

CCU - Test & Calibration

NOTE: You must have a watch with a timer or secondhand to perform this procedure.
Time required to complete all tests is approximately 2 hours.

Connect Calibration Check Unit to M1000

- 1 WARNING: Ensure Control Unit water level is FULL before starting any tests.
- 2 Remove the Fluid Delivery Line from the M1000 (make sure the unit has been recently purged to avoid any water leakage from the Fluid Delivery Line).
- 3 Attach the CCU to the M1000 in the same manner as a fluid delivery line. Lock the CCU in place by moving the locking handle all the way to the right
- 4 Disconnect the patient temperature adaptor cable from the M1000. Attach the blue connector labeled "PT1" from the CCU to the patient temperature port on the M1000 labeled "1"
- 5 Attach the blue connector labeled "PT2" from the CCU to the patient temperature port on the M1000 labeled "2"
- 6 Connect the CCU Black circular connector labeled "TO" to the M1000 black connector labeled "TEMP OUT"

Prewarm & Flow Check (10 Minutes)

- 7 Record CCU Label Data & Hospital Data in Table 1
- 8 On the CCU, locate Switch 1 (S1), Switch 2 (S2) & Switch 4 (S4)
- 9 On the CCU, Set Switches: S1 - B, S2 - A
- 10 Turn on the M1000 in User Diagnostic (UD) mode. This is done by pressing and holding the Auto **AND** Purge keys while turning on the unit. Release the keys 5 seconds after the first audible beep.
- 11 Press the "Up" Key once to scroll to the UD4 Screen
- 12 Press the Enter Key to initiate the Test and Calibration Mode
- 13 Press Enter Key to begin "Pre-Warm & Check Flow" (**Requires approximately 10 minutes**)
- 14 Record Final Flow Rate (FL) shown in upper right of display in Table 2
- 15 Press Enter Key
- 16 Press Enter Key again to Begin "Check Inlet Pressure Offset"
- 17 Disconnect CCU from Inlet & then Press Enter
- 18 Upon test completion, record Inlet Pressure (IP) shown in upper right of display in Table 2
- 19 Reconnect CCU when prompted
- 20 Press Enter

Patient Temperature 1 Check (5 Minutes)

- 21 Press Enter to begin "Check Patient Temperature 1"
- 22 Press Enter to change the displayed value "CTU Value A"
- 23 Adjust "CTU Value A" using up/down arrows until it matches "A" listed on CCU label
- 24 Press Enter to accept value
- 25 Press Enter to continue
- 26 Press Enter to change the displayed value "CTU Value B"
- 27 Adjust "CTU Value B" using up/down arrows until it matches "B" listed on CCU label
- 28 Press Enter to accept value
- 29 Press Enter to continue
- 30 Press Enter to change the displayed value "CTU Value C"
- 31 Adjust "CTU Value C" using up/down arrows until it matches "C" listed on CCU label
- 32 Press Enter to accept value
- 33 Press Enter to continue
- 34 Press Enter to change the displayed value "CTU Value D"
- 35 Adjust "CTU Value D" using up/down arrows until it matches "D" listed on CCU label
- 36 Press Enter to accept value
- 37 Press Enter to continue
- 38 Set Switches S1-B, S2-A (if not already set in this configuration)
- 39 Press Enter
- 40 When prompted, Set Switches S1-C, S2-A
- 41 Press Enter
- 42 When prompted, Set Switches S1-D, S2-A
- 43 Press Enter
- 44 When prompted, Set Switches S1-E, S2-A
- 45 Press Enter

- 46 When Displayed, Record PT1 Check Results in Table 2
- 47 Press Enter

Patient Temperature 2 Check (5 Minutes)

- 48 Press Enter again to begin "Check Patient Temperature 2"
- 49 Set Switches S1-B, S2-B
- 50 Press Enter
- 51 When prompted, Set Switches S1-C, S2-B
- 52 Press Enter
- 53 When prompted, Set Switches S1-D, S2-B
- 54 Press Enter
- 55 When prompted, Set Switches S1-E, S2-B
- 56 Press Enter
- 57 When Displayed, Record PT2 Check Results in Table 2
- 58 Press Enter

Temperature Out (Echo Out) Check (5 Minutes)

- 59 Press Enter again to begin "Check Echo Output"
- 60 Set Switches S1-B, S2-A
- 61 Press Enter
- 62 When prompted, Set Switches S1-C, S2-A
- 63 Press Enter
- 64 When prompted, Set Switches S1-D, S2-A
- 65 Press Enter
- 66 When prompted, Set Switches S1-E, S2-A
- 67 Press Enter
- 68 When Displayed, Record EC Check Results in Table 2
- 69 Press Enter

Water Temperature Check (30 Minutes)

- 70 Press Enter again to begin "Check Water Temperatures"
- 71 Press Enter to change the displayed value "CTU Value E"
- 72 Adjust "CTU Value E" using up/down arrows until it matches "E" listed on CCU label
- 73 Press Enter to accept value
- 74 Press Enter to continue
- 75 Press Enter to change the displayed value "CTU Value F"
- 76 Adjust "CTU Value F" using up/down arrows until it matches "F" listed on CCU label
- 77 Press Enter to accept value
- 78 Press Enter to continue
- 79 Press Enter to change the displayed value "CTU Value G"
- 80 Adjust "CTU Value G" using up/down arrows until it matches "G" listed on CCU label
- 81 Press Enter to accept value
- 82 Press Enter to continue
- 83 Set Switches S1-B, S2-B
- 84 Press Enter (**Requires approximately 25 minutes to complete**)
- 85 Record T1 Check Results in Table 2
- 86 Press Enter to continue
- 87 Record T2 Check Results in Table 2
- 88 Press Enter to continue
- 89 Record T3 Check Results in Table 2
- 90 Press Enter to continue
- 91 Record Heat & Cool Results in Table 2
- 92 Press Enter to continue
- 93 Review the above sheet. If ANY step FAILS, then the Control Unit fails the calibration check, unit is out of calibration and should be recalibrated (see below). If ALL the steps passed, the calibration steps below are still required in order to tighten the tolerance on the machine. Contact Technical Support if you have any questions or issues.

Control Unit **Pass** _____ **Fail** _____

Calibration (35 Minutes)

- 94 Record Calibration Hours in Table 2
- 95 Press Enter again to begin "Calibrate System"
- 96 Set Switches S1-B, S2-C
- 97 Press Enter (Requires approximately 30 minutes to complete)
- 98 When prompted, after "Calibration Complete", Press Enter
- 99 Press Enter to "Save Calibration Values"
- 100 Press Enter "All Cal Parameters Will Be Saved"
- 101 When Prompted, Press Enter to continue
- 102 Press Enter to "Return to Top Cal Menu"
- 103 Display will read "Connect Cal Test Unit, <Enter to Begin>"
- 104 Turn off power to the M1000

Verify Calibration Was Successful (5 Minutes)

- 105 Power up M1000 in "Normal" mode
- 106 If calibration was successful the third screen displayed will read as shown below
- 107 "System calibration due in 2000 hours or 250 uses"

Calibration Successful Yes / No

NOTE: If after the Calibration Step is complete, the machine reads "Calibration Unsuccessful" contact Technical Support.

High Water Temperature Alarm Test #1 (10 Minutes)

- 108 Read all instructions for this test before starting
- 109 Remove the Fluid Delivery Line from the M1000 (make sure the unit has been recently purged to avoid any water leakage from the Fluid Delivery Line).
- 110 Attach the CCU to the M1000 in the same manner as a fluid delivery line. Lock the CCU in place by moving the locking handle all the way to the right
- 111 Do not attach CCU cables to the control unit
- 112 Connect the power cord to the CCU & plug the other end to an electrical outlet
- 113 Turn on the M1000 in User Diagnostic (UD) mode. This is done by pressing and holding the Auto **AND** Purge keys while turning on the unit. Release the keys 5 seconds after the first audible beep.
- 114 Press the "Up" Key once to scroll to the UD4 Screen
- 115 Press "Manual" key
- 116 Press "Down" key once
- 117 Press "Enter"
- 118 Use "Up/Down" keys to change water target temperature to 42 °C
- 119 Press "Enter"
- 120 Press "Home" key
- 121 Allow water temperature T1 to stabilize at 42.00 °C (+/- 0.10 °C)
- 122 Press & Hold CCU Switch 4 (Heater Switch) on bottom of CCU near power cord connection
- 123 Monitor User Interface T1 temperature
- 124 When T1 temperature reaches 43.01 °C, start a timer. **CAUTION: If T1 drops below 43.01 °C after timer has been started, reset timer and begin this step again.**
- 125 Alarm 37 must sound in less than 18 seconds
- 126 Release Switch 4 when alarm sounds
- 127 Record results in Table 2
- 128 Press "Alarm Clear" key
- 129 Verify T1 temperature does not exceed 44.01 °C for more than 2 seconds as this will trigger Alarm 36
- 130 If Alarm 36 occurs, this test must be repeated
- 131 Turn off power to the M1000
- 132 Allow unit to cool for 5 minutes before powering up again

High Water Temperature Alarm Test #2 (10 Minutes)

- 133 Read all instructions for this test before starting
- 134 Power up M1000 in "Normal" mode
- 135 Press "Manual" key
- 136 Press "Down" key once
- 137 Press "Enter"
- 138 Use "Up/Down" keys to change water target temperature to 42 °C
- 139 Press "Enter"
- 140 Press "Home" key
- 141 Allow water temperature to stabilize at 42.0 °C (+/- 0.1 °C)
- 142 Press & Hold CCU Switch 4 (Heater Switch) on bottom of CCU near power cord connection
- 143 Monitor User Interface water temperature
- 144 When water temperature reaches 42.6 °C, start a timer
- 145 Alarm 34 must sound in less than 14 seconds
- 146 Release Switch 4 when alarm sounds
- 147 Record results in Table 2
- 148 Press "Alarm Clear" key
- 149 Press "Manual" key
- 150 Verify water temperature does not exceed 44.1 °C for more than 2 seconds as this will trigger Alarm 33.
- 151 If Alarm 33 occurs, this test must be repeated.

Purge, Remove, and Store CCU (5 Minutes)

- 152 Press "Purge" key to remove water from CCU
- 153 When display reads "Purge Complete", turn off power to the M1000
- 154 Allow unit to cool for 5 minutes before powering up again
- 155 Remove power cord from electrical outlet first & then from the CCU
- 156 Remove all CCU cables from M1000
- 157 Remove CCU from M1000
- 158 Reconnect operator cables & Fluid Delivery Lines to M1000
- 159 Turn CCU upside down to drain any remaining water
- 160 Store CCU & power cord in CCU case

**NOTE: If the M1000 fails either of the temperature tests, run temperature tests again.
If the M1000 fails either of the temperature tests a second time, contact technical support.**

BIOMED

Fax a copy of the completed form to:

Kimberly Clark Corporation
1400 Holcomb Bridge Road
B300/1
Roswell, GA 30076
Attn: Tech Support – Temp Mgmt Team (Victor Myers)

Fax No: 920-380-5951

SALES

Fax a copy and Mail the original completed form to:

Kimberly Clark Corporation
1400 Holcomb Bridge Road
B300/1
Roswell, GA 30076
Attn: Tech Support – Temp Mgmt Team (Victor Myers)

Fax No: 920-380-5951

TABLE 1

| | |
|-----------------|-----------|
| CCU Serial #: | Hospital: |
| Control Unit #: | Street: |
| Tested By: | City: |
| Date Tested: | State: |

| Default Factory Values | Values Listed On This CCU |
|------------------------|---------------------------|
| A = 10.87 | A = |
| B = 25.54 | B = |
| C = 34.35 | C = |
| D = 39.97 | D = |
| E = 0.0 | E = |
| F = 0.0 | F = |
| G = 0.0 | G = |

TABLE 2

| Step | Keywords | Criteria | Record Result | Pass/Fail |
|------|-----------------|--|---------------|---|
| 14 | Flow | $2550 \leq FL \leq 3150$ | FL = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 18 | Pressure | $-0.2\text{psi} \leq IP \leq 0.2$ | IP = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 46 | Patient Temp 1 | $-0.3 \text{ }^\circ\text{C} \leq CK1 \leq 0.3 \text{ }^\circ\text{C}$ | CK1 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.3 \text{ }^\circ\text{C} \leq CK2 \leq 0.3 \text{ }^\circ\text{C}$ | CK2 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.1 \text{ }^\circ\text{C} \leq CK3 \leq 0.1 \text{ }^\circ\text{C}$ | CK3 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.3 \text{ }^\circ\text{C} \leq CK4 \leq 0.3 \text{ }^\circ\text{C}$ | CK4 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 57 | Patient Temp 2 | $-0.3 \text{ }^\circ\text{C} \leq CK1 \leq 0.3 \text{ }^\circ\text{C}$ | CK1 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.3 \text{ }^\circ\text{C} \leq CK2 \leq 0.3 \text{ }^\circ\text{C}$ | CK2 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.1 \text{ }^\circ\text{C} \leq CK3 \leq 0.1 \text{ }^\circ\text{C}$ | CK3 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.3 \text{ }^\circ\text{C} \leq CK4 \leq 0.3 \text{ }^\circ\text{C}$ | CK4 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 68 | Temp Out 3 | $-0.2 \text{ }^\circ\text{C} \leq CK1 \leq 0.2 \text{ }^\circ\text{C}$ | CK1 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.2 \text{ }^\circ\text{C} \leq CK2 \leq 0.2 \text{ }^\circ\text{C}$ | CK2 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.2 \text{ }^\circ\text{C} \leq CK3 \leq 0.2 \text{ }^\circ\text{C}$ | CK3 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.2 \text{ }^\circ\text{C} \leq CK4 \leq 0.2 \text{ }^\circ\text{C}$ | CK4 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 85 | Water Temp 1 | $-0.4 \text{ }^\circ\text{C} \leq CK1 \leq 0.4 \text{ }^\circ\text{C}$ | CK1 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.4 \text{ }^\circ\text{C} \leq CK2 \leq 0.4 \text{ }^\circ\text{C}$ | CK2 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.2 \text{ }^\circ\text{C} \leq CK3 \leq 0.2 \text{ }^\circ\text{C}$ | CK3 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 87 | Water Temp 2 | $-0.4 \text{ }^\circ\text{C} \leq CK1 \leq 0.4 \text{ }^\circ\text{C}$ | CK1 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.4 \text{ }^\circ\text{C} \leq CK2 \leq 0.4 \text{ }^\circ\text{C}$ | CK2 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.2 \text{ }^\circ\text{C} \leq CK3 \leq 0.2 \text{ }^\circ\text{C}$ | CK3 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 89 | Water Temp 3 | $-0.4 \text{ }^\circ\text{C} \leq CK1 \leq 0.4 \text{ }^\circ\text{C}$ | CK1 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.4 \text{ }^\circ\text{C} \leq CK2 \leq 0.4 \text{ }^\circ\text{C}$ | CK2 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | $-0.4 \text{ }^\circ\text{C} \leq CK3 \leq 0.4 \text{ }^\circ\text{C}$ | CK3 = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 91 | Heat/Cool | Heat ≤ 120 seconds | Time = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | Cool ≤ 240 seconds | Time = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 94 | Calibration Hrs | Calibration Hours | Hours = | Reference Only |
| 127 | Hi Water Temp | Alarm 37 | Alarm # _____ | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | Less than 18 seconds | Time = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| 147 | Hi Water Temp | Alarm 34 | Alarm # _____ | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |
| | | Less than 14 seconds | Time = | <input type="checkbox"/> Pass <input type="checkbox"/> Fail |

CALIBRATION SUCCESSFUL & PASS BOTH HI WATER TEMP TESTS (Circle One)

Yes / No

Signature: _____