CardioCommand, Inc.

Esophageal Pulse Generator

TAPSYSTEM™ MODEL 2A

Operator's Manual

CARDIOCOMMAND, INC.

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ESOPHAGEAL PULSE GENERATOR

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TABLE OF CONTENTS

	Page
Indications, description and applications	3
Controls and Indicators	4
Specifications	5
Battery Replacement	6
Maintenance, Cleaning, Service and Warranty	7
Procedure for Pacing and Trouble Shooting	8
Electrosurgical Immunity Test	9
Cautions, Warnings and Contraindications	10
Adverse Reactions, Potential Malfunctions and Technical Questions	11

INDICATIONS

The TAPSYSTEM Model 2A is indicated for the treatment of cardiac condition disorders that require alteration of rate or rhythm and for the alteration of rate as required for certain diagnostic studies.

Specific indications include:

1. Temporary Pacing – which is long duration (minutes to hours) pacing usually at physiologic rates (approximately 60 to 180 bpm), begun when a patient's rate falls below some predetermined threshold rate, to achieve a therapeutic goal of maintaining a physiologic heart rate.
2. Burst Pacing – which is short duration (less than 30 seconds), high rate (up to 200 bpm) pacing intended to interrupt a reentry type arrhythmia such as atrial flutter or supraventricular (reciprocating) tachycardia without necessarily capturing or pacing the heart.
3. Overdrive Pacing – which is medium duration (seconds to minutes) pacing at usually physiologic rates (approximately 60 to 180 bpm) but above the patient's intrinsic rate to achieve a diagnostic purpose such as inducing angina as in drug studies inducing conduction aberrations, latent conduction abnormalities or ectopy or inducing ECG ST segment changes either independently or in conjunction with diagnostic cardiac ultrasound procedures.

DESCRIPTION

The CardioCommand, Inc. TAPSYSTEM Model 2A is a battery powered pulse generator system designed for the treatment of cardiac dysrhythmias. It is used primarily with an esophageal stethoscope containing pacing electrodes. (TAPSCOPE™).

The TAPSYSTEM Model 2A is intended for use by physicians or qualified medical personnel under the direct supervision of a physician for indications described above where an increase in heart rate is desirable to improve hemodynamics and other interventions are less ideal, not effective, immediately available or appropriate.

The output pulse produced by the TAPSYSTEM Model 2A is 10 milliseconds in duration at user adjustable rates of 50 to 200 beats per minute. The pulse current is adjustable from 5.5 to 40 milliamperes.

The TAPSYSTEM Model 2A is defibrillator protected; however, caution must be exercised to prevent defibrillation or cardioversion discharge through an indwelling esophageal catheter. The catheter should be removed during defibrillation or cardioversion.

APPLICATIONS

A major advantage of using the TAPSYSTEM Model 2A is the speed and ease with which pacing may be initiated because of the rapid method of placing the esophageal pacing catheter.

The use of the TAPSYSTEM Model 2A should not interfere with or preclude the application of other life saving measures including other forms of pacing, intubation, airway management, defibrillation, cardioversion, or routine cardiopulmonary resuscitation procedures.

CONTROLS AND INDICATORS

EXHIBIT A

- **CURRENT** – The CURRENT range is 5.5 to 40 mA. The CURRENT dial has a lock nut knob to maintain the knob pointer at the designated current setting. The lock nut is activated by rotating the lock ring clockwise until tight. To unlock, turn the lock ring counterclockwise.

- **RATE** – The RATE range is 50 to 200 bpm. The RATE dial has a lock nut knob to maintain the knob pointer at the selected rate. The RATE dial includes a RATE REMINDER feature as a means for reminding the operator when the rate setting exceeds 120 bpm.

- **POWER** – The POWER switch turns the unit ON or OFF.

- **PACING INDICATOR** – The GREEN lamp (LED) flashes at the pacing rate when current flows between the catheter electrodes. It does not necessarily indicate that the heart is being paced.

- **LOW BATTERY INDICATOR** – The Yellow LOW BATTERY INDICATOR illuminates when batteries need replacing. To ensure proper performance, always replace both batteries when this indicator is illuminated.

- **CABLE CONNECTION** – Locate the raised arrow on the cable near the connector with the silver collar. With the arrow facing up, connect this end of the cable to the unit by rotating the connector housing (part with the arrow) slightly to the right or left until it drops in place. Next, apply a slight pressure while turning the collar clockwise until the threads engage. Continue to tighten the collar until it is snug and the connector is fully seated.

SPECIFICATIONS

PHYSICAL

Size: 6.70” wide x 4.73” deep x 2.92” high (sloping to 1.5”) (17cm x 12 cm x 7.4 cm)

Weight: .70 Kilograms w/o batteries

MATERIALS

Case: High Impact ABS Plastic

Panel: Mylar™ on Metal

OPERATING

Wave Form:	Rectangular
Rate:	50 to 200 BPM
Pulse Duration:	10 milliseconds +/- 10% at Vbatt = 2.8 Vdc
Current:	5.5 to 40 mA
Load Independence:	At the midrange current setting of 20 mA, a constant current is delivered across a range of output impedances up to 2000 ohms.
Batteries:	Use Alkaline batteries only. The batteries should provide a total of 70 hours of continuous pacing. Both Alkaline batteries (D-CELLS) should be replaced when the Low-Battery Indicator light is on. Continued operation with the low-battery indicator light on may result in erratic output.
Defibrillation:	Protected up to 400 joules.

Note: To conserve battery life, always make certain the Model 2A power switch is turned off after a procedure is completed.

BATTERY REPLACEMENT

EXHIBIT B

Turn POWER switch to OFF position. Locate the battery compartment on the side of the TAPSYSTEM Model 2A. Open the compartment by turning the cover until metal plate is exposed or groove on tab is horizontal. Remove the cover. The batteries are oriented with + terminals facing the battery compartment cover. Verify polarity before inserting the batteries. Insert batteries and replace compartment cover.

Battery Indicator: Check LOW BATTERY INDICATOR light prior to each use. Both batteries should be replaced if YELLOW indicator is illuminated.

MAINTENANCE

Test and Calibration – In the event of damage or suspected damage, the TAPSYSTEM Model 2A should be tested by a qualified biomedical technician with suitable test instruments to verify that RATE, CURRENT, and PULSE WIDTH functions are within specification. See SPECIFICATIONS section for detail tolerances. If any parameter is out of specification, the TAPSYSTEM Model 2A should be returned to CardioCommand, Inc., after obtaining return authorization.

CLEANING

The TAPSYSTEM Model 2A may be cleaned with a sponge or cloth dampened only with water or mild detergent. Caustic solvents should not be used.

The TAPSYSTEM Model 2A CANNOT BE AUTOCLAVED.

SERVICE

CardioCommand, Inc. recommends that the TAPSYSTEM Model 2A be serviced by an authorized biomedical engineer. To request repair service, contact:

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

(800) 231-6370 or (813) 289-5555

WARRANTY

For a period of one year, CardioCommand, Inc. warrants that the TAPSYSTEM Model 2A, when used in accordance with the directions, is fit for the purpose and indications described in the labeling.

CardioCommand's sole obligation under this warranty shall be, at its option, to repair or replace the product.

In no event shall CardioCommand be liable for incidental or consequential damages.

Unless the products are used in accordance with directions, this warranty, and all other expressed or implied warranties, are void and of no effect.

ATRIAL PACING WITH THE TAPSYSTEM MODEL 2A

1. Obtain a surface electrocardiogram.
2. Lubricate the TAPSCOPE by placing in warm water or using a gel.
3. Insert the TAPSCOPE into patient's esophagus, aligning the 33-cm mark on the TAPSCOPE with the patient's front teeth.
4. Turn POWER switch ON; confirm battery life by observing the yellow LOW BATTERY INDICATOR. If the INDICATOR light is on, replace batteries.
5. Turn POWER switch OFF.
6. Plug the round connector on the TAPSCOPE into the gray cord connected to the Model 2A Pulse Generator, making sure the raised portion on the plug aligns with the notch in the gray cord receptacle.
7. Set the CURRENT dial to 20 mA.
8. Set the RATE dial as desired making certain the setting is approximately 10 bpm above the patient's intrinsic heart rate.
9. Turn the TAPSYSTEM 2A Power switch ON to initiate a pacing stimulus to the patient.
10. Verify capture as indicated by surface EKG or palpable pulse. There will be a one-to-one relationship on the EKG between the pacing spike and the QRS complex.
11. If capture is not achieved, adjust CURRENT and/or insertion depth as needed.
12. After capture, tape the scope to the patient to maintain proper insertion depth and verify the position periodically.

Note: When pacing is initiated, make sure the Rate setting on the pulse generator is at least 10 bpm above the patient's intrinsic heart rate.

Esophageal pacing may produce a variable degree of patient discomfort in awake patients. If clinical conditions permit, anesthesia or sedation may be beneficial.

Follow the usually accepted routine cardio-pulmonary resuscitation (CPR) procedure if needed. Obtain and have a defibrillator and other life support equipment ready.

TROUBLESHOOTING

If unable to achieve capture:

1. Adjust the TAPSCOPE insertion depth.
2. Increase CURRENT setting.
3. Verify battery power.
4. Check all connections.
5. Monitor electrocardiogram for signs of A.V. Block.

Model 2A Electrosurgical Immunity Test

To date, current regulatory standards for Electromagnetic Compliance do not address the interference characteristics of many Electrosurgical Units (ESU's). Some of these devices may radiate extremely large electric fields, which may cause malfunctions in patient monitoring and therapeutic equipment including the CardioCommand Model 2A. The following precautionary test should be used as a tool to help indicate if the Model 2A is susceptible to your ESU. (It is a meaningful minimum ESU immunity test and is not a guarantee that the unit will function properly during the use of the ESU.)

Procedure:

1. Connect the interface cable and a TAPSCOPE to the Model 2A.

2. Using the Safety procedures pertaining to the operation of your ESU, place the dispersive electrode of the ESU on an appropriate surface next to a container of .9% saline solution.

3. Insert the TAPSCOPE into the saline solution and submerge the electrodes. Place the Model 2A unit in its normal proximity relative to the ESU as if an Electrosurgery procedure were taking place.

4. Set the Model 2A Rate to 50 bpm and the Current to 20 mA. Turn the unit ON.

5. Verify that the Green Pacing LED is flashing at the correct rate.

6. Set the ESU to maximum power in the cutting mode and hold the knife (activate electrode) within 2 or 3 inches of the beaker and dispersive electrode taking care to prevent the knife from contacting anything.

   Note: It is not necessary to generate an arc to the dispersive electrode for this test.

7. Turn the power to the ESU on and engage the activation switch (usually a foot switch). While the ESU is engaged, observe the Model 2A's flashing Green LED for any irregular pulsing or significant changes in pulse frequency.

   Verify immunity by engaging the ESU activation switch several times while observing the Model 2A.

8. Repeat step 7 after setting the ESU to maximum power in Coagulate mode.

9. Do not use the Model 2A during electrosurgery if susceptibility was observed during this test.

Note: Although a good indicator of susceptibility, this test does not guarantee proper Model 2A operation in the presence of ESU use during surgery. Verify proper functioning during use.

CAUTIONS, WARNINGS AND CONTRAINDICATIONS

CAUTION

Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

Some electrosurgical units can affect the paced rate. If esophageal pacing is being done during use of electrosurgical equipment, verify maintenance of the desired heart rate. If an affect on the heart rate is seen, discontinue pacing during the electrosurgical procedure.

WARNINGS

Improper placement of the catheter may result in mechanical or electrical injury to vital tissues. Incorrect placement of the catheter in the trachea may result in respiratory distress, damage to the airway and inability to pace the heart.

Inadequately grounded patients may receive esophageal thermal injury during electrosurgical and electrocautery procedures.

PRECAUTIONS

Cardiac pacing should be done by or under the direction of a physician. EKG monitoring should be used in conjunction with the use of the TAPSYSTEM 2A. Cardiac defibrillation equipment should be available for immediate use in the event of ventricular tachycardia and electrodes should be insulated from accidental contact with electrical sources. Ensure TAPSYSTEM 2A batteries and catheter are in good working order before use.

While using this device caution must be exercised if clinical conditions require use simultaneously with epicardial or endocardial pacing leads using either temporary or permanent pacing devices. The stimulus artifact from the TAPSYSTEM Model 2A may cause inappropriate sensing and/or inhibition of the other temporary or permanent pacing devices.

HAZARDS

The presence of an electrical conductor in the esophagus constitutes a potential hazard, in part, by providing a low resistance electrical path to the heart.

CONTRAINDICATIONS

Contraindications are the same as, but not limited to those of placing a nasoesophageal catheter, pacing transesophageally and cardiac pacing. These include esophageal injury or disease, such as esophageal varices, malignancy, stenosis, and left atrial hypertrophy.

Pacing is contraindicated for hypoxia and hypothermia.

The TAPSYSTEM 2A is contraindicated for use in pregnant women, patients with a complete AV heart block and in any patient for whom cardiac pacing is contraindicated.

ADVERSE REACTIONS

Potential complications in using the TAPSYSTEM 2A include, but are not limited to the following:

1. High rate stimulation of the ventricles resulting in ventricular tachycardia and high rate cardiac failure.
2. Ventricular fibrillation during or after pacing.
3. Traumatic injury to the esophagus from catheter placement.
4. Accidental electrical discharge through an indwelling electrical conductor in the esophageal tract from an unintended electrical source.
5. Possible gagging, choking and discomfort may occur during pacing in awake patients.

POTENTIAL MALFUNCTIONS

Potential malfunctions arising from failure of the TAPSYSTEM 2A components include, but are not limited to the following:

1. No pulse output or insufficient pulse output.
2. Irregular pulse frequency.
3. Weak or ineffective batteries.
4. Malfunctioning catheter.
5. Improper cable connection between catheter and cable.
6. Cable not properly connected to TAPSYSTEM 2A.

TECHNICAL QUESTIONS

The TAPSYSTEM 2A is manufactured for CardioCommand, Inc. Technical questions regarding the system function should be directed to Customer Service at (800) 231-6370 or (813) 289-5555 Fax (813) 289-5454.

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