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Short Research Article

Carbon Dioxide Level in Neonatal Incubator: A Comparative Study of Two Baby Air Flow Input Methods in Incubator Chamber

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Abstract

Preterm neonates often have to spend a long time in incubator which simulates necessary enviromental conditions to maintain patients in stable condition. Authors have found neglected problem with Carbon Dioxide (CO2) concentration in newborn inhaled gas when using "oxygen hood" into infant incubator that has not been studied very closely. Methods in this experiement were carried out as condition monitoring while changing some parameters and positions. Results have shown that CO2 level is letally high in some aspects. Situation is alarming as CO2 level in incubator is not limited by current regulation, as IEC60601-2-19: 2009 +A1:2016. Currently the Incubator manufacturers declare that CO2 maximal concentration should be periodically checked by users, which are hospitals. Some commercially available incubators have the maximum allowed CO2 level 8000 ppm, which is much higher than recommended 2000 ppm CO2 level in indoor working place. There is no limitation of maximal level of CO2 using "oxygen hood", which are specified in incubator operation manual. This paper goal is to show the correlation of CO2 level versus gas flow into oxygen hood.

Keywords

Incubators, Neonates, Carbon Dioxide, CO2 level, indoor air

1. Introduction

With no doubt seems that modern medicine system has been developed high tech care cabinets for newborn infants, but nevertheless there are still some effects being unresolved. Thus, preterm infants are still in great danger of having functional disorders during intensive care (Soudabeh, LaTrice,

Melissa, & Sue, 2021).

1.1 Factors Affecting Infant Health

Research studies has shown that preterm infants develop large amount of stress that further manifests as health, sensory and cognitive deficits (Rachel et al., 2008). The neonatal intensive care unit (NICU) plays an essential role in preservation of premature baby stable life conditions. One of the main indicator which signalizes about infants condition is their sleep. Previous studies have shown many influencing factors and the main problematics which doctors and nurses in NICU should take care about (Debra, Diane, & Dawn, 2005). System of health affecting factors is very complex and diverse which makes hard for doctors to find the right treatment plan. Despite the complexity and unresolved issues, authors have found that there is one very important factor that have not been studied a lot – carbon dioxide level influence on premature babies health. These studies are based on air regulation process in incubator camera affecting total CO2 and O2 concentration ratio which is essential for infant well-being during intensive care.

1.2 Current Manufacturer Regulations for CO2 Level in Incubators

According EU Directive 93/42/EEC (Note 1), follows the Medical electrical equipment standard BS EN 60601-2-19:2009+A1:2016 (Note 2), which declares that manufacturer shall specify the maximum CO2 concentration which will occur in the compartment under normal conditions. This regulation allows manufacturers to produce equipment as they see fit, without any CO2 limitations or thresholds to monitor which becomes utterly dangerous to newborn health system.

1.3 Action Programm

High CO2 level can be regulated by air circulation system in chamber and also by mixing O2 and air concentration in input. Taking into account EN 60601-2-19:2009 regulation, air velocity cannot excend 0.35 m/s.

CO2 level directly depends on chamber volume and flow velocity.

1.4 Objective

During studies question occured, why the regulation does not limit the level of CO2 in the incubator chamber, when in the workplace adults have long had research on how CO2 adversely affects the human body in elevated CO2 conditions (Note 3, Tyler, Jasdeep, Michael, Rudolf, Keith, & William, 2019). There are also studies taken on rats. The role of CO2 and central chemoreception in the control of breathing in the fetus and the neonate which ephasizes big CO2 role on neonate development (Robert, 2010). At the same time, incubator manufacturers are not limited to maintain certain CO2 level. IEC60601-2-19: 2009 +A1:2016 regulated parameters, like noise level and maximum air velocity might be maintained as well by decreasing air ventilation and as a result, increasing the CO2 level. Same commercially available incubators have the maximum allowed CO2 level up to 8000 ppm, which is 4 time higher than recommended <2000 ppm CO2 level in indoor working place (Note 4).

2. Materials and Methods

Tests were carried out at Armgate Ltd laboratory. Alltogether experimental part took 4 weeks. Measurements have made no harm to human health, in process were used baby doll with tube inserted in the doll mouth. Test has been done according EN 60601-2-19:2009, which simulated breathing process as an infant.

2.1 Short Description about Draeger Incubator

Incubator model Caleo from manufacturer Draeger (Note 5) was used in experimental part. Current model in comparison with the most popular and high rated incubators ranks around in the middle. Incubator has specification: <0.5 Vol% of maximum Carbon Dioxide (CO2) concentration in the incubator measured in accordance with IEC 60601-2-19. Authors choose this incubator model because it has very similar parameters with the most common incubators in hospitals (with CO2 level specified <2000 ppm - < 8000ppm).

2.2 Compared Model Position Description

Two different baby model situations were compared:

(1) Positions without head hood in Caleo chamber;

(2) Positions with head hood in Caleo chamber.

Compared positions were simulated by following conditions:

(1) The same air mixture concentration ratio;

(2) The same incubator humidity level and tempearture level;

(3) One location for measurement probe in the first position (as regulation has definied 15 cm above infants matress);

(4) Two locations for measurement probe in the second position (first location: as regulation has definied 15 cm above infants matress, second location: next to the infant head on matress).

2.3 Data Managment and Process Programms

All tests were done with Testo multifunctional instrument Testo 480 (Note 6). Data were processed by software EasyClimate 3.4 and MS Excel programm. Incubator condition was checked by Fluke INCU II incubator tester (Note 7). The equipment was calibrated before measurements.

2.4 Method Type

Authors choose experimental laboratory method, which is condition monitoring in infant chamber by changing input air flow parameters.

3. Results and Discussions

The results are presented in Table 1. As can been seen from Figure 1, very large impact causes head hood, it can be explained by air volume change. Table 1 illustrates flow differences between those two positions, which shows that during process with head hood on the baby there were no flow detected in probes measuring range (+-0.1 cm/s). That leads us further to suspect that conditions for baby can not be optimal, there are not enough air exchange and CO2 level has been far too high.

Table 1. CO2 Level and Flow Velocity Differences between Two Baby Model Positions

Flow volume, l/min	Average CO2 level, ppm (without head hood) $p < 0.05$	Average CO2 level, ppm (with head hood) $p < 0.05$	Flow velocity, cm/s (without head hood)	Flow velocity, cm/s (with head hood)
2	1078	6786	4,5	0,0
4	1090	7631	4,9	0,0
6	1103	7469	3,2	0,0
8	1107	7330	2,7	0,0
10	1099	6334	5,2	0,0
12	1092	6310	4,1	0,0

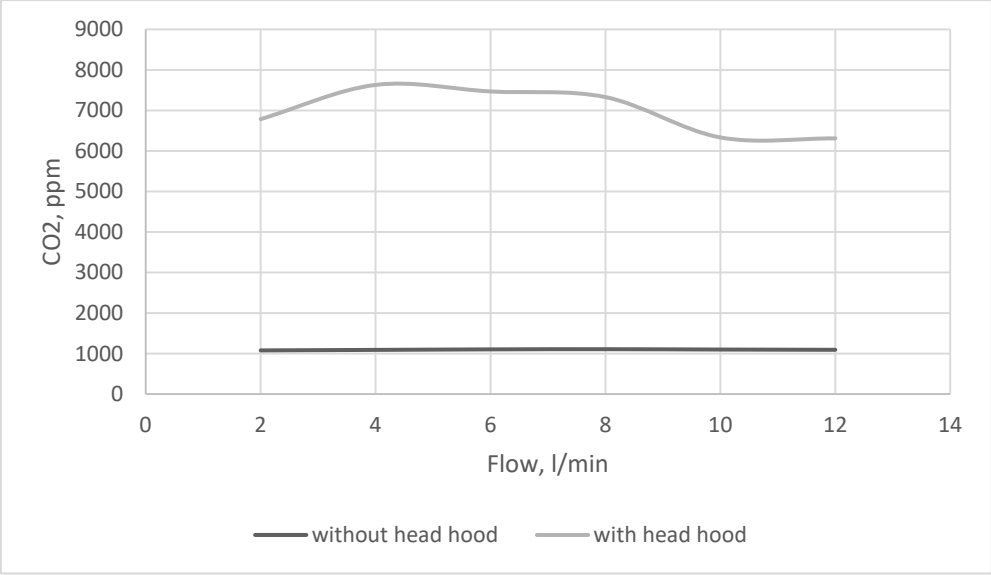

Figure 1. CO2 Diffreneces between Baby Position with Head Hood and without Head Hood

Since in NICU common procedure is to use head hoods, authors decided to run additional tests to discover case with head hood more closely.

Situation was simulated with 4 l/min flow rate with two standard positions, where infant is in head hood and the third position, where infant had been given more air space in head hood comparing with two previous positions. Figure 2 shows highly dangerous situation for infant health. Probe is measuring from low position, which means that air cloud which surrounds an infant is with high CO2 concentration level.

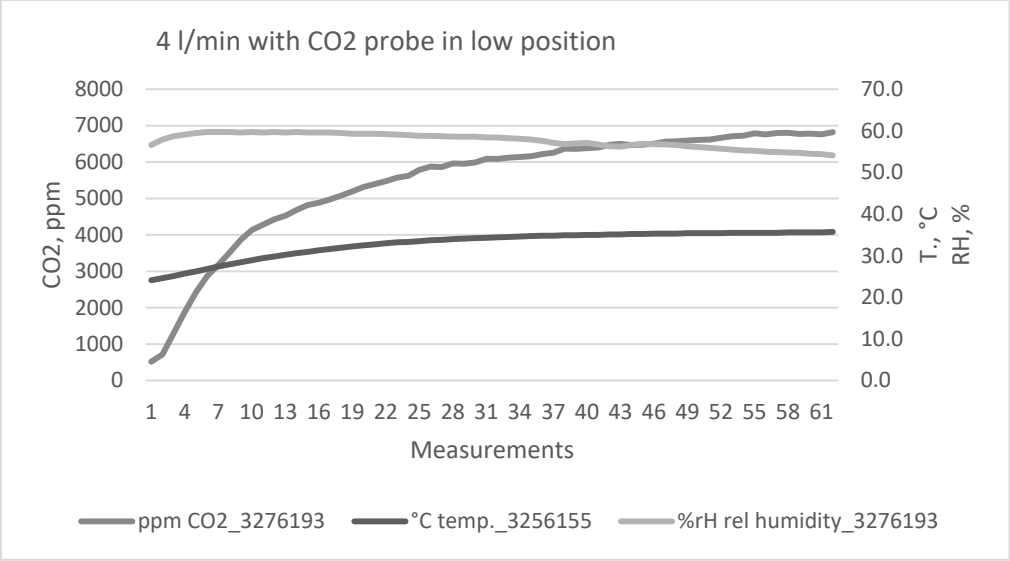

Figure 2. Infant Enviroment Conditions with Head Hood. Probe is Located in Low Position

Interesting data occured when the same situation has been monitored from EU regulation aspect – 15 cm above the matress. See Figure 3.

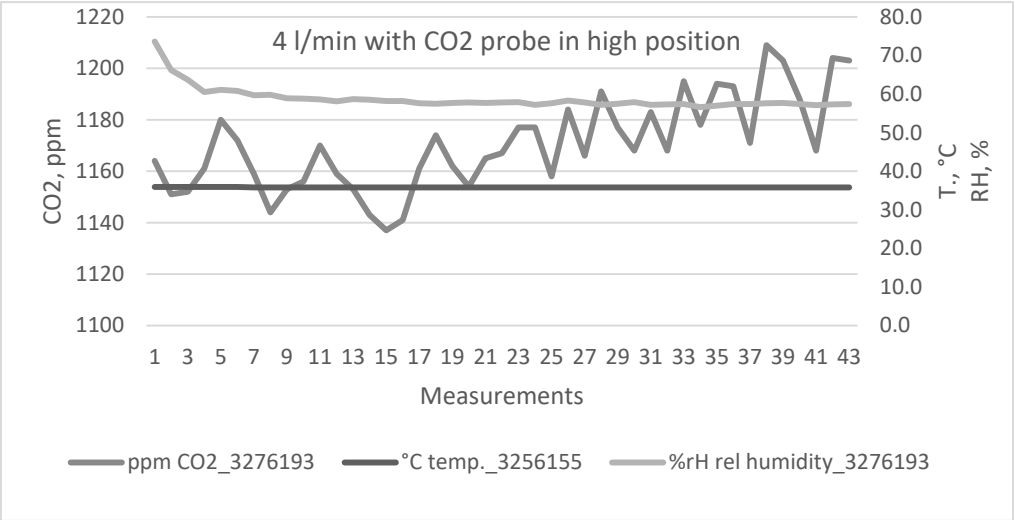

Figure 3. Infant Enviroment Conditions with Head Hood. Probe is Located in High Position

Data shows that CO2 level is fluctuating and slowly growing higher, but still CO2 level is in acceptable level. These results emphasizes that in head hood there are two air layers, one with acceptable concentration, another with dangerous concentration, whick leads us further to conclude, that there is need to increase air flow. Continuing test session, infant was simulated with around 1/3 bigger breathing space options comparing with two previous measurements. As can been seen from Figure 4, results were shocking, CO2 level was letally high and fluctuating between 8200 ppm and 9400 ppm. Which means that the problem has to be studied more closely.

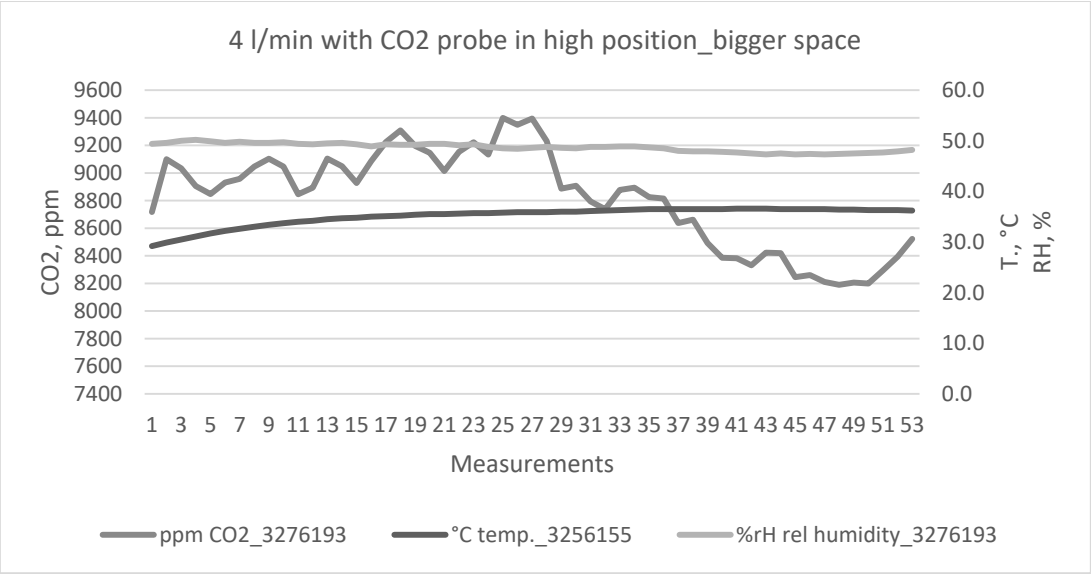

Figure 4. Infant Enviroment Conditions with Head Hood with Bigger Breathing Space. Probe is Located in High Position

The results are very different from each other, which leads us to discussion, that this problem is not studied enough. Society still needs new research work on infant chamber development and interdependance of parameters which allows technology to control chamber environment depending on infant health conditions.

4. Conclusions

The resulting material allows to draw following conclusions:

(1) Studies have shown that CO2 level for baby in position with head hood is possibly endangering cognitive system and development process;

(2) Air velocity is important for CO2 concentration and oxygen/CO2/AIR gas layer mixing. Increasing flow from 3 l/min to 10 l/min showed that is not effective enough to achieve CO2 level to at least recomended <2000 ppm for indoor working place;

(3) CO2 dependance from different aspects still needs to be studied more closely;

(4) CO2 level monitoring under the head hood is reccomended when head hood is used.

The reccomendation is to discuss within neonatologists and incubator vendors community to work out regulation for limitation of max CO2 level in incubators.

Acknowledgments

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Tyler, A. J., Jasdeep, S. K., Michael, T. H., Rudolf, K. B., Keith, C. M., & William, E. F. (2019). Direct human health risks of increased atmospheric carbon dioxide. *Nature Sustainability*, *2*, 691-701. https://doi.org/10.1038/s41893-019-0323-1

Notes

Note 1. EU Directive, Medical Devices directive, 1993, https://www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF

Note 2. British Standard, Medical electrical equipment, Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators BS EN 60601-2-19:2009+A1:2016, (IEC 60601-2-19:2009), https://www.en-standard.eu/bs-en-60601-2-19-2009-a1-2016-medical-electrical-equipment-particular-requirements-for-the-basic-safety-and-essential-performance-of-infant-incubators/

Note 3. Occupational Safety and Health Administration, https://www.osha.gov/dts/osta/otm/otm_iii/otm_iii_2.html

Note 4. Medical Device Databases, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/default.cfm

Note 5. Drager Ltd., https://www.draeger.com/en-us_us/Home

Note 6. Testo 480, https://www.testo.com/en-UK/products/testo-480

Note 7. INCU™ II Incubator Tester, https://www.flukebiomedical.com/products/biomedical-test-equipment/incubator-radiant-warmer-analyzers/incu-ii-incubator-radiant-warmer-analyzer