

Draeger Medical Systems, Inc.

To customers of Dräger Babyroo TN300 with Resuscitation Modules

December 21, 2022

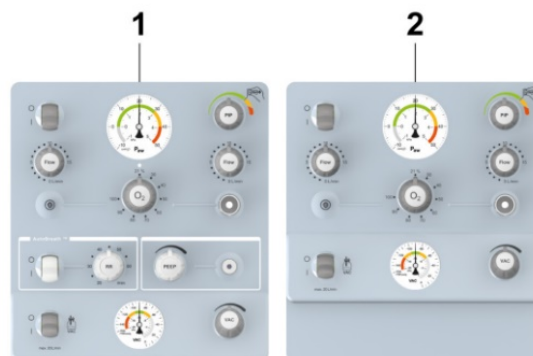
Important safety notice regarding slow response of airway pressure gauge

Dear Customer,

Our continuous production qualification of Babyroo TN300, built with an optional Resuscitation Module, found that some airway pressure gauges are slow to respond to user adjustments. Specifically, when the user sets the Peak Inspiratory Pressure (PIP) control to desired setting (e.g., 20 cmH₂O), the reading on the airway pressure gauge may not indicate the desired setting during cycling. This may result in the user misinterpreting the gauge reading, resulting in over adjustment of PIP and PEEP values.

Our records indicate that you own a Babyroo TN300 with one of the following Resuscitation Modules:

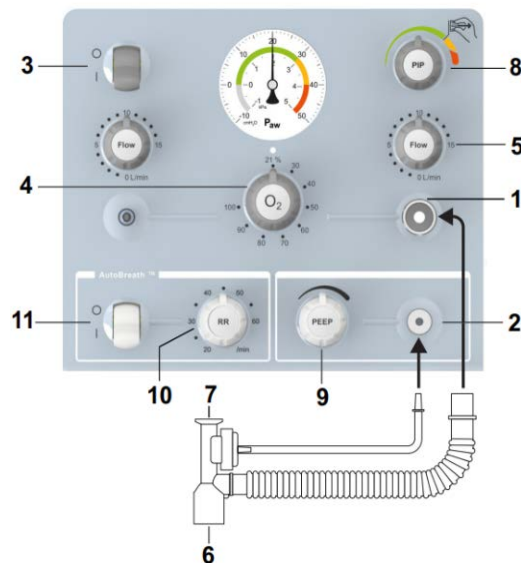
1. Resuscitation module with gas mixer and AutoBreath (1)
2. Resuscitation module with gas mixer (2)



Please follow the instructions below to identify if the device in your possession exhibits the above-mentioned behavior.

Checking slow response gauge on Resuscitation Module with gas mixer and AutoBreath

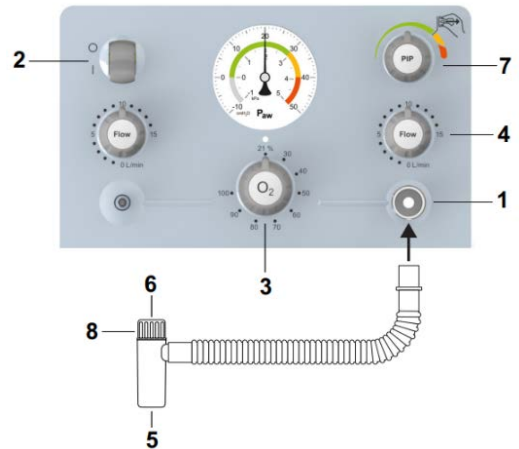
1. Connect the automatic breathing circuit to the primary patient outlet (1)
2. Connect the expiratory valve tubing to the expiratory valve port (2)
3. Set the O₂ (4), FLOW (5), and RR (10) control to 12 o'clock
4. Switch on the gas flow using the on/off (3) switch
5. Occlude the patient port (6)
6. Adjust PEEP (9) to approximately 5 cmH₂O (as displayed on the airway pressure gauge)
7. Occlude the patient port (6) and the exhaust port (7)
8. Adjust PIP (8) to approximately 20 cmH₂O (as displayed on the airway pressure gauge)
9. Occlude patient port (6). Do not occlude the exhaust port (7)
10. Switch on the AutoBreath infant resuscitator using the on/off switch (11)
11. Verify that the airway pressure gauge reaches a PIP value of 20 cmH₂O and a PEEP value of 5 cmH₂O



Checking the slow response gauge on Resuscitation Module with a gas mixer

1. Connect the breathing circuit (T-piece) to the primary patient outlet (1)
2. Set the O₂ (3) and FLOW (4), to 12 o'clock
3. Switch on the gas flow using the on/off (2) switch

4. Occlude patient port (5), and using the PEEP control (8) of the breathing circuit, adjust the PEEP setting to approximately 5 cmH₂O (as displayed on the airway pressure gauge)
5. Occlude the patient port (5) and the exhaust port (6) on the breathing circuit, and adjust the PIP (7) value to approximately 20 cmH₂O (as displayed on the airway pressure gauge)
6. Simulate ventilating the patient at a rate of approximately 60 breaths per minute (1 breath/second) by closing and opening the exhaust port with your thumb
7. Verify that the airway pressure gauge reaches a PIP value of 20 cmH₂O and a PEEP value of 5 cmH₂O



Please take the device out of service if the airway pressure gauge values for PIP and PEEP during cycling do not match the set values. We apologize for any inconveniences resulting from this action and appreciate your patience and cooperation. Dräger is committed to customer satisfaction and patient safety. Please contact your local Dräger representative in case of further questions and to discuss options with regards to affected Resuscitation Modules. We ask you to kindly fill out the attached response form so we can take necessary actions to minimize device downtime.

Kind regards,

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