

**URGENT FIELD SAFETY NOTICE**

(EU Version)

**AtomLab™ 500 Dose Calibrator and AtomLab™ 500Plus Dose Calibrator**

<b>Device</b>	<b>Serial Number Range</b>
<b>AtomLab™ 500 Dose Calibrator</b>	<b>17081557-21062362</b>
<b>AtomLab™ 500Plus Dose Calibrator</b>	<b>17080651-21061047</b>

September 3, 2021

Dear Customer/Distributor,

The purpose of this letter is to advise you that Biodex is issuing a Field Safety and Corrective Action Notice the AtomLab™ 500 Dose Calibrator and the AtomLab™ 500Plus Dose Calibrator. The recall is revision 2.0.00 through Revision 2.0.08, inclusive. The Atomlab™ Dose Calibrators are intended to measure the activity of a radioactive source of a known isotope. This measurement may be for purposes of determining or verifying a radiopharmaceutical dose.

**Reason for the Field Safety and Corrective Action:**

When deleting a previously entered custom isotope, the software deletes the isotope, but not the associated dial setting. **Thus, it is possible other stored custom isotopes may then have incorrect dial settings.**

The software error is limited to the custom isotope module only and does not affect any other module or the 99 preset dial values.

**Risk to Health:**

An incorrect dial setting may lead to an incorrect dose measurement and/or misadministration.




**How to recognize software error:**

Review the dial settings associated with custom isotope and confirm they have not been changed. Compare the measured activity with a dose calibrator from another manufacturer.

**Actions to be Taken by the Customer/Distributor:**

The error can be immediately corrected by restarting the system.

We recommend that you promptly download new software. The error is corrected in Software Revision 2.0.10. The corrected software upgrade is available as a download from the Biodex website at the following link [Atomlab 500 Dose Calibrator Software Update v2.0.10 - Software Updates - Nuclear Medicine | Biodex](http://www.biodex.com/software-update/atomlab500). System registration is required for download.

<p><b>Find Your Serial Number Here:</b></p>  <p>Product: ATOMLAB 500 DOSE CALIBRATOR</p> <p>Model: 086-330      Serial No: 17101599-178697</p> <p>Volts: 100-240 VAC      Watts:</p> <p>Amps: 1.5-0.75A      Fuse:</p> <p>Cycles: 50/60HZ      Oct-2017</p> <p><b>MEDICAL ELECTRICAL EQUIPMENT</b>      Inertek 63757      TYPE B EQUIPMENT      CE 0413</p> <p>CERTIFIED TO: CAN/CSA STD C22.2, NO. 601.1</p>  <p><b>BIODEX</b> Biodex Medical Systems, Inc. 20 Ramsey Road, Shirley, NY 11967-4704 USA</p>	<p><b>Download the Software Update:</b></p> <p>Scan the QR code below or visit: <a href="http://www.biodex.com/software-update/atomlab500">www.biodex.com/software-update/atomlab500</a></p>  <p>For additional instructions, visit: <a href="http://www.biodex.com/software/a500">www.biodex.com/software/a500</a></p>
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To minimize risk of illness or injury, please download the software correction, as soon as possible.

If you have any questions or require any additional information, please contact [supportservices@biodex.com](mailto:supportservices@biodex.com).

**Competent Authorities**

The appropriate Competent Authorities have been notified of the FSCA.

Please email us at [supportservices@biodex.com](mailto:supportservices@biodex.com) to acknowledge receipt of this letter and confirm commitment to download the software update.

**Acknowledgement of Notice**

I acknowledge receipt of FSCA by signing below. Alternately, software downloads require registration and will also confirm receipt of FSCA.

_____	_____
Name	email
_____	_____
Facility	Atomlab 500 Serial Number