Touched by technology: automated tactile stimulation in the treatment of apnoea of prematurity

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CHAPTER 2

Caregivers' response to cardiorespiratory events in preterm infants in the NICU – a quantitative overview

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ABSTRACT

AIM

Cardiorespiratory events in preterm infants pose a major challenge in the Neonatal Intensive Care Unit as they require a prompt response. We aimed to describe caregivers' responses to these events.

METHODS

We performed a prospective observational study in 19 preterm infants (28 ± 2 weeks) on non-invasive respiratory support using video recordings of the inside of the incubator for 72 (55-72) hours. Caregivers' responses to these events were then identified from the videos.

RESULTS

We recorded and assessed 1851 cardiorespiratory events with a median duration of 11.0 (5.0-23.0) seconds. No response was observed in the majority of the events (91.5%). In the remaining 8.5% events, caregivers responded by pausing the alarm, adjusting devices and/or providing tactile stimulation with an average response time of 25.4 (13.8-35.9) seconds. Stimulation was the most observed response and was applied in 38 different ways. On average, stimulation lasted 18.7 (11.6-44.6) seconds and the cardiorespiratory events were resolved 30.6 (19.5-47.6) seconds after stimulation started.

CONCLUSIONS

Our study showed that cardiorespiratory events are common in preterm infants in the NICU, but often not followed by intervention of the caregiver. The indication, timing and execution of responses to cardiorespiratory events is highly variable.

INTRODUCTION

Preterm infants have difficulties establishing and maintaining regular and effective breathing due to, amongst others, the immaturity of their lungs and musculature, poor respiratory drive and increased metabolic oxygen consumption. In order to avoid potentially harmful invasive ventilation, spontaneous breathing is commonly supported by providing continuous positive airway pressure (CPAP) and/or administration of caffeine. Although these interventions are proven effective, cardiorespiratory events such as apnoea, bradycardia and desaturation remain very common [1, 2].

As frequent or long lasting events can lead to serious cerebral injury and adverse neurodevelopmental outcome [3-5], caregivers are expected to promptly intervene by providing an escalating sequence of interventions. This includes tactile stimulation, supplemental oxygen, positive pressure ventilation and eventually intubation and artificial ventilation. Manually applied tactile stimulation is the first, most frequently used and arguably the most important intervention in response to cardiorespiratory events in preterm infants. However, albeit recommended and commonly used for many years, there are no guidelines available defining when, where, how and how long to stimulate and data on when and how it is actually applied in clinical practice is lacking.

In order to design guidelines, protocols or future studies on the use of tactile stimulation, more quantitative data on the response to cardiorespiratory events in preterm infants is vital. Therefore, the aim of this study was to observe caregivers in the NICU and to provide a quantitative overview of their way of responding to cardiorespiratory events.

PATIENTS AND METHODS

STUDY SETTING

We performed a prospective observational study at the NICU of the Leiden University Medical Center (LUMC), a tertiary care centre with a total of 25 NICU beds, divided over 17 private rooms and 4 twin rooms.

All infants who are admitted to the unit are continuously monitored via a patient monitor at the bedside (Philips Intellivue MP70, Philips Medical Systems, the Netherlands). The parameters and associated alarms from the patient monitors, connected ventilators (SLE6000, SLE Limited, UK) and infusion pumps (Infusomat Space, BBraun, Germany) are aggregated at the central post (PIC iX, Philips Medical Systems, the Netherlands) and automatically logged in a data warehouse (PIIC iX, Data Warehouse Connect, Philips Medical

Systems, the Netherlands). All modes of ventilatory support are provided using the SLE6000 ventilator and can be supplemented with automated titration of the fraction of inspired oxygen (FiO2) using the embedded “OxyGenie” option. This means that the ventilator controls the FiO2 delivery in order to keep the patient within a SpO2 target range set by the caregiver. In addition to the desaturation alarms indicating a low SpO2 value, caregivers will receive oxygenation alarms indicating high FiO2 requirement or a steep increase in FiO2, hence possible deterioration of the infant.

All activated cardiorespiratory alarms are visible on the devices it originates from as well as the Philips monitor. The caregivers wear handheld devices (Xcover 3, Samsung, South-Korea), via which they receive a selection of the alarms within a few seconds after the onset. These alarms includes: apnoea, desaturation and oxygenation alarm from the ventilator, and bradycardia directly via the patient monitor. Alarms indicating a low heart frequency are only visible on the Philips monitor and not transferred to the handhelds. Apnoea alarms based on impedance via the electrocardiogram (ECG) leads are disabled. More information about the alarm settings in our unit is provided in the supplemental material (Appendix S1 and Table S1).

STUDY POPULATION AND PROCEDURES

Preterm infants born between 24 and 32 weeks of gestation, receiving non-invasive ventilation support (high flow nasal cannula (HFNC), CPAP, or non-invasive positive pressure ventilation (NIPPV)), were considered eligible for this study. As there was no data available on which to base a sample size, the observations were conducted within a predetermined period of 4 months.

The incubators of included infants were equipped with a custom-built infrared camera affixed underneath the cover at the foot end side. Video recording started at the onset of a clinical alarm and stopped 5 minutes after the most recent alarm ended. Onset and end of the alarms were detected using a light sensor placed on top of the alarm light of the patient monitor which was connected to a small computer (Raspberry Pi 3, Raspberry Pi Foundation, UK), on which the videos were temporarily stored (Figure 1). Audio was not recorded.

Infants received standard treatment and all alarm parameters, including alarm limits, delays and averaging times, were set at the discretion of the caregiver during the study. The observations were terminated when invasive ventilation was required, respiratory support was no longer needed or the infant was discharged from our NICU.

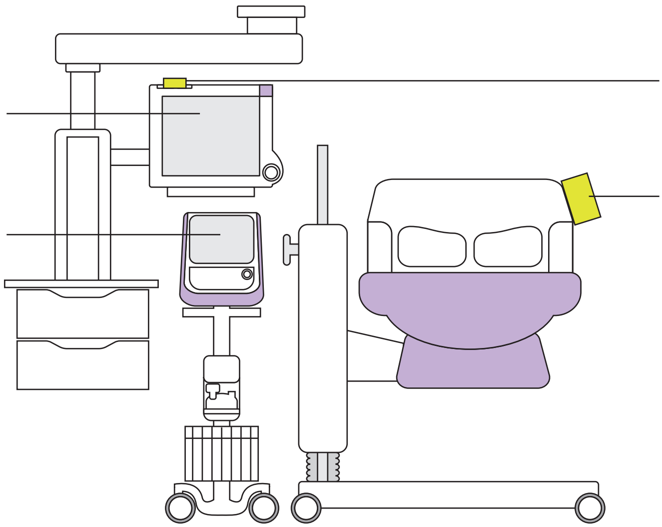

Figure 1. Study set-up

The Leiden-Den Haag-Delft Ethics Review Committee (METC LDD) issued a statement of no objection for this study (P18.182). For each infant, written informed parental consent for collecting and using patient data was acquired prior to participation.

DATA COLLECTION AND ANALYSIS

Clinical details and patient demographics were retrieved from the patient record. Oxygen saturation (SpO2), heart rate (HR), respiratory rate (RR) and FiO2, as well as the timestamps and labels of all clinical alarms were collected from the data warehouse. The recorded videos were subsequently matched to the vital signs and alarm labels based on its time stamps.

For each patient, a maximum of three consecutive days of data were used for analysis. The caregivers' bedside notes were used to select days where the patients showed cardiorespiratory instability. In case a patient was included for less than three days, all available data was used for analysis.

The detected alarms were first assessed on relevance, meaning that only cardiorespiratory alarms were selected for further analysis. Subsequently, the alarms were labelled as isolated or clustered alarms, where the latter was defined as multiple alarms starting within 15 seconds after each other. Based on the alarm labels, the alarm(s) were then classified as a type of event. We distinguished 5 different cardiorespiratory events: (1) apnoea events (consisting only of apnoea alarm(s) from the pressure breath detection of our ventilator or chest impedance), (2) bradycardia events (consisting only of low heart frequency and/or bradycardia alarm(s) from the ECG leads), (3) desaturation events (consisting only of desaturation alarm(s) from pulse oximetry), (4) oxygenation events (consisting only of oxygenation alarms from the OxyGenie) and (5) a combination of these (i.e. a bradycardia alarm followed by an oxygenation alarm). Finally, the responses to the events were analysed using the videos. Events for which the reactive response could not be assessed were excluded from analysis. This included videos where: (1) the infant was not visible due to kangaroo care or a displaced or misfunctioning camera, (2) the caregivers were already providing care or performing a planned intervention and (3) parents were already touching the infant when the alarm went off. All assessments were performed by the same researcher (SC) and in case of uncertainty reviewed by a second researcher (JD).

For the included events, the following items were assessed: duration of the entire event (time between alarm onset and end), whether there was a response and, if applicable, the type of response, response time (time from alarm onset until a visible response), completion time (time from start response until alarm end), stimulation location, stimulation technique and stimulation duration. Stimulation location and technique were assessed using the same categories as an earlier performed study on tactile stimulation [6].

STATISTICAL ANALYSIS

All data analysis was performed using IBM SPSS Statistics V.25 (IBM, Chicago, Illinois, USA, 2021). Continuous data were given as mean ± SD or median (IQR), as appropriate. Dichotomous data were given in percentages. A binary regression was performed to predict the likelihood that a caregiver responds to an event by using the event duration. Two-tailed p-values of < 0.05 were considered statistically significant.

RESULTS

Between January and April 2019, a total of 19 infants were included in the study (baseline characteristics in Table 1). These infants generated 7286 alarms during the study period, of which 4007 (55%) alarms were considered relevant. Of these relevant alarms, 1708 represented isolated events and 2299 occurred in clusters around 750 events. In 607 of these 2458 events the response could not be assessed (235 events where the camera was blocked or turned away, 192 events where the infant was not visible in the incubator because of kangaroo care, 166 events where the caregiver was already providing regular care time and 14 events where parents were already touching the infant), resulting in 1851 events included for analysis. A visual overview of all results is presented in Figure 2.

Table 1. Patient characteristics

	n=19
Gestational age (weeks.days)[a]	28.1 (± 2.1)
Birth weight (grams)[a]	1117 (± 335)
Gender (female/male)	6/13
Postnatal age at study entry (days)[a]	14.2 (± 11.8)
Ventilation mode at study entry (NIPPV/CPAP/HFNC)	1/14/4
OxyGenie (on/off)	17/2
Hours of video monitoring per patient[b]	72 (55 – 72)

Data is presented as mean ± SD for normally distributed data (a) or median (IQR) for data that were not normally distributed (b)

EVENT TYPES AND DURATION

The total number of events consisted of 40 apnoea's, 344 bradycardia's, 855 desaturations, 311 oxygenation events and 301 combined events with an overall median duration of 11 (5-23) seconds (Table 2).

RESPONSE TYPES, RATES AND TIME

In 91.5% of the events no response was seen. In the remaining events, four types of response could be distinguished: (1) alarms were paused on the monitor without further intervention, meaning that the alarm sound was suppressed and alarm transfer to the handheld was stopped while the alarm condition was still existed (Pause; 1.8% of events), (2) medical device placement (i.e. CPAP mask and saturation probe) was checked or adjusted (Devices; 1.5% of events), (3) medical device placement was checked and tactile stimulation was provided (Devices + stimulation ; 1.1% of events) and (4) only tactile stimulation was provided (Stimulation; 4.1% of events)(Table 2). When dividing the events per type, the percentage of alarms that were responded to was 3% for apnoea, 16% for bradycardia, 2% for desaturation, 2% for oxygenation and 25% for combined events.

In general, short-lasting events (<20 seconds) were more common than longer lasting events (21-40 seconds, 41-60 seconds and >60 seconds), but were less frequently responded to (Table 3). For the events lasting >60 seconds, caregivers responded primarily to bradycardia events (11/12, 92%), followed by combination events (36/53, 68%), oxygenation events (3/6, 50%) and finally desaturation events (5/24, 21%). There were no apnoea events lasting > 60 seconds. For all 158 events that were responded to, the median response time was 25.4 (13.8-35.9) seconds.

Table 2. Event incidence, duration, response rate and response rate subdivided by event type

Event type	Number, n	Duration, median (IQR)	No response, n(%)	Response, n(%)	Response			
					Pause, n(%)	Devices, n(%)	Devices + stimulation, n(%)	Stimulation, n(%)
Apnoea	40	4 (3-7)	39 (97.5)	1 (2.5)	0 (0)	1 (2.5)	0 (0)	0 (0)
Bradycardia	344	12 (5-24)	288 (83.7)	56 (16.3)	13 (3.8)	8 (2.3)	5 (1.5)	30 (8.7)
Desaturation	855	9 (5-15)	836 (97.8)	19 (2.2)	8 (0.9)	3 (0.4)	1 (0.1)	7 (0.8)
Oxygenation	311	11 (5-20)	304 (97.7)	7 (2.3)	2 (0.6)	3 (1.0)	2 (0.6)	0 (0.0)
Combination	301	34 (20-54)	226 (75.1)	75 (24.9)	11 (3.7)	13 (4.3)	13 (4.3	38 (12.6)
Total	1851	11 (5-23)	1693 (91.5)	158 (8.5)	34 (1.8)	28 (1.5)	21 (1.1)	75 (4.1)

Table 2. Event incidence and response rate subdivided by event duration

Event duration	Number, n	No response, n(%)	Response, n(%)	Response			
				Pause, n(%)	Devices, n(%)	Devices + stimulation, n(%)	Stimulation, n(%)
0-20 seconds	1320	1305 (98.9)	15 (1.1)	8 (0.6)	3 (0.2)	0 (0)	4 (0.3)
21-40 seconds	320	273 (85.3)	47 (14.7)	14 (4.4)	8 (2.5)	4 (1.3)	21 (6.6)
41-60 seconds	116	75 (64.7)	41 (35.3)	7 (6.0)	10 (8.6)	5 (4.3)	19 (16.4)
>60 seconds	95	40 (42.1)	55 (57.9)	5 (5.3)	7 (7.4)	12 (12.6)	31 (32.6)

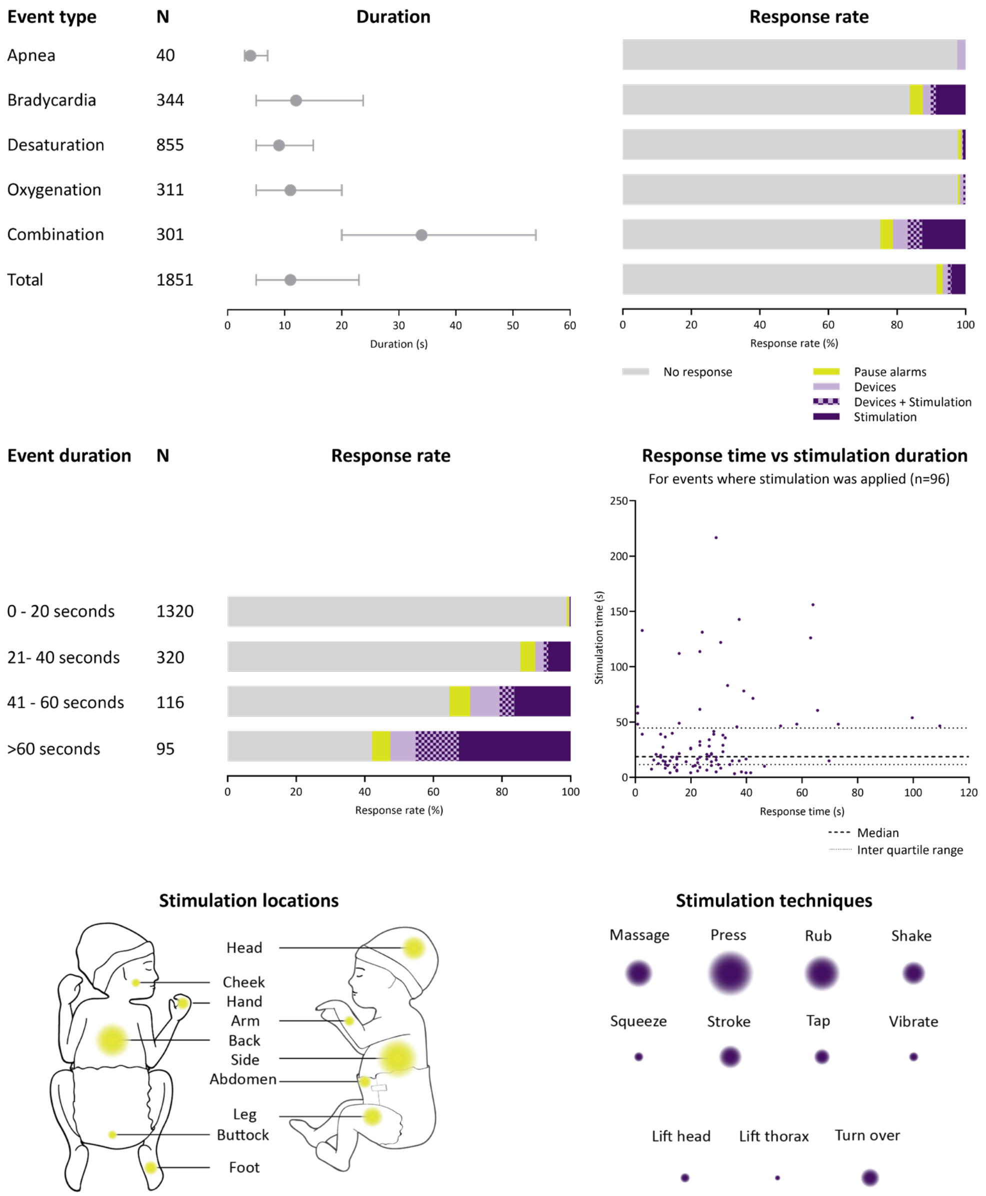

Figure 2. Overview of results showing (at the top) the number, the median (IQR) duration and response rate to the total amount of events and per event type, (in the middle) the number of events of different ranges in duration, the response rate to these events and a visual representation of the relation between event duration and response time and (at the bottom) a visual representation of the different stimulation locations and methods that where observed, with the size of the circle indicating the extent to which each occurred.

A binary logistic regression was performed to evaluate the association of the event duration on the likelihood that a caregiver responded to the alarms. The model was statistically significant, $\chi2(7)=52.4$, $p<0.001$, explained 31.8% (Nagelkerke R2) of the variance in response and correctly classified 91.5% of cases. A longer event duration was associated with an increased likelihood of response.

STIMULATION METHODS AND TIME

When tactile stimulation was applied following an event, this consisted on average of 2 (1-3) sequentially applied stimulation methods. There were 38 different methods observed, of which 35 consisted of a combination of 1 out of 10 identified stimulation locations and 1 out of 8 identified stimulation techniques (Figure 2). The other three methods involved interventions with a location specific tactile component: supporting the head, lifting the thorax and turning over to side or back.

The most selected locations for stimulation were the side (50%), back (40%) and head (20%) of the infants (Figure 2). Providing pressure on the skin, rubbing the skin and massaging the skin were the most used stimulation techniques (64%, 39%, 24%). Overall, the most common stimulation methods seen were providing pressure on the side (32%), rubbing the back (23%), providing pressure on the head (19%), massaging the side (15%) and shaking the side of the patient (11%).

Tactile stimulation lasted on average 18.7 (11.6-44.6) seconds per event and the completion time following stimulation was on average 30.6 (19.5-47.6) seconds.

DISCUSSION

This is the first study to provide a detailed description of current practice on how caregivers respond to cardiorespiratory events within a NICU. Using video recordings, we observed four ways of responding to cardiorespiratory events, of which providing tactile stimulation was most frequent provided, although with a large degree of variability in the way it was executed. However, our most important finding is that for the vast majority of events (>90%), no active response was provided, although longer event durations were associated with an increased likelihood of response.

Previous studies that looked at the response rate of NICU caregivers to alarms in general [7], and to hypoxia [8] and bradycardia [9] alarms specifically, reported similar results. From our data we hypothesize several different causes that could be responsible for the low response rate that is generally reported. Firstly, the majority of events in this population are short-lived and therefore likely to be resolved before a caregiver is able to respond.

This is reflected by the fact that the median duration of events in our study was 11 seconds while the average response time was 25 seconds. Another explanation is that caregivers deliberately wait to intervene to see whether the patient recovers on its own in order to minimize unnecessary interruptions in their work [7] and/or with the intention of minimal handling. This could clarify why in our study caregivers responded by pausing the alarms but refrained from intervening thereafter. However, the fact that in 40% of long-lasting events (>60 seconds) any form of response was omitted makes it plausible that unintentional non-response due to for example alarm fatigue or high workload also frequently occurs [7, 10].

In addition to pausing the alarms, caregivers responded by checking and adjusting medical devices on the infant, providing stimulation or a combination of both. While the idea of adjusting the medical devices is probably to remove (possible) external causes of the event, such as a displaced and leaking CPAP mask, tactile stimulation is provided in order to assist the recovery of the patient. Manually providing NIPPV or increasing the FiO2 level would serve the same goal, but these responses were not observed in our study. We assume that this is the result of utilizing the OxyGenie algorithm in 17/19 of the included patients, acting directly on a fall in SpO2. Although caregivers can manually override the FiO2 settings of the algorithm, a previous study in our centre showed that this is rarely done [11]. In addition, applying Oxygenie is probably the reason why tactile stimulation was mainly observed in response to bradycardia and combined events, particularly as it is believed to positively affect respiratory effort and oxygenation [12-15]. The relatively high response rate to bradycardia events, including both HR<80 and HR<100 alarms, stands out because HR<100 alarms were not transferred to the caregivers' handhelds and thus may have resulted in less and/or delayed awareness compared to apnoea, desaturation and oxygenation events. It is possible that the caregivers consider a high chance of spontaneous recovery without (tactile) intervention and rely on the automated response of the Oxygenie, even in the case of long lasting desaturation.

In accordance with previously reported manikin studies [6, 16], our data shows that when caregivers do choose to apply tactile stimulation, they use a wide range of different methods. Contrary to what caregivers showed on a manikin, stimulation was most commonly applied to the torso and in the majority of cases consisted of at least providing static pressure. Very vigorous interventions, such as turning over the infant or lifting the thorax were far less common. On average, the stimulation duration was shorter than the completion time of the event, which again seems to imply that caregivers are reticent in intervening.

Recognizing it is impossible for caregivers to respond to all events, it is unclear whether the apparent current reticence and prudence regarding active intervention is justified and desirable. While evidence exists that excessive exposure to stimuli is associated with adverse consequences in the short and long term [17-19], others report beneficial effects of tactile intervention [20-23]. Despite the fact that caregivers focus mainly on longer events, short-lasting and self-limiting events might also benefit from active intervention as they contribute substantially to physiological instability – and thus clinical outcome – given their numerical preponderance [24]. Automated response systems could aid the caregiver in maintaining or restoring cardiorespiratory stability of the patient. However, the trade-off between the possible burden and benefit of timely intervention needs further research.

This study is limited by the fact that it is a single-centre design, in which the results are affected by a wide range of factors that are unique for our unit, particularly the use of automated oxygen supply, type of monitoring devices used, alarm settings, architectural ward layout, patient population and alarm culture [7, 8, 25-30]. The distribution of the number of alarms in our study is however exemplary for a preterm population, with the vast majority of events being due to desaturation, followed by bradycardia and apnoea . The proportion of apnoea events is indeed low, which is likely attributable to the fact that apnoea alarms based on respiratory impedance are silenced in our unit and the ventilator's apnoea alarm is only activated by default during NIPPV. Finally, the caregivers might have adjusted their behaviour due to awareness of the recordings. However, we expect this effect to be small, given the long study duration and the placement of the camera underneath the covers of the incubator. Although our results require verification by other NICU's, it gives a unique first impression of the reactive responses to cardiorespiratory events in preterm infants.

CONCLUSION

We observed caregivers in the NICU using a video-observation study in order to quantify their responsiveness to cardiorespiratory events. In >90% of the recorded events no response was observed, although an increased event duration was associated with a higher response rate. Tactile stimulation was the most performed intervention, but with a large variability in execution. Our results emphasize that the indication, timing and execution of responses to cardiorespiratory events in preterm infants is very subjective and optimal response to these events is currently unknown.

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SUPPLEMENTAL MATERIAL

CARDIORESPIRATORY ALARM SETTINGS

Alarms that are activated for cardiorespiratory monitoring by default are (1) low heart frequency (HF<100 bpm) and bradycardia (HF<80 bpm) alarms originating from the electrocardiogram (ECG) signal via the Philips monitor, (2) desaturation alarms (SpO2<90%) originating from the ventilator's built-in pulse oximeter (Masimo SET, Masimo, USA), (3) alarms indicating an (automated) increase in FiO2 above a set limit (FiO2>0.6) originating from the ventilator and (4) alarms indicating a steep automated increase in FiO2 (0.05 over 30 sec) originating from the ventilator. Apnoea alarms based on impedance from the ECG leads are disabled but apnoea alarms originating from the ventilator's pressure breath detection module (no breaths detected for 15 sec) are occasionally activated on discretion of the caregiver. Only a selection of these alarms is transferred to the handhelds of the caregivers, including apnoea, bradycardia, desaturation and alarms related to the automated FiO2 titration. During the study, caregivers were allowed to deviate from the default settings as we were primarily interested in the response to the alarm, irrespective of its limit.

Table S1. Overview of cardiorespiratory alarm settings

Event type used for data analysis	Alarm type	Detection method	Device	Default alarm limit	Status	Transferred to handheld caregivers	Delay/
Apnoea	Apnoea	Impedance via ECG leads	Philips patient monitor	-	Disabled	No	N/A
	Apnoea	Breath detection via a pressure line	SLE 6000	No breath detected for 15 seconds	Activated on discretion of the caregiver	Yes	None/None
Bradycardia	Low heart rate	ECG	Philips patient monitor	<100 bpm	Activated by default	No	None/12 most recent R-R intervals
	Bradycardia	ECG	Philips patient monitor	<80 bpm	Activated by default	Yes	None/12 most recent R-R intervals
Desaturation	Desaturation	SpO2 via pulse oximeter	Masimo SET module build in SLE6000 ventilator	<90%	Activated by default	Yes	None/2-4 seconds
Oxygenation	High FiO2 requirement	Oxygen sensor	SLE6000, Oxygenie	FiO2 > 0.6	Activated when OxyGenie is used	Yes	None/None
	Steep automated FiO2 increase	Oxygen sensor	SLE6000, Oxygenie	0.05 increase over 30 seconds	Activated when OxyGenie is used	Yes	None/None