

IT IS UNSAFE TO START USING THIS DEVICE WITHOUT FIRST READING AND
UNDERSTANDING THIS MANUAL IN ITS ENTIRETY

OPERATOR MANUAL

FOR

BIPRO MM₅P BICARBONATE
MIXER FOR HEMODIALYSIS

IMPORTANT DOCUMENT PLEASE SAFEGUARD

November 9, 2017

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| This section consists of thirteen (13) pages OPI-001 1/13 to OPI -001 13/13 | |

USER ASSISTANCE INFORMATION

ASSISTANCE IS AVAILABLE: Monday through Friday (excluding holidays)
8:00 am to 4:00 pm Central time.

Call: 913-438-9700

Emergency assistance is available after normal operating hours,

Call: 913-269-5681 JACK DILLON'S CELL

If the phone fails to answer please leave a message, include the contact name and a phone number that will be answered before business hours.

GENERAL DESCRIPTION

The BiPro MM5p Bicarbonate mixing system is a single tank pump driven bicarbonate mixer. When operating instructions are followed mixing bicarbonate in quantities up to 50 gallons is easy and accurate. It is possible to disinfect the system with multiple disinfection solutions.

The specific instructions for all procedure's are included in this manual.

WARNINGS, CAUTIONS & RECOMMENDATIONS

WARNING: It is unsafe to operate the Bicarbonate system without first reading and understanding the Operator's Instruction Manual

WARNING: Misuse, improper operation, and/or improper monitoring of the system could result in serious injury, death, or serious reactions to patients undergoing hemodialysis treatment.

CAUTION: When used as a medical device, Federal law restricts this device to sale by or on the order of a physician.

NOTE: Where water is mentioned, it must be AMA standard quality water

NOTE: Once the BiPro SDS MM5P system has been delivered to you, it is the responsibility of the Medical Director to ensure that the system is used, monitored, and maintained in such a manner so as to satisfy all applicable standards.

RECOMMENDATIONS:

Disinfection of this system prior to use and on a recurring schedule is required. Disinfection chemicals and quantities are to be determined by the medical director. Common disinfectants approved for use with this equipment are, chlorine bleach in a 100:1, ratio, Renlin in a 100:1ratio.

Precipitate removal can be accomplished with vinegar or acetic acid used in a 20:1 ratio.

Disinfection scheduling is to be determined by the Medical Director of the facility.

Precipitate removal should be accomplished on a minimum of a monthly basis.

Filter changes for the 0.2 micron air filters are to be accomplished on a annual basis..

BICARBONATE CONCENTRATE MIXING PROCEDURE.

PURPOSE: EQUIPMENT EQUIPMENT:

TO PROPERLY PREPARE BICARBONATE CONCENTRATE.

- 1) MEDICAL SOLUTIONS BICARB MIXING SYSTEM
- 2) APPROPRIATE BICARB POWDER PACKAGES
- 3) APPROPRIATE CONCENTRATE TESTING METHODOLOGY (EG. SPECIFIC GRAVITY, CONDUCTIVITY)
- 4) AAMI STANDARD PURIFIED WATER USED TO PREPARE CONCENTRATE FOR HEMODIALYSIS

PROCEDURE: 1. START WITH;

| | |
|-------------------------|---------------|
| SPRAY VALVE (#1) | CLOSED |
| MIX VALVE (#2) | OPEN |
| JUG FILL (#3) | CLOSED |
| DRAIN VALVE (#4) | CLOSED |

2. RAISE OR LOWER WAND TO SELECT THE DESIRED FILL LEVEL, **PRESS FILL - ON**, THIS WILL FILL THE MIXING TANK TO THE REQUESTED VOLUME.
3. THE FILL WILL STOP WHEN WATER REACHES DESIRED LEVEL **ROTATE PUMP TIMER SWITCH:** TO TURN ON THE MIXING PUMP.
4. SLOWLY ADD THE APPROPRIATE AMOUNT OF BICARB POWDER TO THE TANK. AFTER POWDER IS ADDED ALLOW TO CONTINUE MIXING FOR 1 MINUTE. VERIFY DESIRED QUANTITY OF BICARB IS CORRECT.
5. ALLOW THE SOLUTION TO MIX FOR A MINIMUM OF 10 (TEN) MINUTES. **SWITCH WILL TURN THE PUMP OFF**, WHEN THE MIXING TIME IS COMPLETED.
6. TEST THE MIXED SOLUTION WITH THE FACILITY APPROVED TESTING METHODOLOGY AT THE **JUG FILL VALVE (#3)** (CLEAR THE VALVE BEFORE TESTING).
7. IF THE SOLUTION PASSES THE SELECTED TEST, PROCEED TO STEP NUMBER 9.

8. IF THE SOLUTION DOES NOT PASS THE SELECTED TEST, AFFIRM QUANTITY OF WATER AND POWDER ARE CORRECT (IF NOT TAKE CORRECTIVE ACTION). CONTINUE TO MIX THE SOLUTION IN 5 (FIVE) MINUTE INTERVALS, AND REPEAT TESTING.
9. DESPENSE INTO JUGS AS NEEDED.

BICARBONATE CHEMICAL DISINFECT PROCEDURES

PURPOSE: TO PROPERLY DISINFECT SYSTEM

EQUIPMENT; 1) MEDICAL SOLUTIONS BICARB MIXING SYSTEM
2) APPROPRIATE DISINFECTANT
3) APPROPRIATE CONCENTRATE TESTING
METHODOLOGY
4) AAMI STANDARD PURIFIED WATER

PROCEDURE: 1). **START WITH;**

| | |
|-------------------------|---------------|
| SPRAY VALVE (#1) | CLOSED |
| MIX VALVE (#2) | OPEN |
| JUG FILL (#3) | CLOSED |
| DRAIN VALVE (#4) | CLOSED |

2. RAISE OR LOWER WAND TO SELECT THE DESIRED FILL LEVEL, **PRESS FILL - ON**, THIS WILL FILL THE MIXING TANK TO THE REQUESTED VOLUME.
3. THE FILL WILL STOP WHEN WATER REACHES DESIRED LEVEL **ROTATE PUMP TIMER SWITCH:** TO TURN ON THE MIXING PUMP.
- 4) SLOWLY ADD THE APPROPRIATE AMOUNT OF DISINFECTANT TO THE TANK.
- 5) ALLOW THE SOLUTION TO MIX FOR 1(ONE) MINUTE.
- 6) **ROTATE PUMP TIMER SWITCH:** TO TURN ON THE MIXING PUMP.
- 7) TEST THE MIXED SOLUTION WITH THE APPROPRIATE TESTING METHODOLOGY AT THE **JUG FILL VALVE (#3)** (CLEAR THE VALVE BEFORE TESTING).
- 8) IF THE SOLUTION PASSES THE SELECTED TEST, PROCEED TO STEP NUMBER 9.
- 9) IF THE SOLUTION DOES NOT PASS THE SELECTED TEST, AFFIRM QUANTITY OF WATER AND DISINFECTANT IS CORRECT AND CONTINUE TO MIX THE SOLUTION IN 1 (ONE) MINUTE INTERVALS, AND REPEAT TESTING.

- 10) **OPEN THE SPRAY VALVE (#1) ROTATE PUMP TIMER SWITCH:** TO TURN ON THE MIXING PUMP. The Disinfectant will spray the interior of the tank.
- 11) **OPEN THE MIX TANK DRAIN ALLOW TO DRAIN AND WAIT FOR THE PRE DETERMINED AND APPROVED CONTACT TIME.**

**NEVER LEAVE DISINFECTANT IN
THE SYSTEM
PROCEED TO RINSING THE
SYSTEM.**

BICARBONATE PRECIPITATE REMOVAL PROCEDURE

PURPOSE: TO PROPERLY REMOVE PRECIPITATE FROM THE SYSTEM

EQUIPMENT; 1) MEDICAL SOLUTIONS BICARB MIXING SYSTEM
2) APPROPRIATE DISINFECTANT
3) APPROPRIATE CONCENTRATE TESTING
METHODOLOGY
4) AAMI STANDARD PURIFIED WATER

PROCEDURE: 1). **START WITH;**

| | |
|-------------------------|---------------|
| SPRAY VALVE (#1) | CLOSED |
| MIX VALVE (#2) | OPEN |
| JUG FILL (#3) | CLOSED |
| DRAIN VALVE (#4) | CLOSED |

2. RAISE OR LOWER WAND TO SELECT THE DESIRED FILL LEVEL, **PRESS FILL - ON**, THIS WILL FILL THE MIXING TANK TO THE REQUESTED VOLUME.
3. THE FILL WILL STOP WHEN WATER REACHES DESIRED LEVEL **ROTATE PUMP TIMER SWITCH:** TO TURN ON THE MIXING PUMP.
- 4) SLOWLY ADD THE APPROPRIATE AMOUNT OF CHEMICAL OF CHOICE TO THE TANK.
- 5) ALLOW THE SOLUTION TO MIX FOR 1(ONE) MINUTE.
- 6) **ROTATE PUMP TIMER SWITCH:** TO TURN ON THE MIXING PUMP.
- 7) TEST THE MIXED SOLUTION WITH THE APPROPRIATE TESTING METHODOLOGY AT THE **JUG FILL VALVE (#3)** (CLEAR THE VALVE BEFORE TESTING).
- 8) IF THE SOLUTION PASSES THE SELECTED TEST, PROCEED TO STEP NUMBER 9.
- 9) IF THE SOLUTION DOES NOT PASS THE SELECTED TEST, AFFIRM QUANTITY OF WATER AND DISINFECTANT IS CORRECT AND CONTINUE TO MIX THE SOLUTION IN 1 (ONE) MINUTE INTERVALS, AND REPEAT TESTING.

- 10) **OPEN THE SPRAY VALVE (#1)ROTATE PUMP TIMER SWITCH:** TO TURN ON THE MIXING PUMP. The Disinfectant will spray the interior of the tank.
- 11) **OPEN THE MIX TANK DRAINALLOW TO DRAIN AND WAIT FOR THE PRE DETERMINED AND APPROVED CONTACT TIME.**

**NEVER LEAVE DISINFECTANT IN
THE SYSTEM
PROCEED TO RINSING THE
SYSTEM.**

RINSING THE SYSTEM

PURPOSE: TO PROPERLY RINSE THE BICARB MIXING SYSTEM.

EQUIPMENT: 1) MEDICAL SOLUTIONS BICARB MIXING SYSTEM
2) AAMI STANDARD PURIFIED WATER

PROCEDURE:

1). START WITH;

| | |
|-------------------------|---------------|
| SPRAY VALVE (#1) | CLOSED |
| MIX VALVE (#2) | OPEN |
| JUG FILL (#3) | CLOSED |
| DRAIN VALVE (#4) | CLOSED |

1. ADJUST THE WAND TO FILL TO 25 GALLON LEVEL, **PRESS FILL...ON**
2. AFTER 30 SECONDS OPEN THE **SPRAY VALVE (#1)**
CLOSE THE **FILL/MIX VALVE (#2)**.
4. FLUSH THE **JUG FILL SAMPLE PORT** AND TEST FOR THE ABSENCE OF DISINFECTANT.
WHEN SATISFIED NO DISINFECTANT REMAINS, PROCEED:
5. AFTER TWO MINUTES TURN PRESS THE EMERGENCY FILL STOP.
6. ALLOW THE TANK TO DRAIN. WHEN THE TANK IS EMPTY,
CLOSE **DRAIN VALVE (#4)**,
OPEN **FILL/MIX VALVE (#2)**
7. **PRESS FILL ON**, FILL WILL STOP WHEN WATER REACHES THE 25 GALLON LEVEL. TEST AT THE **JUG FILL SAMPLE PORT** FOR THE ABSENCE OF DISINFECTANT WHEN SATISFIED NO DISINFECTANT REMAINS, PROCEED: IF DISINFECTANT IS DETECTED OPEN THE DRAIN AND REFILL TO THE 25 GALLON MARK, THEN RETEST AND CONTINUE:
8. OPEN THE **DRAIN VALVE (#4) ALLOW TO DRAIN.**



Medical Solutions

I N T E R N A T I O N A L

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