

bellavista[™] Software 6.1 US e-learning module

© 2021 Vyaire. Vyaire and the Vyaire logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.



bellavista 6.1 US e-learning module

Objectives

- Learn about the scope of the software changes
- Get detailed knowledge about the changes and enhancements for TargetVent
- Understand the Vt/kg setting in Configuration assist





Release notes software version 6.1

Dear valued customer,

With this software release we have executed 33 changes and enhancements to deliver a substantially improved user experience by listening to your inputs and ideas. We're pleased to release this software to support you better in your daily routine and practice. This release is available for:

- bellavista[™] 1000/1000select
- bellavista™ 1000e

The following pages will facilitate working with bellavista after the software update has been performed. We have made changes in these categories:

- Patient settings
- Configurability
- Ventilation settings
- Monitoring
- Service





1. Patient settings

Release Notes software Version 6.1 US

© 2021 Vyaire. Vyaire and the Vyaire logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.



Mandatory height, weight and gender

With the 6.1 software, height, weight and gender are preset when starting up the ventilator. This enables bellavista[™] to constantly calculate a Vt/kg monitoring value to ensure that additional lung protective monitoring is always available. When entering the start screen, bellavista[™] automatically selects the largest patient population available and chooses preset settings for height and weight:

Patient type	Adult	Pediatric	Neonatal
	Adult 170 cm, female	80 cm	2 kg

The default settings can be changed for individual profiles or with the "New Patient" profile. Height and weight settings can also be changed in the Ventilation Menu and Patient Info during ventilation. When starting up bellavista for the first time you will be prompted to decide for the default value, before starting ventilation.

Profile

Last patient

New patient





Weight settings for neonatal patients

Weight settings for neonates and infants are now available with settings from 0.3-30 kg or 4.4 to 66 lbs, to enable a Vt/kg monitoring for the smallest patients ventilated with bellavista[™].

The weight setting can be changed during ventilation to easily adapt to the growth of these patients. Weight settings can also be stored with any profile for individualized and customized ventilation settings.

The increments for the weight settings are the following:

Weight	Increment
0.3–1 kg	0.01 kg
1–5 kg	0.05 kg
5–30 kg	0.1 kg









Minimal tidal volume for adult patients

- To match with the new Vt/kg preferred settings we have enhanced the range for adult patients in target and volume controlled modes from 250 to 150 mL.
- Tidal volume alarms have been enhanced accordingly. This ensures lung protective ventilation for small adults with bellavista[™].

Vt_{Insp} 150 mL PEEP 5 mbar





Reset of trending data with each new patient

All trending data will be reset when a new patient is chosen and when ventilation has commenced.

All trending data will still be stored and can be retrieved via Data Assist or the new "Export all data" button.





2. Ventilation settings

Release notes software version 6.1 US

© 2021 Vyaire. Vyaire and the Vyaire logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.



beMode Integration

All TargetVent modes have been moved from an isolated beMode to SingleVent, which means they're now easily accessible and have joined the other SingleVent ventilation modes to facilitate your workflow.

For the mode availability, please see table below:

ICU Configuration	Adult/	Pediatric	Ne	onatal	IMC Configuration	Adult	/Pediatric	Nec	onatal
		Non-invasive		Non- invasive			Non-invasive		Non-invasive
P-A/C _{Target*}	\checkmark	\checkmark	\checkmark	\checkmark	S/T _{Target*}	\checkmark	\checkmark	\checkmark	\checkmark
PC-SIMV _{Target*}	\checkmark	\checkmark	\checkmark	x	S _{Target}	\checkmark	\checkmark	\checkmark	\checkmark
PSV _{Target}	\checkmark	\checkmark	\checkmark	\checkmark	P-A/C _{Target*}	\checkmark	\checkmark	\checkmark	\checkmark



TargetVent beMode selection with software 6.0



TargetVent now unified with SingleVent modes in 6.1

*available as Backup modes

© 2021 Vyaire. Vyaire and the Vyaire logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.





Cockpit View

In Cockpit view the TargetVent modes act like any other SingleVent mode now, so no separate target volume activation is necessary anymore.

When a ventilation mode change is required, you can just enter the Settings Assist and adjust your settings. This enables a simple and easy operation.



TargetVent activation button in Cockpit view with software 6.0



TargetVent as a direct operation mode in 6.1

	ſ	D _{Peak}		2	4	Adult 🍳	61
_		PEEP mbar			3	O ₂ S 10 11	uction 00% 20s
		√t _{Exp} mL			440	Manual Breath	रिः 30 min Insp
-		MV _{Exp} L/min Rate	12	FiO ₂	5.70	Stop ve Duration	ntilation : 49m 05s
	ľ	^{bpm} ● P-A	/C _{Ta}	% rget ^{Si}	ngle Ven	t	Backup On
. 1		Vt _{Targ}	et	Р	EEP	Rate	Oxygen
		490)		5	12	21
s	<	mL		n	nbar	bpm	%
			~	r			×
		N	<i>Ionit</i>	oring		Alarm	Settings



Changing ventilation mode

When changing a mode in the Settings Assist, all enabled TargetVent modes are displayed in the new arranged mode table.



Settings Assist limited to beMode TagetVent modes with software 6.0



TargetVent modes available and the new ventilation mode table for better visibility in 6.1

]
	beLevel	APRV	
 Image: A set of the set of the	PC-SIMV _{Target}	PSV _{Target}	
r			Cancel
5	T _{Cycl} 5.0 s I:E 1:1.94	s	Apply
w Tri	g Rise		Oxygen
2.0	Auto		21
min			%
	~	T	×
	Monit	oring	Alarm Settings



TargetGraph

The TargetVent screen is now replaced by a regular curve element that is available like other curve elements in the context menu from the side bar.



Configuration of the Target graph in the curve element context menu



TargetVent screen with software 6.0



TargetVent graph now integrated as curve element in 6.1



Settings Assist

With 6.1, the ventilation settings in Target modes have been unified as well. All settings are now available in the settings bar. P_{InspMax} is now replaced by P_{limit} (Fig.1) which includes the PEEP value like in AVM. P_{InspMin} is available too.

In the Settings Assist graphic, P_{Limit} and P_{InspMin} are visualized by a blue dotted line (Fig.2), so the inspiratory pressure range is instantly visible. The P_{aw} real-time curve shows the P_{Limit} with a dotted blue line as well, so you are always able to see where the pressure limit is set(Fig.3).



Settings Assist enhanced with pressure limits for PL imit and PLINSMIN











Fig. 2 Visualization of P_{Limit} and P_{InspMin} limits (Arrows) in the Settings Assist graphic



Fig.3 New dotted line (blue) to display P_{Limit} in Target modes



Backup modes and DualVent

Target modes are now available in as Backup modes for Apnea ventilation.

Please see the table below for further detail:

ICU Configuration	Adult/F	Pediatric	Ne	onatal	IMC Configuration	Adul	t/Pediatric	Neo	natal
	Backup	DualVent	Backup	DualVent		Backup	DualVent	Backup	DualVent
P-A/C _{Target*}	\checkmark	\checkmark	\checkmark	\checkmark	S/T _{Target*}	\checkmark	\checkmark	\checkmark	\checkmark
PC-SIMV _{Target*}	\checkmark	\checkmark	\checkmark	\checkmark	P-A/C _{Target*}	V	\checkmark	\checkmark	\checkmark
PSV _{Target}	-	\checkmark	-	\checkmark					





Available Target backup modes in ICU configuration in 6.1



Selection of Target modes in DualVent in 6.1

© 2021 Vyaire. Vyaire and the Vyaire logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.

	Cancel			
	Apply			
Rise				
Kr		\sim	~~	
Settings	M	onitoring	Alarm Setting	s

VC-SIMV		
PC-SIMV 🖌		
PC-SIMV _{Target}		
PEE	EP 5 mbar	Cancel
5	T _{Cyd} 5.0 s I:E 1:1.94 s	Apply
s Flow Trig Exp Tri	T _{Cyd} 5.0 s I:E 1:1.94 s	Apply Oxygen
Flow Trig Exp Tri 2.0 25	T _{Cyst} 5.0 s I:E 1:1.94 s g Rise Auto	Apply Oxygen 21
Flow Trig 2.0 2.7 L/min %	g Rise Auto	Apply Oxygen 21 %
Flow Trig 2.0 L/min %	r _{Cyd} 5.0 s I:E 1:1.94 s	Apply Oxygen 21 %



New Settings Assist and Start Screen ventilation mode table

Ventilation modes are now displayed with a table to enhance overview and visibility.

Modes are now consolidated by control variable (Volume, Pressure) or breath type (Spontaneous, Adaptive).



New ventilation mode table on Start Screen



New ventilation mode table in Settings Assist

avn integrated	1 •
Rise Auto	
el APRV	



Enhanced settings takeover

Ventilation settings takeover is much more enhanced with 6.1. Whether you're switching from a volume or pressure controlled mode, the new takeover logic converts tidal volumes into inspiratory pressures or vice versa.

Settings which are not part of a certain mode will be displayed as default settings when switching between modes.

The only exception is the APRV ventilation mode where timing and pressures and also the monitoring is different from a conventional mode, so volumes, timing and pressures won't be taken over.

Mode	Vt _{Insp}	P _{Support}	PEEP	Rate	T _{Insp}	Plateau	Press Trig	Pattern	Exp Tri	
VC-SIMV	420	15	6	17	1.4	0	1.0	Dec50	25	
	mL	mbar	mbar	bpm	s	%	mbar		%	
Initial settings in VC-SIMV mode										
Mode	P _{Insp}	PEEP	Rate	T _{Insp}	Press Trig	Rise				
P-A/C	16	6	17	1.4	1.0	Auto				
	mbar	mbar	bpm	S	mbar					
Setting takeove	r converts volu	me into inspira	tory pressure w	hen switched fr	rom a volume ir	nto a pressure r	node			
Mode	Vt _{Target}	PEEP	P _{Limit}	P _{Insp Min}	Rate	T _{Insp}	Press Trig	Rise		
P-A/C _{Target}	400	6	35	5	17	1.4	1.0	Auto		
	mL	mbar	mbar	mbar	bpm	S	mbar			

Setting takeover converts pressure into target volume when taken over from a pressure mode









New default mode for NIV ventilation

PSV will be automatically selected when switching to NIV instead of P-A/C.

Circuit Test
Circuit TestE

PSV is always default when switching to NIV





Preventing Standby when still connected to a patient

With 6.1 bellavista detects if a patient is still connected when switching to Standby.

When a patient is still connected, ventilation resumes after a detection phase of about two seconds. A confirmation window shows up asking the user to either continue ventilation or stop ventilation in case of a potentially wrong detection.

This feature is only available for invasive Adult/Pediatric ventilation with proximal flow sensor (Circuit D and E) and with PEEP values \geq 2 mbar.



When stopping ventilation you are prompted to disconnect patient



Detecting if a patient is still connected when ventilation has been stopped.



Humidification selection available in ventilation menu

The humidification type is selectable during ventilation now. In the ventilation menu you can toggle the humidification type between active humidification and HME/Filter.



Humidification type available now in ventilation menu



Highlighted Start Ventilation button

To enhance visibility the "Start Ventilation" button on the Start Screen is now highlighted with a green border.

Settings



Highlighted Start ventilation button



New circuit test memory

Previously performed circuit tests will be taken over to new patient settings or profiles when they match:

- Patient type
- Circuit type

to allow starting ventilation with the circuit and flow sensor calibration from an already prepared and switched off device.

bellavista[™] will remind you with a confirmation after 30 days when a new circuit test hasn't been performed. Always execute a circuit test with:

- Each new patient
- Each new flow sensor or circuit
- With each "Calibrate flow sensor alarm"



Performed circuit test are now valid as long as patient and circuit type are not changed



Sidestream CO₂ calibration

bellavista[™] supports the newest Sidestream ISA device from Masimo and when connected manual calibration are not longer supported since the ISA device has a self-calibration routine.



Sensor calibration is inactive when connected to a sidestream sensor





3. Monitoring

Release notes software version 6.1 US

© 2021 Vyaire. Vyaire and the Vyaire logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.



AVM Target Graph facelift

The AVM Target Graph has been updated to increase situation awareness and enhance visibility. The differences are:

Highlighted protection window

The protection window is now highlighted green to enhance visibility

New target and patient symbols

- The target and patient symbol has also been ٠ changed for visibility reasons
- A legend has been implemented to for better • understanding which symbol belongs to patient or target

Monitoring differences

- Height information has been changed to IBW ٠
- %MinVol and Target MinVol are now displayed ٠ in the upper left corner of the graph



Updated AVM Target Graph



New "Patient" monitoring value

With 6.1 it is even easier now to check your patient settings during ventilation.

The "Patient" monitoring value is offering more information about your patient settings.

Additionally to the patient group information, the ideal body weight (or weight for neonatal) is displayed together with the chosen gender in all tile sizes.





Tidal volume available with in CPAP with "A" circuit

Tidal Volume (Vt) is available now, when using an «A» circuit for non-invasive ventilation.



Tidal volume in CPAP with «A» circuit



Updated I:E graphic in Settings Assist for volume controlled modes

In volume controlled modes, the settings graphic has been updated to calculate I:E ratios by including the plateau time in the inspiratory time setting.







Settings Assist in volume controlled modes with 6.1. Plateau time is now included in I:E ratio calculation



Alarm priority change for disabled oxygen sensor

When oxygen monitoring has been disabled in Configuration Assist, a medium priority alarm is triggered. Initially this alarm is acoustical and visual until the alarm is acknowled by touching the checkmark.

After that the alarm will visually stay active until the oxygen sensor is enabled again. The alarm will stay active after restart.

It is important to monitor oxygen with an external oxygen measurement device and to replace and activate the oxygen sensor as soon as possible.





Oxygen monitoring disabled alarm (ID225) stays silently active after confirmation



O₂ suction displays temporarily delivered FiO₂

When an O_2 suction maneuver is performed, the 6.1 software highlights the active maneuver and displays the temporarily delivered oxygen during the suction maneuver or O2 flush.

After the maneuver, the FiO₂ setting switches back to the previous value.



O₂ suction now highlighted the current oxygen concentration during suction maneuver



O₂ suction configurable for adult and pediatric patients

High oxygen concentration can be harmful, when applied to often. So with the new bellavista software, the O2 suction concentration and duration can be configured like for neonatal patients.

The duration can be adjusted between 60 and 120 seconds. The O2 suction concentration can be adjusted between +5-+79% oxygen.

The setting is persistent, so once configured it will apply to all settings and profiles.



O₂ suction concentration and duration are now configurable for adult and pediatric patients



New Alarms - Eventlog

Any applied user input, start up and tests of the device will be stored in the Eventlog of bellavista. All alarms and events occurring are saved. The alarm and event list remains saved even in the event of a power failure.

The stored alarms and events will not remain in case of a software update.

The captured events are:

- Ventilation settings
- Configuration changes
- Connectivity (SpO2, CO2, HL7 etc.)
- Alarm settings and muting
- Start up/Shutdown
- Calibrations
- Export/Import, Download

Up to 5000 events and alarms are stored.

Device events like e.g. changes in the Configuration Assist are displayed with the «Device Event» icon

Patient events like e.g. changes of ventilation settings are displayed with the «Patient Event» icon

Various events which do not fall under the abovementioned events are summarized with the «Various Event» icon



33

Alarms - Eventlog

Description of the Alarms-Eventlog screen

	abled		Oxyge	29 s	Alarms • E				
1	2	3	4		Category	All	Alarm	Event	
Туре	Category	Date / Time	Message						
×	Events	6/8/2022 3:16:33 PM	Alarm unmute						
×	Events	6/8/2022 3:16:05 PM	Confirm Alarm Oxygen monito	oring disabled					
X	Events	6/8/2022 3:15:01 PM	Alarm mute						
1	Alarms ID 225	6/8/2022 3:14:03 PM	Oxygen monitoring disabled						
*	Events	6/8/2022 3:14:03 PM	O ₂ monitoring Off						
X	Events	6/8/2022 3:08:00 PM	O ₂ monitoring On						
X	Events	6/8/2022 3:02:44 PM	Confirm Alarm Oxygen monito	oring disabled					
1	Alarms ID 225	6/8/2022 3:02:17 PM	Oxygen monitoring disabled						
*	Events	6/8/2022 3:02:17 PM	O ₂ monitoring Off						
ý	Events	6/8/2022							
			K K 6	1 >	>> > Entries: 1 - 100 (754 total)	7			
Syr	Symbol Description		1						
1		Event type		5	Tabs for alarms or events only, or all event	ts			
2	Category (Alar		ns, Events)	6	Page counter				
3		Date and time		7	Number of total entries				
4		Alarm or Event	Message						

© 2021 Vyaire. Vyaire and the Vyalre logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.





Updated Nurse call behavior

When nurse call is connected to bellavista, the alarm on the nurse call is muted when the alarm is muted on bellavista.



35



4. Service menu

Release Notes Software Version 6.1 US

© 2021 Vyaire. Vyaire and the Vyaire logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.



"Export all data" button

To capture all data available on bellavista[™] at once we created the "Export all data" button in the service menu (password protected)

When bellavista[™] is in Standby and by entering the service menu, the "Export all data" button is located in the device configuration section. When a USB stick is plugged in, the button will be activated.

Once touched, the download process will start. Please note that the USB stick does not need to be "bellavista ready". Due to the possibly significant amount of data the download process can take up to 20 minutes, so please download only when the ventilator is not urgently needed. After the download is performed a confirmation window will show up and the USB stick can be removed.

A .zip file is created now which can be sent over e-mail or uploaded to a cloud platform to be processed or analysed by TechSupport, Clinical Support or Product Management.



All data download in progress

© 2021 Vyaire. Vyaire and the Vyaire logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.



After plugging an USB stick into bellavista the Export button is enabled





Knowledge check

© 2021 Vyaire. Vyaire and the Vyaire logo are trademarks or registered trademarks of Vyaire Medical, Inc., or one of its affiliates.



1. How many events and alarms are stored in the new Alarms-Event Log?

- a. 1000 events
- b. 2000 alarms only
- c. 5000 events and alarms
- d. Alarms and events are stored over a months period



2. Weight for neonatal can be set now between...?

- a. 0-5 kg
- b. 0.5-10 kg
- c. 5-50 kg
- d. 0.3-30 kg



3. TargetVent modes can still be switched off within the mode setting.

- a. True
- b. False





4. Performed circuit tests are only voided when...

- a. Changing the patient group
- b. Changing the circuit type
- c. Changing the ventilation type
- d. Changing the patient group and circuit type
- e. Circuit tests can't be voided anymore



5. The new minimal tidal volume for adult patients is?

- a. 250 mL
- b. 110 mL
- c. 150 mL
- d. 300 mL
- e. is calculated with IBW





Global Headquarters

Vyaire Medical, Inc. 26125 N. Riverwoods Blvd. Mettawa, IL 60045 USA

vyaire.com

