



DOC-0746 Rev. A00

- R&D QA General
 Production

SW 4.34 Release Notes


COVER PAGE

APPROVAL

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REVISION HISTORY TABLE

Rev	Date	ECO no.	Changes
A00	06/12/2021	ECO-002619	Initial version

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1 MAJOR CHANGES

There are some major changes in the system regarding alarms priorities, behavior and performance; Apnea backup ventilation settings and performance and some UI changes.

1.1 Alarms

1.1.1 Alarm's performance changes

To comply with regulatory requirements listed in "IEC 60601-1-8{ed2.1} 2012 General requirements, tests and guidance for alarm systems" some changes were made in the device alarm system.

1.1.1.1 Audible alarms

- Low priority alarms audio sequence is changed to 1-pulse cycle with inter-burst interval of about 20 sec.
- Medium priority alarms audio sequence is changed to 3-pulses cycle
- High priority alarms audio sequence is changed for 10-pulses cycle.
- Former High priority alarms sound sequence (proprietary "siren" sound) is removed from the system.

1.1.1.2 Visual alarms (red led)

Visual alarms now have different frequencies for each type of the alarms:

- Low priority visual alarms are constantly on
- Medium priority visual alarms are blinking with frequency 0.5Hz
- High priority visual alarms are blinking with frequency 2Hz

1.1.1.3 Alarms labels colors

Alarm labels on the screen:

- **Yellow** for Low and Medium priority alarms
- **Red** for High priority alarms

1.1.2 Changes in alarms table

Due to Regulatory requirements several alarms priorities were changed from Medium to High.

The following table shows previous vs. current alarm signals (audible and visible) for the alarms that were affected by the changes.

Alarm	Color in 4.33	Alarm freq. in 4.33	Sound in 4.33	Color in 4.34	Alarm freq. in 4.34	Sound in 4.34
Power Switchover	YELLOW	Off	3 notes	YELLOW	On	1 note
Battery Caution	YELLOW	Off	3 notes	YELLOW	On	1 note
Sec Battery ONLY	YELLOW	Off	3 notes	YELLOW	On	1 note
O2 Supply will be OFF	NEW	NEW	NEW	YELLOW	On	1 note
Check O2 Supply	YELLOW	Off	3 notes	YELLOW	On	1 note
Check Backup Sensor	YELLOW	Off	3 notes	YELLOW	On	1 note
Possible O2 Leak	YELLOW	Off	3 notes	YELLOW	On	1 note
FiO2 HIGH	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
CHECK O2 LEAK SENSOR	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
PROX LINE	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
BATTERY LOW	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
FiO2 LOW	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
HIGH MV INS	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
HIGH MV EXH	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
HIGH RATE	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
LOW Vti	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
LOW Vte	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
LOW PBASE	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
CHECK FiO2 SENSOR	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
LOW RATE	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
VT NOT REACHED	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes


PC NOT REACHED	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
VT EXCEEDED	RED	~0.5Hz	10 notes	YELLOW	~2Hz	3 notes
HIGH PRESSURE	RED	~0.5Hz	10 notes	RED	~0.5Hz	10 notes
APNEA	RED	~0.5Hz	10 notes	RED	~0.5Hz	10 notes
HIGH PBASE	RED	~0.5Hz	10 notes	RED	~0.5Hz	10 notes
OCCLUSION	RED	~0.5Hz	10 notes	RED	~0.5Hz	10 notes
O2 LEAK DETECTED	RED	~0.5Hz	10 notes	RED	~0.5Hz	10 notes
MEMORY FAULT	RED	~0.5Hz	10 notes	RED	~0.5Hz	10 notes
Main BAT FAULT	RED	~0.5Hz	10 notes	RED	~0.5Hz	10 notes
Sec BAT FAULT	RED	~0.5Hz	10 notes	RED	~0.5Hz	10 notes
EMPTY BAT	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes
LOW PRESSURE	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes
LOW MV INS	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes
LOW MV EXH	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes
BUV	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes
O2 SUPPLY IS OFF	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes
NO O2 SUPPLY	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes
CHECK CIRCUIT	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes
MOTOR FAULT	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes
POWER FAULT	RED	~0.5Hz	siren	RED	~0.5Hz	10 notes

1.1.3 New alarms

1.1.3.1 Circuit disconnection alarm

Instead of the previously used “Check circuit” alarm there are 2 alarm with the same title, but with different explanations (in logs):

- “Patient disconnection” is signaling in case of detected patient circuit disconnection from the patient (i.e. after the FLT) or due to an extensive leak

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- “Circuit disconnection” is signaling in case of detected patient circuit disconnection from the outlet

Important: in NIV the “Patient disconnection” alarm is disabled, but the “Circuit disconnection” alarm is active.

1.1.4 Alarms changed behavior

- Alarm “Low MVE” is not active in case of NIV.

1.1.5 Removed alarms

The following alarms are removed from the system:

1.1.5.1 Low priority alarms (previously called "cautions"):

- Custom BUV is active!
- Purge Operation
- Calibrate O2 Leak Sensor
- Check Circuit Alarm Off
- Low P Alarm Off

1.1.5.2 Medium priority alarms:

- Ventilation Was Stopped
- Flow Sensor Error

1.2 **Apnea and Back up ventilation (BUV)**

1.2.1 Initiations of the Apnea alarm


As off this SW version Apnea alarm and back-up ventilation (BUV) are applicable only for non-mandatory modes of ventilation, i.e., SPONT and VtG.

1.2.2 Apnea BUV settings

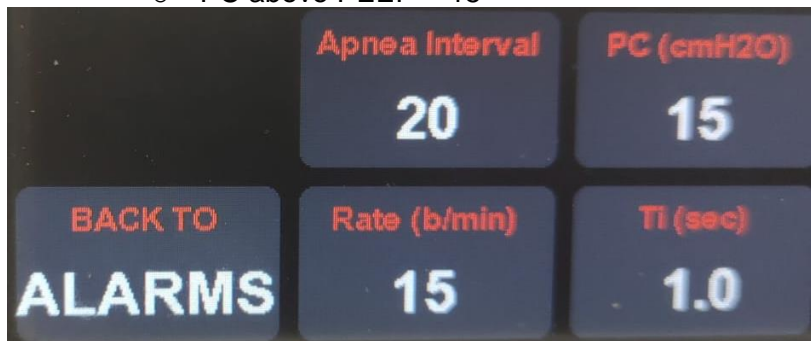
- The “Custom BUV” advanced technician feature is removed from the system.
- Apnea back-up ventilation ventilation is always SIMV PCV mode.
- Apnea back-up ventilation parameters are Rate, Ti and PC above PEEP.
- The rest of the parameters stay the same as was in the ventilation mode before entering Apnea BUV.

1.2.3 Apnea BUV parameters UI

- Operator may change the Apnea interval and the back-up ventilation parameters on settings and during the ventilation if one of the spontaneous modes (SPONT or VtG) is chosen.

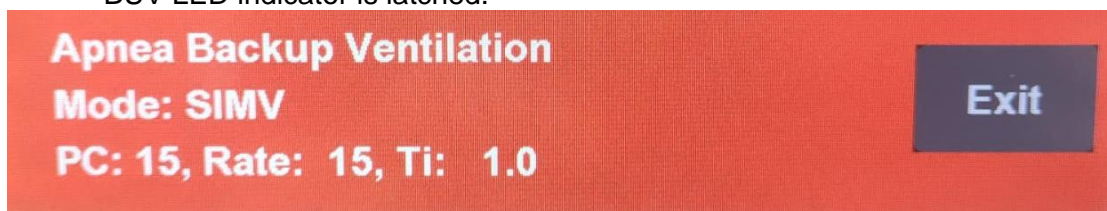
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- Apnea back-up ventilation parameters are limited by current PEEP preventing reaching a total pressure of 80 cmH2O..
- When the user changes the PEEP in SPONT or VtG mode the Apnea BUV PC parameter is updated automatically preventing the total pressure from reaching 80 cmH2O.
- All the Apnea BUV parameters buttons(including Apnea interval)are placed on the additional screen “APNEA”
- In order to reach APNEA screen, operator should enter ALARMS screen and choose “APNEA” button
- Allowed value of the parameters are:
 - Interval = [10 -60] sec, resolution: 10 sec
 - Rate = [1- 99] bpm, resolution: 1bpm
 - Ti = [0.1- 3.0] sec, resolution: 0.1 sec
 - PC above PEEP = [5- 80-PEEP] cmH2O, resolution: 1 cmH2O
- The default parameters are:
 - Interval=20
 - Rate=15
 - Ti=1.0
 - PC above PEEP = 15



1.2.4 UI during BUV

- When the system enters Apnea back-up ventilation, all the parameters buttons are blocked – i.e. the operator cannot change any ventilation parameters before exiting BUV
- BUV pop-up window appears on the screen, displaying the current back-up ventilation setting parameters
- An “Exit” button is also located on this window
- Pressing on the “Exit” button cancels BUV mode, the pop-up window disappears, parameters buttons appear again and the system is back to the prescription that was set before entering BUV.
- 2 consecutive patient triggered breathes also cancels BUV mode, but the BUV LED indicator is latched.



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1.3 Hour meters' changes

There is a new hour counter in addition to the motor hours counter that was in the previous releases.

There are 2 different counters:

- Motor hours' meter
- Ventilator hours' meter

1.4 UI changes

1.4.1 Mode selector

The mode selector has two pages instead one.

On the first page the following options are displayed:

- ACMV
- SIMV
- SPONT
- More

On the second page the following options are displayed:

- VtG
- MVG
- B-LEV
- More

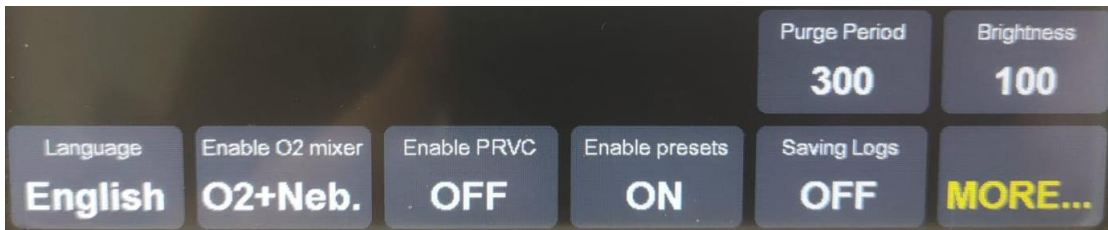
Pressing on one of the mode options and OK changes the mode of ventilation..


Pressing on "More" button changes the page of the selector.

1.4.2 VG mode selector

Since now both VtG and MVG are accessible from the mode selector, the VG button was removed from the Extended screen.

1.4.3 Changes in Advanced (Service) screens



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Experimental feature "Universal circuit" is removed from the system.
Special Japanese configuration is also removed from the system.

place	4.33 old names	4.34 new names
Technical screen	"Advanced screen"	"SERVICE"
Advanced (Service) screen	"Additional Configuration"	removed
Additional configuration window	"Quick Start", "Japanese configuration"	removed
Advanced (Service) screen	"Universal circuit"	removed
Advanced (Service) screen	"Enable VG"	removed
Advanced (Service) screen	"Enable B-LEVEL"	removed
Advanced (Service) screen	"Screen Intensity"	"Brightness"
Advanced (Service) screen	"Quick Start"	"Enable Presets"
Advanced (Service) screen	"Service screen"	"More.."
Advanced (Service) screen (MORE)	"Service"	"Configure System"
Advanced (Service) screen (MORE)	"Advanced screen"	"More.."

2 MINOR CHANGES, BUG FIXING AND IMPROVEMENTS

2.1 UI changes

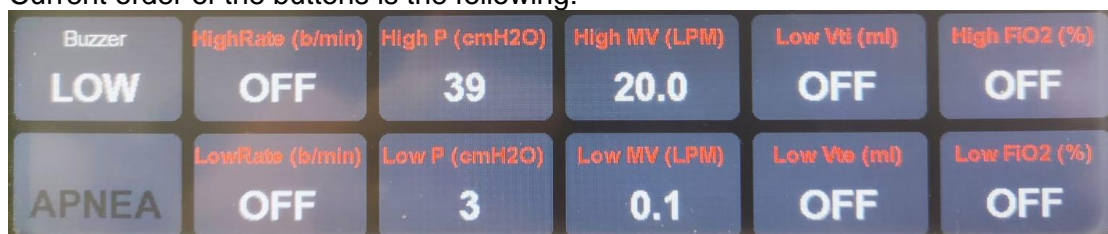
2.1.1 Parameters units


Units were added to the parameters.

2.1.2 Alarms screen

The locations of all the buttons are changed due to adding button "APNEA" and removing "Apnea interval" from the Alarms screen.

Current order of the buttons is the following:



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2.1.3 “Alarms Off” signal

- Adding “Alarm Off” signal, as per regulatory requirement, "Alarm off" signal will appear if at least one alarm is off.
- In order to check which alarms are off the operator needs to enter the Alarms screen.

2.1.4 Alarms texts

- All motor related alarms are displayed on the screen as “Motor Fault”
- All main battery related alarms are displayed on the screen as “Main Bat Fault”
- All secondary battery related alarms are displayed on the screen as “Sec Bat Fault”
- The corresponding log texts stay the same

2.2 **Improvement in oxygen functionalities:**

- Improvements of ‘O2 supply fail’ alarm following reported fault alarms in the field.
- Improvements in the O2 leak sensor measuring were made in order to prevent false O2 leak alarms.
- Automatic O2 leak sensor zeroing (initialization) when the ventilator powers ON.
- The following messages will appear on high level O2 leak alarm: “O2 supply will be OFF”

2.3 **“Motor Fault” behavior**

The Motor Fault alarm appears after 3 timed breathes without rotating motor.

3 **KNOW ISSUES:**

- ALARMS log may be full with batteries fault alarms on and off on every breath if the batteries are close to be fully discharged.
- This release version is not fully translated to other languages. There will be an additional release version after translating.
- There may be “artifacts” on the screen after changing languages
- There may be “artifacts” on the screen after enabling/disabling presets on the service screen