

To: All MAXAIR Systems Users

Subject: An Urgent Reminder To Not Leave Batteries On Chargers After Fully Charged

Previously you received a notice from Bio-Medical Devices, Inc., the manufacturer of your MAXAIR PAPR System. We introduced a MAXAIR Ensure Readiness program to all of our many healthcare users. The program called your critical attention to the proper care and handling of the lithium-ion batteries (LIB) and chargers which you purchased. We pointed out that this program was designed to provide your institution with a trade-in¹ program with significant discounts to upgrade older batteries and older technology chargers in order to avoid potential hazards that are known to occur with the aging of the batteries and specific chargers.

While MAXAIR Systems have a very reliable history – perhaps the longest duration of any LIB powered PAPR System, our attention to the recent occurrences with LIB use in general has prompted our own studies of the MAXAIR batteries in use. Those studies and input from independent consultants, prompted us to offer the Ensure Readiness Program. And, at the same time, we want to remind our users of the important guidelines to better assure the safety and effectiveness of MAXAIR through vigilant oversight of the aging batteries and chargers that may be still in your possession.

1. Do not leave a MAXAIR LIB connected to its MAXAIR Charger any longer than necessary for it to reach its fully charged status, as indicated by the Charger LED being lighted Green when the two are connected with the Charger powered on.

Maximum charge times must never be exceeded without recognizing the potential of causing a catastrophic incident. Refer to our Ensure Readiness Program, Technical Bulletin, and User's Instructions.

A healthy LIB will maintain its full charge to within approximately 90% or higher for as long as a year; there is essentially no benefit to keeping it connected to a powered on charger after reaching full charge status.

- 2. <u>Always connect the MAXAIR Charger to an appropriately rated surge protector</u> to guard against potentially harmful factors from sources external to the MAXAIR System Components.
- **3.** <u>Retire and replace all LIBs that exceed four years life</u>. The first four digits of the Lot Number on the LIB label indicate the year and month of assembly. For example, the lot number of a (4 year old) battery assembled in March of 2015 would look like "1503XXX...". Any LIB with this lot number or lower, e.g. 1405, 1107, etc., would be more than 4 years old and should be retired and replaced.

Our Ensure Readiness Program provides a substantial trade-in¹ incentive for even older LIBs that are 6 years of age.

4. <u>Retire and replace Battery Chargers with older circuit technology.</u> The current MAXAIR Battery Charger with our newest circuit technology is the 2600-01.

Older technology 2610-01 MAXAIR Battery Chargers should be retired and replaced.

Refer to our Ensure Readiness Program for a substantial trade-in¹ incentive for older technology 2610-01 Battery Chargers.



It is essential to understand that among the most critical components for your effective MAXAIR use and safety, the lithium-ion batteries and their chargers must be evaluated according to our guidelines. Please see the previously sent, attached copy, for our recommendations for your batteries' use and maintenance, as well as our current Ensure Readiness Program to assist your institution in updating your MAXAIR Systems (You can also find our recommendations on LIB proper care and handling on our website, www.maxair-systems. com, at HOME>SUPPORT>SPECIAL PROGRAMS>CLICK for Ensure Readiness Program).

<u>WARNING</u>: Even though your MAXAIR LIBs and 2610-01 Chargers may still appear to be working properly, internal damage may already exist², most especially if <u>your</u> past protocol allowed them to remain connected for long periods while the charger was connected to a main power source. Any existing internal damage is not reversible and will (likely) increase over time.

Our goal has always been to provide the MAXAIR PAPR user with a safe and most effective personal respiratory system. Please visit our website for more information or contact our Customer Service representatives if your Libs have a lot number beginning with 1303XXX or lower, and any 2610-01 Chargers. It is essential for your protection that you also consider the significant trade-in¹ allowances that we are offering to you.

Sincerely,

Allan Schultz BMDI Marketing

¹ The MAXAIR *ENSURE READINESS* Trade-In Program is ongoing until further notice.

² Internal damage is not practical and likely impossible to detect and would require destructive dis-assembly to attempt. The only practical and safe protocol is to trade-in or otherwise retire the LIB(s) and Charger(s) from further use.

Attachments on the following pages: 2019-03-Ensure_Readiness_Letter_and_Program.pdf 2019-02-03_Technical Bulletin_Li-IonBattery_Advisory_Rev_D.pdf



Dear Valued MAXAIR Customer,

Lithium-Ion Battery Advisory And MAXAIR ENSURE READINESS Program

Thank you for the trust that you have extended to us by purchasing MAXAIR PAPRs. MAXAIR Systems is very committed to the respiratory protection of workers in all situations where MAXAIR can be of benefit.

Fundamental to the safe and effective use of a MAXAIR PAPR is the battery, the Lithium-Ion Batteries (LIBs) that provide power for the PAPR system. Your MAXAIR *LIBs need to be maintained in optimum condition* to ensure they will be there for you in time of need.

LIBs have significant advantages versus other rechargeable battery chemistries. At the same time, there are some aspects of LIBs that require careful attention when handling/transporting, using/discharging, charging, and storing LIBs.

Since their commercial inception in 1991, LIBs have experienced rapid acceptance to become the preferred rechargeable battery chemistry for the majority of portable and mobile powered devices, including MAXAIR. During this relatively short time span, industry has learned a great deal about their proper use and how to optimize both their performance and their longevity and safety. LIB technology is not perfect and reliability issues have been noted over the years stemming from storage conditions, over-charging, over-discharging, manufacturing inconsistencies, component failures, and physical abuse. These conditions, especially in older LIBs, can lead to diminished performance, overheating, and/or damage.

We have learned with you the importance of having the LIBs ready when you need them, from isolating airborne transmissible disease patients to being prepared for a pandemic or future terrorist attack.

We continue to revise our recommendations regarding what industry learns about optimizing proper handling and use of LIBs. We feel responsible to periodically pass on those recommendations regarding handling, use, and useful life of your MAXAIR LIBs.

Our objective is to ensure that your MAXAIR is always "at the ready" when you need it, and that means a healthy, charged LIB.

To emphasize ensuring readiness and safety of your LIBs, MAXAIR is instituting an *ENSURE READINESS* Program.

The first part of this program is periodically reminding our installed base of the important precautions you should be implementing. The attached "Lithium-Ion (Li-Ion) Battery Advisory" further details the fundamental precautions presented here.

The second part is our **ENSURE READINESS Trade-In Program.** The Trade-In Program encourages you to trade out your aging and older designs for newer technology models, and provides a monetary incentive to do so.

The attached "Lithium-Ion (Li-Ion) Battery Advisory" is information regarding the proper handling, use, charging, and storage of your LIBs. Please read it thoroughly, ensure that personnel that use the MAXAIR PAPRs are familiar with its information, and let us know if you have questions (email us at info@maxair-systems.com).



The most fundamental important periodic precautions you should take are the following:

- A. Before each use, physically inspect the LIB. If you perceive physical damage or tampering, use a different MAXAIR LIB and replace the damaged LIB as soon as possible.
- B. Routinely, every 3-6 months, perform the "LIB Check Procedure" (see Appendix B. LIB Check Procedure in the MAXAIR TECHNICAL BULLETIN: Lithium (Li-Ion) Battery Advisory). If this procedure results in a "Suspect LIB", use a different MAXAIR LIB and replace the Suspect LIB as soon as possible.
- C. Check LIBs that are connected to MAXAIR chargers on a routine and periodic basis. If the charger LED is green, the LIB is ready for use and should be disconnected from the charger immediately.

THIS IS DIFFERENT THAN PREVIOUSLY RECOMMENDED And Supersedes older User's Instructions Manuals

<u>BEFORE</u>: The previous recommendation was to not leave the LIB on a charger longer than one month/4 weeks.

There is no practical benefit to leave a LIB on a charger past its full charge status as indicated by the charger LED turning green. Removing it at that time rather than leaving it connected for long and indefinite periods eliminates the possibility of transmitted harm from electrical storms, intrabuilding electromagnetic phenomena, etc.

<u>NOW & GOING FORWARD:</u> Check LIBs connected to chargers on a daily basis

A. If a LIB is warm-to-hot to the touch, disconnect the LIB from the charger and replace it immediately.

If this condition is ever observed, please mark the specific battery and the specific charger it was connected to when the heating was noted, and contact us for replacement. Call Customer Service, 1-800-443-3842, for return and replacement instructions.

B. If the charger LED is Green, the LIB is fully charged and ready for use, therefore disconnect if from the charger.

C. <u>DO NOT</u> leave the LIBs on the chargers after the charger LED turns Green.

D. MAXAIR Systems highly recommends that all MAXAIR Chargers always be connected to surge protector(s), adequate for all anticipatable occurrences, whenever they are connected to MAXAIR LIBs, as well as whenever they are connected to a mains power source

The Lithium-Ion (Li-Ion) Battery Advisory discusses the approximate four year useful life of a LIB. The MAXAIR *ENSURE READINESS* Trade-In Program assists you with replacing your LIBs as they exceed their useful life.

We urge you to make a specific plan to replace your LIBs no later than after the fourth year after purchase.



Follow the directions of the Trade-In Program to place your LIBs on our shipping priority list.

Additionally, at this time we are including a further offer to Ensure Readiness and Reliability!

Until further notification, you will *ALSO* receive 40% discount on newer technology MAXAIR Chargers for the trade-in of your functional older 2610-01 MAXAIR Chargers.

For each traded-in, functional 2610-01 MAXAIR Charger you will receive a 40% discount from the list price of a new 2600-01 MAXAIR Charger. This offer remains in effect until further notification.

Please review all the safety and reliability recommendations in the attached Technical Bulletin with your staff that work with the MAXAIR Systems, and take advantage of this great trade-in program to update the critical power and charging components of your MAXAIR Systems.

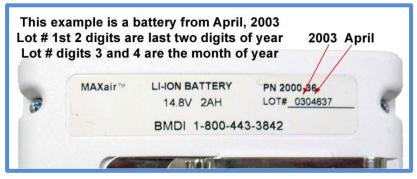
Sincerely,

Allan Schultz BMDI Marketing



The MAXAIR ENSURE READINESS Trade-In Program (MAXAIR SYSTEMS' CHARGERS AND LIB TRADE-IN PROGRAM) ENSURE READINESS Trade-In Program¹ LIBs – After 6-Year Age Qualifying LIB Trade-In: based on Order Numbers (O.N.): 20% off list of new left 4 digits of the lot number² -2000-30, 2000-30T, 2500-36TSC and 2000-36, 2000-36T e.g. as of 03/01/2019 2500-37TSC LIBs lot numbers 1303XXX and lower (older) Chargers – All Functioning Qualifying Charger Trade-In: 2610-01 Chargers Order Number (O.N.): 40% off current list of a new 2610-01 2600-01 Charger ¹ Program remains in effect until further notification

²Lot Number



To take advantage of the **ENSURE READINESS** Trade-In Program:

- A. Send an e-mail to maxairkathi@gmail.com and include the -
 - LIB O.N. (e.g. 2000-30) and the lot number indicated on the LIB label for each LIB.
 - Charger O.N. (2610-01) and lot number on the charger label for each Charger.
- B. MAXAIR Systems Customer Service will then send you an email with a RMA Number, that includes:
 - a. Discount amount and the net price due on your purchase order.
 - b. A schedule for delivery of your new LIBs and/or Chargers (typically within 45-90 days).
- C. Send you purchase order, including RMA number, to info@maxair-systems.com.

When your purchase order and your old LIBs and/or Chargers are received, we will ship your new LIBs and/or Chargers via UPS ground.

If you have any questions regarding this information and program, please contact: Customer Service

Call: 1-800-443-3842 or email: info@maxair-systems.com



2000-36

MAXAIR TECHNICAL BULLETIN : Lithium-Ion (Li-Ion) Battery Advisory

This Bulletin is for those responsible for handling/transporting, using, and storing MAXAIR Systems Lithium-Ion Batteries (LIBs).

It is intended to provide information for the safe handling/transporting, use/discharge, charge, and storage of MAXAIR Systems Li-Ion Batteries (LIBs). It provides good practice guidance and emergency response guidance while considering the hazards offered by Lithium-ion (Li-Ion) batteries.

Lithium-Ion Batteries (LIBs) - Overview

Lithium Ion (Li-Ion) became the battery chemistry of choice beginning in the early 1990s. It was the natural leader as the demand for performance of portable powered devices grew. Lithium is the lightest of all metals, possesses advantageous electrochemical potential, and provides great energy density per weight. With a few precautions, Li-Ion batteries remain the choice for powering portable medium sized electromechanical devices.

Key Li-Ion Battery Advantages:

- High energy density—more power and use per amount of battery weight
- No prolonged priming when new—one regular charge and ready to go
- Low maintenance—no periodic discharge is needed (No memory)
- No scheduled cycling to prolong battery life
- Low self discharge

Li-Ion Battery Limitations:

Due to there very high performance levels, Li-Ion Batteries do have some limitations that require attention.

- Protection devices are included in Li-Ion Battery Packs to maintain voltage and current within safe limits.
- Use, charging, transport, and storage conditions need to be controlled.

You may expect highly advantageous performance from your Li-Ion powered MAXAIR System by following these guidelines and recommendations.

GENERAL WARNINGS

Failure to read and follow these instructions and guidelines may result in fire, personal injury and damage to property. Your MAXAIR LIBs need to be handled/transported, used/discharged, charged, and stored properly. Follow the safety rules listed below.

- 1. Follow these instructions and the instructions in the MAXAIR User's Instructions (UIM) and the Instructions For Use (IFU), and use MAXAIR LIBs in accordance to the warning labels on the MAXAIR LIBs to properly manage and control charging and discharging of all MAXAIR LIBs.
- 2. Keep MAXAIR LIBs and Chargers away from children.
- 3. Test MAXAIR LIBs before using to ensure they are operating properly and safely with the MAXAIR Helmet or on the MAXAIR Charger. (See Appendix B. LIB Check Procedure).
- 4. As with all Li-Ion battery packs, misused and defective Li-Ion cells may explode and cause fire. If at any time a LIB starts to balloon, swell up, smoke or get hot, emit an unusual smell, change color, or appear abnormal in any other way, discontinue

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2000-30

MAXAIR LITHIUM-ION BATTERIES (LIBs)

TECHNICAL BULLETIN Li-Ion Battery Advisory

its use immediately, disconnect the LIB from the Helmet or Charger, and observe it in a safe place for approximately 15 minutes. If any of these conditions occur, the LIB should be replaced.

[®] SYSTEMS

with every breath

CAUTION: These conditions may result in LIB cell leakage. Since delayed chemical reaction can occur, it is best to observe the LIB as a safety precaution in a safe area outside of any building or vehicle and away from any combustible material. In the event of coming in contact with any leakage from a LIB, do not rub or touch the eyes, immediately rinse all contacted areas thoroughly with water, and immediately seek medical care. If left untreated, the LIB leakage could cause eye and other serious injury.

- 5. In the event of any damage or perceived damage to a LIB due to bad shipment or other reason, remove the LIB to a safe location for observation and place it in a safe open area away from any combustible material for approximately 15 minutes.
- 6. Do not place LIBs in direct sunshine, or use or store LIBS inside relatively closed environments (cars, etc.) in hot weather and anywhere extreme temperatures may exist. Doing so may cause the LIB to generate heat, rupture, or ignite. Using the LIB in this manner may also result in a loss of performance and a shortened life expectancy.
- 7. Do not use, charge or store LIBs in or near microwave ovens, high pressure containers, or conduction cookware.
- 8. Do not expose a LIB to water, salt water, any other liquid, or moisture, beyond air with a relative humidity between 10%-90%.
- 9. Do not connect the connection terminals together, even momentarily, with any material including touching with the human body.
- 10. Do not allow a LIB to make contact with a hard object (dropping, throwing, striking, piercing, etc.) so as to subject it to strong impact, shock, or other mechanical stress.

Recommended Temperature Ranges

- 11. Do not open, penetrate, or attempt to disassemble or modify a LIB case in any manner without contacting the manufacturer. The LIB contains safety and protection devices which, if damaged, may cause the LIB to generate heat, rupture, or ignite.
- 12. Do not submit to static electricity.

Degrees Centigrade		Degrees Fahrenheit		Activity				
min.	max.	min.	max.					
0	54	32	129	Handling & Transporting				
0	54	32	129	Use/Discharging				
0	45	32	113	Charging				
0	35	32	95	Storage				

If recommended temperature range is exceeded, let batteries cool down or warm up, as appropriate, to ambient temperature, and ensure all condensation, if any, has evaporated before charging or use.

USE/DISCHARGE:

WARNING

- 1. Do not discharge a LIB by using any device except a MAXAIR Helmet.
- 2. The temperature range over which a LIB is to be discharged is 0° C-54° C (32° F-129° F). Use outside of this temperature range may damage the performance and reduce the life expectancy of the LIB.

CAUTION

When the LIB has reached its usual and customary useful life (See Appendix A. Useful Life) -

- 1. Immediately discontinue use of the LIB and replace it.
- 2. Insulate the connection terminals with adhesive tape or similar material before disposal.



CHARGE:

WARNING

- 1. Always use a MAXAIR charger when charging a LIB; never use any other type of charger for a MAXAIR LIB.
- 2. Never connect a LIB to any device other than a MAXAIR helmet or a MAXAIR charger.
- 3. Never charge a LIB outside the temperature range of 0° C to 45° C (32° F to 113° F). Charging the LIB at temperatures outside of this range may cause the battery to become hot or damaged. Charging the LIB outside of this temperature range may also harm the performance of the LIB or reduce the LIBs life expectancy. When the LIB becomes hot, the built-in safety equipment is activated, preventing charging further. Additional heating can destroy the safety equipment and can cause accelerated temperature increases, ignition, or other damage to the LIB.
- 4. Do not continue charging the LIB if it does not recharge within the maximum charging time. (See Appendix C. Reference Information) Doing so may cause the LIB to become hot, rupture, or ignite.
- 5. Always charge in an isolated area, away from flammable materials.
- 6. When charging LIBs, always monitor the charging process and react to potential problems that may occur.
- 7. Always disconnect the LIB from the Charger when it is fully charged Charger LED is lighted Green or the maximum charge time (Appendix C.) is reached, whichever occurs first.
- 8. Even though LIBs and Chargers may still appear to be working properly, internal damage may already exist, most especially if your past protocol allowed them to remain connected for long periods while the charger was connected to a main power source. Any existing internal damage is not reversible and will (likely) increase over time.

STORE:

WARNING

- 1. Store in closed containers and packaging that prevent short circuits and damage during storage or transportation.
- In case of mixed storage of goods and articles, organize separate storage areas for LIBs, for example, by maintaining a distance of 2.5 meters between the LIB storage area and other goods.
- 3. Store in limited quantities and in isolated area with frequent surveillance.
- 4. Keep in a dry, cool and well-ventilated place, within the recommended storage temperature range of 0° C-35° C (32° F-95° F). Cooler and dryer environments of storage are safer and extend useful life.
- 5. The temperature range of 19° C-25° C (66° F-77° F) at 30%-50% full charge will optimize battery useful life.
- 6. Perform a boost charge and LIB Check Procedure (Appendix B.) every 3 to 6 months; this will help prevent the potential of an over-discharge.

HANDLING & TRANSPORT:

Lithium-Ion batteries are classified as Dangerous Goods for the Transport by Road/Rail, Sea and Air. When considering transporting LIBs to other locations, conform to the requirements of the UN Regulation on the Transport of Dangerous Goods.

Internal transfer of Lithium-Ion batteries should follow the minimum safety rules imposed by the local legislation/regulation regarding the handling of Dangerous Goods.

When handling LIBs, use caution, specifically to avoid shorting the connector terminals.

WARNING

- 1. Do not exceed the temperature range of 0° C-54° C (32° F-129° F) when handling and transporting LIBs.
- 2. Do not expose battery packs to direct sunlight and/or heat for extended periods.



Appendix A. Useful Life

Li-lon batteries begin aging when they are manufactured - not when you begin using the battery. Lithium-lon batteries are prone to aging somewhat rapidly. The useful capacity (Recoverable Capacity) of a Lithium-lon battery decreases about 10% to 20% each year. Therefore, Lithium-lon batteries have a useful aging-service life of approximately four years.

Li-lon batteries have a useful capacity-service life of 300-500 cycles (one cycle being the time of one full use from a full charge).

Therefore, the recommended useful life expectancy, or replacement schedule, for a Li-Ion battery is after four years or 300-500 discharge cycles, whichever occurs first.



Appendix B. LIB Check Procedure

MAXAIR LIB Test for Diminishing Battery Capacity

Note: A MAXAIR helmet and MAXAIR charger are required to perform this basic battery test. The helmet and power cord must be in good working order. Set the helmet Air Flow Switch to Low for the test.

CAUTION

If the LIB performs in one of the "Suspect LIB" categories below, discontinue using it and replace that LIB as soon as possible.

Case 1: The LIB has been connected to a charger and the charger green LED is on.

Procedure: Unplug the LIB from the charger and plug the helmet power cord to the LIB. Allow the helmet to settle for about 10 seconds.

Good LIB: The helmet runs with 3 or 2 green indicator lights on.

Suspect LIB: The helmet runs with only 1 green indicator light on. Suspect LIB: The helmet runs with the red indicator light on.

Suspect LIB: The helmet doesn't run.

Case 2: The LIB has been in storage.

Procedure: Plug the helmet power cord to the LIB to be tested. Allow the helmet to settle for about 10 seconds.

Good LIB: The helmet runs with 3, 2 or 1 green indicator light on.

Suspect LIB: The helmet runs with the red indicator light on. Suspect LIB: The helmet doesn't run.

Case 3: The LIB is connected to the MAXAIR Charger.

Good LIB: the LIB is felt to be about room temperature.

Suspect LIB: the LIB is warm or hot to the touch.



Appendix C. Reference Information

Lithium-ion Battery main components:

MSDS for Li-Ion Battery Cells available upon request. Call Customer Service, 1-800-443-3842.

Typical Charging Time Specifications:

Time to fully charge a fully discharged MAXAIR LIB

CHARGING TIME								
BATTERY	2600-01	Charger	2610-01 Charger					
	Typical	Maximum	Typical	Maximum				
2000-30/30T, 2500-30TSC	5 hrs	10 hrs	7.5 hrs	15.0 hrs				
2500-37TSC	3.8 hrs	7.5 hrs	5.8 hrs	11.3 hrs				
2000-36/30T 2500-36TSC	2.5 hrs	5.0 hrs	4.0 hrs	7.5 hrs				



Appendix D. Surge Protection

All electrical devices may be harmed or damaged by electrical power surges, such as from electrical storms, while connected to wall outlets without specific surge protection.

MAXAIR Systems highly recommends that all MAXAIR Chargers always be connected to surge protector(s), adequate for all anticipatable occurrences, whenever they are connected to MAXAIR LIBs, as well as whenever they are connected to a mains power source.

To choose an appropriate surge protector you should consult with your Engineering department regarding specifics to your physical plant and geographical environment. You may want to consider the following common fundamentals -

- ▲ Indicator light surge protectors will not last forever when a surge protector properly diverts a surge, the protector itself can be damaged in the process. An indicator light will indicate that the surge protector is working fine.
- ▲ UL Rating good surge protectors come with a UL rating (or equivalent regulatory mark for non U.S. countries, e.g. CE Mark, etc.), a rating put out by the independent Underwriters Laboratories that tests the safety of electronic devices.
- ▲ Clamping voltage the voltage measurement that prompts the surge protector to start redirecting the excess electricity away from the plugged-in devices.
- ▲A surge protector with a lower clamping voltage will trigger earlier, thus better protecting electrical devices.
- ▲ Joule rating the maximum amount of energy the surge protector can absorb. If the surge exceeds this maximum, the surge protector will be rendered useless. The higher the joule rating, the more energy can be absorbed by the surge protector, therefore, a higher joule rating will often indicate a longer lifespan for the product.



LIB

Lithium Ion Battery, Li-Ion Battery

Self Discharge

The rate at which the battery charge level declines while it is just sitting in storage, usually quoted as a decline in %-per-month. Self-discharge increases with age, cycling and elevated temperature.

Discard a battery if the self-discharge reaches 30 percent in 24 hours.

Recoverable Capacity

The amount that a battery can be "fully charged back to" over time, usually quoted as a certain % of the full charge level when the battery was initially manufactured.