

CAS MEDICAL SYSTEMS, INC.

Ami[®] & Ami[®] Plus
Infant Apnea Monitor
Bench Test Procedure

using the PS415 Simulator

CASMED[®]
FOR WHAT'S VITAL

44 East Industrial Road
Branford, CT 06405 USA
www.techsrv@camed.com
www.camed.com

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I. Scope

The purpose of this procedure is to provide a means by which a qualified person can perform a Bench Test to an Ami or Ami Plus monitor.

II. Maintenance Intervals

CAS Medical Systems, Inc. recommends the following Maintenance Intervals for the Ami or Ami Plus monitor.

- Preventative Maintenance – In-Between Patients
- Bench Testing – Once every year
- Battery Replacement – Every (2) two years

III. Equipment Required


To perform this procedure, you will need the following:

- Ami or Ami Plus monitor (hereafter referred to as Ami)
- Fluke Biomedical Model PS415 Multi-Parameter Simulator
- AC Power Cord (p/n 01-02-0395, 120 VAC)
- Patient Cable (p/n 01-05-0429)
- Lead Wires (p/n 01-05-0007)
- Stopwatch or equivalent
- Remote Alarm (p/n 01-05-0506) (Optional)
- Ami RG Software (p/n 01-05-0176) or CAS Express™ Software (p/n 01-04-0191) (Optional)
- Direct Download Cable (p/n 01-05-0283) (Optional)
- Ami and Ami Plus Clinician's Manual (reference material) (p/n 21-02-0116)
- Ami Report Generator (RG) Software Manual (reference material) (p/n 01-05-0150)
- Fluke Biomedical Model PS415 User's Manual (reference material)

Note:

Simulator

This procedure is based on the Fluke Biomedical Model PS415 Multi-Parameter Patient Simulator. Should this not be available, a compatible, fully calibrated, simulator with similar settings will be acceptable. The simulator's Make, Model and Calibration Date should be noted on the Data Sheet. The Data Sheet should also be marked with the values that were used during the procedure for each step.

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Data Sheet Requirement

This procedure uses a Data Sheet as the record for verifying monitor performance. Once the procedure is completed, CAS recommends the Data Sheet be kept with the respective monitor's Device History Record should verification of monitor performance be questioned.


IV. Initial Setup

- A. Connect the Ami power cord to the power receptacle on the rear panel of the monitor. Plug the other end of the power cord into a properly grounded A.C. outlet. Verify the green CHARGING visual indicator on the monitor is lit.
- B. Connect the Patient lead wires to the Patient Cable (white to RA and black to LA). Connect the end of the lead wires onto the Simulator (white to RA white jack and black to LA black jack).
- C. Connect the Patient Cable to the PATIENT CABLE input receptacle located on the front panel of the Ami monitor.

V. Equipment Setup

1. Simulator Setup


- A. Set the switches on the simulator to:
 1. BP = 40
 2. RESPIRATION
 - BASE = 500
 - LEAD = I
 3. TEMP = 30 °C
- B. Turn the Simulator "ON" by pressing the POWER key switch.
- C. Once the Simulator has completed its power on sequence, verify one of the following:
 1. The simulator displays the numerical code for the default setting for ECG rate (34).
 2. If the 9 Volt battery needs to be replaced, the numerical code will flash.
- D. Set the simulator for an ECG Rate of **140 BPM** (enter code # 38). Press the EXECUTE key switch to enter the value.
- E. Set the simulator for a RESPIRATION Rate of **60 BrPM** (enter code # 85). Press the EXECUTE key switch to enter the value.

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2. AMI Monitor Setup

- A. Power up the Ami monitor in the Setup mode.
To get into Setup Mode – On the bottom of the Ami apnea monitor, press the **UP Arrow** and the **ENTER** buttons and hold them. At the same time, press the **POWER** button on the front of the monitor, release the **POWER** button after the alarm, then release the **UP Arrow** and **ENTER** buttons. While in the Setup Mode, use the **UP** and **DOWN** Arrow keys to select a setting. Use the **ENTER** key to lock in the setting and move to the next selection. Use the **MODE** key to finish and move to the next screen. Refer to the Setting Parameters section in the Clinician's Manual for assistance.
- B. At NEW PATIENT, select **YES** by pressing the **DOWN Arrow** button.
- C. At ARE YOU SURE?, select **YES** by pressing the **ENTER** button. Verify, the monitor displays CLEARING MEMORY.
- D. At PATIENT NAME, enter your initials. (Use the **UP** and **DOWN Arrows** to change the letter, after each letter press **ENTER**), when completed press **MODE**.
- E. At PATIENT NUMBER, enter **1234**. (Use the **UP** and **DOWN Arrows** to change the number, after each number press **ENTER**), when completed press **MODE**.
- F. Set BRADYCARDIA OPTION to **3 BEAT, 6 SECOND MAX**. Press **MODE**.
- G. Set AUX. PORT 1 to **O2 SAT**. Press **MODE**.
- H. Set OXIMETER CHOICE to **NPB-290/295/395**. Press **MODE**.
- I. Set AUX. PORT 2 to **O2 PR**. Press **MODE**.
- J. Set AUX. PORT 3 to **AIR FLOW**. Press **MODE**.
- K. Set PRIORITY/FIFO/CONT to **FIFO**. Press **MODE**.
- L. Set FIXED/FULL LENGTH to **FIXED 2 MINUTE**. Press **MODE**.
- M. Set APNEA MONITOR ALARM LIMIT to **10 SEC**. Press **ENTER**.
- N. Set HEART FAST MONITOR ALARM LIMIT to **250 BPM**. Press **ENTER**.
- O. Set the HEART SLOW MONITOR ALARM LIMIT to **130 BPM**. Press **ENTER** followed by **MODE**.
- P. Set the APNEA EVENT LOG LIMIT to **10 SEC**. Press **ENTER**.
- Q. Set the HEART FAST EVENT LOG LIMIT to **250 BPM**. Press **ENTER**.
- R. Set the HEART SLOW EVENT LOG LIMIT to **130 BPM**. Press **ENTER**.
- S. Set the O2 SAT EVENT LOG LIMIT to **85%**. Press **ENTER** followed by **MODE**.
- T. Scroll past AUX. PORT 1, 2, and 3 test screens (no selections are available). Press **MODE (4) times**.
- U. Set TIME/DATE to current date and time. (Use the **UP** and **DOWN Arrows** and the **ENTER** buttons to make changes), when completed press **MODE**.
- V. At SETUP COMPLETE?, select **YES**, by pressing the **ENTER** button.
- W. At ARE YOU SURE?, select **YES** by pressing the **DOWN Arrow** button.

NOTE: Wait for the monitor to complete its power down sequence (approximately 25 – 35 seconds), which will be distinguished by an audio sound.


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VI. Bench Test

1. Functional Test

1.1 Human Alarm Test 1

- A. Press the POWER button on the monitor. Once the monitor has completed its power up sequence (approximately 45 seconds), verify Good Connection/Best Signal or Best Connection/Best Signal on the monitor LCD.
- B. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- C. Set the simulator to the following settings:
 - a. Set the ECG Rate to **160 BPM** (code # 40).
 - b. Set the RESPIRATION Rate to **30 BrPM** (code # 83).
- D. Set the simulator for an ECG Rate of **270 BPM** (code # 46). Verify, the monitor HEART FAST visual indicator and audible alarm activates.
- E. Set the simulator for an ECG Rate of **240 BPM** (code # 45). Verify, the monitor audible alarm silences and the HEART FAST visual indicator remains on.
- F. Press the RESET button on the monitor. Verify, the HEART FAST visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.
- G. Set the simulator for an ECG Rate of **120 BPM** (code # 37). Verify, the monitor HEART SLOW visual indicator and audible alarm activates.
- H. Set the simulator for an ECG Rate of **140 BPM** (code # 38). Verify, the monitor audible alarm silences and the HEART SLOW visual indicator remains on.
- I. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.
- J. Set the simulator for an APNEA of **12 seconds** (code # 95). Press the EXECUTE key switch to begin the apnea event.
 1. Begin timing for apnea with the last Respiration pulse. Stop timing when the apnea visual and audio alarm activates. Verify, the time is 10 +/- 1.0 second.
- K. Once the Apnea event has timed out, verify, 1) the RESPIRATION indicator is flashing at the rate set on the simulator 2) the monitor audible alarm silences and 3) the APNEA visual indicator on the monitor remains on.
- L. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.

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M. Turn the Ami monitor "OFF".


To turn OFF the Ami Apnea Monitor – Press and hold the **RESET** button, then press the **POWER** button at the same time. Release the **POWER** button (while still pressing the **RESET** button). Then release the **RESET** button. Wait for the monitor to complete its power down sequence (approximately 25 – 35 seconds), which will be distinguished by an audio sound.

Proceed to Human Alarm Test 2.

1.2 Human Alarm Test 2

Note: Do not choose New Patient when selecting new Human Alarm settings.

- A. Power up the Ami monitor in Setup mode and select the following settings on the monitor:
 - a. Set APNEA to **30 SEC**.
 - b. Set HEART FAST to **125 BPM**.
 - c. Set HEART SLOW to **40 BPM**.
 - d. Default through to SETUP COMPLETE?, ARE YOU SURE? Select **YES**.
- B. Set the simulator to the following settings:
 - a. Set the ECG Rate to **120 BPM** (code # 37).
 - b. Set the RESPIRATION Rate to **20 BrPM** (code # 82).
- C. Press the POWER button on the monitor. Once the monitor has completed its power up sequence (approximately 45 seconds), verify Good Connection/Best Signal or Best Connection/Best Signal on the monitor LCD.
- D. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- E. Set the simulator for an ECG Rate of **140 BPM** (code # 38). Verify, the monitor HEART FAST visual indicator and audible alarm activates.
- F. Set the simulator for an ECG Rate of **120 BPM** (code # 37). Verify, the monitor audible alarm silences and the HEART FAST visual indicator remains on.
- G. Press the RESET button on the monitor. Verify, the HEART FAST visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.
- H. Set the simulator for an ECG Rate of **30 BPM** (code # 30). Verify, the monitor HEART SLOW visual indicator and audible alarm activates.
- I. Set the simulator for an ECG Rate of **60 BPM** (code # 32). Verify, the monitor audible alarm silences and the HEART SLOW visual indicator remains on.
- J. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.

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- K. Set the simulator for an APNEA of **32 seconds** (code # 96). Press the EXECUTE key switch to begin the apnea event.
 - 1. Begin timing for apnea with the last Respiration pulse. Stop timing when the apnea visual and audio alarm activates. Verify, the time is 30 +/- 1.0 second.
- L. Once the Apnea event has timed out, verify, 1) the RESPIRATION indicator is flashing at the rate set on the simulator 2) the monitor audible alarm silences and 3) the APNEA visual indicator on the monitor remains on.
- M. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.
- N. Turn the Ami monitor "OFF". Wait for the monitor to complete its power down sequence (approximately 25 – 35 seconds), which will be distinguished by an audio sound.

Proceed to ECG Response Test.

1.3 ECG Response Test

Note: Do not choose New Patient when selecting new Human Alarm settings.

- A. Power up the monitor in Setup mode and select the following settings on the monitor.
 - a. Set APNEA to **15 SEC**.
 - b. Set HEART FAST to **OFF**.
 - c. Set HEART SLOW to **40 BPM**.
 - d. Default to SETUP COMPLETE?, ARE YOU SURE? Select **YES**.
- B. Set the simulator to the following settings:
 - a. Set the ECG Rate to **160 BPM** (code # 40).
 - b. Set the RESPIRATION Rate to **20 BrPM** (code # 82).
- C. Press the POWER button on the monitor. Once the monitor has completed its power up sequence (approximately 45 seconds), verify Good Connection/Best Signal or Best Connection/Best Signal on the monitor LCD.
- D. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.


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- E. Set the simulator for an ECG Rate of **60 BPM** (code # 32) and the ECG Amplitude to **0.5 mV** (code # A0). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- F. Set the simulator for an ECG Amplitude of **2.0 mV** (code # A3). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- G. Set the simulator for an ECG Rate of **270 BPM** (code # 46) and the ECG Amplitude to **0.5 mV** (code # A0). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- H. Set the simulator for an ECG Amplitude of **2.0 mV** (code # A3). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- I. Set the ECG Rate of **160 BPM** (code # 40) and the ECG Amplitude to **1.0 mV** (code # A1).

Proceed to the Inverted Polarity Test.

1.4 Inverted Polarity Test


- A. Disconnect the white and black lead wires from the simulator. Verify, the LOOSE LEAD visual indicator and audible alarm activate.
- B. Connect the white lead to the LA jack and the black lead to the RA jack on the simulator. Verify, the audible alarm silences and the LOOSE LEAD visual indicator remains on. (leave the connections reversed).
- C. Press the RESET button on the monitor. Verify, the LOOSE LEAD visual indicator clears.
- D. Set the simulator for an ECG Rate of **60 BPM** (code # 32) and the ECG Amplitude to **0.5 mV** (code # A0). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- E. Set the simulator for an ECG Amplitude of **2.0 mV** (code # A3). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- F. Set the simulator for an ECG Rate of **270 BPM** (code # 46) and the ECG Amplitude to **0.5 mV** (code # A0). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- G. Set the simulator for an ECG Amplitude of **2.0 mV** (code # A3). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

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- H. Set the ECG Rate to **160 BPM** (code # 40) and the ECG Amplitude to **1.0 mV** (code # A1).
 - I. Disconnect the lead wires from the simulator. Re-connect the white and black lead wires onto their appropriate jacks on the simulator. Verify, the LOOSE LEAD visual indicator and audible alarm activate until the Lead Wires are reconnected.
 - J. Once the lead wires have been re-connected, verify, the audible alarm silences and the LOOSE LEAD visual indicator remains on.
 - K. Press the RESET button on the monitor. Verify, the LOOSE LEAD visual indicator clears.
- Proceed to the Heart Beat = Respiration Test.

1.5 Heart Beat = Respiration Test

- A. Set the simulator to the following settings:
 - a. Set the ECG Rate to **120 BPM** (code # 37).
 - b. Set the RESPIRATION Rate to **60 BrPM** (code # 85).
 - B. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
 - C. Set the simulator to the following settings:
 - a. Set the ECG Rate to **100 BPM** (code # 36).
 - b. Set the RESPIRATION Rate to **100 BrPM** (code # 87).
 - D. Verify, 1) the HEART BEAT indicator continues to flash at the rate set on the simulator 2) the RESPIRATION indicator is no longer flashing and 3) the monitor audible alarm and APNEA visual indicator are activated after 15 seconds.
 - E. Set the simulator for a RESPIRATION Rate of **60 BrPM** (code # 85). Verify, 1) the monitor audible alarm silences 2) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator and 3) the APNEA visual indicator remains on.
 - F. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears.
- Proceed to the Lead Alarm Test.

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1.6 Lead Alarm Test

- A. Set the simulator to the following settings:
 - a. Set the ECG Rate to **120 BPM** (code # 37).
 - b. Set the RESPIRATION Rate to **60 BrPM** (code # 85).
- B. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- C. Set the simulator's RESPIRATION Base switch to the **1K** position. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- D. Set the simulator's RESPIRATION Base switch to the **500** position.

Proceed to the Respiration Response Test.

1.7 Respiration Response Test

- A. Set the simulator to the following settings:
 - a. Set the ECG Rate to **220 BPM** (code # 44).
 - b. Set the RESPIRATION Rate to **30 BrPM** (code # 83).
- B. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- C. Set the simulator for a RESPIRATION Delta Ω of **0.2 OHMS** (code # 91). Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.
- D. Set the simulator for a RESPIRATION Delta Ω of **0.1 OHMS** (code # 90). Verify, 1) the RESPIRATION indicator is no longer flashing 2) the HEART BEAT indicator continues to flash at the rate set on the simulator and 3) the monitor audible alarm and APNEA visual indicator are activated after 15 seconds.
- E. Set the simulator for a RESPIRATION Delta Ω of **0.2 OHMS** (code # 91). Verify, 1) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator 2) the monitor audible alarm silences and 3) the APNEA visual indicator remains on.
- F. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears.

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- G. Set the simulator for a RESPIRATION Rate of **15 BrPM** (code # 81) and the RESPIRATION Delta Ω of **0.5 OHMS** (code # 92). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.
- H. Set the simulator for a RESPIRATION Rate of **120 BrPM** (code # 88) and the RESPIRATION Delta Ω of **0.5 OHMS** (code # 92). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.
- I. Set the simulator for a RESPIRATION Rate of **120 BrPM** (code # 88) and the RESPIRATION Delta Ω of **3.0 OHMS** (code # 94). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.
- J. Set the simulator for a RESPIRATION Rate of **15 BrPM** (code # 81) and the RESPIRATION Delta Ω of **3.0 OHMS** (code # 94). Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.
- K. Set the simulator to the following settings:
 - a. Set the ECG Rate to **120 BPM** (code # 37).
 - b. Set the RESPIRATION Rate to **60 BrPM** (code # 85).
 - c. Set the RESPIRATION Delta Ω to **1.0 OHMS** (code # 93).

Proceed to Improper Shutoff Test (Sibling Protection Alarm).

1.8 Improper Shutoff Test (Sibling Protection Alarm)

- A. Press the POWER button on the monitor. Verify, 1) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator and 2) an audible alarm is active with NO Human visual alarm indicators lit.
- B. Press the POWER button on the monitor. Verify, 1) the audible alarm silences and 2) the monitor continues to count at the rate set on the simulator.

Proceed to Remote Alarm Test.

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1.9 Remote Alarm Test (Optional)

- A. Obtain the Remote Alarm and cable used with the monitor and connect them to the Remote Alarm jack, located on the rear panel of the monitor.
- B. Turn the Remote Alarm "ON". To turn the Remote Alarm "ON", pull out the ON/OFF switch and flip it up.
- C. Set the simulator for a RESPIRATION Rate of **0 BrPM** (code # 80). Verify, 1) an APNEA visual and audible alarm on the monitor after 15 seconds and 2) a red ALARM visual indicator and audible alarm on the Remote Alarm.
- D. Set the simulator for a RESPIRATION Rate of **60 BrPM** (code # 85). Verify on the Remote Alarm, the audible alarm silences and the ALARM visual indicator is no longer lit.
- E. Turn the Remote Alarm "OFF". To turn the Remote Alarm "OFF", pull out the ON/OFF switch and flip it down.
- F. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears.
- G. Turn the Ami monitor "OFF". Wait for the monitor to complete its power down sequence (approximately 25 – 35 seconds), which will be distinguished by an audio sound.
- H. Disconnect the Remote Alarm from the monitor.

Proceed to Download Verification.


1.10 Download Verification (Optional)

- A. Connect the monitor to the computer using the Direct Download Cable.
- B. Turn the monitor "ON".
- C. Launch the software program and perform a Direct Download of the data stored in the monitor.
- D. Review the Patient Report and verify, 1) correct Date and Time information 2) correct APNEA, Low Heart Rate (LHR) and High Heart Rate (HHR) Alarm Limit changes and 3) Monitor Off / On and Total Time Log Entry Events.
- E. Review the Patient Events and verify, 1) correct Date and Time information 2) correct APNEA, Bradycardia (LHR) and Tachycardia (HHR) Event Type and Duration.
- F. Print a copy of the Patient Report. Attach it to the back of the completed Data Sheet.
- G. Turn the monitor "OFF".
- H. Turn the simulator "OFF". Disconnect the monitor from the simulator and computer as needed.

This concludes the Ami / Ami Plus Bench Test Procedure.

Should you have any questions, do not hesitate to contact CAS Technical Support at 203-488-6056 / 800-581-7806 (US only) (phone), 203-488-9438 (fax) or www.techsrv@camed.com (email).

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VII. Test Data Sheet

Date: _____

Tested By: _____

Ami & Ami Plus Infant Apnea Monitor

using the PS415 Simulator

Home Care Dealer / Hospital:

Ami Type: (select one) Ami (); Ami Plus ()

Address: _____

Ami Serial Number: _____

City: _____

Simulator Type / Serial Number: _____

State: _____ Zip: _____

Simulator Calibration Date: _____

IV. Initial Setup

- | | |
|--|-------------------------|
| A. Connect the power cord to the Ami monitor. Verify, green CHARGING indicator is lit. | Pass () Fail () |
| B. Connect the Patient Leads to the Patient Cable and Simulator. | Completed () |
| C. Connect the Patient Cable to the Patient Cable input on the Ami monitor. | Completed () |

V. Equipment Setup

1. Simulator Setup

- | | |
|---|-------------------------|
| A. Set the switches on the simulator: | |
| a. BP | Completed () |
| b. RESPIRATION | Completed () |
| c. TEMP | Completed () |
| B. Turn the simulator "ON". | Completed () |
| C. Verify one of the following conditions: | |
| 1. Simulator displays default code for ECG Rate (34). | Pass () Fail () |
| 2. Numerical code is not flashing | Pass () Fail () |
| D. Set the simulator's ECG Rate to 140 BPM. Press the EXECUTE key switch. | Pass () Fail () |
| E. Set the simulator's RESPIRATION Rate to 60 BrPM. Press the EXECUTE key switch. | Pass () Fail () |

2. Ami Monitor Setup

- | | |
|--|-------------------------|
| A. Power up the monitor in the Setup Mode. | Completed () |
| B. At NEW PATIENT, select YES. | Completed () |
| C. At ARE YOU SURE?, select YES. Verify, monitor displays CLEARING MEMORY. | Pass () Fail () |
| D. At PATIENT NAME, enter your initials. | Completed () |
| E. At PATIENT NUMBER, enter 1234. | Completed () |
| F. Set BRADYCARDIA OPTION to 3 BEAT, 6 SECOND MAX. | Completed () |
| G. Set AUX. PORT 1 to O2 SAT. | Completed () |
| H. Set OXIMETER CHOICE to NPB-290/295/395. | Completed () |
| I. Set AUX. PORT 2 to O2 PR. | Completed () |
| J. Set AUX. PORT 3 to AIR FLOW. | Completed () |
| K. Set PRIORITY/FIFO/CONTINUE to FIFO. | Completed () |

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- L. Set FIXED/FULL LENGTH to FIXED 2 MINUTE. Completed ()
- M. Set APNEA MONITOR ALARM LIMIT to 10 SEC. Completed ()
- N. Set HEART FAST MONITOR ALARM LIMIT to 250 BPM. Completed ()
- O. Set HEART SLOW MONITOR ALARM LIMIT to 130 BPM. Completed ()
- P. Set APNEA EVENT LOG LIMIT to 10 SEC. Completed ()
- Q. Set HEART FAST EVENT LOG LIMIT to 250 BPM. Completed ()
- R. Set HEART SLOW EVENT LOG LIMIT to 130 BPM. Completed ()
- S. Set O2 SAT EVENT LOG LIMIT to 85%. Completed ()
- T. Scroll past AUX. PORT 1, 2 and 3 test screens. Completed ()
- U. Set TIME and DATE information. Completed ()
- V. At SETUP COMPLETE?, select YES. Completed ()
- W. At ARE YOU SURE?, select YES. Verify, proper monitor power down. Pass () Fail ()

VI. Bench Test

1. Functional Test

1.1 Human Alarm - Test 1

- A. Press the POWER button on the monitor.
Verify, Good Connection/Best Signal or Best Connection/Best Signal on LCD. Pass () Fail ()
- B. Verify, monitor counts rate set on simulator with no alarms. Pass () Fail ()
- C. Set the simulator to the following settings:
 - a. Set the ECG Rate to 160 BPM. Completed ()
 - b. Set the RESPIRATION Rate to 30 BrPM. Completed ()
- D. Set the simulator's ECG RATE to 270. Verify, HEART FAST visual and audible alarms. Pass () Fail ()
- E. Set the simulator's ECG RATE to 240. Verify, audible stops and HEART FAST visual remains on. Pass () Fail ()
- F. Press RESET. Verify, HEART FAST visual clears and monitor counts rates set on simulator. Pass () Fail ()
- G. Set the simulator's ECG RATE to 120. Verify, HEART SLOW visual and audible alarms. Pass () Fail ()
- H. Set the simulator's ECG RATE to 140. Verify, audible stops and HEART SLOW visual remains on. Pass () Fail ()
- I. Press RESET. Verify, HEART SLOW visual clear and monitor counts rates set on simulator. Pass () Fail ()
- J. Set the simulator for an Apnea of 12 seconds. Press EXECUTE and verify;
 - 1. Verify, the time to be 10 +/- 1.0 seconds. Pass () Fail ()
- K. Once the Apnea event has timed out, verify;
 - a. the RESPIRATION indicator is flashing at rate set on simulator. Pass () Fail ()
 - b. the audible stops. Pass () Fail ()
 - c. the APNEA visual remains on. Pass () Fail ()
- L. Press RESET on monitor. Verify, APNEA visual clears and monitor counts rates set on simulator. Pass () Fail ()
- M. Turn the monitor "OFF". Verify, proper monitor power down. Pass () Fail ()


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1.4 Inverted Polarity Test

- A. Disconnect the Lead Wires from the simulator. Verify LOOSE LEAD visual and audible alarms. Pass () Fail ()
- B. Connect the white lead to the LA jack and the black lead to the RA jack. Verify, the audible stops and the LOOSE LEAD visual remains on. Pass () Fail ()
- C. Press RESET. Verify, LOOSE LEAD visual clears. Pass () Fail ()
- D. Set the simulator's ECG RATE to 60 and the ECG Amplitude to 0.5. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- E. Set the ECG Amplitude to 2.0. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- F. Set the simulator's ECG RATE to 270 and the ECG Amplitude to 0.5. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- G. Set the ECG Amplitude to 2.0. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- H. Set the ECG RATE to 160 and the ECG AMPLITUDE to 1.0. Completed ()
- I. Disconnect the Lead Wires from the simulator. Re-connect the white and black lead wires onto their appropriate jacks on the simulator. Verify, LOOSE LEAD visual and audible alarms activate. Pass () Fail ()
- J. Once the lead wires have been reconnected. Verify, the audible alarm silences and the LOOSE LEAD visual remains on. Pass () Fail ()
- K. Press RESET. Verify, LOOSE LEAD visual clears. Pass () Fail ()

1.5 Heart Beat = Respiration Test

- A. Set the simulator to the following settings:
 - a. ECG RATE = 120. Completed ()
 - b. RESPIRATION RATE = 60. Completed ()
- B. Verify, monitor counts rate set on simulator with no alarms. Pass () Fail ()
- C. Set the ECG RATE and RESPIRATION RATE to 100. Completed ()
- D. Verify,
 - 1) the HEART BEAT indicator continues to flash at the rate set on the simulator. Pass () Fail ()
 - 2) the RESPIRATION indicator is no longer flashing. Pass () Fail ()
 - 3) the monitor audible alarm and APNEA visual indicator are activated after 15 seconds. Pass () Fail ()
- E. Set the RESPIRATION RATE to 60. Verify,
 - 1) the monitor audible alarm silences. Pass () Fail ()
 - 2) the HEART BEAT and RESPIRATION indicators flash at the rates set on the simulator. Pass () Fail ()
 - 3) the APNEA visual indicator remains on. Pass () Fail ()
- F. Press RESET. Verify, APNEA visual clears. Pass () Fail ()

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1.6 Lead Alarm Test


- A. Set the simulator to the following settings:
 - a. ECG RATE = 120. Completed ()
 - b. RESPIRATION RATE = 60. Completed ()
- B. Verify, monitor counts rate set on simulator with no alarms. Pass () Fail ()
- C. Set the RESPIRATION Base switch to 1K. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- D. Set the RESPIRATION Base to 500. Completed ()

1.7 Respiration Response Test

- A. Set the simulator to the following settings:
 - a. ECG RATE = 220. Completed ()
 - b. RESPIRATION RATE = 30. Completed ()
- B. Verify, monitor counts rates set on simulator with no alarms. Pass () Fail ()
- C. Set the simulator for a RESPIRATION Delta Ω of 0.2 Ohms. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- D. Set the simulator for a Respiration Delta Ω of 0.1 Ohms. Verify,
 - 1) the RESPIRATION indicator is no longer flashing. Pass () Fail ()
 - 2) the HEART BEAT indicator continues to flash at the rate set on simulator. Pass () Fail ()
 - 3) the audible alarm and APNEA visual are active after 15 seconds. Pass () Fail ()
- E. Set the simulator for a RESPIRATION Delta Ω of 0.2 Ohms. Verify,
 - 1) the HEART BEAT and RESPIRATION indicators flash at the rates set on the simulator. Pass () Fail ()
 - 2) the audible alarm silences. Pass () Fail ()
 - 3) the APNEA visual indicator remains on. Pass () Fail ()
- F. Press RESET. Verify, APNEA visual clears. Pass () Fail ()
- G. Set the RESPIRATION Rate to 15 and the RESPIRATION Delta Ω of 0.5 Ohms. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- H. Set the RESPIRATION Rate to 120 and the RESPIRATION Delta Ω of 0.5 Ohms. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- I. Set the RESPIRATION Rate to 120 and the RESPIRATION Delta Ω of 3.0 Ohms. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- J. Set the RESPIRATION Rate to 15 and the RESPIRATION Delta Ω of 3.0 Ohms. Verify, monitor continues to count rates set on simulator with no alarms. Pass () Fail ()
- K. Set the simulator to the following settings:
 - a. ECG RATE = 120. Completed ()
 - b. RESPIRATION Rate = 60. Completed ()
 - c. RESPIRATION Delta Ω = 1.0. Completed ()

1.8 Improper Shutoff Test (Sibling Protection Alarm)

- A. Press the POWER button on the monitor. Verify,
 - 1) the HEART BEAT and RESPIRATION indicators flash at the rates set on the simulator. Pass () Fail ()
 - 2) an audible alarm is active with no human visual alarm indicators lit. Pass () Fail ()
- B. Press the POWER button on the monitor. Verify,
 - 1) the audible alarm silences. Pass () Fail ()
 - 2) the monitor continues to count at the rates set on the simulator. Pass () Fail ()

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1.9 Remote Alarm Test

- A. Connect the Remote Alarm to the monitor. Completed ()
- B. Turn the Remote Alarm "ON". Completed ()
- C. Set the RESPIRATION Rate to 0. Verify,
 - 1) the RESPIRATION indicator is no longer flashing. Pass () Fail ()
 - 2) the audible alarm and APNEA visual are active after 15 seconds. Pass () Fail ()
 - 3) a red ALARM visual indicator and an audible alarm on the Remote Alarm. Pass () Fail ()
- D. Set the RESPIRATION Rate to 60. Verify on the Remote Alarm, the audible alarm silences and the ALARM visual indicator is no longer lit. Pass () Fail ()
- E. Turn the Remote Alarm "OFF". Completed ()
- F. Press the RESET button on the monitor. Verify, the APNEA visual clears. Pass () Fail ()
- G. Turn the monitor "OFF". Verify, proper monitor power down. Pass () Fail ()
- H. Disconnect the Remote Alarm from the monitor. Completed ()


1.10 Download Verification

- A. Connect the monitor to the computer using the Direct Download Cable. Completed ()
- B. Turn the monitor "ON". Completed ()
- C. Launch the software program and perform a Direct Download of data stored in the monitor. Completed ()
- D. Review the Patient Report and verify,
 - 1) correct date and time information. Pass () Fail ()
 - 2) correct Apnea, Low Heart Rate (LHR) and High Heart Rate (HHR) Alarm Limit changes. Pass () Fail ()
 - 3) Monitor Off/On and Total Time Log Entry Events. Pass () Fail ()
- E. Review the Patient Events and verify,
 - 1) correct date and time information. Pass () Fail ()
 - 2) correct Apnea, LHR and HHR Event Type and Duration. Pass () Fail ()
- F. Print a copy of both reports. Attach them to the completed Data Sheet. Completed ()
- G. Turn the monitor "OFF". Completed ()
- H. Turn the simulator "OFF". Disconnect from simulator and computer. Completed ()

If the monitor fails to pass any part of this procedure, please return a copy of this Data Sheet with the monitor when it is returned for service.

Comments: _____

This concludes the Ami/Ami Plus Test Data Sheet.

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VIII. Certification Acknowledgement Sign-Off Sheet

Home Care Dealer / Hospital: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax Phone: _____

By signing below, I have read and understood the Ami & Ami Plus Bench Test Procedure and agree to adhere to it using the equipment required to the best of my ability.

Print Name, as it would appear on the certificate of the individual being certified:

Signature: _____ Date: _____

Email Address: _____

Would you like to be contacted concerning any product updates / improvements? Yes () No ()

Once completed, keep a copy for your records and mail the original sign-off sheet to:

CAS Medical Systems, Inc.
44 E. Industrial Rd
Branford, CT 06405 USA

203-488-6056 / 800-227-4414 (US only)(phone)
203-488-9438 (fax)
www.casmed.com

ATTN: Technical Support
techsrv@casmed.com

This Sign-Off Sheet may be copied if additional individuals will be certified.