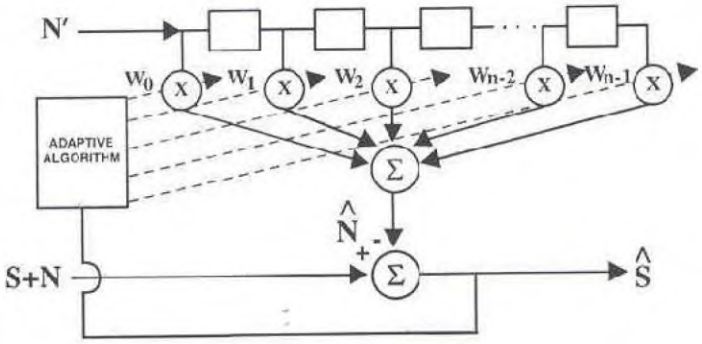
While pulse oximetry is readily accepted as a standard of care in the Operating Room, Recovery Room and most Intensive Care Units, its performance in high motion environments or in patients with low perfusion is substantially less than ideal. The reported high incidence of false alarms due to motion artifact and the inability of conventional pulse oximetry systems to provide information during times of crisis have led to its characterization as a “fair weather friend.” Confronted with the problem of motion artifact, false alarms and poor "signal to noise" environments, medical equipment manufacturers have utilized band-pass filtering in an attempt to address these confounding clinical problems. Band-pass filters, whether in analog or digital form, are designed to allow only a physiologic window of interest to pass while rejecting frequencies outside the desired frequency band. With the advent of Digital Signal Processing (Digital Filtering), the performance of band-pass filtering was improved, but was still unable to address the problem of noise occurring within the bandwidth of interest.




## ADAPTIVE FII

To address the confounding issue of "in-band" noise, a class of filters known as adaptive digital filters has evolved. These filters take advantage of the fact that the construction of the filter itself is contained within the memory of the microprocessor, allowing its multiplication coefficients, symbolized as W0, W1,...Wn-1, to be changed in real time, hence altering the filter's characteristic. Thus, the filter can be tuned “on the fly.” The multiplication coefficients determine whether the frequency components of an input signal should be cancelled (e.g., multiplied by zero) or allowed to pass (e.g., multiplied by one). Given that the filter's coefficients can be rapidly changed, adaptive filters derive their name in their ability to change their filtering characteristics in response to changing in-band noise.

The detected physiologic signal is generally composed of both desired signal (S) and undesired signal (N) or noise portions. To remove the effects of the undesired signal, some knowledge of the noise characteristics, or equivalently its noise reference (N'), must be known. The adaptive filter will adjust its filtering characteristics, so that the noise reference input is transformed into an estimate of the undesired signal portion (N^ ) of the physiologic signal. A subtracter subsequently removes the undesired signal from the physiologic signal to yield an estimate of the desired signal portion (S^ ). The combination comprising the adaptive filter and the subtracter is commonly called an adaptive noise canceller (ANC).

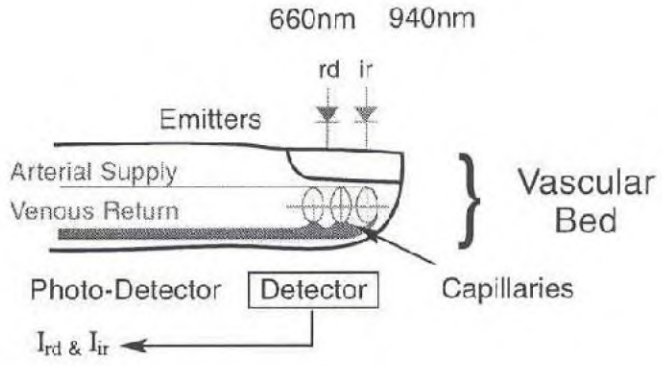



**Adaptive Noise Canceller (ANC) block diagram**

This approach has been widely used in the telecommunications and aerospace industries where a suitable noise reference is accessible. Probes are utilized to obtain a noise reference that can then be used in conjunction with an adaptive noise canceller to extract a desired signal portion from a composite signal containing both desired and undesired signal portions. The problem in applying this technique to physiological monitoring is that a noise reference is rarely available. In addition, both the noise and the desired signal vary from patient to patient and are quickly and continually changing in terms of frequency, amplitude and phase, even within the same patient. In pulse oximetry, the noise reference signal required to make an adaptive noise canceller work in real time was unavailable until the advent of Masimo Signal Extraction Technology.

## CONVENTIONAL PULSE OXIMETRY

The conventional "red over infrared" approach measures the differential optical density of red (o) and infrared (Iir) light as projected through a vascular bed and calculates a ratio (r) of the optical densities. Utilizing the optical density ratio, an arterial oxygen saturation (SpO2) value is empirically reported based on the ratio obtained.



Basis For Measurement:

$$\frac{I_{rd}}{I_{ir}} = \frac{S_{rd} + N_{rd}}{S_{ir} + N_{ir}} = \text{Ratio (r)} \rightarrow \%\ SpO_2$$

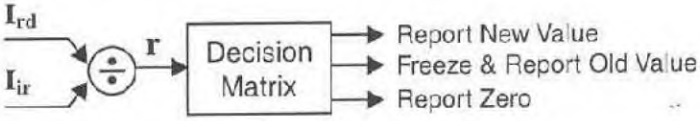
In the presence of patient motion, the optical densities of red and infrared light contain noise portions (Nrd, Nir), thereby falsely altering the optical density ratio and providing an inaccurate saturation value. During periods of routine patient motion or low perfusion, the noise components within the physiologic signals can be much larger than the desired signals (Srd, Sir). In these cases, the optical density ratio is primarily determined by the noise contributions. This represents a situation whereby the noise is simply "drowning out" the desired signal.

In a large noise environment, conventional wisdom holds that pulse oximetry will yield an optical density ratio substantially equivalent to "noise over noise" or a ratio of one. This is equivalent to a saturation value of approximately 82% in most conventional systems.

If: $N >> S$,

Then: $\frac{I_{rd}}{I_{ir}} = \frac{N_{rd}}{N_{ir}} \cong 1 \rightarrow 82\%\ SpO_2$

Confronted with the problems of overwhelming noise and prevented from utilizing adaptive digital filters, pulse oximetry manufacturers have resorted to "managing" false alarms. This can include extending averaging times or employing a decision matrix to freeze when it decides it has detected motion. If the motion persists, it reports zero.



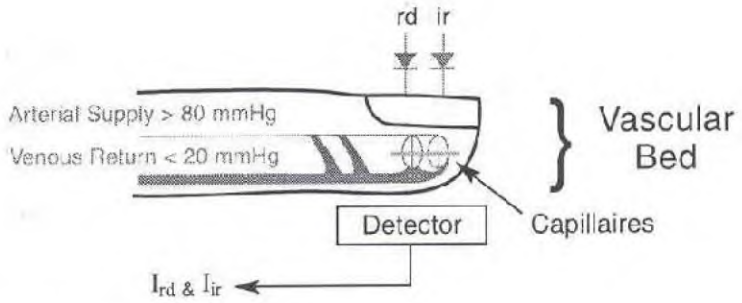

The attempt to treat the "symptom" rather than the "core problem" does not provide clinicians with continuous real-time information and can be unreliable in critical medical situations.

**MASIMO SET® PULSE OXIMETRY**

Masimo Signal Extraction Technology rejects the conventional wisdom and begins with an understanding that during patient motion the venous blood, being at a relatively low pressure, is quite susceptible to the local effects of perturbation during motion. Considering the finger for example, the venous blood in the vascular bed will be easily deformed during motion, representing a significant source of in-band noise within the frequency bandwidth of interest. In addition, the venous blood is a strong absorber of light. Hence, it can represent a significant contributor to the total optical density during motion episodes. Furthermore, the venous blood

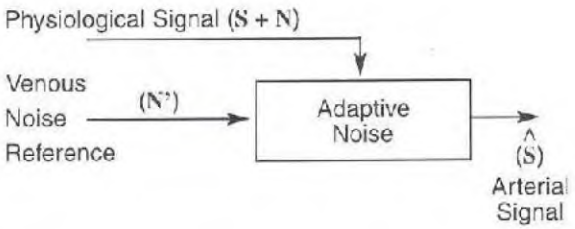
saturation is normally lower than the arterial blood saturation. This explains why saturation values tend to drop in conventional pulse oximeter systems during episodes of patient motion.

During routine patient motions (shivering, waving, tapping, etc.), the resulting noise can be quite substantial and can easily overwhelm a conventional ratio based oximetry system. Having identified the venous blood as a significant contributor to noise during motion, it follows that if the noise reference corresponding to the venous component could be measured, then an adaptive noise canceller might be utilized to cancel its contribution.




## GENERATING A NOISE REFERENCE

The detected physiologic signals in response to both red (Ird) and infrared (Iir) light consist of desired signal portions (Srd, Sir) as well as undesired signal portions (Nrd, Nir). It is commonly understood in pulse oximetry that the desired signal portions are proportional to one another through the arterial optical density ratio (ra). This suggests that one should simply subtract the product of the arterial optical density ratio and the physiologic signal due to infrared light from the physiologic signal due to red light. The resultant is a reference signal that contains only noise portions. This is the noise reference signal (N')




If the arterial optical density ratio is known, one can easily calculate the noise reference as just described. However, if it were known, one could simply calculate the arterial oxygen saturation directly. One would not need to utilize the adaptive noise cancellation process. How does one

then use the power of adaptive filters and noise reference signals for pulse oximetry? The answer lies in the Discrete Saturation Transform® algorithm.

## DISCRETE SATURATION TRANSFORM®

The Discrete Saturation Transform algorithm allows one to separate and, consequently, calculate the optical density ratios that correspond to both the arterial oxygen saturation (ra) and an estimate of the venous oxygen saturation (rv).

These optical densities are not known beforehand but are required to obtain the appropriate reference signals for adaptive noise cancellation. Every optical density ratio, corresponding to the patient's physiological range (SpO2 = 1% to 100%) must be considered. Therefore, the DST® algorithm not only uses a noise reference signal, but a whole family of reference signals. Each reference signal is used in the adaptive noise cancellation process and each yields information regarding the oxygen saturation content of the physiological signals.

| If: | Then: |
|---|---|
| ① $I_{rd} = S_{rd} + N_{rd}$ | $I_{rd} - [I_{ir} \cdot r_a] = [S_{rd} + N_{rd}] - [S_{ir} r_a + N_{ir} r_a]$ |
| ② $I_{ir} = S_{ir} + N_{ir}$ | Substituting $S_{ir} r_a$ for $S_{rd}$, we get: |
| ③ $r_a = \frac{S_{rd}}{S_{ir}}$ | $= [S_{ir} r_a + N_{rd}] - [S_{ir} r_a + N_{ir} r_a]$ |
| $S_{rd} = r_a \cdot S_{ir}$ | $= N_{rd} - N_{ir} r_a$ |
| | $= N'$ (Noise Reference) |

A family of reference signals, N'(r), is generated similar to that of a noise reference signal. The reference signal, as discussed earlier, is the difference between the physiologic signal due to red light (Ird) and the product of an arbitrary optical density ratio (r) and the physiologic signal due to infrared light (Ird). Although there is a family of reference signals, based on the selected optical density ratio, there are only three distinct cases to consider. If one selects an optical density ratio that does not correspond to either arterial or venous oxygen saturation (Case I), the reference signal consists of a desired signal portion and an undesired signal portion. In the adaptive noise cancellation process, such a signal will not only remove the undesired signal portions of the physiologic signal, but also remove the desired signal portions. When an optical density ratio that corresponds to the venous oxygen saturation is selected (Case II), the reference signal only contains signal portions. Therefore, the output of the adaptive noise canceller will consist of the undesired signal portions only. Similarly, when an optical density ratio that corresponds to the arterial oxygen saturation is selected (Case III), the reference signal only contains noise portions. Therefore, the output of the adaptive noise canceller will consist of the desired signal portions only.

$I_{rd} = S_{rd} + N_{rd}$, $I_{ir} = S_{ir} + N_{ir}$

$S_{rd} = r_a S_{ir}$, $N_{rd} = r_v N_{ir}$

r: optical density ratio
$r_a$: arterial optical density ratio
$r_v$: venous optical density ratio

Reference Signal: $N'(r) = I_{rd} - r\, I_{ir}$

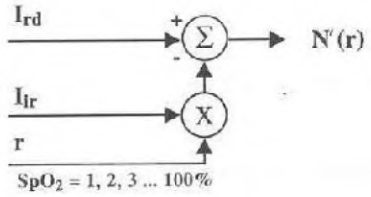
Case I: $r \neq r_a, r_v$ $N'(r) = (r_a - r) S_{ir} + (r_v - r) N_{ir}$

Case II: $r = r_v$ $N'(r_v) = (r_a - r_v) S_{ir}$

Case III: $r = r_a$ $N'(r_a) = (r_v - r_a) N_{ir}$

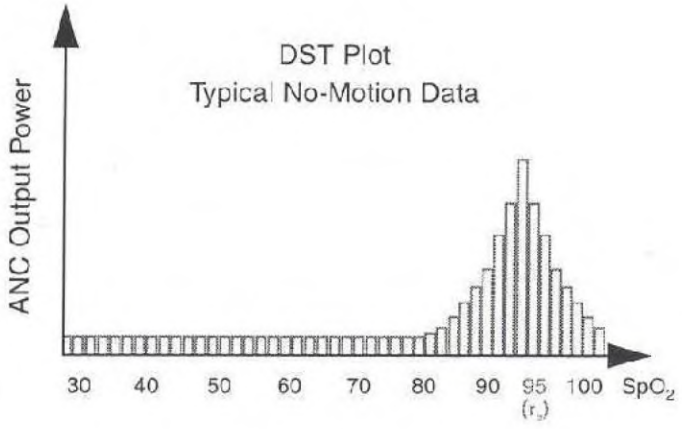
For each selected value of the optical density ratio, the corresponding reference signal is calculated and subsequently processed through an adaptive noise canceller.

$I_{rd} - [I_{ir} \cdot r] = N'(r)$ Or :




When the selected value for the optical density ratio does not correspond to either the arterial or the venous oxygen saturation (Case I), the corresponding output signal will contain little power. When the selected value for the optical density corresponds to either the venous oxygen saturation (Case II) or the arterial oxygen saturation (Case III), the output signal will contain significant output power.

The power output of the adaptive noise canceller represents the probability that the selected optical density ratio, or its corresponding saturation value, is present in the physiologic signal. The output power or probability value is plotted for a series of consecutive ratio values generating the DST transform. During periods of no motion, a singular peak is generated in the DST transform corresponding to the arterial oxygen saturation.



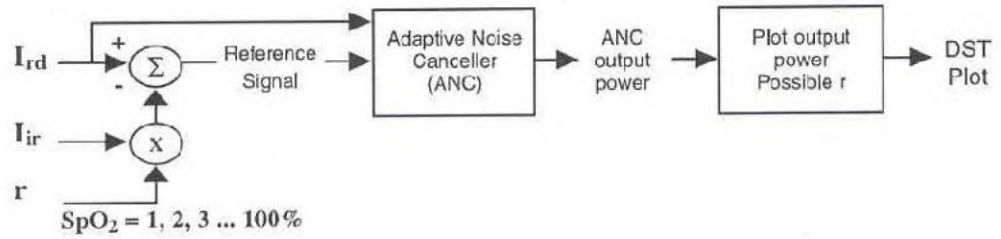
In summary, the procedure for determining the arterial oxygen saturation utilizing Masimo SET processing is as follows:

1) Sweep all optical density ratios that correspond to oxygen saturations of 1% to 100%.

2) Compute the reference signal for each optical density ratio.

3) Measure the output power of the adaptive noise canceller for each reference signal.

4) Identify the appropriate peak in the DST transform that corresponds to the arterial oxygen saturation (largest SpO2 value).




The procedure demonstrates another important feature of Masimo SET pulse oximetry. It is able to calculate the arterial oxygen saturation without first extracting or determining discrete pulses in the physiologic data. For Masimo SET processing, the saturation algorithm is independent of the pulse rate algorithm. This is a significant distinction between Masimo SET systems and conventional pulse oximetry systems where the recognition of a clean pulse is a prerequisite for the calculation of accurate arterial oxygen saturation. Another advantage of Masimo SET technology is that it can monitor arterial oxygen saturation and pulse rate even if the motion starts before the pulse oximeter is turned on. It does not require clean data during instrument start-up.

**Results of clinical research and evaluation performed for determining Rainbow measurement accuracy**

1. SPO2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SPO2, 0-40% SpCO, and 0-15% SpMet against a laboratory CO-Oximeter. SPO2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO2 and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SPO2 and 0.9% SpMet.
2. The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SPO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
3. The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SPO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
4. The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation wich encompasses 68% of the population.
5. The Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
6. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8-17 g/dl SpHb against a laboratory CO-Oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.
7. The following substances may interfere with pulse CO-Oximetry measurements:

   - Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SPO2 and SpCO measurements.
   - Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SPO2 measurements.
   - Very low arterial Oxygen Saturation (SPO2) levels may cause inaccurate SpCO and SpMet measurements.
   - Severe anemia may cause erroneous SPO2 readings.
   - Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
   - Elevated levels of total bilirubin may lead to inaccurate SPO2, SpMet, SpCO and SpHb readings.

# APPENDIX VI
# ISA Design and Theory

## 1. Gas measurements

The measurement of CO2, N2O and anesthetic agents is based on the fact that different gases absorb infrared light at specific wavelengths. The analysis of respiratory gases by the ISA gas analyzers are therefore performed by continuously measuring the infrared light absorption in the gas flow through an infrared spectrometer. Oxygen, on the other hand, does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods.

### The gas analysis

At the heart of an ISA gas analyzer, the SIGMA spectrometer is seated. The SIGMA spectrometer uses a proprietary broadband infrared radiation source to transmit light through the gas sample. Before reaching the gas sample, the light path is intersected by narrowband optical filters that only let through light corresponding to selected wavelength peaks of the measured gases. At the other end of the light path, a sensor detects the portion of the light that is not absorbed by the gas. The amplitude of the detector output is an inverse function of the gas concentration. Thus, at a concentration of zero, the amplitude is at its maximum.

If the gas sample is a mixture of several components that absorb light at the same wavelength, such as a mixture of two anesthetic agents, the absorbed radiation will be the sum of the absorption of the agents. To determine the concentration of each of the individual gases, several filters have to be used. The ISA gas analyzers therefore uses the SIGMA spectrometer, which contains up to nine different narrowband filters to facilitate simultaneous measurement of CO2, N2O and a mixture of any two of the five anesthetic agents.

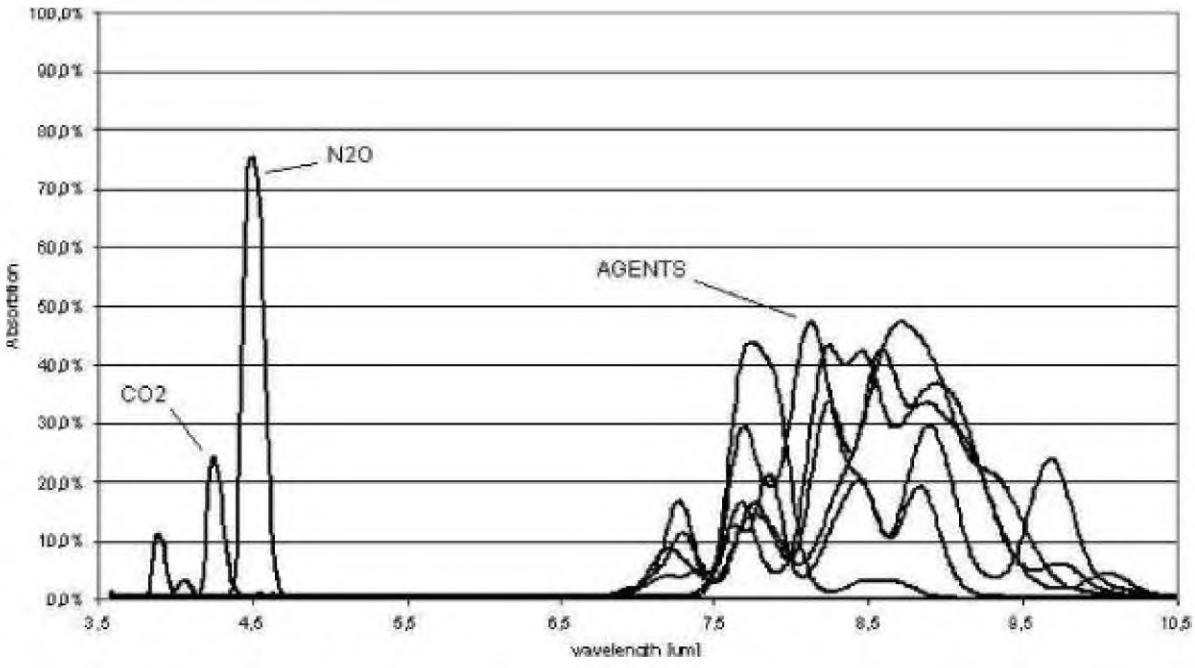



***Figure 1.*** *Gas absorption spectra*

The selection of the optical filters within the spectrometer is crucial to the characteristics and performance of the gas analyzers. The SIGMA spectrometer uses the strong absorption peaks at 4.2 and 4.5 µm for CO2 and N2O measurements and five wavelengths in the 8 to 10 µm long wave infrared range (LWIR) for the anesthetic agent calculations. The LWIR contains strong absorption peaks for the anesthetic agents and negligible interference from other common respiratory gases, such as alcohol and acetone, that could degrade measurement accuracy.

In addition to the measurement filters, two optical filters appropriately located within the 4 to 10 µm range are used as references.

## 2. Oxygen measurement

Oxygen does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods. The ISA OR+ analyzer is fitted with a paramagnetic oxygen sensor, and the ISA AX+ module is designed be fitted with either a paramagnetic or a galvanic (fuel-cell) oxygen sensor.

### Paramagnetic oxygen analysis

Paramagnetic oxygen analyses are based on measurements of the attractive force exerted by a strong magnetic field applied to the oxygen molecules in a gas mixture. The paramagnetic analyzer distinguishes oxygen from other gases as a function of their magnetic susceptibility. Due to its paramagnetic nature, oxygen is attracted into the magnetic field, while most other gases are not. On a scale, where oxygen is assigned the value 100, most other gases have a magnetic susceptibility of close to zero.

### The Servomex sensor

An oxygen sensor well suited for the ISA gas analyzer is the PM1116 paramagnetic oxygen sensor from Servomex. In this sensor, a symmetrical non-uniform magnetic field is created. If oxygen is present, it will be attracted into the strongest part of this field. Two nitrogen-filled glass spheres are mounted on a rotating suspension within the magnetic field. Centrally on this suspension, a mirror is mounted. A light beam projected on the mirror is reflected onto a pair of photocells. Oxygen attracted into the magnetic field will push the glass spheres from the strongest part of the magnetic field, causing the suspension to rotate. When this rotation is detected by the photocells, a signal is generated and passed to a feedback system. The feedback system will pass a current around a wire mounted on the suspension, causing a restoring torque that keeps the suspension in its original position. The current flowing around the wire is measured. This current is directly proportional to the oxygen concentration.

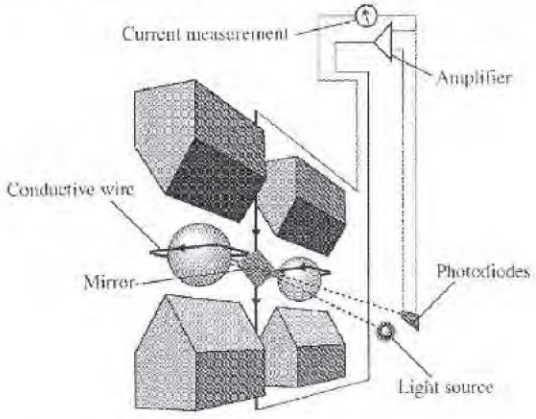



***Figure 2.*** *Oxygem measurement with Servomex PM1116 paramagnetic oxygen sensor.*

The most important benefits of the paramagnetic oxygen sensor are:

•Fast rise time

•High stability and accuracy

•No chemicals to replace or renew

•Low maintenance requirements

Galvanic oxygen analysis

As an alternative to the paramagnetic sensor, the ISA gas analyzer is designed be fitted with a galvanic oxygen sensor. A galvanic fuel-cell oxygen sensor uses a membrane that allows diffusion of O2 into the sensor. Inside the sensor, there is a sensing electrode (cathode) made of a noble metal such as gold or platinum, and a working electrode made of a base metal such as lead or zinc. The electrodes are immersed in an electrolyte. Fuel-cell oxygen sensors are current generators and do not require any external power supply. By connecting a resistor between the anode and the cathode, a voltage proportional to the O2 concentration is generated.

Since the measurement involves a chemical reaction, the fuel cell is gradually consumed during the process (also when the equipment is not in use), and requires replacement at regular intervals.

## 3. Sampling

A sidestream gas analyzer continuously removes a gas sample flow from the respiratory circuit, for example a nasal cannula, a respiratory mask or the Y-piece of an intubated patient. The gas sample is fed through a sampling line to the gas analyzer. The sampled gas is usually warm and humid, and cools down in contact with the wall of the sampling line. Water therefore condenses in form of droplets on the inner wall of the sampling line. These droplets could potentially occlude the sampling line and interfere with the gas measurement.

**The Nomoline**

To overcome the shortfalls of current gas sampling solutions, the Nomoline sampling line has been developed for the ISA sidestream gas analyzers.

**Warning**: Use only Nomoline sampling lines manufactured by PHASEIN.

Unlike traditional solutions that remove water vapor and collect water in a container, the Nomoline sampling line incorporates a unique water separation section, the NOMO section. This section is made of a special polymer and a hydrophobic bacteria filter that removes water vapor and aspired or condensed water. Water and water vapor passes through the membrane-like surface of the sampling line and evaporates into the surrounding air, while leaving O2, CO2 and anesthetic gases unaffected.

***Figure 3.*** *The Nomoline (no moisture) sampling line.*

To protect the ISA analyzer, the Nomoline includes a filter with the bacterial filter efficiency of ≥ 99.9980 %. It is important to be aware that secretions and nebulized medications may attach to the surface of the bacteria filter, and may cause clogging.

**Warning:** Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

The Nomoline sampling lines are specially designed for 50 ml/min low sample flow applications. The Nomoline has a very low dead space that results in an ultra-fast rise time, making measurements of CO2, N2O and anesthetic agents possible even at high respiratory rates. ISA sidestream gas analyzers are therefore suitable for adult, pediatric and infant patients.

The Nomoline sampling line is available in 2 and 3 meter versions and comes with a male Luer Lock type connector to work with different kinds of third-party sampling equipment, including patient interfaces for intubated, nasal and oral sampling. Although the selection of optimal patient interfaces is crucial, the Nomoline sampling line fits in any normal configuration.

**Flow control**

During normal operation, a sidestream gas analyzer is continuously fed with a small sample gas flow. To pull the gas through the sampling line and maintain a steady flow, a high-precision flow control system is required. In ISA sidestream gas analyzers, the flow control system consists of an integrated micro pump, a zero valve and a flow controller. The pump is fitted with a low-power brushless motor having three miniature ball bearings to ensure trouble free operation without regular maintenance. Its balanced shaft design and integrated pneumatic filter virtually eliminate pressure and flow variations.

**System response**

In any sidestream gas monitoring system, there are three major time parameters involved:

•Total system response time

•Delay time

•Rise time

When designing a sidestream gas monitoring system, the physical characteristics of several components have to be considered. Parameters such as sampling volume, tubing material, tubing diameter and the physical design of the sampling interfaces play decisive roles in determining the responsiveness of the system.

Generally, the total system response time equals the delay time plus the rise time.

The delay time is defined as the time required for a step function change at the sampling site to result in 10% of the final value. Parameters affecting the delay time are the sample flow rate, tubing length and tubing inner diameter. In mainstream gas monitoring, where no tubing exist, the delay time is virtually zero, whereas a sidestream system has a sample delay time of a few seconds.

The rise time is defined as the time required for a step function change at the sampling site to bring about a rise from 10% to 90% of the final gas concentration value.

## 4. Gas data concentration

### Gas measurement units

Gas concentration is reported in units of volume percent. The concentration is defined as:

$$\% \text{ gas} = \frac{\text{Partial pressure of gas component}}{\text{Total pressure of gas mixture}} * 100$$

The total pressure of the gas mixture is measured by a cuvette pressure sensor in the ISA gas analyzer.

For conversion to other units, the actual atmospheric pressure sent from the ISA sidestream analyzer may be used, e.g.

CO2 in mmHg = (CO2 concentration) x (atm. pressure value in kPa from ISA) x (750 / 100).

Example: 5.0 vol% CO2 @ 101.3 kPa Ö 0.05 x 101.3 x 750 / 100 = 38 mmHg

### Effects of humidity

The partial pressure and the volume percentage of CO2, N2O, O2 and anesthetic agents depend on the amount of water vapor in the measured gas. The O2 measurement will be calibrated to show 20.8 vol% at actual ambient temperature and humidity level, instead of showing actual partial pressure. 20.8 vol% O2 corresponds to the actual O2 concentration in room air with 0.7 vol % H2O concentration (at 1013 hPa this equals for example 25°C and 23% RH). The measurement of CO2, N2O, and anesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.

In the alveoli of the patient, the breathing gas is saturated with water vapor at body temperature (BTPS).

When the breathing gas is sampled, and passing the sampling line, the gas temperature will get close to the ambient temperature before reaching the ISA sidestream gas analyzer. As the Nomoline

removed all condensed water, no water will reach the ISA gas analyzer. The relative humidity of the sampled gas will be about 95%.

If CO2 values at BTPS are required, the following equation can be used:

EtCO2 (BTPS) = EtCO2 * ( 1 – ( 3.8 / Pamb) )

where:

EtCO2 = EtCO2 value sent from ISA [vol %] Pamb = Ambient pressure sent from ISA [kPa]

3.8 = Typical partial pressure of water vapor condensed between patient circuit and ISA [kPa]
EtCO2(BTPS) = EtCO2 gas concentration at BTPS [vol%]

O2 is assumed to be room air calibrated at a humidity level of 0.7 vol% H2O.

**Spectral broadening**

The presence of oxygen and nitrous oxide can cause some interference in the CO2 measurement. This is known as spectral broadening.

**Nitrous oxide, N2O:**

ISA sidestream analyzers capable of N2O measurements automatically compensates for spectral broadening caused by nitrous oxide.

When using an ISA sidestream gas analyzer without this capability, the current nitrous oxide concentration should be transmitted to the ISA Gas analyzer using the SetN2O command.

For most applications, sufficient accuracy in CO2 measurement will be achieved by setting N2O to one standard concentration used always with N2O in use, as recommendation 50 vol%, SetN2O 50 for actual concentrations in the span 30 – 70 vol% N2O. When N2O is not in use send SetN2O 0. The default value is 0.

By using this range, see table below, the maximum CO2 error with N2O compensation on (30-70%) will be limited to 3.2 % relative.

| N2O range | N2O parameter |
|---|---|
| 0-30 vol% | 0 |
| 30-70 vol% | 50 |

**Oxygen, O2:**

ISA sidestream analyzers capable of O2 measurements automatically compensates for spectral broadening caused by nitrous oxide.

When using an ISA sidestream gas analyzer without this capability, the current nitrous oxide concentration should be transmitted to the ISA Gas analyzer using the SetO2 command.

For most applications, sufficient accuracy in CO2 measurement will be achieved by dividing the oxygen concentration into three ranges: "high", "medium" and "low". By using these ranges, along with the SetO2 values in the table below, the maximal relative CO2 error will be limited to 1.2%.

| O2 range | O2 parameter |
|---|---|
| 0-30 vol% | 0 |
| 30-70 vol% | 50 |
| 70-100 vol% | 85 |

**5. Interfering gas and vapor effects**

| Gas or vapor | Gas level | CO2 | | Agents | N2O |
|---|---|---|---|---|---|
| | | ISA CO2 | ISA AX+ | - [1] | - [1] |
| N2O [4] | 60 V% | - [2] | | - [1] | - [1] |
| HAL [4] | 4 V% | - [1] | | - [1] | - [1] |
| ENF , ISO , SEV [4] | 5 V% | +8 % of reading [3] | | - [1] | - [1] |
| DES [4] | 15 V% | +12 % of reading [3] | | - [1] | - [1] |
| Xe (Xenon) [4] | 80 V% | -10 % of reading [3] | | - [1] | - [1] |
| He (Helium) [4] | 50 V% | -6 % of reading [3] | | - [1] | - [1] |
| Metered dose inhaler propellants [4] | Not for use with metered dose inhaler propellants | | | | |
| $C_2H_5OH$ (Ethanol) [4] | 0.3 V% | - [1] | - [1] | - [1] | - [1] |
| $C_3H_7OH$ (Isopropanol) [4] | 0.5 V% | - [1] | - [1] | - [1] | - [1] |
| $CH_3COCH_3$ (Acetone) [4] | 1 V% | - [1] | - [1] | - [1] | - [1] |
| CH4 (Methane) [4] | 3 V% | - [1] | - [1] | - [1] | - [1] |
| CO (Carbon monoxide) [5] | 1 V% | - [1] | - [1] | - [1] | - [1] |
| NO (Nitrogen monoxide) [5] | 0.02 V% | - [1] | - [1] | - [1] | - [1] |
| O2 [5] | 100 V% | - [2] | - [2] | - [1] | - [1] |

**Note 1:** Negligible interference, effect included in the specification "Accuracy, all conditions" above.

**Note 2:** Negligible interference with N2O / O2 concentrations correctly set, effect included in the specification "Accuracy, all conditions" above.

**Note 3:** Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO2 and 50 vol% Helium, the actual measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.

**Note 4:** According to the EN ISO 21647:2004 standard.

**Note 5:** In addition to the EN ISO 21647:2004 standard.

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POOYANDEGAN RAH
SAADAT Co.

STF-DoC-v0

# EC Declaration of Conformity

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## Product Identification

**SAADAT Patient Care Monitors**

**Novin S1600**, **Novin S1800**, **Zagros**

**ALBORZ B5**, **ALBORZ B7**, **ALBORZ B9**

Class II b (MDD, Annex IX)

## Conformity Assessment

**Route to Compliance**: Annex II.3 of MDD, 93/42/EEC the Medical Devices Directive

We hereby declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacture.

## Notified Body

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**New Issue date:** 10/03/2012 **Expiration date:** 22/10/2015