

BIODEX

Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704

April 25, 2016

Re: Atomlab 400 and Atomlab 500 Dose Calibrators

To Whom It May Concern:

In 2015 NIST published an article in the Journal of Nuclear Medicine revising the conversion factor to use when calibrating for F-18 using A Ge/Ga-68 Standard. NIST adjusted the Ge/Ga-68 conversion factor by approximately 4%.

There also has been testing performed with more than 25 Ge/Ga-68 dose calibrator standards. The dial value for Ge/Ga-68 has been modified from 10.1 to a **new Dial value of 10.2**. This is a 1% change to the current factory dial value.

Based on the NIST Article and the testing with multiple standards Biodex is adjusting the factory dial values for the Dose Calibrator for both Ge/Ga-68 and for F-18. RadQual who makes one of the Ge/Ga-68 Dose Cal standards, also changed their conversion factor for F-18 using the Ge/Ga Standard by 4%.

The 4% NIST change plus the 1% change for the Ge/Ga-68 dial value changing from 10.1 to 10.2 gives a total 5% change for F-18. The current dial value for F-18 in the Atomlab 400 and 500 is 9.6. Adjusting the Dial value up 5% gives a **new dial value for F-18 of 10.1**.

Because of these changes we have incorporated the new dial value calibrations in software release Version 1.34.

Sincerely,

Clyde Schlein
Vice President, Regulatory Affairs & Compliance

CS/dv