
- AN EVALUATION OF MB-MASK 203 WITH BREATHING INDICATOR

A co-operation between Danderyd hospital AB and
MB Filter Products AB.



Rapport

17 June 2005



Danderyd hospital

1. Summary

This report contains an evaluation of a new type of breathing mask for oxygen treatment of patients: MB-mask 203 with breathing indicator.

The evaluation is a co-operation between MB Filter Products and Danderyd hospital AB.

The task of Danderyd hospital was to provide MB Filter Products with the following:

- Risk analysis
- Expertise and advice regarding CE-certification.
- An evaluation of MB-mask 203 used in pre-hospital care in the Stockholm area.
- A comparative test of the MB-mask and another breathing mask available on the Swedish market.

The risk analysis is made in accordance to SS-EN ISO 14971. The result of the risk assessment shows that MB-mask 203 meets the demands stated by the law (1993:584) on medical device products and also the regulations in LVFS 2003:11 on medical device products and can therefore be CE-certified. A simple manual linked to the risk assessment has been developed.

Ambulance personnel employed in pre-hospital care in Stockholm have made an evaluation of MB-mask 203. The result of the evaluation has been summarised and is presented in the report.

Generally, health professionals who have tried the mask are very satisfied with its functionality and design.

A comparative test with another mask available on the market shows the advantages of MB- mask 203. Danderyd hospital is not responsible for the functionality, performance, complaints, and possible compensation claims of defective masks. The co-operation between Danderyd hospital and MB Filter Products has been very good and the project was finished within scheduled project time.

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2. Purpose

To evaluate the safety and functionality of a new type of breathing mask, MB-mask 203 with breathing indicator, for oxygen treatment of patients. MB-mask 203 is designed for use in healthcare.

3. Scope

User-friendliness, technical qualities, and safety of the MB-mask have been tested and evaluated by personnel at Danderyd hospital. A risk analysis according to ISO 14971 (appendix 2) with reference to LVFS 2003:11 has been performed and an easy-to-use manual (appendix 3) connected to the risk analysis has been developed. These form the basis of the CE-certification of MB-mask 203. Ambulance personnel in the pre-hospital health care in Stockholm have evaluated MB-mask 203. This evaluation is included in the present report. A comparative test between MB-mask 203 and another mask available in the market, measuring effectiveness of oxygen supply and letting out of carbon dioxide, has been made at the hospital's medical technical unit (MTA). However, Danderyd hospital is not responsible for the MB-mask's functionality, performance, and possible compensation claims. The evaluation has taken ten weeks to finish.

4. Background

Danderyd hospital/DS Innovation provided MB Filter Products with an evaluation of a new type of oxygen mask, developed by MB Filter Products, during spring 2005. A paramedic Paul Eksell, who works with oxygen masks on a daily basis, brought up the idea of a filtering oxygen mask. This filtering oxygen mask could better meet the needs of a patient in need of oxygen treatment during ambulance transports. MB Filter Products have further developed the mask and equipped it with a breathing indicator and re-established contact with DS Innovation at Danderyd hospital in order to perform an evaluation of the mask. MB Filter Products have chosen to make this evaluation of their product in co-operation with Danderyd hospital so that safety and user-friendliness of the masks could be assessed for the impending CE-certification and also to make use of the good reputation of the hospital.

5. References

1. Rulebook for medical device products LVFS 2003:11
2. The law on medical device products SFS 1993:584

6. Those responsible

Chief supervisor: Lars Carlsson, MTA, Danderyd hospital

Project buyer: Stefan Persson, MTA

Project leader: Olle Hillborg, MTA

Project owner: MB Filter Products

7. Implementation

7.1 Evaluation

An evaluation of MB-mask 203 was performed by Danderyd hospital.

The evaluation consists of four parts:

- Risk analysis
- Fulfilling the demands made in regulations LVFS 2003:11
- An evaluation of the MB-mask in pre-hospital health care in the Stockholm area.
- A comparative test between the MB-mask and another breathing mask available on the market.

7.1.1 Risk analysis

A risk analysis in accordance with ISO 14971 has been made (appendix 2) and forms the basis for the CE-certification of MB-mask 203. CE-certification is a prerequisite for the mask to be tested by patients. The purpose was to verify the safety of the MB-mask.

The areas taken into consideration in the risk analysis are:

- Energy (mechanical force, moving parts, etc).
- Biological factors (material used, infections, gas supply, etc).
- Environment (contamination, waste products, etc).
- Incorrect usage (unqualified personnel, complicated usage instructions, etc).
- Functionality, maintenance, and ageing (durability).
- The human factor (incorrect connections, incorrect application, etc).

7.1.2 Fulfilling the demands made in prescriptions LVFS 2003:11

A further prerequisite for the MB-mask to become CE-certified is that it satisfies demands made by the Medical Products Agency in LVFS 2003:11 (appendix 1), regarding construction and manufacture. MB-mask 203 with breathing indicator is considered to satisfy the requirements.

7.1.3 The MB-mask evaluated by ambulance personnel

An evaluation of the MB-mask has been made by ambulance personnel employed in pre-hospital health care within the Stockholm area. The evaluation consisted of a questionnaire (appendix 5) that was answered by the ambulance personnel. The results of this evaluation have been compiled and are described as follows:

- o **Evaluation of MB-mask 203**

Questionnaires answered in total: 17

1 questionnaire / patient, 11 paramedics

The replies were answered on a scale from 1-5, where 5 corresponds to full agreement. The results of the evaluation is compiled and described as follows:

1. The product is easy to apply on patients?

All in all: Agree fully!

Grade: 5, 0

Comments:

- The MB-mask has a good fit despite the varying shapes of face of patients.

2. Is the patient able to communicate well when wearing the mask?

All in all: Agree fully!

Grade: 4,8

Comments:

- Very good, communication is much alleviated!
- The patient is heard loud and clear!

3. Is the connection to the oxygen source functioning well?

All in all: Agree fully/partially!

Grade: 4,6

Comments:

- An extra tube is needed.
- A little fiddly to attach the tube to the mask's small nipple.

4. Does the mask's breathing indicator function well?

All in all: Agree fully!

Grade: 4,9

Comments:

- The new MB-mask with breathing indicator is an improvement. It is easier to count the breathing rate than without a mask! The click that the breathing indicator emits is very easy to count.
- Yes, it is clearly visible.
- Counting breathing rate becomes more natural.

5. The product is reliable and functions properly?

All in all: Agree fully!

Grade: 5,0

Comments:

- Good reaction of absorption of oxygen. The patient was quickly saturated.
- Saturation increases quickly.
- Good effect even when using low oxygen flow.

6. Do you think that the patient is safe when using the MB-mask?

All in all: Agree fully!

Grade: 4, 9

Comments:

- Comfortable!
- Bad fit due to patient's beard.

7. Do you feel safe when using the MB-mask?

All in all: Agree fully!

Grade: 4, 9

Comments:

- Filter in the mask between patient and carer.

8. Does using the MB-mask alleviate your work?

All in all: Agree fully!

Grade: 4,9

Comments:

- Counting the breathing rate is very easy.
- Nice to have protection against germs.
- Good that it also protects against dust.
- The patient feels better with a good mask that is efficient and the application is the same.

9. Could other units within health care find the MB-mask useful?

All in all: Agree fully!

Grade: 4, 8

Comments:

- For example infection units.
- When treating patients carrying airborne diseases.
- Emergency clinics.

- Any clinic where oxygen is administered.

10. Is the MB-mask suitable for use in medical care?

All in all: Agree fully!

Grade: 4, 8

Comments:

- What happens if the mask gets soaked due to heavy rain?
- Seems to be effective even at low oxygen levels.

11. Would you like to recommend others to use the MB-mask?

All in all: Agree fully!

Grade: 4, 8

Comments:

- Fits the face nicely and is therefore very efficient.

- **OTHER QUESTIONS**

How much would you be willing to pay for this product?

Comments:

- I don't know.
- No opinion.
- A little more than one would pay for ordinary masks, as the MB-mask is clearly better.

Due to the filter material used in the mask it retains the moisture from the patient's exhalations. How do you think this affects the patient?

Comments:

- Does not make the airways dry and sore.
- Positively.
- No dry mouth as is the case when using plastic oxygen masks.
- The patient gets a runny nose.
- Better for the mucous membranes.

- Some patients find that it gets a little warm under the mask but other than that comments have been positive.
- Of course, this is good both for patient and carer.

As the MB-mask is not transparent it becomes more difficult to notice blue lips as a result of bad oxygen concentrations. In order to compensate for this the MB-mask has been fitted with a breathing indicator. To what degree is the usage of the MB-mask affected due to it not being transparent? Is the application of the breathing indicator a good solution to make it possible to count breathing rate and to assess volume per minute?

Comments:

- Not affected at all, cyanosis can be seen on the patient's nail bed and on saturation meters.
- Regular oxygen masks become foggy, which also leads to diminished visibility of the patient's lips.
- No problem.
- Yes, very good, an improvement!
- Easy to count breathing rate.
- It would be nice to see the mouth.

7.1.4 Comparative test

A comparative test was made, focusing on effectiveness in oxygen supply and oxygen levels in the mask during exhalation, between MB-mask 203 and another oxygen mask available on the market (plastic mask without reservoir, fig 1).



A test facility was constructed to simulate the gas exchange that occurs in oxygen treatment of patients.

A Plexiglass sheet was used onto which a silicon sheet was fastened. A loop kept the mask in place. Into a hole on the back of the sheet a tube was fastened with an inset rubber tube out of which oxygen (100%) that was connected to the mask's nipple was sampled (side stream). At the same time a test subject breathed into the tube's nozzle. Measured values at different oxygen flows and breathing rates were registered and are presented here in fig 4 and fig 5.

In order to acquire a measurement of the carbon dioxide level in the air that was still inside the mask after exhalation, a test probe was inserted into the mask, and carbon dioxide was measured at each inhalation and exhalation. The results of this procedure at different oxygen flows and breathing frequencies were registered and are here presented in fig 5 and fig 6.

Please note that these measurements are not completely statistically reliable and only registered as a rough comparison between the oxygen masks mentioned above.

Results:

The results of the measurements made show that MB-mask 203 delivered a little more oxygen in inhalation air than the other mask. One reason for this can be that the material in MB-mask 203 is more penetrable and therefore the gas exchange with the surrounding air is increased. Another theory is that the plastic mask's larger 'dead space', a closed lower portion of the mask, results in a lower volume of oxygen during inhalation.

The measured amounts of carbon dioxide show that MB-mask 203 generally had lower carbon dioxide measurements. A theory that could explain this fact is that the material in MB-mask 203 allows carbon dioxide to escape.

MEASUREMENTS

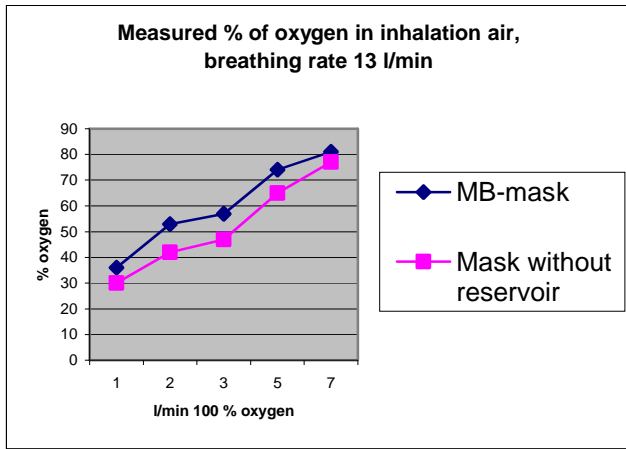


Fig 4

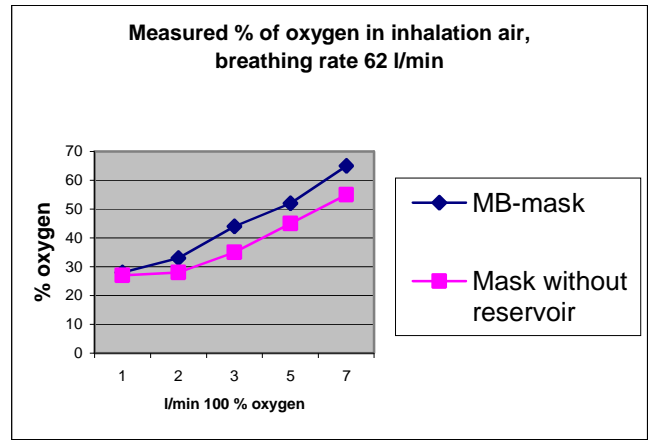


Fig 5

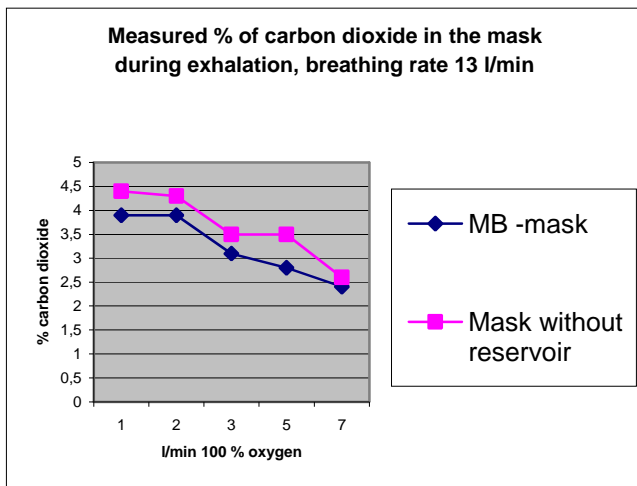


Fig 6

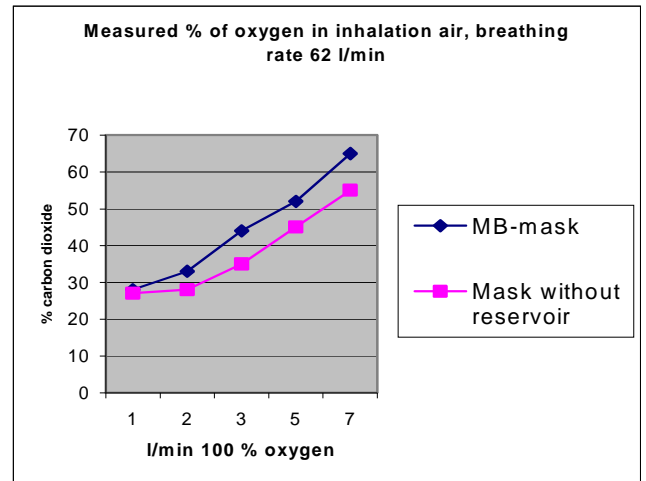


Fig 7

8. Results

The result of the risk analysis (appendix 2) that has been made shows that MB-mask 203 with breathing indicator meets the demands stated by law (1993:584) on medical device products and the demands in regulations LVFS 2003:11 on medical device products. Therefore, MB-mask 203 could be used and evaluated in pre-hospital care in Stockholm.

A simple manual (appendix 3) containing handling instructions for the MB-mask has been developed and used in the evaluation.

The patients and the nursing staff involved in the evaluation of the MB-mask have generally found the MB-mask very satisfactory. They experienced the MB-mask as comfortable, functional and easy to use. The MB-mask with its advantages, among others the breathing indicator, has been shown to function extremely well in oxygen treatment of patients.

Comparative tests between the MB-mask and another oxygen mask (plastic mask) available on the market show that the MB-masks supplies oxygen and let out carbon dioxide at least as well as the other mask.

The co-operation between MB Filter Products and Danderyd hospital AB has been very satisfactory. A simple and open-minded dialogue between the two has enabled a positive result of the evaluation of MB-mask 203 with breathing indicator.

Lars Carlsson
Head of operation MTA
Danderyd hospital AB

9. Appendix

1. Essential demands. 17 June 2005
2. Risk analysis according to SS-EN ISO 14971. 17 June 2005
3. Handling instructions & routine maintenance. 17 June 2005
4. Affirmation about agreement. 17 June 2005
5. Questionnaire