Subject: **Set-up and Use of the Breas Vivo 50 Ventilator**

Initiating Mechanical Ventilation with the Breas Vivo 50 Ventilator

Overview:

The Breas Vivo 50 ventilator is a microprocessor-controlled ventilator intended for use in the home, hospitals and institutions (LTAC or SNF) and transport environments. The Breas Vivo 50 is FDA-cleared for both invasive and non-invasive ventilation of patients weighing 10kg or more.

The Breas Vivo 50 supports the following ventilation modes:

- AC in Volume Control (VCV) or Pressure Control (PCV)
- SIMV in VCV or PCV
- Pressure Support Ventilation (PSV)
- Target Volume (TgV) in PSV, PCV mode
- CPAP

The Breas Vivo 50 offers the following advanced features:

- eSync (trigger technology)
- Profiles (pre-set up to 3 different patient ventilation profiles)
- Inspiratory & Expiratory Trigger (sensitivity settings)
- Sigh (adjustable between every 50-250 breaths and 125%-200% of actual set pressure or tidal volume)
- EtCO2 and SpO2 monitoring
- Graphic waveform monitoring (including adjustable trending)
- "I" button (an all-inclusive information/help button)

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Policy:

1. Mechanical ventilation will be initiated only on the order of a licensed physician (or other approved practitioner, e.g., PA, CNP).

2. Only authorized clinical personnel who have received documented training and orientation in the set-up and use of the Breas Vivo 50 ventilator may set-up and operate this ventilator for patient use.

3. The written order/prescription must include at a minimum:
   - the prescribed mode (e.g., VCV, PCV, TgV, AC, SIMV)
   - the prescribed volume or pressure
   - breath rate
   - FIO_2 (if applicable, i.e., > 21%) or O_2 liter flow (if applicable)
   - PEEP or CPAP setting (if applicable)
   - Duration (e.g., continuous, nocturnally, etc.)

4. A prescription for a heated humidifier may also be required if one is to be used.

5. If the ventilator is being used non-invasively, the size and type of mask should be specified (e.g., medium wide, full face mask). The prescription may also direct the clinician to "adjust pressure level to patient comfort," but a pressure range is required for this type of order (e.g., "adjust inspiratory pressure to patient comfort between 8-12 cmH2O).

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Procedure:

1. Plug ventilator power cord into an appropriate electrical outlet (the LED on the left front panel of the ventilator will illuminate).
2. Power-on the ventilator by pressing the "ON/OFF" button located on the right side of the ventilator.
3. The Vivo 50 monitoring screen should be illuminated and the ventilator will be in the Stand-by mode.
4. Make sure the ventilator is in the "Clinical Mode" ("VENTILATOR STANDBY" will appear at the top of the screen with monitoring data below). If a digital clock and the date appears below "VENTILATOR STANDBY" the Vivo 50 is in the Home Mode.
5. If the ventilator is not in the Clinical Mode, switch to clinical mode by simultaneously depressing the "-" and "+" key located on the right side of the monitoring screen.
6. Attach the patient circuit and any associated accessories at this time (e.g., filters, HME, humidifier).
7. On the lower right of the monitoring screen will be a dialogue box reading, "Pre-use Test." At the bottom of the dialog box will be a prompt for either "Yes" or "No." **NOTE:** the Pre-use test should be performed with every new patient set-up and each time the patient circuit is changed. Directions on how to run the Pre-use test must be followed as written (displayed on the monitoring screen). This test may be by-passed (by selecting "No") if the circuit or any of its components have not changed since the last use.
8. If this is a new patient set-up or the circuit or any of the components in the circuit have been changed (e.g., bacteria filter, HME, humidifier reservoir) you must run the Pre-use test by selecting "Yes" at the prompt in the dialogue box.
9. Follow the directions on the screen to run the Pre-use test.
10.   If the Pre-use test fails, do not use for patient treatment until the problem has been identified and corrected and the test passes.
11.   Once the Pre-use test is successfully completed you are ready to begin programming the patient settings. **NOTE:** the Vivo 50 will default to the last programmed settings when powered-off

so you must ensure that settings are programmed for the specific patient for whom the ventilator is intended to be used.

12.   Press the "Mode" button at the bottom left under the monitoring screen and the select the desired mode by navigating through the options using the "^" or "v" button (located on the right side of the monitoring screen) as appropriate.

13.   Once you have selected the Mode, press the Setup" button located at the bottom left under the monitoring screen. **NOTE: if you select a mode different from the one currently selected when the Vivo 50 is powered on, you will be automatically guided through the set-up procedures and there will be no need to press the "Setup" button.**

14.   Select the parameters according to the physician's prescription.

15.   Once you have selected the appropriate parameters, press the "Alarm" button located at the bottom under the monitoring screen.

16.   Set the alarms as appropriate. If any alarms are to be disabled, High alarm settings are disabled by scrolling toward the highest setting and Low alarm settings are disabled by scrolling toward the lowest setting. **NOTE:** there are 3 pages in the Alarm menu – to access subsequent alarm menus press the "Alarm" button again.

17.   When you have set all the alarms select the monitoring screen you desire to view by pressing the "Monitor" button located at the bottom under the monitoring screen. **NOTE:** there are 3 options that may be selected by pressing the "Monitor" button.

18.   If you are going to be setting additional Patient Profiles you may do that at this time by pressing the "Others" button located at the bottom under the monitoring screen and selecting, "Profiles" by using the "v" button located to the right side of the monitoring screen to navigate to "Profiles" and then pressing the "+" button to select "Profiles." NOTE: when you initially select a Profile (e.g., Profile 2) the settings will be the same as those last selected for that Profile, or if no Profile had been previously selected they will

be the same as the parameters you entered in steps 12-17 above until you change them.

19.   If you will be using the * FiO2 or EtCO2 monitor, "Home Adjust Mode" or other options listed in the "Others" menu, select those at this time. * (FiO2/CO2 Calibration).

20.   Once you have set all your modes and parameters you are ready to begin ventilating the patient.

21.   Begin ventilation by pressing larger "Standby/On button located in the center below the monitoring screen.

22.   After verifying that all parameters are set correctly attach the patient circuit to the patient.

23.   Monitor the patient closely for a few minutes to ensure they are being ventilated safely and appropriately.

24.   To pause ventilation, press the "Standby/On" button located in the center below the monitoring screen; you will be prompted to press the ON/OFF power button located on the right side of the ventilator to complete the steps of putting the ventilator in "Standby" Mode.

25.   Before leaving the facility or the patient's home, put the ventilator in the Home Mode setting by simultaneously pressing the "-" and "+" keys until the scroll bar completes and the Home Setting screen appears.

26.   To Power Off the ventilator, after pausing ventilation, press the ON/OFF power button on the right side of the ventilator until the ventilator shuts down.

27.   NOTE: if you are using the internal battery the ventilator will continue to consume battery power even in the Standby mode unless you plug-in the Vivo 50 electric power cord to an appropriate AC power source.