REVISION	
REV	DESCRIPTION
AB	RELEASE/CHANGE PER EC124632

CPU Software Requirements Specification
PB560

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ANY CHANGES TO THIS DOCUMENT MUST BE COORDINATED WITH THE AUTHOR AND DONE ONLY IN REQUISITE PRO.

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1 REVISION HISTORY

Revision	Author	Change Description
A	[redacted]	Initial Release
B	[redacted]	Corrections and USB functions additions.
C	[redacted]	Corrections
D	[redacted]	Corrections: Default for Exh sens change to 75%, update of the translation file
E	[redacted]	Exhalation valve control update
F	[redacted]	Trigger specification update
G	[redacted]	CDP-RMS-0000156 software update changes, including high pressure alarm.
H	[redacted]	Revised to include updated GUI strings.
J	[redacted]	CDP-RMS-0000420 software update changes, including Circuit Check, RR = 1, Inspiratory Time, 0P Trigger and ESENS.
K	[redacted]	Revised to address SCR126 and SCR148.
L	[redacted]	Revised to support complaince to IEC 60601-8:2006.
M	[redacted]	Revised due to SCR 139 and 177
N	[redacted]	Revised due to SCR 189 & SCR 201. Added a setup 2 menu and an alarm tone setting. Modified FIO2 ranges.
P	[redacted]	Added Restore Defaults setting.
R	[redacted]	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	[redacted]	As per CDP-0006093, corrected Monitored Insp. Time and Monitored Exh. Time Ranges. Update Table of Contents page numbers.
U	[redacted]	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

		Updated AC power disconnect and DC disconnect alarm to only display an alarm message. SCR 220
V	[redacted]	Updated the AC power disconnect alarm's cancel conditions to remove both the informational and medium priority alarm. SCR 220
W	[redacted]	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	[redacted]	SCR 247 - Update End of Battery and Low Battery requirements to check if the battery is installed or not.
AA	[redacted]	SCR 258 - Update End of Battery and Low Battery requirements to add additional alarm conditions to eliminate multiple alarm declarations
AB	[redacted]	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

% 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.

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.

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)

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.

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 xxxxxxx 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

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.
OCCLUSION : 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.

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 LUXXXXX 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.

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.

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 SWHICHED 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.

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 trigged
- 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 SWHICHED 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.

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 messaged 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

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.

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_COMMA
ND_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

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

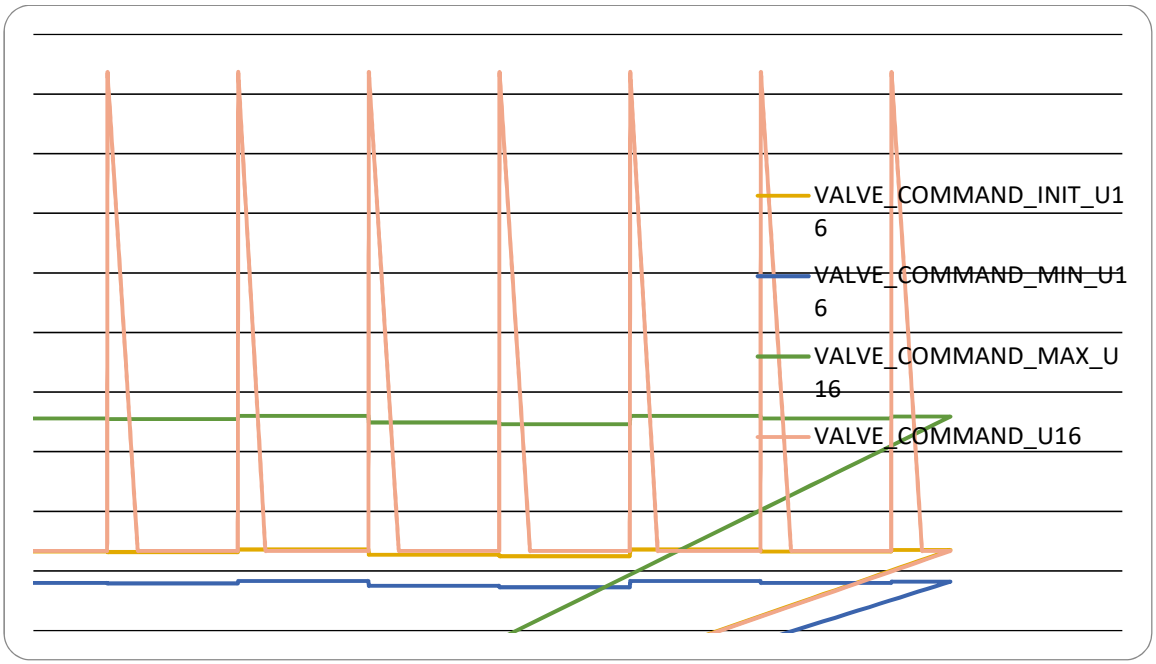
Pressure slope corrections:
The VALVE_COMMAND_COEFF must be used to apply a correction factor to the breath to breath valve command steps with the following formula: VALVE_COMMAND_COEFF = (PWM_PRESSURE SLOPE / REFERENCE_PWM PRESSURE_SLOPE)*1000.

Exhalation valve pressure calibration

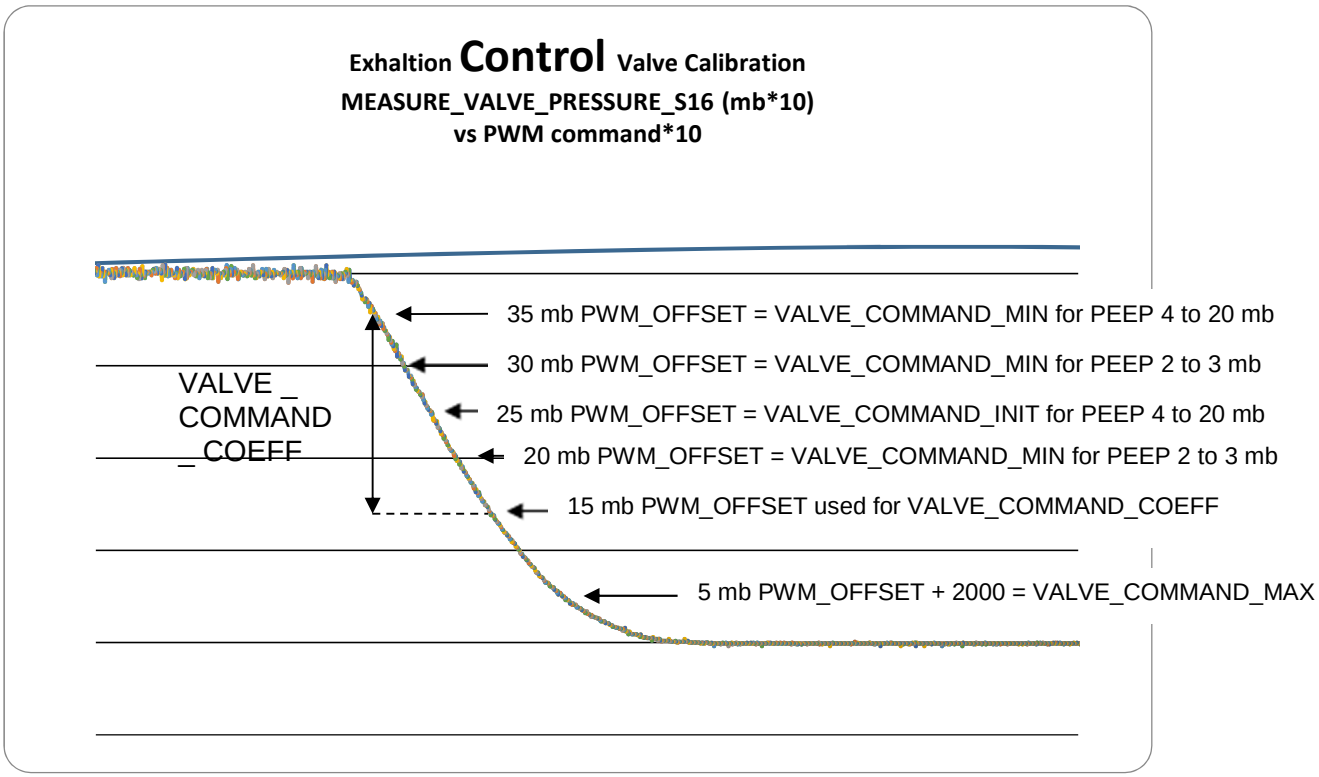
The valve pressure calibration will control the blower at 40 mb on the INTERNAL PRESSURE sensor and decrease the exhalation valve command from PWM 2672 to 0 with steps of 1 and memorize the PWM commands at 5 mb, 10 mb, 15 mb, 20 mb, 25 mb, 30 mb and 35 mb. The calibration will collect I_REF at PWM 0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



Example of exhalation valve pressure calibration curve



SFSYST4.7

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) (cmH20): 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 substract 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

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 TI = 0 to MIN FLOW SET POINT at TI = TICONTROL

SFSYST6.4
if the VTI measurement is between VOL CONTROL +/-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 >20mL or [300%;50%] of THEORETICAL FLOW SET POINT if THEORETICAL FLOW SET POINT <20mL.

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 = VOL CONTROL / TI CONTROL/1000*60 + 4

SFSYST6.9
For D RAMP: THEORETICAL MAX FLOW SET POINT = 3/2*(VOL CONTROL / TI CONTROL/1000*60) + 4 (+/-10%)

SFSYST6.10
For D RAMP: THEORETICAL MIN FLOW SET POINT = (1/2)*(VOL CONTROL / TI CONTROL/1000*60) + 4 (+/-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 TI / 2 to MIN FLOW SET POINT at 0 and TI.

SFSYST6.12
If a sigh is set to YES, at each CPT SIGH cycles, the software must control the flow during a computed TI x VT SIGH

SFSYST6.13

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

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 then 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*Ti 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 form 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

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.

SFSYST10.16
a VIM must be delivered after the end of the PS breath exhalation (2*Ti 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 form 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 cmH2O less than or equal to 29 cmH2O and INSPIRATORY PRESSURE SET POINT + 10 cmH2O greater than or equal to 30 cmH2O but limited to 90 cmH2O. 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 PMAX setting.

SFSYST13
INTERNAL PRESSURE to PROXIMAL PRESSURE switch
The software must detect a PROXIMAL PRESSURE loss if the following conditions are gathered:

((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 cmH2Oduring 400ms.
And
PROXIMAL PRESSURE = PATIENT PRESSURE +/- Delta Pressure cmH2Oduring 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*Qinsp2 + 0.0853*Qinsp + 1;
For adult circuits:
Delta Pressure = 0.0004*Qinsp2 + 0.0373*Qinsp + 1;
Minimum value limitation:
Delta Pressure = 4cmH2O (at least)
Maximum value limitation for pressure cycles:
Dela 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 si 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 >= 2 and all the rest stays the same.

When the ventilator is in a non-leak configuration mode with a detection of a leak and PEEP >= 4 cmH20, the delta pressure condition shall be replaced by PROXIMAL PRESSURE >= 2.

When the ventilator is in a non-leak configuration mode with a detection of a leak and PEEP < 4 cmH20, the delta pressure condition shall be replaced by PEEP >= PIP or PIP <= 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 <= 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)

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.

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 (bpm) = 60 / (TI + TE)

SFSYST18.6
If EXHALATION VALVE is detected, then VTI (ml) = TI x S[QI (dl/min)] / 60 during inspiration
Else VTI (ml) = TI x S[Qcorrected (dl/min)] / 60; with Qcorrected = QI - (LEAK FACTOR x sqrt Patient Pressure) during inspiration
In valve mode QI is set to 0 if Patient pressure < Peep measured + 2 mb and Ti_measured < 200ms to avoid leakage error in the Vti compute.

SFSYST18.7
VTE (ml) = S[QE (dl/min) – EQI (dl/min) / 60 during exhalation
VTE (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 (tidal volume for current breath - VTE(n-1)) > 5 + 0.15 * VTE(n-1)

SFSYST18.8
VM (lpm) = VTI (ml) x R (bpm) / 1000

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

SFSYST18.13
LEAK = Mean value of QI over EXHALATION STEADY PHASE - sqrt(monitored PEEP) x Sqrt4mmLeakFactor
Sqrt4mmLeakFactor = 29 (Leak factor equivalent to a 4mm diameter leak)

SFSYST18.15
FiO2 = FiO2 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

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.

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)

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

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 alarmsdefined 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

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

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 FiO2 > 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 = Qleak^2 / PEEP at the end of the exhalation for each breath.
Qleak = 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

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 <= 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 <= [INSPIRATORY PRESSURE SET POINT - 20%] In PSV, CPAP,PRES A/C, PRES SIMV modes.
or
When PROXIMAL PRESSURE <= LOW PIP) In VOL A/C and VOL SIMV mode.)
and
HIGH PRESSURE ALARM < 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 <= 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 >= 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)

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 cmH2O less than or equal to29 cmH2O and INSPIRATORY PRESSURE SET POINT + 10 cmH2O greater than or equal to 30 cmH2O limited to 90 cmH2O. 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
Resetconditions: ventilation change; Ventilation std-by
Replaceventifpersistmessage: No
Circuit: all

SFSYSTAL3
APNEA

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

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

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

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
Replaceventifpersistmessage: 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)

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
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: No
Circuit: all

SFSYSTAL19
CHECK BUZZER

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)

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 DECTECTION 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

Circuit: all

SFSYSTAL25
CHECK PROXIMAL LINE (PROX DISCONNECTION)
Detection Conditions: If (PROXI DETECTED = FALSE
And
Counter cycle >=4th CYCLE) then
switch PROX DISCONNECTION from FALSE to DETECTED status.

if (CHECK PROXIMAL alarm to FALSE status.
And
DECTECTION 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 >= 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>20mL)
OR (VALVE CURRENT > 50.0 mA) OR (VALVE CURRENT < 40.0 mA) OR
((VEN_FLEAK_MEASURED < VEN_TARGET_FLOW*0.8) AND (INSP_FLOW_MEASURED < -
15 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

Validation Delay: 6 consecutive cycles after saturation of auto adaptative 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: sum(IQE) > 0.7 x sum(QI) during inspiration
and VTI>40mL.
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: ALARM_REMOTE_STATE != 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

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

SFSYSTAL37
SPEED FAULT (n°6)
Detection Conditions: SPEED SET POINT - 20 % < SPEED < 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

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

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

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
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: 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

Actions: Replace the offset failed by the default one +
Event CALIBRATION FAILURE
Resetconditions: N/A
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: Yes
Circuit: all

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

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.

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

Modes: VOL A/C; VOL SIMV
Actions: Event INSPRATORY FLOW FAILURE + END OF INSPIRATORY 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

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
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: No
Circuit: all

SFSYSTAL65
CHECK VALVE PRESSURE

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

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

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

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.

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
Replaceventifpersistmessage: 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
Replaceventifpersistmessage: 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

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: (Vti < =20 ml and INSPIRATORY FLOW > 60 lpm)
or
FILTERED PATIENT PRESSURE <= (INSPIRATORY PRESSURE SET POINT - 20%)
Validation Delay: Max [Disconnection time, 60/R-Rate] PC
Max [Disconnection time, Apnea Time + 2 sec] CPAP, PSV

Cancel Conditions: INSPIRATION FLOW <= 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

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

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>20mL
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.

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

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.

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

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

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

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

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 5cmH2O or 5lpm.

SFSYSTHMI9.3.2

during the first screen which follow the starting of the ventilator, the software displays the maximum pressure scale = 100 cmH2O

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.

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 Qcorrected = f(t) during inspiration and QE-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.

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

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 Pi+PEEP = XX mbar/cmH2O/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

- 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

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:
VtI, 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)

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

- 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:

a. Leak - 0.0 in units of Lpm
b. Test Status - NOT RUN
c. 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:

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

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

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

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

CONTRAST
Unit: N.A.
Min Value: 0
Max Value: 100
List of Values: N.A.
Step: 0
Default Value: 50
Links: N.A.
Auto-adjustement: 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-adjustement: 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-adjustement: 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-adjustement: N.A.
Comments: No comment

SFSYSTSET1.17
ALTITUDE COMP.
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: 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.

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

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

LOW VTE <= VOL CONTROL - 10
HIGH VTE >= VOL CONTROL + 10
Vol control x Vt sigh <= 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

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

Sigh = YES thenCONTROL R >= 4Auto-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: 0FF (=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)
0FF (=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

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 <= HIGH PIP – 8
LOW PIP >= 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 <= HIGH PIP – 8
PEEP + 10 <= 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 <= 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 <= 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

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

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 lpm <= (VOL CONTROL x 60) /(TI CONTROL*1000) <= 100 lpm in R RAMP
3 lpm <= 3*(VOL CONTROL x 60) / 2*(TI CONTROL*1000) <= 100 lpm in D RAMP and S RAMP
TI CONTROL <= (0.5*60 / CONTROL R)
Comments: I:E <= 1:1

SFSYSTSET3
PRES CONTROL settings

SFSYSTSET3.1
P CONTROL
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: IIn 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 Pres
Comments: No comment

SFSYSTSET3.2
CONTROL R
Unit: bpm
Min Value: 1
Max Value: 60
List of Values: N.A.
Step: 1

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: 0FF (=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

Default Value: 2
Links: N.A.
Auto-adjustement: 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 <= HIGH VTI - 20
Low Vti <= Vt target - 10
Auto-adjustement: 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 >= LOW VTI + 20
High Vti >= Vt target + 10
Auto-adjustement: 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 <= HIGH VTE - 20
Low vte <= Vt target - 10
Auto-adjustement: 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

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-adjustement: 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-adjustement: 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-adjustement: 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

Default Value: Pcontrol + 3
Links: Pcontrol <= MaxPres <= Pcontrol +20 in relative and absolute pressure mode

MaxPres + PEEP <= 55 in relative pressure
Auto-adjustement: 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-adjustement: 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

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.

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 <= (60*1/2)/BACK UP R
BACK UP R <= HIGH R - 5
30/BackupR <= 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 <= 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.

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 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-adjustement: 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-adjustement: 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-adjustement: N.A.
Comments: OFF is available by the DOWN KEY

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 >= LOW VTI + 20
High Vti >= 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 <= HIGH VTE - 20
Low Vte <= 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 <= 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

Links: LOW VTE <= HIGH VTE - 20
High Vte >= Vt target + 10
Auto-adjustement: 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-adjustement: 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-adjustement: 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-adjustement: N.A.
Comments: available only if no valve is detected
OFF is available upside
OFF = 200 output value = 200

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 lpm <= (VOL CONTROL*60) / (TI CONTROL*1000) <= 100 lpm
LOW VTE <= VOL CONTROL - 10
VOL CONTROL <= 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 lpm <= (VOL CONTROL*60) / (TI CONTROL*1000) <= 100 lpm
APNEA TIME >= 2 * TI CONTROL
if CONTROL R >= 8 :
TI CONTROL <= 0.33 * 60 / CONTROL R
if CONTROL R < 8 :
TI CONTROL <= 2.4
Auto-adjustement: APNEA TIME
Comments: Step is 0.1

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

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 >= 2 * TI 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.

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

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

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

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

Default Value: Auto = 12
Links: APNEA TIME >= 2 * TI CONTROL
Auto-adjustement: 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-adjustement: 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-adjustement: 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-adjustement: 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-adjustement: N.A.
Comments: loop setting

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-adjustement: 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 <= HIGH VTI - 20
Auto-adjustement: 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 >= LOW VTI + 20
Auto-adjustement: 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 <= HIGH VTE - 20
Auto-adjustement: N.A.
Comments: OFF is available by the DOWN KEY

SFSYSTSET6.17

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-adjustement: 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-adjustement: 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-adjustement: 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-adjustement: N.A.
Comments: No comment

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.

Auto-adjustement: 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-adjustement: 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-adjustement: 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-adjustement: 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.

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-adjustement: 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-adjustement: N.A.

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-adjustement: 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

- 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

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.

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.

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:

- 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

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

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

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

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

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

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

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

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

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

the software shall record this event when a new Rise Time is set

SFSYSTEV2.4
Back-up R
the software shall record this event when a new Back-up R is set

SFSYSTEV2.5
Apnea Time
the software shall record this event when a new Apnea Time is set

SFSYSTEV2.6
Insp Sens
the software shall record this event when a new Insp Sens is set

SFSYSTEV2.7
Exh Sens
the software shall record this event when a new Exh Sens is set

SFSYSTEV2.8
Ti min
the software shall record this event when a new Ti min is set

SFSYSTEV2.9
Ti max
the software shall record this event when a new Ti max is set

SFSYSTEV2.10
Vol Control
the software shall record this event when a new Vol Control is set

SFSYSTEV2.11
Ti Control
the software shall record this event when a new Ti Control is set

SFSYSTEV2.12
Control R
the software shall record this event when a new Control R is set

SFSYSTEV2.13
P Control
the software shall record this event when a new P Support is set

SFSYSTEV2.14
RAMP
the software shall record this event when a new ramp is set

SFSYSTEV2.15
Low VTI
the software shall record this event when a new Low VTI is set

SFSYSTEV2.16
High VTI

the software shall record this event when a new High VTI is set

SFSYSTEV2.17
Low VTE
the software shall record this event when a new Low VTE is set

SFSYSTEV2.18
DELETED

SFSYSTEV2.19
DELETED

SFSYSTEV2.20
High R
the software shall record this event when a new High R is set

SFSYSTEV2.21
Low PIP
the software shall record this event when a new Low PIP is set

SFSYSTEV2.22
High PIP
the software shall record this event when a new High PIP is set

SFSYSTEV2.23
High VTE
The software shall record this event when a new HIGH VTE is set

SFSYSTEV2.24
Date (RTC)
The software shall memorize any date change in order to retrieve the former date.

SFSYSTEV2.25
Hour (RTC)
The software shall memorize any hour change in order to retrieve the former hour.

SFSYSTEV2.26
I:E
DEL

SFSYSTEV2.27
Vt target
the software shall record this event when a new Vt target is set

SFSYSTEV2.28
Pmax
the software shall record this event when a new Pmax is set

SFSYSTEV2.29
I/T

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

the software shall record this event when the VALIDATION KEY is SHORT PRESS on the Exh Flow calibration field

SFSYSTEV3.5
DISCONNECTION
the software shall record this event when the DISCONNECTION alarm is detected

SFSYSTEV3.6
END OF DISCONNECTION
the software shall record this event when the DISCONNECTION alarm is cancelled

SFSYSTEV3.7
HIGH PRESSURE
the software shall record this event when the HIGH PRESSURE alarm is detected

SFSYSTEV3.8
END OF HIGH PRESSURE
the software shall record this event when the HIGH PRESSURE alarm is cancelled

SFSYSTEV3.9
APNEA
the software shall record this event when the APNEA alarm is detected

SFSYSTEV3.10
END OF APNEA
the software shall record this event when the APNEA alarm is cancelled

SFSYSTEV3.11
HIGH VTI
the software shall record this event when the HIGH VTI alarm is detected

SFSYSTEV3.12
END OF HIGH VTI
the software shall record this event when the HIGH VTI alarm is cancelled

SFSYSTEV3.13
LOW VTI
the software shall record this event when the LOW VTI alarm is detected

SFSYSTEV3.14
END OF LOW VTI
the software shall record this event when the LOW VTI alarm is cancelled

SFSYSTEV3.15
LOW VTE
the software shall record this event when the LOW VTE alarm is detected

SFSYSTEV3.16
END OF LOW VTE
the software shall record this event when the LOW VTE alarm is cancelled

SFSYSTEV3.17

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

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

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

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

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

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

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

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

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

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

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.

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.

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.

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

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

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.

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)

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

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 FFFFFFFFFFFF (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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Unit: ma/h

SFSYSTCOMDP93.2.19
Battery remaining time jauge
Offset (byte): 28
29
Format: 2*8 bits
Data: Jauge 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 implementedOffset (byte): 38
Format: 8 bits
Data: Not implemented
Range: Not implemented
Unit: NA

SFSYSTCOMDP93.2.25
Not implementedOffset (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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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).

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).

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).

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).