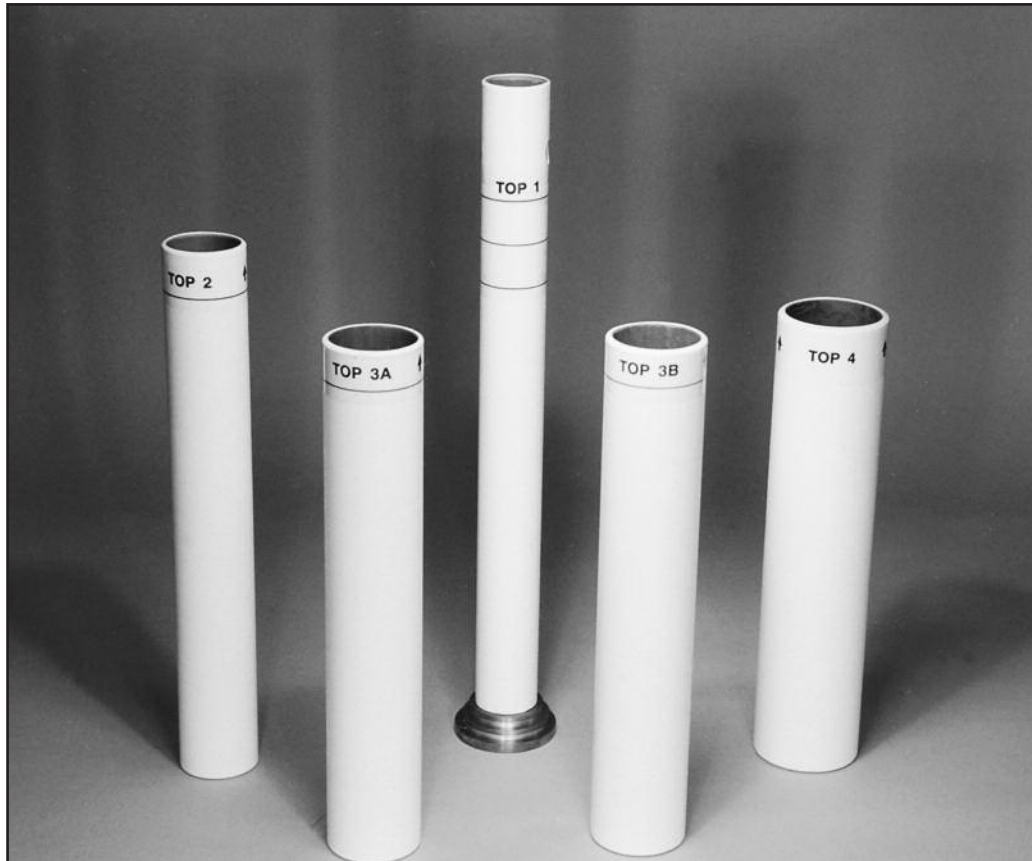


# LINEATOR

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## INSTALLATION/ OPERATION MANUAL

086-509



**BIODEX**  
Biodex Medical Systems, Inc.

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## LINEATOR

This manual covers installation and operation procedures for the following product:

#086-509 Lineator

## INTRODUCTION

The Lineator is a simple device for testing linearity and dynamic range of isotope calibrator instruments. Its use simplifies compliance with the Nuclear Regulatory Commission Appendix B of Regulatory Guide 10.8, 10 CFR, October 1986, and various state requirements.

The Nuclear Regulatory Commission, and other licensing agencies typically require a license amendment before use of the Lineator is authorized. A sample license amendment form is included in these instructions as Appendix A. This form should be transferred to your stationery, signed by authorized personnel, and sent to the appropriate agencies with any required fees. When the amendment is received use of the Lineator is authorized. Note that the NRC Regulatory Guide 10.8 Appendix B dated October 1986 requires a test of calibrator linearity at installation and quarterly thereafter. State and local requirements may differ. The Lineator may be used for this quarterly calibration. The concentration of Mo-99 should be less than .1  $\mu\text{Ci}$  per mCi of Tc-99m.

The Lineator consists of five tubes, four of which are lead-lined, which can be arranged concentrically. You only use four tubes when doing a test. The smallest diameter tube is labeled 1 and is used to contain and position a source of Technetium 99m of the maximum activity to be measured in the dose calibrator in normal service. The lead-lined tubes, labeled 2, 3a, 3b and 4, slide over tube 1, and are used singularly, or in combination. Tube 3a or 3b is used in combination with the other tubes. Tube 3a is used if starting with less than 55 millicuries of Tc-99m. Tube 3b is used if the facility administers therapeutic doses. Tube 3b will cover a range of 380 millicuries down to 10 microcuries. If testing with greater than 380 millicuries, then a two stage process using two sources of different activities must be used. Each of these outer tubes absorbs some of the radiation from the source and reduces the *effective* source activity seen by the dose calibrator. Use of the Lineator thus allows the operator to simulate a total of eight different source strengths with only one source. The effective reduction increases from tubes 2 to 3 to 4, and is affected slightly by the shape of the source used, and by the characteristics of the isotope calibrator.

The principle operation of the Lineator is reproducibility over a wide dynamic range, rather than absolute calibration. Initially the linearity of the dose calibrator must be established by conventional means, such as dilution or decay of a Technetium source. The initial calibration using the Lineator then establishes the effective reductions in activity (ratios of activity with lead tubes inserted relative to source in central tube alone). All subsequent use of the Lineator will show the same effective ratios unless:

- a. The dose calibrator becomes defective, at which time it must be repaired, or
- b. The Lineator components are damaged or replaced. Care should be taken that the bottom end of the Lineator components are not damaged.

**NOTE:** The linearity of the dose calibrator must be established by standard means (i.e. decay or dilution methods) before proceeding with the instructions.

## GENERAL INSTRUCTIONS

1. Remove *all sources* from the region of the calibrator to be tested.
  2. Remove the dipper from the calibrator. Remove the chamber liner, only if necessary, to allow insertion of the central Lineator tube, tube 1.
  3. Set the calibrator to Tc-99m, check background reading using most sensitive scales. Zero out the background reading or note the value for later calculations. Check zero on all ranges if the unit has ranges. Note that background readings which vary widely may indicate a defective machine or a changing radiation environment which will affect the calibration.
  4. The Lineator is designed for use ONLY with Tc-99m. Load tube 1 with a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator). The base is formed to center a 10ml or a 20ml vial. Place the tube in the calibrator chamber with the open end up. Use caution to avoid damaging the calibrator or the Lineator. The source and central tube will stay in place until the calibration procedure is complete.
  5. Be prepared to work quickly. Arrange Lineator components, data sheets and clock for ease of operation. A complete calibration requires less than five minutes. Completion in six minutes introduces only a 1% total error due to decay of Tc-99m.
- NOTE:** If linearity test duration exceeds six minutes, the procedure should be repeated.
6. If the dose calibrator has a range switch, set the range switch, as necessary, to read the activity to three significant figures.

**NOTE:** The NRC requires test of linearity from the largest activity to be assayed down to 10  $\mu\text{Ci}$ . If the largest activity is greater than 380 mCi, the linearity test must be done in two steps, using one source of the largest activity, and a second source which is less than 55 mCi.

**NOTE:** Some states regulations allow linearity tests to end at activities greater than 10  $\mu\text{Ci}$ . You may discontinue the linearity test at the activity which your state regulations permit.

## CALIBRATION PROCEDURES

**NOTE:** Having established the linearity of the calibrator by standard means, an initial calibration provides the factors to be expected for all future linearity checks, so long as the calibrator maintains its linearity and the Lineator components are not damaged.

After performing the steps given in the General Instructions, continue with the following steps, adjusting range switch if necessary to obtain three significant figures.

7. Record the time and the initial activity with the source in tube 1, and only tube 1 inserted in the calibrator. Use a data sheet similar to or a copy of Appendix B1 or B2 for an initial calibration or a copy of Appendix D1 or D2 for linearity test work sheets.

8. Gently lower tube 2 over tube 1. Record reading 2.

9. Remove tube 2 and place tube 3 carefully over tube 1. Record reading 3.

**NOTE:** If using up to 380 millicuries use tube 3b. If using a lower activity, up to 55 millicuries, use tube 3a.

10. Insert tube 2 between tube 1 and tube 3. Record reading 2, 3.

11. Remove tubes 2 and 3, insert tube 4. Record reading 4.

12. Add tube 2. Record reading 2, 4.

13. Remove tube 2, add tube 3. Record reading 3,4.

14. Add tube 2. Record reading 2, 3, 4.

15. Record time.

16. Remove and store lineator components. Store source in lead shield.

17. Calculate the eight factors as indicated on your Appendix D work sheets. (See Appendix C for samples of completed work sheets.) Divide the value for tube 1 only by the value for each reading for each tube combination and enter results in column headed "Present Factors." Be sure *all* readings are in the same units (e.g. mCi or  $\mu$ Ci). If this is an initial calibration the factors should be retained for future reference and transferred to a master work sheet similar to a copy of Appendix B, in the column labeled "Initial Factors." Copies of this master work sheet will be used for subsequent calibrations.

**NOTE:** If not performing an initial calibration, continue with the following steps.

18. Divide each entry in "Present Factors" column by corresponding entry in column labeled "Initial Factors." Enter results times 100 in column labeled "Percent Ratio." The ratios should have values near 100.

19. Examine entries in "Percent Ratio" column (3) to be sure that each is within the allowed tolerance limit for the present radioactive material license. For example, if the license allows 5% variation, all the values in the ratio column should be between 95 and 105. If all ratio values are within acceptable range, the calibration is complete and the isotope calibrator has been proven to have acceptable linearity.

If any value of the Percent Ratio is outside the acceptable range, renormalize by finding an average value for all eight percent ratio values and dividing each ratio by this average, then multiplying each by 100.

20. If final reading is greater than 10  $\mu$ Ci make a second source of  $\sim$ 30 mCi and repeat.

**NOTE:** If linearity is beyond tolerance, the problem may be due to:

A. Changing background conditions, including activity in nearby patients. Stabilize background activity and repeat.

B. Failure to properly subtract background for each reading. Check and repeat procedure if appropriate.

C. Damage to lineator components. Inspect and replace as necessary. Each component may be purchased separately, but will require a new initial calibration.

D. A defect in the dose calibrator. This requires repair of the calibrator, followed by a demonstration of linearity using conventional methods, and an initial calibration to establish the factors to be expected with future operation with the Lineator.

E. The leaded tubes were not seated properly.

F. Test time was greater than six minutes.

21. Sign data sheet and retain for future proof of calibration and compliance with regulations.

## SPECIFICATIONS

**Weight:** 6 lb (3 kg)

Authorized European Community Representative:

PROTHIA

26, rue serpollet

75020 Paris, France

(011)33.1.40.31.60.20

**— APPENDIX A —  
AMENDMENT REQUEST**

In order to be in compliance, please send the following to your license authority (state or NRC). Remember to use your facility stationery and reference the license number.

NRC or State License #: \_\_\_\_\_

Facility: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Contact: \_\_\_\_\_  
(Technologist, Consultant, Doctor, Administrator or RSO)

Phone: \_\_\_\_\_

Gentlemen:

Please amend our license to allow our dose calibrator to be checked for dose linearity with the model 086-509 Lineator manufactured by Biodex Medical Systems. Test results will be maintained in forms similar to those provided in the manufacturers operation manual. The test will be performed as per the operation manual. All corrective actions indicated will be made.

**— APPENDIX B1 —  
INITIAL CALIBRATION WORK SHEET**

(This should be completed and retained for your records.)

Date: \_\_\_\_\_

Calibrator Serial No.: \_\_\_\_\_

Operator: \_\_\_\_\_

Source: \_\_\_\_\_

Zero (Background) Reading: \_\_\_\_\_

Range: \_\_\_\_\_

Start Time: \_\_\_\_\_

<b>Tube(s)</b>	<b>Reading-Background</b>	<b>Present Factor (1)</b>	<b>Initial Factor (2)</b>	<b>Percent Ratio (3)</b>
1 only	_____	1	1	100
1 + 2	_____	_____	_____	_____
1 + 3a	_____	_____	_____	_____
1 + 2, 3a	_____	_____	_____	_____
1 + 4	_____	_____	_____	_____
1 + 2, 4	_____	_____	_____	_____
1 + 3a, 4	_____	_____	_____	_____
1 + 2, 3a, 4	_____	_____	_____	_____

Completion Time: \_\_\_\_\_

Notes: (1) Each factor is the ratio of the reading-background for tube 1 only to the reading-background for that entry.  
 (2) Values determined from initial calibration.  
 (3) % Ratios of Entries:  $100 \times \text{Col. (1)}/\text{Col. (2)}$ . If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

**— APPENDIX B2 —  
INITIAL CALIBRATION WORK SHEET**

(This should be completed and retained for your records.)

Date: \_\_\_\_\_

Calibrator Serial No.: \_\_\_\_\_

Operator: \_\_\_\_\_

Source: \_\_\_\_\_

Zero (Background) Reading: \_\_\_\_\_

Range: \_\_\_\_\_

Start Time: \_\_\_\_\_

<b>Tube(s)</b>	<b>Reading-Background</b>	<b>Present Factor (1)</b>	<b>Initial Factor (2)</b>	<b>Percent Ratio (3)</b>
1 only	_____	1	1	100
1 + 2	_____	_____	_____	_____
1 + 3b	_____	_____	_____	_____
1 + 4	_____	_____	_____	_____
1 + 2, 3b	_____	_____	_____	_____
1 + 2, 4	_____	_____	_____	_____
1 + 3b, 4	_____	_____	_____	_____
1 + 2, 3b, 4	_____	_____	_____	_____

Completion Time: \_\_\_\_\_

Notes: (1) Each factor is the ratio of the reading-background for tube 1 only to the reading-background for that entry.  
 (2) Values determined from initial calibration.  
 (3) % Ratios of Entries:  $100 \times \text{Col. (1)}/\text{Col. (2)}$ . If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

**— APPENDIX C1 —  
SAMPLE WORK SHEET**

Date: \_\_\_\_\_

Calibrator Serial No.: \_\_\_\_\_

Operator: \_\_\_\_\_

Source: \_\_\_\_\_

Zero (Background) Reading:       .04 mCi      

Range:       auto scaling      

Start Time:       8:20      

Tube(s)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
1 only	<u>      30 mCi      </u>	<u>      1      </u>	<u>      1      </u>	<u>      100      </u>
1 + 2	<u>      6.15      </u>	<u>      4.878      </u>	<u>      4.87      </u>	<u>      100.16      </u>
1 + 3a	<u>      4.05      </u>	<u>      7.407      </u>	<u>      7.40      </u>	<u>      100.09      </u>
1 + 2, 3a	<u>      .831      </u>	<u>      36.10      </u>	<u>      36.11      </u>	<u>      99.97      </u>
1 + 4	<u>      .162      </u>	<u>      185.19      </u>	<u>      182.32      </u>	<u>      101.6      </u>
1 + 2, 4	<u>      .0355      </u>	<u>      845.07      </u>	<u>      847.53      </u>	<u>      99.71      </u>
1 + 3a, 4	<u>      .0238      </u>	<u>      1260.50      </u>	<u>      1268.46      </u>	<u>      99.37      </u>
1 + 2, 3a, 4	<u>      .0052      </u>	<u>      5769.23      </u>	<u>      5738.87      </u>	<u>      100.53      </u>

Completion Time:       8:23      

Notes: (1) Each factor is the ratio of the reading-background for tube 1 only to the reading-background for that entry.  
 (2) Values determined from initial calibration.  
 (3) % Ratios of Entries: 100 x Col. (1)/Col. (2). If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

**— APPENDIX C2 —  
SAMPLE WORK SHEET**

Date: \_\_\_\_\_

Calibrator Serial No.: \_\_\_\_\_

Operator: \_\_\_\_\_

Source: \_\_\_\_\_

Zero (Background) Reading:       .06 mCi      

Range:       auto scaling      

Start Time:       8:10      

Tube(s)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
1 only	<u>      305 mCi      </u>	<u>      1      </u>	<u>      1      </u>	<u>      100      </u>
1 + 2	<u>      62.4      </u>	<u>      4.888      </u>	<u>      4.868      </u>	<u>      100.41      </u>
1 + 3b	<u>      5.13      </u>	<u>      59.45      </u>	<u>      59.32      </u>	<u>      100.22      </u>
1 + 4	<u>      1.676      </u>	<u>      181.98      </u>	<u>      181.9      </u>	<u>      100.04      </u>
1 + 2, 3b	<u>      1.083      </u>	<u>      281.63      </u>	<u>      280.88      </u>	<u>      100.27      </u>
1 + 2, 4	<u>      .361      </u>	<u>      844.86      </u>	<u>      845.13      </u>	<u>      99.97      </u>
1 + 3b, 4	<u>      .0328      </u>	<u>      9298.78      </u>	<u>      9197.43      </u>	<u>      101.10      </u>
1 + 2, 3b, 4	<u>      .00757      </u>	<u>      40290.62      </u>	<u>      38716.2      </u>	<u>      104.10      </u>

Completion Time:       8:14      

Notes: (1) Each factor is the ratio of the reading-background for tube 1 only to the reading-background for that entry.  
 (2) Values determined from initial calibration.  
 (3) % Ratios of Entries: 100 x Col. (1)/Col. (2). If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.



**— APPENDIX C3 —  
SAMPLE WORK SHEET**

Date: \_\_\_\_\_

Calibrator Serial No.: \_\_\_\_\_

Operator: \_\_\_\_\_

Source: \_\_\_\_\_

Zero (Background) Reading:     .06 mCi    

Range:     auto scaling    

Start Time:     8:30    

Tube(s)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
1 only	<u>    1134 mCi    </u>	<u>    1    </u>	<u>    1    </u>	<u>    100    </u>
1 + 2	<u>    232.2    </u>	<u>    4.884    </u>	<u>    4.868    </u>	<u>    100.32    </u>
1 + 3b	<u>    18.96    </u>	<u>    59.81    </u>	<u>    59.32    </u>	<u>    100.83    </u>
1 + 4	<u>    6.18    </u>	<u>    183.49    </u>	<u>    181.9    </u>	<u>    100.88    </u>
1 + 2, 3b	<u>    4.00    </u>	<u>    283.5    </u>	<u>    280.88    </u>	<u>    100.93    </u>
1 + 2, 4	<u>    1.334    </u>	<u>    850.07    </u>	<u>    845.13    </u>	<u>    100.59    </u>
1 + 3b, 4	<u>    .123    </u>	<u>    9219.51    </u>	<u>    9197.43    </u>	<u>    100.24    </u>
1 + 2, 3b, 4	<u>    .0296    </u>	<u>    38310.81    </u>	<u>    38716.2    </u>	<u>    98.95    </u>

Completion Time:     8:34    

Notes: (1) Each factor is the ratio of the reading-background for tube 1 only to the reading-background for that entry.

(2) Values determined from initial calibration.

(3) % Ratios of Entries: 100 x Col. (1)/Col. (2). If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

**NOTE:** This work sheet demonstrates activity that could be obtained when milking a generator. A two stage linearity is required. After counting for the high activity, take a smaller activity (i.e. 30 mCi) and count that on another sheet.

**— APPENDIX D1 —  
WORK SHEET**

Date: \_\_\_\_\_

Calibrator Serial No.: \_\_\_\_\_

Operator: \_\_\_\_\_

Source: \_\_\_\_\_

Zero (Background) Reading: \_\_\_\_\_

Range: \_\_\_\_\_

Start Time: \_\_\_\_\_

<b>Tube(s)</b>	<b>Reading-Background</b>	<b>Present Factor (1)</b>	<b>Initial Factor (2)</b>	<b>Percent Ratio (3)</b>
1 only	_____	1	1	100
1 + 2	_____	_____	_____	_____
1 + 3a	_____	_____	_____	_____
1 + 2, 3a	_____	_____	_____	_____
1 + 4	_____	_____	_____	_____
1 + 2, 4	_____	_____	_____	_____
1 + 3a, 4	_____	_____	_____	_____
1 + 2, 3a, 4	_____	_____	_____	_____

Completion Time: \_\_\_\_\_

Notes: (1) Each factor is the ratio of the reading-background for tube 1 only to the reading-background for that entry.  
 (2) Values determined from initial calibration.  
 (3) % Ratios of Entries:  $100 \times \text{Col. (1)}/\text{Col. (2)}$ . If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

**— APPENDIX D2 —  
WORK SHEET**

Date: \_\_\_\_\_

Calibrator Serial No.: \_\_\_\_\_

Operator: \_\_\_\_\_

Source: \_\_\_\_\_

Zero (Background) Reading: \_\_\_\_\_

Range: \_\_\_\_\_

Start Time: \_\_\_\_\_

<b>Tube(s)</b>	<b>Reading-Background</b>	<b>Present Factor (1)</b>	<b>Initial Factor (2)</b>	<b>Percent Ratio (3)</b>
1 only	_____	1	1	100
1 + 2	_____	_____	_____	_____
1 + 3b	_____	_____	_____	_____
1 + 4	_____	_____	_____	_____
1 + 2, 3b	_____	_____	_____	_____
1 + 2, 4	_____	_____	_____	_____
1 + 3b, 4	_____	_____	_____	_____
1 + 2, 3b, 4	_____	_____	_____	_____

Completion Time: \_\_\_\_\_

Notes: (1) Each factor is the ratio of the reading-background for tube 1 only to the reading-background for that entry.  
 (2) Values determined from initial calibration.  
 (3) % Ratios of Entries:  $100 \times \text{Col. (1)}/\text{Col. (2)}$ . If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.



*Certified Quality Management System*

# BIODEX

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