

REVISION	
REV	DESCRIPTION
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# CPU Software Requirements Specification PB560

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# 1 REVISION HISTORY

Revision	Author	Change Description
A		Initial Release
B		Corrections and USB functions additions.
C		Corrections
D		Corrections: Default for Exh sens change to 75%, update of the translation file
E		Exhalation valve control update
F		Trigger specification update
G		CDP-RMS-0000156 software update changes, including high pressure alarm.
H		Revised to include updated GUI strings.
J		CDP-RMS-0000420 software update changes, including Circuit Check, RR = 1, Inspiratory Time, OP Trigger and ESENS.
K		Revised to address SCR126 and SCR148.
L		Revised to support compliance to IEC 60601-8:2006.
M		Revised due to SCR 139 and 177
N		Revised due to SCR 189 & SCR 201. Added a setup 2 menu and an alarm tone setting. Modified FIO2 ranges.
P		Added Restore Defaults setting.
R		As per CDP-0012095, added the following changes: Added negative flow detection requirements for SCR 194 Added copyright to the startup screen for SCR 216 Added section SFSYST13.1 for SCR 211 Added a requirement for an approved or unknown battery. SCR 217
T		As per CDP-0006093, corrected Monitored Insp. Time and Monitored Exh. Time Ranges. Update Table of Contents page numbers.
U		As per CDP-0014971, added the following changes: Modified High pressure limit to 90, Low pressure limit to 82 and changed High PIP alarm setting under VC A/C and VSIMV to 90. SCR 195 Changed Max Leak medium priority to a high priority alarm. SCR 206 Added Insp sensitivity helper text requirement. SCR 218 Updated the occlusion and check exh valve validation delay. SCR 219

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		Updated AC power disconnect and DC disconnect alarm to only display an alarm message. SCR 220
V	██████	Updated the AC power disconnect alarm's cancel conditions to remove both the informational and medium priority alarm. SCR 220
W	██████	Updated VTE to include averaging base on SCR 253, AC and DC Power disconnection alarms based on SCR 220, Low Battery and Empty battery alarms base on SCR 247. Also added Low priority LED and alarm tone specifications.
Y	██████	SCR 247 - Update End of Battery and Low Battery requirements to check if the battery is installed or not.
AA	██████	SCR 258 - Update End of Battery and Low Battery requirements to add additional alarm conditions to eliminate multiple alarm declarations
AB	██████	SCR 258 - Updated the Low and Empty Battery requirement to eliminate an issue where the Low and Empty Battery alarm can declare a High Priority alarm even though the ventilator is plugged into AC.

## 2 INTRODUCTION

### 2.1 Objective

The objective of this document is to specify the functional requirements for the CPU software for the PB560.

Note: In the PB520 SRS, it focuses on the difference with PB560 requirements. Thus all the CPU software requirements from PB560 will be applicable for the PB520 unless the requirement is specific only to the PB520, which will reside in the PB520 SRS.

### 2.2 Scope

This document is the Software Requirements Specification for the PB 560 CPU software.

### 2.3 Reference Documents

Reference	Part Number	Revision	Document Title
[R1]	10035478	N/A	General Development Plan, PB560-520

### 2.4 Acronyms and abbreviations

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% SPONT: % of spontaneous breaths for a 24 hours period.  
 24V CHECK: SUPPLY voltage displayed in maintenance menu.  
 AC: AC electrical supply  
 AC POWER FAIL: Alarm occurring in case of main supply failure  
 AC SELECTED: Logical AC Led State.  
 AI: Apnea Index: number of apnea events for a 24 hour period.  
 ALARM COMMAND: Cpu board command for main buzzers  
 ALARM MEMORY MENU: Menu displaying the 9 last alarms.  
 ALARM MENU: Menu displaying the alarm settings.  
 ALARM TONE SETTING: Allows the user to switch between the original alarm tone or the EN 60601-1-8:2006 compliant alarm tone.  
 AMBIENT TEMPERATURE ALERT: Alarm triggering when the ambient temperature is too high or too low.  
 APNEA: Alarm occurring when the patient does not make any INSPIRATORY TRIGGER during APNEA TIME.  
 APNEA TIME: Time to activate controlled cycles if no INSPIRATORY TRIGGER occurred.  
 BACK UP R: Rate of the controlled cycles in PSV mode.  
 BACKLIGHT: Screen back-light.  
 BACK-UP BUZZER: Security buzzer that sound when the main buzzers are out of order  
 BARGRAPH: Pressure variation graphic representation in the ventilation menu.  
 BATTERY CHARGE VOLTAGE: Internal battery charge voltage  
 BATTERY END: Flag from supply management board indicating the presence of an END OF BATTERY alarm.  
 BATTERY LEVEL : Display of battery picture and the remaining capacity battery in %;  
 BATTERY LEVEL HOURMETER : Display of the battery picture and the remaining capacity battery with time remaining in hours and minutes  
 BATTERY OK : Flag from supply management board to inform about the battery right functioning  
 BATTERY PRESENCE : Flag from supply management board to inform about the battery presence.  
 BATTERY SYMBOL : Symbol displayed on the screen to inform that the device is functioning on internal battery.  
 BATTERY TEMPERATURE : Internal battery temperature measurement  
 BATTERY TEMPERATURE ALERT : Alarm triggering when the internal battery temperature is too low or too high.  
 BATTERY TEMPERATURE LEVEL : Internal battery temperature measurement  
 BATTERY VOLTAGE : Battery voltage measured directly at the battery 24V output.  
 BIAS FLOW : Exhalation turbine flow to avoid REBREATHING.  
 BLOWER TEMP : Blower temperature measurement  
 BREATH TIME CYCLED : Alarm triggering when too much breath are terminated by a time limit in SIMV modes. Typically trigger when too much leak is present in the patient interface.  
 BURST : Group of buzzer PULSE corresponding to the alarm priority.  
 BUZZER BATTERY CHARGE FAILURE : Alarm triggering when the buzzer battery is not able to be charged by the ventilator.  
 BUZZER CHECK : BUZZER VOLTAGE display and buzzer activation in maintenance menu.  
 BUZZER COMMAND : Boolean level that triggers the buzzer sound  
 BUZZER VOLTAGE : Buzzer command voltage.  
 CAN : Analogical to Numerical Converter output value.  
 CANCELLATION SYMBOL : Symbol displayed on the screen to inform that an alarm has been cancelled.  
 CHECK BATTERY : Alarm occurring when a battery default is detected.  
 CHECK BATTERY CHARGE : Flag from supply management board to inform that the battery charge has failed.

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CHECK BUZZER : Alarm occurring when a buzzer default is detected.

CHECK FIO2 : Alarm triggering when the FIO2 is below 18% which means the sensor may be faulty.

CHECK PRESSURE : Alarm occurring when an INTERNAL PRESSURE default is detected.

CHECK PROXIMAL : Alarm occurring when a PROXIMAL PRESSURE default is detected.

CHECK REMOTE : Alarm occurring when the remote control

CHECK SETTINGS : Alarm occurring when NEW VERSION, EEPROM OUT OF RANGE or LOOSING SETTINGS event is detected.

CHECK SUPPLY : Alarm occurring when INFO SUPPLY is not consistent with INFO LED AC and INFO LED DC

CHECK VALVE : Alarm occurring when a significant rebreathing is detected.

CHECK VALVE PRESSURE : Alarm triggering when the valve pressure is faulty.

CHECK VOLUME : Alarm occurring when a QI default or a VTI deviation from consign is detected.

CIRCUIT CHECK: Test used to check the patient circuit for leaks.

CIRCUIT CHECK MENU: GUI menu that allows the user to execute CIRCUIT CHECK

CLOCK FAULT : Visual indication occurring when a clock fault is detected.

CONNECT VALVE : Alarm triggering when the ventilation mode is not compatible with a leak configuration.

CONNECT VALVE / CHANGE PRES : Alarm triggering when the pressure settings are not compatible with a leak configuration.

CONTROL R : Rate of the controlled cycles in VOL A/C, PRES A/C and SIMV modes.

CONTROLLED CYCLES : Visual alarm (message only) indicating an apnea backup ventilation is in progress when the APNEA alarm is turned off.

CONTROLLED TIME : Period corresponding to the CONTROL R setting in VOL SIMV and PRES SIMV modes.

CPAP : Continuous Positive Airway Pressure mode.

CPT SIGH : Number of cycles defining the frequency of the SIGH breaths delivery

CPU 5V CHECK : Cpu 5 V voltage displayed in maintenance menu.

CPU REFERENCE FAILURE : Alarm triggering when the cpu board reference voltage is out of bounds.

CURVES DISPLAY : Choice between PRES+FLOW and LOOPS types of curves to be displayed in the WAVEFORM MENU.

CURVES TYPE : Choice between LINE or HISTOGRAM types of curves to be displayed in the WAVEFORM MENU.

D RAMP : Decelerated flow control in VOL A/C cycles.

DATE : Date displayed in the SET-UP MENU.

DC : DC electrical supply

DC DISCONNECTION : Alarm triggering when the external DC power is lost.

DC POWER FAIL : Alarm occurring in case of external continuous supply failure.

DC SELECTED : Logical DC Led State.

DELETED : DELETED

DISCONNECT VALVE : Alarm triggering when the pressure settings is not compatible with a valve configuration.

DISCONNECT VALVE / CHANGE PRES : Alarm triggering when the pressure settings are not compatible with a valve configuration.

DISCONNECTION : Alarm occurring in case of patient disconnection from the device.

DOUBLE PRESS : Two consecutives key presses during 1 second

DOWN KEY : Key allowing the user to go to the lower step or to decrease a setting value.

EEPROM OUT OF RANGE : Event associated to CHECK SETTINGS alarm when settings are lost (except for the settings associated to LOOSING SETTINGS event).

EMPTY BATTERY : Alarm occurring in case of low battery level detected.

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END OF CHECK BATTERY : End of alarm Event  
 END OF CHECK BATTERY CHARGE : End of alarm Event  
 END OF CHECK BUZZER : End of alarm Event  
 END OF CHECK PRESSURE : End of alarm Event  
 END OF CHECK PROXIMAL : End of alarm Event  
 END OF CHECK REMOTE ALARM : End of alarm Event  
 END OF CHECK SETTINGS : End of alarm Event  
 END OF CHECK SUPPLY : End of alarm Event  
 END OF CHECK VALVE : End of alarm Event  
 END OF CHECK VOLUME : End of alarm Event  
 END OF DISCONNECTION : End of alarm Event  
 END OF HIGH PRESSURE : End of alarm Event  
 END OF HIGH RATE : End of alarm Event  
 END OF HIGH VM : End of alarm Event  
 END OF HIGH VTI : End of alarm Event  
 END OF LOW VM : End of alarm Event  
 END OF LOW VTE : End of alarm Event  
 END OF LOW VTI : End of alarm Event  
 END OF NO BATTERY : End of alarm Event  
 END OF NO VALVE DETECTION : End of alarm Event  
 END OF PROXIMAL DISCONNECTION : End of alarm Event  
 END OF REVERSE I:E : DELETED  
 End of alarm Event  
 END OF TECHNICAL PROBLEM : End of alarm Event  
 END OF UNKNOWN BATTERY : End of alarm Event  
 END OF VALVE LEAKAGE : End of alarm Event  
 EQI : Inspiratory flow during exhalation.  
 ERROR VERSION : message displayed when a wrong software version is downloaded  
 ESTIMATED PROXIMAL PRESSURE : Estimation of the proximal when only INTERNAL pressure is available.  
 EVTI : Inspiratory volume during exhalation.  
 EXH FLOW CALIBRATION : Exhalation flow sensor calibration.  
 EXH FLOW OFFSET DEFAULT : Visual indication occurring when a calibration OFFSET is out of range on the expiratory flow sensor.  
 EXH SENS : EXHALATION TRIGGER sensitivity in %.  
 EXHALATION FLOW : QE displayed and calibrated in the MAINTENANCE MENU.  
 EXHALATION STEADY PHASE : Period during which QI becomes steady at the end of the exhalation period.  
 EXHALATION TRIGGER : Detection of an exhalation demand generated by the patient.  
 EXHALATION VALVE : Valve allowing the patient to exhale outside the patient circuit.  
 EXTERNAL SOFTWARE : Software which allow to display the recorded events, values and alarms.  
 FAULT CHECK MENU : 10 last faults visualization menu  
 FILTERED PATIENT PRESSURE : filtered patient pressure measure.  
 FIO2 : Oxygen concentration in the delivered gas.  
 FiO2 CALIBRATION : FiO2 sensor calibration.  
 FIO2 CALIBRATION NEEDED : Alarm triggering when a FIO2 sensor has been connected but not calibrated at ventilation start.  
 FIO2 OFFSET FAULT : visual indication for service when FIO2 calibration failed  
 FiO2 sensor detected flags : Flag which indicates if the FiO2 sensor is detected  
 FLAT\_INT : Flag meaning the internal pressure measurement is flat (disconnected or faulty)  
 FLAT\_PROX : Flag meaning the proximal pressure is flat (disconnected or faulty)

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FLOW MAX : Maximum flow detected during inspiration.

FLOW SET POINT : Inspiratory flow consign during volume controlled breathes in VOL A/C and VOL SIMV modes.

HIGH FIO2 : Setting and corresponding alarm triggering when the FIO2 is higher than the setting.

HIGH LEAK : Setting and corresponding alarm triggering when LEAK exceeds the set threshold.

HIGH PIP : PATIENT PRESSURE limit to trigger a HIGH PRESSURE alarm.

HIGH PRESSURE : Alarm occurring when the PATIENT PRESSURE is exceeding the HIGH PIP Limit.

HIGH PRESSURE LEVEL : High pressure alarm setting

HIGH PRIORITY LED : High priority alarm led

HIGH R : R limit to trigger a HIGH RATE ALARM.

HIGH RATE : Alarm occurring when the monitored R is exceeding the HIGH R limit.

HIGH SUPPLY OFFSET : BATTERY LEVEL upper offset during stand by

HIGH VENTILATION SUPPLY OFFSET : BATTERY LEVEL upper offset during ventilation

HIGH VM : Alarm occurring when the monitored VM is exceeding the HIGH VM limit.

HIGH VTI : Alarm occurring when the monitored R is exceeding the HIGH R limit.

HISTOGRAM CURVE : Histogram curve type.

HMI : Human Machine Interface

HP : High priority alarm level

I:E : Inspiration versus exhalation ratio displayed in VENTILATION MENU and ALARM MENU.

INFO SUPPLY : Voltage indicating the current supply.

INHIBITION KEY : Keyboard key allowing to pause the sound alarm during 60 s.

INHIBITION SYMBOL : Symbol to inform about the presence of inhibited alarms.

INITIALIZATION PHASE : Auto-test phase occurring at the device start and allowing to switch to SET UP MENU.

INSP FLOW CALIBRATION : Inspiratory flow sensor calibration.

INSP FLOW DEFAULT : Visual indication occurring when a QI default is detected.

INSP FLOW OFFSET DEFAULT : Visual indication occurring when a calibration OFFSET is out of range on the inspiratory flow sensor.

INSP SENS : INSPIRATORY TRIGGER sensitivity.

INSP TIME : Inspiratory time

INSPIRATION FLOW : QI displayed in MAINTENANCE MENU.

INSPIRATORY FLOW FAILURE : Alarm triggering when the inspiratory flow sensor is faulty.

INSPIRATORY PRESSURE SET POINT : Pressure consign during inspiration.

INSPIRATORY TRIGGER : Detection of an inspiratory effort generated by the patient

INTERNAL PRESSURE : Patient pressure measured on the internal pressure sensor.

INTERNAL PRESSURE OFFSET DEFAULT : Visual indication occurring when a calibration OFFSET is out of range on the INTERNAL PRESSURE sensor.

INTERNAL TEMPERATURE : Internal device temperature.

INVOLUNTARY STOP : Involuntary stop event. (Stopping device by the power switch during ventilation)

INVOLUNTARY SWHICHED OFF : Switching off the on/off switch during ventilation.

IQE : Expiratory flow during inspiration.

KEY SOUND : PREFERENCE MENU Setting to choose the presence of key sound and validation beeps.

KEYBOARD FAULT : Visual indication occurring when a Keyboard fault is detected.

KEYLOCK : Settings modification lock function.

LANGUAGE : Different labels and messages language choice.

LEAK : Monitored leak of the patient interface at the exhalation pressure. A nominal theoretical leak is deduced from the total leak to compute this data.

LEAK MEAN : Average LEAK for a 24 hours period.

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LEAK OCCLUSION : Alarm triggering when the leak is not sufficient to prevent rebreathing in leak configuration.

LEVEL OF PRIORITY : Way to define the alarms criticism and the corresponding sound and visual aspects.

LIMIT SPEED : Maximum turbine speed in case of patient disconnection.

LINE CURVE : Linear curve type.

LONG PRESS : Key press during more than 3 s.

LOOPS : Loop curves Flow=f(Volume) and Pressure=f(Volume) displayed in the WAVEFORM MENU.

LOOSE FLASH POINTER FAULT : Alarm triggering when the flash memory pointer is lost (means not able to store logs).

LOOSING SETTINGS : Event associated to CHECK SETTINGS alarm when LANGUAGE, SCREEN SAVER or SERIAL PORT RATE setting is lost.

LOW BATTERY : LOW BATTERY alarm occurring when the battery autonomy is less than minimum required.

LOW BATTERY : Flag from supply management board to inform about the presence of a LOW BATTERY alarm.

LOW BUZZER BATTERY : Alarm triggering when the buzzer battery is too low to provide 2 minutes of involuntary stop alarm.

LOW FIO2 : Setting and corresponding alarm triggering when the FIO2 is lower than the setting.

LOW PIP : Low pressure limit to trigger a DISCONNECTION alarm.

LOW PRESSURE LEAK : Alarm triggering in low pressure or patient disconnection conditions.

LOW PRIORITY : Low priority alarm level.

LOW SUPPLY OFFSET : BATTERY LEVEL lower offset during stand-by

LOW VENTILATION SUPPLY OFFSET : BATTERY LEVEL lower offset during ventilation

LOW VM : Alarm occurring when the VM does not reach the LOW VM limit.

LOW VTE : Alarm occurring when the VTE does not reach the LOW VTE limit.

LOW VTI : Alarm occurring when the VTI does not reach the LOW VTI limit.

LXxxxxxx : Software version basis. (the xxxxxxxx are replaced by numbers according to the software evolutions).

LP : Low Priority alarm level.

MACHINE HOURS : Ventilation counter of the device displayed in MAINTENANCE MENU.

MAINTENANCE MENU : Menu displaying technical information and providing calibration functions.

MAP : Mean Airway Pressure : Average pressure during a ventilation cycle.

MAX FALL TIME : Maximum delay to reach the set PEEP.

MAX FLOW : Maximum Scale value for the flow curve.

MAX FLOW SET POINT : Starting flow set point of D RAMP flow control in VOL A/C mode

MAX PRESSURE : Maximum Scale value for the pressure curve.

MAX SPEED : Maximum turbine speed consign in MAINTENANCE MENU.

MAX TIME : Maximum Time scale value for the PRESS + FLOW curves.

MAX VT : Maximum Vt scale value for LOOPS curves.

MEAN\_INSP\_VALVE\_CURRENT: average current of the exhalation control valve during inspiration

MEAN VENTILATION : Average ventilation time per day since the last PATIENT COUNTER reset.

MED SUPPLY OFFSET : BATTERY LEVEL medium offset during stand-by

MED VENTILATION SUPPLY OFFSET : BATTERY LEVEL medium offset during ventilation

MEDIUM PRIORITY : Medium priority alarm level.

MEDIUM PRIORITY LED : Medium priority alarm led for low and medium priority alarms.

MIN EXH DELAY : Minimum exhalation time before allowing the patient INSPIRATORY TRIGGER

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MIN FLOW SET POINT : Ending flow set point of D RAMP flow control in VOL A/C mode

MONITORED VALUES : Computed values displayed in VENTILATION MENU, ALARM MENU, WAVEFORM MENU and VENTILATION REPORT MENU.

MP : Medium Priority alarm level.

N.A. : Non Applicable.

NAVIGATION KEY : Key which allow to navigate from one menu to another.

NEUTRAL SYMBOL : Symbol to inform that a monitoring value is unavailable.

NEW VERSION : Event associated to CHECK SETTINGS alarm when a new software version is download

NO BATTERY : Alarm occurring when there is no battery.

NO FIO2 SENSOR : Alarm triggering when FIO2 alarms are set and no sensor is connected.

NO VALVE DETECTION : Alarm occurring when a VALVE PRESSURE default is detected.

OCCCLUSION : Alarm triggering when the patient circuit is occluded in pressure breaths.

OFF : Inactivation setting state.

OFFSET : Recorded CAN value corresponding to a calibration step.

P CONTROL : Inspiratory pressure support for controlled cycles of PRES A/C and PRES SIMV modes.

P MAX : Maximum Pressure allowed to reach the TARGET VT

P SUPPORT : Inspiratory pressure support for spontaneous cycles of PSV and SIMV modes.

PATIENT COUNTER : Patient ventilation counter displayed in SET UP MENU.

PATIENT HOURS : Hour meter of patient device using.

PATIENT PRESSURE : PROXIMAL PRESSURE measure if present or INTERNAL PRESSURE measure instead.

PATIENT PRESSURE CALIBRATION : Patient pressure sensor calibration.

PAUSE : Curves freezing function.

PAW MEAN : Average Peak inspiratory pressure for a 24 hours period.

PEEP : Positive End Expiratory Pressure.

PFI : Voltage measure of the Watchdog PFI inlet.

PIM : Patient Initiated Mandatory breath in SIMV modes.

PIP : Peak Inspiratory Pressure : Maximum pressure during Inspiration.

POST : Power On Self Test: critical component tests performed by the device at startup

POST FAILURE : alarm triggering when any of the POST tests fails. When triggered, the device go in a safety state.

POWER SUPPLY LOSS : Alarm occurring when all supplies are lost or when the on/off switch is switched off during ventilation.

PREFERENCE MENU : Menu displaying preference settings (screen saver, sound level, contrast and validation beep).

PRES SIMV : Pressure Synchronized Intermittent Mandatory Ventilation mode.

PRESS + FLOW CURVES : Standard curves Flow=f(t) and Pressure=f(t) displayed in the WAVEFORM MENU.

PRESS A/C : Pressure Assisted / Controlled Ventilation mode.

PROX DISCONNECTION : Alarm occurring when the proximal pressure tubing is disconnected

PROXIMAL DISCONNECTION : Alarm occurring when the PROXIMAL PRESSURE is lost during ventilation.

PROXIMAL PRESSURE : Patient pressure measured on the proximal pressure sensor.

PROXIMAL PRESSURE OFFSET DEFAULT : Visual indication occurring when a calibration OFFSET is out of range on the PROXIMAL PRESSURE sensor.

PS : Pressure support Spontaneous breath in SIMV modes.

PSV : Pressure Support Ventilation Mode.

PWM : Pulse Width Modulation. Micro controller outlet used to control actuators.

PWM\_OFFSET : Valve command in PWM corresponding to a given pressure in the exhalation valve pressure calibration process.

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PWM\_PRESSURE SLOPE : Valve command increment between two different PWM\_OFFSET.  
This slope is used to compute VALVE COMMAND COEFF.  
QE : Exhalation flow measure.  
QI : Inspiratory flow measure.  
QMAX : Maximum inspiratory flow.  
R : Monitored Rate.  
R RAMP : Rectangular flow control in VOL A/C cycles.  
RAMP : Flow ramp selection in VOL A/C mode.  
RATE MEAN : Average R for a 24 hours period.  
RE-BREATHING : Presence of patient exhalation gazes in the inspiratory flow.  
REFERENCE PWM\_PRESSURE SLOPE: Pressure slope used as a reference for computing VALVE COMMAND COEFF  
RELATIVE PRESSURE : Change the pressure setting to relative convention (added to PEEP setting for INSPIRATORY FLOW SET POINT calculation) when turned on. Absolute pressure applies when this setting is turned off.  
REMOTE ALARM : Device connected to the ventilator in order to provide remote alarms  
RESTORE DEFAULT SETTING: Allows the user restore all settings back to Manufacturing defaults except for Language, date, and time settings.  
RISE TIME : Theoretical time to reach the inspiratory pressure in pressure cycles.  
RTC : Real Time Clock  
S RAMP : Sinus ramp setting for volume breath in VOL A/C and SIMV modes.  
SAMPLING MONITORING FREQUENCY : sent monitoring frame frequency  
SCREEN CONTRAST : adjustable screen contrast  
SCREEN CONTRAST : Function allowing the user to set the screen contrast.  
SCREEN SAVER : Possibility to have an automatic back-light cut off after one minute with no key action.  
SERIAL PORT RATE : Rate of the serial port communication.  
SETUP MENU : Menu displaying settings related to the system configuration  
SHORT BEEP : Sound indicator. Time length < 1 sec  
SHORT PRESS : Key press during less than 3 s.  
SIGH : Longer and higher volume breath delivered when setting on according to VT SIGH ratio and CPT SIGH frequency in VOL A/C mode.  
SIMV BACK UP R : Security Rate of the SIMV mode occurring when the patient doesn't make any INSPIRATORY TRIGGER.  
SOFTWARE VERSION ERROR : Alarm occurring when the software is not a LUXXXXXX version.  
SOUND LEVEL : Adjustable sound alarm level.  
SPEED : Turbine speed measure.  
SPEED CONSIGN : Turbine speed consign displayed.  
SPEED DEFAULT : Visual indication occurring when the TURBINE SPEED TEST as failed.  
SPEED SET POINT : Turbine speed consign.  
START DEVICE : Start device event.  
START VENTILATION : Start ventilation event  
STOP DEVICE : Stop device event  
STOP VENTILATION : Stop ventilation event  
SUPPLY BUS DEFAULT : Flag from supply management board bus driver to inform that the communication with supply board is interrupted (three missed frames).  
SUPPLY MEASURE : Supply 24 V voltage measure.  
T Apnea : Total time of apnea for a 24 hours period.  
TARGET VT : Setting that defines a target VT in PS and Pres A/C modes.  
TE : Computed expiratory time.  
TECHNICAL PROBLEM : Alarm occurring when a PFI default is detected.

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TEMP\_CORRECTION\_FACTOR\_OFFSET: Correction made to valve current to optimize thermal correction. Value 280.

TEMP\_RISE\_OPEN\_VALVE: Time for the valve command to go from the full opened valve PWM command (2672) to VEN\_COMMAND\_FLOW.

THEORETICAL FLOW SET POINT : First flow set point value in a volumetric mode

THEORETICAL MAX FLOW SET POINT : First cycle starting flow set point of D RAMP flow control in VOL A/C mode

THEORETICAL MIN FLOW SET POINT : First cycle ending flow set point of D RAMP flow control in VOL A/C mode

THERMAL\_CORRECTION\_FACTOR : Correction factor for thermal impact on the valve command versus valve pressure profile.

TI : Computed inspiratory time.

TI CONTROL : Inspiration time of the controlled cycles in SIMV modes.

TI MAX : Maximum inspiratory time limit for PSV mode.

TI MIN : Minimum inspiratory time limit for PSV mode.

TIME : Set and displayed in the SET UP MENU.

TURBINE SPEED : speed turbine measure displayed in MAINTENANCE MENU.

TURBINE SPEED TEST : Turbine speed measurement test occurring at the beginning of the ventilation.

UNKNOWN BATTERY : Alarm occurring when the battery is not recognized by the software.

UP KEY : Key allowing the user to go to the upper step or to increase a setting value.

VALIDATION KEY : Key allowing the user to validate the settings modifications.

VALVE COMMAND COEFF : Based on exhalation vave pressure calibration. This is a correction factor for the VEN\_COMMAND\_FLOW steps in the breath to breath adaptation. This factor aims at keeping a stable valve pressure increment for the same difference of Bias Flow on various exhalation valve control hardwares.

VALVE\_COMMAND\_MIN : Low saturation for the VEN\_COMMAND\_FLOW

VALVE\_COMMAND\_MAX : High saturation for the VEN\_COMMAND\_FLOW

VALVE\_COMMAND\_INIT : Initialization value for VEN\_COMMAND\_FLOW

VEN\_VALVE\_CURRENT\_SAT : Valve current fault flag indicating the valve current is out of range.

VALVE LEAKAGE : Alarm occurring when a flow is detected on exhalation flow sensor during inspiration.

VALVE PRESSURE : Exhalation valve pressure measured on the valve pressure sensor.

VALVE PRESSURE CALIBRATION : Valve pressure sensor calibration

VALVE PRESSURE OFFSET DEFAULT : Visual indication occurring when a calibration OFFSET is out of range on the VALVE PRESSURE sensor.

VEN\_COMMAND\_FLOW : Valve command at the end of exhalation (in PWM)

VEN\_FLEAK\_MEASURED : Measurement of the bias flow at the end of exhalation

VEN\_TARGET\_FLOW : Bias flow target for the end of exhalation (in lpm\*10)

VENTILATION KEY : Key allowing the user to start and stop ventilation.

VENTILATION LED : Visual indicator to advert that starting the ventilation is allowed.

VENTILATION MENU : Menu displaying ventilation settings.

VENTILATION REPORT DATE : Date corresponding to displayed VENTILATION REPORT data (refreshed at 8 am with the previous day date).

VENTILATION REPORT MENU : Menu accessible from the PREFERENCE MENU displaying average patient data for a 24 hours period.

VENTILATION STATE : States of a ventilation cycle (inspiration / exhalation) and states types (triggered / controlled)

VERY LOW INTERNAL PRESSURE : Visual indication occurring when the INTERNAL PRESSURE is saturated to a very low value.

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VERY LOW PROXIMAL PRESSURE : Visual indication occurring when the PROXIMAL PRESSURE is saturated to a very low value.

VERY LOW VALVE PRESSURE : Visual indication occurring when the VALVE PRESSURE is saturated to a very low value.

VIM : Ventilator Initiated Mandatory breath in SIMV modes.

VM : Minute Volume.

VM MEAN : Average minute volume for a 24 hours period.

VOL A/C : Volumetric Assisted / Controlled Ventilation mode.

VOL CONTROL : controlled cycles tidal volume of the VOL A/C and VOL SIMV modes.

VOL SIMV : Volumetric Synchronized Intermittent Mandatory Ventilation mode.

VOLUNTARILY SWITCHED OFF : Switching off the on/off switch out of ventilation.

VOLUNTARY STOP : Alarm triggering when the ventilation is voluntarily stopped.

VT SIGH : Ratio that defines the SIGH volume and breath time increase

VTE : Exhalation Tidal Volume.

VTE MEAN : Average VTE for a 24 hours period.

VTI : Inspiratory Tidal Volume.

VTI MEAN : Average VTI for a 24 hours period.

WATCHDOG CHECK : PFI display and buzzer activation in maintenance menu.

WAVEFORM DISPLAY : Choice in the PREFERENCE MENU to display the WAVEFORM MENU or not.

WAVEFORM MENU : Menu displaying ventilation PRESS+FLOW or LOOPS curves.

WAVEFORM SET UP MENU : Menu displaying settings related to curves.

WELCOME MENU : Menu displaying software version, counters and DATE/TIME.

ZOOM : Ventilation and alarm setting values modification zoom function.

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### 3 Functional requirements

#### 3.1 General Requirements

SFSYST1  
device start  
No text (title)

##### SFSYST1.1

When the user starts the device:

- first the safety buzzer shall be triggered
- then the main buzzers ordered by the INVOLUNTARY STOP and the remote alarm shall be triggered simultaneously
- and finally the main buzzers ordered by the software shall be triggered .

The software shall also control and turn on HP, MP and ventilation Leds at the same time.

##### SFSYST1.2

When the user starts the device, the software must turn on the BACKLIGHT

##### SFSYST1.3

When the inhibition key is pressed continuously during the INITIALIZATION PHASE and the ventilation was VOLUNTARILY SWITCHED OFF, the software starts in SETUP MENU.

##### SFSYST1.4

When the supply switch is on and the device was VOLUNTARILY SWITCHED OFF:

- first, the software must start and display the product logo during 3 seconds
- then, the software must display the WELCOME MENU during 3 seconds including: the firmware version numbers, machine hour counter, patient hour counter, copyright, date and time.
- and, the software must display the recorded VENTILATION MENU

##### SFSYST1.5

The first time the supply switch is on the software must display the VENTILATION MENU with PRES A/C mode and its default settings

##### SFSYST1.6

when the VENTILATION KEY is pressed during the WELCOME MENU, the software must display the last used VENTILATION MENU and start the ventilation.

##### SFSYST1.7

When the supply switch is on and the device was INVOLUNTARILY SWITCHED OFF :

- first, the software must start and display the Product logo during 3 seconds.
- and, the software must start the ventilation with the previous settings and display the last used VENTILATION MENU.

##### SFSYST2

P.O.S.T. and Safe-state

At start-up the software executes a Power On Self Test defined by SFSYSYAL60 alarm. This process must last less than 15 s from the startup to the ventilation menu display.

If the software fails any of those tests, it goes into a Safe State, display an error message and stops the software execution. The exhalation valve must be opened in this state.

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### SFSYST3

the ventilation start/stop :  
No text (title)

#### SFSYST3.1

If the ventilation is off and the VENTILATION KEY is SHORT PRESS, the software must start the ventilation, turn off the ventilation led and trigger a validation short beep.

#### SFSYST3.2

when the ventilation starts , the software must perform a TURBINE SPEED TEST

#### SFSYST3.3

If the ventilation is on and the VENTILATION KEY is pressed and not released, the software must:

- display a message to keep press for 3s to stop the ventilation
- and after 3s, display a message to release the ventilation key to stop the ventilation and trigger two short validation beeps

Once the VENTILATION KEY is released after 3s the software shall display a confirmation message. If the confirmation message is not accepted within 5s by pressing the VENTILATION KEY the message will disappear and ventilation will continue.

If the confirmation message is accepted within 5 s by pressing the VENTILATION KEY ventilation must stop, and the alarm VOLUNTARY STOP is displayed.

#### SFSYST3.4

the software must light on the VENTILATION LED when the ventilation is off.

#### SFSYST3.5

When the ventilation is off, the software must stop the blower (PWM 0 and brake at 100%).

### SFSYST4

Ventilation mode requirements  
No text (title)

#### SFSYST4.1

When the ventilation is on, the software must apply a mode change at the beginning of the next exhalation phase if it occurs during inspiration or immediately if it occurs in exhalation.. If switching from CPAP mode to another mode, the software must apply the mode change immediately.

#### SFSYST4.2

when the ventilation is on, the software must apply a parameter change at the end of the exhalation phase

#### SFSYST4.3

when the ventilation is on, the software must apply the INSP SENS change immediately after setting validation.

#### SFSYST4.4

If the PATIENT PRESSURE measure is under 1 mbar, into pressure modes, the software must limit the turbine command to PWM 400

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## SFSYST4.5

### Bias Flow

In valve configuration, the software must generate an exhalation BIAS FLOW to compensate abnormal leakage and prevent RE-BREATHING.

In single branch adult, the bias flow target (VEN\_TARGET\_FLOW) must be 10 lpm for peep 2 to 5 mb and linearly increase from 10 lpm to 30 lpm for peep from 5 to 12 mb.

VEN\_TARGET\_FLOW must linearly increase from 35 lpm to 60 lpm for peep from 13 to 15 mb and must be set to 60 lpm for peep from 15 to 20 mb.

In other configurations than single branch adult, the bias flow target (VEN\_TARGET\_FLOW) must be 10 lpm for peep 2 to 5 mb and linearly increase from 10 lpm to 30 lpm for peep from 5 to 15 mb. VEN\_TARGET\_FLOW must be set to 30 lpm for peep from 15 to 20 mb.

VEN\_TARGET\_FLOW must not be used for peep Off (0) and 1 since the valve is fully opened during the exhalation.

### Exhalation valve control during exhalation

For PEEP Off (0) and 1 the exhalation valve command must be fixed to 2672 during entire exhalation.

For PEEP 2 to 20 mb the exhalation valve command must start at 2672 (MAX PWM) and decrease to VEN\_COMMAND\_FLOW within TEMP\_RISE\_OPEN\_VALVE timer in ms.

TEMP\_RISE\_OPEN\_VALVE must be initialized to 600 ms for PEEP 2 adult configuration.

TEMP\_RISE\_OPEN\_VALVE must be initialized to 300 ms for pediatric configuration.

TEMP\_RISE\_OPEN\_VALVE must be initialized from 500 ms to 200 ms linearly decreasing from PEEP 5 to PEEP 15 in adult configurations.

For PEEP higher than 1 TEMP\_RISE\_OPEN\_VALVE must be adapted breath to breath with 10% increments to optimize peep drop or peep overshoot.

TEMP\_RISE\_OPEN\_VALVE variations must be limited to a minimum of 200 ms to 120 ms linearly decreasing from PEEP 5 to PEEP 15 in adult single branch configuration.

TEMP\_RISE\_OPEN\_VALVE variations must be limited to a minimum of 200 ms in adult double branch configurations.

TEMP\_RISE\_OPEN\_VALVE variations must be limited to a minimum of 120 ms in pediatric configurations.

TEMP\_RISE\_OPEN\_VALVE maximum value must be limited to a maximum of 1000 ms to 300 ms linearly decreasing from PEEP 9 to PEEP 2 in adult single branch configuration.

### VEN\_COMMAND\_FLOW Breath to breath adaptation

VEN\_COMMAND\_FLOW must be limited between VALVE\_COMMAND\_MIN and VALVE\_COMMAND\_MAX.

VEN\_COMMAND\_FLOW must be initialized when starting ventilation, when a PEEP setting is changed or when a circuit disconnection is detected.

VEN\_COMMAND\_FLOW must be initialized to VALVE\_COMMAND\_INIT.

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VEN\_COMMAND\_FLOW will be adjusted breath to breath and thermally corrected as following:

- 1) For Adult single branch configuration with PEEP setting > 9 mb (pressures are in mb \*10 and flows in lpm\*10):

```

IF (VEN_FLEAK_MEASURED > VEN_TARGET_FLOW + 20%)
  IF ((VEN_FLEAK_MEASURED - VEN_TARGET_FLOW) > 150) THEN VEN_COMMAND_FLOW = VEN_COMMAND_FLOW - (100*(VEN_TARGET_FLOW)/(3*((PEEP setting)+10)) * VALVE_COMMAND_COEFF) / 1000
  IF ((VEN_FLEAK_MEASURED - VEN_TARGET_FLOW) > 70) THEN
    VEN_COMMAND_FLOW = VEN_COMMAND_FLOW - (30*(VEN_TARGET_FLOW)/(3*((PEEP setting)+10)) * VALVE_COMMAND_COEFF) / 1000
  IF ((VEN_FLEAK_MEASURED - VEN_TARGET_FLOW) > 0) THEN
    VEN_COMMAND_FLOW = VEN_COMMAND_FLOW - (6*(VEN_TARGET_FLOW)/(3*((PEEP setting)+10)) * VALVE_COMMAND_COEFF) / 1000

IF (VEN_FLEAK_MEASURED < VEN_TARGET_FLOW - 20%)
  IF ((CHECK_VALVE >= ALARM_DETECTED) && (VEN_VALVE_CURRENT_SAT = FALSE)) THEN VEN_COMMAND_FLOW = VEN_COMMAND_FLOW + 400
  IF ((VEN_TARGET_FLOW - VEN_FLEAK_MEASURED) > 150) THEN
    VEN_COMMAND_FLOW = VEN_COMMAND_FLOW + (250*(VEN_TARGET_FLOW)/(3*((PEEP setting)+10)) * VALVE_COMMAND_COEFF) / 1000
  IF ((VEN_TARGET_FLOW - VEN_FLEAK_MEASURED) > 70) THEN
    VEN_COMMAND_FLOW = VEN_COMMAND_FLOW + (75*(VEN_TARGET_FLOW)/(3*((PEEP setting)+10)) * VALVE_COMMAND_COEFF) / 1000
  IF ((VEN_TARGET_FLOW - VEN_FLEAK_MEASURED) > 0) THEN
    VEN_COMMAND_FLOW = VEN_COMMAND_FLOW + (15*(VEN_TARGET_FLOW)/(3*((PEEP setting)+10)) * VALVE_COMMAND_COEFF) / 1000

```

- 2) For others configuration : (pressures are in mb \*10 and flows in lpm\*10)

```

IF (VEN_FLEAK_MEASURED > VEN_TARGET_FLOW + 20%)
  IF ((VEN_FLEAK_MEASURED - VEN_TARGET_FLOW) > 150) THEN
    VEN_COMMAND_FLOW = VEN_COMMAND_FLOW - (100*(VEN_TARGET_FLOW)/((PEEP setting)+10) * VALVE_COMMAND_COEFF) / 1000
  IF ((VEN_FLEAK_MEASURED - VEN_TARGET_FLOW) > 70) THEN
    VEN_COMMAND_FLOW = VEN_COMMAND_FLOW - (30*(VEN_TARGET_FLOW)/((PEEP setting)+10) * VALVE_COMMAND_COEFF) / 1000
  IF ((VEN_FLEAK_MEASURED - VEN_TARGET_FLOW) > 0) THEN
    VEN_COMMAND_FLOW = VEN_COMMAND_FLOW - (6*(VEN_TARGET_FLOW)/((PEEP setting)+10) * VALVE_COMMAND_COEFF) / 1000

IF (VEN_FLEAK_MEASURED < VEN_TARGET_FLOW - 20%)
  IF ((CHECK_VALVE >= ALARM_DETECTED) && (VEN_VALVECURRENTSAT = FALSE)) THEN VEN_COMMAND_FLOW = VEN_COMMAND_FLOW + 400

```

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```

IF ((VEN_TARGET_FLOW - VEN_FLEAK_MEASURED) > 150) THEN
VEN_COMMAND_FLOW = VEN_COMMAND_FLOW +
(250*(VEN_TARGET_FLOW)/((PEEP setting)+10) * VALVE_COMMAND_COEFF) /
1000
IF ((VEN_TARGET_FLOW - VEN_FLEAK_MEASURED) > 70) THEN
VEN_COMMAND_FLOW = VEN_COMMAND_FLOW +
(75*(VEN_TARGET_FLOW)/((PEEP setting)+10) * VALVE_COMMAND_COEFF) / 1000
IF((VEN_TARGET_FLOW - VEN_FLEAK_MEASURED) > 0) THEN
VEN_COMMAND_FLOW = VEN_COMMAND_FLOW +
(15*(VEN_TARGET_FLOW)/((PEEP setting)+10) * VALVE_COMMAND_COEFF) / 1000

```

#### Pressure slope corrections:

The VALVE\_COMMAND\_COEFF must be used to apply a correction factor to the breath to breath valve command steps with the following formula:  $VALVE\_COMMAND\_COEFF = (PWM\_PRESSURE\_SLOPE / REFERENCE\_PWM\_PRESSURE\_SLOPE) * 1000$ .

#### Exhalation valve pressure calibration

The valve pressure calibration will control the blower at 40 mb on the INTERNAL PRESSURE sensor and decrease the exhalation valve command from PWM 2672 to 0 with steps of 1 and memorize the PWM commands at 5 mb, 10 mb, 15 mb, 20 mb, 25 mb, 30 mb and 35 mb. The calibration will collect I\_REF at PWM 0 for thermal correction.

The 5 mb PWM\_OFFSET + 200 must be used as the high saturation value (VALVE\_COMMAND\_MAX) for end exhalation VEN\_COMMAND\_FLOW.

The 10 mb PWM\_OFFSET is not used.

The 15 mb PWM\_OFFSET must be used as the low value for VALVE COMMAND COEFF calculation.

The 20 mb PWM\_OFFSET must be used as the initialization value (VALVE\_COMMAND\_INIT) for end exhalation valve command at peeps 2 and 3.

The 25 mb PWM\_OFFSET must be used as the initialization value (VALVE\_COMMAND\_INIT) for end exhalation valve command at peeps 4 to 20.

The 30 mb PWM\_OFFSET must be used as the low saturation value (VALVE\_COMMAND\_MIN) for end exhalation valve command at peeps 2 and 3.

The 35 mb PWM\_OFFSET must be used as the low saturation value (VALVE\_COMMAND\_MIN) for end exhalation valve command at peeps 4 to 20 and must be used for higher value of the VALVE COMMAND COEFF calculation.

#### Thermal correction:

VALVE\_COMMAND\_MIN, VALVE\_COMMAND\_MAX, VALVE\_COMMAND\_INIT and VALVE COMMAND COEFF must be thermally corrected with the following formula:

$THERMAL\_CORRECTION\_FACTOR = (MEAN\_INSP\_VALVE\_CURRENT - TEMP\_CORRECTION\_FACTOR\_OFFSET) / (I\_REF - TEMP\_CORRECTION\_FACTOR\_OFFSET)$

THERMAL\_CORRECTION\_FACTOR must be set to off (no impact) if MEAN\_INSP\_VALVE\_CURRENT current is out of 350 to 550 (in mA\*10) range.

Example of exhalation valve command data during ventilation (valve command not refreshed but equals 0 during inspiration)

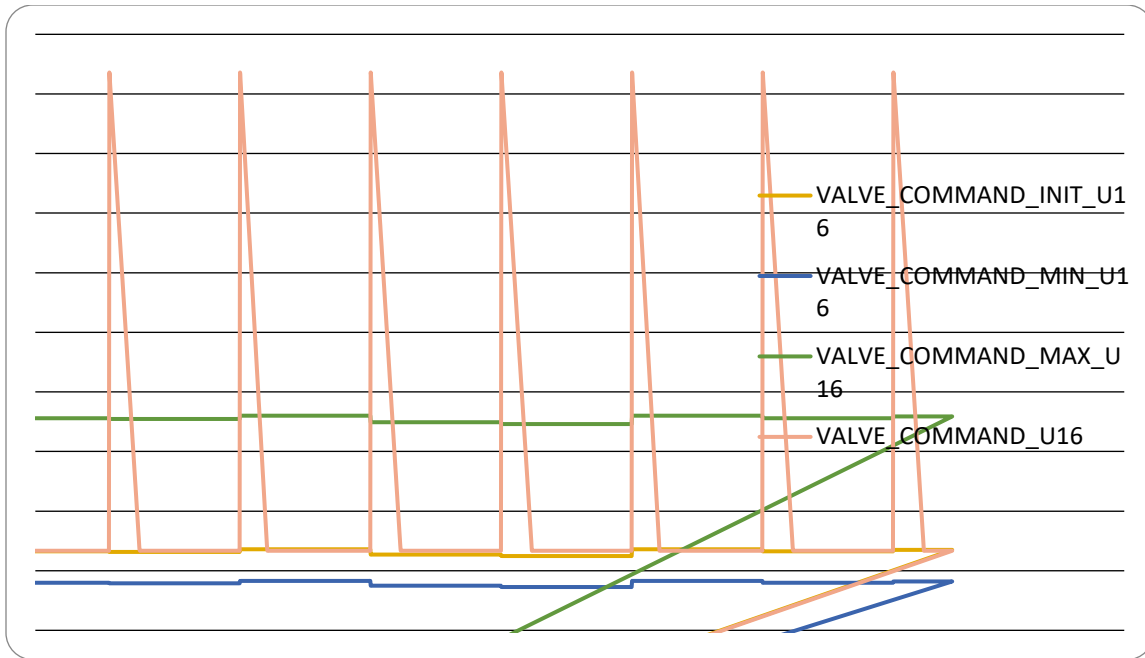
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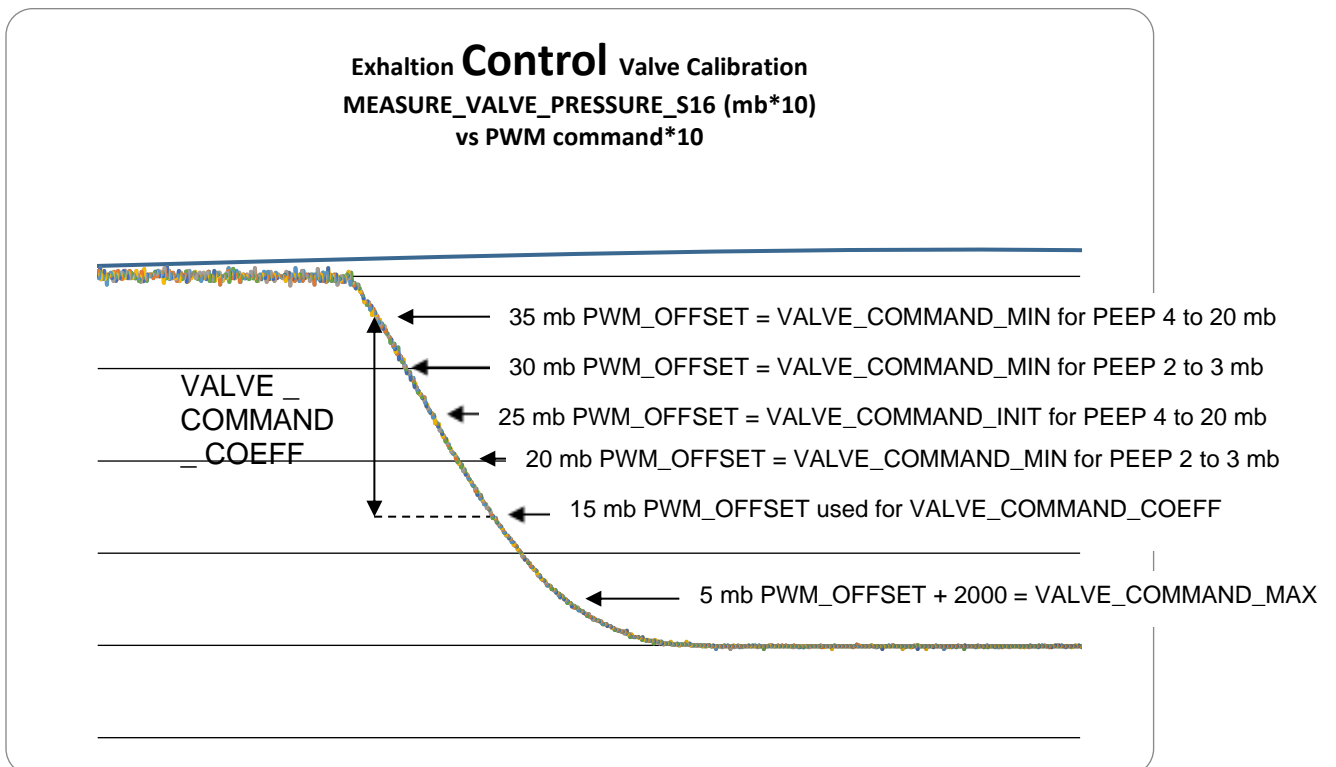
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Example of exhalation valve pressure calibration curve



SFSYST4.7

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If the altitude compensation is active, the software must apply a correction on the inspiration flow and exhalation flow for volume calculation and flow set point in volume breath. (that means it does not apply for flow monitoring in maintenance menu)

The calculation is : corrected flow = calibrated flow x current barometric pressure x reference temperature (btps) / reference barometric pressure (btps) x reference temperature (slpm).

The sensor measurement range shall be limited from 600 to 1100 hpa by the software.

btps reference temperature = 37°C

slpm reference temperature = 21°C

slpm reference barometric pressure = 1013 hPa

#### SFSYST4.8

The software must subtract monitored and delivered VTI and VTE with a tubing compensation factor K \* (PIP-PEEP) (cmH2O): In single branch pediatric K = 0.3 ml/cmH2O, in double branch pediatric K = 0.6 ml/cmH2O, in single branch adult K = 0.6 ml/cmH2O, in double branch adult K = 1.2 ml/cmH2O. This compensation must be limited to 100 ml.

#### SFSYST4.9

The software must subtract a correction factor to the internal pressure when pediatric circuit is used..

correction factor = K x Qi (dl/min) x Qi (dl/min)

K = 0.01

This correction factor is used only for the determination of the pressure sensor internal or proximal as defined in SFSYST13

#### SFSYST5

PRES A/C mode (valve/leak)

No text (title)

##### SFSYST5.1

the software must control the PATIENT PRESSURE to reach the INSPIRATORY PRESSURE SET POINT at the end of the adjusted RISE TIME.

##### SFSYST5.2

After rise time and until the end of computed TI, the software must control the PATIENT PRESSURE to the INSPIRATORY PRESSURE SET POINT level.

##### SFSYST5.3

the software must apply an EXPIRATORY PRESSURE SET POINT to the adjusted PEEP until the patient INSPIRATORY TRIGGER if an INSP SENS is adjusted or until the end of the computed TE.

#### SFSYST6

VOL A/C mode (valve)

No text (title)

##### SFSYST6.1

during a computed TI , the software must control the INSPIRATORY FLOW according to the FLOW SET POINT.

##### SFSYST6.2

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if the R RAMP is set, FLOW SET POINT is constant for each inspiration.

#### SFSYST6.3

if the D RAMP is set, the software must control the INSPIRATORY FLOW according to a decelerated flow from MAX FLOW SET POINT at  $T_I = 0$  to MIN FLOW SET POINT at  $T_I = T_{ICONTROL}$

#### SFSYST6.4

if the VTI measurement is between VOL CONTROL  $\pm 2$  ml or if a HIGH PRESSURE occurs, the software mustn't adapt the FLOW SET POINT, MAX FLOW SET POINT and MIN FLOW SET POINT

#### SFSYST6.5

At the first cycle :

FLOW SET POINT = THEORETICAL FLOW SET POINT

MAX FLOW SET POINT = THEORETICAL MAX FLOW SET POINT

MIN FLOW SET POINT = THEORETICAL MIN FLOW SET POINT

#### SFSYST6.6

After the first cycle, if the VTI measurement is below VOL CONTROL - 2 ml or above VOL CONTROL + 2 ml, the software must increase or decrease proportionally the inspiratory FLOW SET POINT with a 5% maximum variation within [200%;50%] of THEORETICAL FLOW SET POINT if THEORETICAL FLOW SET POINT  $> 20$  mL or [300%;50%] of THEORETICAL FLOW SET POINT if THEORETICAL FLOW SET POINT  $< 20$  mL.

#### SFSYST6.7

the software must control the PATIENT PRESSURE according to the adjusted PEEP until the patient INSPIRATORY TRIGGER if an INSP SENS is adjusted or until the end of the computed TE.

#### SFSYST6.8

For SQUARE Flow Pattern THEORETICAL FLOW SET POINT =  $\text{VOL CONTROL} / T_I \text{ CONTROL} / 1000 * 60 + 4$

#### SFSYST6.9

For D RAMP: THEORETICAL MAX FLOW SET POINT =  $3/2 * (\text{VOL CONTROL} / T_I \text{ CONTROL} / 1000 * 60) + 4$  ( $\pm 10\%$ )

#### SFSYST6.10

For D RAMP: THEORETICAL MIN FLOW SET POINT =  $(1/2) * (\text{VOL CONTROL} / T_I \text{ CONTROL} / 1000 * 60) + 4$  ( $\pm 10\%$ )

#### SFSYST6.11

if the S RAMP is set, the software must control INSPIRATORY FLOW according to a sinusoidal flow from MAX FLOW SET POINT at  $T_I / 2$  to MIN FLOW SET POINT at 0 and  $T_I$ .

#### SFSYST6.12

If a sigh is set to YES, at each CPT SIGH cycles, the software must control the flow during a computed  $T_I \times V_T$  SIGH

#### SFSYST6.13

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If a sigh is set to YES, at each CPT SIGH cycles, the software must control the EXPIRATORY FLOW SETPOINT to the adjusted PEEP until the patient INSPIRATORY TRIGGER if an INSP SENS is adjusted or until the end of the VT SIGH x TE.

#### SFSYST7

PSV mode (valve/leak)

No text (title)

##### SFSYST7.1

After the RISE TIME and until the patient EXHALATION TRIGGER or the end of TI MAX, the software must control the PATIENT PRESSURE according to the INSPIRATORY PRESSURE SET POINT.

##### SFSYST7.2

After the end of TI MIN, the software must allow the EXHALATION TRIGGER detection

##### SFSYST7.3

after the adjusted RISE TIME, the software pressure target must reach the INSPIRATORY PRESSURE SET POINT

##### SFSYST7.4

the software must control the PATIENT PRESSURE according to the adjusted PEEP until a INSPIRATORY TRIGGER or the end of APNEA TIME (if Apnea alarm is equal to YES or OFF in preferences menu), if the BACK UP R was set.

The software must control the adjust PEEP until the end of TE if the BACK UP R is active.

$TE = (60/BACK\ UP\ R) - TI$

##### SFSYST7.5

$TI\ MAX = \min [TI\ MAX\ setting, 30 / R]$

If TIMAX is set to auto, the TIMAX must not exceed 3 s.

This applies only in PSV cycles of PSV mode and SIMV modes

##### SFSYST7.6

$TI\ MIN = \max [RISE\ TIME + 300\ ms, TI\ MIN\ setting]$

This applies to all pressure breath cycles.

##### SFSYST7.7

TIMIN has priority on TIMAX : TIMIN must be achieved before allowing TIMAX to stop the inspiratory phase.

#### SFSYST8

CPAP mode (leak)

the software must control the PRESSURE SET POINT to the adjusted PEEP

#### SFSYST9

VOL SIMV mode (valve)

No text (title)

##### SFSYST9.6

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The software must deliver a VIM two seconds after the ventilation has started (starting at the end of the turbine test) if no inspiratory trigger is detected during this period. The SIMV period (60/rate) then starts from the beginning of this VIM.

#### SFSYST9.7

The software must deliver a PIM if an inspiratory trigger is detected during two seconds after the ventilation has started (starting at the end of the turbine test). The SIMV period (60/rate) then starts from the beginning of this PIM.

#### SFSYST9.8

The software must deliver a PS breath if an inspiratory trigger is detected before a period of INSP TIME from the end of the SIMV period.

#### SFSYST9.9

The software must deliver a VIM after a period of 60/Rate since the beginning of the latest VIM. The following cases are exceptions to this rule :

- if a PS inspiration is in progress
- if the duration of the exhalation phase in progress is less than twice the inhalation time

See SFSYST9.14 and SFSYST9.16 for the exception cases.

#### SFSYST9.10

The software must deliver a PIM if a trigger is detected during a period of INSP TIME before the end of the latest SIMV period.

#### SFSYST9.11

If no breath (either VIM, PIM or PS) is delivered in a period equal to APNEA TIME (if Apnea alarm is equal to YES or OFF in preferences menu), the software must start an apnea ventilation with Vol AC breaths at Backup Rate.

#### SFSYST9.12

The software must deliver PS (Pressure Support) breathes like in PSV mode breath with default settings defined in the setting section.

#### SFSYST9.13

The software must deliver PIMs (Patient initiated Mandatory breath) and the VIMs (Ventilator Initiated Mandatory breath) with square flow controlled like in Vol AC mode.

#### SFSYST9.14

a VIM must be delivered after the end of the PS breath exhalation ( $2 \times T_i$  minimum) if it cannot be delivered at the end of the SIMV period unless a PIM is triggered during PS exhalation. If a PIM is triggered after the end of the previous SIMV period, the next SIMV period will start from the beginning of this PIM.

#### SFSYST9.16

If a VIM or a PIM is delivered after the SIMV period (60/rate) ends, the following period is delayed and starts from the beginning of this VIM or PIM.

In case of a PIM triggered before the end of the SIMV period the following period is not delayed and starts at the end of the previous period.

#### SFSYST9.17

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When the ventilator is delivering VIMs during apnea ventilation, three consecutive PIMs would switch back to normal SIMV ventilation. The third consecutive PIM is the first breath of the next SIMV period.

SFSYST10  
PRES SIMV mode (valve)  
No text (title)

#### SFSYST10.6

The software must deliver a VIM two seconds after the ventilation has started (starting at the end of the turbine test) if no inspiratory trigger is detected during this period.

#### SFSYST10.7

The software must deliver a PIM if an inspiratory trigger is detected during two seconds after the ventilation has started (starting at the end of the turbine test). The SIMV period (60/rate) then starts from the beginning of this PIM.

#### SFSYST10.8

The software must deliver a PS breath if an inspiratory trigger is detected before a period of INSP TIME from the end of the SIMV period.

#### SFSYST10.9

The software must deliver a VIM after a period of 60/Rate since the beginning of the latest VIM excepted in the following cases:

- if a PS inspiration is in progress
- if an exhalation is in progress since less than 2xInsp time of the last breath

See 10.14 and 10.16 for those exceptions cases

#### SFSYST10.10

The software shall deliver a PIM if a trigger is detected during a period of INSP TIME before the end of the latest SIMV period.

#### SFSYST10.11

If no breath (either VIM, PIM or PS) is delivered in a period equal to APNEA TIME (if Apnea alarm is equal to YES or OFF in preferences menu), the software must start an apnea ventilation with Pres AC breathes at Backup Rate.

#### SFSYST10.12

The software must deliver PS (Pressure Support) breathes like in PSV mode breath with default settings defined in the setting section.

#### SFSYST10.13

The software must deliver the PIM (Patient initiated Mandatory) and the VIM (Ventilator Initiated Mandatory) with pressure controlled breathes like in Pres AC mode.

#### SFSYST10.14

If a VIM or a PIM is delivered after the SIMV period (60/rate) ends, the following period is delayed and starts from the beginning of this VIM or PIM.

In case of a PIM triggered before the end of the SIMV period the following period is not delayed and starts at the end of the previous period.

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#### SFSYST10.16

a VIM must be delivered after the end of the PS breath exhalation ( $2 \cdot T_i$  minimum) if it cannot be delivered at the end of the 60/rate period unless a PIM is triggered during PS exhalation. If a PIM is triggered after the end of the previous SIMV period, the next SIMV period will start from the beginning of this PIM.

#### SFSYST10.17

When the ventilator is delivering VIMs during apnea ventilation, three consecutive PIMs would switch back to normal SIMV ventilation. The third consecutive PIM is the first breath of the next SIMV period.

#### SFSYST11

##### HIGH PRESSURE

This applies to Valve and Leak configurations. In leak configuration, HIGH PIP, VALVE PRESSURE and EXHALATION valve actions do not apply.

##### SFSYST11.1

if the INTERNAL PRESSURE, PROXIMAL PRESSURE or VALVE PRESSURE are over an HIGH PRESSURE LEVEL in an inspiratory phase, the software must switch to an exhalation phase and maintain the set rate by increasing exhalation time.

##### SFSYST11.2

HIGH PRESSURE LEVEL = HIGH PIP or INSPIRATORY PRESSURE SET POINT + 5 cmH<sub>2</sub>O less than or equal to 29 cmH<sub>2</sub>O and INSPIRATORY PRESSURE SET POINT + 10 cmH<sub>2</sub>O greater than or equal to 30 cmH<sub>2</sub>O but limited to 90 cmH<sub>2</sub>O. The pressure signals used for high-inspiratory pressure alarm conditions shall be filtered to minimize transient pressures caused by the patient (e.g. coughing and talking). The interval from the moment that the ventilator breathing system pressure equals the limit until the pressure starts to decline shall not exceed 200 ms.

##### SFSYST11.3

If PROXIMAL PRESSURE, INTERNAL PRESSURE or VALVE PRESSURE are over HIGH PRESSURE LEVEL during more than 100 ms in an exhalation phase, the software must open the EXHALATION VALVE and stop the turbine.

#### SFSYST12

##### INSPIRATORY PRESSURE SET POINT

If TARGET VT is not active and RELATIVE PRESSURE is on INSPIRATORY PRESSURE SET POINT = P SUPPORT + PEEP or INSPIRATORY PRESSURE SET POINT = P CONTROL + PEEP.

If TARGET VT is not active and RELATIVE PRESSURE is off INSPIRATORY PRESSURE SET POINT = P SUPPORT or INSPIRATORY PRESSURE SET POINT = P CONTROL.

If TARGET VT is active the software must control INSPIRATORY PRESSURE SET POINT with 0.5, 1 and 2 mb steps to reach a VTI between TARGET VT and TARGET VT + 20% within the limit of the P<sub>MAX</sub> setting.

#### SFSYST13

##### INTERNAL PRESSURE to PROXIMAL PRESSURE switch

The software must detect a PROXIMAL PRESSURE loss if the following conditions are gathered:

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```
((PROXIMAL PRESSURE != PATIENT PRESSURE +/- Delta Pressure cmH2O during 50ms
  And FLAT_INT = FALSE
)
Or
(FLAT_PROX = TRUE
  And
  FLAT_INT = FALSE)
Or
Ventilation is disable)
```

Internal pressure sensor signal is not flat over the last breath cycle (ie vary more than 0.4 cmH2O for all mode except CPAP: 0.2 cmH2O) FLAT\_INT = FALSE. Else, FLAT\_INT = TRUE  
 Proximal pressure sensor signal is not flat over the last breath cycle (ie vary more than 0.4 cmH2O for all mode except CPAP: 0.3 cmH2O) ) FLAT\_PROX = FALSE. Else, FLAT\_PROX = TRUE.

The software must detect PROXIMAL PRESSURE presence, if the following conditions are gathered.

```
((PROXIMAL PRESSURE is > 0.4 cmH2O during 400ms.
  And
  PROXIMAL PRESSURE = PATIENT PRESSURE +/- Delta Pressure cmH2O during 400ms.
  And
  FLAT_PROX = FALSE)
Or
(FLAT_PROX = FALSE
  And
  FLAT_INT = TRUE))
And
Ventilation is in inspiration phase.)
```

Delta Pressure depends on the flow value.

For pediatric circuits:

Delta Pressure =  $0.0007 \cdot Q_{insp2} + 0.0853 \cdot Q_{insp} + 1$ ;

For adult circuits:

Delta Pressure =  $0.0004 \cdot Q_{insp2} + 0.0373 \cdot Q_{insp} + 1$ ;

Minimum value limitation:

Delta Pressure = 4cmH2O (at least)

Maximum value limitation for pressure cycles:

Delta pressure threshold = Pisetpoint- AdjustPE (at most)

If the PROXIMAL PRESSURE loss is detected the software shall switch the PATIENT PRESSURE measurement from PROXIMAL PRESSURE sensor to INTERNAL PRESSURE sensor and set the PROXI DETECTION flag to FALSE.

If the PROXIMAL PRESSURE presence is detected the software shall switch the PATIENT PRESSURE measurement from INTERNAL PRESSURE sensor to PROXIMAL PRESSURE sensor and set the PROXI DETECTION flag to TRUE

In leak configuration, the delta pressure condition is replaced by PROXIMAL PRESSURE  $\geq 2$  and all the rest stays the same.

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When the ventilator is in a non-leak configuration mode with a detection of a leak and PEEP  $\geq$  4 cmH<sub>2</sub>O, the delta pressure condition shall be replaced by PROXIMAL PRESSURE  $\geq$  2.

When the ventilator is in a non-leak configuration mode with a detection of a leak and PEEP  $<$  4 cmH<sub>2</sub>O, the delta pressure condition shall be replaced by PEEP  $\geq$  PIP or PIP  $\leq$  CIRCUIT\_DISCONNECT LOW PRESS LIMIT.

#### SFSYST13.1

The ventilator shall use the INTERNAL PRESSURE sensor instead of PROXIMAL PRESSURE during exhalation and it is applicable in all ventilation modes (SFSYST5, SFSYST6, SFSYST7, SFSYST9, SFSYST10) except leak configuration mode.

#### SFSYST14

##### MIN EXH DELAY

MIN EXH DELAY = 300 ms if INSP SENS = 0P

MIN EXH DELAY = 500 ms if INSP SENS = 1P

MIN EXH DELAY = 700 ms if VTI  $<$  50 ml and INSP SENS  $>$  1.

MIN EXH DELAY =  $700 + (1100 - 700) * (VTI - 50) / (250 - 50)$  ms if VTI  $<$  250 ml and INSP SENS  $>$  1

MIN EXH DELAY =  $1100 + (2000 - 1100) * (VTI - 250) / (2000 - 250)$  ms if  $250 < VTI \leq 2000$  ml and INSP SENS  $>$  1

MIN EXH DELAY = 2000 ms if VTI  $>$  2000 and INSP SENS  $>$  1

#### SFSYST14.1

DELETED

#### SFSYST15

##### INSPIRATORY TRIGGER

No text (title)

#### SFSYST15.1

The software must detect the INSPIRATORY TRIGGER when the (current QI + 2 x previous QI)/3 is varying more than INSP SENS in 20 ms during the exhalation phase after MIN EXH DELAY.

#### SFSYST15.10

INSP SENS 0P level = 0.6 lpm (PEEP = 0 to 20)

Flow thresholds decrease of 0.1 lpm every 750 ms from the beginning of exhalation, and a maximum decrease of 0.2 lpm after 1.5 ms with a minimum level of 0.4 lpm.

#### SFSYST15.2

INSP SENS 1 level = 0.8 lpm (PEEP = 0 to 20)

Flow thresholds decrease of 0.1 lpm every 750 ms from the beginning of exhalation, with a maximum of 0.4 lpm after 3 seconds.

#### SFSYST15.3

INSP SENS 2 level = 1.1 lpm (PEEP = 0 to 14)

INSP SENS 2 level = 1.3 lpm (PEEP = 15 to 20)

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Flow thresholds decrease of 0.1 lpm every 750 ms from the beginning of exhalation, with a maximum of 0.4 lpm after 3 seconds.

#### SFSYST15.4

INSP SENS 3 level = 1.3 lpm (PEEP = 0 to 14)

INSP SENS 3 level = 1.5 lpm (PEEP = 15 to 20)

Flow thresholds decrease of 0.1 lpm every 750 ms from the beginning of exhalation, with a maximum of 0.4 lpm after 3 seconds.

#### SFSYST15.5

INSP SENS 4 level = 1.4 lpm (PEEP = 0 to 14)

INSP SENS 4 level = 1.6 lpm (PEEP = 15 to 20)

Flow thresholds decrease of 0.1 lpm every 750 ms from the beginning of exhalation, with a maximum of 0.4 lpm after 3 seconds.

#### SFSYST15.6

INSP SENS 5 level = 1.6 lpm (PEEP = 0 to 14)

INSP SENS 5 level = 1.8 lpm (PEEP = 15 to 20)

Flow thresholds decrease of 0.1 lpm every 750 ms from the beginning of exhalation, with a maximum of 0.4 lpm after 3 seconds.

#### SFSYST15.8

The software must set the INSP SENS level to 1.2 l/min in CPAP mode.

#### SFSYST16

##### EXHALATION TRIGGER

The software must detect an EXHALATION TRIGGER When  $QI < EXH\ SENS * FLOWMAX / 100$  after QMAX has been reached and after RISE TIME elapsed and if the EXH SENS convention setting is  $> 0$

#### SFSYST17

##### RISE TIME

No text (title)

##### SFSYST17.1

RISE TIME 1 = 200 ms

##### SFSYST17.2

RISE TIME 2 = 400 ms

##### SFSYST17.3

RISE TIME 3 = 600 ms

##### SFSYST17.4

RISE TIME 4 = 800 ms

##### SFSYST17.5

if  $TI\ CONTROL < adjusted\ RISE\ TIME + 300\ ms$ , the software must switch to the appropriate RISE TIME to respect this equation. for  $TI\ CONTROL < 500\ ms$  the rise time is 200 ms.

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SFSYST18  
MONITORED VALUES  
No text (title)

SFSYST18.1  
 $I/E = 1 / (TE/TI)$

SFSYST18.2  
PIP = Max [ PATIENT PRESSURE] during TI rounded down to the nearest 0.5 mb

SFSYST18.3  
PEEP (mb) = end exhalation pressure during 100 ms rounded down to the nearest 0.5 mb

SFSYST18.5  
 $R \text{ (bpm)} = 60 / (TI + TE)$

SFSYST18.6  
If EXHALATION VALVE is detected, then  $V_{TI} \text{ (ml)} = TI \times S[QI \text{ (dl/min)}] / 60$  during inspiration  
Else  $V_{TI} \text{ (ml)} = TI \times S[Q_{corrected} \text{ (dl/min)}] / 60$ ; with  $Q_{corrected} = QI - (LEAK \text{ FACTOR} \times \sqrt{\text{Patient Pressure}})$  during inspiration  
In valve mode QI is set to 0 if Patient pressure < Peep measured + 2 mb and  $Ti_{\text{measured}} < 200\text{ms}$  to avoid leakage error in the  $V_{ti}$  compute.

SFSYST18.7  
 $VTE \text{ (ml)} = S[Q_E \text{ (dl/min)} - EQI \text{ (dl/min)}] / 60$  during exhalation  
 $VTE \text{ (n)}$  shall be an average based on the last 5 full breaths or the number of breaths since power up or the number of breaths since the last time the average was reset such that  $VTE(n)$  is the average unless the following condition resets the average:

$ABS \text{ (tidal volume for current breath - } VTE(n-1)) > 5 + 0.15 \times VTE(n-1)$

SFSYST18.8  
 $VM \text{ (lpm)} = V_{TI} \text{ (ml)} \times R \text{ (bpm)} / 1000$

SFSYST18.12  
 $I/T = TI / (TI + TE)$

SFSYST18.13  
LEAK = Mean value of QI over EXHALATION STEADY PHASE -  $\sqrt{\text{monitored PEEP}} \times \sqrt{4\text{mmLeakFactor}}$   
 $\sqrt{4\text{mmLeakFactor}} = 29$  (Leak factor equivalent to a 4mm diameter leak)

SFSYST18.15  
 $FiO_2 = FiO_2 \text{ measure average over a ventilation cycle}$

SFSYST18.17  
 $TI$  = counting from inspiration start to inspiration stop

SFSYST18.18  
 $TE$  = counting from expiration start to expiration stop

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SFSYST18.20

no requirement (title)

SFSYST18.22

AI = sum [Controlled cycles event] per hour in a 24 hour period

SFSYST18.23

T APNEA = mean [Tstop Controlled cycles - Tstart Controlled cycles] in a 24 hour period

SFSYST18.24

% SPONT = (sum [spontaneous breaths] / number of breath) \* 100 in a 24 hour period

SFSYST18.25

VM MEAN = mean [VM] on a 24 hours period

SFSYST18.26

PAW MEAN = mean [PIP] on a 24 hours period

SFSYST18.27

VTE MEAN = mean [VTE] on a 24 hours period

SFSYST18.28

LEAK MEAN = mean [LEAK] on a 24 hours period

SFSYST18.29

VTI MEAN = mean [VTI] on a 24 hours period

SFSYST18.30

RATE MEAN = mean [R] on a 24 hours period

SFSYST18.31

The 24 hours periods goes from 08:00:00 of Day1 to 08:00:00 of Day2

SFSYST18.32

VENTILATION TIME = patient counter at the end of the 24h period - patient counter at the beginning of the 24h period

SFSYST18.33

If the ventilator is stopped and each hours, the software shall record the previous and the current 24 hours periods average values of : RATE MEAN, VTI MEAN, VTE MEAN, LEAK MEAN, VM MEAN, PAW MEAN, empty (reserved for future SpO2), vide (reserved for future cardiac frequency), IA, TAPNEA, and % SPONTvalues. The 24 hours periods goes from 08:00:00 to 19:59:59 and from 20:00:00 to 7:59:59.

SFSYST19

BACKLIGHT

No text (title)

SFSYST19.1

The software must light on the BACKLIGHT, when it starts.

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#### SFSYST19.2

The software must light on the BACKLIGHT, when the BACKLIGHT is off and an alarm is detected.

#### SFSYST19.3

The software must light on the BACKLIGHT, when the BACKLIGHT is off and a key is pressed.

#### SFSYST19.4

The software must always activate the BACKLIGHT, when the BACKLIGHT setting is on .

#### SFSYST19.5

The software must light off the BACKLIGHT, when the BACKLIGHT is off and no key was pressed and no alarm was present for 1 minute.

#### SFSYST20

device sound features

#### SFSYST20.1

The software must control buzzers according to the IEC 60601-1-8 features depending on the LEVEL OF PRIORITY defined in the alarms specifications with the following characteristics:

- x = 50 ms to 125 ms
- td HIGH PRIORITY= 75 ms to 200 ms
- td LOW and MEDIUM PRIORITY = 125 ms to 250 ms
- tb HIGH PRIORITY = 2500 ms to 15000 ms
- tb MEDIUM PRIORITY = 2500 ms to 30000 ms
- tb LOW PRIORITY shall be greater than 15s or no repeat
- inter half burst = 350 ms to 1300 ms
- y = 125 ms to 250 ms
- tr = 10% - 40% of td (RISE TIME)
- tf <= ts – tr (FALL TIME)

#### SFSYST20.2

If KEY SOUND is set to "OFF" in the PREFERENCE MENU, the software must not trigger any sound when a key is pressed (except ventilation key) nor when USB free space calculation ends. If KEY SOUND is set to "key tone" in the PREFERENCE MENU, the software must trigger a navigation sound (click) when any key is pressed.

#### SFSYST20.3

If KEY SOUND is set to "accept tone" in the PREFERENCE MENU, the software must trigger a validation short beep when the VALIDATION KEY is pressed to validate a setting and when USB free space calculation ends.

#### SFSYST20.4

If KEY SOUND is set to "all tones on" in the PREFERENCE MENU, the software must trigger a validation short beep when the VALIDATION KEY is pressed, a short beep when USB free space calculation ends and a navigation sound (click) when any other key is pressed.

#### SFSYST20.5

the software must increase the sound level to maximum level when a high priority alarm lasts longer then 1 minute (without inhibition)

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#### SFSYST20.6

Two SHORT BEEPS are triggered when a USB key is connected or disconnected.

#### SFSYST21

##### LOW AND MEDIUM PRIORITY LED

No text (title)

#### SFSYST21.1

[DEL]

#### SFSYST21.2

The software must light on in a blinking way the medium priority alarm Yellow Led at 0.5 Hz, when a medium priority alarm is activated.

#### SFSYST21.3

The software shall activate a solid Yellow LED light, when a low priority alarm is activated.

#### SFSYST22

##### HIGH PRIORITY LED

The software must light on in a blinking way the high priority alarm Red Led at 2 Hz, when a high priority alarm is activated.

#### SFSYST23

##### alarms features

No text (title)

#### SFSYST23.1

the software must display (sounds and leds) the highest priority level alarm when several alarms are active.

#### SFSYST23.2

the software must reactivate the sound when an alarm occurs even if the inhibition function is running.

#### SFSYST23.3

When inhibition key is SHORT PRESS, the software must cancel alarms sound of silenceable alarms for 60 seconds (except if KEYBOARD alarm is on).

#### SFSYST23.4

When inhibition key is DOUBLE PRESS, the software must cancel the cancelable alarms (as described in the alarms settings).

#### SFSYST23.5

the software must keep the auditory alarm at least one half BURST for an HIGH PRIORITY and one full BURST for a LOW and MEDIUM PRIORITY, unless alarm is inhibited or cancelled by the user

#### SFSYST23.6

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the software must cancel the alarms, as defined in alarm specification by auto cancel attributes, when the ventilation is off or when a mode is changed during ventilation

#### SFSYST23.7

the software must reactivate alarms which has been manually cancelled or inhibited when the field "Reactivate paused alarms " is validated in ALARM MEMORY MENU. The software must reactivate only alarms for which conditions are still true.

#### SFSYST23.8

If one of the alarms defined in alarm specification by the attributes "replace vent if persists" = Yes, is displayed during more than 30s, the software shall display a message "restart / srvc if persists" which will last until none of those alarms is active.

#### SFSYST24

##### KEYLOCK

No text (title)

#### SFSYST24.1

the software activates and deactivates the KEYLOCK function when the user LONG PRESS the UP KEY and DOWN KEY in VENTILATION MENU or in ALARM MENU.

#### SFSYST24.2

when the KEYLOCK function is on, the software prohibit the field changes (except for MEMORY ALARM MENU), the parameters changes, the mode change and the PREFERENCE MENU and SET UP MENU access.

#### SFSYST24.3

when the KEYLOCK function is on, the software allows the alarm inhibition, VENTILATION MENU, ALARM MENU, WAVEFORM MENU, USB MENU and ALARM MEMORY MENU access, start and stop of the ventilation and curves play/pause.

#### SFSYST25

##### memorization

No text (title)

#### SFSYST25.1

the software shall record the ventilation and alarm settings of each mode, SET UP MENU , PREFERENCE MENU, and MACHINE HOURS, PATIENT HOURS.

#### SFSYST25.2

the software shall record the current ventilation mode and settings.

#### SFSYST25.3

the software shall record the events defined in the SFSYSTEV specifications.

#### SFSYST25.4

for each recorded event the software must record at least all ventilation settings, all alarm settings, ventilation mode, monitored values corresponding to the ventilation cycle of the event detection, machine hours, patient counter, the supply type, BATTERY LEVEL or BATTERY

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CHARGE VOLTAGE, voluntary stop alarm, relative pressure, barometric compensation, sound level, pediatric circuit, disconnection delay, apnea alarm, date and time of the event detection .

#### SFSYST25.5

The software shall record, in the trend memory, a buffer of trend when buffer size reaches 512 bytes.

One trend data frame (as defined in SFSYSTCOMDP303) is added to the buffer every minute of ventilation.

The software shall record, in the buffer, one 0xFF frame then two 0x00 frames the first time ventilation is started after a device power on.

When the device is turned off, the current buffer of trends which are not yet recorded in the trend memory is lost.

#### SFSYST25.6

The software shall record, in the detailed monitoring memory, a date and time frame (as defined in SFSYSTCOMDP72) every time ventilation is started or stopped and each 15 min of ventilation.

The software shall record, in the detailed monitoring memory, a monitoring data frame (as defined in SFSYSTCOMDP1) each 40 ms of ventilation .

The software shall record, in the detailed monitoring memory, one 0xFF frame then two 0x00 frames then another date and time frame (as defined in SFSYSTCOMDP72) the first time ventilation is started after a device power on.

When ventilation is turned off, the current 2048 octets buffer of detailed monitoring data frames is filled with complete date and time frames (as defined in SFSYSTCOMDP72) and is stored in the detailed monitoring memory.

#### SFSYST27

Turbine stop

the software must stop the turbine while the alarm TURBINE OVERHEAT is active (PWM 0 and brake at 100%)

#### SFSYST28

Oxygen supply management

the oxygen supply is allowed only if the device is ventilating and the TURBINE\_OVER\_HEAT alarm is not activated, else the oxygen supply valve is closed.

#### SFSYST33

Messages and translation requirements

The messages that will be described in the GUI shall be found in the PB560\_messages.xls file attached to the CPU SRS.

#### SFSYST77

Exhalation Valve detection

#### SFSYST77.1

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if VALVE PRESSURE > 1,5 mbar during TURBINE SPEED TEST, the software must detect the valve connection

#### SFSYST77.2

if VALVE PRESSURE < 1,5 mbar during TURBINE SPEED TEST, the software must detect the valve disconnection. In that case the valve command must be off

#### SFSYST80

FiO2 sensor detection

if  $FiO_2 > 0.3V$  during 2s, the software must detect a FiO2 sensor .

The software must display FiO2 value when a sensor is detected and ventilation is on.

#### SFSYST81

FiO2 sensor calibration

when the FiO2 sensor calibration is launched, the software must,

- close the O2 valve until the end of the process
- memorize the FIO2 OFFSET
- a message must be displayed during the calibration process

#### SFSYST102

LEAK FACTOR

##### SFSYST102.1

The software shall determine the length of the EXHALATION STEADY PHASE by applying the following rules:

- 1 The EXHALATION STEADY PHASE terminates at the end of exhalation when the next breath is a controlled breath.
- 2 The EXHALATION STEADY PHASE terminates 100 ms before the end of exhalation when the next breath is a patient triggered breath.
- 3 The EXHALATION STEADY PHASE must not last more than exhalation duration /2
- 4 The EXHALATION STEADY PHASE must not last more than 600 ms
- 5 The average flow over exhalation last 100 ms must not vary more than 5% from the average flow over the first 100 ms considered.
- 6 The EXHALATION STEADY PHASE can take the following values: 100, 200, 300, 400, 500, 600 ms

##### SFSYST102.2

The software shall estimate the LEAK FACTOR which is  $K = Q_{leak}^2 / PEEP$  at the end of the exhalation for each breath.

$Q_{leak}$  = estimated flow at the end of exhalation obtained by linear regression interpolation over the exhalation steady phase.

PEEP = Patient pressure over the exhalation steady phase.

When the proximal pressure is not detected, the estimated proximal pressure is used (refer to SFSYST4.9) instead of the internal pressure raw measurement.

##### SFSYST102.3

DELETED

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SFSYST102.4

#### CIRCUIT CHECK

Upon execution the software shall close the EXHALATION VALVE and command the turbine to 30,000 RPM.

During execution the software shall measure the INSPIRATION FLOW every 2 seconds.

The CIRCUIT CHECK shall complete after 10 seconds.

Upon completion or cancelation the software shall open the EXHALATION VALVE and command the turbine to stop.

If the last measured INSPIRATION FLOW  $\leq 1.0$  sLpm then CIRCUIT CHECK is denoted as passing.

If the last measured INSPIRATION FLOW is  $> 1.0$  sLpm then CIRCUIT CHECK is denoted as failing.

### 3.2 Alarm Requirements

SFSYSTAL1

#### LOW PRESSURE

Detection Conditions: (INSPIRATION FLOW  $> 130$  lpm in inspiration phase

or

When PROXIMAL PRESSURE  $\leq$  [INSPIRATORY PRESSURE SET POINT - 20%] In PSV, CPAP, PRES A/C, PRES SIMV modes.

or

When PROXIMAL PRESSURE  $\leq$  LOW PIP) In VOL A/C and VOL SIMV mode.)

and

HIGH PRESSURE ALARM  $< \text{TRUE}$

Validation Delay: Max [Disconnection time, 60/R-Rate] PC, VC

Max [Disconnection time, Apnea Time + 2 sec] PSV

Max [Disconnection time, 60/R-Rate + Insp Time] PSIMV, VSIMV

Cancel Conditions: (INSPIRATION FLOW  $\leq 130$  lpm during inspiration after 240 ms

AND

FILTERED PATIENT PRESSURE  $>$  (INSPIRATORY PRESSURE SET POINT - 20%) In PSV, CPAP, PRES A/C, PRES SIMV modes

AND

FILTERED PATIENT PRESSURE  $>$  LOW PIP In VOL A/C and VOL SIMV modes)

OR

HIGH PRESSURE ALARM  $\geq \text{TRUE}$

Priority: High priority

Audio Pause: yes

Alarm Pause: No

Modes: All

Actions: Events DISCONNECTION + END OF DISCONNECTION

Resetconditions: ventilation change; Ventilation std-by

Replaceventifpersistmessage: Yes

Circuit: valve

SFSYSTAL2

#### HIGH PRESSURE

Detection Conditions: (PATIENTPRESSURE $>$  HIGH PRESSURE LEVEL

or (PROXIMAL PRESSURE $>$  HIGH PRESSURE LEVEL and CHECK PROXIMAL ALARM = FALSE)

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or (VALVE PRESSURE > HIGH PRESSURE LEVEL and CHECK PRESSURE ALARM > FALSE and CHECK PROXIMAL ALARM > FALSE)

In Volume cycles:

HIGH PRESSURE LEVEL is HIGH PIP

In pressure cycles :

HIGH PRESSURE LEVEL is INSPIRATORY PRESSURE SET POINT + 5 cmH<sub>2</sub>O less than or equal to 29 cmH<sub>2</sub>O and INSPIRATORY PRESSURE SET POINT + 10 cmH<sub>2</sub>O greater than or equal to 30 cmH<sub>2</sub>O limited to 90 cmH<sub>2</sub>O. The pressure signals used for high-inspiratory pressure alarm conditions shall be filtered to minimize transient pressures caused by the patient (e.g. coughing and talking). The interval from the moment that the ventilator breathing system pressure equals the limit until the pressure starts to decline shall not exceed 200 ms.

Validation Delay: For all modes except SIMV modes:

3 consecutive breath cycles with high pressure during inspiration.

For SIMV modes only:

3 consecutive PIM or VIM breath cycles with high pressure during inspiration.

or

3 consecutive PS breath cycles with high pressure during inspiration.

For all modes:

3 consecutive breath cycles with high pressure during exhalation.

In addition, conditions must persist 100 ms in any mode for detection during exhalation

Cancel Conditions: For all modes except SIMV modes:

If the alarm has been activated by 3 consecutive high pressure breaths during inspiration, then the alarm will be canceled by the first breath without high pressure during inspiration.

For SIMV modes only:

If the alarm has been activated by 3 consecutive VIM or PIM high pressure breaths during inspiration, then the alarm will be canceled by the first VIM or PIM breath without high pressure during inspiration.

If the alarm has been activated by 3 consecutive PS high pressure breaths during inspiration, then the alarm will be canceled by the first PS breath without high pressure during inspiration.

For all modes: High Pressure detected during exhalation:

If the alarm has been activated by 3 consecutive high pressure breaths during exhalation, then the alarm will be canceled by the first breath without high pressure during exhalation.

Priority: High priority

Audio Pause: yes

Alarm Pause: No

Modes: VOL A/C; PRES A/C; PSV; VOL SIMV; PRES SIMV

Actions: Switch to exhalation phase if it occurs in inspiratory phase.

Stop the turbine and open EXHALATION VALVE if it occurs in exhalation phase

Events HIGH PRESSURE + END OF HIGH PRESSURE

Reset conditions: ventilation change; Ventilation std-by

Replaceventifpersistmessage: No

Circuit: all

SFSYSTAL3

APNEA

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Detection Conditions: when the patient does not receive any breath during the apnea time and apnea setting in preference menu is set to Yes  
 Validation Delay: Apnea Time starting from the beginning of inspiration  
 Cancel Conditions: when the third successive patient breath is triggered and apnea setting is set to Yes in preference  
 Or apnea setting is set to No in preferences  
 Priority: Medium priority  
 Audio Pause: yes  
 Alarm Pause: Yes (except in CPAP mode)  
 Modes: PSV; VOL SIMV; PRES SIMV; CPAP  
 Actions: Pressure Support cycles in PSV mode  
 Pressure Controlled cycles in PRES SIMV mode  
 Volume Controlled cycles in VOL SIMV  
 Events APNEA + END OF APNEA  
 Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: all

#### SFSYSTAL4

##### HIGH VTI

Detection Conditions: when VTI > HIGH VTI  
 Validation Delay: 3 consecutive cycles  
 Cancel Conditions: Auto + DISCONNECTION alarm on  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: PRES A/C; PSV; PRES SIMV; CPAP  
 Actions: Events HIGH VTI + END OF VTI  
 Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: all

#### SFSYSTAL5

##### LOW VTI

Detection Conditions: when VTI < LOW VTI  
 Validation Delay: 3 consecutive cycles  
 Cancel Conditions: Auto + DISCONNECTION alarm on  
 Priority: Medium priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: PRES A/C; PSV; PRES SIMV; CPAP  
 Actions: Events LOW VTI + END OF LOW VTI  
 Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: all

#### SFSYSTAL6

##### LOW VTE

Detection Conditions: when VTE < LOW VTE  
 Validation Delay: 3 consecutive cycles  
 Cancel Conditions: Auto + DISCONNECTION alarm on  
 Priority: Medium priority

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Audio Pause: yes  
Alarm Pause: No  
Modes: VOL A/C; PRES A/C; PSV; VOL SIMV; PRES SIMV  
Actions: Events LOW VTE + END OF LOW VTE  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No  
Circuit: valve

SFSYSTAL9  
HIGH RATE  
Detection Conditions: R > HIGH R  
Validation Delay: 3 consecutive cycles  
Cancel Conditions: Auto  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: No  
Modes: All  
Actions: Events HIGH RATE + END OF HIGH RATE  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL10  
POWER SUPPLY LOSS  
Detection Conditions: internal and external power failure or device stop when the ventilation is on.  
Validation Delay: Immediate  
Cancel Conditions: Auto, INHIBITION KEY, SHORT PRESS  
Priority: Very high priority  
Audio Pause: no  
Alarm Pause: no  
Modes: All  
Actions: The sequence below is processed in this priority order:  
- Activation of main buzzers.  
- Event UNVOLUNTARY STOP VENTIL  
- Memorization of counters and ventilation state.  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL11  
AC POWER DISCONNECTION (AC POWER FAIL)  
Detection Conditions:

- 1) If CHECK SUPPLY alarm off  
INFO SUPPLY = DC  
or  
INFO SUPPLY = BAT  
Validation Delay: immediate

- 2) If CHECK SUPPLY alarm on  
AC SELECTED = 0

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Validation Delay: 5 s if the ventilation is off or during 2 cycles if the ventilation is on

Cancel Both Conditions:

If CHECK SUPPLY alarm off and INFO SUPPLY = AC OR

If CHECK SUPPLY alarm on and AC SELECTED = 1

Priority: For condition 1, Low priority shall be declared.

For condition 2, Medium priority shall be declared.

Audio Pause: yes

Alarm Pause: yes

Modes: All

Actions: Events AC POWER FAIL + AC RETURN

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

SFSYSTAL13

CHECK SUPPLY (ERROR CODE 20)

Detection Conditions: SUPPLY BUS DEFAULT flag = yes (three missed frames)

Validation Delay: Immediate

Cancel Conditions: Auto

Priority: Medium priority

Audio Pause: yes

Alarm Pause: yes

Modes: All

Actions: Events CHECK SUPPLY + END OF CHECK SUPPLY + display neutral symbol instead of BATTERY LEVEL HOURMETER or BATTERY % LEVEL

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

SFSYSTAL15

LOW BATTERY

Detection Conditions:

If NO BATTERY and END OF BATTERY alarm are NOT Active, then check the following conditions:

1. if CHECK SUPPLY alarm off AND  
INFO SUPPLY != NONE AND  
BATTERY LOW flag = TRUE  
If INFO SUPPLY == AC  
Priority: Low priority  
Else  
Priority: High priority
2. if CHECK SUPPLY alarm on AND  
SUPPLY MEASURE <= 23.5 V  
If AC SELECTED =1  
Priority: Low priority  
Else  
Priority: High priority

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Validation Delay: 100 ms  
Cancel Conditions:

If END OF BATTERY alarm is Active  
OR NO BATTERY alarm is Active  
OR (AlarmCheckSupply != PrevAlarmCheckSupply)  
OR  
if CHECK SUPPLY alarm off AND  
(BATTERY LOW flag = FALSE OR (PrevPowerType != PowerType))  
OR  
If CHECK SUPPLY alarm on AND  
SUPPLY MEASURE > 23.5 V OR  
(AC\_Selected != PreviousAcSelected)

Audio Pause: yes  
Alarm Pause: No  
Modes: All  
Actions: Event LOW BATTERY  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL16  
EMPTY BATTERY (END OF BATTERY)  
Detection Conditions:

If NO BATTERY alarm is NOT Active, then check the following conditions:

1. if CHECK SUPPLY alarm off AND  
INFO SUPPLY != NONE AND  
BATTERY END flag = TRUE  
If INFO SUPPLY == AC  
Priority: Low priority  
Else  
Priority: High priority
2. if CHECK SUPPLY alarm on AND  
SUPPLY MEASURE <= 22.5 V  
If AC SELECTED =1  
Priority: Low priority  
Else  
Priority: High priority

Validation Delay: 100 ms  
Cancel Conditions:

If NO BATTERY alarm is Active  
OR (AlarmCheckSupply != PrevAlarmCheckSupply)

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OR  
 If CHECK SUPPLY alarm off AND  
 (BATTERY END flag = FALSE OR (PrevPowerType != PowerType))  
 OR  
 if CHECK SUPPLY alarm on AND  
 SUPPLY MEASURE > 22.5 V OR  
 (AC\_Selected != PreviousAcSelected)

Audio Pause: no  
 Alarm Pause: No  
 Modes: All  
 Actions: Event END OF BATTERY  
 Resetconditions: N/A  
 Replaceeventifpersistmessage: No  
 Circuit: all

SFSYSTAL17  
 CHECK BATTERY  
 Detection Conditions: BATTERY OK flag = No  
 Validation Delay: Immediate  
 Cancel Conditions: Auto  
 or CHECK SUPPLY alarm on  
 Priority: Medium priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: All  
 Actions: Events CHECK BATTERY + END OF CHECK BATTERY + display neutral symbol on  
 BATTERY LEVEL HOURMETER displayed  
 Resetconditions: N/A  
 Replaceeventifpersistmessage: No  
 Circuit: all

SFSYSTAL18  
 NO BATTERY  
 Detection Conditions: BATTERY PRESENCE flag = No  
 Validation Delay: Immediate  
 Cancel Conditions: Auto  
 or CHECK SUPPLY alarm on  
 Priority: Medium priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: All  
 Actions: Events NO BATTERY + END OF NO BATTERY + display neutral symbol on BATTERY  
 LEVEL HOURMETER displayed  
 Resetconditions: N/A  
 Replaceeventifpersistmessage: No  
 Circuit: all

SFSYSTAL19  
 CHECK BUZZER

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Detection Conditions: (BUZZER VOLTAGE < BUZZER ALARM LEVEL and BUZZER COMMAND = 1) and (BUZZER BATTERY VOLTAGE < 4.8 V) during the initialization buzzer test  
OR  
when an alarm is active : (BUZZER VOLTAGE < BUZZER ALARM LEVEL and BUZZER COMMAND = 1)

BUZZER ALARM LEVEL= (SOUND LEVEL-20)\*6.2 + 100

Validation Delay: 5 s

Cancel Conditions: N/A

Priority: Medium priority

Audio Pause: yes

Alarm Pause: No

Modes: All

Actions: Events CHECK BUZZER + activation of BACK-UP BUZZER

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

SFSYSTAL20

ERROR CODE 21 (TECHNICAL PROBLEM)

Detection Conditions: PFI > 30 V

Validation Delay: Immediate

Cancel Conditions: Auto

Priority: Medium priority

Audio Pause: yes

Alarm Pause: Yes

Modes: All

Actions: Events TECHNICAL PROBLEM + END OF TECHNICAL PROBLEM

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

SFSYSTAL21

CHECK SETTINGS

Detection Conditions: setting out of range  
or download of a new LXxxxxx version  
or loss of SETUP MENU Settings

Validation Delay: Immediate

Cancel Conditions: No

Priority: Medium priority

Audio Pause: yes

Alarm Pause: Yes

Modes: All

Actions: Lock key function deactivation  
default value for out of range settings.

Events NEW VERSION + EEPROM OUT OF RANGE + LOOSING SETTINGS

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

SFSYSTAL23

ERROR CODE 22 (CHECK PRESSURE)

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Detection Conditions: If FLAT\_INT= TRUE (see SFSYST13) then  
switch CHECK PRESSURE from FALSE to DETECTED status.

If (VALIDATION DELAY elapsed  
And  
DISCONNECTION Alarm has not been greater than FALSE status during validation delay - 1 s)  
Validation Delay: Max [Disconnection time, 60/R-Rate] PC, VC  
Max [Disconnection time, Apnea Time + 2 sec] CPAP, PSV  
Max [Disconnection time, 60/R-Rate + Insp Time] PSIMV, VSIMV  
Cancel Conditions: If FLAT\_INT= FALSE (see SFSYST13)  
then switch CHECK PRESSURE from DETECTED or TRUE status to FALSE status.  
Priority: High priority  
Audio Pause: yes  
Alarm Pause: No  
Modes: All  
Actions: Events CHECK PRESSURE + END OF CHECK PRESSURE  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL24  
ERROR CODE 23 (CHECK PROXIMAL)  
Detection Conditions: If (FLAT\_PROXI= TRUE (see SFSYST13)  
And  
(PROXIMAL PRESSURE > Adjust PEEP + 1.5cm H2O  
Or  
PROXIMAL PRESSURE< AdjustPEEP - 1.5cm H2O)  
And  
PROXIMAL PRESSURE > 1.5 cm H2O)  
then switch CHECK PROXIMAL from FALSE to DETECTED status.

if DETECTION DELAY elapsed  
then switch CHECK PROXIMAL from DETECTED to TRUE status  
Validation Delay: Max [Disconnection time, 60/R-Rate] PC, VC  
Max [Disconnection time, Apnea Time + 2 sec] CPAP, PSV  
Max [Disconnection time, 60/R-Rate + Insp Time] PSIMV, VSIMV  
Cancel Conditions: If (FLAT\_PROXI= FALSE (see SFSYST13)  
Or  
(PROXIMAL PRESSURE < Adjust PEEP + 1.5cm H2O  
And  
PROXIMAL PRESSURE> AdjustPEEP - 1.5cm H2O)  
Or  
PROXIMAL PRESSURE < 1.5 cm H2O)  
switch PROX CHECK PROXIMAL from DETECTED or TRUE status to FALSE status.  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: Yes  
Modes: All  
Actions: Events CHECK PROXIMAL + END OF CHECK PROXIMAL  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No

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Circuit: all

#### SFSYSTAL25

##### CHECK PROXIMAL LINE (PROX DISCONNECTION)

Detection Conditions: If (PROXI DETECTED = FALSE

And

Counter cycle  $\geq 4$ th CYCLE) then

switch PROX DISCONNECTION from FALSE to DETECTED status.

if (CHECK PROXIMAL alarm to FALSE status.

And

DETECTION DELAY elapsed) then

switch PROX DISCONNECTION from DETECTED to TRUE status

Validation Delay: Max [Disconnection time +2, 60/R-Rate + 2] PC, VC

Max [Disconnection time + 2, Apnea Time + 4 sec] CPAP, PSV

Max [Disconnection time + 2, 60/R-Rate + Insp Time + 2] PSIMV, VSIMV

Cancel Conditions: If (PROXI DETECTED = TRUE

Or

CHECK PROXIMAL alarm  $\geq$  TRUE status)

then switch PROX DISCONNECTION from DETECTED or TRUE status to FALSE status.

Priority: Medium priority

Audio Pause: yes

Alarm Pause: No

Modes: All

Actions: Events PROX DISCONNECTION + END OF PROX DISCONNECTION

Resetconditions: ventilation change; Ventilation std-by

Replaceventifpersistmessage: Yes

Circuit: all

#### SFSYSTAL28

##### CHECK EXH. VALVE (CHECK VALVE)

Detection Conditions: During exhalation phase ( $EVTI < -VTI * 4/10$  and  $VTI > 20\text{mL}$ )

OR (VALVE CURRENT  $> 50.0\text{ mA}$ ) OR (VALVE CURRENT  $< 40.0\text{ mA}$ ) OR

((VEN\_FLEAK\_MEASURED  $< VEN\_TARGET\_FLOW * 0.8$ ) AND (INSP\_FLOW\_MEASURED  $< -15\text{ lpm}$  at 500 ms after exhalation start))

Validation Delay: shall be no more than two breath cycles or 5 s, whichever is greater.

Cancel Conditions: Auto

Priority: High priority

Audio Pause: yes

Alarm Pause: No

Modes: VOL A/C; PRES A/C; PSV; VOL SIMV; PRES SIMV

Actions: Events CHECK VALVE + END OF CHECK VALVE

Resetconditions: ventilation change; Ventilation std-by

Replaceventifpersistmessage: Yes

Circuit: valve

#### SFSYSTAL29

##### CHECK VOLUME

Detection Conditions:  $VTI < VOL\_CONTROL - 10\%$  and DISONNECTION alarm = off and

HIGH PRESSURE alarm = off and

INSPIRATORY FLOW FAILURE alarm = off

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Validation Delay: 6 consecutive cycles after saturation of auto adaptive adjustment loop  
 Cancel Conditions: Auto  
 or alarm disconnection = true  
 or alarm high pressure = true  
 or alarm Inspiratory Flow Failure = true  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: VOL A/C; VOL SIMV  
 Actions: Events CHECK VOLUME + END OF CHECK VOLUME  
 Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: Yes  
 Circuit: valve

SFSYSTAL30  
 EXH. VALVE LEAKAGE (VALVE LEAKAGE)  
 Detection Conditions:  $\text{sum(IQE)} > 0.7 \times \text{sum(QI)}$  during inspiration and  $\text{VTI} > 40\text{mL}$ .  
 Validation Delay: 3 consecutive cycles  
 Cancel Conditions: Auto  
 Priority: Medium priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: VOL A/C; PRES A/C; PSV; VOL SIMV; PRES SIMV  
 Actions: Events VALVE LEAKAGE + END OF VALVE LEAKAGE  
 Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: valve

SFSYSTAL31  
 CHECK REMOTE ALARM  
 Detection Conditions:  $\text{ALARM\_REMOTE\_STATE} \neq \text{BUZZER COMMAND}$  during the initialization buzzer test or when an alarm is active.  
 Validation Delay: 1 s  
 Cancel Conditions: N/A  
 Priority: Medium priority  
 Audio Pause: yes  
 Alarm Pause: Yes  
 Modes: All  
 Actions: Events CHECK REMOTE  
 Resetconditions: N/A  
 Replaceventifpersistmessage: No  
 Circuit: all

SFSYSTAL33  
 INSP FLOW OFFSET FAULT (n°2)  
 Detection Conditions: inspiration flow sensor offset out of range after calibration  
 Validation Delay: Immediate  
 Cancel Conditions: NA  
 Priority: Visual  
 Audio Pause: no  
 Alarm Pause: No

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Modes: All  
Actions: default offset + Event INSP FLOW OFFSET  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL34  
EXH FLOW OFFSET FAULT (n°3)  
Detection Conditions: exhalation flow sensor offset out of range after calibration  
or  
ventilation starts during calibration process  
Validation Delay: Immediate  
Cancel Conditions: NA  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: default offset + Event EXH FLOW OFFSET  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL35  
VALVE PRESSURE OFFSET FAULT (n°4)  
Detection Conditions: valve pressure offsets or I\_REF out of range during calibration. Successive valve PWM offsets difference lower than 15.  
Validation Delay: Immediate  
Cancel Conditions: NA  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: default offset  
or precedent PWM offset -15 if difference with precedent is lower than 15  
+ Event VALVE PRESSURE OFFSET  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL36  
INTERNAL PRESSURE OFFSET FAULT (n°5)  
Detection Conditions: internal pressure sensor offset out of range after calibration  
Validation Delay: Immediate  
Cancel Conditions: NA  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: default offset + Event INTERNAL PRESSURE OFFSET  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

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**SFSYSTAL37****SPEED FAULT (n°6)**

Detection Conditions:  $\text{SPEED SET POINT} - 20 \% < \text{SPEED} < \text{SPEED SET POINT} + 20 \%$   
during the INITIALIZATION PHASE

Validation Delay: Immediate

Cancel Conditions: NA

Priority: Visual

Audio Pause: no

Alarm Pause: No

Modes: All

Actions: Event SPEED DEFAULT

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

**SFSYSTAL38****CLOCK FAULT (n°7)**

Detection Conditions: loss of clock parameters

Validation Delay: Immediate

Cancel Conditions: NA

Priority: Visual

Audio Pause: no

Alarm Pause: no

Modes: All

Actions: Event CLOCK

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

**SFSYSTAL39****KEYBOARD FAIL**

Detection Conditions: long pressing of any key

Validation Delay: 45 s

Cancel Conditions: auto

Priority: High priority

Audio Pause: no

Alarm Pause: No

Modes: All

Actions: Event KEYBOARD + END OF KEYBOARD + inhibition prohibited

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

**SFSYSTAL40****PROXIMAL PRESSURE OFFSET FAULT (n°8)**

Detection Conditions: proximal pressure sensor offset out of range after calibration

Validation Delay: Immediate

Cancel Conditions: NA

Priority: Visual

Audio Pause: no

Alarm Pause: No

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Modes: All  
Actions: default offset + Event PROXI PRESS OFFSET  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL41  
VERY LOW PROXIMAL PRESSURE (n°9)  
Detection Conditions: PROXIMAL PRESSURE < -10 cmH2O  
Validation Delay: 15 s  
Cancel Conditions: NA  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: Event VERY LOW PROXI PRESS  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL42  
VERY LOW INTERNAL PRESSURE (n°10)  
Detection Conditions: INTERNAL PRESSURE < -10 cmH2O  
Validation Delay: 15 s  
Cancel Conditions: NA  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: Event VERY LOW INTERNAL PRESSURE  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL43  
VERY LOW VALVE PRESSURE (n°11)  
Detection Conditions: VALVE PRESSURE < -10 cmH2O  
Validation Delay: 15 s  
Cancel Conditions: NA  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: Event VERY LOW VALVE PRESSURE  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL44  
UNKNOWN BATTERY  
Detection Conditions: UNKNOWN BATTERY flag = TRUE  
Validation Delay: immediate

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Cancel Conditions: Auto  
or  
CHECK SUPPLY alarm on  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: No  
Modes: All  
Actions: Events UNKNOWN BATTERY + END OF UNKNOWN BATTERY + display neutral symbol on BATTERY LEVEL HOURMETER displayed  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL45  
CHECK BATTERY CHARGE  
Detection Conditions: CHARGE BATTERY KO flag = TRUE  
Validation Delay: immediate  
Cancel Conditions: Auto  
or  
CHECK SUPPLY alarm on  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: Yes  
Modes: All  
Actions: Events CHECK BATTERY CHARGE + END OF CHECK BATTERY CHARGE  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL46  
HIGH VTE  
Detection Conditions: when VTE > HIGH VTE  
Validation Delay: 3 consecutive cycles  
Cancel Conditions: auto  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: No  
Modes: VOL A/C; PRES A/C; PSV; VOL SIMV; PRES SIMV  
Actions: Events HIGH VTE + END OF HIGHVTE  
Resetconditions: ventilation change; Ventilation std-by  
Replaceeventifpersistmessage: No  
Circuit: valve

SFSYSTAL47  
CALIBRATION FAILURE  
Detection Conditions: Failure of one calibration point of exhaled flow sensor  
Validation Delay: immediate  
Cancel Conditions: N.A.  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: Yes  
Modes: All

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Actions: Replace the offset failed by the default one +  
Event CALIBRATION FAILURE  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL48  
COOLING FAN FAILURE  
Detection Conditions: COOLING\_FAN\_FAILURE\_FLAG = TRUE  
Validation Delay: immediate  
Cancel Conditions: auto  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: Yes  
Modes: All  
Actions: Events COOLING FAN FAILURE + END OF COOLING FAN FAILURE  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL49  
AMBIENT TEMP. ALERT (AMBIENT TEMP OUTOFBOUNDS)  
Detection Conditions: AMBIENT\_TEMP\_OUTOFBOUNDS = TRUE  
Validation Delay: immediate  
Cancel Conditions: auto  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: Yes  
Modes: All  
Actions: Events AMBIANT TEMP FAILURE + END OF AMBIANT TEMP FAILURE  
Resetconditions: N/A  
Replaceeventifpersistmessage: Yes  
Circuit: all

SFSYSTAL50  
BAT TEMP. ALERT (BAT TEMP OUTOFBOUNDS)  
Detection Conditions: BAT\_TEMP\_OUTOFBOUNDS = TRUE  
Validation Delay: immediate  
Cancel Conditions: auto  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: Yes  
Modes: All  
Actions: Events BAT TEMP OUTFOBOUNDS + END OF BAT TEMP OUTOFBOUNDS  
Resetconditions: N/A  
Replaceeventifpersistmessage: Yes  
Circuit: all

SFSYSTAL51  
ERROR CODE 24 (SUPPLY MEASURE FAILURE)  
Detection Conditions: SUPPLY\_MEASURE\_FAILURE = TRUE  
Validation Delay: immediate

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Cancel Conditions: auto  
 Priority: Medium priority  
 Audio Pause: yes  
 Alarm Pause: Yes  
 Modes: All  
 Actions: Events SUPPLY MEASURE FAILURE + END OF SUPPLY MEASURE FAILURE  
 Resetconditions: N/A  
 Replaceventifpersistmessage: No  
 Circuit: all

SFSYSTAL52  
 ERROR CODE 26 (FAILURE 24V)  
 Detection Conditions: FAILURE\_24V = TRUE  
 Validation Delay: immediate  
 Cancel Conditions: auto  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: All  
 Actions: Events FAILURE 24V + END OF FAILURE 24V  
 Resetconditions: N/A  
 Replaceventifpersistmessage: No  
 Circuit: all

SFSYSTAL53  
 TURBINE OVERHEAT  
 Detection Conditions: SPEED BLOWER < 1000 rpm during 5 seconds  
 and  
 (BLOWER TEMP > 70°C  
 or  
 BLOWER TEMP < -30°C)  
 and  
 blower pwm is not constant (except for max blower speed command in service mode)  
 Validation Delay: 5 seconds  
 Cancel Conditions: NA  
 Priority: High priority  
 Audio Pause: no  
 Alarm Pause: No  
 Modes: All  
 Actions: Turbine stop + Oxygen supply stop + Events TUBINE OVERHEAT  
 Reset Conditions: N/A  
 Replace Ventilator persist message: No  
 Circuit: all

SFSYSTAL54  
 OCCLUSION  
 Detection Conditions: VT < 20 ml  
 and  
 INSPIRATORY PRESSURE SET POINT - 20% < PIP < INSPIRATORY PRESSURE SET  
 POINT + 20%  
 And  
 No negative flow detection for more than 50ms consecutively during inhalation phase.

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Validation Delay: shall be no more than two breath cycles or 5 s, whichever is greater.  
 Cancel Conditions: auto  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: PRES A/C; PSV; PRES SIMV  
 Actions: Event OCCLUSION + Event END OF OCCLUSION  
 Reset Conditions: ventilation change; Ventilation std-by  
 Replace ventilator persist message: Yes  
 Circuit: valve; leak

SFSYSTAL55  
 ERROR CODE 25 (CPU REFERENCE FAILURE )  
 Detection Conditions: 5 V reference flag true (1 s delayed)  
 and  
 10 V reference flag true (1 s delayed)  
 Validation Delay: immediate  
 Cancel Conditions: auto  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: All  
 Actions: Events CPU REFERENCE FAILURE + END OF CPU REFERENCE FAILURE  
 Resetconditions: N/A  
 Replaceventifpersistmessage: No  
 Circuit: all

SFSYSTAL57  
 BREATH TIME CYCLED  
 Detection Conditions: If at least 4 of the 6 last spontaneous breaths over the past one minute are terminated by time.  
 Validation Delay: immediate  
 Cancel Conditions: if 2 or less spontaneous cycles are terminated by time over the last spontaneous six cycles or no spontaneous breath occurred over the past one minute.  
 Priority: Medium priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: VOL SIMV; PRES SIMV  
 Actions: Event BREATH TIME CYCLED + END OF BREATH TIME CYCLED  
 Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: valve

SFSYSTAL58  
 INSPIRATORY FLOW FAILURE  
 Detection Conditions: If the inspiratory flow is constant +/- 2 lpm and TURBINE OVERHEAT alarm is not true and SPEED DEFAULT is not true and DISCONNECTION alarm = false  
 Validation Delay: 1 ventilation cycle (inspiration + exhalation) starting after the second cycle  
 Cancel Conditions: auto or DISCONNECTION alarm = true  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No

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Modes: VOL A/C; VOL SIMV  
Actions: Event INSPRATORY FLOW FAILURE + END OF INSPRATORY FLOW FAILURE  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No  
Circuit: valve

#### SFSYSTAL59

##### LOW BUZZER BATTERY

Detection Conditions: BUZZER BATTERY VOLTAGE < 4.8 V  
and

BUZZER BATTERY CHARGE FAILURE = false

Validation Delay: 2 min.

Cancel Conditions: BUZZER BATTERY VOLTAGE > 4.9 V  
or

BUZZER BATTERY CHARGE FAILURE = true

Priority: Medium priority

Audio Pause: yes

Alarm Pause: Yes

Modes: All

Actions: Event LOW BUZZER BATTERY+ END OF LOW BUZZER BATTERY

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

#### SFSYSTAL60

##### P.O.S.T. FAILURE

Detection Conditions: FLASH computed checksum at startup not matching with the recorded checksum.

or

EEPROM computed checksum at startup not matching with the recorded checksum.

or

5 V reference flag true or 10 V reference flag true.

or

RAM read/write not matching on the overall memory.

or

Software version not matching with hardware identification flags (PB520 hardware detected) or PREVIOUS software version starting with LX, LM or LS.

Validation Delay: immediate

Cancel Conditions: Auto after a restart of the device

Priority: Very high priority

Audio Pause: no

Alarm Pause: No

Modes: All

Actions: Switch to safe state

Events FLASH CHECK SUM POST ERROR, RAM CHECK SUM POST ERROR, VOLT REF POST ERROR, EEPROM POST ERROR, POST VERSION ERROR

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

#### SFSYSTAL61

##### BUZZER BATTERY CHARGE FAILURE

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Detection Conditions: BUZZER BATTERY VOLTAGE < 4.8V (battery not chargeable)  
Validation Delay: 15 min  
Cancel Conditions: BUZZER BATTERY VOLTAGE > 4.9V

Priority: High priority  
Audio Pause: yes  
Alarm Pause: No  
Modes: All  
Actions: Events BUZZER BATTERY CHARGE FAILURE +  
EVENT\_AL\_END\_BUZZER\_BATTERY\_CHARGE\_FAILURE  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL62  
LOOSE FLASH POINTER FAULT (n°12)  
Detection Conditions: The pointer address is not at a value consistent with the event logs size  
Validation Delay: immediate  
Cancel Conditions: NA  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: Event LOOSE FLASH POINTER DEFAULT  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL63  
DELETED

SFSYSTAL64  
DC DISCONNECTION  
Detection Conditions: If CHECK SUPPLY alarm off  
INFO SUPPLY = BAT  
and  
INFO SUPPLY was DC  
Validation Delay: immediate  
Cancel Conditions: Auto +  
if CHECK SUPPLY alarm off and INFO SUPPLY = AC or INFO SUPPLY = DC  
if CHECK SUPPLY alarm on and AC SELECTED = 1  
Priority: Low Priority.  
Audio Pause: yes  
Alarm Pause: yes  
Modes: All  
Actions: Events DC POWER FAIL + DC RETURN  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL65  
CHECK VALVE PRESSURE

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Detection Conditions: VALVE PRESSURE = Constant (+/- 1 cmH2O)  
 Validation Delay: Max [Disconnection time, 60/R-Rate + 2] PC, VC  
 Max [Disconnection time, Apnea Time + 4 sec] CPAP, PSV  
 Max [Disconnection time, 60/R-Rate + Insp Time + 2] PSIMV, VSIMV  
 Cancel Conditions: Auto  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: VOL A/C; PRES A/C; PSV; VOL SIMV; PRES SIMV  
 Actions: Events CHECK VALVE PRESSURE + END OF CHECK VALVE PRESSURE  
 Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: valve

#### SFSYSTAL66

##### CONNECT VALVE / CHANGE PRES

Detection Conditions: No valve detected during initialization phase and (PEEP < 4mbar or  
 Pcontrol / P support > 30 mbar)  
 Validation Delay: immediate  
 Cancel Conditions: Auto  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: PRES A/C; PSV  
 Actions: don't allow the ventilation and continue the turbine speed test

Events CONNECT VALVE CHANGE PI PE + END OF CONNECT VALVE CHANGE PI PE

Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: valve

#### SFSYSTAL67

##### DISCONNECT VALVE/ CHANGE PRES

Detection Conditions: Valve detection during initialization phase and Psupport/Pcontrol - PEEP <  
 5 mbar  
 Validation Delay: immediate  
 Cancel Conditions: Auto  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: PRES A/C; PSV; CPAP  
 Actions: don't allow the ventilation and continue the turbine speed test

Events DISCONNECT VALVE CHANGE PI PE + END OF DISCONNECT VALVE CHANGE PI  
 PE

Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: leak

#### SFSYSTAL68

##### CONNECT VALVE

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Detection Conditions: No valve detected during initialization phase and CV/ACV or SIMV modes are set.

Validation Delay: immediate

Cancel Conditions: Auto

Priority: High priority

Audio Pause: yes

Alarm Pause: No

Modes: VOL A/C; VOL SIMV; PRES SIMV

Actions: don't allow the ventilation and continue the turbine speed test

Events CONNECT VALVE + END OF CONNECT VALVE

Resetconditions: ventilation change; Ventilation std-by

Replaceventifpersistmessage: No

Circuit: valve

SFSYSTAL69

DISCONNECT VALVE

Detection Conditions: Valve detection during initialization phase and CPAP mode is set

Validation Delay: immediate

Cancel Conditions: Auto

Priority: High priority

Audio Pause: yes

Alarm Pause: No

Modes: CPAP

Actions: don't allow the ventilation and continue the turbine speed test

Events DISCONNECT VALVE + END OF DISCONNECT VALVE

Resetconditions: ventilation change; Ventilation std-by

Replaceventifpersistmessage: No

Circuit: leak

SFSYSTAL70

DELETED

SFSYSTAL71

HIGH LEAKAGE

Detection Conditions: leak > HIGH LEAK

and

DISCONNECTION alarm FALSE

Validation Delay: 3 consecutives cycles

Cancel Conditions: Auto or DISCONNECTION alarm >= TRUE

Priority: High priority

Audio Pause: yes

Alarm Pause: No

Modes: PRES A/C; PSV; CPAP

Actions: Events LEAKAGE + END OF LEAKAGE

Resetconditions: ventilation change; Ventilation std-by

Replaceventifpersistmessage: No

Circuit: leak

SFSYSTAL72

LOW FIO2

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Detection Conditions: FIO2 MEASURE < LOW FIO2  
and  
FiO2 CALIBRATION = YES  
Validation Delay: 45s  
Cancel Conditions: FIO2 MEASURE >= LOW FIO2  
or  
FiO2 CALIBRATION <> YES  
or  
CHECK FIO2 = displayed  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: No  
Modes: All  
Actions: Events LOW FIO2 + END OF LOW FIO2  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL73  
HIGH FIO2  
Detection Conditions: FIO2 MEASURE > HIGH FIO2  
and  
FiO2 CALIBRATION = YES  
Validation Delay: 45s  
Cancel Conditions: FIO2 MEASURE <= HIGH FIO2  
or  
FiO2 CALIBRATION <> YES  
Priority: Medium priority  
Audio Pause: yes  
Alarm Pause: No  
Modes: All  
Actions: Events HIGH FIO2 + END OF HIGH FIO2  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL74  
NO FIO2 SENSOR  
Detection Conditions: No FIO2 SENSOR detected except during first cycle  
and  
FiO2 min or FiO2 max = YES

Detection is done only during ventilation  
Validation Delay: 1 cycle  
Cancel Conditions: Auto  
Priority: High priority  
Audio Pause: yes  
Alarm Pause: Yes  
Modes: All  
Actions: Events NO FIO2 SENSOR + END OF NO FIO2 SENSOR  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No

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Circuit: all

#### SFSYSTAL75

##### FIO2 OFFSET FAULT (n°13)

Detection Conditions: FIO2 sensor offset out of range

Validation Delay: immediate

Cancel Conditions: NA

Priority: Visual

Audio Pause: no

Alarm Pause: No

Modes: All

Actions: Event FIO2 OFFSET + default offset

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

#### SFSYSTAL76

##### USB DISCONNECTION

Detection Conditions: USB key disconnected during data transfer

Validation Delay: immediate

Cancel Conditions: USB key connection

or

USB management page exit

Priority: Visual

Audio Pause: no

Alarm Pause: No

Modes: All

Actions: Event USB KEY DISCONNECTED DURING OPERATION + stops the USB key transfer

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

#### SFSYSTAL77

DELETED

#### SFSYSTAL78

##### TOO MANY KEYS

Detection Conditions: 2 USB keys connected on the device

Validation Delay: immediate

Cancel Conditions: one USB key disconnection

Priority: Visual

Audio Pause: no

Alarm Pause: No

Modes: All

Actions: Event USB TOO MANY KEYS CONNECTED

Resetconditions: N/A

Replaceventifpersistmessage: No

Circuit: all

#### SFSYSTAL79

##### USB TRANSFER ERROR

Detection Conditions: Abnormal termination of any transfer function.

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Validation Delay: immediate  
Cancel Conditions: USB key disconnection  
or  
USB function start  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: Event USB TRANSFER ERROR  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL80  
ERASE KEY ERROR  
Detection Conditions: Abnormal termination of erase key function.  
Validation Delay: immediate  
Cancel Conditions: USB key disconnection  
or  
USB function start  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: Event USB ERASE KEY ERROR  
Resetconditions: N/A  
Replaceeventifpersistmessage: No  
Circuit: all

SFSYSTAL81  
DELETED

SFSYSTAL82  
DELETED

SFSYSTAL83  
DELETED

SFSYSTAL84  
DELETED

SFSYSTAL85  
KEY CAPACITY  
Detection Conditions: message displayed  
(when "monitoring transfer" is latched from USB cable command  
or  
when "continuous transfer" field is validated  
or  
when " trend transfer" field is validated)  
and  
the capacity of the key is not sufficient.  
Validation Delay: immediate

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Cancel Conditions: USB key disconnection  
or  
USB key erase  
or  
transfer continuously  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: Event USB KEY FULL  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL86  
TRANSFER TIME  
Detection Conditions: message displayed during a "monitoring transfer" or a  
" trend transfer".  
Validation Delay: immediate  
Cancel Conditions: Data transfer stopped  
or  
USB key disconnection  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: None  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL87  
ERASE TIME  
Detection Conditions: message displayed during an erase key  
Validation Delay: immediate  
Cancel Conditions: USB key disconnection  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: None  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL88  
LOW PRESSURE LEAK  
Detection Conditions: ( $V_{ti} < = 20$  ml and INSPIRATORY FLOW > 60 lpm)  
or  
FILTERED PATIENT PRESSURE  $\leq$  (INSPIRATORY PRESSURE SET POINT - 20%)  
Validation Delay: Max [Disconnection time, 60/R-Rate] PC  
Max [Disconnection time, Apnea Time + 2 sec] CPAP, PSV

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Cancel Conditions: INSPIRATION FLOW  $\leq$  60 lpm during inspiration after 240 ms and Vti > 20 ml  
and  
FILTERED PATIENT PRESSURE > (INSPIRATORY PRESSURE SET POINT - 20%) In  
PSV/CPAP, PRES A/C modes  
Priority: High priority  
Audio Pause: yes  
Alarm Pause: No  
Modes: PRES A/C; PSV; CPAP  
Actions: Events DISCONNECTION + END OF DISCONNECTION  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No  
Circuit: leak

#### SFSYSTAL89

##### CONTROLLED CYCLES

Detection Conditions: when the patient does not receive any breath during the apnea time  
Validation Delay: immediate  
Cancel Conditions: when the third successive patient breath is triggered  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: PSV; VOL SIMV; PRES SIMV  
Actions: Event CONTROLLED CYCLES + END OF CONTROLLED CYCLES  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No  
Circuit: all

#### SFSYSTAL91

##### WAIT

Detection Conditions: message displayed when a USB key is detected and at the end of every USB key write operation (ERASE KEY, TRANSFER CONTINUOUSLY, TRANSFER DETAILED MONITORING, TRANSFER TRENDS) completed normally or interrupted manually and with no error.  
Validation Delay: immediate  
Cancel Conditions: when the free space calculation ends  
Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: None  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

#### SFSYSTAL92

##### TRANSFER REMAINING TIME

Detection Conditions: message displayed during a continuous transfer  
Validation Delay: immediate  
Cancel Conditions: Data transfer stopped  
or  
USB key disconnection

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Priority: Visual  
Audio Pause: no  
Alarm Pause: No  
Modes: All  
Actions: None  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL93  
CHECK FIO2  
Detection Conditions: FIO2 MEASURE < 18 %  
and  
FiO2 CALIBRATION = YES  
Validation Delay: 15s  
Cancel Conditions: FIO2 MEASURE >= 18 %  
or  
FiO2 CALIBRATION <> YES  
Priority: High priority  
Audio Pause: yes  
Alarm Pause: No  
Modes: All  
Actions: Event CHECK FIO2 + END OF CHECK FIO2  
Resetconditions: ventilation change; Ventilation std-by  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL94  
VOLUNTARY STOP  
Detection Conditions: each voluntary stop  
Validation Delay: immediate  
Cancel Conditions: Auto  
or  
Ventilation restart  
Priority: High priority  
Audio Pause: yes  
Alarm Pause: yes  
Modes: All  
Actions: Event VOLUNTARY STOP + END OF VOLUNTARY STOP  
Resetconditions: N/A  
Replaceventifpersistmessage: No  
Circuit: all

SFSYSTAL95  
FIO2 CALIBRATION NEEDED  
Detection Conditions: FIO2 sensor offset out of range  
or  
Ventilation is on  
and  
FiO2 SENSOR DETECTED = YES  
and  
FiO2 CALIBRATION = NO

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Validation Delay: immediate  
 Cancel Conditions: FiO2 CALIBRATION = YES  
 or  
 FiO2 SENSOR DETECTED = NO  
 Priority: Medium priority  
 Audio Pause: yes  
 Alarm Pause: yes  
 Modes: All  
 Actions: Event FIO2 CALIBRATION NEEDED  
 Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: all

SFSYSTAL96  
 LEAK OCCLUSION  
 Detection Conditions:  $EVTI < -VTI * 4/10$  and  $VTI > 20\text{mL}$   
 Validation Delay: 15 s  
 Cancel Conditions: Auto  
 Priority: High priority  
 Audio Pause: yes  
 Alarm Pause: No  
 Modes: PRES A/C; PSV; CPAP  
 Actions: Event LEAK OCCLUSION + END OF EVENT LEAK OCCLUSION  
 Resetconditions: ventilation change; Ventilation std-by  
 Replaceventifpersistmessage: No  
 Circuit: leak

### 3.3 HMI Requirements

SFSYSTHMI1  
 ALARM MEMORY MENU  
 No text (title)

#### SFSYSTHMI1.1

the software must display the 8 last alarms in reverse chronological order with their date/time of occurrence.

the software must display below a field of reactivation of cancelled alarms then the field "Back"

#### SFSYSTHMI1.2

the software must switch from the ALARM MEMORY MENU to the ALARM MENU if a high priority alarm occurs, if the field "Back" is validated, if ventilation is started or after 30 seconds without key action.

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## SFSYSTHMI2

### ventilation stop

When VENTILATION KEY is press during ventilation, the software must display the following message " Keep (Vent key symbol) for 3 sec to stop " during 1 second in a case of a SHORT PRESS and 3 seconds in a case of a LONG PRESS. After the 3 second elapsed, the software must display the following message "Release (Vent key symbol) for complete stop".

And, if the key press has been a LONG PRESS, the message must be replaced by "Press (Vent key symbol) again to confirm stop". If the VENTILATION KEY is pressed within 5 seconds of this message then the message must be replaced by "Press (Vent key symbol) to start ventilation " when the ventilation stops, otherwise the confirmation message will disappear after 5 seconds without a VENTILATION KEY press.

## SFSYSTHMI3

### alarm messages

#### No text (title)

### SFSYSTHMI3.1

the software must display the alarm messages alternating between normal and reverse video display

### SFSYSTHMI3.2

the software must display all the alarm messages scrolling when several alarms occur.

### SFSYSTHMI3.3

the software must display the last recorded alarm continuously in the ALARM MENU with its date and time of detection when no alarm is active

## SFSYSTHMI4

### symbols

#### No text (title)

### SFSYSTHMI4.1

the software must display a NEUTRAL SYMBOL instead of MONITORED VALUES during the first breath cycle and on the VTE monitoring when using a single branch / exhalation valve patient circuit and on FiO2 if no sensor is connected.

### SFSYSTHMI4.3

the software must display an INSPIRATORY TRIGGER symbol in the VENTILATION MENU, ALARM MENU and WAVEFORM MENU during the inspiration phase when the INSPIRATORY TRIGGER is detected

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#### SFSYSTHMI4.4

the software must display a battery symbol and a BATTERY LEVEL HOURMETER in the VENTILATION MENU, WAVEFORM MENU and ALARM MENU when the supply power is the internal battery and there is no change mode activation.

If the BATTERY HOURMETER AVAILABLE flag = no the BATTERY LEVEL in % will be displayed after 15s instead of the BATTERY LEVEL HOURMETER. If any of CHECK SUPPLY, CHECK BATTERY, UNKNOWN BATTERY alarms is on there will be no autonomy display (neutral symbol).

#### SFSYSTHMI4.5

when an alarm is inhibited, the software must display an INHIBITION SYMBOL in the VENTILATION MENU, WAVEFORM MENU and ALARM MENU

#### SFSYSTHMI4.6

the software must erase the INHIBITION SYMBOL when :

- the inhibition time is over or,
- the alarm autocancels or,
- the INHIBITION KEY is DOUBLE PRESS in the case of an cancelable alarm or,
- a new alarm occurs

#### SFSYSTHMI4.7

when an alarm is manually cancelled, the software must display a CANCELLATION SYMBOL in the VENTILATION MENU, WAVEFORM MENU and ALARM MENU

#### SFSYSTHMI4.8

the software must erase the CANCELLATION SYMBOL when :

- the alarm autocancels
- in ALARM MEMORY MENU, the field of reactivation of cancelled alarms is validated

#### SFSYSTHMI4.9

the software must display a pause symbol in the WAVEFORM MENU when the PAUSE function is activated

#### SFSYSTHMI4.10

the software must display a keylock symbol in the VENTILATION MENU and ALARM MENU when the KEYLOCK function is activated.

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#### SFSYSTHMI4.11

the software must display an ALARM OFF SYMBOL in the VENTILATION MENU, WAVEFORM MENU and ALARM MENU when the apnea alarm setting is set to OFF

#### SFSYSTHMI4.12

the software must erase the ALARM OFF SYMBOL when the apnea alarm setting is set to YES

#### SFSYSTHMI4.13

the software must display a VALVE SYMBOL when the valve is detected at the beginning of the ventilation or during a change mode during ventilation

#### SFSYSTHMI4.14

the software must display a NO VALVE SYMBOL when the valve is not detected at the beginning of the ventilation or during a change mode during ventilation. In stand by mode, no symbol is displayed.

#### SFSYSTHMI4.15

the software must erase the pause symbol in the WAVEFORM MENU when the PLAY function is activated

#### SFSYSTHMI4.16

the software must erase the keylock symbol in the VENTILATION MENU and ALARM MENU when the KEYLOCK function is inactivated.

#### SFSYSTHMI4.17

The software must display ABS in the first line of Ventilation menu if absolute has been set in SETUP menu

#### SFSYSTHMI4.18

The software must display REL in the first line of Ventilation menu if relative has been set in SET UP menu.

#### SFSYSTHMI5 Navigation

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No text (title)

#### SFSYSTHMI5.1

When the NAVIGATION KEY is SHORT PRESS, and the ventilation is on, the software must switch :

- from VENTILATION MENU to the ALARM MENU
- from the ALARM MENU to the WAVEFORM MENU
- from the WAVEFORM MENU to the VENTILATION MENU if no USB key is detected
- from the WAVEFORM MENU to the USB MANAGEMENT MENU if a USB key is detected
- from the USB MANAGEMENT MENU to the VENTILATION MENU if a USB key is detected
- from ALARM MENU to the VENTILATION MENU if Waveform Display has not been validated to OFF

#### SFSYSTHMI5.2

When the NAVIGATION KEY is SHORT PRESS, and the ventilation is off or if a change mode is activated during ventilation, the software must switch :

- from VENTILATION MENU to the ALARM MENU
- from ALARM MENU to the USB MANAGEMENT MENU if a USB key is detected
- from USB MANAGEMENT MENU to VENTILATION MENU if a USB key is detected
- from ALARM MENU to the VENTILATION MENU if no USB key is detected

#### SFSYSTHMI5.3

the software must switch from the WAVEFORM MENU to the ALARM MENU if a high priority alarm occurs

#### SFSYSTHMI5.4

When the VALIDATION KEY is SHORT PRESS on the alarm memory field, the software must display the corresponding menu.

#### SFSYSTHMI5.5

When the VALIDATION KEY is SHORT PRESS on the preference field, the software must display the corresponding menu.

#### SFSYSTHMI5.7

When the UP KEY is SHORT PRESS, the software must select the next upper field (and fill the empty cursor corresponding to the selected setting) or the last setting field of the current page if the cursor was on the upper field.

#### SFSYSTHMI5.8

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When the UP KEY is LONG PRESS, the software must select the first field and stops except in MAINTENACE MENU, SET UP MENU and MEASUREMENTS CHECK

#### SFSYSTHMI5.9

When the DOWN KEY is SHORT PRESS, the software must select the next lower field (and fill the empty cursor corresponding to the selected setting) or the first field of the current page if the cursor was on the last field.

#### SFSYSTHMI5.10

When the DOWN KEY is LONG PRESS, the software must select the last field and stops except in MAINTENACE MENU, SET UP MENU and MEASUREMENTS CHECK

#### SFSYSTHMI5.11

when the VALIDATION KEY is SHORT PRESS on the back field, the software must display the previous menu:

- in preference the previous menu is ventilation menu
- in ventilation report menu the previous menu is preference
- in alarm log menu the previous menu is alarm menu
- in maintenance menu the previous menu is set up menu
- in fault check menu the previous menu is maintenance menu
- in measurement check menu the previous menu is maintenance menu
- in internal battery menu the previous menu is measurement check menu

#### SFSYSTHMI5.13

the software must switch from the USB MANAGEMENT MENU to the ALARM MENU if a high priority alarm occurs and stay in ALARM MENU even in case of SFSYSTAL91 (WAIT) message in USB MENU.

#### SFSYSTHMI6

##### KEYLOCK

when the KEYLOCK function is activated, for all the prohibited fields the rectangular cursor is then replaced by a NEUTRAL SYMBOL.

All fields are prohibited in ventilation menu.

All fields except the alarm log are prohibited in alarm menu.

#### SFSYSTHMI7

##### BARGRAPH

No text (title)

#### SFSYSTHMI7.1

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the software must display the PATIENT PRESSURE in a BARGRAPH of the VENTILATION MENU during ventilation and while in standby mode.

#### SFSYSTHMI7.2

the software must display a mark of the PIP

#### SFSYSTHMI7.3

the software must refresh the PIP mark each exhalation start

#### SFSYSTHMI7.4

the software must display a mark of the PEEP

#### SFSYSTHMI7.5

the software must refresh the PEEP mark each inspiration start

#### SFSYSTHMI8

##### SCREEN CONTRAST

when the INHIBITION KEY and the UP KEY or DOWN KEY are SHORT PRESS and the ventilation is off, in the VENTILATION MENU, ALARM MENU, PREFERENCE MENU, USB MANAGEMENT MENU or ALARM LOGS MENU, the software must increase or decrease the SCREEN CONTRAST

#### SFSYSTHMI9

##### WAVEFORM MENU

No text (title)

##### SFSYSTHMI9.1

###### PAUSE

No text (title)

###### SFSYSTHMI9.1.1

in the WAVEFORM MENU, if the DOWN KEY is SHORT PRESS, the software must freeze the curves and the monitored displays

###### SFSYSTHMI9.1.2

in the WAVEFORM MENU, if the UP KEY is SHORT PRESS (while the curves have been frozen) the software must reset and refresh the curves and monitored displays

###### SFSYSTHMI9.1.3

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the software must keep the PAUSE function when the user get out and return to WAVEFORM MENU and no USB keys are connected

#### SFSYSTHMI9.3

Y Autoscale

No text (title)

##### SFSYSTHMI9.3.1

The software must set the scale max value to the maximum measured value of the 3 latest cycles + 10% of the previous screen rounded to 5cmH<sub>2</sub>O or 5lpm.

##### SFSYSTHMI9.3.2

during the first screen which follow the starting of the ventilator, the software displays the maximum pressure scale = 100 cmH<sub>2</sub>O

##### SFSYSTHMI9.3.3

during the first screen which follow the starting of the ventilator, the software displays the maximum flow scale = 200 lpm

#### SFSYSTHMI9.4

X Autoscale

No text (title)

##### SFSYSTHMI9.4.1

The software must set the scale max value to the period corresponding to the three last ventilation cycles : Max Time (s) = 120 / R (bpm) + 10% rounded to + 1 s .

##### SFSYSTHMI9.4.2

during the first screen, the software displays the maximum time scale = 6 s

#### SFSYSTHMI9.5

Autoscale

No text (title)

##### SFSYSTHMI9.5.1

The software must do the auto-scales when refreshing the screen.

##### SFSYSTHMI9.5.2

The software must display a max Yscale line corresponding to the maximum measure of the previous screen.

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### SFSYSTHMI9.5.3

the software must adapt the Y scale in a way to delete the negative part of the flow curve if the exhalation flow measurement is not available (for example in the case of use of a single branch patient circuit and in leakage)

### SFSYSTHMI9.6

curves display

No text (title)

#### SFSYSTHMI9.6.1

The software must display a curve of PATIENT PRESSURE =  $f(t)$  and a curve of  $Q_{corrected} = f(t)$  during inspiration and  $Q_E - EQI = f(t)$  during expiration

#### SFSYSTHMI9.6.2

The software must overwrite the curves of the current page on the curves of the previous page.

#### SFSYSTHMI9.6.5

In case of no detection of exhalation flow monitoring, the software must display the positive part only of the flow Y scale.

### SFSYSTHMI9.7

curves type

No text (title)

#### SFSYSTHMI9.7.1

The software must display a line to represent the curves.

### SFSYSTHMI9.8

out of range

if there is no curves display on the screen (wrong scale setting), the software must display the message "out of range"

### SFSYSTHMI10

Mode change

No text (title)

#### SFSYSTHMI10.1

When the VALIDATION KEY is SHORT PRESS on the mode field, the software allows to select an other mode.

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## SFSYSTHMI10.2

When VALIDATION KEY is SHORT PRESS on a selected new mode in stand by mode, the software must display the new mode settings

## SFSYSTHMI10.3

When VALIDATION KEY is SHORT PRESS on a selected new mode during the ventilation, the software must

- display the settings of the new mode
- display the MONITORED VALUES and the alarms messages of the running mode
- replace Preference and Alarm memory fields by Accept mode field with Yes blinking
- display the label No Active blinking close to the new mode
- display the label Active close to the running mode
- erase the BATTERY LEVEL HOURMETER, BATTERY LEVEL, INHIBITION SYMBOL, CANCELLATION SYMBOL, ALARM OFF SYMBOL, VALVE SYMBOL, NO VALVE SYMBOL if they are displayed.
- allow the user to change new mode parameters in VENTILATION MENU and ALARM MENU

## SFSYSTHMI10.4

When VALIDATION KEY is SHORT PRESS on the field "Change mode : YES" during the ventilation, the software must

- display the settings of the new mode
- display the MONITORED VALUES and the alarms messages of the new mode
- replace change mode field by Preference and Alarm memory fields
- display BATTERY LEVEL HOURMETER, BATTERY LEVEL, INHIBITION SYMBOL, CANCELLATION SYMBOL, ALARM OFF SYMBOL, VALVE SYMBOL, NO VALVE SYMBOL according to SFSYSTHMI4

## SFSYSTHMI10.5

the software shall record the new mode settings and display the running mode settings if there is no key action before 14 s

## SFSYSTHMI10.6

the software must display and activate the new mode settings, if the Accept mode is set to Yes

## SFSYSTHMI10.7

If a valve is detected, only Vol control, Pres Control, PSV, PSIMV and VSIMV modes are available

## SFSYSTHMI10.8

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If no valve is detected, only CPAP, Pres Control and PSV modes are available

SFSYSTHMI12  
settings change  
No text (title)

#### SFSYSTHMI12.1

When the VALIDATION KEY is SHORT PRESS on the setting field, the software must:

- replace the white rectangular cursor by a +/- cursor
- display the corresponding value blinking
- replace the monitored values by a blinking ZOOM of the parameter setting blinking (only for VENTILATION and ALARM MENU but except on mode field)
- display  $P_i + PEEP = XX \text{ mbar/cmH}_2\text{O/hPa}$  in the zoom if relative has been set in SET UP menu
- display the I:E or I/T calculation in the zoom window when changing CONTROL R or INSP TIME
- display INSP SENS helper text when changing INSP SENS between 0P to 5.

#### SFSYSTHMI12.2

When the UP KEY or DOWN KEY are SHORT PRESS on a selected setting field the software must:

- increase or decrease the value with a step as define in SFSYSTSET or SFSYSTSETUP
- control the setting limits as define in SFSYSTSET or SFSYSTSETUP
- display the result value

#### SFSYSTHMI12.3

When the UP KEY or DOWN KEY are LONG PRESS on a selected setting field, the software must:

- increase or decrease the value continuously with a step as define in SFSYSTSET or SFSYSTSETUP
- control the setting limits as define in SFSYSTSET or SFSYSTSETUP
- display the result value

#### SFSYSTHMI12.4

When the UP KEY or DOWN KEY are pressed on a selected setting field and a link limit is reached, the software must increase or decrease the auto-adjustable linked values with steps as define in SFSYSTSET or SFSYSTSETUP when the VALIDATION KEY is pressed

#### SFSYSTHMI12.5

When the UP KEY or DOWN KEY are pressed on a selected setting field and a link limit is reached, the software must:

- block setting increasing according to the linked limits if not auto-adjustable

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- display a message concerning the blocking parameter

#### SFSYSTHMI12.6

When the VALIDATION KEY is SHORT PRESS on the selected single setting field or if there is no key press until 7 seconds, the software must :

- replace the +/- cursor by a white rectangular cursor
- display the monitored values
- display the setting

#### SFSYSTHMI12.7

When the VALIDATION KEY is SHORT PRESS on the selected multi setting field, the software must :

- display the new selected value continuously
- select the next setting and display it in a blinking way

#### SFSYSTHMI13

Exhalation Flow calibration

When the VTE MIN alarm field is validated, the software must display a message "Exhalation Flow calibration ?". If the answer Yes is validated, the software must start a exhalation flow calibration procedure like described in the SFSYSTCAL requirements displaying only "... Exp Calib Processing" in the central field instead of the displays described in the SFSYSTCAL requirements.

If the answer OFF is validated or when exh calibration ends, the software must go to VTE max field.

#### SFSYSTHMI15

VENTILATION MENU HMI MANAGEMENT

##### SFSYSTHMI15.1

VOL CONTROL MENU HMI Management

The following adjustable parameters shall appear on the VOL CONTROL MENU display:

VOL CONTROL, PEEP, FLOW PATTERN, CONTROL R, Ti, INSP SENS, Sigh, Sigh Vt and Sigh Rate if Sigh is set to YES

The following monitoring parameters shall appear on the VOL CONTROL MENU display:

PIP, VTE, R, Ti, FiO2, VM

##### SFSYSTHMI15.2

PRES CONTROL MENU HMI Management

The following adjustable parameters shall appear on the PRES CONTROL MENU display:

P CONTROL, PEEP, RISE TIME, CONTROL R, Ti, INSP SENS, Vt target and Max P if Vt target is set to a value

The following monitoring parameters shall appear on the PRES CONTROL MENU display:

VTI, VTE or leak if no valve detected, VM, R, Ti, FiO2

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### SFSYSTHMI15.3

#### PSV MENU HMI Management

The following adjustable parameters shall appear on the PSV MENU display:

P SUPPORT, PEEP, RISE TIME, INSP SENS, EXH SENS, BACK UP R, APNEA TIME, Vt target and Max P if Vt target is set to a value.

The following monitoring parameters shall appear on the PSV/CPAP MENU display:

VTI, VTE or leak if no valve detected, VM, R, Ti, FiO2.

### SFSYSTHMI15.4

#### PRES SIMV MENU HMI Management

The following adjustable parameters shall appear on the PRES SIMV MENU display:

P CONTROL, P SUPPORT, PEEP, CONTROL R, TI CONTROL, INSP SENS, APNEA TIME, EXH SENS, RISE TIME.

The following monitoring parameters shall appear on the PRES SIMV MENU display:

VTI, VTE, VM, R, Ti, FiO2

### SFSYSTHMI15.5

#### VOL SIMV MENU HMI Management

The following adjustable parameters shall appear on the VOL SIMV MENU display:

VOL CONTROL, P SUPPORT, PEEP, CONTROL R, TI CONTROL, INSP SENS, APNEA TIME, EXH SENS, RISE TIME.

The following monitoring parameters shall appear on the VOL SIMV MENU display:

PIP, VTE, R, Ti, FiO2, VM

### SFSYSTHMI15.6

#### CPAP MENU HMI Management

The following adjustable parameters shall appear on the CPAP MENU display:

PEEP, APNEA TIME.

The following monitoring parameters shall appear on the VOL SIMV MENU display:

Vtl, Leak, R, Ti, FiO2, VM

### SFSYSTHMI28

#### USB MENU

### SFSYSTHMI28.1

The USB MANAGEMENT MENU must display the serial number of the device, Transfer continuously, Transfer trends, Erase key, and stop (when a USB function is running) fields.

### SFSYSTHMI28.2

The USB MANAGEMENT MENU must display an USB INFORMATION WINDOWS (for all USB alarms messages)

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### SFSYSTHMI28.3

The software must display the USB MANAGEMENT MENU automatically when a new USB message have to be displayed, except when a medium or high priority alarm is active and except for first wait message when a key is connected at device start up.

### SFSYSTHMI28.4

DELETED

### SFSYSTHMI28.5

The software must display the VENTILATION MENU automatically when the USB key is disconnected except if an USB transfer error or erase key error message is present.

### SFSYSTHMI28.6

DELETED

### SFSYSTHMI28.7

The software shall display a NEUTRAL SYMBOL instead of the rectangular cursor in front of each field (except stop field) when any action is running on USB key.

## SFSYSTHMI36 VENTILATION REPORT MENU

### SFSYSTHMI36.1

When the VALIDATION KEY is SHORT PRESS on the VENTILATION REPORT field of the PREFERENCE MENU, the software must display the corresponding menu with the following fields:

- Vent time
- on (date)
- VTi
- VTE
- Paw
- Rate
- leak
- AI
- Apnea Ti
- Spont cycle
- machine hours

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- patient hours
- back

#### SFSYSTHMI36.2

when the VENTILATION REPORT is displayed and the VALIDATION KEY is pressed on the back field, the software must display the PREFERENCE MENU

#### SFSYSTHMI36.3

the software must switch to the PREFERENCE MENU if there is no key activation until 5 minutes

#### SFSYSTHMI36.4

the software must switch to the ALARM MENU if a high priority alarm occurs

#### SFSYSTHMI36.6

the ventilator report must display machine and patient hours

#### SFSYSTHMI36.7

The software shall display the CIRCUIT CHECK MENU once the user presses and holds the NAVIGATION KEY during power-up and ventilation has been stopped using the VENTILATION KEY. The software shall not exit the CIRCUIT CHECK MENU when any key is pressed.

#### SFSYSTHMI36.8

Upon initial display of the CIRCUIT CHECK MENU the software shall display the following information:

- Leak - 0.0 in units of Lpm
- Test Status - NOT RUN
- Message to ensure patient is disconnected and instructions to run CIRCUIT CHECK

#### SFSYSTHMI36.9

The software shall execute CIRCUIT CHECK once the VALIDATION KEY is pressed and sound a SHORT BEEP.

During execution of CIRCUIT CHECK, the CIRCUIT CHECK MENU shall display the following information:

- Leak - measured value, updated every two seconds in units of Lpm
- Test Status - RUNNING

During execution of CIRCUIT CHECK a SHORT BEEP will sound each time the measured leak value is updated.

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#### SFSYSTHMI36.10

During execution the software shall cancel CIRCUIT CHECK once the DOWN KEY, UP KEY, VENTILATION KEY, NAVIGATION KEY or VALIDATION KEY is pressed.

After cancelling CIRCUIT CHECK, the CIRCUIT CHECK MENU shall display the following information:

- a. Leak – last measured value in units of Lpm
- b. Test Status – NOT RUN
- c. Message to ensure patient is disconnected and instructions to run CIRCUIT CHECK

#### SFSYSTHMI36.11

The software shall complete CIRCUIT CHECK after 10 seconds.

Upon completion of CIRCUIT CHECK the CIRCUIT CHECK MENU shall display the following information:

- a. Leak – final measured value in units of Lpm
- b. Test Status – PASS or FAIL
- c. Message to ensure patient is disconnected and instructions to run CIRCUIT CHECK

Upon completion of CIRCUIT CHECK a LONG BEEP will sound.

### 3.4 Settings Requirements

All pressure limits are given for absolute (ABS) pressure convention and need to be converted for relative (REL) pressure convention by subtracting the PEEP setting.

#### SFSYSTSET1

SET UP / PREFERENCE settings

##### SFSYSTSET1.1

LANGUAGE

Unit: N.A.

Min Value: Chinese

Max Value: Turkce

List of Values: English,

English (US)

Français, Portugues, Greek, Russian, Deutsch, Nederlands, Polski, Turkce, Espanol, Italiano, Japanese, Korean, Chinese, Suomi, Dansk, Norsk, Svenska,

Step: 0

Default Value: English

Links: N.A.

Auto-adjustement: N.A.

Comments: No comment  
common in all mode

##### SFSYSTSET1.2

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DATE  
Unit: N.A.  
Min Value: 01 JAN 2004  
Max Value: 31 DEC 2099  
List of Values: N.A.  
Step: 0  
Default Value: N.A.  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment  
common in all mode

SFSYSTSET1.3  
TIME  
Unit: N.A.  
Min Value: 00:00:00  
Max Value: 23:59:59  
List of Values: N.A.  
Step: 0  
Default Value: N.A.  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment  
common in all mode

SFSYSTSET1.5  
Backlight  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: Yes, OFF  
Step: 0  
Default Value: OFF  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment  
common in all mode

SFSYSTSET1.12  
SOUND LEVEL  
Unit: %  
Min Value: 20  
Max Value: 100  
List of Values: N.A.  
Step: 0  
Default Value: 60  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment  
common in all mode

SFSYSTSET1.13

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CONTRAST

Unit: N.A.

Min Value: 0

Max Value: 100

List of Values: N.A.

Step: 0

Default Value: 50

Links: N.A.

Auto-adjustment: N.A.

Comments: No comment  
common in all mode

SFSYSTSET1.14

KEY SOUND

Unit: N.A.

Min Value: N.A.

Max Value: N.A.

List of Values: OFF, Accept tone, Key tone, All tones on

Step: 0

Default Value: Accept tone

Links: N.A.

Auto-adjustment: N.A.

Comments: No comment  
common in all mode

SFSYSTSET1.15

WAVEFORM DISPLAY

Unit: N.A.

Min Value: N.A.

Max Value: N.A.

List of Values: YES / OFF

Step: 0

Default Value: OFF

Links: N.A.

Auto-adjustment: N.A.

Comments: No comment

SFSYSTSET1.16

EXH CALIBRATION

Unit: N.A.

Min Value: N.A.

Max Value: N.A.

List of Values: YES / OFF

Step: 0

Default Value: OFF

Links: N.A.

Auto-adjustment: N.A.

Comments: No comment

SFSYSTSET1.17

ALTITUDE COMP.

Unit: N.A.

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Min Value: N.A.  
Max Value: N.A.  
List of Values: YES / OFF  
Step: 0  
Default Value: YES  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: In Measurements check menu

SFSYSTSET1.18  
PEDIATRIC TUBING  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: YES, OFF  
Step: 0  
Default Value: OFF  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: N.A.

SFSYSTSET1.19  
Cycling mode  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: I:E, I/T  
Step: 0  
Default Value: I:E  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment  
common in all mode  
loop setting

SFSYSTSET1.20  
Pressure Unit  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: mbar, cmH2O, hPa  
Step: 0  
Default Value: mbar  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment  
common in all mode

SFSYSTSET1.21  
ESens Settings  
Unit: N.A.  
Min Value: N.A.

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Max Value: N.A.  
List of Values: Positive, Negative  
Step: 0  
Default Value: Positive  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment  
common in all mode

#### SFSYSTSET1.22

Reset Hours  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: Yes, OFF  
Step: 0  
Default Value: OFF  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment

#### SFSYSTSET1.23

Apnea alarm  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: Yes, OFF  
Step: 0  
Default Value: Yes  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment  
common in all mode

#### SFSYSTSET1.24

Disconnection alarm  
Unit:  
Min Value: 5  
Max Value: 62  
List of Values: N.A.  
Step: 1  
Default Value: 15  
Links:  
Auto-adjustement: N.A.  
Comments: Common setting for all modes  
common in all mode

#### SFSYSTSET1.25

Relative pressure  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.

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List of Values: Yes  
OFF  
Step: 0  
Default Value: OFF  
Links: N.A  
Auto-adjustement: N.A  
Comments: No comment  
common in all mode  
loop setting

SFSYSTSET1.26  
Voluntary stop alarm  
Unit:  
Min Value: N.A.  
Max Value: N.A.  
List of Values: Yes, OFF  
Step: 0  
Default Value: Yes  
Links:  
Auto-adjustement:  
Comments:

SFSYSTSET2  
VOL CONTROL settings

SFSYSTSET2.1  
VOL CONTROL  
Unit: ml  
Min Value: 50  
Max Value: 2000  
List of Values: N.A.  
Step: 10  
Default Value: 500  
Links:  $3 \text{ lpm} \leq (\text{VOL CONTROL} \times 60) / (\text{TI CONTROL} \times 1000) \leq 100 \text{ lpm}$  in R RAMP  
 $3 \text{ lpm} \leq 3 \times (\text{VOL CONTROL} \times 60) / 2 \times (\text{TI CONTROL} \times 1000) \leq 100 \text{ lpm}$  in D RAMP and S RAMP

LOW VTE  $\leq$  VOL CONTROL - 10  
HIGH VTE  $\geq$  VOL CONTROL + 10  
Vol control x Vt sigh  $\leq$  2000ml  
Auto-adjustement: LOW VTE  
HIGH VTE  
Comments: No comment

SFSYSTSET2.2  
CONTROL R  
Unit: bpm  
Min Value: 1  
Max Value: 60  
List of Values: N.A.  
Step: 1

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Default Value: 13  
Links: CONTROL R <= HIGH R - 5  
TI CONTROL <= (0.5\*60 / CONTROL R)

Sigh = YES then CONTROL R >= 4 Auto-adjustement: HIGH R  
Comments: I:E <= 1:1

#### SFSYSTSET2.4 FLOW PATTERN

Unit: N.A.

Min Value: D

Max Value: SQ

List of Values: D, SQ, S

Step: 1

Default Value: D

Links:

3 lpm <= (VOL CONTROL x 60) / (TI CONTROL\*1000) <= 100 lpm to allow R RAMP

3 lpm <= 3\*(VOL CONTROL x 60) / 2\*(TI CONTROL\*1000) <= 100 lpm to allow D RAMP and S RAMP

Auto-adjustement: N.A.

Comments: loop setting

#### SFSYSTSET2.5

PEEP

Unit: cmH2O, mbar, hPa

Min Value: 1

Max Value: 20

List of Values: N.A.

Step: 1

Default Value: OFF (=0) output value = 1

Links: LOW PIP >= PEEP + 2

PEEP + 10 <= HIGH PIP

Auto-adjustement: HIGH PIP

LOW PIP

Comments: Possibility to set OFF (down side)

OFF (=0) output value = 1

#### SFSYSTSET2.6

INSP SENS

Unit: N.A.

Min Value: 0P

Max Value: 5

List of Values: N.A.

Step: 1

Default Value: 2

Links: N.A.

Auto-adjustement: N.A.

Comments: OFF available under the minimum value OFF. output value = 0  
loop setting.

HIGH R = OFF if INSP SENS = OFF

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**SFSYSTSET2.7****LOW PIP**

Unit: cmH2O, mbar, hPa

Min Value: 2

Max Value: 82

List of Values: N.A.

Step: 1

Default Value: 2

Links: LOW PIP &lt;= HIGH PIP – 8

LOW PIP &gt;= PEEP + 2

Auto-adjustement: N.A.

Comments: No comment

**SFSYSTSET2.8****HIGH PIP**

Unit: cmH2O, mbar, hPa

Min Value: 12

Max Value: 90

List of Values: N.A.

Step: 1

Default Value: 40

Links: LOW PIP &lt;= HIGH PIP – 8

PEEP + 10 &lt;= HIGH PIP

Auto-adjustement: N.A.

Comments: No comment

**SFSYSTSET2.9****LOW VTE**

Unit: ml

Min Value: 30

Max Value: 1990

List of Values: N.A.

Step: 10

Default Value: 300

Links: LOW VTE &lt;= VOL CONTROL - 10

Auto-adjustement: N.A.

Comments: OFF is available by the DOWN KEY.

OFF (=30), output value 30

exhalation spirometer calibration available after validation of this setting

**SFSYSTSET2.12****HIGH R**

Unit: bpm

Min Value: 10

Max Value: 70

List of Values: N.A.

Step: 1

Default Value: OFF (=20) output value = 20

Links: CONTROL R &lt;= HIGH R - 5

Auto-adjustement: N.A.

Comments: OFF is available by the UP KEY. output value = 70

setting not available if insp sens is set to OFF

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SFSYSTSET2.13  
HIGH VTE  
Unit: ml  
Min Value: 80  
Max Value: 3000  
List of Values: N.A.  
Step: 10  
Default Value: 1000  
Links: HIGH VTE + 10 >= VOL CONTROL  
Auto-adjustement: N.A.  
Comments: OFF is available by the UP KEY  
output value = 3000

SFSYSTSET2.16  
Sigh  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: Yes, OFF  
Step: 1  
Default Value: OFF  
Links: CONTROL R >= 4  
Auto-adjustement: N.A.  
Comments: when set to Yes, GUI displays Vt sigh and Cpt sigh

SFSYSTSET2.17  
Vt Sigh  
Unit: N.A.  
Min Value: 1.0  
Max Value: 2.0  
List of Values: N.A.  
Step: 0  
Default Value: 1.0  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: available only if Sigh is set to Yes  
step is 0.1

SFSYSTSET2.18  
Cpt Sigh  
Unit: N.A.  
Min Value: 50  
Max Value: 250  
List of Values: N.A.  
Step: 50  
Default Value: 50  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: available only if Sigh is set to Yes

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## SFSYSTSET2.19

### TI CONTROL

Unit: s

Min Value: 0.3

Max Value: 6.0

List of Values: N.A.

Step: 0.1

Default Value: 1.5

Links:  $3 \text{ lpm} \leq (\text{VOL CONTROL} \times 60) / (\text{TI CONTROL} \times 1000) \leq 100 \text{ lpm}$  in R RAMP

$3 \text{ lpm} \leq 3 \times (\text{VOL CONTROL} \times 60) / 2 \times (\text{TI CONTROL} \times 1000) \leq 100 \text{ lpm}$  in D RAMP and S RAMP

$\text{TI CONTROL} \leq (0.5 \times 60 / \text{CONTROL R})$

Comments: I:E  $\leq$  1:1

## SFSYSTSET3

### PRES CONTROL settings

## SFSYSTSET3.1

### P CONTROL

Unit: cmH<sub>2</sub>O, mbar, hPa

Min Value: 5 in valve ventilation or 6 in leak ventilation or 2 in standby

Max Value: 55 in valve ventilation or in standby

30 in leak ventilation

List of Values: N.A.

Step: 1

Default Value: 15

Links: IIn valve ventilation :

$\text{PEEP} \leq \text{Pcontrol} - 5$  in absolute pressure

$\text{Pcontrol} + \text{PEEP} \leq 55$  in relative pressure

In leak ventilation

$\text{PEEP} \leq \text{Pcontrol} - 2$  in absolute pressure

$\text{Pcontrol} + \text{PEEP} \leq 30$  in relative pressure

in stand by:

$\text{PEEP} \leq \text{Pcontrol} - 2$  in absolute pressure

$\text{Pcontrol} + \text{PEEP} \leq 55$  in relative pressure

both:

$\text{Pmax} + \text{PEEP} \leq 55$  in relative pressure

Auto-adjustement: Max Pres

Comments: No comment

## SFSYSTSET3.2

### CONTROL R

Unit: bpm

Min Value: 1

Max Value: 60

List of Values: N.A.

Step: 1

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Default Value: 13  
Links: CONTROL R <= HIGH R - 5 Auto-adjustement: HIGH RATE  
Comments: No comment

#### SFSYSTSET3.4

##### RISE TIME

Unit: N.A.

Min Value: 1

Max Value: 4

List of Values: N.A.

Step: 1

Default Value: 2

Links: N.A.

Auto-adjustement: N.A.

Comments: loop setting

#### SFSYSTSET3.5

##### PEEP

Unit: cmH2O, mbar, hPa

Min Value: OFF (=0) in valve ventilation or standby

4 in leak ventilation

Max Value: 20

List of Values: N.A.

Step: 1

Default Value: OFF (=0) output value = 1

Links: In valve ventilation :

PEEP <= Pcontrol - 5 in absolute pressure

Pcontrol+ PEEP <= 55 in relative pressure

In leak ventilation

PEEP <= Pcontrol - 2 in absolute pressure

Pcontrol+ PEEP <= 30 in relative pressure

in stand by:

PEEP <= Pcontrol - 2 in absolute pressure

Pcontrol+ PEEP <= 55 in relative pressure

both:

Pmax + PEEP <= 55 in relative pressure

Auto-adjustement: MAX PRESS = PRESSURE CONTROL if VT TARGET = OFF and PEEP >= (55 - PMAX)

Comments: Possibility to set OFF (down key) in valve ventilation

OFF (=0) output value = 1.

#### SFSYSTSET3.6

##### INSP SENS

Unit: N.A.

Min Value: 0P

Max Value: 5

List of Values: N.A.

Step: 1

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Default Value: 2

Links: N.A.

Auto-adjustment: High Rate = OFF if Insp Sens = OFF

Comments: OFF is available only under minimum value OFF. output value =0.

HIGH R = OFF if INSP SENS = OFF

loop setting.

#### SFSYSTSET3.7

LOW VTI

Unit: ml

Min Value: 30

Max Value: 2000

List of Values: N.A.

Step: 10

Default Value: 300

Links: LOW VTI  $\leq$  HIGH VTI - 20

Low Vti  $\leq$  Vt target - 10

Auto-adjustment: N.A.

Comments: OFF is available downside. OFF(=30) output value = 30

#### SFSYSTSET3.8

HIGH VTI

Unit: ml

Min Value: 80

Max Value: 3000

List of Values: N.A.

Step: 10

Default Value: 2000

Links: HIGH VTI  $\geq$  LOW VTI + 20

High Vti  $\geq$  Vt target + 10

Auto-adjustment: N.A.

Comments: OFF is available upside

OFF = 3000 output value = 3000

#### SFSYSTSET3.9

LOW VTE

Unit: ml

Min Value: 30

Max Value: 1990

List of Values: N.A.

Step: 10

Default Value: 300

Links: LOW VTE  $\leq$  HIGH VTE - 20

Low vte  $\leq$  Vt target - 10

Auto-adjustment: N.A.

Comments: OFF is available downside  
display only if exhalation valve is detected

OFF ( =30) output value = 30

#### SFSYSTSET3.12

HIGH R

Unit: bpm

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Min Value: 10  
 Max Value: 70  
 List of Values: N.A.  
 Step: 1  
 Default Value: OFF (20) output value = 20  
 Links: CONTROL R <= HIGH R - 5  
 Auto-adjustment: N.A.  
 Comments: OFF is available upside  
 setting not available if insp sens is set to OFF  
 OFF (=70) output value = 70

SFSYSTSET3.13  
 HIGH VTE  
 Unit: ml  
 Min Value: 80  
 Max Value: 3000  
 List of Values: N.A.  
 Step: 10  
 Default Value: 1000  
 Links: LOW VTE <= HIGH VTE - 20  
 High Vte >= Vt target +10  
 Auto-adjustment: N.A.  
 Comments: OFF is available upside  
 display only if exhalation valve is detected  
 OFF (=3000) output value = 3000

SFSYSTSET3.16  
 Vt target  
 Unit: ml  
 Min Value: 50  
 Max Value: 2000  
 List of Values: N.A.  
 Step: 10  
 Default Value: OFF (=100) output value =100  
 Links: Low Vte <= Vt target -10  
 High Vte >= Vt target +10  
 Low Vti <= Vt target -10  
 High Vti >= Vt target +10  
 Auto-adjustment: Low Vte  
 High Vte  
 High Vti  
 Low Vti  
 Comments: OFF is available downside  
 OFF(=50) output value =50

SFSYSTSET3.17  
 MaxPres  
 Unit: cmH2O, mbar, hPa  
 Min Value: 8  
 Max Value: 55  
 List of Values: N.A.  
 Step: 1

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Default Value: Pcontrol + 3

Links: Pcontrol <= MaxPres <= Pcontrol +20 in relative and absolute pressure mode

MaxPres + PEEP <= 55 in relative pressure

Auto-adjustment: N.A.

Comments: Not displayed if Vt target is set to OFF

#### SFSYSTSET3.18

High leak

Unit: lpm

Min Value: 5

Max Value: 150

List of Values: N.A.

Step: 5

Default Value: OFF (=200) output value = 200

Links: N.A.

Auto-adjustment: N.A.

Comments: available only if no valve is detected

OFF is available upside

OFF = 200 output value = 200

#### SFSYSTSET3.21

TI CONTROL

Unit: s

Min Value: 0.3

Max Value: 6.0

List of Values: N.A.

Step: 0.1

Default Value: 1.5

Links: TI CONTROL <= (0.5\*60 / CONTROL R)

Auto-adjustment: N.A.

Comments: I:E <= 1:1

#### SFSYSTSET4

PSV settings

#### SFSYSTSET4.1

P SUPPORT

Unit: cmH2O, mbar, hPa

Min Value: 5 in valve ventilation or 6 in leak ventilation or 2 in standby

Max Value: 55 in valve ventilation or in standby

30 in leak ventilation

List of Values: N.A.

Step: 1

Default Value: 15

Links: In valve ventilation :

PEEP <= Pcontrol - 5 in absolute pressure

Pcontrol+ PEEP <= 55 in relative pressure

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In leak ventilation  
PEEP <= Pcontrol - 2 in absolute pressure  
Pcontrol+ PEEP <= 30 in relative pressure

in stand by:  
PEEP <= Pcontrol - 2 in absolute pressure  
Pcontrol+ PEEP <= 55 in relative pressure

both:  
Pmax + PEEP <= 55 in relative pressure  
Auto-adjustement: Max Pres  
Comments: No comment

SFSYSTSET4.2  
PEEP  
Unit: cmH2O, mbar, hPa  
Min Value: OFF (=0) in valve ventilation or standby

4 in leak ventilation  
Max Value: 20  
List of Values: N.A.  
Step: 1  
Default Value: OFF (=0) output value = 1  
Links: In valve ventilation :  
PEEP <= Pcontrol - 5 in absolute pressure  
Pcontrol+ PEEP <= 55 in relative pressure

In leak ventilation  
PEEP <= Pcontrol - 2 in absolute pressure  
Pcontrol+ PEEP <= 30 in relative pressure

in stand by:  
PEEP <= Pcontrol - 2 in absolute pressure  
Pcontrol+ PEEP <= 55 in relative pressure

both:  
Pmax + PEEP <= 55 in relative pressure  
Auto-adjustement: MAX PRESS = PRESSURE CONTROL if VT TARGET = OFF and PEEP >= (55 - PMAX)  
Comments: Possibility to set OFF downside  
OFF (=0) output value = 1

SFSYSTSET4.3  
RISE TIME  
Unit: N.A.  
Min Value: 1  
Max Value: 4  
List of Values: N.A.  
Step: 1  
Default Value: 2  
Links: N.A.

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Auto-adjustement: N.A.  
Comments: loop setting

#### SFSYSTSET4.4

##### BACK UP R

Unit: bpm

Min Value: 4

Max Value: 40

List of Values: N.A.

Step: 1

Default Value: 13

Links: TI MIN  $\leq (60 \times 1/2)/\text{BACK UP R}$

BACK UP R  $\leq \text{HIGH R} - 5$

30/BackupR  $\leq \text{Apnea time}$

Auto-adjustement: HIGH R

TI MIN

Apnea time = Auto

Comments: No comment

#### SFSYSTSET4.5

##### APNEA TIME

Unit: s

Min Value: 1

Max Value: 60

List of Values: N.A.

Step: 1

Default Value: Auto = 4,6

output value = 4

Links: 30/backupR  $\leq \text{apnea time}$

Auto-adjustement: N.A.

Comments: Auto is reached upside

updated after backup R modification

Auto = max (3s, 60/backupR).

#### SFSYSTSET4.6

##### INSP SENS

Unit: N.A.

Min Value: 0P

Max Value: 5

List of Values: N.A.

Step: 1

Default Value: 2

Links: N.A.

Auto-adjustement: N.A.

Comments: loop setting.

#### SFSYSTSET4.7

##### EXH SENS

Unit: %

Min Value: 5

Max Value: 95

List of Values: N.A.

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Step: 5  
 Default Value: Auto = 75  
 Output value =75  
 Links: N.A.  
 Auto-adjustment: N.A.  
 Comments: Available if Esens in setup menu is set to Positive  
 Auto = 75 output value = 75  
 Auto available by Down key

SFSYSTSET4.8  
 TI MIN  
 Unit: s  
 Min Value: 0.1  
 Max Value: 2.8  
 List of Values: N.A.  
 Step: 0  
 Default Value: Auto = 0.7 output value = 0.7  
 Links: TI MIN <= (60\*1/2)/BACK UP R

TI MIN <= TI MAX  
 Auto-adjustment: N.A.  
 Comments: Auto is available by the DOWN KEY  
 Step is 0.1  
 Auto = Rise time +300 ms

SFSYSTSET4.9  
 TI MAX  
 Unit: s  
 Min Value: 0.8  
 Max Value: 3  
 List of Values: N.A.  
 Step: 0  
 Default Value: Auto = 3s output value = 3s  
 Links: TI MIN <= TI MAX  
 Auto-adjustment: N.A.  
 Comments: Auto is available by the UP KEY  
 Step is 0.1  
 Auto = Min [ 3s;(60\*1/2)/R]

SFSYSTSET4.10  
 LOW VTI  
 Unit: ml  
 Min Value: 30  
 Max Value: 2000  
 List of Values: N.A.  
 Step: 10  
 Default Value: 300  
 Links: LOW VTI <= HIGH VTI - 20  
 Low Vti <= Vt target -10  
 Auto-adjustment: N.A.  
 Comments: OFF is available by the DOWN KEY

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OFF (30) output value = 30

SFSYSTSET4.11

HIGH VTI

Unit: ml

Min Value: 80

Max Value: 3000

List of Values: N.A.

Step: 10

Default Value: 2000

Links: HIGH VTI  $\geq$  LOW VTI + 20

High Vti  $\geq$  Vt target + 10

Auto-adjustement: N.A.

Comments: OFF is available by the UP KEY

OFF (=3000) output value = 3000

SFSYSTSET4.12

LOW VTE

Unit: ml

Min Value: 30

Max Value: 1990

List of Values: N.A.

Step: 10

Default Value: 300

Links: LOW VTE  $\leq$  HIGH VTE - 20

Low Vte  $\leq$  Vt target - 10

Auto-adjustement: N.A.

Comments: OFF is available by the DOWN KEY

available only if a valve is detected

OFF (=30) output value =30

SFSYSTSET4.15

HIGH R

Unit: bpm

Min Value: 10

Max Value: 70

List of Values: N.A.

Step: 1

Default Value: OFF (70) output value = 70

Links: BACK UP R  $\leq$  HIGH R - 5

Auto-adjustement: N.A.

Comments: OFF is available by the UP KEY

OFF (=70) output value = 70

SFSYSTSET4.16

HIGH VTE

Unit: ml

Min Value: 80

Max Value: 3000

List of Values: N.A.

Step: 10

Default Value: 1000

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Links: LOW VTE <= HIGH VTE - 20  
 High Vte >= Vt target + 10  
 Auto-adjustment: N.A.  
 Comments: OFF is available by the UP KEY  
 available only if a valve is detected  
 OFF (3000) output value = 3000

#### SFSYSTSET4.17

Vt target  
 Unit: ml  
 Min Value: 50  
 Max Value: 2000  
 List of Values: N.A.  
 Step: 10  
 Default Value: OFF (=100) output value =100  
 Links: Low Vte <= Vt target -10  
 High Vte >= Vt target +10  
 Low Vti <= Vt target -10  
 High Vti >= Vt target +10  
 Auto-adjustment: Low Vte  
 High Vte  
 High Vti  
 Low Vti  
 Comments: OFF is available downside  
 OFF(=100) output value =100

#### SFSYSTSET4.18

Max Pres  
 Unit: cmH2O, mbar, hPa  
 Min Value: 8  
 Max Value: 55  
 List of Values: N.A.  
 Step: 1  
 Default Value: Psupport + 3  
 Links: P SUPPORT <= MaxPres <= P SUPPORT +20  
 MaxPres + PEEP <= 55 in relative pressure  
 Auto-adjustment: N.A.  
 Comments: Not displayed if Vt target is set to OFF

#### SFSYSTSET4.19

High leak  
 Unit: lpm  
 Min Value: 5  
 Max Value: 150  
 List of Values: N.A.  
 Step: 5  
 Default Value: OFF (=200) output value = 200  
 Links: N.A.  
 Auto-adjustment: N.A.  
 Comments: available only if no valve is detected  
 OFF is available upside  
 OFF = 200 output value = 200

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SFSYSTSET4.20  
 Exh Sens (negative)  
 Unit: %  
 Min Value: -5  
 Max Value: -95  
 List of Values: N.A.  
 Step: 5  
 Default Value: Auto = -75 output value = -75  
 Links: N.A.  
 Auto-adjustement: N.A.  
 Comments: Available if Esens in setup menu is set to Negative  
 Auto = -75 output value = -75  
 Auto is reached by down key

SFSYSTSET5  
 VOL SIMV settings

SFSYSTSET5.1  
 VOL CONTROL  
 Unit: ml  
 Min Value: 50  
 Max Value: 2000  
 List of Values: N.A.  
 Step: 10  
 Default Value: 500  
 Links:  $3 \text{ lpm} \leq (\text{VOL CONTROL} * 60) / (\text{TI CONTROL} * 1000) \leq 100 \text{ lpm}$   
 $\text{LOW VTE} \leq \text{VOL CONTROL} - 10$   
 $\text{VOL CONTROL} \leq \text{HIGH VTE} - 10$   
 Auto-adjustement: LOW VTE  
 HIGH VTE  
 Comments: No comment

SFSYSTSET5.2  
 TI CONTROL  
 Unit: s  
 Min Value: 0.3  
 Max Value: 2.4  
 List of Values: N.A.  
 Step: 0  
 Default Value: 1.5  
 Links:  $3 \text{ lpm} \leq (\text{VOL CONTROL} * 60) / (\text{TI CONTROL} * 1000) \leq 100 \text{ lpm}$   
 $\text{APNEA TIME} \geq 2 * \text{TI CONTROL}$   
 if  $\text{CONTROL R} \geq 8$  :  
 $\text{TI CONTROL} \leq 0.33 * 60 / \text{CONTROL R}$   
 if  $\text{CONTROL R} < 8$  :  
 $\text{TI CONTROL} \leq 2.4$   
 Auto-adjustement: APNEA TIME  
 Comments: Step is 0.1

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SFSYSTSET5.3  
 CONTROL R  
 Unit: bpm  
 Min Value: 1  
 Max Value: 40  
 List of Values: N.A.  
 Step: 1  
 Default Value: 13  
 Links: CONTROL R <= HIGH R - 5

if CONTROL R >= 8 :  
 TI CONTROL <= 0.33 \* 60 / CONTROL R  
 if CONTROL R < 8 :  
 TI CONTROL <= 2.4  
 Auto-adjustement: HIGH R  
 Comments: No comment

SFSYSTSET5.4  
 P SUPPORT  
 Unit: cmH2O, mbar, hPa  
 Min Value: 5  
 Max Value: 55  
 List of Values: N.A.  
 Step: 1  
 Default Value: 15  
 Links: PEEP <= Psupport - 5 in absolute pressure  
 P SUPPORT + PEEP <= 55 in relative pressure  
 P SUPPORT + PEEP >= LOW PIP in relative pressure  
 P SUPPORT + PEEP <= HIGH PIP - 2 in relative pressure  
 P SUPPORT >= LOW PIP in absolute pressure  
 P SUPPORT <= HIGH PIP - 2 in absolute pressure  
 Auto-adjustement: LOW PIP  
 HIGH PIP  
 Comments: No comment

SFSYSTSET5.5  
 PEEP  
 Unit: cmH2O, mbar, hPa  
 Min Value: 1  
 Max Value: 20  
 List of Values: N.A.  
 Step: 1  
 Default Value: OFF  
 Links: PEEP <= Psupport - 5 in absolute pressure  
 P SUPPORT + PEEP <= 55 in relative pressure  
 P SUPPORT + PEEP <= HIGH PIP - 2 in relative pressure  
 P SUPPORT + PEEP >= LOW PIP in relative pressure  
 LOW PIP >= PEEP + 2 in absolute pressure  
 Auto-adjustement: LOW PIP  
 HIGH PIP  
 Comments: Possibility to set OFF

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SFSYSTSET5.6  
 APNEA TIME  
 Unit: s  
 Min Value: 1  
 Max Value: 60  
 List of Values: N.A.  
 Step: 1  
 Default Value: Auto = 12  
 Links: APNEA TIME  $\geq 2 * TI \text{ CONTROL}$   
 Auto-adjustement: N.A.  
 Comments: Auto is reached by the DOWN KEY

SFSYSTSET5.7  
 INSP SENS  
 Unit: N.A.  
 Min Value: 0P  
 Max Value: 5  
 List of Values: N.A.  
 Step: 1  
 Default Value: 2  
 Links: N.A.  
 Auto-adjustement: N.A.  
 Comments: No comment.

SFSYSTSET5.8  
 TI MIN  
 Unit: s  
 Min Value: N.A.  
 Max Value: N.A.  
 List of Values: N.A.  
 Step: 0  
 Default Value: Auto = Rise time + 300ms  
 Links: N.A.  
 Auto-adjustement: N.A.  
 Comments: No comment

SFSYSTSET5.9  
 TI MAX  
 Unit: s  
 Min Value: N.A.  
 Max Value: N.A.  
 List of Values: N.A.  
 Step: 0  
 Default Value: Auto = Min [ 3s;(60\*1/2)/R]  
 Links: N.A.  
 Auto-adjustement: N.A.  
 Comments: No comment

SFSYSTSET5.10  
 FLOW PATTERN  
 Unit: N.A.  
 Min Value: N.A.

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Max Value: N.A.  
List of Values: N.A.  
Step: 0  
Default Value: SQ  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: No comment

SFSYSTSET5.11  
RISE TIME  
Unit: N.A.  
Min Value: 1  
Max Value: 4  
List of Values: 1  
Step: 1  
Default Value: 2  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: loop setting

SFSYSTSET5.12  
EXH SENS  
Unit: %  
Min Value: 5  
Max Value: 95  
List of Values: N.A.  
Step: 5  
Default Value: 75  
Links: N.A.  
Auto-adjustement: N.A.  
Comments: Available if Esens in setup menu is set to Positive  
Auto = 75 output value = 75  
Auto available downside

SFSYSTSET5.13  
LOW PIP  
Unit: cmH2O, mbar, hPa  
Min Value: 2  
Max Value: 52  
List of Values: N.A.  
Step: 1  
Default Value: 2  
Links: in relative pressure:  
P SUPPORT + PEEP >= LOW PIP  
in absolute pressure:  
P SUPPORT >= LOW PIP  
in both:  
LOW PIP >= PEEP + 2  
LOW PIP <= HIGH PIP - 8  
Auto-adjustement: N.A.  
Comments: No comment

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SFSYSTSET5.14  
HIGH PIP  
Unit: cmH2O, mbar, hPa  
Min Value: 12  
Max Value: 90  
List of Values: N.A.  
Step: 1  
Default Value: 40  
Links: in relative pressure:  
P SUPPORT + PEEP <= HIGH PIP - 2  
in absolute pressure:  
P SUPPORT <= HIGH PIP - 2  
in both:  
LOW PIP <= HIGH PIP - 8  
Auto-adjustement: N.A.  
Comments: No comment

SFSYSTSET5.17  
LOW VTE  
Unit: ml  
Min Value: 30  
Max Value: 1990  
List of Values: N.A.  
Step: 10  
Default Value: 300  
Links: LOW VTE <= VOL CONTROL - 10  
Auto-adjustement: N.A.  
Comments: OFF is available by the DOWN KEY

SFSYSTSET5.20  
HIGH R  
Unit: bpm  
Min Value: 17  
Max Value: 70  
List of Values: N.A.  
Step: 1  
Default Value: OFF (70)  
Links: CONTROL R <= HIGH R - 5  
Auto-adjustement: N.A.  
Comments: OFF is available by the UP KEY

SFSYSTSET5.21  
HIGH VTE  
Unit: ml  
Min Value: 80  
Max Value: 3000  
List of Values: N.A.  
Step: 10  
Default Value: 1000  
Links: HIGH VTE >= VOL CONTROL + 10  
Auto-adjustement: N.A.  
Comments: OFF is available by the UP KEY

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SFSYSTSET5.22  
 BACK UP R  
 Unit:  
 Min Value: N.A.  
 Max Value: N.A.  
 List of Values: N.A.  
 Step: 0  
 Default Value: max[8,CONTROL R]  
 Links:  
 Auto-adjustement: N.A  
 Comments: No comment

SFSYSTSET6  
 PRES SIMV settings

SFSYSTSET6.1  
 P CONTROL  
 Unit: cmH2O, mbar, hPa  
 Min Value: 5  
 Max Value: 55  
 List of Values: N.A.  
 Step: 1  
 Default Value: 15  
 Links: in absolute pressure:  
 PEEP <= P CONTROL - 5  
 in relative pressure:  
 P CONTROL + PEEP <= 55  
 Auto-adjustement: N.A.  
 Comments: No comment

SFSYSTSET6.2  
 TI CONTROL  
 Unit: s  
 Min Value: 0.3  
 Max Value: 2.4  
 List of Values: N.A.  
 Step: 0  
 Default Value: 1.5  
 Links: if CONTROL R >= 8 :  
 TI CONTROL <= 0.33 \* 60 / CONTROL R  
 if CONTROL R < 8 :  
 TI CONTROL <= 2.4

APNEA TIME >= 2 \* TI CONTROL  
 Auto-adjustement: APNEA TIME  
 Comments: Step is 0.1

SFSYSTSET6.3  
 CONTROL R

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Unit: bpm  
 Min Value: 1  
 Max Value: 40  
 List of Values: N.A.  
 Step: 1  
 Default Value: 13  
 Links: CONTROL R <= HIGH R - 5  
 if CONTROL R >= 8 :  
 TI CONTROL <= 0.33 \* 60 / CONTROL R  
 if CONTROL R < 8 :  
 TI CONTROL <= 2.4  
 Auto-adjustement: HIGH R  
 Comments: No comment

SFSYSTSET6.4  
 P SUPPORT  
 Unit: cmH2O, mbar, hPa  
 Min Value: 5  
 Max Value: 55  
 List of Values: N.A.  
 Step: 1  
 Default Value: 15  
 Links: in absolute pressure:  
 PEEP <= P SUPPORTL - 5  
 in relative pressure:  
 P SUPPORT + PEEP <= 55  
 Auto-adjustement: N.A.  
 Comments: No comment

SFSYSTSET6.5  
 PEEP  
 Unit: cmH2O, mbar, hPa  
 Min Value: 1  
 Max Value: 20  
 List of Values: N.A.  
 Step: 1  
 Default Value: OFF  
 Links: in absolute pressure:  
 PEEP <= P SUPPORT - 5  
 in relative pressure:  
 P CONTROL + PEEP <= 55  
 P SUPPORT + PEEP <= 55  
 Auto-adjustement: N.A.  
 Comments: Possibility to set OFF

SFSYSTSET6.6  
 APNEA TIME  
 Unit: s  
 Min Value: 1  
 Max Value: 60  
 List of Values: N.A.  
 Step: 1

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Default Value: Auto = 12  
Links: APNEA TIME  $\geq 2 * TI$  CONTROL  
Auto-adjustment: N.A.  
Comments: Auto is reached by the down key

#### SFSYSTSET6.7

##### INP SENS

Unit: N.A.  
Min Value: 1  
Max Value: 5  
List of Values: N.A.  
Step: 1  
Default Value: 2  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: No comment

#### SFSYSTSET6.8

##### TI MIN

Unit: s  
Min Value: N.A.  
Max Value: N.A.  
List of Values: N.A.  
Step: 0  
Default Value: Auto = Rise time + 300ms  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: No comment

#### SFSYSTSET6.9

##### TI MAX

Unit: s  
Min Value: N.A.  
Max Value: N.A.  
List of Values: N.A.  
Step: 0  
Default Value: Auto = Min [ 3s; (60\*1/2)/R ]  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: No comment

#### SFSYSTSET6.10

##### RISE TIME

Unit: N.A.  
Min Value: 1  
Max Value: 4  
List of Values: N.A.  
Step: 0  
Default Value: 2  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: loop setting

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**SFSYSTSET6.11****EXH SENS**

Unit: %

Min Value: 5

Max Value: 95

List of Values: N.A.

Step: 5

Default Value: 75

Links: N.A.

Auto-adjustment: N.A.

Comments: Available if Esens in setup menu is set to Positive

Auto = 75 output value = 75

Auto available downside

**SFSYSTSET6.12****LOW VTI**

Unit: ml

Min Value: 30

Max Value: 2000

List of Values: N.A.

Step: 10

Default Value: 300

Links: LOW VTI &lt;= HIGH VTI - 20

Auto-adjustment: N.A.

Comments: OFF is available by the DOWN KEY

**SFSYSTSET6.13****HIGH VTI**

Unit: ml

Min Value: 80

Max Value: 3000

List of Values: N.A.

Step: 10

Default Value: 2000

Links: HIGH VTI &gt;= LOW VTI + 20

Auto-adjustment: N.A.

Comments: OFF is available by the UP KEY

**SFSYSTSET6.14****LOW VTE**

Unit: ml

Min Value: 30

Max Value: 1990

List of Values: N.A.

Step: 10

Default Value: 300

Links: LOW VTE &lt;= HIGH VTE - 20

Auto-adjustment: N.A.

Comments: OFF is available by the DOWN KEY

**SFSYSTSET6.17**

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HIGH R  
Unit: bpm  
Min Value: 17  
Max Value: 70  
List of Values: N.A.  
Step: 1  
Default Value: OFF (20)  
Links: CONTROL R <= HIGH R - 5  
Auto-adjustment: N.A.  
Comments: OFF is available by UP key

SFSYSTSET6.18  
HIGH VTE  
Unit: ml  
Min Value: 80  
Max Value: 3000  
List of Values: N.A.  
Step: 10  
Default Value: 1000  
Links: LOW VTE <= HIGH VTE - 20  
Auto-adjustment: N.A.  
Comments: OFF is available by the UP KEY

SFSYSTSET6.19  
BACK UP R  
Unit: Bpm  
Min Value: N.A.  
Max Value: N.A.  
List of Values: N.A.  
Step: 0  
Default Value: max[8,CONTROL R]  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: No comment

SFSYSTSET31  
CPAP settings

SFSYSTSET31.1  
Cpap  
Unit: cmH2O, mbar, hPa  
Min Value: 4  
Max Value: 20  
List of Values: N.A.  
Step: 1  
Default Value: 10  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: No comment

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### SFSYSTSET31.2

Apnea

Unit: s

Min Value: 1

Max Value: 60

List of Values: N.A.

Step: 1

Default Value: Auto = 30

output value = 30

Links: N.A.

Auto-adjustement: N.A.

Comments: not available if Apnea alarm is set to No in preference menu

Auto = 30

reached downside

output value = 30

### SFSYSTSET31.3

LOW VTI

Unit: ml

Min Value: 30

Max Value: 2000

List of Values: N.A.

Step: 10

Default Value: 300

Links: LOW VTI <= HIGH VTI - 20

Auto-adjustement: N.A.

Comments: OFF is reached downside

OFF (=30) output value = 30

### SFSYSTSET31.4

HIGH VTI

Unit: ml

Min Value: 80

Max Value: 3000

List of Values: N.A.

Step: 10

Default Value: 2000

Links: LOW VTI <= HIGH VTI - 20

Auto-adjustement: N.A.

Comments: OFF is reached upside

OFF (=3000) output value = 3000

### SFSYSTSET31.5

High leak

Unit: lpm

Min Value: 5

Max Value: 150

List of Values: N.A.

Step: 5

Default Value: OFF (=0)

output value = 5

Links: N.A.

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Auto-adjustment: N.A.  
Comments: OFF is reached upside  
OFF(=0) output value = 5

#### SFSYSTSET31.6

High R  
Unit: bpm  
Min Value: 10  
Max Value: 70  
List of Values: N.A.  
Step: 1  
Default Value: OFF (=70) output value = 70  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: OFF is reached upside  
OFF(=70) output value = 70

#### SFSYSTSET31.7

Insp Sens  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: N.A.  
Step: 0  
Default Value: 2  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: No comment

#### SFSYSTSET31.10

Exh sens  
Unit: %  
Min Value: N.A.  
Max Value: N.A.  
List of Values: N.A.  
Step:  
Default Value: 25  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: No comment

#### SFSYSTSET42

Low FiO2  
Unit: %  
Min Value: 18  
Max Value: 90  
List of Values: N.A.  
Step: 1  
Default Value: OFF (=18) output value = 18  
Links: Low FiO2 <= High FiO2 - 10  
Auto-adjustment: N.A.

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Comments: OFF is available below Min value.  
OFF setting is not allowed if an oxygen sensor is detected.  
OFF (=18) output value = 18.  
This setting applies to all ventilation modes simultaneously.

#### SFSYSTSET43

High FiO2

Unit: %

Min Value: 30

Max Value: 100

List of Values: N.A.

Step: 1

Default Value: OFF (=100) output value = 100

Links: Low FiO2 <= High FiO2 - 10

Auto-adjustment: N.A.

Comments: OFF is available above Max value.

OFF setting is not allowed if an oxygen sensor is detected.

This setting applies to all ventilation modes simultaneously.

#### SFSYSTSET44

USB menu

##### SFSYSTSET44.1

Erase key

Unit: N.A.

Min Value: N.A.

Max Value: N.A.

List of Values: Yes, OFF

Step: 0

Default Value: OFF

Links: N.A.

Auto-adjustment: N.A.

Comments: Not available during any USB key operation.

= OFF when an USB key operation is finished.

##### SFSYSTSET44.2

DELETED

##### SFSYSTSET44.3

Continuous transfer

Unit: N.A.

Min Value: N.A.

Max Value: N.A.

List of Values: Yes, OFF

Step: 0

Default Value: OFF

Links: N.A.

Auto-adjustment: N.A.

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Comments: Not available during any USB key operation.  
= OFF when an USB key operation is finished.

SFSYSTSET44.4  
DELETED

SFSYSTSET44.5  
Trend transfer  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: OFF, 3, 6, 9, 12  
Step: 0  
Default Value: OFF  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: Not available during any USB key operation.  
= OFF when an USB key operation is finished.

SFSYSTSET44.6  
DELETED

SFSYSTSET44.7  
ALARM TONE  
Unit: N.A.  
Min Value: Original  
Max Value: Compliant  
List of Values: Original, Compliant  
Step: 1  
Default Value: Compliant  
Comments: This is only available in Service Mode.

SFSYSTSET44.8  
Restore Defaults  
Unit: N.A.  
Min Value: N.A.  
Max Value: N.A.  
List of Values: Yes, OFF  
Step: 0  
Default Value: OFF  
Links: N.A.  
Auto-adjustment: N.A.  
Comments: This is only available in Service Mode. Allows the user restore all settings back to Manufacturing defaults except for Language, date, and time settings.

### 3.5 Set-up Requirements

SFSYSTSETUP1  
MAINTENANCE MENU  
In the MAINTENANCE MENU the software must provide following fields :  
- CPU soft

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- power supply soft
- serial number
- fault check
- measurement check
- sensor calibration
- turbine speed
- back

#### SFSYSTSETUP1.1

software version

the software must display the software versions of the CPU board and power management board

#### SFSYSTSETUP1.3

default check

No text (title)

##### SFSYSTSETUP1.3.1

the software must display the last nine technical defaults in reverse chronological order with their occurrence date/time and machine hours.

##### SFSYSTSETUP1.3.2

the software must display the message "No Data" if there is no recorded defaults

##### SFSYSTSETUP1.3.3

when the VALIDATION KEY is SHORT PRESS on the back field, the software must display the MAINTENANCE MENU

##### SFSYSTSETUP1.3.4

When the INHIBITION KEY is LONG PRESS on the default check field, the software must erase anomalies records, set to zero the patient counter and erase the data concerning the ventilation report

##### SFSYSTSETUP1.3.5

The software must activate the buzzer when the default check menu is erased

#### SFSYSTSETUP1.4

Voltage check

No text (title)

##### SFSYSTSETUP1.4.1

the software must display the SUPPLY MEASURE.

##### SFSYSTSETUP1.4.2

when the supply is the internal battery, the software must display the BATTERY SYMBOL

##### SFSYSTSETUP1.4.4

the software must display the Watchdog voltage

##### SFSYSTSETUP1.4.5

the software must display the BUZZER VOLTAGE

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#### SFSYSTSETUP1.4.6

when the VALIDATION KEY is pressed on one of the buzzers field, the software must activate the corresponding buzzer.

#### SFSYSTSETUP1.4.7

The software must display the Barometric Pressure

#### SFSYSTSETUP1.4.8

The software must display the INTERNAL TEMPERATURE and the BLOWER TEMPERATURE

#### SFSYSTSETUP1.4.9

The software must display the Internal Battery menu

#### SFSYSTSETUP1.4.11

the software must display a NEUTRAL SYMBOL when the value of a parameter is not available

#### SFSYSTSETUP1.4.12

The software must display the altitude compensation setting

#### SFSYSTSETUP1.5

Sensors calibration

No text (title)

#### SFSYSTSETUP1.5.1

the software provides two INTERNAL PRESSURE offsets to calibrate : 0 cmH2O and 40 cmH2O

#### SFSYSTSETUP1.5.2

the software provides two PROXIMAL PRESSURE offsets to calibrate : 0 cmH2O and 40 cmH2O

#### SFSYSTSETUP1.5.3

the software provides one VALVE PRESSURE offset to calibrate : 0 cmH2O

#### SFSYSTSETUP1.5.4

the software provides eight QI offset to calibrate: 0 lpm, 5 lpm, 12 lpm, 20 lpm, 37 lpm, 60 lpm, 90 lpm, 130 lpm

#### SFSYSTSETUP1.5.5

the software provides eight QE offset to calibrate automatically: 0 lpm, 5 lpm, 12 lpm, 20 lpm, 37 lpm, 60 lpm, 90 lpm, 130 lpm. When pediatric circuit set to YES, the software must skip the 130 lpm point and keep the previous value that was stored.

#### SFSYSTSETUP1.5.6

the software must display all sensors measures not being calibrated

#### SFSYSTSETUP1.5.7

the software must provide one FiO2 offset to calibrate if a FiO2 sensor is detected: 21%.  
FiO2 calibration must not be available if no sensor is detected.

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#### SFSYSTSETUP1.6

turbine speed

No text (title)

##### SFSYSTSETUP1.6.1

when the MENU KEY is SHORT PRESS on the turbine speed field, the software commands the turbine to the MAX SPEED.

##### SFSYSTSETUP1.6.2

when the UP KEY or DOWN KEY are SHORT PRESS on the turbine speed field, the software stops the turbine

##### SFSYSTSETUP1.6.3

when the UP KEY or DOWN KEY are SHORT PRESS on the turbine selected speed field, the software increase or decrease the SPEED CONSIGN

##### SFSYSTSETUP1.6.4

when the VALIDATION KEY is SHORT PRESS on the turbine selected speed field, the software maintains a continuous SPEED SET POINT

#### SFSYSTSETUP1.7

Navigation

when the VALIDATION KEY is SHORT PRESS the "Back" field, the software displays the SET UP MENU.

#### SFSYSTSETUP1.10

Serial number

the software must display the serial number of the ventilator

#### SFSYSTSETUP2

SET UP MENU

In the SETUP MENU the software must provide following fields :

- machine hours
- language
- date
- time
- intentional vent stop
- pressure unit
- alarm tone
- patient hours
- Restore Defaults
- maintenance
- next

##### SFSYSTSETUP2.1

NAVIGATION

When the VALIDATION KEY is SHORT PRESS the maintenance field, the software must display the corresponding menu.

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## SFSYSTSETUP2.2

### PATIENT COUNTER

when the VALIDATION KEY is SHORT PRESS on the PATIENT COUNTER field, the cursor must go on the field "Reset Counter". To reset the PATIENT COUNTER the user must first make a SHORT PRESS on VALIDATION KEY then press on UP KEY to change the display from "OFF" to "YES" and finally make a SHORT PRESS on VALIDATION KEY to reset the counter. When the PATIENT COUNTER is reset, a long beep must be triggered.

## SFSYSTSETUP2.3

### MACHINE HOURMETER

No text (title)

#### SFSYSTSETUP2.3.1

the software must preserve the MACHINE HOURS even if a down load occurs

#### SFSYSTSETUP2.3.2

the software must display the MACHINE HOURS value with 5 digits.

#### SFSYSTSETUP2.3.3

the software must increase the MACHINE HOURS value each hour of turbine functioning

## SFSYSTSETUP3

### PREFERENCE MENU

In the PREFERENCE MENU the software must provide following fields :

- Back light
- Screen Contrast
- Alarm Sound Level
- Key Sound
- Apnea Alarm
- Disconnection alarm
- Pediatric circuit
- Waveform Display
- Ventilation Report
- Back to ventilation

#### SFSYSTSETUP3.1

### ALARM SOUND LEVEL

No text (title)

#### SFSYSTSETUP3.1.1

when the VALIDATION KEY is SHORT PRESS on the sound level field, the software must :

- display a white triangular cursor and display the +/- symbol instead of the rectangular cursor
- activate a high level priority sound in the buzzer

#### SFSYSTSETUP3.1.2

when the UP KEY or DOWN KEY are SHORT PRESS on the selected sound level field, the software must:

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- increase or decrease the SOUND LEVEL
- shift the cursor
- modify the BARGRAPH consequently

#### SFSYSTSETUP3.1.3

when the VALIDATION KEY is SHORT PRESS on the selected sound level field, the software must :

- display a black triangular cursor and display the rectangular symbol instead of the +/- cursor
- deactivate the buzzer

#### SFSYSTSETUP3.1.4

if there is no UP KEY or DOWN KEY action before 7s, the software must:

- display a black triangular symbol
- replace the +/- symbol by a white rectangular symbol
- let the volume to the previous SOUND LEVEL.

#### SFSYSTSETUP3.2

##### SCREEN CONTRAST

No text (title)

#### SFSYSTSETUP3.2.1

when the VALIDATION KEY is SHORT PRESS on the SCREEN CONTRAST field, the software must :

- display a white triangular cursor
- display the +/- symbol instead of the rectangular cursor

#### SFSYSTSETUP3.2.2

when the UP KEY or DOWN KEY are SHORT PRESS on the selected contrast field, the software must:

- increase or decrease the SCREEN CONTRAST
- shift the cursor
- modify the BARGRAPH consequently

#### SFSYSTSETUP3.2.3

when the VALIDATION KEY is SHORT PRESS on the SCREEN CONTRAST selected field, the software must display a black triangular cursor and display the rectangular symbol instead of the +/- cursor

#### SFSYSTSETUP3.2.4

if there is no UP KEY or DOWN KEY action before 7s, the software must:

- display a black triangular symbol
- replace the +/- symbol by a white rectangular symbol
- let the SCREEN CONTRAST to the previous value recorded.

#### SFSYSTSETUP3.3

navigation

No text (title)

#### SFSYSTSETUP3.3.1

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when the VALIDATION KEY is SHORT PRESS on "Back to ventilation" field, the software must display the VENTILATION MENU

#### SFSYSTSETUP3.3.2

the software must switch to the VENTILATION MENU if there is no key activation until 14 seconds or if a high priority alarm occurs or if the ventilation is launched (one press on ventilation key)

#### SFSYSTSETUP3.4

##### Waveform Display

Once the Waveform Display field has been selected, the software must display in loop "YES" or "OFF" when the UP KEY or DOWN KEY is pressed.

If "YES" is validated, the software must display WAVEFORM MENU when the ventilation is running.

If "NO" is validated, the software mustn't display WAVEFORM MENU.

#### SFSYSTSETUP3.5

##### Pediatric circuit

The software must allow the user to select a pediatric circuit (yes/no) when once this field is selected.

#### SFSYSTSETUP3.6

##### Ventilation report

when the VALIDATION KEY is SHORT PRESS on the "Ventilation report" field, the software must display the Ventilation Report menu

#### SFSYSTSETUP3.7

##### Apnea alarm

Once the Apnea alarm field has been selected, the software must display in loop "YES" or "OFF" when the UP KEY or DOWN KEY is pressed.

If "YES" is validated, the apnea alarm works normally (When a apnea is detect, the apnea alarm is trigged (sound + message + light)).

If "OFF" is validated, the apnea alarm can be detected but without sound, message and light. Moreover the action following the alarm should be available.

#### SFSYSTSETUP3.9

##### Disconnection delay

The software must allow the user to set a disconnection delay.

#### SFSYSTSETUP4.0

##### SET UP 2 MENU

In the SETUP 2 MENU the software must provide following fields:

- Cycling Mode
- Relative Pressure
- E Sens Setting
- Back

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SFSYSTSETUP15  
INTERNAL BATTERY MENU  
No text (title)

SFSYSTSETUP15.1  
Internal Battery menu fields  
In the Internal Battery Menu, the software must provide following fields :  
- Supplier  
- Theoretical capacity  
- capacity  
- First use date  
- Cycles done  
- Battery voltage  
- Battery temperature  
- Back

SFSYSTSETUP15.2  
First use date  
The software must display the manufacturing date and time. If the battery manufacturing date/time is illegible, the software must display "UNKNOWN" instead of the date

SFSYSTSETUP 15.3  
Internal battery menu shall display "UNKNOWN" battery if a non-approved supplier of the battery is inserted or "APPROVED" if an approved battery is installed.

### 3.6 Calibration Requirements

See CPU Software Requirements Specification, PB 540 (10025034), same requirements apply.

### 3.7 Monitoring Display Requirements

SFSYSTMON1  
VTI  
Min Val: 0  
Max Val: 3000  
Rounded to: 1

SFSYSTMON2  
VTE  
Min Val: 20  
Max Val: 3000  
Rounded to: 1

SFSYSTMON3  
VM / VMI  
Min Val: 0  
Max Val: 99.9  
Rounded to: 0.1

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SFSYSTMON4

R

Min Val: 0

Max Val: 99

Rounded to: 1

SFSYSTMON5

I:E

Min Val: 1:199

Max Val: 9.9:1

Rounded to: 0.1 for values [0.1... 99.9] and 1 for values of 1 and [100... 199].

SFSYSTMON6

PIP

Min Val: 0

Max Val: 99

Rounded to: 1

SFSYSTMON8

PEEP

Min Val: 0

Max Val: 99

Rounded to: 1

SFSYSTMON9

BATTERY TIME LEVEL

Min Val: 0h00min

Max Val: 24h00min

Rounded to: 10

SFSYSTMON10

DATE

Min Val: 01 JAN 2004

Max Val: 31 DEC 2099

Rounded to: N.A.

SFSYSTMON11

TIME

Min Val: 00:00:00

Max Val: 23:59:59

Rounded to: 01 sec

SFSYSTMON12

PATIENT COUNTER

Min Val: 0h00min

Max Val: 65000h00min

Rounded to: 01 min

SFSYSTMON13

24 V CHECK

Min Val: 0

Max Val: 99.9

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Rounded to: 0.1

SFSYSTMON15  
WATCHDOG CHECK  
Min Val: 0  
Max Val: 99.9  
Rounded to: 0.1

SFSYSTMON16  
BUZZER CHECK  
Min Val: 0  
Max Val: 9.9  
Rounded to: 0.1

SFSYSTMON17  
MACHINE HOURS  
Min Val: 0  
Max Val: 65000  
Rounded to: 1

SFSYSTMON18  
INTERNAL PRESSURE  
Min Val: -99.9  
Max Val: 99.9  
Rounded to: 0.1

SFSYSTMON19  
PROXIMAL PRESSURE  
Min Val: -99.9  
Max Val: 99.9  
Rounded to: 0.1

SFSYSTMON20  
VALVE PRESSURE  
Min Val: -99.9  
Max Val: 99.9  
Rounded to: 0.1

SFSYSTMON21  
INSPIRATORY FLOW  
Min Val: -999.9  
Max Val: 999.9  
Rounded to: 0.1

SFSYSTMON23  
EXHALATION FLOW  
Min Val: -999.9  
Max Val: 999.9  
Rounded to: 0.1

SFSYSTMON25  
TURBINE SPEED

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Min Val: 0  
Max Val: 65535  
Rounded to: 1

SFSYSTMON26  
INTERNAL TEMPERATURE  
Min Val: -99.9  
Max Val: 99.9  
Rounded to: 0.1

SFSYSTMON27  
BATTERY TEMPERATURE  
Min Val: -99.9  
Max Val: 99.9  
Rounded to: 0.1

SFSYSTMON30  
BATTERY VOLTAGE  
Min Val: 0  
Max Val: 99.9  
Rounded to: 0.1

SFSYSTMON32  
BAROMETRIC PRESSURE  
Min Val: 0  
Max Val: 999.9  
Rounded to: 0.1

SFSYSTMON33  
FIRST USE DATE  
Min Val: 01 JAN 2004  
Max Val: 31 DEC 2099  
Rounded to: N.A.

SFSYSTMON34  
CYCLE DONE (BATTERY CYCLE COUNTER)  
Min Val: 0  
Max Val: 655  
Rounded to: 1

SFSYSTMON36  
BATTERY PERCENT LEVEL  
Min Val: 0  
Max Val: 100  
Rounded to: 1

SFSYSTMON37  
TI  
Min Val: 0  
Max Val: 9.9  
Rounded to: 0.1

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SFSYSTMON38

TE

Min Val: 0

Max Val: 59.9

Rounded to: 0.1

SFSYSTMON39

CAPACITY (INTERNAL BATTERY CAPACITY)

Min Val: 0

Max Val: 9999

Rounded to: 1

SFSYSTMON40

THEORETICAL CAPACITY

Min Val: 0

Max Val: 9999

Rounded to: NA

SFSYSTMON41

FIRST USE TIME

Min Val: 00:00:00

Max Val: 23:59:59

Rounded to: 1 s

SFSYSTMON42

BLOWER TEMPERATURE

Min Val: -99.9

Max Val: 99.9

Rounded to: 0.1

SFSYSTMON44

FiO2

Min Val: 0

Max Val: 250

Rounded to: 1

SFSYSTMON45

MEAN VENTILATION

Min Val: 0h00min

Max Val: 23h59min

Rounded to: 1min

SFSYSTMON46

AI

Min Val: 0

Max Val: 999

Rounded to: 1

SFSYSTMON47

TAPNEA

Min Val: 0

Max Val: 999

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Rounded to: 1

SFSYSTMON48

% SPONT (VENTILATION REPORT MENU)

Min Val: 0

Max Val: 100

Rounded to: 1

SFSYSTMON50

I/T

Min Val: 1

Max Val: 95

Rounded to: 1

SFSYSTMON51

LEAK MEAN (VENTILATION REPORT MENU)

Min Val: 0

Max Val: 999

Rounded to: 1

SFSYSTMON52

VENTILATION REPORT DATE

Min Val: 01 JAN 2004

Max Val: 31 DEC 2099

Rounded to: NA

SFSYSTMON53

VTI MEAN (VENTILATION REPORT MENU)

Min Val: 0

Max Val: 6553

Rounded to: 1

SFSYSTMON54

VTE MEAN (VENTILATION REPORT MENU)

Min Val: 20

Max Val: 6553

Rounded to: 1

SFSYSTMON55

PAW MEAN (VENTILATION REPORT MENU)

Min Val: 0

Max Val: 99

Rounded to: 1

SFSYSTMON56

RATE MEAN (VENTILATION REPORT MENU)

Min Val: 0

Max Val: 99

Rounded to: 1

SFSYSTMON57

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LEAK  
Min Val: 0  
Max Val: 150  
Rounded to: 1

SFSYSTMON58  
TRANSFER TIME (USB DATA TRANSFER TIME)  
Min Val: 0h1min  
Max Val: 0h17min  
Rounded to: 1 min

SFSYSTMON59  
ERASE TIME (USB STICK ERASE TIME)  
Min Val: 0h1min  
Max Val: 0h1min  
Rounded to: NA

SFSYSTMON60  
TRANSFER TIME REMAINING (USB DATA TRANSFER REMAINING)  
Min Val: 0h1min  
Max Val: 71h29min  
Rounded to: 1min

### 3.8 Events Requirements

SFSYSTEV1  
GENERAL EVENTS REQUIREMENTS

SFSYSTEV1.1  
START DEVICE  
the software shall record this event at each INITIALIZATION PHASE

SFSYSTEV1.2  
START VENTILATION  
the software shall record this event when the VENTILATION KEY is SHORT PRESS

SFSYSTEV1.3  
STOP VENTILATION  
the software shall record this event when the VENTILATION KEY is LONG PRESS

SFSYSTEV1.4  
STOP DEVICE  
the software shall record this event when the user switch off the device and the ventilation was off

SFSYSTEV1.5  
CHANGE MODE  
the software shall record this event when the VALIDATION KEY is SHORT PRESS on the change mode field to yes

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**SFSYSTEV1.6****INVOLUNTARY STOP**

the software shall record this event when the POWER SUPPLY LOSS alarm is detected

**SFSYSTEV1.7****AC return**

the software shall record this event when the AC SELECTED changes from 0 to 1

**SFSYSTEV1.8****DC return**

the software shall record this event when the DC SELECTED changes from 0 to 1

**SFSYSTEV1.9****maintenance menu access**

the software shall record this event when the INHIBITION KEY is LONG PRESS during the INITIALIZATION PHASE

**SFSYSTEV1.10****Alarm Inhibition**

the software shall record this event when the INHIBITION KEY is SHORT PRESS and an alarm is active

**SFSYSTEV1.11****Alarm Cancellation**

the software shall record this event when the INHIBITION KEY is LONG PRESS and a manually cancelable alarm is active

**SFSYSTEV1.18****SETTINGS TRANSFER FROM KEY**

the software shall record this event when the SETTINGS TRANSFER FROM KEY alarm is detected

**SFSYSTEV1.21****PATIENT COUNTER RESET**

The software shall record the PATIENT COUNTER RESET

**SFSYSTEV2****ADJUST EVENT REQUIREMENTS****SFSYSTEV2.1****P Support**

the software shall record this event when a new P Support is set

**SFSYSTEV2.2****PEEP**

the software shall record this event when a new PEEP is set

**SFSYSTEV2.3****Rise Time**

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the software shall record this event when a new Rise Time is set

#### SFSYSTE2.4

Back-up R

the software shall record this event when a new Back-up R is set

#### SFSYSTE2.5

Apnea Time

the software shall record this event when a new Apnea Time is set

#### SFSYSTE2.6

Insp Sens

the software shall record this event when a new Insp Sens is set

#### SFSYSTE2.7

Exh Sens

the software shall record this event when a new Exh Sens is set

#### SFSYSTE2.8

Ti min

the software shall record this event when a new Ti min is set

#### SFSYSTE2.9

Ti max

the software shall record this event when a new Ti max is set

#### SFSYSTE2.10

Vol Control

the software shall record this event when a new Vol Control is set

#### SFSYSTE2.11

Ti Control

the software shall record this event when a new Ti Control is set

#### SFSYSTE2.12

Control R

the software shall record this event when a new Control R is set

#### SFSYSTE2.13

P Control

the software shall record this event when a new P Support is set

#### SFSYSTE2.14

RAMP

the software shall record this event when a new ramp is set

#### SFSYSTE2.15

Low VTI

the software shall record this event when a new Low VTI is set

#### SFSYSTE2.16

High VTI

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the software shall record this event when a new High VTI is set

SFSYSTE2.17

Low VTE

the software shall record this event when a new Low VTE is set

SFSYSTE2.18

DELETED

SFSYSTE2.19

DELETED

SFSYSTE2.20

High R

the software shall record this event when a new High R is set

SFSYSTE2.21

Low PIP

the software shall record this event when a new Low PIP is set

SFSYSTE2.22

High PIP

the software shall record this event when a new High PIP is set

SFSYSTE2.23

High VTE

The software shall record this event when a new HIGH VTE is set

SFSYSTE2.24

Date (RTC)

The software shall memorize any date change in order to retrieve the former date.

SFSYSTE2.25

Hour (RTC)

The software shall memorize any hour change in order to retrieve the former hour.

SFSYSTE2.26

I:E

DEL

SFSYSTE2.27

Vt target

the software shall record this event when a new Vt target is set

SFSYSTE2.28

Pmax

the software shall record this event when a new Pmax is set

SFSYSTE2.29

I/T

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DEL

SFSYSTEV2.30

HIGH LEAK

the software shall record this event when a new high leak is set

SFSYSTEV2.31

HIGH FiO2

the software shall record this event when a new High FiO2 is set

SFSYSTEV2.32

LOW FiO2

the software shall record this event when the LOW FiO2 is set

SFSYSTEV2.33

DISCONNECTION DELAY

the software shall record this event when the DISCONNECTION DELAY is set

SFSYSTEV2.34

SIGH COUNT

the software shall record this event when the SIGH COUNT is set

SFSYSTEV2.35

SIGH COEF

the software shall record this event when the SIGH COEF is set

SFSYSTEV2.36

CIRCUIT CHECK

the software shall record this event when CIRCUIT CHECK MENU is displayed

SFSYSTEV3

ALARM EVENT REQUIREMENTS

SFSYSTEV3.1

Patient pressure calibration

the software shall record this event when the VALIDATION KEY is SHORT PRESS on the Patient pressure calibration field

SFSYSTEV3.2

Valve pressure calibration

the software shall record this event when the VALIDATION KEY is SHORT PRESS on the Valve pressure calibration field

SFSYSTEV3.3

Insp Flow calibration

the software shall record this event when the VALIDATION KEY is SHORT PRESS on the Insp Flow calibration field

SFSYSTEV3.4

Exh Flow calibration

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the software shall record this event when the VALIDATION KEY is SHORT PRESS on the Exh Flow calibration field

**SFSYSTE3.5**

**DISCONNECTION**

the software shall record this event when the DISCONNECTION alarm is detected

**SFSYSTE3.6**

**END OF DISCONNECTION**

the software shall record this event when the DISCONNECTION alarm is cancelled

**SFSYSTE3.7**

**HIGH PRESSURE**

the software shall record this event when the HIGH PRESSURE alarm is detected

**SFSYSTE3.8**

**END OF HIGH PRESSURE**

the software shall record this event when the HIGH PRESSURE alarm is cancelled

**SFSYSTE3.9**

**APNEA**

the software shall record this event when the APNEA alarm is detected

**SFSYSTE3.10**

**END OF APNEA**

the software shall record this event when the APNEA alarm is cancelled

**SFSYSTE3.11**

**HIGH VTI**

the software shall record this event when the HIGH VTI alarm is detected

**SFSYSTE3.12**

**END OF HIGH VTI**

the software shall record this event when the HIGH VTI alarm is cancelled

**SFSYSTE3.13**

**LOW VTI**

the software shall record this event when the LOW VTI alarm is detected

**SFSYSTE3.14**

**END OF LOW VTI**

the software shall record this event when the LOW VTI alarm is cancelled

**SFSYSTE3.15**

**LOW VTE**

the software shall record this event when the LOW VTE alarm is detected

**SFSYSTE3.16**

**END OF LOW VTE**

the software shall record this event when the LOW VTE alarm is cancelled

**SFSYSTE3.17**

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DELETED

SFSYSTEV3.18  
DELETED

SFSYSTEV3.19  
DELETED

SFSYSTEV3.20  
DELETED

SFSYSTEV3.21  
HIGH RATE  
the software shall record this event when the HIGH RATE alarm is detected

SFSYSTEV3.22  
END OF HIGH RATE  
the software shall record this event when the HIGH RATE alarm is cancelled

SFSYSTEV3.23  
AC POWER FAIL  
the software shall record this event when the AC POWER FAIL alarm is detected

SFSYSTEV3.24  
DC POWER FAIL  
the software shall record this event when the DC POWER FAIL alarm is detected

SFSYSTEV3.25  
END OF BATTERY  
the software shall record this event when the END OF BATTERY alarm is detected

SFSYSTEV3.26  
LOW BATTERY  
the software shall record this event when the LOW BATTERY alarm is detected

SFSYSTEV3.27  
CHECK BATTERY  
the software shall record this event when the CHECK BATTERY alarm is detected

SFSYSTEV3.28  
END OF CHECK BATTERY  
the software shall record this event when the CHECK BATTERY alarm is cancelled

SFSYSTEV3.29  
NO BATTERY  
the software shall record this event when the NO BATTERY alarm is detected

SFSYSTEV3.30  
END OF NO BATTERY  
the software shall record this event when the NO BATTERY alarm is cancelled

SFSYSTEV3.31

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CHECK BUZZER

the software shall record this event when the CHECK BUZZER alarm is detected

SFSYSTEV3.33

TECHNICAL PROBLEM

the software shall record this event when the TECHNICAL PROBLEM alarm is detected

SFSYSTEV3.34

DELETED

SFSYSTEV3.35

DELETED

SFSYSTEV3.36

DELETED

SFSYSTEV3.37

DELETED

SFSYSTEV3.38

CHECK PRESSURE

the software shall record this event when the CHECK PRESSURE alarm is detected

SFSYSTEV3.39

END OF CHECK PRESSURE

the software shall record this event when the CHECK PRESSURE alarm is cancelled

SFSYSTEV3.40

CHECK PROXIMAL

the software shall record this event when the CHECK PROXIMAL alarm is detected

SFSYSTEV3.41

END OF CHECK PROXIMAL

the software shall record this event when the CHECK PROXIMAL alarm is cancelled

SFSYSTEV3.42

PROXIMAL DISCONNECTION

the software shall record this event when the PROXIMAL DISCONNECTION alarm is detected

SFSYSTEV3.43

END OF PROXIMAL DISCONNECTION

the software shall record this event when the PROXIMAL DISCONNECTION alarm is cancelled

SFSYSTEV3.46

DELETED

SFSYSTEV3.48

CHECK VALVE

the software shall record this event when the CHECK VALVE alarm is detected

SFSYSTEV3.49

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END OF CHECK VALVE

the software shall record this event when the CHECK VALVE alarm is cancelled

SFSYSTEV3.50

CHECK VOLUME

the software shall record this event when the CHECK VOLUME alarm is detected

SFSYSTEV3.51

END OF CHECK VOLUME

the software shall record this event when the CHECK VOLUME alarm is cancelled

SFSYSTEV3.52

VALVE LEAKAGE

the software shall record this event when the VALVE LEAKAGE alarm is detected

SFSYSTEV3.53

END OF VALVE LEAKAGE

the software shall record this event when the VALVE LEAKAGE alarm is cancelled

SFSYSTEV3.54

CHECK REMOTE ALARM

the software shall record this event when the CHECK REMOTE ALARM alarm is detected

SFSYSTEV3.56

DELETED

SFSYSTEV3.57

INSP FLOW OFFSET DEFAULT

the software shall record this event when the INSP FLOW OFFSET DEFAULT is detected

SFSYSTEV3.58

EXH FLOW OFFSET DEFAULT

the software shall record this event when the EXH FLOW OFFSET DEFAULT is detected

SFSYSTEV3.59

VALVE PRESSURE OFFSET DEFAULT

the software shall record this event when the VALVE PRESSURE OFFSET DEFAULT is detected

SFSYSTEV3.60

INTERNAL PRESSURE OFFSET DEFAULT

the software shall record this event when the INTERNAL PRESSURE OFFSET DEFAULT is detected

SFSYSTEV3.61

SPEED DEFAULT

the software shall record this event when the SPEED DEFAULT is detected

SFSYSTEV3.62

CLOCK DEFAULT

the software shall record this event when the CLOCK DEFAULT is detected

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SFSYSTEV3.63

KEYBOARD

the software shall record this event when the KEYBOARD alarm is detected

SFSYSTEV3.64

PROXIMAL PRESSURE OFFSET DEFAULT

the software shall record this event when the PROXIMAL PRESSURE OFFSET DEFAULT is detected

SFSYSTEV3.65

VERY LOW PROXIMAL PRESSURE

the software shall record this event when the VERY LOW PROXIMAL PRESSURE default is detected

SFSYSTEV3.66

VERY LOW INTERNAL PRESSURE

the software shall record this event when the VERY LOW INTERNAL PRESSURE default is detected

SFSYSTEV3.67

VERY LOW VALVE PRESSURE

the software shall record this event when the VERY LOW VALVE PRESSURE default is detected

SFSYSTEV3.68

CHECK SUPPLY

the software shall record this event when the CHECK SUPPLY alarm is detected

SFSYSTEV3.69

END OF CHECK SUPPLY

the software shall record this event when the CHECK SUPPLY alarm is cancelled

SFSYSTEV3.70

UNKNOWN BATTERY

the software shall record this event when the UNKNOWN BATTERY alarm is detected

SFSYSTEV3.71

END OF UNKNOWN BATTERY

the software shall record this event when the UNKNOWN BATTERY alarm is cancelled

SFSYSTEV3.72

CHECK BATTERY CHARGE

the software shall record this event when the CHECK BATTERY CHARGE alarm is detected

SFSYSTEV3.73

END OF CHECK BATTERY CHARGE

the software shall record this event when the CHECK BATTERY CHARGE alarm is cancelled

SFSYSTEV3.74

NEW VERSION

the software shall record this event when a new version of the software is downloaded

SFSYSTEV3.75

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#### EEPROM OUT OF RANGE

the software shall record this event when settings are lost (except for the following settings :  
LANGUAGE, SCREEN SAVER and SERIAL PORT RATE)

#### SFSYSTEV3.76

##### LOST SETTINGS

the software shall record the event when LANGUAGE, SCREEN SAVER or SERIAL PORT RATE  
settings are lost.

#### SFSYSTEV3.78

##### HIGH VTE

The software shall record this event when a HIGH VTE alarm is detected

#### SFSYSTEV3.79

##### END OF HIGH VTE

the software shall record this event when the HIGH VTE alarm is cancelled

#### SFSYSTEV3.80

##### TURBINE OVERHEAT

the software shall record this event when the TURBINE OVERHEAT alarm is detected

#### SFSYSTEV3.81

##### COOLING FAN FAILURE

the software shall record this event when the COOLING FAN FAILURE alarm is detected

#### SFSYSTEV3.82

##### AMBIENT TEMP OUTOFBOUNDS

the software shall record this event when the AMBIENT TEMP OUTOFBOUNDS alarm is  
detected.

#### SFSYSTEV3.83

##### BAT TEMP OUTOFBOUNDS

the software shall record this event when the BAT TEMP OUTOFBOUNDS alarm is detected

#### SFSYSTEV3.84

##### SUPPLY MEASURE FAILURE

the software shall record this event when the SUPPLY MEASURE FAILURE alarm is detected

#### SFSYSTEV3.85

##### FAILURE 24V

the software shall record this event when the FAILURE 24V alarm is detected

#### SFSYSTEV3.87

##### END OF COOLING FAN FAILURE

the software shall record this event when the COOLING FAN FAILURE alarm is cancelled

#### SFSYSTEV3.88

##### END OF AMBIENT TEMP OUTOFBOUNDS

the software shall record the event when the AMBIENT TEMP OUTOFBOUNDS alarm is  
cancelled

#### SFSYSTEV3.89

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END OF BAT TEMP OUTOFBOUNDS

the software shall record this event when the BAT TEMP OUTOFBOUNDS alarm is cancelled

SFSYSTEV3.90

END OF SUPPLY MEASURE FAILURE

the software shall record this event when the SUPPLY MEASURE FAILURE alarm is cancelled

SFSYSTEV3.91

END OF 24V FAILURE

the software shall record this event when the 24V FAILURE alarm is cancelled

SFSYSTEV3.92

END OF KEYBOARD

the software shall record this event when the KEYBOARD alarm is cancelled

SFSYSTEV3.93

OCCLUSION

the software shall record when the OCCLUSION alarm is detected

SFSYSTEV3.94

END OF OCCLUSION

the software must detect when the OCCLUSION alarm is cancelled

SFSYSTEV3.95

CPU REFERENCE

the software shall record this event when the CPU REFERENCE alarm is detected

SFSYSTEV3.96

END OF CPU REFERENCE

the software shall record this event when the CPU REFERENCE alarm is cancelled

SFSYSTEV3.97

BREATH TIME CYCLED

the software shall record this event when the BREATH TIME CYCLED default is detected

SFSYSTEV3.98

END OF BREATH TIME CYCLED

the software shall record this event when the BREATH TIME CYCLED default is canceled

SFSYSTEV3.99

CALIBRATION

the software shall record this event when a CALIBRATION failure is detected

SFSYSTEV3.100

LOOSE FLASH POINTER

the software shall record this event when a LOOSE FLASH POINTER is detected

SFSYSTEV3.101

DELETED

SFSYSTEV3.102

LOW BUZZER BATTERY

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the software shall record this event when the LOW BUZZER BATTERY alarm is detected

SFSYSTEV3.103  
DELETED

SFSYSTEV3.104  
END OF LOW BUZZER BATTERY  
the software shall record this event when the LOW BUZZER BATTERY alarm is cancelled

SFSYSTEV3.108  
END OF BUZZER BATTERY CHARGE FAILURE  
the software shall record this event when a BUZZER BATTERY CHARGE FAILURE is cancelled

SFSYSTEV3.109  
INSP FLOW FAILURE  
the software shall record this event when the INSP FLOW FAILURE alarm is detected

SFSYSTEV3.110  
BUZZER BATTERY CHARGE FAILURE  
the software shall record this event when the BUZZER BATTERY CHARGE FAILURE alarm is detected

SFSYSTEV3.111  
END OF INSP FLOW FAILURE  
the software shall record this event when the END OF INSP FLOW FAILURE alarm is detected

SFSYSTEV3.118  
CONNECT VALVE / CHANGE PRESS  
the software shall record this event when the CONNECT VALVE / CHANGE PRESS alarm is detected

SFSYSTEV3.119  
END OF CONNECT VALVE / CHANGE PRESS  
the software shall record this event when the CONNECT VALVE / CHANGE PRESS alarm is canceled

SFSYSTEV3.120  
DISCONNECT VALVE / CHANGE PI PE  
the software shall record this event when the DISCONNECT VALVE / CHANGE PI PE alarm is detected

SFSYSTEV3.121  
END OF DISCONNECT VALVE / CHANGE PI PE  
the software shall record this event when the DISCONNECT VALVE / CHANGE PI PE alarm is canceled

SFSYSTEV3.122  
CONNECT VALVE  
the software shall record this event when the CONNECT VALVE alarm is detected

SFSYSTEV3.123  
END OF CONNECT VALVE

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the software shall record this event when the CONNECT VALVE alarm is cancelled

SFSYSTEV3.124

DISCONNECT VALVE

the software shall record this event when the DISCONNECT VALVE alarm is detected

SFSYSTEV3.125

END OF DISCONNECT VALVE

the software shall record this event when the CONNECT VALVE alarm is cancelled

SFSYSTEV3.126

DELETED

SFSYSTEV3.127

DELETED

SFSYSTEV3.128

LEAKAGE

the software shall record this event when the LEAKAGE alarm is detected

SFSYSTEV3.129

END OF LEAKAGE

the software shall record this event when the LEAKAGE alarm is cancelled

SFSYSTEV3.130

LOW FiO2

the software shall record this event when the LOW FiO2 alarm is detected

SFSYSTEV3.131

END OF LOW FiO2

the software shall record this event when the LOW FiO2 alarm is cancelled

SFSYSTEV3.132

HIGH FiO2

the software shall record this event when the HIGH FiO2 alarm is detected

SFSYSTEV3.133

END OF HIGH FiO2

the software shall record this event when the HIGH FiO2 alarm is cancelled

SFSYSTEV3.134

NO FiO2 SENSOR

the software shall record this event when the NO FiO2 SENSOR alarm is detected

SFSYSTEV3.135

END OF NO FiO2 SENSOR

the software shall record this event when the NO FiO2 SENSOR alarm is cancelled

SFSYSTEV3.136

DELETED

SFSYSTEV3.137

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#### FiO2 OFFSET

the software shall record this event when the FiO2 OFFSET DEFAULT alarm is detected

#### SFSYSTEV3.138

##### FiO2 calibration

the software shall record this event when the VALIDATION KEY is SHORT PRESS on the FiO2 calibration field

#### SFSYSTEV3.139

##### TOO MANY KEYS

the software shall record this event when the TOO MANY KEYS alarm is detected

#### SFSYSTEV3.140

##### KEY DISCONNECTED

the software shall record this event when the KEY DISCONNECTED alarm is detected

#### SFSYSTEV3.141

##### TRANSFER ERROR

the software shall record this event when the TRANSFER ERROR alarm is detected

#### SFSYSTEV3.142

##### ERASE KEY ERROR

the software shall record this event when the ERASE KEY ERROR alarm is detected

#### SFSYSTEV3.143

##### DEL

#### SFSYSTEV3.144

##### DEL

#### SFSYSTEV3.145

##### KEY FULL

the software shall record this event when the KEY FULL alarm is detected

#### SFSYSTEV3.147

##### FLASH CHECKSUM POST ERROR

##### DEL

#### SFSYSTEV3.148

##### RAM CHECK SUM POST ERROR

##### DEL

#### SFSYSTEV3.149

##### VOLT REF POST ERROR

##### DEL

#### SFSYSTEV3.150

##### EEPROM POST ERROR

##### DEL

#### SFSYSTEV3.151

##### POST VERSION ERROR

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DEL

SFSYSTEV3.152

LEAK OCCLUSION

the software shall record this event when the LEAK OCCLUSION alarm is detected

SFSYSTEV3.153

END OF LEAK OCCLUSION

the software shall record this event when the LEAK OCCLUSION alarm is cancelled

SFSYSTEV3.154

CHECK FIO2

the software shall record this event when the CHECK FIO2 alarm is detected

SFSYSTEV3.155

END OF CHECK FIO2

the software shall record this event when the CHECK FIO2 alarm is cancelled

SFSYSTEV3.156

CHECK VALVE PRESSURE

the software shall record this event when the CHECK VALVE PRESSURE alarm is detected

SFSYSTEV3.157

END OF CHECK VALVE PRESSURE

the software shall record this event when the CHECK VALVE PRESSURE alarm is cancelled

SFSYSTEV3.158

CONTROLLED CYCLES

the software shall record this event when the CONTROLLED CYCLES alarm is detected

SFSYSTEV3.159

END OF CONTROLLED CYLES

the software shall record this event when the CONTROLLED CYCLES alarm is cancelled

SFSYSTEV3.160

VOLUNTARY STOP

the software shall record this event when the VOLUNTARY STOP alarm is detected

SFSYSTEV3.161

END OF VOLUNTARY STOP

the software shall record this event when the VOLUNTARY STOP alarm is cancelled

SFSYSTEV3.162

NEEDED FiO2 CALIB

the software shall record this event when the FiO2 CALIBRATION NEEDED alarm is detected

### 3.9 USB Requirements

SFSYSTUSB1

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## USB KEY

### SFSYSTUSB1.1 GENERAL

#### SFSYSTUSB1.1.1

The software shall calculate and store free space available on key in bytes when a key is detected and after every USB write operation (ERASE KEY, TRANSFER CONTINUOUSLY, TRANSFER DETAILED MONITORING, TRANSFER TRENDS) completed normally or interrupted manually and with no error. Calculation accuracy is 10 000 bytes. During this calculation, "wait" message is displayed if USB menu is active (Refers to SFSYSTAL91).

#### SFSYSTUSB1.1.5

The software shall detect FAT32 USB keys only.

#### SFSYSTUSB1.1.8

The software, when there is no running operation on key, shall detect if a second FAT 32 key is connected and then not allow any USB key operation (Refers to SFSYSTAL78).

### SFSYSTUSB1.2 ERASE KEY

#### SFSYSTUSB1.2.1

The software shall erase the whole key.

#### SFSYSTUSB1.2.2

The software shall display the erase operation duration = 1 minute. (Refers SFSYSTAL87)

### SFSYSTUSB1.4 TRANSFER CONTINUOUSLY

#### SFSYSTUSB1.4.1

The software shall create a continuous transfer file on key root directory with creation date and time.

#### SFSYSTUSB1.4.2

The software shall name the continuous transfer file as following : MTC\_serial number\_date hour minute second.mtc

#### SFSYSTUSB1.4.3

The software shall read every event in flash memory and write it in continuous transfer file when it happens.

#### SFSYSTUSB1.4.4

While ventilation is running, the software shall read detailed monitoring datas in database and write it in continuous transfer file every 40ms.

#### SFSYSTUSB1.4.5

While ventilation is running, the software shall write a date and time frame in continuous transfer file every 15min instead of a detailed monitoring frame.

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When ventilation is started, the software shall write a date and time frame in continuous transfer file instead of the first detailed monitoring frame.

When ventilation is running and a continuous transfer is started, the software shall write a date and time frame in continuous transfer file instead of the first detailed monitoring frame.

#### SFSYSTUSB1.4.6

While ventilation is running, the software shall read trends datas in database and write a trend frame in continuous transfer file every ventilatory cycle.

#### SFSYSTUSB1.4.7

The software shall write in continuous transfer file according to the following priorities : trends, monitoring then events.

#### SFSYSTUSB1.4.8

The software shall write in continuous transfer file according to SFSYSTCOMFILE2.

#### SFSYSTUSB1.4.9

The software shall calculate and display transfer time available on key which is : minimum between free space available on key and file size limit / transfer speed (free space available on key = free space available at T0 - 1048576 bytes - number of bytes transferred) (file size limit = maximum file size at T0 - number of bytes transferred) (maximum file size at T0 = 64454400 bytes) (transfer speed = number of detailed monitoring bytes per minute + number of trend bytes per minute according to ventilatory frequency). (refers to SFSYSTAL92)

#### SFSYSTUSB1.4.11

The software shall check if there is more than 1Mo of free space on key before continuous transfer. If not, writing operation is forbidden (Refers to SFSYSTAL77).

#### SFSYSTUSB1.4.12

The software shall stop continuous transfer when stop function is activated or when free space available on key becomes less than 1Mo or when file size limit reaches 0 (file size limit = maximum file size at T0 - number of bytes transferred) (maximum file size at T0 = 64454400 bytes) and shall correctly close the file.

#### SFSYSTUSB1.4.13

The software shall create an event file on key root directory with creation date and time when continuous transfer file is closed.

#### SFSYSTUSB1.4.14

The software shall name the event file as following : EVN\_serial number\_date hour minute second.evn

#### SFSYSTUSB1.4.15

The software shall read the event flash and write events in the event file according to SFSYSTCOMFILE5.

#### SFSYSTUSB1.4.16

The software shall display the transfer duration = 0 h 1 min. (Refers to SFSYSTAL86)

#### SFSYSTUSB1.4.21

The software shall stop event transfer when stop function is activated or when all events have been transmitted and shall correctly close the file.

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#### SFSYSTUSB1.4.22

The software shall create a settings file on key root directory with creation date and time when events file is closed.

#### SFSYSTUSB1.4.23

The software shall name the settings file as following : SPR\_serial number\_date hour minute second.spr

#### SFSYSTUSB1.4.24

The software shall read the settings in database and write them in the settings file according to SFSYSTCOMFILE1.

#### SFSYSTUSB1.4.26

The software shall stop settings transfer when all settings have been transmitted and shall correctly close the file.

### SFSYSTUSB1.5

#### TRANSFER DETAILED MONITORING

#### SFSYSTUSB1.5.1

The software shall create a detailed monitoring file on key root directory with creation date and time when an ask for detailed monitoring frame is received according to SFSYSTCOMFR32.

#### SFSYSTUSB1.5.2

The software shall name the detailed monitoring file as following : DTS\_serial number\_date hour minute second.dts

#### SFSYSTUSB1.5.3

The software shall write a dating (horodatage) frame at the beginning of the detailed monitoring file if ventilation is ON. The software shall read the monitoring flash and write detailed monitoring in the detailed monitoring file depending on the sent parameter received according to SFSYSTCOMFR with a 0.1% precision and according to SFSYSTCOMFILE3.

#### SFSYSTUSB1.5.5

The software shall calculate and display transfer duration which is : (number of bytes still to transfer / transfer speed) + 1min (number of bytes still to transfer = (number of hours selected \* number of bytes per hour) - number of transferred bytes) (number of bytes per hour = memorization frequency of monitoring frames per hour \* monitoring frame size) (transfer speed = 2400000 bytes / min). (Refers to SFSYSTAL86)

#### SFSYSTUSB1.5.7

The software shall check if there is more free space on key than the amount of bytes to write + 1MB (amount of bytes to write = selected duration of monitoring to transfer \* number of bytes per hour) (number of bytes per hour = memorization frequency of monitoring frames per hour \* monitoring frame size) before detailed monitoring transfer. If not, writing operation is forbidden (Refers to SFSYSTAL77).

#### SFSYSTUSB1.5.8

The software shall stop detailed monitoring transfer when stop function is activated or when all detailed monitoring have been transmitted and shall correctly close the file.

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#### SFSYSTUSB1.5.9

The software shall transfer an acknowledgement code via USB cable according to SFSYSTCOMFR33

#### SFSYSTUSB1.5.10

The software shall create an event file on key root with creation date and time when detailed monitoring file is closed if detailed monitoring transfer was not interrupted by stop function.

#### SFSYSTUSB1.5.11

The software shall name the event file as following : EVN\_serial number\_date hour minute second.evn

#### SFSYSTUSB1.5.12

The software shall read the event flash and write events in the event file according to SFSYSTCOMFILE5.

#### SFSYSTUSB1.5.13

The software shall display the transfer duration = 0 h 1 min. (Refers to SFSYSTAL86)

#### SFSYSTUSB1.5.14

The software shall stop event transfer when stop function is activated or when all events have been transmitted and shall correctly close the file.

#### SFSYSTUSB1.5.15

The software shall create a settings file on key root with creation date and time when events file is closed.

#### SFSYSTUSB1.5.16

The software shall name the settings file as following : SPR\_serial number\_date hour minute second.spr

#### SFSYSTUSB1.5.17

The software shall read the settings in database and write them in the settings file according to SFSYSTCOMFILE1.

#### SFSYSTUSB1.5.19

The software shall stop settings transfer when all settings have been transmitted and shall correctly close the file.

#### SFSYSTUSB1.6

##### TRANSFER TRENDS

#### SFSYSTUSB1.6.1

The software shall create a trend file on key root with creation date and time.

#### SFSYSTUSB1.6.2

The software shall name the trend file as following : TND\_serial number\_date hour minute second.tnd

#### SFSYSTUSB1.6.3

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The software shall read the trend flash and write trends in the trend file depending on selected duration with a 0.1% precision and according to SFSYSTCOMFILE4.

#### SFSYSTUSB1.6.13

The software shall calculate and display transfer duration which is : (number of bytes still to transfer / transfer speed) + 1min (number of bytes still to transfer = (maximum number of days in the selected number of months \* 24h \* 60min \* trend frame size) - number of transferred bytes) (transfer speed = 2400000 bytes / min). (Refers to SFSYSTAL86)

#### SFSYSTUSB1.6.14

The software shall check if there is more free space on key than the amount of bytes to write + 1MB (amount of bytes to write = maximum number of days in the selected number of months \* 24h \* 60min \* trend frame size) before continuous transfer. If not, writing operation is forbidden (Refers to SFSYSTAL77).

#### SFSYSTUSB1.6.15

The software shall stop trends transfer when stop function is activated or when all trends have been transmitted and shall correctly close the file.

#### SFSYSTUSB1.6.16

The software shall create an event file on key root with creation date and time when trends file is closed if trend transfer was not interrupted by stop function.

#### SFSYSTUSB1.6.17

The software shall name the event file as following : EVN\_serial number\_date hour minute second.evn

#### SFSYSTUSB1.6.18

The software shall read the event flash and write events in the event file according to SFSYSTCOMFILE5.

#### SFSYSTUSB1.6.19

The software shall display the transfer duration = 0 h 1 min. (Refers to SFSYSTAL86)

#### SFSYSTUSB1.6.20

The software shall stop event transfer when stop function is activated or when all events have been transmitted and shall correctly close the file.

#### SFSYSTUSB1.6.21

The software shall create a settings file on key root with creation date and time when events file is closed.

#### SFSYSTUSB1.6.22

The software shall name the settings file as following : SPR\_serial number\_date hour minute second.spr

#### SFSYSTUSB1.6.23

The software shall read the settings in database and write them in the settings file according to SFSYSTCOMFILE1.

#### SFSYSTUSB1.6.25

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The software shall stop settings transfer when all settings have been transmitted and shall correctly close the file.

## SFSYSTUSB2 USB CABLE

### SFSYSTUSB2.7 TRANSFER SERIAL NUMBER

**SFSYSTUSB2.7.1**  
The software shall read database and transfer serial number via USB cable according to SFSYSTCOMFR17 and SFSYSTCOMDP10 when an ask for serial number frame is received according to SFSYSTCOMFR1.

**SFSYSTUSB2.7.2**  
The software shall receive serial number via USB cable and write it in database according to SFSYSTCOMFR17 and SFSYSTCOMDP10 when a send serial number frame is received SFSYSTCOMFR1.

### SFSYSTUSB2.8 TRANSFER MACHINE COUNTER

**SFSYSTUSB2.8.1**  
The software shall read database and transfer machine counter via USB cable according to SFSYSTCOMFR17 and SFSYSTCOMDP325 when an ask for machine counter frame is received according to SFSYSTCOMFR1.

**SFSYSTUSB2.8.2**  
The software shall receive machine counter via USB cable and write it in database according to SFSYSTCOMFR17 and SFSYSTCOMDP325 when a send machine counter frame is received according to SFSYSTCOMFR1.

### SFSYSTUSB2.9 TRANSFER COM READY

**SFSYSTUSB2.9.1**  
The software shall transmit reception buffer state (indicates if reception buffer is ready to receive data or not) according to SFSYSTCOMFR17 and SFSYSTCOMDP329 when an ask for ready frame is received according to SFSYSTCOMFR1.

### SFSYSTUSB2.10 TRANSFER DATABASE

**SFSYSTUSB2.10.1**  
The software shall read database and transfer once database values via USB cable according to SFSYSTCOMFR29 when a database request frame is received according to SFSYSTCOMFR28.

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#### SFSYSTUSB2.10.2

The software shall receive database values via USB cable and write it in database when a database send frame is received according to SFSYSTCOMFR30.

#### SFSYSTUSB2.10.3

The software shall read database and transfer continuously database values via USB cable according to SFSYSTCOMFR29 when a full speed database request frame is received according to SFSYSTCOMFR31.

#### SFSYSTUSB2.10.4

The software shall stop database full speed transfer when a database request frame is received according to SFSYSTCOMFR28.

#### SFSYSTUSB2.11

##### TRANSFER EEPROM

#### SFSYSTUSB2.11.1

The software shall read EEPROM and transfer all EEPROM values via USB cable when an ask for EEPROM frame is received according to SFSYSTCOMFR1.

#### SFSYSTUSB2.11.2

The software shall transmit all EEPROM bytes (4kB) from the lower EEPROM address to the upper one.

### 3.10 USB Communication Interface Data Packet Requirements

#### SFSYSTCOMDP1

##### DETAILED MONITORING DATA PACKET

#### SFSYSTCOMDP1.1

##### DETAILED MONITORING DATA PACKET SIZE

Detailed monitoring data packet size is 9 bytes.

#### SFSYSTCOMDP1.2

##### DETAILED MONITORING DATA PACKET CONTENT

#### SFSYSTCOMDP1.2.1

Data packet type

Offset (byte): 0

Format: 8 bits

Data: Data type

Range: 0 = Monitoring

(1 = Dating)

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Unit: NA

#### SFSYSTCOMDP1.2.2

Ventil State

Offset (byte): 1

Format: 8 bits

Data: State

Range: 251 = Exhalation

252 = Controlled inspiration

253 = Trigger inspiration

254 = Ventilation disable

Unit: NA

#### SFSYSTCOMDP1.2.3

Inspired flow

Offset (byte): 4

5

Format: 2\*8 bits

Data: If valve detected : Inspired flow

Else : Corrected inspired flow

Range: -200 to 2000

Unit: dl/min

#### SFSYSTCOMDP1.2.4

Exhaled flow

Offset (byte): 6

7

Format: 2\*8 bits

Data: If valve detected : Exhaled flow

Else : Not used

Range: -200 to 2000

Not used = 65535

Unit: dl/min

#### SFSYSTCOMDP1.2.5

Leakage measure

Offset (byte): 8

Format: 8 bits

Data: If valve detected : Not used

Else : Leak measure

Range: 0 to 150

Not used = 255

Unit: l/min

#### SFSYSTCOMDP1.2.6

Patient pressure + 2000

Offset (byte): 2

3

Format: 2\*8 bits

Data: Pressure

Range: 1800 to 2900

Unit: 10-1 mbar

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SFSYSTCOMDP10  
SERIAL NUMBER DATA PACKET

SFSYSTCOMDP10.1  
SERIAL NUMBER DATA PACKET SIZE  
Serial number data packet size is 12 bytes.

SFSYSTCOMDP10.2  
SERIAL NUMBER DATA PACKET CONTENT

SFSYSTCOMDP10.2.1  
Serial number  
Offset (byte): 0  
Format: 12\*8 bits  
Data: Serial number  
Range: 0x34303936364B303030303030 to 0x34303936364B FFFFFFFF (ex :  
40966KXXXXXX in ASCII)  
Unit: NA

SFSYSTCOMDP14  
SETTINGS DATA PACKET

SFSYSTCOMDP14.1  
SETTINGS DATA PACKET SIZE  
Settings data packet size is 108 bytes.

SFSYSTCOMDP14.2  
SETTINGS DATA PACKET CONTENT

SFSYSTCOMDP14.2.1  
Ventilator type  
Offset (byte): 000  
Format: 8 bits  
Data: Compatibility  
Range: 0 = XL2  
1 = S2  
2 = M2  
3 = ERROR  
Unit: NA

SFSYSTCOMDP14.2.2  
Ventilation mode  
Offset (byte): 001

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Format: 8 bits  
Data: Mode  
Range: 0 = VOL A  
1 = PSVT  
2 = PRES A  
3 = VSIMV  
4 = CPAP  
5 = VOL C  
6 = PSV  
7 = PRES C  
14 = PSIMV  
Unit: NA

#### SFSYSTCOMDP14.2.3

Cycling convention  
Offset (byte): 002  
003  
Format: 16 bits  
Data: cycling mode  
Range: 0 = I/T  
1 = I :E  
Unit: NA

#### SFSYSTCOMDP14.2.55

Pressure unit  
Offset (byte): 004  
005  
Format: 16 bits  
Data: pressure unit  
Range: 0 = mbar  
1 = cmH2O  
2 = hPa  
Unit: NA

#### SFSYSTCOMDP14.2.4

Not implemented yet  
Offset (byte): 006  
007  
Format: 16 bits  
Data: low spo2  
Range: Not implemented yet  
Unit: NA

#### SFSYSTCOMDP14.2.5

Not implemented yet  
Offset (byte): 008  
009  
Format: 16 bits  
Data: spo2 low select  
Range: Not implemented yet  
Unit: NA

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SFSYSTCOMDP14.2.6  
Not implemented yet  
Offset (byte): 010  
011  
Format: 16 bits  
Data: high spo2  
Range: Not implemented yet  
Unit: NA

SFSYSTCOMDP14.2.7  
Not implemented yet  
Offset (byte): 012  
013  
Format: 16 bits  
Data: spo2 high select  
Range: Not implemented yet  
Unit: NA

SFSYSTCOMDP14.2.8  
Vt setting  
Offset (byte): 014  
015  
Format: 16 bits  
Data: vol control  
Range: 50 to 2000  
AA AA = not used  
Unit: ml

SFSYSTCOMDP14.2.9  
Pi setting  
Offset (byte): 016  
017  
Format: 16 bits  
Data: p control  
Range: 20 to 550  
AA AA = not used  
Unit: mbar/10

SFSYSTCOMDP14.2.10  
Pi setting  
Offset (byte): 018  
019  
Format: 16 bits  
Data: p support  
Range: 20 to 550  
AA AA = not used  
Unit: mbar/10

SFSYSTCOMDP14.2.11  
Pe setting  
Offset (byte): 020  
021

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Format: 16 bits  
Data: peep  
Range: 0 to 200  
Unit: mbar/10

SFSYSTCOMDP14.2.56  
Not implemented yet  
Offset (byte): 022  
023  
Format: 16 bits  
Data: Reserved  
Range: Not implemented yet  
Unit: NA

SFSYSTCOMDP14.2.12  
Pi Slope setting  
Offset (byte): 024  
025  
Format: 16 bits  
Data: rise time  
Range: 1 to 4  
AA AA = not used  
Unit: NA

SFSYSTCOMDP14.2.13  
Ramp setting  
Offset (byte): 026  
027  
Format: 16 bits  
Data: ramp  
Range: 0 = Decelerated  
1 = Rectangle  
2 = Sinus  
AA AA = not used  
Unit: NA

SFSYSTCOMDP14.2.14  
Not implemented  
Offset (byte): 028  
029  
Format: 16 bits  
Data: Not implemented  
Range: Not implemented  
  
Unit: N/A

SFSYSTCOMDP14.2.15  
Not implemented  
Offset (byte): 030  
031  
Format: 16 bits  
Data: Not implemented

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Range: Not implemented  
Unit: NA

SFSYSTCOMDP14.2.16  
Not implemented  
Offset (byte): 032  
033  
Format: 16 bits  
Data: Not implemented  
Range: 1 to 40

Unit: NA

SFSYSTCOMDP14.2.17  
Frequency setting  
Offset (byte): 034  
035  
Format: 16 bits  
Data: control r  
Range: 1 to 60  
AA AA = not used  
Unit: bpm

SFSYSTCOMDP14.2.18  
Backup frequency setting  
Offset (byte): 036  
037  
Format: 16 bits  
Data: backup r  
Range: 4 to 40  
AA AA = not used  
Unit: NA

SFSYSTCOMDP14.2.19  
Backup frequency flag  
Offset (byte): 038  
039  
Format: 16 bits  
Data: backup r no select  
Range: 0 = backup r ON  
1 = backup r OFF  
AA AA = not used  
Unit: NA

SFSYSTCOMDP14.2.20  
Apnea setting  
Offset (byte): 040  
41  
Format: 16 bits  
Data: apnea  
Range: 1000 to 60000  
AA AA = not used

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Unit: ms

SFSYSTCOMDP14.2.21

Apnea flag

Offset (byte): 042

043

Format: 16 bits

Data: auto apnea select

Range: 0 = apnea not AUTO

1 = apnea AUTO

AA AA = not used

Unit: NA

SFSYSTCOMDP14.2.22

I Trigger setting

Offset (byte): 044

045

Format: 16 bits

Data: insp sens

Range: 0 to 6

AA AA = not used

Unit: NA

SFSYSTCOMDP14.2.23

I Trigger flag

Offset (byte): 046

047

Format: 16 bits

Data: insp sens no select

Range: 0 = insp sens ON

1 = insp sens OFF

Unit: NA

SFSYSTCOMDP14.2.24

E Trigger setting

Offset (byte): 048

049

Format: 16 bits

Data: exh sens

Range: 5 to 95

AA AA = not used

Unit: %

SFSYSTCOMDP14.2.25

E Trigger flag

Offset (byte): 050

051

Format: 16 bits

Data: auto exh sens select

Range: 0 = exh sens not AUTO

1 = exh sens AUTO

AA AA = not used

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Unit: NA

SFSYSTCOMDP14.2.26

Vt Target setting

Offset (byte): 052

053

Format: 16 bits

Data: target vt

Range: 50 to 2000

AA AA = not used

Unit: ml

SFSYSTCOMDP14.2.27

Vt Target flag

Offset (byte): 054

055

Format: 16 bits

Data: target vt select

Range: 0 = target vt OFF

1 = target vt ON

AA AA = not used

Unit: NA

SFSYSTCOMDP14.2.28

Pi max setting

Offset (byte): 056

057

Format: 16 bits

Data: max pressure

Range: 80 to 550

AA AA = not used

Unit: mbar/10

SFSYSTCOMDP14.2.29

Vti mini setting

Offset (byte): 058

059

Format: 16 bits

Data: low vti

Range: 30 to 2000

AA AA = not used

Unit: ml

SFSYSTCOMDP14.2.30

Vti mini flag

Offset (byte): 060

061

Format: 16 bits

Data: low vti no select

Range: 0 = low vti ON

1 = low vti OFF

AA AA = not used

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Unit: NA

SFSYSTCOMDP14.2.31

Vti maxi setting  
Offset (byte): 062  
063  
Format: 16 bits  
Data: high vti  
Range: 80 to 3000  
AA AA = not used  
Unit: ml

SFSYSTCOMDP14.2.32

Vti maxi flag  
Offset (byte): 064  
065  
Format: 16 bits  
Data: high vti no select  
Range: 0 = high vti ON  
1 = high vti OFF  
AA AA = not used  
Unit: NA

SFSYSTCOMDP14.2.33

Vte mini setting  
Offset (byte): 066  
067  
Format: 16 bits  
Data: low vte  
Range: 30 to 2000  
AA AA = not used  
Unit: ml

SFSYSTCOMDP14.2.34

Vte mini flag  
Offset (byte): 068  
069  
Format: 16 bits  
Data: low vte no select  
Range: 0 = low vte ON  
1 = low vte OFF  
AA AA = not used  
Unit: NA

SFSYSTCOMDP14.2.35

Vte maxi setting  
Offset (byte): 070  
071  
Format: 16 bits  
Data: high vte  
Range: 80 to 3000  
AA AA = not used

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Unit: ml

#### SFSYSTCOMDP14.2.36

Vte maxi flag

Offset (byte): 072

073

Format: 16 bits

Data: high vte no select

Range: 0 = high vte ON

1 = high vte OFF

AA AA = not used

Unit: NA

#### SFSYSTCOMDP14.2.37

P high setting

Offset (byte): 074

075

Format: 16 bits

Data: high pip

Range: 15 to 60

AA AA = not used

Unit: mbar

#### SFSYSTCOMDP14.2.38

P low setting

Offset (byte): 076

077

Format: 16 bits

Data: low pip

Range: 2 to 35

AA AA = not used

Unit: mbar

#### SFSYSTCOMDP14.2.39

Fr maxi setting

Offset (byte): 078

079

Format: 16 bits

Data: high r

Range: 10 to 120

Unit: bpm

#### SFSYSTCOMDP14.2.40

Fr maxi flag

Offset (byte): 080

081

Format: 16 bits

Data: high r no select

Range: 0 = high r ON

1 = high r OFF

Unit: NA

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#### SFSYSTCOMDP14.2.41

Leakage maxi setting

Offset (byte): 082

083

Format: 16 bits

Data: high leak

Range: 5 to 150

AA AA = not used

Unit: lpm

#### SFSYSTCOMDP14.2.42

Leakage maxi flag

Offset (byte): 084

085

Format: 16 bits

Data: high leak select

Range: 0 = high leak OFF

1 = high leak ON

AA AA = not used

Unit: NA

#### SFSYSTCOMDP14.2.43

Ti mini setting

Offset (byte): 086

087

Format: 16 bits

Data: ti min

Range: 100 to 2800

AA AA = not used

Unit: ms

#### SFSYSTCOMDP14.2.44

Ti mini flag

Offset (byte): 088

089

Format: 16 bits

Data: ti min auto select

Range: 0 = ti min not AUTO

1 = ti min AUTO

AA AA = not used

Unit: NA

#### SFSYSTCOMDP14.2.45

Ti maxi setting

Offset (byte): 090

091

Format: 16 bits

Data: ti max

Range: 800 to 3000

AA AA = not used

Unit: ms

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#### SFSYSTCOMDP14.2.46

Ti maxi flag

Offset (byte): 092

093

Format: 16 bits

Data: ti max auto select

Range: 0 = ti max not AUTO

1 = ti max AUTO

AA AA = not used

Unit: NA

#### SFSYSTCOMDP14.2.47

Disconnection alarm tempo setting

Offset (byte): 094

095

Format: 16 bits

Data: disconnection delay

Range: 3000 to 30000

Unit: ms

#### SFSYSTCOMDP14.2.48

Disconnection alarm tempo flag

Offset (byte): 096

097

Format: 16 bits

Data: disconnection delay auto

Range: 0 = disconnection delay not AUTO

1 = disconnection delay AUTO

Unit: NA

#### SFSYSTCOMDP14.2.49

Sigh setting

Offset (byte): 098

099

Format: 16 bits

Data: sigh select

Range: 0 = sigh OFF

1 = sigh ON

AA AA = not used

Unit: NA

#### SFSYSTCOMDP14.2.50

Vt Sigh setting

Offset (byte): 100

101

Format: 16 bits

Data: sigh vt coef

Range: 1.0 to 2.0

AA AA = not used

Unit: NA

#### SFSYSTCOMDP14.2.51

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Cpt Sigh setting  
Offset (byte): 102  
103  
Format: 16 bits  
Data: sigh cpt  
Range: 50 to 250  
AA AA = not used  
Unit: NA

SFSYSTCOMDP14.2.52  
Apnea alarm activation  
Offset (byte): 104  
105  
Format: 16 bits  
Data: apnea alarm activation  
Range: 0 = apnea alarm OFF  
1 = apnea alarm ON  
Unit: NA

SFSYSTCOMDP14.2.53  
Pediatric circuit in use  
Offset (byte): 106  
107  
Format: 16 bits  
Data: pediatric circuit  
Range: 0 = pediatric circuit OFF  
1 = pediatric circuit ON  
Unit: NA

SFSYSTCOMDP14.2.54  
Absolute or relative pressure  
Offset (byte): 108  
109  
Format: 16 bits  
Data: pressure support relative  
Range: 0 = absolute pressure  
1 = relative pressure  
Unit: NA

SFSYSTCOMDP72  
DATING DETAILED MONITORING DATA PACKET

SFSYSTCOMDP72.10  
DATING DETAILED MONITORING DATA PACKET SIZE  
Dating detailed monitoring data packet size is 9 bytes.

SFSYSTCOMDP72.11

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## DATING DETAILED MONITORING DATA PACKET CONTENT

### SFSYSTCOMDP72.11.1

Data packet type

Offset (byte): 0

Format: 8 bits

Data: Data type

Range: (0 = Monitoring)

1 = Dating

Unit: NA

### SFSYSTCOMDP72.11.2

Day

Offset (byte): 1

Format: 8 bits

Data: Day

Range: 1 to 31

Unit: d

### SFSYSTCOMDP72.11.3

Month

Offset (byte): 2

Format: 8 bits

Data: Month

Range: 1 to 12

Unit: m

### SFSYSTCOMDP72.11.4

Hour

Offset (byte): 4

Format: 8 bits

Data: Hour

Range: 0 to 23

Unit: h

### SFSYSTCOMDP72.11.5

Minute

Offset (byte): 5

Format: 8 bits

Data: Minute

Range: 0 to 59

Unit: mn

### SFSYSTCOMDP72.11.6

Second

Offset (byte): 6

Format: 8 bits

Data: Second

Range: 0 to 59

Unit: s

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SFSYSTCOMDP72.11.7

NA

Offset (byte): 7

Format: 8 bits

Data: If first ventilation start after device power up : 0x00

Else : 0x55

Range: NA

Unit: NA

SFSYSTCOMDP72.11.8

NA

Offset (byte): 8

Format: 8 bits

Data: If first ventilation start after device power up : 0x00

Else : 0x55

Range: NA

Unit: NA

SFSYSTCOMDP72.11.9

Year - 2000

Offset (byte): 3

Format: 8 bits

Data: Year

Range: 4 to 99

Unit: y

SFSYSTCOMDP93

EVENT DATA PACKET

SFSYSTCOMDP93.1

EVENT DATA PACKET SIZE

Event data packet size is 96 bytes.

SFSYSTCOMDP93.2

EVENT DATA PACKET COMMON PART CONTENT

SFSYSTCOMDP93.2.1

Event number

Offset (byte): 00

Format: 8 bits

Data: Event N°

Range: 1 to 256

Unit: NA

SFSYSTCOMDP93.2.2

Day

Offset (byte): 01

Format: 8 bits

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Data: Day  
Range: 1 to 31  
Unit: d

SFSYSTCOMDP93.2.3  
Month  
Offset (byte): 02  
Format: 8 bits  
Data: Month  
Range: 1 to 12  
Unit: m

SFSYSTCOMDP93.2.4  
Hour  
Offset (byte): 04  
Format: 8 bits  
Data: Hour  
Range: 0 to 23  
Unit: h

SFSYSTCOMDP93.2.5  
Minute  
Offset (byte): 05  
Format: 8 bits  
Data: Minute  
Range: 0 to 59  
Unit: mn

SFSYSTCOMDP93.2.6  
Second  
Offset (byte): 06  
Format: 8 bits  
Data: Second  
Range: 0 to 59  
Unit: s

SFSYSTCOMDP93.2.7  
Machine hour  
Offset (byte): 07  
08  
Format: 2\*8 bits  
Data: Machine Hour  
Range: 0 to 65536  
Unit: h

SFSYSTCOMDP93.2.8  
Ventilation mode  
Offset (byte): 09  
Format: 8 bits  
Data: Mode  
Range: 0 = COM\_VOL\_A  
1 = COM\_PSVT

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2 = COM\_PRES\_A  
 3 = COM\_VSIMV  
 4 = COM\_CPAP  
 5 = COM\_VOL\_C  
 6 = COM\_PSV  
 7 = COM\_PRES\_C  
 14 = COM\_PSIMV  
 Unit: NA

#### SFSYSTCOMDP93.2.9

Ventilation type  
 Offset (byte): 10  
 Format: 8 bits  
 Data: Type  
 Range: 0 = Leak, 1 = Valve  
 Unit: NA

#### SFSYSTCOMDP93.2.10

Exhalation trigger convention  
 Offset (byte): 11  
 Format: 8 bits  
 Data: Trig E Conv  
 Range: 0 = negative , 1 = positive  
 Unit: NA

#### SFSYSTCOMDP93.2.11

Pressure unit setting  
 Offset (byte): 12  
 Format: 8 bits  
 Data: P unit conv  
 Range: 0 = mbar , 1 = cmH2O , 2 = hPa  
 Unit: NA

#### SFSYSTCOMDP93.2.12

Schema version/Cycling convention  
 Offset (byte): 13  
 Format: 8 bits

Schema Version (upper 4 bits)	Cycling Convention (lower 4 bits)
----------------------------------	--------------------------------------

Data: Version/Cycling

Range:  
 Version:  
 0-15  
 Version = 0 (previous schema without version information)  
 Version = 1 current  
 Cycling:  
 0 = I/T  
 1 = I :E

Unit: NA

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SFSYSTCOMDP93.2.13  
Measure battery buzzer voltage  
Offset (byte): 16  
17  
Format: 2\*8 bits  
Data: Battery buzzer voltage  
Range: 0 to 999  
Unit: 10-1 V

SFSYSTCOMDP93.2.14  
Measure V Watchdog  
Offset (byte): 18  
19  
Format: 2\*8 bits  
Data: Watchdog  
Range: 0 to 999  
Unit: 10-1 V

SFSYSTCOMDP93.2.15  
Measure T°  
Offset (byte): 20  
21  
Format: 2\*8 bits  
Data: T° interne  
Range: 0 to 999  
Unit: 10-1 °C

SFSYSTCOMDP93.2.16  
Measure V Battery  
Offset (byte): 22  
23  
Format: 2\*8 bits  
Data: Battery Volt  
Range: 0 to 999  
Unit: 10-1 V

SFSYSTCOMDP93.2.17  
Measure T° Battery  
Offset (byte): 24  
25  
Format: 2\*8 bits  
Data: T° battery  
Range: 0 to 999  
Unit: 10-1 °C

SFSYSTCOMDP93.2.18  
Battery capacity  
Offset (byte): 26  
27  
Format: 2\*8 bits  
Data: Battery Capa  
Range: 0 to 5000

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Unit: ma/h

SFSYSTCOMDP93.2.19  
Battery remaining time gauge  
Offset (byte): 28  
29  
Format: 2\*8 bits  
Data: Gauge minute  
Range: 0 to 1440  
Unit: min

SFSYSTCOMDP93.2.20  
Fc measure  
Offset (byte): 32  
Format: 8 bits  
Data: FC  
Range: 18 to 300  
Unit: bpm

SFSYSTCOMDP93.2.21  
Pmax measure  
Offset (byte): 33  
34  
Format: 2\*8 bits  
Data: Pmax  
Range: 0 to 999  
Unit: 10-1 mbar

SFSYSTCOMDP93.2.22  
Pep measure  
Offset (byte): 35  
36  
Format: 2\*8 bits  
Data: Pep  
Range: 0 to 999  
Unit: 10-1 mbar

SFSYSTCOMDP93.2.23  
Not implemented  
Offset (byte): 37  
Format: 8 bits  
Data: Not implemented  
Range: Not implemented  
Unit: N/A

SFSYSTCOMDP93.2.24  
Not implemented  
Offset (byte): 38  
Format: 8 bits  
Data: Not implemented  
Range: Not implemented  
Unit: NA

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SFSYSTCOMDP93.2.25  
Not implemented  
Offset (byte): 39  
Format: 8 bits  
Data: Not implemented  
Range: Not implemented  
Unit: NA

SFSYSTCOMDP93.2.26  
Frequency measure  
Offset (byte): 40  
Format: 8 bits  
Data: Frequency  
Range: 0 to 99  
Unit: c/min

SFSYSTCOMDP93.2.27  
Vti measure  
Offset (byte): 41  
42  
Format: 2\*8 bits  
Data: Vti  
Range: 0 to 9999  
Unit: ml

SFSYSTCOMDP93.2.28  
Vte measure  
Offset (byte): 43  
44  
Format: 2\*8 bits  
Data: Vte  
Range: 0 to 9999  
Unit: ml

SFSYSTCOMDP93.2.29  
Vm measure  
Offset (byte): 45  
46  
Format: 2\*8 bits  
Data: Vm  
Range: 0 to 999  
Unit: 10-1 l/min

SFSYSTCOMDP93.2.30  
Leakage measure  
Offset (byte): 47  
Format: 8 bits  
Data: Leakage  
Range: 0 to 150  
Unit: l/min

SFSYSTCOMDP93.2.31  
Ti measure

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Offset (byte): 48  
49  
Format: 2\*8 bits  
Data: Ti  
Range: 0 to 9999  
Unit: ms

SFSYSTCOMDP93.2.32  
Te measure  
Offset (byte): 50  
51  
Format: 2\*8 bits  
Data: Te  
Range: 0 to 9999  
Unit: ms

SFSYSTCOMDP93.2.33  
Alimentation type  
Offset (byte): 52  
Format: 8 bits  
Data: Alimentation  
Range: AC=0,  
DC =1,  
BATTERY= 2,  
BAT\_DEFAULT=3  
Unit: NA

SFSYSTCOMDP93.2.34  
Battery level  
Offset (byte): 53  
Format: 8 bits  
Data: Battery  
Range: 0 to 256  
Unit: %

SFSYSTCOMDP93.2.35  
Circuit type  
Offset (byte): 57  
Format: 8 bits  
Data: Pediatric circuit  
Range: 0 = ADULT  
1 = PEDIATRIC  
Unit: NA

SFSYSTCOMDP93.2.36  
Pressure convention  
Offset (byte): 54  
Format: 8 bits  
Data: Absolute pressure  
Range: 0 = RELATIVE  
1 = ABSOLUTE  
Unit: NA

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SFSYSTCOMDP93.2.37  
FiO2 measure  
Offset (byte): 30  
Format: 8 bits  
Data: FIO2  
Range: 0 = NO, 0 to 100  
Unit: %

SFSYSTCOMDP93.2.38  
SpO2 measure  
Offset (byte): 31  
Format: 8 bits  
Data: SpO2  
Range: 0 = NO, 0 to 100  
Unit: %

SFSYSTCOMDP93.2.39  
FIO2 setting  
Offset (byte): 62  
Format: 8 bits  
Data: FIO2  
Range: 0 to 99  
Unit: %

SFSYSTCOMDP93.2.40  
FiO2 min setting  
Offset (byte): 63  
Format: 8 bits  
Data: FiO2 mini  
Range: 0 to 99  
Unit: %

SFSYSTCOMDP93.2.41  
FiO2 max setting  
Offset (byte): 64  
Format: 8 bits  
Data: FiO2 maxi  
Range: 0 to 99  
Unit: %

SFSYSTCOMDP93.2.42  
Year - 2000  
Offset (byte): 03  
Format: 8 bits  
Data: Year  
Range: 4 to 99  
Unit: y

SFSYSTCOMDP93.2.43  
Measure 24V  
Offset (byte): 14

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15

Format: 2\*8 bits

Data: Alim 24V

Range: 0 to 999

Unit: 10-1 V

#### SFSYSTCOMDP93.2.44

Voluntary stop alarm activation.

Offset (byte): 60

Format: 8 bits

Data: Voluntary stop alarm activation setting

Range: OFF=0, YES=1

Unit: %

#### SFSYSTCOMDP93.2.45

Barometric compensation

Offset (byte): 55

Format: 8 bits

Data: Barometric compensation flag

Range: OFF=0, YES=1

Unit: NA

#### SFSYSTCOMDP93.2.46

Sound level

Offset (byte): 56

Format: 8 bits

Data: Sound level value

Range: 20 to 100

Unit: %

#### SFSYSTCOMDP93.2.47

High SPO2 alarm.

Offset (byte): 61

Format: 8 bits

Data: SpO2 maxi setting

Range: 90 to 100

Unit: %

#### SFSYSTCOMDP93.2.48

Disconnection delay

Offset (byte): 58

Format: 8 bits

Data: Disconnection delay

Range: 5 to 62

Unit: s

#### SFSYSTCOMDP93.2.49

Apnea alarm activation

Offset (byte): 59

Format: 8 bits

Data: Apnea alarm activation flag

Range: OFF=0, YES=1

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Unit: NA

SFSYSTCOMDP93.3  
EVENT DATA PACKET FOR PSV MODE CONTENT

SFSYSTCOMDP93.3.1

Pi setting  
Offset (byte): 65  
Format: 8 bits  
Data: P Support  
Range: 4 to 60  
Unit: mbar

SFSYSTCOMDP93.3.2

Reserved  
Offset (byte): 66  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.3.3

Pe setting  
Offset (byte): 67  
Format: 8 bits  
Data: Pe  
Range: 0 to 20  
Unit: mbar

SFSYSTCOMDP93.3.4

Pi Slope setting  
Offset (byte): 68  
Format: 8 bits  
Data: Pi Slope  
Range: 1 to 4  
Unit: NA

SFSYSTCOMDP93.3.5

Reserved  
Offset (byte): 69  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.3.6

E Trigger setting  
Offset (byte): 70  
Format: 8 bits  
Data: E Trigger

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Range: 5 to 95  
Unit: %

SFSYSTCOMDP93.3.7

Reserved  
Offset (byte): 71  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.3.8

Frequency setting  
Offset (byte): 72  
Format: 8 bits  
Data: Frequency  
Range: 0 to 60  
Unit: c/min

SFSYSTCOMDP93.3.9

I Trigger setting  
Offset (byte): 73  
Format: 8 bits  
Data: I Trigger  
Range: 0 to 6  
Unit: NA

SFSYSTCOMDP93.3.10

Apnea setting  
Offset (byte): 74  
Format: 8 bits  
Data: Apnea  
Range: 3 to 30  
Unit: s

SFSYSTCOMDP93.3.11

Vt Target setting  
Offset (byte): 75  
76  
Format: 2\*8 bits  
Data: Vt Target  
Range: 0 to 2000  
Unit: ml

SFSYSTCOMDP93.3.12

Pi maxi setting  
Offset (byte): 77  
Format: 8 bits  
Data: Pi maxi  
Range: 0 to 60  
Unit: mbar

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SFSYSTCOMDP93.3.13

Vti mini setting  
Offset (byte): 78  
79  
Format: 2\*8 bits  
Data: Vti mini  
Range: 30 to 1800  
Unit: ml

SFSYSTCOMDP93.3.14

Vti maxi setting  
Offset (byte): 80  
81  
Format: 2\*8 bits  
Data: Vti maxi  
Range: 80 to 3000  
Unit: ml

SFSYSTCOMDP93.3.15

Vte mini setting  
Offset (byte): 82  
83  
Format: 2\*8 bits  
Data: Vte mini  
Range: 30 to 1800  
Unit: ml

SFSYSTCOMDP93.3.16

Vte maxi setting  
Offset (byte): 84  
85  
Format: 2\*8 bits  
Data: Vte maxi  
Range: 80 to 3000  
Unit: ml

SFSYSTCOMDP93.3.17

Fr maxi setting  
Offset (byte): 86  
Format: 8 bits  
Data: Fr maxi  
Range: 10 to 120  
Unit: c/min

SFSYSTCOMDP93.3.18

Leak maxi setting  
Offset (byte): 87  
Format: 8 bits  
Data: Leak maxi  
Range: 0 to 150  
Unit: l/min

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SFSYSTCOMDP93.3.19

Ti mini setting  
Offset (byte): 88  
Format: 8 bits  
Data: Ti mini  
Range: 1 to 28  
Unit: 10-1 s

SFSYSTCOMDP93.3.20

Ti maxi setting  
Offset (byte): 89  
Format: 8 bits  
Data: Ti maxi  
Range: 8 to 30  
Unit: 10-1 s

SFSYSTCOMDP93.3.21

Reserved  
Offset (byte): 90  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.3.22

Reserved  
Offset (byte): 91  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.3.23

Reserved  
Offset (byte): 92  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.3.24

P atm measure  
Offset (byte): 93  
94  
Format: 2\*8 bits  
Data: P atm  
Range: 0 to 1000  
Unit: mmHg

SFSYSTCOMDP93.3.25

Reserved  
Offset (byte): 95

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Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

#### SFSYSTCOMDP93.4 EVENT DATA PACKET FOR PRES MODE CONTENT

SFSYSTCOMDP93.4.1  
Pi setting  
Offset (byte): 65  
Format: 8 bits  
Data: Pi  
Range: 4 to 60  
Unit: mbar

SFSYSTCOMDP93.4.2  
Reserved  
Offset (byte): 66  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.4.3  
Pe setting  
Offset (byte): 67  
Format: 8 bits  
Data: Pe  
Range: 0 to 20  
Unit: mbar

SFSYSTCOMDP93.4.4  
Pi Slope setting  
Offset (byte): 68  
Format: 8 bits  
Data: Pi Slope  
Range: 1 to 4  
Unit: NA

SFSYSTCOMDP93.4.5  
Not implemented  
Offset (byte): 69  
Format: 8 bits  
Data: Not implemented  
Range: Not implemented  
Unit: N/A

SFSYSTCOMDP93.4.6  
Not implemented

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Offset (byte): 70  
Format: 8 bits  
Data: Not implemented  
Range: Not implemented  
Unit: NA

SFSYSTCOMDP93.4.7  
Not implemented r  
Offset (byte): 71  
Format: 8 bits  
Data: Not implemented  
Range: Not implemented  
Unit: NA

SFSYSTCOMDP93.4.8  
Frequency setting  
Offset (byte): 72  
Format: 8 bits  
Data: Frequency  
Range: 0 to 60  
Unit: c/min

SFSYSTCOMDP93.4.9  
I Trigger setting  
Offset (byte): 73  
Format: 8 bits  
Data: I Trigger  
Range: 0 to 6  
Unit: NA

SFSYSTCOMDP93.4.10  
Reserved  
Offset (byte): 74  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.4.11  
Vt Target setting  
Offset (byte): 75  
76  
Format: 2\*8 bits  
Data: Vt Target  
Range: 0 to 2000  
Unit: ml

SFSYSTCOMDP93.4.12  
Pi maxi setting  
Offset (byte): 77  
Format: 8 bits  
Data: Pi maxi

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Range: 0 to 60  
Unit: mbar

#### SFSYSTCOMDP93.4.13

Vti mini setting  
Offset (byte): 78  
79  
Format: 2\*8 bits  
Data: Vti mini  
Range: 30 to 1800  
Unit: ml

#### SFSYSTCOMDP93.4.14

Vti maxi setting  
Offset (byte): 80  
81  
Format: 2\*8 bits  
Data: Vti maxi  
Range: 80 to 3000  
Unit: ml

#### SFSYSTCOMDP93.4.15

Vte mini setting  
Offset (byte): 82  
83  
Format: 2\*8 bits  
Data: Vte mini  
Range: 30 to 1800  
Unit: ml

#### SFSYSTCOMDP93.4.16

Vte maxi setting  
Offset (byte): 84  
85  
Format: 2\*8 bits  
Data: Vte maxi  
Range: 80 to 3000  
Unit: ml

#### SFSYSTCOMDP93.4.17

Fr maxi setting  
Offset (byte): 86  
Format: 8 bits  
Data: Fr maxi  
Range: 10 to 120  
Unit: c/min

#### SFSYSTCOMDP93.4.18

Leak maxi setting  
Offset (byte): 87  
Format: 8 bits  
Data: Leak maxi

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Range: 0 to 150  
Unit: l/min

SFSYSTCOMDP93.4.19  
Inspiration Time  
Offset (byte): 88  
Format: 8 bits  
Data: Inspiration Time  
Range: 3 to 60  
Unit: s/10

SFSYSTCOMDP93.4.20  
Reserved  
Offset (byte): 89  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.4.21  
Reserved  
Offset (byte): 90  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.4.22  
Reserved  
Offset (byte): 91  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.4.23  
Reserved  
Offset (byte): 92  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.4.24  
P atm measure  
Offset (byte): 93  
94  
Format: 2\*8 bits  
Data: P atm  
Range: 0 to 1000  
Unit: mmHg

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#### SFSYSTCOMDP93.4.25

Reserved  
Offset (byte): 95  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

#### SFSYSTCOMDP93.5

##### EVENT DATA PACKET FOR VOL MODE CONTENT

#### SFSYSTCOMDP93.5.1

Vt setting  
Offset (byte): 65  
66  
Format: 2\*8 bits  
Data: Vt  
Range: 50 to 2000  
Unit: ml

#### SFSYSTCOMDP93.5.2

Pe setting  
Offset (byte): 67  
Format: 8 bits  
Data: Pe  
Range: 0 to 20  
Unit: mbar

#### SFSYSTCOMDP93.5.3

Ramp setting  
Offset (byte): 68  
Format: 8 bits  
Data: Ramp  
Range: 0 = D , 1 = R  
Unit: NA

#### SFSYSTCOMDP93.5.4

Reserved  
Offset (byte): 69  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: N/A

#### SFSYSTCOMDP93.5.5

Reserved  
Offset (byte): 70  
Format: 8 bits  
Data: Reserved  
Range: 0

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Unit: NA

SFSYSTCOMDP93.5.6

Reserved

Offset (byte): 71

Format: 8 bits

Data: Reserved

Range: 0

Unit: NA

SFSYSTCOMDP93.5.7

Frequency setting

Offset (byte): 72

Format: 8 bits

Data: Frequency

Range: 5 to 60

Unit: c/min

SFSYSTCOMDP93.5.8

I Trigger setting

Offset (byte): 73

Format: 8 bits

Data: I Trigger

Range: 0 to 6

Unit: NA

SFSYSTCOMDP93.5.9

Reserved

Offset (byte): 74

Format: 8 bits

Data: Reserved

Range: 0

Unit: NA

SFSYSTCOMDP93.5.10

Reserved

Offset (byte): 75

Format: 8 bits

Data: Reserved

Range: 0

Unit: NA

SFSYSTCOMDP93.5.11

Reserved

Offset (byte): 76

Format: 8 bits

Data: Reserved

Range: 0

Unit: NA

SFSYSTCOMDP93.5.12

Reserved

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Offset (byte): 77  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.5.13  
P low setting  
Offset (byte): 78  
Format: 8 bits  
Data: P low  
Range: 2 to 35  
Unit: mbar

SFSYSTCOMDP93.5.14  
Reserved  
Offset (byte): 79  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.5.15  
P high setting  
Offset (byte): 80  
Format: 8 bits  
Data: P high  
Range: 15 to 60  
Unit: mbar

SFSYSTCOMDP93.5.16  
Reserved  
Offset (byte): 81  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.5.17  
Vte mini setting  
Offset (byte): 82  
83  
Format: 2\*8 bits  
Data: Vte mini  
Range: 30 to 1800  
Unit: ml

SFSYSTCOMDP93.5.18  
Vte maxi setting  
Offset (byte): 84  
85  
Format: 2\*8 bits

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Data: Vte maxi  
Range: 80 to 3000  
Unit: ml

SFSYSTCOMDP93.5.19  
Fr maxi setting  
Offset (byte): 86  
Format: 8 bits  
Data: Fr maxi  
Range: 10 to 120  
Unit: c/min

SFSYSTCOMDP93.5.20  
Reserved  
Offset (byte): 87  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.5.21  
Inspiration Time  
Offset (byte): 88  
Format: 8 bits  
Data: Inspiration time  
Range: 3 to 60  
Unit: s/10

SFSYSTCOMDP93.5.22  
Reserved  
Offset (byte): 89  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.5.23  
Sigh setting  
Offset (byte): 90  
Format: 8 bits  
Data: Sigh  
Range: 0 or 1  
Unit: NA

SFSYSTCOMDP93.5.24  
Cpt Sigh setting  
Offset (byte): 91  
Format: 8 bits  
Data: Cpt Sigh  
Range: 50 to 250 0 = not used  
Unit: NA

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SFSYSTCOMDP93.5.25  
Vt Sigh setting  
Offset (byte): 92  
Format: 8 bits  
Data: Vt Sigh  
Range: 1.0 to 2.0 0 = not used  
Unit: NA

SFSYSTCOMDP93.5.26  
P atm measure  
Offset (byte): 93  
94  
Format: 2\*8 bits  
Data: P atm  
Range: 0 to 1000  
Unit: mmHg

SFSYSTCOMDP93.5.27  
Reserved  
Offset (byte): 95  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

## SFSYSTCOMDP93.6 EVENT DATA PACKET FOR VSIMV MODE CONTENT

SFSYSTCOMDP93.6.1  
Vt setting  
Offset (byte): 65  
66  
Format: 2\*8 bits  
Data: Vt  
Range: 50 to 2000  
Unit: ml

SFSYSTCOMDP93.6.2  
Pe setting  
Offset (byte): 67  
Format: 8 bits  
Data: Pe  
Range: 0 to 20  
Unit: mbar

SFSYSTCOMDP93.6.3  
Rise time  
Offset (byte): 68  
Format: 8 bits  
Data: Rise time

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Range: 1 to 4  
Unit: NA

SFSYSTCOMDP93.6.4

Inspiration time  
Offset (byte): 69  
Format: 8 bits  
Data: Inspiration time  
Range: 3 to 60  
Unit: s/10

SFSYSTCOMDP93.6.5

Exhalation trigger  
Offset (byte): 70  
Format: 8 bits  
Data: Exhalation trigger setting  
Range: 5 to 95  
Unit: %

SFSYSTCOMDP93.6.6

Reserved  
Offset (byte): 71  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.6.7

Frequency setting  
Offset (byte): 72  
Format: 8 bits  
Data: Frequency  
Range: 5 to 60  
Unit: c/min

SFSYSTCOMDP93.6.8

I Trigger setting  
Offset (byte): 73  
Format: 8 bits  
Data: I Trigger  
Range: 0 to 6  
Unit: NA

SFSYSTCOMDP93.6.9

Apnea setting  
Offset (byte): 74  
Format: 8 bits  
Data: Apnea  
Range: 3 to 30  
Unit: s

SFSYSTCOMDP93.6.10

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Pi setting  
Offset (byte): 75  
Format: 8 bits  
Data: P Support  
Range: 4 to 60  
Unit: mbar

SFSYSTCOMDP93.6.11  
Reserved  
Offset (byte): 76  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.6.12  
Reserved  
Offset (byte): 77  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.6.13  
P low setting  
Offset (byte): 78  
Format: 8 bits  
Data: P low  
Range: 2 to 35  
Unit: mbar

SFSYSTCOMDP93.6.14  
Reserved  
Offset (byte): 79  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.6.15  
P high setting  
Offset (byte): 80  
Format: 8 bits  
Data: P high  
Range: 15 to 60  
Unit: mbar

SFSYSTCOMDP93.6.16  
Reserved  
Offset (byte): 81  
Format: 8 bits  
Data: Reserved

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Range: 0  
Unit: NA

SFSYSTCOMDP93.6.17  
Vte mini setting  
Offset (byte): 82  
83  
Format: 2\*8 bits  
Data: Vte mini  
Range: 30 to 1800  
Unit: ml

SFSYSTCOMDP93.6.18  
Vte maxi setting  
Offset (byte): 84  
85  
Format: 2\*8 bits  
Data: Vte maxi  
Range: 80 to 3000  
Unit: ml

SFSYSTCOMDP93.6.19  
Fr maxi setting  
Offset (byte): 86  
Format: 8 bits  
Data: Fr maxi  
Range: 10 to 120  
Unit: c/min

SFSYSTCOMDP93.6.20  
Reserved  
Offset (byte): 87  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.6.21  
Reserved  
Offset (byte): 88  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.6.22  
Reserved  
Offset (byte): 89  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

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SFSYSTCOMDP93.6.23

Reserved  
Offset (byte): 90  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.6.24

Reserved  
Offset (byte): 91  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.6.25

Reserved  
Offset (byte): 92  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.6.26

P atm measure  
Offset (byte): 93  
94  
Format: 2\*8 bits  
Data: P atm  
Range: 0 to 1000  
Unit: mmHg

SFSYSTCOMDP93.6.27

Reserved  
Offset (byte): 95  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.7

EVENT DATA PACKET FOR PSIMV MODE CONTENT

SFSYSTCOMDP93.7.1

Pi setting  
Offset (byte): 65  
Format: 8 bits  
Data: Pi

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Range: 4 to 60  
Unit: mbar

#### SFSYSTCOMDP93.7.2

Reserved  
Offset (byte): 66  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

#### SFSYSTCOMDP93.7.3

Pe setting  
Offset (byte): 67  
Format: 8 bits  
Data: Pe  
Range: 0 to 20  
Unit: mbar

#### SFSYSTCOMDP93.7.4

Inspiration time  
Offset (byte): 69  
Format: 8 bits  
Data: Inspiration time  
Range: 3 to 60  
Unit: s/10

#### SFSYSTCOMDP93.7.5

Exhalation trigger  
Offset (byte): 70  
Format: 8 bits  
Data: Exhalation trigger setting  
Range: 5 to 95  
Unit: %

#### SFSYSTCOMDP93.7.6

Rise time  
Offset (byte): 68  
Format: 8 bits  
Data: Rise time  
Range: 1 to 4  
Unit: NA

#### SFSYSTCOMDP93.7.7

Reserved  
Offset (byte): 71  
Format: 8 bits  
Data: Reserved  
Range: 1 to 40  
Unit: NA

#### SFSYSTCOMDP93.7.8

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Frequency setting  
Offset (byte): 72  
Format: 8 bits  
Data: Frequency  
Range: 5 to 60  
Unit: NA

SFSYSTCOMDP93.7.9  
I Trigger setting  
Offset (byte): 73  
Format: 8 bits  
Data: I Trigger  
Range: 0 to 6  
Unit: NA

SFSYSTCOMDP93.7.10  
Apnea setting  
Offset (byte): 74  
Format: 8 bits  
Data: Apnea  
Range: 3 to 30  
Unit: s

SFSYSTCOMDP93.7.11  
Pi setting  
Offset (byte): 75  
Format: 8 bits  
Data: P Support  
Range: 4 to 60  
Unit: mbar

SFSYSTCOMDP93.7.12  
Reserved  
Offset (byte): 76  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.7.13  
Reserved  
Offset (byte): 77  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.7.14  
Vti mini setting  
Offset (byte): 78  
79  
Format: 2\*8 bits

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Data: Vti mini  
Range: 30 to 1800  
Unit: ml

SFSYSTCOMDP93.7.15

Vti maxi setting  
Offset (byte): 80  
81  
Format: 2\*8 bits  
Data: Vti maxi  
Range: 80 to 3000  
Unit: ml

SFSYSTCOMDP93.7.16

Vte mini setting  
Offset (byte): 82  
83  
Format: 2\*8 bits  
Data: Vte mini  
Range: 30 to 1800  
Unit: ml

SFSYSTCOMDP93.7.17

Vte maxi setting  
Offset (byte): 84  
85  
Format: 2\*8 bits  
Data: Vte maxi  
Range: 80 to 3000  
Unit: ml

SFSYSTCOMDP93.7.18

Fr maxi setting  
Offset (byte): 86  
Format: 8 bits  
Data: Fr maxi  
Range: 10 to 120  
Unit: c/min

SFSYSTCOMDP93.7.19

Reserved  
Offset (byte): 87  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.7.20

Reserved  
Offset (byte): 88  
Format: 8 bits  
Data: Reserved

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Range: 0  
Unit: NA

SFSYSTCOMDP93.7.21

Reserved  
Offset (byte): 89  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.7.22

Reserved  
Offset (byte): 90  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.7.23

Reserved  
Offset (byte): 91  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.7.24

Reserved  
Offset (byte): 92  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.7.25

P atm measure  
Offset (byte): 93  
94  
Format: 2\*8 bits  
Data: P atm  
Range: 0 to 1000  
Unit: mmHg

SFSYSTCOMDP93.7.26

Reserved  
Offset (byte): 95  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

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SFSYSTCOMDP93.8  
EVENT DATA PACKET FOR CPAP MODE CONTENT

SFSYSTCOMDP93.8.1

Reserved  
Offset (byte): 65  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.2

Reserved  
Offset (byte): 66  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.3

Pe setting  
Offset (byte): 67  
Format: 8 bits  
Data: Pe  
Range: 0 to 20  
Unit: mbar

SFSYSTCOMDP93.8.4

Reserved  
Offset (byte): 68  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.5

Reserved  
Offset (byte): 69  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.6

Reserved  
Offset (byte): 70  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

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SFSYSTCOMDP93.8.7

Reserved  
Offset (byte): 71  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.8

Reserved  
Offset (byte): 72  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.9

Reserved  
Offset (byte): 73  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.10

Apnea setting  
Offset (byte): 74  
Format: 8 bits  
Data: Apnea  
Range: 3 to 30 0 = not used  
Unit: s

SFSYSTCOMDP93.8.11

Reserved  
Offset (byte): 75  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.12

Reserved  
Offset (byte): 76  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.13

Reserved  
Offset (byte): 77

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Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.14  
Vti mini setting  
Offset (byte): 78  
79  
Format: 2\*8 bits  
Data: Vti mini  
Range: 30 to 1800  
Unit: ml

SFSYSTCOMDP93.8.15  
Vti maxi setting  
Offset (byte): 80  
81  
Format: 2\*8 bits  
Data: Vti maxi  
Range: 80 to 3000  
Unit: ml

SFSYSTCOMDP93.8.16  
Reserved  
Offset (byte): 82  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.17  
Reserved  
Offset (byte): 83  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.18  
Reserved  
Offset (byte): 84  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.19  
Reserved  
Offset (byte): 85  
Format: 8 bits  
Data: Reserved

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Range: 0  
Unit: NA

SFSYSTCOMDP93.8.20  
Fr maxi setting  
Offset (byte): 86  
Format: 8 bits  
Data: Fr maxi  
Range: 10 to 120  
Unit: c/min

SFSYSTCOMDP93.8.21  
Leak maxi setting  
Offset (byte): 87  
Format: 8 bits  
Data: Leak maxi  
Range: 0 to 150  
Unit: l/min

SFSYSTCOMDP93.8.22  
Reserved  
Offset (byte): 88  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.23  
Reserved  
Offset (byte): 89  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.24  
Reserved  
Offset (byte): 90  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.25  
Reserved  
Offset (byte): 91  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.26

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Reserved  
Offset (byte): 92  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP93.8.27  
P atm measure  
Offset (byte): 93  
94  
Format: 2\*8 bits  
Data: P atm  
Range: 0 to 1000  
Unit: mmHg

SFSYSTCOMDP93.8.28  
Reserved  
Offset (byte): 95  
Format: 8 bits  
Data: Reserved  
Range: 0  
Unit: NA

SFSYSTCOMDP303  
TREND DATA PACKET

SFSYSTCOMDP303.1  
TREND DATA PACKET SIZE  
Trend data packet size is 25 bytes.

SFSYSTCOMDP303.2  
TREND DATA PACKET CONTENT

SFSYSTCOMDP303.2.1  
Day  
Offset (byte): 00  
Format: 8 bits  
Data: Day  
Range: 1 to 31  
Unit: d

SFSYSTCOMDP303.2.2  
Month  
Offset (byte): 01  
Format: 8 bits  
Data: Month  
Range: 1 to 12

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Unit: m

#### SFSYSTCOMDP303.2.3

Hour

Offset (byte): 03

Format: 8 bits

Data: Hour

Range: 0 to 23

Unit: h

#### SFSYSTCOMDP303.2.4

Minute

Offset (byte): 04

Format: 8 bits

Data: Minute

Range: 0 to 59

Unit: mn

#### SFSYSTCOMDP303.2.5

Second

Offset (byte): 05

Format: 8 bits

Data: Second

Range: 0 to 59

Unit: s

#### SFSYSTCOMDP303.2.6

Ventilation mode

Offset (byte): 06

Format: 8 bits

Data: Mode

Range: 0 = COM\_VOL\_A

1 = COM\_PSVT

2 = COM\_PRES\_A

3 = COM\_VSIMV

4 = COM\_CPAP

5 = COM\_VOL\_C

6 = COM\_PSV

7 = COM\_PRES\_C

14 = COM\_PSIMV

Unit: NA

#### SFSYSTCOMDP303.2.7

Ventil State

Offset (byte): 07

Format: 8 bits

Data: State

Range: 251 = Exhalation

252 = Controlled inspiration

253 = Trigger inspiration

254 = Ventilation disable

Unit: NA

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SFSYSTCOMDP303.2.8  
Pmax measure  
Offset (byte): 08  
09  
Format: 2\*8 bits  
Data: Pmax  
Range: 0 to 999 modulo 256  
Unit: 10-1 mbar

SFSYSTCOMDP303.2.9  
PeeP measure  
Offset (byte): 10  
11  
Format: 2\*8 bits  
Data: PeeP  
Range: 0 to 999 modulo 256  
Unit: 10-1 mbar

SFSYSTCOMDP303.2.10  
Leakage measure  
Offset (byte): 12  
13  
Format: 2\*8 bits  
Data: Leakage  
Range: 0 to 9999  
Unit: 10-1 l/min

SFSYSTCOMDP303.2.11  
Vm measure  
Offset (byte): 14  
15  
Format: 2\*8 bits  
Data: Vm  
Range: 0 to 999  
Unit: 10-1 l/min

SFSYSTCOMDP303.2.12  
E ratio setting numerator  
Offset (byte): 16  
Format: 8 bits  
Data: I:E numerator  
Range: 1 to 40  
Unit: NA

SFSYSTCOMDP303.2.13  
E ratio setting denominator  
Offset (byte): 17  
Format: 8 bits  
Data: I:E denominator  
Range: 1 to 40  
Unit: NA

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SFSYSTCOMDP303.2.14

Frequency measure

Offset (byte): 18

Format: 8 bits

Data: Frequency

Range: 0 to 99

Unit: bpm

SFSYSTCOMDP303.2.15

Vti measure

Offset (byte): 19

20

Format: 2\*8 bits

Data: Vti

Range: 0 to 9999

Unit: ml

SFSYSTCOMDP303.2.16

Vte measure

Offset (byte): 21

22

Format: 2\*8 bits

Data: Vte

Range: 0 to 9999

Unit: ml

SFSYSTCOMDP303.2.17

Fc measure

Offset (byte): 23

Format: 8 bits

Data: Fc

Range: 18 to 300

Unit: bpm

SFSYSTCOMDP303.2.18

SpO2 measure

Offset (byte): 24

Format: 8 bits

Data: SpO2

Range: 0 to 100

Unit: %

SFSYSTCOMDP303.2.19

Year - 2000

Offset (byte): 02

Format: 8 bits

Data: Year

Range: 4 to 99

Unit: y

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SFSYSTCOMDP325  
MACHINE COUNTER DATA PACKET

SFSYSTCOMDP325.1  
MACHINE COUNTER DATA PACKET SIZE  
Machine counter packet size is 2 bytes.

SFSYSTCOMDP325.2  
MACHINE COUNTER PACKET CONTENT

SFSYSTCOMDP325.2.1  
Machine counter  
Offset (byte): 0  
Format: 2\*8 bits  
Data: Machine counter  
Range: 0 to 65535  
Unit: h

SFSYSTCOMDP329  
COM READY DATA PACKET

SFSYSTCOMDP329.1  
COM READY DATA PACKET SIZE  
Com ready packet size is 1 byte.

SFSYSTCOMDP329.2  
COM READY PACKET CONTENT

SFSYSTCOMDP329.2.1  
Com ready flag  
Offset (byte): 0  
Format: 8 bits  
Data: Com ready flag  
Range: 0 = FALSE  
1 = TRUE  
Unit: NA

### 3.11 USB Communication Interface File Format Requirements

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#### SFSYSTCOMFILE1

##### SETTINGS FILE FORMAT

Settings data shall be recorded in a "SPR\_Settings.spr" file.

Settings file shall have the following format :

- Serial Number (12 bytes).

- Date and Hour (5 bytes).

- Setting data packet (108 bytes) (Refers to SFSYSTCOMDP14).

- CCITT CRC (2 bytes) (CRC computed on all data excepted the 2 last bytes).

#### SFSYSTCOMFILE2

##### CONTINUOUS TRANSFER FILE FORMAT

Continuous transfer data shall be recorded in a "MTC\_serial number\_date hour minute second.mtc" file.

Continuous transfer file shall have the following format :

- Serial Number (12 bytes).

- x data packet defined as follows :

  - Message ID (1 byte) ( 01 = Monitoring, 02 = Trend, 03 = Event).

  - Data packet (each packet with a size depending on ID value) (Refers to SFSYSTCOMDP1, SFSYSTCOMDP72, SFSYSTCOMDP93 and SFSYSTCOMDP303).

#### SFSYSTCOMFILE3

##### DETAILED MONITORING FILE FORMAT

Detailed monitoring data shall be recorded in a "DTS\_serial number\_date hour minute second.dtc" file.

Detailed monitoring binary file shall have the following format :

- Serial Number (12 bytes).

- x data packet (9 bytes) (Refers to SFSYSTCOMDP1 and SFSYSTCOMDP72).

#### SFSYSTCOMFILE4

##### TREND FILE FORMAT

Trend data shall be recorded in a "TND\_serial number\_date hour minute second.tnd" file.

Trend file shall have the following format :

- Serial Number (12 bytes).

- x data packet (25 bytes) (Refers to SFSYSTCOMDP303).

#### SFSYSTCOMFILE5

##### EVENT FILE FORMAT

Event data shall be recorded in a "EVN\_serial number\_date hour minute second.evn" file.

Event file shall have the following format :

- Serial Number (12 bytes).

- x data packet (96 bytes) (Refers to SFSYSTCOMDP93).

- CCITT CRC (2 bytes) (CRC computed on all data excepted the 2 last bytes).

### 3.12 USB Communication Interface Frame Format Requirements

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SFSYSTCOMFR1  
REQUEST FRAME

SFSYSTCOMFR1.1  
REQUEST FRAME STRUCTURE

Data request frame shall have the following format :

STX : Start sequence (0x02, 0x05, 0x07) (3 bytes).

ID : Request ID from request ID list (1 byte).

ETX : End sequence (0x07, 0x05, 0x02) (3 bytes).

SFSYSTCOMFR1.2  
REQUEST ID LIST

SFSYSTCOMFR1.2.7  
Send serial number  
ID: 0X50

SFSYSTCOMFR1.2.8  
Send machine counter  
ID: 0X51

SFSYSTCOMFR1.2.10  
Ask for ready  
ID: 0X97

SFSYSTCOMFR1.2.11  
Ask for machine counter  
ID: 0X98

SFSYSTCOMFR1.2.12  
Ask for serial number  
ID: 0X99

SFSYSTCOMFR1.2.13  
Ask for EEPROM  
ID: 0XEE

SFSYSTCOMFR17  
ANSWER FRAME

SFSYSTCOMFR17.1  
ANSWER FRAME STRUCTURE

Answer frame shall have the following format :

STX : Start sequence (0x02, 0x05, 0x07) (3 bytes).

ID : Answer ID from answer ID list (1 byte).

(Size) : Data frame Size (1 byte) (Only available for Trend & Detailed Monitoring).

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Data : Answer data packet (0x00 in case of end of transmission frame).  
CRC : CCITT CRC (2 bytes) (CRC computed on data (and Size)).  
ETX : End sequence (0x07, 0x05, 0x02) (3 bytes).

SFSYSTCOMFR17.2  
ANSWER ID LIST

SFSYSTCOMFR17.2.1  
Ventilator serial number  
ID: 0X01

SFSYSTCOMFR17.2.2  
Machine hour  
ID: 0X08

SFSYSTCOMFR17.2.7  
End of transmission  
ID: 0X07

SFSYSTCOMFR17.2.8  
Com ready  
ID: 0X09

SFSYSTCOMFR28  
DATABASE REQUEST FRAME  
Database request frame shall have the following format :  
STX : Start sequence (0x02, 0x05, 0x07) (3 bytes).  
0xBA : Request ID (1 byte).  
Nb arg : Number of data to transmit (1 byte).  
Base Id : Base ID (1 byte).  
Data Id : Data ID (1 byte).  
... : Repeat Base Id and Data Id as many times as Nb arg.  
ETX : End sequence (0x07, 0x05, 0x02) (3 bytes).

SFSYSTCOMFR29  
DATABASE ANSWER FRAME  
Database answer frame shall have the following format :  
STX : Start sequence (0x02, 0x05, 0x07) (3 bytes).  
0xBB : Answer ID (1 byte).  
Data : Answer data (2 bytes).  
... : Repeat Data as many times as Nb arg.  
CRC : XOR CRC (1 byte) (CRC computed on all data except CRC and ETX).  
ETX : End sequence (0x07, 0x05, 0x02) (3 bytes).

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### SFSYSTCOMFR30

#### DATABASE SEND FRAME

Database send frame shall have the following format :

- STX : Start sequence (0x02, 0x05, 0x07) (3 bytes).
- 0xBC : Send ID (1 byte).
- Base Id : Base ID (1 byte).
- Data Id : Data ID (1 byte).
- Data : Sent data (2 bytes).
- CRC : XOR CRC (1 byte) (CRC computed on all data except CRC and ETX).
- ETX : End sequence (0x07, 0x05, 0x02) (3 bytes).

### SFSYSTCOMFR31

#### FULL SPEED DATABASE REQUEST FRAME

Database request frame shall have the following format :

- STX : Start sequence (0x02, 0x05, 0x07) (3 bytes).
- 0xBF : Request ID (1 byte).
- Nb arg : Number of data to transmit (1 byte).
- Base Id : Base ID (1 byte).
- Data Id : Data ID (1 byte).
- ... : Repeat Base Id and Data Id as many times as Nb arg.
- ETX : End sequence (0x07, 0x05, 0x02) (3 bytes).

### SFSYSTCOMFR32

#### USB MONITORINGS TRANSFER REQUEST FRAME

USB monitorings transfer request frame shall have the following format :

- STX : Start sequence (0x02, 0x05, 0x07) (3 bytes).
- 0x42 : Request ID (1 byte).
- Amount of monitoring : amount of monitoring to transfer (0 -> no transfer; 1 -> 4h; 2 -> 8h ... 5 -> 20; 6 -> 24h; 7 -> 36h; 8 -> 48h) (1 byte).
- ETX : End sequence (0x07, 0x05, 0x02) (3 bytes).

### SFSYSTCOMFR33

#### USB MONITORINGS TRANSFER ANSWER FRAME

USB monitoring transfer answer frame shall have the following format :

- STX : Start sequence (0x02, 0x05, 0x07) (3 bytes).
- 0x06 : Answer ID (1 byte).
- Error code : answer error code (0x00 -> COM\_MONIT\_TO\_KEY\_TRANSFER\_START\_OK  
0x01 ->  
COM\_MONIT\_TO\_KEY\_TRANSFER\_ERROR\_NO\_KEY  
0x02 ->  
COM\_MONIT\_TO\_KEY\_TRANSFER\_ERROR\_TOO\_MANY\_KEYS  
0x03 ->  
COM\_MONIT\_TO\_KEY\_TRANSFER\_ERROR\_FLASH\_BUSY  
0x04 ->  
COM\_MONIT\_TO\_KEY\_TRANSFER\_NOT\_IN\_USB\_MENU) (1 bytes).
- CRC : CCITT CRC (2 bytes) (CRC computed on answer error code).

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ETX : End sequence (0x07, 0x05, 0x02) (3 bytes).

## 4 Supplementary Requirements

### SSOFT3

#### Program size

The executable software size must be less than 800 Ko

### SSOFT9

#### Timing1

The software sampling, control and security functions must be timed with a 20 ms maximum period.

### SSOFT10

#### Timing2

The software HMI functions must be timed with a 40 ms maximum period.

### SSOFT11

#### RAMemory

The software must use less than 512 Kb of RAM

### SSOFT12

#### watchdog function

the software must be protected from a 200 ms software task overflow (watchdog function).

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