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| Topic: | 30 l/min oxygen bleed-in Vivo 45/45LS/50/55/60/65 and NIPPY 4/4+ |
| To:    | Breas Commercial Teams   |
| From:  | Product Management   |
| Date:  | 2020-03-25   |
| MAR:   | MAR-000478 Rev 0   |

## INTERNAL AND EXTERNAL COMMUNICATION

Under the actual circumstances of COVID-19 outbreak and with the increased demand for ventilators in combination with the shortage of critical care ventilators worldwide we are receiving questions from customers if it is possible to bleed-in higher oxygen flow than the rated 15 l/min.

We have verified bleed-in oxygen flow up to 30 l/min on the following Breas ventilators:

- Vivo 45
- Vivo 45 LS\*
- Vivo 50\*
- Vivo 55\*
- Vivo 60\*
- Vivo 65\*
- NIPPY 4
- NIPPY 4+\*

As a result of the verification we can confirm that oxygen rates of up to 30 l/min do not have a negative impact on the performance accuracy of the tested ventilators.

\* Breas current Instructions for Use include a contraindication for patients who need to be ventilated with oxygen concentrations (FiO<sub>2</sub>) higher than achievable when combining inlet from a low-pressure oxygen source at 15 l/min with actual ventilator settings.

However, the EU Commission has recently issued a recommendation\*\* to allow that national market surveillance authorities, for the duration of the 'current health crisis', may authorize use of the ventilators and other medical equipment outside the specifications in the Instructions for Use.

\*\* Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat