

Field Safety Notice



AlterG, Inc.
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June 26, 2017

Dear AlterG Distributors:

This letter is to announce a Field Safety Notice for the M320 product built prior to June 6, 2016.

A condition was recently reported by one of our distributors in which an M320 unit unexpectedly surged in speed to the maximum allowed by the treadmill. The treadmill E-Stop was not effective in stopping the runaway condition and power had to be cut from the treadmill to halt the belt.

Fortunately, no one was injured, but we do see the potential for injury as a result of this condition repeating.

AlterG has completed a full analysis of the event and determined the root cause to be a diode (d23) on the Lower Motor Controller (part number 102647). The diode failed in such a way that the treadmill was not responding to commands. AlterG previously identified this diode as a potential failure point and changed the component to a more robust and insulated device in June of 2016. All Lower Motor Control Boards with Revision G have this fix which was implemented on Serial number M300-1117 and higher.

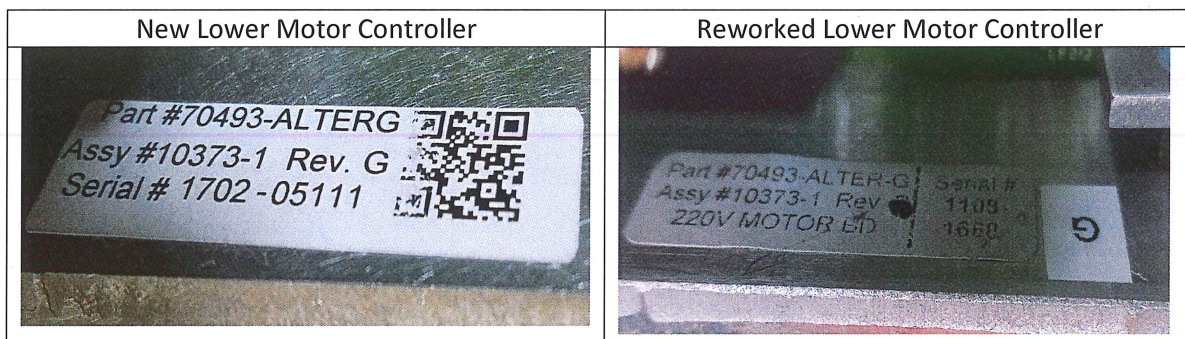
AlterG has completed a full analysis of the event and reported this event to the FDA (report 3007033433-2017-00001):

- The probability of this event is remote, with an estimated frequency of 1 in 1,000,001 to 2,000,000 patient uses.
- The severity of the issue is considered moderate; patient may require professional medical attention with full recovery expected

Next Steps:

AlterG will be making available updated Lower Motor Control Boards for replacement of field installations. AlterG recommends that distributors perform a count of current Lower Motor Control Boards in their stock as spares and request an RMA for the return and replacement of these devices.

The revision of the Lower Motor Controller can be found on a label as indicated here:



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Note, all down revision Lower Motor Control Boards can be repaired and revised to Revision G. As such we are encouraging the return of these boards to AlterG using our Sales Order process:

- Requested replacements will be shipped on SO's with full value to the distributor and an equivalent quantity RMA for planned returns.
- RMA returns of the down revision Lower Motor Controller Boards will cancel any charges to the distributor.
- Returns must be initiated within 30-days to avoid charges.

What do you need to do?

- Determine your current spares stock for the proper revision (revision G).
- Assess your capability to perform repairs and request supplies that match your service capability.
- Contact AlterG Support to request initial supply (we recommend a request of approximately 10% of install base to start the process).
- Request an RMA for existing stock of spares that are not at revision G.
- Make a plan to replace these boards at the next convenient visit to your customer.
- Track the changes for each affected unit (by serial number) to ensure completion of the task
- Return all replaced Lower Motor Controllers ASAP to avoid any charges for non-returns.

AlterG will be targeting to complete all exchanges within a 24-month timeline.

We value our relationship with you, and thank you for choosing an AlterG Anti-Gravity Treadmill for your facility. We regret any inconvenience due to this exchange process. If you have any questions about this exchange program or if there are any other ways we can be of assistance to you, please email us at support@alterg.com. You can also call our support team at any time at 510-270-5369.

Sincerely,

A handwritten signature in blue ink, appearing to read "Mike Phillips", is written over a horizontal line.

Mike Phillips

VP Operations and Engineering
AlterG Inc.