REDUCING VENTILATOR ALARMS THROUGH DECREASED RAINOUT IN VENTILATOR CIRCUITS: A BENCH STUDY

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Abstract

Alarm fatigue is a significant problem in healthcare, particularly in high acuity settings such as intensive care, surgery, and emergency departments. Alarms are triggered by various devices such as anesthesia machines, ventilators, patient monitors or humidifiers. Heated humidifiers (HH) used with mechanical ventilators, while necessary to prevent other complications associated with mechanical ventilators, may cause condensation in the ventilator circuit, prompting occlusion alarms indicating a risk for the patient. Technological advances in HH circuits may reduce rainout in the circuits and therefore occlusion alarms. Bench experiments measured alarms and rainout of two commercially available humidifiers (AirLife DuoTherm™ and Fisher & Paykel MR850) and four different pediatric and adult patient breathing circuits. The tests examined condensation accumulation in the circuits after 24 hours of low-, nominal-, or high-flow rates of gas at low-, nominal-, and high-ambient temperature settings. Dual-limb designs of adult- and neonate-sized circuits underwent evaluation. Data on alarms was collected for each system. Low temperature and occlusion alarms were less common in DuoTherm vs. MR850 HH circuits (6 vs. 68 alarms, respectively). DuoTherm products accumulated significantly less rainout for both circuit sizes at all ambient temperatures. In general, the set flow rate did not dramatically affect the amount of rainout for adult and infant circuits, but low versus high ambient temperatures yielded increased rainout for all circuit types (p < 0.02). The DuoTherm HH device and patient circuits developed significantly less alarms due to rainout and low temperatures compared to those from MR850 under all the conditions tested. Such reduction in patient alarms should help reduce alarm fatigue among healthcare workers in critical care settings.

Introduction

Alarm fatigue is a major problem in critical care settings. Alarms are triggered by various devices such as anesthesia machines, ventilators, patient monitors or humidifiers. According to the Joint Commission on Health Care Organizations, between 150 and 400 alarms per patient per day may be seen in a critical care unit [1]. While most of those alarms are not actionable, some indicate the need for an urgent intervention by the health care team. Listening for and sorting out the alarms causes fatigue among healthcare workers, raising the risk that some important alarms may be missed [2–7]. Several researchers have developed elaborate plans to reduce alarm fatigue while minimizing errors in care related to alarm fatigue [8–10]. It is incumbent on developers of medical devices to optimize the performance of their devices to reduce non-actionable alarms.

Many patients in critical care settings require exogenous oxygen via mechanisms that bypass physiologic humidification of dry air. Specifically, invasive mechanical ventilation circumvents the upper airway, lowers the humidity within the respiratory tract, and hinders humidification. The resulting dry gas flow creates irritation and pain, thwarts the mucociliary transport system, and increases airway resistance [11]. Dry air also promotes the development of hypothermia, coughing, bronchospasm, atelectasis, and airway obstruction, such as when airway secretions thicken to narrow or close the endotracheal (ET) tube [12–14].

Active humidification systems including heated humidifiers (HH) plus their associated tubing circuits actively warm and add moisture to the gas flow within a patient breathing circuit and can restore gas to its optimal humidity levels. The American Association for Respiratory Care (AARC) Clinical Practice Guideline recommends humidification of gas flow with invasive mechanical ventilation which, by its design, uses

pressurized cold and dry gas [14]. The AARC guidance notes invasive ventilation using an air-oxygen mix should maintain a humidity level between 33 and 44 mg/L at a temperature between 34 and 41 °C, as measured at the patient's breathing circuit Y-piece, with 100% relative humidity [14].

Active HH or passive heat and moisture exchangers are prone to "rainout," the condensation and accumulation of water in the lowest physical points within the tubing of breathing circuits that creates gas flow resistance or inhibition [12]. With sufficient resistance to gas flow, the monitor triggers an occlusion alarm. The healthcare team must adjust the patient or the equipment to remove the condensation to maintain target ventilation support of the patient. As shown by several studies [15–17], rainout adversely affects the ventilator performance and can lead to ventilator shut down. Schwarz et al. [18] showed that rainout may also cause double triggering of the ventilator. This is particularly dangerous in the neonatal units given the smaller diameter of the tubing [17, 19].

The temperature of the room and the gas before humidification, the HH type, the ventilator type and settings, and a patient's minute ventilation all impact the HH performance and contribute to humidification effectiveness and rainout risk [20]. For example, warmer rooms prevent gas cooling between the ventilator and the water reservoir, which hinders humidification. Moreover, if a warmer room yields a higher reservoir inlet chamber temperature, the heating plate can turn off and cool the water enough to encumber evaporation needed to moisten passing air [14]. In contrast, cooler rooms may lower the temperature in the breathing circuit tubing, increasing the relative humidity and density, increasing condensation, and slowing gas flows after humidification.

To reduce the influence of ambient temperature on circuit condensation, a HH device may maintain gas flow temperature with heated wires along the inspiratory limb. Circuits use sensors at the HH outlet and at the Y-piece near the patient to create a feedback mechanism to automate increases to the water temperature and/or heater wire duty cycle to help regulate gas temperature at the Y-piece. Importantly, the location in the circuit matters when assessing gas flow temperature, as a 2 to 4 °C drop temperature may occur at the proximal end of the ET tube, a point that more closely reflects inhaled air dynamics.

This study evaluated occlusion alarms and temperature alarms in two different HH systems. We also measured the active humidification and rainout of the devices under different ventilation modes and patient circuit sizes as well as with different flow rates and ambient temperatures.

Methods

Experimental setup

A series of bench experiments were performed to compare the amount of rainout within different models of patient breathing circuits with HH ("circuit codes"): the DuoTherm adult-pediatric (Vyaire Medical Inc., Mettawa, Illinois, US), DuoTherm neonatal (Vyaire Medical, Inc.), MR850 Adult Dual Limb with Evaqua 2 Technology (Fisher & Paykel Healthcare Corporation Limited, Auckland, New Zealand), and MR850 Infant Dual Limb (>4LPM) with Evaqua 2 Technology (Fisher & Paykel Healthcare Corporation Limited). These setups included only dual-limb patient circuits with two different ventilators at three different flow rates and at different ambient temperatures.

Table A1 in Appendix summarizes the ventilation settings for the test runs. The tests were conducted at low-, nominal-, and high-flow gas rates and at low, nominal, and high ambient temperatures. Dual-limb patient circuits were attached to a mechanical ventilator (AVEA™ from Vyaire or Puritan-Bennett™ 840 (PB840), Medtronic, Minneapolis, MN). Two PB840 machines and eight AVEA machines were used each day for 36 days of testing with the circuit codes on a rotating basis, resulting in 360 data points. The use of the circuit codes was equally distributed amongst ventilators.

For each test, HH and humidification chambers were used from the same manufacturer as the patient circuit under evaluation (Vyaire devices: HH 377HTR and Humidification Chamber 377CBR; MR850 devices: Respiratory Humidifier MR850 and Auto-Fill Humidification Chamber MR290). Inspiratory limbs with the attached temperature probes were weighed, then expiratory limbs were weighed. The test lungs (B&B Medical Adult Test Lung – 1.0L #25405, B&B Medical Pediatric Test Lung – 0.5L #20120, and IngMar Medical NeoLung – Infant Test Lung) were weighed separately. HH temperatures were set at 40.0 °C and lung simulators were set at 37.0 °C. Humidifiers were set to "invasive mode". Ambient temperatures were set according to manufacturers' specifications of acceptable operating temperatures for each system.

For the tests, the inspiratory limb of the circuit was attached to the HH outlet, and the patient end of the inspiratory limb was attached to a heat and moisture exchanger (AirLife® 003005, Vyaire), then to the test lung. Each circuit was evaluated at three flow rates characterized as low, nominal, and high (Table A1). For all tests, positive end-expiratory pressure (PEEP) was set to 4 cmH₂O and fraction of inspired oxygen (FiO₂) to 40%. The ventilators were used in volume-targeted assist control mode.

Ambient temperature and humidity were recorded at the start and conclusion of each test using an analog

temperature and humidity chart recorder (Portable/Wireless Universal Circular Chart SUPERECORDER™ CTXL-TRH-W, Omega Engineering, Norwalk, CT, US) along with a digital OMEGA recorder (part # OM-HL-EH-TC, Omega Engineering, Norwalk, CT, US) for redundancy. For each day of testing, the test machines were moved to different locations within the laboratory to minimize the potential effects of cool and warm spots in the room.

All tests ran for a duration of 24 hours. Circuits were weighed immediately before each test and immediately after their conclusions. Rainout was defined as the increase in circuit weight from the start to the end of the test. Rainout in the inspiratory and expiratory limbs were quantified separately, and total rainout was calculated as the sum of rainout in the inspiratory and expiratory limbs. All alarms triggered according to manufacturers' specifications were recorded for each device at the end of the 24-hour test run. Condensation was not cleared from the circuit during the test as it would have altered the end weight of the circuit. No test runs were interrupted to clear alarms.

Sample size justification

A binomial calculation was used to "calculate reliability confidence intervals by setting the cumulative probability to one minus the confidence level for a lower one-sided bound" [16]. A 90% reliability, lower bound, with a 95% confidence was selected for this protocol to produce an acceptable sample size. Zero (0) failures are acceptable for this test. See below for the applicable equation:

- $1 - Confidence = R^n$
- $1 - 0.95 = 0.90^n$
- $n = \log 0.05 / \log 0.9 = 28.43$
- Round to 30 samples

Therefore, 30 samples (rainout data points) were used per circuit code (circuit model plus humidifier base).

Data analysis

Mean rainout was measured across the multiple samples collected for each circuit type, flow rate, and manufacturer. Unpaired t-tests performed for each of the four circuit types at the three flow rates compared the mean rainout within the DuoTherm and MR850 circuits. Data analysis was performed using Minitab (Minitab, LLC, State College, PA). Statistical significance was set at $p<0.05$.

Results

In all, 360 test runs were completed over 36 days of testing. Data were collected regarding the patient category (adult vs. pediatric), the ventilator used,

ventilator settings (low, nominal, or high), the weight of the inspiratory limb before testing and after, and the weight of the expiratory limb before testing and after. Room temperature was recorded at the beginning of testing. The DuoTherm HH and patient circuits triggered significantly fewer alarms compared to the MR850 HH and circuits under all conditions and circuit types tested ($p<0.005$). Of the 76 alarms triggered during the study, eleven were unrelated to the heating units. Sixty-two alarms were seen in MR850 circuits compared to seven in DuoTherm circuits; 45 alarms were seen in adult circuits and 31 were generated in infant/neonate circuits. Of all alarms, 36 were circuit occlusion alarms and 29 were patient temperature alarms. All adult DuoTherm alarms (5/7 total DuoTherm alarms) occurred at 18–20 °C; 2/7 DuoTherm alarms occurred in neonate circuits. MR850 circuits triggered 62 alarms including 34 in adult circuits and 28 in infant circuits. Nineteen of the adult MR850 alarms occurred at 18–20 °C; fifteen adult MR850 alarms occurred at 21–23 °C. In the MR850 infant circuits, 11/28 occurred at 20–22 °C, 11/28 occurred at 22–24 °C, and 6/28 occurred at 24–26 °C. No tests were interrupted to drain circuits. These data are represented graphically in Fig. 1.
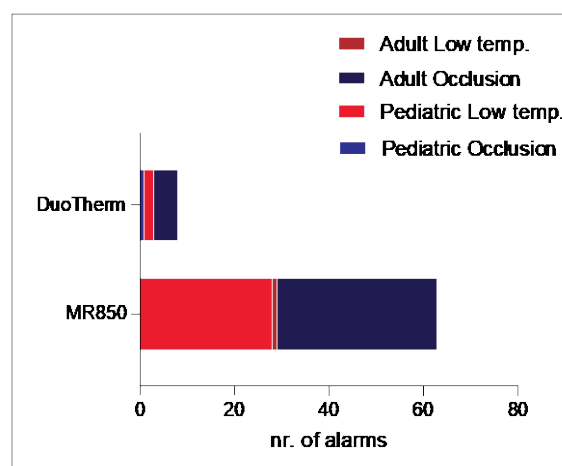

Fig. 1: Circuit occlusion alarms.

The DuoTherm HH and patient circuits developed significantly less rainout compared to the MR850 HH and circuits under all conditions and circuit types tested ($p<0.001$) (Table A2 in Appendix). An analysis of weights of the inspiratory arms and the expiratory arms of each circuit type is presented in Fig. 2 and Fig. 3 and in Table A2. There was a statistically significant difference in change in weight seen in the 20–22 °C and 22–24 °C ranges in infant inspiratory limbs but not at the 24–26 °C range. A similar pattern was seen in the adult inspiratory limbs. There was less of a difference noted in the expiratory limbs for infants and for adults, and indeed the expiratory limb for the DuoTherm adult circuit accumulated more weight than that of the MR850. At all ambient temperatures, the DuoTherm

patient circuits accumulated less total rainout compared to those from MR850 for all three circuit sizes except at the 24–26 °C temperature range where the difference did not reach statistical significance (p=0.0671).
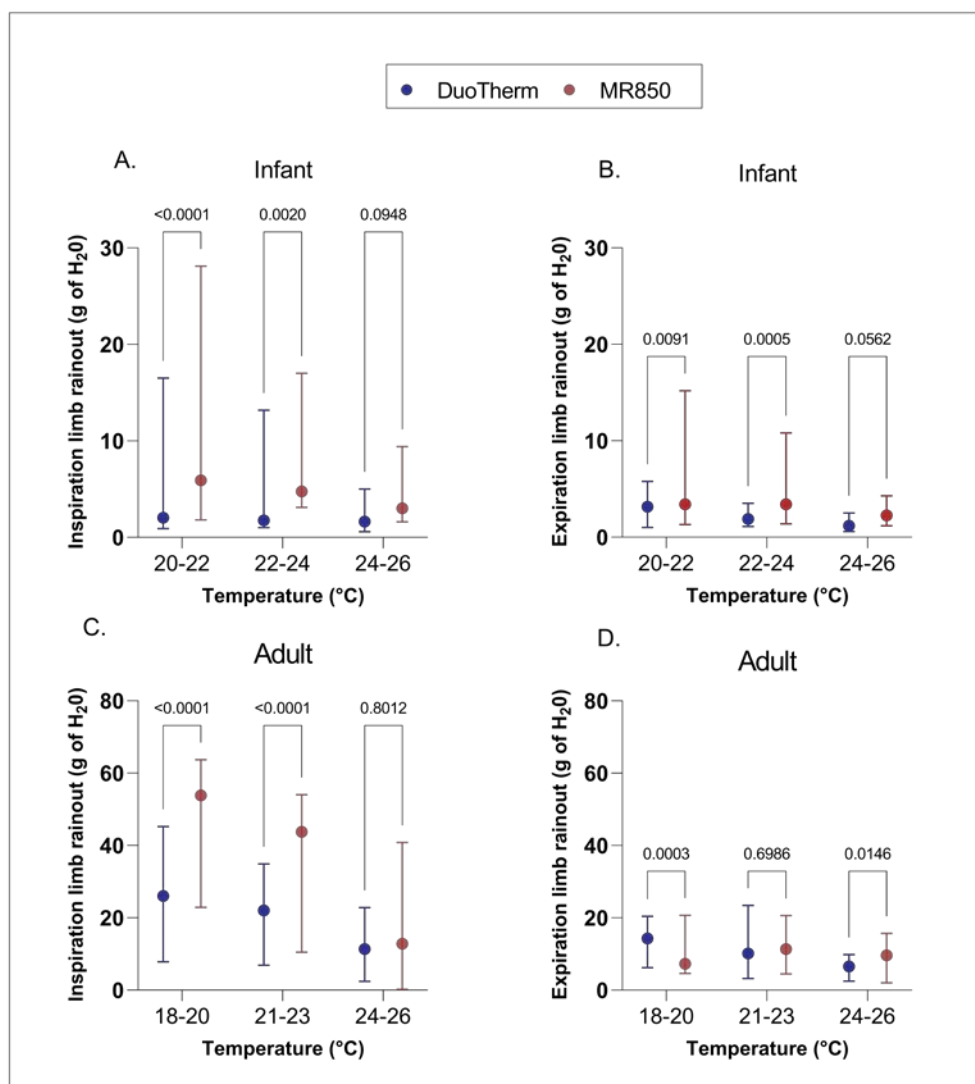

Fig 2: Rainout for inspiration and expiration arms by circuit type at varying ambient temperatures.
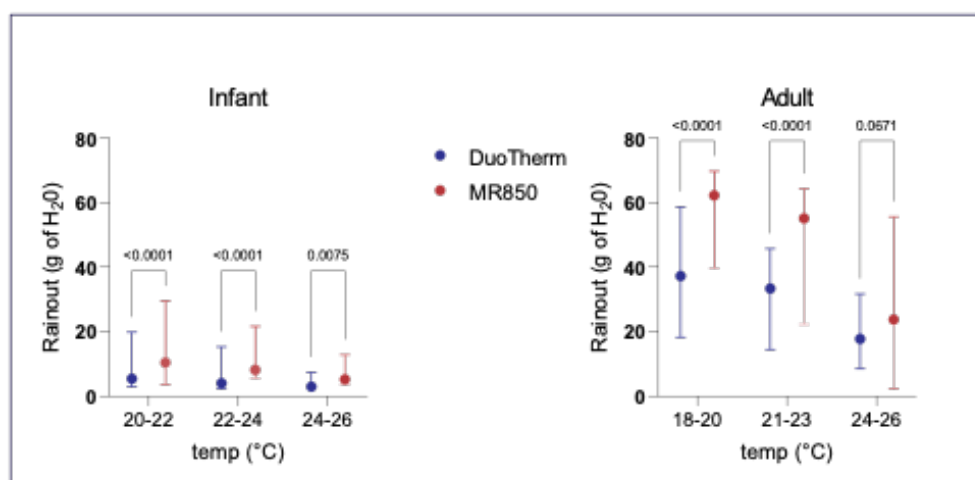

Fig. 3: Heated humidification system rainout test results.

Discussion

To our knowledge, this is the first study that compared the performance of two humidifiers and evaluated rainout and alarms. Our results show that DuoTherm generated significantly less rainout for the pediatric and the adult circuits as well as for different ambient temperatures. Due to the reduction in rainout, the number of tube occlusion alarms were lower for DuoTherm humidifier. In addition to reducing rainout, DuoTherm also reduced the temperature alarms compared to MR850.

The reduced alarms will potentially reduce the risk of alarm fatigue in health care workers. As shown by Lewandowska et al. [21] who evaluated 389 nurses working in different intensive care units, nurses felt overburdened with an excessive number of duties and a continuous wave of alarms. The authors concluded that alarm fatigue may have serious consequences, both for patients and for nursing personnel. One paper in 2016 reported that about 10% of patients were responsible for nearly 60% of alarms, and the authors recommended adjusting alarm sensitivity on a case-by-case basis [22]. According to another study, nurses have a tendency to respond to alarms in patients who are known to be physiologically less stable and did not record most alarms [23].

Ventilators generate a large proportion of alarms in some critical care settings. In a study by Belteki, ventilators in the neonatal intensive care unit triggered 603 alarms per baby per day, an average of 10 per hour [24]. Most of the alarms were related to inappropriate settings and were brief, but some were ignored by staff for prolonged periods of time. These alarms are audible and loud enough to disturb the baby, the parents, and the staff. Another study, this from Johns Hopkins Hospital, studied alarms generated by ventilators in adults [25]. The study found an average of 6-8 alarms per hour generated by the ventilators, many of which resulted in a cascade of other notifications by telemetry, pagers, and telephone calls to nurses and respiratory therapists. About 5% of the alarms were related to the "Other" category which included circuit occlusions, but they did not specifically quantify rainout or condensation. The current study set-up only allowed the recording of one alarm per 24-hour test period, so our alarm rates cannot be compared to those of previous studies.

In general functionality, devices such as the MR850 HH and the DuoTherm HH system are similar in design as they are both pass-over humidification systems. However, to improve rainout control and alarms, the DuoTherm heated breathing circuits add an additional outer corrugate that creates an insulating airgap between the breathing gas pathway and the patient room environment. Also, the DuoTherm expiratory heater wire provides constant output, but remains adjustable to the user, in contrast to that of the MR850, which mirrors the actions of the inspiratory limb.

The finding that more alarms and more rainout occurred at lower ambient temperatures was anticipated because of the increased cooling effect on the walls of the heated breathing circuit. Both active humidification systems in this study humidified the breathing gas at the same chamber outlet temperatures to nearly 100% relative humidity, so any drop in temperature can create condensation. The DuoTherm HH system likely performed better because of its ability to maintain the gas pathway temperature in comparison to the MR850 system, thereby reducing the amount of condensation that forms on the walls of the breathing circuit. The more consistent temperature may be due to a combination of the dual-wall design, the heater wire design, and the temperature management algorithms of the heater base.

Differences in rainout at higher ambient temperatures were less substantial because HH in such situations do not run at maximum capacity and can easily maintain gas-pathway temperatures. In these conditions, the smaller temperature gradient between the inside and outside of the breathing circuit results in very little condensation and the advantage of the dual-wall breathing circuit is diminished. Mid-level to sub-maximal flow rates (~20 to 50 L/m) also reduce the opportunity for the breathing gases to cool while in the breathing circuit.

The differences in rainout measured in the expiratory limbs of the two systems were similar. The MR850 Adult Dual Limb with Evaqua 2 Technology comes with a vapor permeable expiratory limb that allows (to a certain extent) condensation to exit the expiratory limb. The DuoTherm does not have this property. This permeability likely reduces the weight of the expiratory limb in the MH850. Reductions in total rainout seen in the DuoTherm are more attributable to decreases in the inspiratory limb where condensation is more likely to cause interruptions in breathing and occlusion alarms.

One of the consequences of rainout in ventilator circuits is an occlusion alarm. Alarms prompt the care team to stop what they are doing to assess the patient [26]. Consistent with lower rain-out, there were fewer alarms in the DuoTherm circuits compared to the MR850 circuits. Rainout alarms and patient temperature alarms are actionable alarms, since they indicate that the patient may be at risk for an adverse event. Many approaches described in the literature aimed to alter the team's response to alarms [8–10]. With lower rainout, the critical care team can be less burdened with alarms and more able to respond to other physiologic alarms. A clinical assessment of true positives, false negatives, and alarm fatigue would aid in the assessment of potential benefits or harms.

Limitations of the testing included controlling the air currents within the test lab, which were minimized via the installation of baffling on the room's air ducts, but

the investigators noted that areas of the room were draftier than others. For this reason, the physical arrangement of test setups was changed daily to reduce the influence of warm or cool spots in the laboratory. The ten ventilators were moved and the HH-circuits were alternated among the ventilators, minimizing the effect of temperature fluctuations in the room. Also, documentation captured minor fluctuations in room temperature, although this is common with all ventilation systems. Temperature was recorded only at the beginning and the end of each test. It would be interesting to analyze fluctuations in ambient temperature during the day to ensure that there were no large fluctuations that may have influenced the outcomes. Other limitations include that lab testing does not always reflect device performance in clinical settings and the inherent variability of rainout testing. Minor limitations included sample size due to room space and ventilator availability, and the use of endpoints for testing rather than continuous monitoring during active ventilation trials. However, the collection of multiple samples enabled robust statistical analyses. The overall alarm rates in both circuit types were much lower than those reported in the literature, probably because only one alarm was recorded for each circuit per day. In a patient care scenario, condensation would be cleared from the tubing to clear an alarm, and pressure deviations would be corrected, allowing each ventilator system to trigger multiple alarms per day (or even per hour). Because this study was primarily designed to measure rainout, we did not interrupt testing to drain off condensation or to correct pressure errors. However, this limitation applies equally to both ventilators and all circuits.

Conclusions

Alarm fatigue can be mitigated by clinician training or by engineering changes to devices. The ideal device design would generate few or zero nuisance alarms while remaining sensitive to changing patient statuses. The DuoTherm HH systems developed less rainout and consequently fewer alarms than the MR850 circuits. The DuoTherm product design appears to deliver the heated humidified air required by adult and neonate ventilated patients without circuit occlusions at normal room temperatures.

Declarations

Appendix

Table A1: Settings used for comparing two different heated humidifiers and circuits with standard ventilators. We used appropriate ventilator modes using breath rates of 10–20/minute for adult and 30–60/minute for neonatal/pediatric circuits.

Vyaire AVEA Ventilator Settings with DuoTherm adult-pediatric circuits and MR850 Adult Dual Limb with Evaqua 2 Technology			
Ventilation settings	Low	Nominal	High
Mode	Volume AC	Volume AC	Volume AC
Breath Rate (BPM)	20	15	10
Tidal Volume (mL)	300	500	800
Peak Flow (L/min)	25	30	60
Insp Pause (s)	0	0	0
PEEP (cmH$_2$O)	4	4	4
Flow Trigger (L/min)	2	2	2
FiO$_2$ (%)	40	40	40

Medtronic PB840 Ventilator Settings with DuoTherm adult-pediatric circuits and MR850 Adult Dual Limb with Evaqua 2 Technology

Ventilation settings	Low	Nominal	High
Mode	VC/AC	VC/AC	VC/AC
F (bpm)	20	15	10
VT (mL)	300	500	800
Vmax (L/min)	40	60	80
O_2 (%)	40	21	40
PEEP (cmH_2O)	4	4	4

Vyaire AVEA Ventilator Settings with DuoTherm neonatal and MR850 Infant Dual Limb (>4LPM) with Evaqua 2 Technology

Ventilation settings	Low	Nominal	High
Mode	Pressure Control with Volume Guarantee	Volume AC	Volume AC
Breath Rate (BPM)	60	50	30
Tidal Volume (mL)	8	15	50
Peak Flow (L/min)	NA	4	6
Insp Pause (s)	0	0	0
PEEP (cmH_2O)	4	4	4
Flow Trigger (L/min)	1	1	1
FiO_2 (%)	40	40	40

Medtronic PB840 Ventilator Settings with DuoTherm neonatal and MR850 Infant Dual Limb (>4LPM) with Evaqua 2 Technology

Ventilation settings	Low	Nominal	High
Mode	VC/AC	VC/AC	VC/AC
F (bpm)	60	50	30
VT (mL)	8	15	50
Vmax (L/min)	2	4	6
O_2 (%)	40	40	40
PEEP (cmH_2O)	4	4	4

Table A2: Results of rainout measurements in grams.

Temperature (°C)	DuoTherm (Mean (SD))	MR850 (Mean (SD))	p-value
Infant			
Inspiratory arms			
20–22	3.42 (3.62)	7.22 (4.80)	<0.0001
22–24	2.66 (2.60)	5.39 (2.49)	0.002
24–26	1.79 (0.95)	3.49 (1.92)	0.0948
Expiratory arms			
20–22	3.04 (1.05)	4.64 (3.60)	0.0091
22–24	2.04 (0.62)	4.12 (2.57)	0.0005
24–26	1.25 (0.46)	2.50 (0.87)	0.0562
Total			
20–22	6.46 (3.79)	11.86 (5.83)	<0.0001
22–24	4.70 (2.60)	9.51 (3.49)	<0.0001
24–26	3.04 (1.15)	5.99 (2.32)	0.0075

Adult			
Temperature (°C)	DuoTherm (Mean (SD))	MR850 (Mean (SD))	p-value
Inspiratory arms			
18–20	25.54 (10.96)	49.83 (11.32)	<0.0001
21–23	21.95 (7.14)	39.45 (11.76)	<0.0001
24–26	11.91 (5.52)	13.80 (9.29)	0.8012
Expiratory arms			
18–20	13.46 (3.99)	9.00 (5.21)	0.0003
21–23	10.31 (4.12)	11.27 (3.62)	0.6986
24–26	6.52 (1.93)	9.35 (2.93)	0.0146
Total			
18–20	38.99 (10.97)	58.73 (8.49)	<0.0001
21–23	32.26 (8.65)	50.72 (11.52)	<0.0001
24–26	18.44 (6.60)	23.15 (11.44)	0.0571

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