

ATP Calibrator Set

GENERAL DESCRIPTION

The calibration devices in this kit are used for performance verification and calibration of the LIGHTNING MVP ICON™ and LIGHTNING MVP® systems. The luminescent calibrator consists of a ¹⁴C radioactive source that emits a very low level (5×10^5 d.p.m., or 0.225 microcuries) of low energy β radiation in a plastic scintillation matrix. This matrix is configured to give constant light output, within 10% of its original value, at a sufficiently high level to make consistent verification and calibration functions possible over the five-year life of the calibrator. The non-luminescent black plastic calibrator provides a reliable low-end or “dark” source reading.

Part No. 64012-00

KIT COMPONENTS

One luminescent calibrator

One non-luminescent calibrator

RECOMMENDED USE

A. Performance Verification: If a given test point result or LIGHTNING MVP ICON ATP Positive Control result is not what is expected, it is suggested that the calibrators be used. You may wish to perform daily or weekly performance verification checks consisting of simply inserting and reading the calibrators. Calibrator results should be compared with the Zone value stated on the calibrator label and with previous calibration results. If the calibrator results are within specifications (see **INTERPRETING RESULTS**), you can be confident that the MVP ICON or MVP is functioning properly.

B. Calibration: The instrument’s Zone readings are standardized by a two-point calibration procedure.

Note: All MVP ICON and MVP instruments are factory calibrated prior to being shipped. Because several factors can cause the calibrator results to be out of specification, a full calibration should be performed only if either of these two conditions are true, and all of the conditions in “Causes of Inconsistent Calibrator Readings” have been ruled out:

- (a) Luminescent calibrator readings are consistent within 0.1 Zones of each other but are not within 0.1 Zones of the Zone value printed on the calibrator label.
- (b) Non-luminescent calibrator readings are consistent within ± 0.3 Zones of each other but are not within the 1.0 to 1.5 range. If, after cleaning and repeated tries, consistent calibrator results cannot be obtained, call BioControl Technical Support at 800.245.0113.

Note: Accepting a particular calibration will set the sensitivity for all subsequent readings. It is not possible to change a calibrated instrument back to a former calibration.

STORAGE

Store at 15 – 25 °C in tightly closed container, away from any light sources.

MVP ICON TEST PROCEDURES

The calibrators are inserted and read in the MVP ICON and MVP in the same manner as sampling devices. Unlike the sampling devices, the calibrators do not require activation. **DO NOT ATTEMPT TO ACTIVATE THE LUMINESCENT CALIBRATOR.**

Hold the calibrator by the wider end with two flat sides and insert the opposite end into the MVP ICON or MVP (an arrow on the luminescent calibrator’s label indicates which end is to be inserted into the instrument). When inserting into the MVP ICON, ensure the flat sides of the calibrator’s base chamber are facing left to right.

A. MVP ICON Performance Verification

- (a) Select “Instrument” from the bottom menu and ensure the MVP ICON is in ATP mode.
- (b) Select “Luminescent Cal” or “Non-Luminescent Cal” to run the verification.

B. Calibrating the MVP ICON

- (a) Select “Instrument” from the bottom menu and ensure MVP ICON is in ATP mode.
- (b) Select “Calibrate” and enter the reference value located on the luminescent calibrator label.
- (c) Insert the non-luminescent calibrator and press “Calibrate.” Repeat with the luminescent calibrator.
- (d) The MVP ICON will display “Calibration Successful” when properly calibrated and will store the calibration in the device. The last calibration date will appear on the homescreen of the device. If the “Calibration Failed” message appears, the calibration will need to be repeated. If failed message still appears, contact BioControl Technical Support at 800.245.0113.

LIGHTNING MVP TEST PROCEDURES

A. LIGHTNING MVP Performance Verification

- (a) Open the sample chamber and insert the calibration device.
- (b) Select “Read ATP” from the main menu.
- (c) It is suggested that luminescent and non-luminescent calibrator results be stored in the MVP memory for later retrieval. Assigning these results test point numbers will facilitate data collection and retrieval: for example, 996 non-luminescent, 997 luminescent.
- (d) Assign a test point number (if desired) and press the “Enter” key to begin reading.

A. Calibrating the LIGHTNING MVP

- (a) Select “Calibration” from the ATP Main Menu.
- (b) Enter the integer reference value displayed on the luminescent ¹⁴C calibrator label. Press “Enter” to accept the value.
- (c) Insert the non-luminescent calibrator into the MVP and press “Enter.”
- (d) After the reading is complete, the result is displayed as an integer (not Zone) value. Remove the non-luminescent calibrator from the MVP and insert the luminescent ¹⁴C calibrator. Press “Enter” to initiate the read.

Note: Repeat steps (c) and (d) two additional times. The MVP screens will guide you through this process. Note that the replicate number displays on each screen.

- (e) If the calibration values are within the MVP’s internal specification, the values are displayed. You must accept the values by pressing “Enter” otherwise the calibration will not take effect.

Note: If the variation in replicate results is not within the MVP’s internal specifications, an error message will appear. Press “Enter” to return to Main Menu. The MVP’s calibration remains unchanged and the procedure must be repeated (see

CAUSES OF INCONSISTENT CALIBRATOR READINGS).

INTERPRETING RESULTS

The luminescent calibrator in a properly calibrated MVP ICON or MVP should read within 0.1 Zones of the Zone value displayed on the calibrator’s label.

The non-luminescent calibrator should read 1.0 to 1.5 Zones in a calibrated MVP ICON or MVP system. Readings outside the range of these values can indicate problems with the instrument, calibrators, or improper reading technique (see Chapter 27, Troubleshooting in the MVP ICON User Guide or Section 8, Troubleshooting in the MVP System Guide).

CAUSES FOR INCONSISTENT CALIBRATOR READINGS

Several factors can cause out-of-specification calibrator results. Before trying to re-calibrate the MVP ICON or MVP, rule out the following possible causes of inconsistent calibrator readings:

- (a) Dirty or Damaged Calibrators

Inconsistent calibrator results can arise from the calibrators being dirty or damaged. Clean the outside of both calibrators with a lint free cloth that has been dipped in reagent-grade isopropyl or ethyl alcohol. Air dry and repeat your readings. Damaged luminescent calibrators should be returned to BioControl and replaced with a functioning calibrator.

- (b) Instrument Contamination

Results that have changed suddenly, especially immediately after a number of sampling devices have been run, can indicate a contamination problem. Calibrator results can increase or decrease as a result of

foreign materials fouling the optics chamber of the instrument. If you suspect contamination of the instrument, please refer to the MVP ICON User Guide or MVP System Guide for further instructions.

- (c) Exposure to Light

Inconsistent readings can also arise if the luminescent calibrator is exposed to intense light prior to being read. Insert the calibrator in the MVP ICON or MVP and wait a minimum of 2 minutes before attempting to read again. If repeated readings still fall outside the specified range, it may be necessary to calibrate your instrument.

PRECAUTIONS

Note: The Calibrator Set positive verification has been designed for use in a laboratory or office setting. Do not take the positive verification into factory processing areas. This document assumes that you are familiar with the LIGHTNING MVP ICON sampling devices, test point definition, and “Zone” system of light measurement. Please refer to the MVP ICON User Guide or MVP System Guide if these topics are unfamiliar.

To ensure the stability and longevity of the luminescent calibrator, the following precautions *must* be taken:

Limit Exposure to Light

Store the luminescent calibrator in the dark or in weak ambient light (If the luminescent calibrator is exposed to bright light prior to use, insert in the MVP ICON or MVP and wait a minimum of 2 minutes before proceeding). The kit box provided is recommended as an appropriate dark storage. Do not expose to direct sunlight or intense artificial light before use.

Careful Handling

Avoid crushing, cutting, or dropping the calibrators. Any damage that changes the shape or light transmission properties of the luminescent calibrator can affect the calibrator’s assigned Zone value. Good laboratory and manufacturing precautions should be observed for the care of the calibrators.

Disposal

For US and Canadian customers: The level of radioactive material in the luminescent calibrator does not require special hazardous waste treatment, per United States Federal regulations governing the use and transfer of excepted radioactive materials. To dispose of a luminescent calibrator, remove or deface the “Caution-Radioactive Materials,” emblem from the calibrator label. The calibrator may then be disposed of as common trash.

For other countries: Please refer to your local regulations.

Within the United States, please call BioControl Technical Support at 800.245.0113 for further information on instrument calibration and calibrators. Outside of the United States, please call your nearest BioControl authorized distributor office.

WARRANTY

BioControl Systems, Inc. (BCS) warrants this product to be free from defects in materials and workmanship, when stored under labeled conditions and used as intended until the expiration date stated on the package. BCS agrees during the applicable warranty period to replace all defective products after return to BCS. BCS shall not have obligation under this Limited Warranty to make replacements which result, in whole or in part, from negligence of the Buyer, or from improper use of the products, or use of the product in a manner for which it was not indicated. Buyer shall notify BCS of any products which it believes to be defective during the warranty period. At BCS option, such products shall be returned to BCS, transportation and insurance prepaid. BCS shall replace any such product found to be defective, at no charge. Should BCS examination not disclose any defect covered by the foregoing warranty, BCS shall so advise Buyers and dispose of the product in accordance with Buyer's instructions.

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LIGHTNING MVP ICON ATP CALIBRATORS,
THEIR USE OR OTHER BIOCONTROL PRODUCTS,
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