CAS MEDICAL SYSTEMS, INC.

Ami [®] */ Ami Plus* [®]

Infant Apnea Monitor

Preventative Maintenance
Test Procedure

using the 2301 Simulator

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I. Scope

The purpose of this procedure is to provide a means by which a qualified person can perform a Preventative Maintenance 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)
- Model 2301 Multi-Function Tester / Simulator (p/n 01-05-0025)
- AC Power Cord (p/n 01-05-0139)
- Patient Cable (p/n 01-05-0004)
- Lead Wires (p/n 01-05-0005)
- Stopwatch or equivalent
- Ami and Ami Plus Clinician's Manual (reference material) (p/n 21-02-0116)
- Model 2301 User's Manual (reference material) (p/n 21-02-0102)

Note: 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; black to LA). Plug the male end of the lead wires into the Simulator (white to white jack; black to 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 Model 2301 as follows:
   a. LEAD CHANGE = **OFF**
   b. TEST = **SIMULATE/ELECTRODE TEST**
   c. HEART (BPM) = **120 Beats Per Minute**
   d. BREATH (BPM) = **15 Breaths Per Minute**

B. Turn the Simulator ON.

C. Once the Simulator has completed its power on sequence, verify one of the following:
   1. If the simulator displays a "1" at the far left of the LCD, the value is meaningless and should be disregarded.
   2. If the simulator displays "BAT" in the upper left corner of the LCD, the 9 Volt battery needs to be replaced.

D. Verify, the red APNEA indicator is not lit.

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 **125 BPM**. Press **ENTER**.

O. Set the HEART SLOW MONITOR ALARM LIMIT to **40 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 **125 BPM**. Press **ENTER**.

R. Set the HEART SLOW EVENT LOG LIMIT to **40 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.

VI. Preventative Maintenance Test

1. Functional Test

1.1 Apnea Alarm Test

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. Press the **APNEA** button on the simulator. Verify,

     1. the red APNEA indicator on the simulator is lit.

     2. 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 seconds.

D. Press the **APNEA** button on the simulator. Verify, 1) the red APNEA indicator on the simulator is not lit 2) the RESPIRATION indicator is flashing at the rate set on the simulator 3) the monitor audible alarm silences and 4) the APNEA visual indicator on the monitor remains on.

E. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears.

Proceed to Heart Slow Alarm Test.

1.2 Heart Slow Alarm Test

A. Set the simulator HEART Rate to **30 BPM**. Verify, the monitor HEART SLOW visual indicator and audible alarm activates.

B. Set the simulator HEART Rate to **120 BPM**. Verify, the monitor audible alarm silences and the HEART SLOW visual indicator remains on.

C. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears.

Proceed to Heart Fast Alarm Test.

1.3 Heart Fast Alarm Test

A. Set the simulator HEART Rate to **240 BPM**. Verify, the monitor HEART FAST visual indicator and audible alarm activates.

B. Set the simulator HEART Rate to **120 BPM**. Verify, the monitor audible alarm silences and the HEART FAST visual indicator remains on.

C. Press the RESET button on the monitor. Verify, the HEART FAST visual indicator clears.

Proceed to Loose Lead Alarm Test.

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1.4 Loose Lead Alarm Test

A. Disconnect a lead wire from the simulator. Verify, the monitor LOOSE LEAD visual indicator and audible alarm activate.

B. Reconnect the lead wire to the simulator. Verify, the monitor audible alarm silences and the LOOSE LEAD visual indicator remains on.

C. Press the RESET button on the monitor. Verify, the LOOSE LEAD visual indicator clears.

Proceed to Respiration Rate Test.

1.5 Respiration Rate Test

A. Set the simulator to the following settings:

   a. Set the HEART Rate to **120 BPM**.

   b. Set the BREATH Rate to **15 BrPM**.

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 BREATH Rate to **40 BrPM**. 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 BREATH Rate to **60 BrPM**. 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 BREATH Rate to **80 BrPM**. 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.

F. Set the simulator BREATH Rate to **15 BrPM**.

Proceed to Heart Beat = Respiration Test.

1.6 Heart Beat = Respiration Test

A. Set the simulator to the following settings:

    a. Set the HEART Rate to **60 BPM**.

    b. Set the BREATH Rate to **40 BrPM**.

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 HEART Rate to **60 BPM**.

    b. Set the BREATH Rate to **60 BrPM**.

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 10 seconds.

E. Set the simulator BREATH Rate to **40 BrPM**. 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.

G. 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.

Turn the simulator OFF. Disconnect the monitor from the simulator.

This concludes the Ami / Ami Plus Preventative Maintenance 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@casmed.com (email).

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Date: _____

Tested By: _____

VII. Test Data Sheet

Ami /Ami Plus Infant Apnea Monitor
using the 2301 Simulator

Home Care Dealer / Hospital:

_____

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

Address:_____

Ami Serial Number: _____

City: _____

Simulator 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 2301 simulator:	
	a. LEAD CHANGE = OFF	Completed ( )
	b. TEST = SIMULATE/ELECTRODE TEST	Completed ( )
	c. HEART (BPM) = 120	Completed ( )
	d. BREATH (BPM) = 15	Completed ( )
B.	Turn the simulator ON.	Completed ( )
C.	Verify one of the following conditions:	
	1. Simulator displays a "1" at the far left of the LCD display	Pass ( ) Fail ( )
	2. Simulator displays "BAT" in the upper left corner of the LCD display	Pass ( ) Fail ( )
D.	Verify, the red APNEA indicator is not lit	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 ( )
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 125 BPM.	Completed ( )
O.	Set HEART SLOW MONITOR ALARM LIMIT to 40 BPM.	Completed ( )
P.	Set APNEA EVENT LOG LIMIT to 10 SEC.	Completed ( )
Q.	Set HEART FAST EVENT LOG LIMIT to 125 BPM.	Completed ( )
R.	Set HEART SLOW EVENT LOG LIMIT to 40 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. Preventative Maintenance Test

1. Functional Test

1.1 Apnea Alarm Test

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.	Press the APNEA button on the simulator and verify,	
	1. the red APNEA indicator on the simulator is lit.	Pass ( ) Fail ( )
	2. Verify, the time to be 10 +/- 1.0 seconds.	Pass ( ) Fail ( )
D.	Press the APNEA button on the simulator. Verify,	
	1. the red APNEA indicator on the simulator is not lit.	Pass ( ) Fail ( )
	2. the RESPIRATION indicator is flashing at rate set on simulator.	Pass ( ) Fail ( )
	3. the audible stops.	Pass ( ) Fail ( )
	4. the APNEA visual remains on.	Pass ( ) Fail ( )
E.	Press RESET on monitor. Verify, APNEA visual clears.	Pass ( ) Fail ( )

1.2 Heart Slow Alarm Test

A.	Set the simulator HEART Rate to 30. Verify, HEART SLOW visual and audible alarms.	Pass ( ) Fail ( )
B.	Set the simulator HEART Rate to 120. Verify, audible stops and HEART SLOW visual remains on.	Pass ( ) Fail ( )
C.	Press RESET. Verify, HEART SLOW visual clears.	Pass ( ) Fail ( )

1.3 Heart Fast Alarm Test

A.	Set the simulator HEART Rate to 240. Verify, HEART FAST visual and audible alarms.	Pass ( ) Fail ( )
B.	Set the simulator HEART Rate to 120. Verify, audible stops and HEART FAST visual remains on.	Pass ( ) Fail ( )
C.	Press RESET. Verify, HEART FAST visual clears.	Pass ( ) Fail ( )

1.4 Loose Lead Alarm Test

A.	Disconnect a lead wire from the simulator. Verify, LOOSE LEAD visual and audible alarms.	Pass ( ) Fail ( )
B.	Reconnect the lead wire to the simulator. Verify, the audible stops and LOOSE LEAD visual remains on.	Pass ( ) Fail ( )
C.	Press RESET. Verify, LOOSE LEAD visual clears.	Pass ( ) Fail ( )

1.5   Respiration Rate Test
A.   Set the simulator to the following settings:
   a.   Set the HEART Rate to 120.   Completed (   )
   b.   Set the BREATH Rate to 15.   Completed (   )
B.   Verify, the monitor counts rate set on simulator with no alarms.   Pass (   )   Fail (   )
C.   Set the BREATH Rate to 40. Verify, the monitor counts rate set on simulator with no alarms.   Pass (   )   Fail (   )
D.   Set the BREATH Rate to 60. Verify, the monitor counts rate set on simulator with no alarms.   Pass (   )   Fail (   )
E.   Set the BREATH Rate to 80. Verify, the monitor counts rate set on simulator with no alarms.   Pass (   )   Fail (   )
F.   Set the simulator BREATH Rate to 15.   Completed (   )

1.6   Heart Beat = Respiration Test
A.   Set the simulator to the following settings:
   a.   Set the HEART Rate to 60.   Completed (   )
   b.   Set the BREATH Rate to 40.   Completed (   )
B.   Verify, the monitor counts rate set on simulator with no alarms.   Pass (   )   Fail (   )
C.   Set the simulator HEART Rate and BREATH Rate to 60.   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 10 seconds.   Pass (   )   Fail (   )
E.   Set the simulator BREATH Rate to 40. Verify,
   1)   the monitor audible alarm silences.   Pass (   )   Fail (   )
   2)   the HEART BEAT and RESPIRATION indicators flash at the rate set on the simulator.   Pass (   )   Fail (   )
   3)   the APNEA visual indicator remains on.   Pass (   )   Fail (   )
F.   Press RESET. Verify, APNEA visual clears.   Pass (   )   Fail (   )
G.   Turn the Ami monitor OFF. Verify, proper monitor power down.   Pass (   )   Fail (   )

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.

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 Preventative Maintenance 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.   203-488-6056 / 800-227-4414 (US only)(phone)
44 E. Industrial Rd   203-488-9438 (fax)
Branford, CT 06405 USA   www.casmed.com

ATTN: Anthony F. Cop
            Product Support Manager
             acop@casmed.com

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