

URGENT: MEDICAL DEVICE RECALL

Date: [Insert Date]

To: [Patient Name]

Address: [Patient Address]

Device Model: [Insert Model Name/Number]

Serial Number: [Insert Serial Number]

Dear Patient,

This letter is to inform you of a voluntary medical device recall initiated by [Manufacturer Name] regarding your BiPAP device. We have identified a potential issue where the device may deliver air pressure that is different from the settings prescribed by your physician.

Reason for Recall:

Internal testing has identified a software or hardware variance that may cause the device to provide inaccurate pressure levels. Incorrect pressure settings may lead to ineffective therapy, shortness of breath, or discomfort.

Required Actions:

- Contact your prescribing physician to discuss your treatment plan and the risks of continuing or discontinuing therapy.
- Register your device at [Website URL] or call [Phone Number] to coordinate a repair or replacement.
- Ensure your device software is up to date if an over-the-air update has been released.

Safety Precautions:

If you experience any new or worsening symptoms, please contact your healthcare provider immediately. If you notice the device making unusual sounds or if the airflow feels significantly different, stop use and contact our support team.

We apologize for this inconvenience and are committed to ensuring your safety and the effectiveness of your therapy.

Sincerely,

[Name of Representative]

[Title]

[Company Name]

[Contact Information]