



**NEPHROLOGY PROGRAM
DEPARTMENT POLICIES AND PROCEDURES**

**Biomed Neph - Section 01 - Equipment Maintenance - Neph Tech 1-02
Preventive Maintenance Program for the Gambro Artis System
No.: 01122 (TOH Standardized Policy Number)**

ISSUED BY: Nephrology Technical Practice Committee	DATE OF APPROVAL: 2011/04
APPROVED BY: Program Clinical Director & Division Head	LAST REVIEW/REVISION DATE: 2018/03
CATEGORY: Equipment Maintenance	IMPLEMENTATION DATE: 2011/04

POLICY STATEMENT:

- In order to ensure patient safety all Gambro Artis systems shall go through a semi-annual preventive maintenance program (every 6 months)

PURPOSE:

- To specify the maintenance requirements and frequency for the Gambro Artis system

DEFINITION(S): N/A

ALERTS:

TOOLS AND SUPPLIES REQUIRED

1. Standard hand tools including multimeter, conductivity meter and electrical safety tester
2. Gambro test & calibration kit
3. Beaker (1,000 ml)
4. Appropriate preventive maintenance form:

PM Type	PM Sheet
Semi-annual	Artis Semi-Annual PM revised October 1, 2017
Annual	Artis Annual PM revised March 30, 2018
Every 2 years	Artis PM2 Checklist Form code # 9033248200

5. Appropriate preventive maintenance kit:
 - i. Annual maintenance (2 each 3-way valves part # SO00672 and bubble detector part # SP1409)
 - ii. Gambro PM2 preventive maintenance kit (part # SP01317)
 - iii. Preventative maintenance booklet service code # SP01314

PROCEDURE:

1. The first technologist to initiate the preventive maintenance shall open a NephroCare work order as well as initiate the appropriate preventive maintenance checklist
2. All interventions related to this specific preventive maintenance shall be noted on the preventive maintenance checklist
3. Follow instructions in the Preventative maintenance booklet service code # SP01314
4. Electrical safety testing procedures must be carried out following [Biomed Neph - Section 01 - Equipment Maintenance - Neph Tech 1-08 \(#01061\) Electrical Safety Testing Procedure](#)
5. The technologist completing the maintenance shall be responsible to enter the final information in the NephroCare work order and closing it
6. The technologist completing the maintenance shall update the Equipment Maintenance Log Sheet on the "V" drive
7. The preventive maintenance checklist shall be placed in the appropriate equipment binder along with a copy of the NephroCare work order

RELATED POLICIES / LEGISLATION:

1. Nephrology Policies and Procedures - [Biomed Neph - Section 01 - Equipment Maintenance - Neph Tech 1-07\(#01060\) NephroCare Work Orders](#)
2. Nephrology Policies and Procedures - [Biomed Neph - Section 01 - Equipment Maintenance - Neph Tech 1-08 \(#01061\) Electrical Safety Testing Procedure](#)

REFERENCES:

1. Preventive maintenance booklet service code # SP01314
2. [Artis Semi-annual PM \(TOH\)](#) revised October 1, 2017
3. [Artis Annual-PM \(TOH\)](#) revised March 30, 2018
4. Artis PM2 Checklist Form code # 9033248200

COMMENTS / SIGNIFICANT REVISIONS: N/A

ARTIS SEMI-ANNUAL PM		Machine #	Hrs:
<i>Neph Tech 1-02, revised October 1, 2017.</i>		Nephrocare #:	Date:
PHYSICAL INSPECTION AND CLEANING	Actions:	Verified	Initial
Wheels inspection for rolling ease	Clean and inspect for debris		
Battery tray and cover	Clean and inspect terminals		
Replace/rotate both 12V lead batteries	Label with site name and send to RKU for testing		
Thin client , power cord adaptor and both network cables	inspect and clean		
Blood pressure cuff and tubing	Inspect and clean		
Dialyzer holder	Inspect, clean and tighten screw		
IV pole	Inspect and clean		
Blood pump rotors and doors	Inspect and clean		
A/V/ADR (pressure port Assy.)	Inspect O-rings apply silicone compound		
EVA / ultra-cap door	Inspect seals, doors, hinges and clean module		
Heparin Module	Inspect and clean		
Sensor bar and sampling port	Inspect door hinge tightness and clean		
Bicart / select holder arms O-rings	Inspect O-rings and clean		
Red / blue dialysis tube connector	Inspect O-rings and clean		
Acid connector	Inspect O-rings and clean		
Hydraulic screws (holding hydraulic in)	Inspect screw threads, retaining ring, and insert		
Electronics and inner cabinet	PCB's pushed in tight and air dusted		
PRV regulator	Inspect / tighten: If found loose check calibration		
Hydraulics components, silicon tubing and fittings	Inspect all for wear and leaks, replace if necessary		
Air intake filter (back panel)	Replace or clean with air		
Power cord	Inspect both plug ends and entire cable for integrity		
	Tighten electrical connections on the male plug		
Water inlet and central acid	Inspect tubing and clamps		
Rear panel screws	Lubricate screws and nuts as needed		
FINAL CHECK	Actions:	Verified	Initial
Blood cassette loading arm test	Perform extension test. Must hold for 2 min		
	Inspect ART/VEN cassette arms for cracks		
Blood (PAT) sensor test - calibrate if necessary	Blood line not inserted = 220-250		
	Blood line filled with fluid = 32-67		
PC pump/ORDEG (refer to NPTB for troubleshooting)	PCFREQ: >12200Hz @ 500ml/min _____ Hz		
Power failure and Battery test - sec22.26 pm booklet	Complete T1 tests start 10min simulated TX		
	Power failure battery test, rec.value _____ ≥24.0V		
	Test blood pressure cuff operation		
Heparin module	Functional check of key pad operation		
Perform CleanCart "C" disinfection			
Time check verify clock, must match Nephrocare time			
"Machine Ready" sign	Complete sign and hang on iv pole		

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ARTIS Annual PM	Machine #	Hrs:	
<i>Neph Tech 1-02, revised March 30, 2018.</i>	Nephrocare #:	Date:	
PHYSICAL INSPECTION AND CLEANING	Actions:	Verified	Initial
Wheels inspection for rolling ease	Clean and inspect for debris		
Battery tray and cover	Clean and inspect terminals		
Wet sensor and Ultra Cover Hole	As per PM booklet chapter 20		
Replace/rotate both 12V lead batteries	Label with site name and send to RKU for testing		
Thin client , power cord adaptor and both network cables	Inspect and clean		
Blood pressure cuff and tubing	Inspect and clean		
Dialyzer holder	Inspect, clean and tighten screw		
IV pole	Inspect and clean		
Blood pump rotors and doors	Inspect and clean		
AV/ADR (pressure port assy.)	O-rings apply silicone compound		
EVA / ultra-cap door	Inspect seals, doors, hinges and clean module		
Heparin Module	Inspect and clean		
Sensor bar and sampling port	Inspect door hinge tightness and clean		
Bicart / select holder arms O-rings	Inspect O-rings and clean		
Red / blue dialysis tube connector	Inspect O-rings and clean		
Acid connector	Inspect O-rings and clean		
Hydraulic screws (holding hydraulic in)	Inspect screw threads, retaining ring, and insert		
Electronics and inner cabinet	PCB's pushed in tight and air dusted		
PRV regulator	Inspect / tighten: If found loose check calibration		
Hydraulics components, silicon tubing and fittings	Inspect all for wear and leaks, replace if necessary		
Air intake filter (back panel)	Replace or clean with air		
Power cord	Inspect both plug ends and entire cable for integrity		
	Tighten electrical connections on the male plug		
Water inlet and central acid	Inspect tubing and clamps		
Rear panel screws	Lubricate screws and nuts as needed		
PART REPLACEMENT	Actions:	Verified	Initial
EVDS 1 and EVDS 2 (part# SP00672)	Replace EVDS 1 and EVDS 2 the 3-way valve		
Air Bubble detector (part# SP01409)	Verify age of sensor bar if >5 years replace		
FINAL CHECK	Actions:	Verified	Initial
R1, R2 and PRV calibration	Calibrated, repair or replace if defective		
PET testing perform when machine is open	PET as per PM booklet 22.19		
Blood cassette loading arm test	Perform extension test. Must hold for 2 min		
	Inspect ART/VEN cassette arms for cracks		
Calibrate blood sensor trim pot and blood sensor (PAT sensor)	Blood line not inserted = 220-250		
	Blood line filled with fluid = 32-67		
PC pump/ORDEG (refer to NPTB for troubleshooting)	PCFREQ: >12200Hz @ 500ml/min _____ Hz		

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Simulated treatment	As per PM booklet 22.20 Total ultrafiltration accuracy test		
Heparin module	Functional check of key pad operation		
BP module	Test operation of BP module		
Power failure and Battery test - sec22.26 pm booklet	Power failure battery test, rec.value _____ $\geq 24.0V$		
	Test blood pressure cuff operation		
Time check verify clock, must match Nephrocare time	Change time and/or replace pentium board battery		
Electrical safety	Electrical safety as per Neph-Tech 1-08		
"Machine Ready" sign and disinfection	Compleat machine ready sign and perform disinfection		
Comments or Interventions:			

ARTIS/EVOSYS® Dialysis System – PM2 CHECKLIST FORM

Cust. Name: _____ Work Order: _____

Cust. Nr: _____ Date: _____ Serial Number: _____

This PM2 Checklist Form is only compatible with machines equipped with one of the following software: 8.08.02, 8.09.12, 8.09.13, 8.15.06, 8.33.02 or 8.52.01. This checklist is applicable to the Preventive Maintenance SP01317 Rev. A and Rev. B.

To perform the replacement procedures of the components contained in the Preventive Maintenance SP01317 box, refer to the Preventive Maintenance Booklet (1). To perform the replacement procedure(s) of the single spare part(s), refer to the related Instruction Sheet(s). To perform the calibration, test, verification and other procedures listed below, refer to the Service Manual for the appropriate actions. All items listed in the checklist require a check mark as an entry point for the next step. The checkmark indicates that the item has met manufacturer specification or it has been performed. If components are found out of range, perform the proper calibration procedure and report the out of range values in the Work Order. Mark with N/A any item that does not apply. We recommend performing each item in the listed order. This document may supersede the information included in your Service Manual.

REPLACE ALL THE COMPONENTS LISTED BELOW AND INCLUDED IN THE PM2 BOX: (1)

1. PRESSURE TRANSDUCERS O-RINGS	Replace the O-Rings on the Arterial, Venous and Pre-Dialyzer pressure transducers and apply Silicone Compound (see PM Booklet, Chapter 1)
2. EVACLEAN DOOR CAPS and ULTRA PORT CAP	Replace both Blue and Red EvaClean door caps (see PM Booklet, Chapter 2). Replace the silicone sealing cap on the Ultra Port (see PM Booklet, Chapter 3).
3. UPPER-LOWER SELECTCART AND UPPER BICART HOLDER ARMS O-RINGS (BiCart and SelectCart Holder Version 1)	Replace the upper and lower O-Rings of the SelectCart holder arms and the upper O-Ring of the BiCart holder arm (see PM Booklet, Chapter 5). Perform this step only for Version 1 of BiCart and SelectCart holders. Follow step 29 for BiCart and SelectCart holders Version 2.
4. LOWER BICART HOLDER ARM SPIKE (BiCart Holder Version 1)	Replace the lower BiCart holder arm spike (see PM Booklet, Chapter 6). Perform this step only for Version 1 of BiCart holder. Follow step 30 for BiCart holder Version 2.
5. MALE-FEMALE RED-BLUE DIALYSIS FLUID CONNECTORS/TUBES	Replace the male red and blue dialysis fluid connectors and the female red and blue dialysis fluid tubes (see PM Booklet, Chapter 8).
6. ACID PICK-UP TUBE CONNECTOR O-RINGS and the FEMALE ACID CONCENTRATE CONNECTOR	Replace the O-Rings on the white Acid pick-up tube connector (see PM Booklet, Chapter 9). Replace the Female Acid Concentrate Connector (see PM Booklet, Chapter 10).
7. ULTRAFILTERS HOLDERS O-RINGS AND X-RINGS	Replace the O-Rings and X-Rings on the Ultrafilters Holders (see PM Booklet, Chapter 13).
8. 250 MICRON FILTERS	Replace the F3 filter after pH Probe and F4 filter before EV2 valve (see PM Booklet, Chapter 11).
9. 50 MICRON FILTERS	Replace the F1, F2, F7, F8, F9 and FAIR filters (see PM Booklet, Chapter 12).
10. ORDEG RESTRICTION	Replace the ORDEG restriction in the Degassing Module, compatible only to the Rigid Connectors (see PM Booklet, Chapter 14).
11. R1 PRESSURE REDUCER PIN	Replace the pin in the R1 Pressure Regulator (see PM Booklet, Chapter 15).
12. NON RETURN VALVES	Replace the OWEVD1, OWH20, OWAIR, OWD OWWH01, OWWH02 and OWWH03 non return valves (one way/check valves). Replace the appropriate OWDGL non return valve depending on the machine configuration (see PM Booklet, Chapter 16).
13. AIR INTAKE FILTER	Replace the Air Intake Filter on the Lower Back Panel (see PM Booklet, Chapter 17).
14. Final Check for replaced components	Perform the final tests for the replaced components (see PM Booklet, Chapter 18).

THE FOLLOWING SPARE PARTS ARE MANDATORY AND MUST BE ORDERED SEPARATELY: (2)

15. EVDS1 and EVDS2 3-way valves *3 WAY SOLENOID VALVE PEEK* (spare part code: SP00672)	Replace the EVDS1 and EVDS2 3-way valves on all machines during Preventive Maintenance.
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THE FOLLOWING SPARE PARTS MUST BE ORDERED SEPARATELY AND REPLACED ONLY IF APPLICABLE: (2)

16. Female Central Concentrate Connectors *FEMALE CONC CONN (PPSU)* (spare part code: SP00676)	Replace the Central Concentrate Connectors only if used.
17. EVC and EVD 2-way valves *2WAY SOLENOID VALVE PEEK* (spare part code: SP00673)	Replace the EVC and EVD 2-way valves only if the Yellow and Clear disinfectant connectors are used.
18. F5 and F6 Filters *FILTER 50MICRON AE* (spare part code: 6997415)	Replace the F5 and F6 Filters only if the Yellow and Clear disinfectant connectors are used.
19. EVBP2 2-way valve *2WAY SOLENOID VALVE PEEK* (spare part code: SP00673)	Replace the EVBP2 2-way valve only on machines fully converted into AFB K Configuration (*AFB K Conversion Kit AE*, code 114111 or *CONVERSION KIT AFBK - IEC*, code 955083).
20. YELLOW-CLEAR DISINFECTANT CONNECTORS O-RINGS (use the spare part EXTERNAL O-RINGS KIT AE code 6987747)	Replace the O-Rings if the Yellow and Clear disinfectant connectors are used.
21. FH2O FILTER (use the spare part CWP H2O FILTER code 6973259)	Replace the FH2O water inlet filter if the Integrated Heat Disinfections are used.
22. Silicone Tube on the SelectBag Holder (spare part code: SP00257)	Replace the Silicone tube on the SelectBag Holder if the Select System is used.
23. AFBK AND BICARBONATE MALE CONNECTOR O-RINGS (use the "O" RING 2-008 code 6947998)	Replace the O-Rings if the machine is in the AFB K configuration.
24. PRV PRESSURE REGULATOR MEMBRANE (use the *PRV MEMBRANE AE* code 6996235)	Replace the Membrane if the machine is still in the FXT11 configuration.
25. AFBK AND BICARBONATE FEMALE CONNECTOR (use the *TYPE AF FEMALE CONN.* code 6977698 and *TYPE B FEMALE CONN.* code 6977672)	Replace the female connectors if the machine is in the AFB K configuration.
26. LEAD BATTERIES (use the spare part LEAD BATTERIES (2) BACKUP code SP00724)	The lead batteries should be replaced between 3 to 5 years according also to the *Power Failure & Battery Test*.

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27. PC BOARD BATTERY (use the spare part CPU Battery K8 3V BR1632 code G5050701)	Replace the battery in the PC Board at least every 5 years. The battery should be replaced earlier if the machine has not been used (one pack contains 20pcs).
28. Rigid Connectors in the Heating and Degassing Module (use the spare parts *RIGID CONNECTOR L 8/8" SP00451 and *RIGID CONNECTOR T8/8" SP00450).	It is suggested the replacement of the Rigid Connectors in the Heating and Deaeration module, from the Heat Exchanger to the PC Pump.
29. BICART AND SELECTCART HOLDER ARMS O-RINGS (Version 2) (use the spare part BIC/SELECT ORING NIPPLE code SP00491)	Replace the O-Rings of the BiCart/SelectCart Cartridge Holder Nipples in case of BiCart and/or Select Cart holders Version 2 are installed (one spare part contains 10pcs).
30. Lower Spike of the BiCart holder (Version 2) (use the spare part LOWER SPIKE UNIV.ARM. code SP00490)	Replace the Lower Spike of the BiCart Cartridge Holder Arm in case of BiCart holder Version 2 is installed.
31. AIR BUBBLE DETECTOR (use the spare part AIR BUBBLE DETECTOR code SP01409)	At the time of the scheduled preventive maintenance, replace the Air Bubble Detector if it is more than 5 years old. The first machine installation date is the reference. A subsequent replacing of the Air Bubble Detector (or Sensor Bar) can be used as new reference date only if the related Service Report ID is reported within PM service report.

EQUIPMENT VERIFICATIONS, VERIFY, TEST AND IF NECESSARY RECALIBRATE OR REPLACE:

32. Perform the required Cleaning and Visual Inspection according to the procedures provided in the PM Booklet, Chapter 19.	
33. Perform the Ultra Collector Assembly Maintenance (only for machine in Artis Physio Configuration) according to the procedures provided in the PM Booklet, Paragraph 19.8.	
34. Perform Wet Sensor and Ultrafilter Cover Hole maintenance provided in the PM Booklet, chapter 20, depending on your configuration: <ul style="list-style-type: none"> ➢ Wet Sensor Assembly Maintenance procedure, Paragraph 20.1, if the machine serial number is lower than FX019592 and has not been already retrofitted with Modification Message MM021 *FLUID LEAK DETECTION IMPROVEMENT*. ➢ Ultrafilter Cover Hole and Wet Sensor Assembly Maintenance procedure, Paragraph 20.2, if the machine has already retrofitted with Modification Message MM021 *FLUID LEAK DETECTION IMPROVEMENT* or if the machine serial number is from FX019592 onwards. 	
35. Verify the Power Supply Voltages according to the procedures provided in the PM Booklet, Chapter 21.	
36. Test the R1, R2 and PRV Pressure Regulators. ^(R)	
37. Test the PI Pressure Sensor. ^(R)	The acceptance criteria for the PI, PO, PFS and PDR pressure sensors are: ➢ -400 mmHg = -400 ± 22 on the Hyd. and on the Prot. fields. ➢ 0 mmHg = 0 ± 22 on the Hyd. and on the Prot. fields. ➢ +400 mmHg = +400 ± 22 on the Hyd. and on the Prot. fields.
38. Test the PO Pressure Sensor. ^(R)	
39. Test the PFS Pressure Sensor. ^(R)	
40. Test the PDR Pressure Sensor. ^(R)	
41. Test the PDG Pressure Sensor. ^(R)	The acceptance criteria for the PDG pressure sensor are: ➢ -560 mmHg = +200 ± 22 on the Hyd. and on the Prot. fields. ➢ -660 mmHg = +100 ± 22 on the Hyd. and on the Prot. fields. ➢ -260 mmHg = +500 ± 22 on the Hyd. and on the Prot. fields.
42. Perform the Conductivity Test: ^(R) <ul style="list-style-type: none"> ➢ 2.0 mS/cm = 2.0 ± 68 mS/cm ➢ 4.0 mS/cm = 4.0 ± 68 mS/cm ➢ 12.0 mS/cm = 12.0 ± 6A mS/cm ➢ 16.0 mS/cm = 16.0 ± 6A mS/cm 	Acceptance criteria: 6B = 0.10 on Cond B and on Cond Sel values. 6B = 0.10 between the Cond B and the external meter values. 6A = 0.20 on Cond A and on Cond P values. 6A = 0.20 between the Cond A and the external meter values.
43. Perform the Temperature Test: ^(R) <ul style="list-style-type: none"> ➢ 37.0 °C = 37.0 ± 6T °C 	Acceptance criteria: 6T = 0.5 between TcA (Hyd) and Tp (Prot) values. 6T = +1.0 and -1.8 between TcA (Hyd) and external meter.
44. Test the pH Probe: ^(R) (perform the test only if the pH Probe is installed)	4.0 = 4.0 ± 0.30 pH 8.0 = 8.0 ± 0.30 pH
45. Test the Blood Sensor Trimpot. ^(R)	180 ± 10
46. Test the Blood Sensor. ^(R)	Blood line not inserted into the blood sensor = from 220 to 250 Blood line filled with fluid inserted into the blood sensor = from 32 to 67
47. Calibrate the Hemoscan Sensor. ^(R)	1.10 V
48. Test the Scale Sensor. ^(R) (perform the test only if the scale is installed)	0 g = 0 ± 12 on the Bioslave and on the Prot. fields. WEIGHT USED g = WEIGHT USED ± 90 on the Bioslave and on the Prot. fields.
49. Test the Arterial pressure sensor. ^(R)	0 mmHg ± 7 mmHg on Blood, on Hyd. and on Prot. fields. -250 mmHg ± 22 mmHg on Blood, on Hyd. and on Prot. fields. -350 mmHg ± 22 mmHg on Blood, on Hyd. and on Prot. fields.
50. Test the Venous pressure sensor. ^(R)	0 mmHg ± 7 mmHg on Blood, on Hyd. and on Prot. fields.
51. Test the SN pressure sensor. ^(R)	200 mmHg ± 17 mmHg on Blood, on Hyd. and on Prot. fields. 400 mmHg ± 37 mmHg on Blood, on Hyd. and on Prot. fields.
52. Test the BPM pressure sensor. ^(R)	For HDGPM model: 100 mmHg ± 3 mmHg 150 mmHg ± 3 mmHg 200 mmHg ± 3 mmHg For NBPM model: 100 mmHg ± 3 mmHg 180 mmHg ± 3 mmHg 250 mmHg ± 3 mmHg on the Blood field, on the Blood field, on the Blood field.
53. Perform the Arterial Pump Rotor Occlusion Test according to the procedures provided in the PM Booklet, Paragraph 22.17.	
54. Perform the Venous Pump Rotor Occlusion Test according to the procedures provided in the PM Booklet, Paragraph 22.18.	
55. Perform PET - Protective Earth Test ≤ 300 mOhm according to the procedures provided in the PM Booklet, Paragraph 22.19.	



Note

Ensure that all tie wraps are properly restored on the hydraulic connections when a component is disconnected or replaced.

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SIMULATED DIALYSIS TREATMENT: (1)

56. Use the Total Ultrafiltration Accuracy Test procedure to perform the simulated dialysis treatment. See PM Booklet, Paragraph 22.20.	
– Verify the correct T1 Tests execution. See PM Booklet, Paragraph 22.21.	
– Perform a dialysis treatment with blood detection for the first 10 minutes. See PM Booklet, Paragraph 22.22.	
– Perform a Power Failure & Battery Test according to the procedures provided in the PM Booklet, Paragraph 22.23.	
– Perform the ELT - Earth Leakage Current Test. Refer to the PM Booklet, Paragraph 22.24.	For machines 115V: N.C. ≤300µA; S.F.C. ≤300µA For machines 230V: N.C. ≤400µA; S.F.C. ≤800µA
– Perform the PLT - Patient Leakage Current Test. Refer to the PM Booklet, Paragraph 22.24.	N.C.: ≤10µAa.c. and ≤10µAd.c. S.F.C.: ≤400µAa.c. and ≤40µAd.c. If Central Venous Catheters are used: S.F.C.: ≤40µAa.c.
– Simulate an "Air in Venous Line" alarm and resolve the alarm. See PM Booklet, Paragraph 22.25.	
57. Perform the Water Leakage Check to inspect the main hydraulic compartment for water leakages. See PM Booklet, Paragraph 22.26.	
58. Notify the machine operator to perform a disinfection procedure prior to perform a dialysis treatment. See PM Booklet, Paragraph 22.27.	
59. Attach the optional Preventive Maintenance label to the rear cover of the machine. Mark month and year for the next preventive maintenance. See PM Booklet, Paragraph 22.28.	

REFERENCES:

- (1) Refer to the Preventive Maintenance Booklet (spare part code:SP01314).
- (2) Refer to the Instruction Sheet provided in the Spare Part kit.
- (3) Refer to the "Calibration" Chapter of the Service Manual.

Technician: _____

Time Counter after PM: _____

Reference Instruments: _____