

# statMAP™

Blood Pressure Measurement Device



[www.statmap.net](http://www.statmap.net)  
800-231-6370 or 813-289-5555

Patents Pending  
Ramsey Medical, Inc.

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## DESCRIPTION

statMAP™ is a portable battery-powered blood pressure measuring device. statMAP utilizes the oscillometric, step deflate method for non-invasive blood pressure determination.

statMAP measures all of the blood pressure parameters: systolic, diastolic, mean arterial pressure and heart rate.

Heart rate is derived from the BP determination, which measures peripheral pulses, not the electrical signal of an EKG.

statMAP provides another unique and proprietary feature, the “*Nominal Session BP Value*” (NSV). The NSV is displayed for the user by cycling the power OFF then ON after a BP measurement session is finished. All of the session’s readings are then analyzed by the statMAP and a “*Nominal Session BP Value*” is displayed. This “*Nominal Session Value*” is not an average of the BP readings, but a substantially more robust statistical measure of the nominal BP during the BP session since it eliminates BP outliers in the presence of noise and/or excessive motion.

## EXPLANATION OF SYMBOLS



Type BF applied part (defibrillation-proof)

**IPX1**

Drip –Proof



Attention, refer to accompanying documents



On / Off momentary switch



Multi-Function Button

## IMPORTANT INFORMATION

### Indications for use:

statMAP is a prescription device and is indicated for use to measure systolic and diastolic pressure, mean arterial pressure (MAP) and heart rate of persons ages 12 and over using the oscillometric method of measurement.

statMAP may be used in hospital departments (ICU, CCU, step-down units, recovery, MedSurg, ED, L&D, Radiology), out patient settings, physician offices, EMS environments and home health care.

**Caution:** Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

**Improper cuff size and improper cuff fit will result in inaccurate (or no) BP readings.**

Accurate BP readings require proper cuff size and a “snug-tight” fit (allow 2 fingers between cuff and patient). Use the appropriate cuff markings to ensure the cuff is the correct size. See Table Below:

<b>Mid-Arm Circumference Range</b>	<b>Cuff</b>
Small Adult: 20.0 to 27.0 cm	size 10
Adult: 25.3 to 34.3 cm	size 11
Large Adult: 32.1 to 43.4 cm	size 12

**Warning:** A cuff that is too loose or too tight can result in inaccurate readings. A cuff that fits too tightly can cause venous congestion.

## PRECAUTIONS FOR USE

- Cuff Size – only use the cuff when the artery index marker falls within the printed range indicated on the cuff, otherwise erroneous readings may result.
- Use only cuffs approved by Ramsey Medical Inc. (refer to Accessories section for ordering information).
- Do not allow the cuff to remain on the arm for more than 10 minutes when inflated above 10mmHg. Devices that exert pressure on tissue have been associated with purpura, skin avulsions, compartmental syndrome, ischemia and/or neuropathy.
- When using statMAP, the operator should be monitoring the pressure within the device at all times. When the device is shut off (intentionally or accidentally) the pressure remains within the cuff and the operator must manually deflate the cuff.
- Care should be taken to avoid restriction or compression of the cuff tubing.
- If disposable Lithium AAA batteries are used, they must be UL recognized to standard UL1642. Ramsey Medical recommends Energizer Lithium No. L92.
- When replacing the batteries, always replace both batteries with ones that are known fresh and that are of the proper type.
- Remove the batteries from statMAP if it will not be used for an extended length of time.
- The statMAP, when used with Ramsey Medical approved cuffs, is protected against defibrillator damage.

## PRECAUTIONS FOR USE (con't)

- **Caution:** Care should be taken when using the statMAP to observe the maximum allowed pump-up pressures as follows:

Adults	280mmHg
Pediatrics (12 to 16 years)	200mmHg

- Do not immerse the statMAP in water. If the device is splashed with water or becomes wet, wipe it immediately with a dry cloth.
- Arrhythmias may extend the time required for blood pressure measurement beyond the design capabilities of the statMAP.
- The statMAP may not meet its performance specifications if stored or used outside of the specified temperature and humidity ranges (refer to page 25).
- Blood pressure measurements determined with the statMAP are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, *manual, electronic, or automated sphygmomanometers*. (ANSI/AAMI accuracy standard, 2002).
- The statMAP is designed to conform to Electromagnetic Compatibility (EMC) standard EN 60601-1-2, 2001 and will operate accurately in conjunction with other medical equipment which also meets this requirement. To avoid interference problems affecting the statMAP, do not use it in the presence of equipment which does not conform to these specifications.

## PRECAUTIONS FOR USE (CON'T)

- There is potential for radio/television interference. statMAP has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. The product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on and off, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the separation between the product and receiver.
  - Consult the dealer or an experienced radio/TV technician for help.
- Inaccurate readings may result when an electrosurgical unit (ESU) is used while monitoring with the statMAP. If this is suspected, discontinue use of the statMAP in semi-automatic mode while the (ESU) is in use and use the alternate manual mode for blood pressure measurement.

## ACCESSORIES

The following blood pressure cuffs are approved for use with statMAP :

<b>Cuffs:</b>		<b>Arm Circumference</b>	<b>Cuff</b>
<b>Reorder No.</b>	<b>Type</b>	<b>Range</b>	
8061	Small Adult	20.0 to 27.0 cm	Size 10
8062	Adult	25.3 to 34.3 cm	Size 11
8063	Large Adult	32.1 to 43.4 cm	Size 12

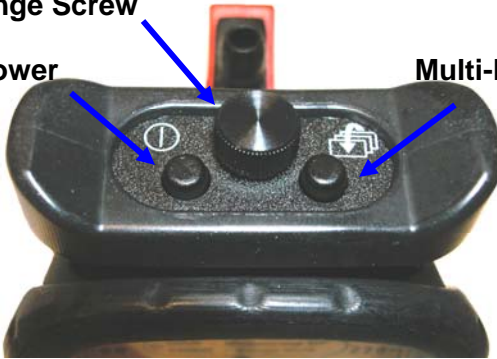
Cuffs are latex-free.

# CONTROLS AND INDICATORS

Battery Change Screw

Power

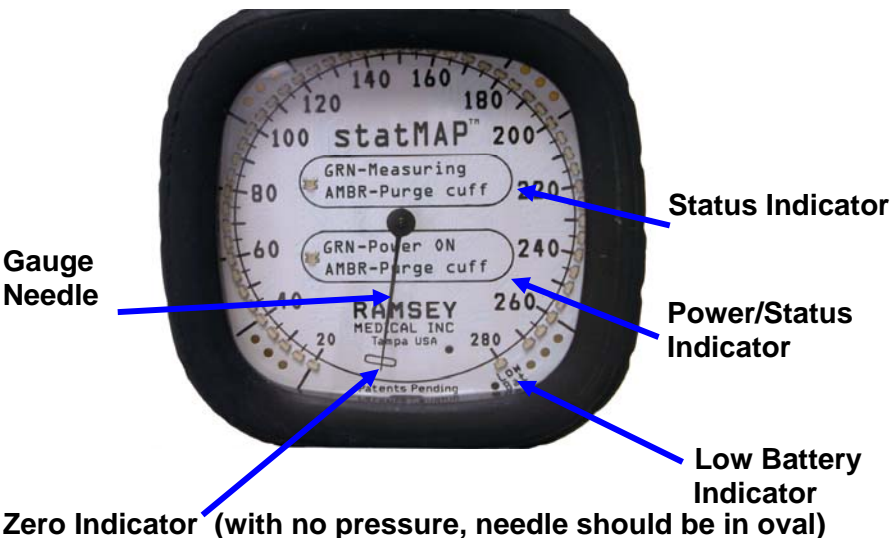
Multi-Function



**Power Button:** Power button turns the device **On/Off**.  
(In order to conserve battery life, the statMAP will automatically shut off after 10 minutes of “no use”).

**Multi-Function Button:** The Multi-Function button is used to control two features of the statMAP:

- 1) Brightness of LED display.
- 2) Blood pressure display to the nearest mmHg.  
(refer to page 17).



Gauge Needle

Status Indicator

Power/Status Indicator

Low Battery Indicator

Zero Indicator (with no pressure, needle should be in oval)

## CONTROLS AND INDICATORS (con't)

**Power/Status Indicator:** This LED indicator illuminates GREEN to inform the user Power is ON.

**Status Indicators:** At the end of a determination, the LEDs in the status ovals will flash AMBR and the automatic valve will open releasing pressure in the cuff. The user **must** purge the cuff by squeezing and holding the deflate trigger until all air is released from the cuff. At that time, the LEDs will stop flashing and the GREEN Power ON LED will remain illuminated, indicating that the statMAP is ready for use. During an automatic determination, the measuring LED will illuminate green indicating a measurement is in progress.

**Low Battery Indicator:** The low battery indicator may illuminate during a determination. This is a warning for battery replacement. When the light remains illuminated, battery replacement is required. Always replace both AAA batteries at the same time to ensure proper performance. Observe the proper orientation of the batteries, since the unit will not function, and may potentially be damaged, if the batteries are not inserted properly.

**Zero Indicator:** The zero indicator is used to verify the gauge needle accuracy. When the cuff is completely deflated, the gauge needle should be over the Zero Indicator. If it is not, open the deflate trigger (see pg. 12) to release any pressure that remains inside the cuff.

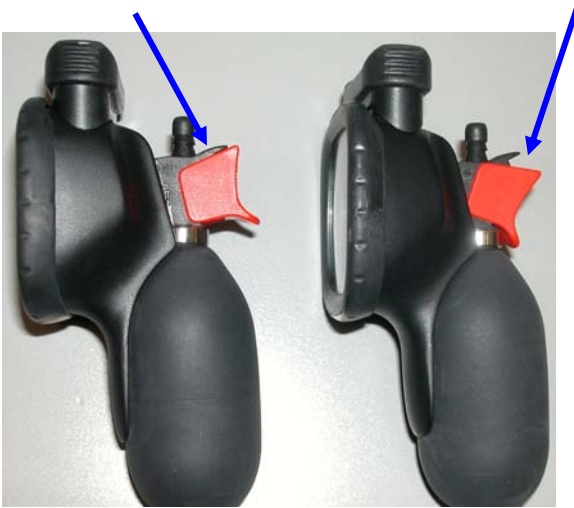
## CONTROLS AND INDICATORS (con't)

### Deflate Trigger:

When the red deflate trigger is in the **up** position (**valve closed**), cuff is ready for inflation.

When the red deflate trigger is in the **down** position (**valve open**), air is released from the cuff.

Deflate  
Trigger  
up  
(valve  
closed)



Deflate  
Trigger  
down  
(valve  
open)

**Cuff Connector:** Attach cuff connector securely to device connector.



**Inflation Bulb:** Use to inflate cuff.



## OPERATING INSTRUCTIONS:

### Semi-Automatic Mode

1. The ideal circumstance for accurate BP measurement is to have the subject relaxed and seated comfortably with the arm free of clothing. The cuffed arm should be supported to maintain the cuff at the patient's heart level.
2. Turn the statMAP ON.  
**Note: the unit should be switched ON before the cuff is attached to assure no input pressure, this is essential for accurate readings.**
3. Select the appropriate cuff size. Place cuff so that the artery mark is aligned with the artery index marker. Wrap cuff snugly around the patient's arm, ensuring that the cuff index marker (line) falls within the range markings.
4. Connect the cuff hose to the statMAP, ensuring that the connection is tight.
5. Open the deflate trigger and verify the needle is located in the zero indicator. This assures zero pressure in the system. (If needle is not in zero indicator, contact customer service).
6. If there is a "Nominal Session BP Value" (NSV) from the previous BP measurement session, it will be displayed until the cuff pressure is raised over 30 mmHg, at which time previous BP measurement data will be erased and removed from the memory, so make sure it has been recorded before starting a new BP session.

## **OPERATING INSTRUCTIONS: Semi-Automatic Mode (con't)**

7. If there is no NSV stored in the unit, there will be a sequential illumination of each of the LEDs to verify that all are functioning properly. (Subsequently, several other LEDs will then flash indicating the version of the operating software. These can be ignored unless needed by customer support.) When a single steady GREEN light appears in the Power/status indicator, the device is ready for cuff inflation to make a BP determination.
8. Verify that the deflate trigger is in the closed (up) position.
9. Inflate the cuff by squeezing the bulb firmly, but gently. Avoid accidentally opening the deflate trigger while inflating the cuff. Inflate the cuff 40 – 50 mmHg higher than the expected systolic pressure. **DO NOT OVER-INFLATE.** Over-inflation (pressures beyond 260 mmHg) may cause damage to the statMAP and harm the patient. The gauge needle and the illuminated LED should track together and agree during the inflation. (If during inflation the gauge needle and LED are not in agreement within approximately +/- 5 mmHg, see Troubleshooting, page 22).
10. After cuff inflation, leave the deflate trigger in the closed (up) position. The statMAP's internal electronic valve will automatically deflate the cuff pressure in a series of steps. As the deflate needle steps down, an LED will light at each step down point. A green light in the status indicator area will illuminate, indicating that a measurement is in progress.

## OPERATING INSTRUCTIONS: Semi-Automatic Mode (con't)

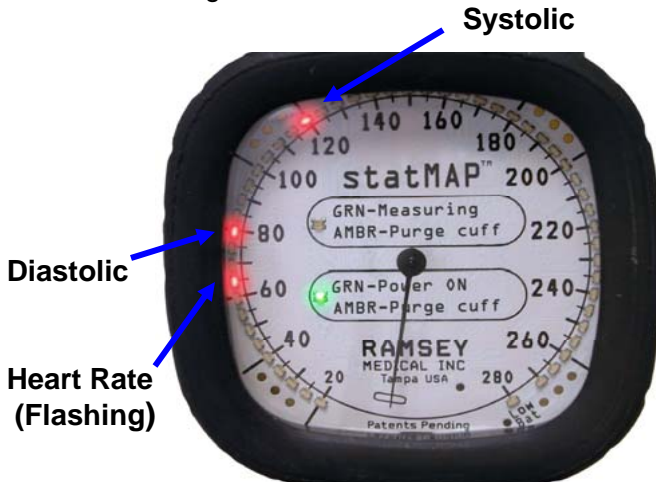
11. When both AMBR lights flash in the status indicator areas, the BP determination is complete. The remaining air must be released from the cuff by squeezing the deflate trigger. The statMAP will indicate BP and Heart Rate at the end of the deflation on the LEDs to the nearest 5mmHg tic mark. To obtain a BP reading to the nearest 1mmHg, refer to page 17.

### Solid LED Illuminations

Highest reading - Systolic  
Lowest reading - Diastolic

### Flashing LED Illumination

Heart Rate



### NOTE:

If there is only 1 solid LED & 1 flashing LED, the flashing LED represents the HR, AND either the Systolic or the Diastolic pressure.

12. To obtain another reading, just re-inflate the cuff. statMAP “remembers” the last 10 readings in a session and uses them to compute the NSV.

**NOTE:** statMAP remembers all readings but can only generate a good NSV if there are 3 or more readings made in a session.

13. The NSV is displayed for the user by cycling the power OFF then ON after a BP measurement session is finished. All of the session readings are then analyzed by the statMAP and a “Nominal Session BP Value” is displayed.

## **OPERATING INSTRUCTIONS: Semi-Automatic Mode (Con't)**

### **14. Resetting statMAP to clear the NSV**

Clearing the NSV from statMAP occurs automatically or manually.

#### ***Automatic***

- 1) Turn Unit OFF and back ON. (Record the NSV on the patient's chart.)
- 2) Begin new BP Session with same or next patient by inflation of the cuff.
- 3) Unit is cleared of all previous session NSV readings.

#### ***Manual***

- 1) Turn Unit Off and back ON.
- 2) Inflate Cuff to approximately 160 mmHg, wait for 1 step down deflation.
- 3) Open the Deflate Trigger in the down position.
- 4) The LEDs will light in sequence sweeping from 20 to 280, the Cuff Site and Mode amber light will flash once or twice and go out, the 20 LED will light and remain solid.
- 5) Unit is cleared of all previous session NSV readings.

**NOTE:** If for any reason the statMAP is unable to get a BP reading, all LEDs will sequence around the dial once to indicate the failure to determine the BP. The AMBR LEDs will flash to indicate to the user to completely purge the cuff, which the user should do by fully opening the deflate trigger (down position). Determine and correct the reason for the BP measurement difficulty. Often the problem is one or more of:

- 1) movement during the determination
- 2) cuff is not proper size or snugness (check size/fit)
- 3) initial cuff inflation is too low (pump cuff higher)

## Blood Pressure Display and MAP (Mean Arterial Pressure) to the nearest mmHg

The statMAP will indicate blood pressure at the end of each measurement on the LED display to the nearest 5mmHg tick mark. The multi-function button can be used to display the BP measurement to the nearest 1 mmHg.

- 1) To display the systolic and diastolic pressures to the nearest mmHg, press and hold the multi-function button down when the BP values are displayed.

The systolic and diastolic pressures are indicated by the bright LED (at a 5mmHg tick mark) plus or minus the number of dimmer LEDs illuminated above or below the brightly lit LED.

Example:

<u>BRIGHT LED</u>	<u>DIM LED</u>	<u>DIM LED</u>	<u>BP VALUE</u>
120	125 (1 above)	130 (2 above)	$120 + 2 = 122$
80	75 (1 below)	70 (2 below)	$80 - 2 = 78$



- 2) Pressing and holding the multi-function down a second time will display the MAP to the nearest mmHg.

The display will toggle between systolic/diastolic and MAP each time the multi-function button is pressed.

## **OPERATING INSTRUCTIONS:**

### **Manual Mode**

1. The ideal circumstance for accurate BP measurement is to have the subject relaxed and seated comfortably with the arm free of clothing. The cuffed arm should be supported to maintain the cuff at the patient's heart level.
2. When using statMAP in the manual mode, the unit should be off (not powered).
3. Select the appropriate cuff size. Place cuff so that the artery mark is aligned with the artery index marker. Wrap cuff snugly around the patient's arm, insuring that the cuff index marker (line) falls within the range markings.
4. Connect the cuff hose to the statMAP, ensuring that the connection is tight.
5. Open the deflate trigger and verify the needle is located in the zero indicator. This assures zero pressure in the system. (If needle is not in zero indicator, contact customer service).
6. Close the deflate trigger valve by placing it in the "up" or pump position. Inflate the cuff by squeezing the bulb firmly, but gently. Avoid accidentally opening the deflate trigger while inflating the cuff. Inflate the cuff 40 – 50 mmHg higher than the expected systolic pressure. **DO NOT OVER-INFLATE.** Over-inflation (pressures beyond 260 mmHg) may cause damage to the statMAP and harm the patient.
7. With the bell or diaphragm of a stethoscope (not included with the statMAP) lightly applied over the brachial artery, watch statMAP and deflate cuff by pressing lightly on the trigger until tension is felt. During the measurement, attempt to keep the deflation rate at 2-3 mmHg per second.  
**NOTE:** Inflate the cuff rapidly and then quickly begin deflation to avoid hazard that may occur due to prolonged over-inflation of the cuff.

## OPERATING INSTRUCTIONS: Manual Mode (con't)

8. As the pressure falls, note Systolic pressure at the first appearance of repetitive sounds (Phase I Korotkoff sounds).
9. Note the diastolic pressure when the Korotkoff sounds disappear.
10. The air must be released from the cuff by squeezing the deflate trigger.

### Battery Replacement:

Loosen the screw on top of the device and remove the cover. Remove old batteries and insert new AAA batteries according to symbols located on the label on the battery compartment. Replace the cover. Pressing the cover down to seat it against the housing of the statMAP, tighten the screw.

**After replacing batteries, turn statMAP ON to confirm proper operation.**



**Use new AAA batteries (Alkaline, Lithium, Nickel Metal Hydride (Rechargeable), no NICAD or "Heavy Duty")**

## MAINTENANCE

### Cleaning:

**statMAP:** Clean with damp cloth. Do not immerse in water or other liquid. Do not use alcohol.

Do not use steam or heat to sterilize the statMAP.

**Cuffs, Tubing and Port Fittings:** Before washing the cuff, remove it from the statMAP, close off the tube with a plug, and place the hook and loop fasteners in closed position.

Use one or more of the following methods and allow to dry:

- ◆ Wipe with mild detergent and water solution (1:9 solution). Rinse.
- ◆ Wipe with Enzol per manufacturer's instructions. Rinse.
- ◆ Wipe with 0.5% bleach and water solution. Rinse.
- ◆ Wipe with 70% isopropyl alcohol.

### Calibration:

Calibration of the statMAP should be checked annually or when there is doubt about the validity of the measurements. Proper calibration is indicated if needle and LED are in alignment during pump up AND subsequent deflation.

## MAINTENANCE (con't)

### Leak Test:

The statMAP should be checked annually for leakage or when there is doubt about the validity of measurements. This check may be accomplished by plugging the outlet port, inflating the device to 200-260 mmHg, and checking for needle movement.

**Caution: Calibration and leak testing should be performed by qualified service personnel.**

### Disposal of waste products:

Solid waste products will be generated when using the statMAP that require proper disposal or recycling. These include batteries and packaging material.

Batteries should be disposed of according to Environmental Protection Agency (EPA) regulations. It is recommended to contact the local EPA office to ensure proper disposal guidelines are followed

Blood pressure cuffs should be cleaned according to instructions. Inspect reusable applied parts for wear, replace as necessary, and dispose of used product as medical waste.

Retain original packaging materials for future use in storing or shipping the statMAP and accessories.

Whenever possible, recycle the packaging materials.

## TROUBLESHOOTING

***NOTE: At the first indication of any statMAP malfunction, the first attempt at resolving the problem should be to:***

- ◆ ***Replace both batteries with known fresh batteries***
- ◆ ***Disconnect the cuff***
- ◆ ***Squeeze out all residual air***
- ◆ ***Verify using correct size cuff***
- ◆ ***Reattach cuff to the statMAP***

***While inflating cuff, if illuminated LED (light emitting diode) and pointer do not track together and agree, within +/- 5 mmHg:***

1. Open the deflation valve with the trigger and assure that there is no pressure in the system. Now turn statMAP OFF and then ON again. The device should automatically reset for correct tracking.
2. If the first power cycle does not correct tracking, repeat On/Off cycle up to 2 additional times.
3. If after the 3<sup>rd</sup> try, the LED and gauge needle are still not tracking together while the cuff is being inflated, the device is out of calibration and should be returned to the manufacturer or service center for checkout and re-calibration.

***Difficulty obtaining consistent BP readings  
(greater than +/- 15 mmHg from reading to reading)***

1. Excessive movement. Keep patient from moving during the measurement cycle
2. Wrong size cuff used.
3. Cuff not properly snug, i.e., not tight enough on initial placement. Tighten cuff on the limb.
4. Cuff is not in correct location on arm. Reposition cuff.
5. Check LoBat light. Replace batteries if indicated.
6. Zero not set properly on power up. Make sure there is no pressure in the system when the statMAP is first powered up by opening the deflate trigger first and/or removing the cuff connector from the unit to assure atmospheric pressure, before turning Power ON.

***Unit will not turn on, or shuts off after powering up.***

1. Replace batteries.
2. If batteries do not fix problem, return unit for service.

***Cuff will not inflate.***

1. Check cuff connection.
2. Verify deflate trigger is in the up position (valve closed position).
3. Check cuff and hose for leaks or damage.

***Strange statMAP behavior.***

1. Replace batteries.
2. If batteries do not fix problem, return unit for service.

# SPECIFICATIONS

## **Indications/Contraindications for use:**

statMAP is a prescription device and is indicated for use to measure systolic and diastolic pressure, mean arterial pressure (MAP) and heart rate of persons ages 12 and over using the oscillometric method of measurement.

There are no contraindications for the use of the statMAP.

## **Method of BP Measurement:**

Oscillometric

## **Parameters Measured:**

Systolic, diastolic, mean arterial pressure (MAP), and heart rate (HR)

## **Modes:**

Semi-Automatic with auto deflate  
Full Manual Mode

## **Blood Pressure Range:**

20-260 mmHg

## **Cuff Pressure Display Accuracy:**

+/- 2 mmHg

## **BP Accuracy:**

BP displayed within +/- 2 mmHg

## **Heart Rate Range:**

40-240 BPM

## **Heart Rate Accuracy:**

+/- 3%

HR displayed within +/- 2 BPM

## **Power:**

2 each AAA batteries (**Alkaline, Lithium (UL1642), Nickel Metal Hydride (Rechargeable), no NICAD or “Heavy Duty”**)

**Battery Life:**

Depends on cuff size and battery type.

Alkaline: adult cuff average 150-200.

Lithium batteries give approximately 2x the readings of alkaline.

**Operating Environment:**

Temperature: 10°C to 40°C (50°F to 104°F)

Humidity: 15-90%, non-condensing

Altitude: - 500 feet (152 meters) below sea level  
to +8,000 feet (2438 meters) above sea level

**Storage Temperature:**

-20°C to 55°C (-4°F to 131°F)

**Dimensions:**

2.75" H x 2.5" W x 5.2"D (7.0cm H x 6.35cm W x 13.2cm D)

**Weight with Batteries:**

6.0 oz., (0.375 lbs), (0.17 kg)

**Drip-Proof: IPX1**

The statMAP is protected against vertically falling drops of water and conforms to the IEC 529 standard at the IPX1 level.



**Type BF Applied Part (defibrillation-proof)**



**Attention, refer to accompanying documents**

MEDICAL EQUIPMENT  
UL 60601-1, CAN / CSA C22.2 NO. 601-1

3VDC 0.5A

**Patents Pending**

## WARRANTY

The Ramsey Medical, Inc. **statMAP™** and cuffs are covered by a one year warranty against defects in materials and workmanship. Damage resulting from inappropriate use or physical abuse is not covered by the warranty. Units returned for warranty service will be repaired or replaced at the discretion of Ramsey Medical, Inc.

## CUSTOMER SERVICE

For questions regarding statMAP operation, call CardioCommand customer service at 813-289-5555 ext. 224 or 800-231-6370 (USA only).

## REPAIRS

The Ramsey Medical statMAP is distributed and supported in the USA by:

CardioCommand, Inc.  
4920 W. Cypress St., Ste. 110  
Tampa, FL 33607

Phone: 813-289-5555 ext. 224  
800-231-6370 (USA only)  
Fax: 813-289-5454

The statMAP contains no user serviceable parts. Units should be returned to CardioCommand, Inc. for repair.

**[www.cardiocommand.com](http://www.cardiocommand.com)**  
**[www.statmap.net](http://www.statmap.net)**

# **RAMSEY MEDICAL INC**

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USA**

statMAP is a registered trademark of  
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Manual Revision  
02/06/09

AWR400057-A  
090201