



URGENT – Field Safety Notice

To all users of the Aerosol Mask (Adult) With Connecting Tube

Re: Aerosol Mask (Adult) With Connecting Tube with potential insufficient output of the medication mist.

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients/user when using the Aerosol Mask (Adult) With Connecting Tube of Mymedic Oxygen Therapy Device which can be identified by our product details as listed below:

Product	Product Code	Item Code	Lot. No
Aerosol Mask (Adult) With Connecting Tube	13.3803.04	AM11107	AM107-2402
			AM107-2405

When does this malfunction occur and what are the potential risks?

Mymedic Innovation Sdn Bhd had received complaint of Aerosol Mask (Adult) With Connecting Tube from Klinik Kesihatan Spaoh, Klinik Kesihatan Bintangor and Klinik Kesihatan Pertang. The complaints described an insufficient output of medication mist during nebulization procedure. The potential insufficient output of medication mist may result in reduced delivery of prescribed medication to the patient, which could affect the effectiveness of the treatment.

What steps can the user take to avoid the potential risk of this issue?

To avoid the potential risk of an insufficient output of medication mist, users can implement the following action:

- **Stable oxygen pressure**
Users shall ensure that the oxygen pressure supply from wall port, portable port or oxygen tank is stable and functioning properly before and during use.
- **Mist output monitoring**
Users are advised to monitor mist output during use. If insufficient mist is observed, discontinue immediately and replace it with a new unit.

How will the issue finally be resolved?

Affected users may contact the establishment for product replacement at no additional cost. Further instructions regarding return or disposal of affected units will be provided upon contact.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.





MYMEDIC INNOVATION SDN BHD 200601037776 (757536-K)

No. 8, Lorong Sukepi 1, Off Jalan Sukepi, Kawasan Perindustrian Jenjarom,
42600 Jenjarom, Selangor Darul Ehsan

+60 3 3191 4868 enquiry@mymedic.com.my

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours

Mohamad Farkhan Bin Damri
Director
Mymedic Innovation Sdn Bhd

Contact person of this notification:

Department : Product Compliance
Telephone : 03-3191 4868 (ext 106)
Fax : 03-3181 7868
E-mail : productcompliance@mymedic.com.my



www.mymedic.com.my



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Acknowledgement of receipt

I hereby confirm as the owner / responsible operator of the *Aerosol Mask (Adult) With Connecting Tube* with the lot number AM107-2402 and AM107-2405 that I received the following document:

Field Safety Notice

Aerosol Mask (Adult) With Connecting Tube with insufficient medication output risk.

Place : _____
Date : _____
Name : _____

Signature : _____

Company stamp:



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