PHYSIO-CONTROL

BIPHASIC DEFIBRILLATION WAVEFORM CLINICAL INVESTIGATION PLAN

1/25/89

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I. Investigation Summary

A. Introduction

Electric counter-shock (defibrillation) is presently the most effective method of terminating the life threatening arrhythmias of ventricular tachycardia and ventricular fibrillation. Defibrillation is accomplished by passage of an appropriate electrical current through the heart sufficient to depolarize a critical mass of the left ventricular myocardium. The defibrillating current is partially dependent upon the amount of energy delivered measured in Joules (J = Watt-seconds), and the form in which it is delivered, or the pulse shape (voltage/current over time). All commercial defibrillators deliver monophasic type pulses (e.g. Edmark, Lown, Pantridge, truncated exponential) which have not undergone much change since their adoption in the early 1960s. The current literature suggests alternative waveforms (e.g. biphasic pulses consisting of both positive and negative phases) may provide more rapid and effective defibrillation, and perhaps induce less myocardial damage or dysfunction than current monophasic pulse waveforms.

Biphasic defibrillation waveform research by Physio-Control actually began in the late 1970s through support of animal model studies conducted by John Schuder, at the University of Missouri, and Janice Jones, at Case Western Reserve University. In 1986, the research was focused on the investigation of waveforms which held promise for commercial application. Schuder performed 120 paired transthoracic 200J shocks in calves utilizing either the "standard", monophasic Edmark waveform, or the "new" biphasic Gurvitch waveform. Preliminary study data indicated an 88% success rate for the Gurvitch waveform, in contrast with the 37% success rate reported for the Edmark waveform. In another recent study, Bardy et. al. evaluated biphasic waveforms in epicardial defibrillation of 22 human subjects found the current and energy required for defibrillation to be significantly less with biphasic pulses. The difference in defibrillation success rate and energy requirements is significant enough to warrant a similar, well-controlled human clinical trial in the electrophysiology (EP) laboratory setting.

B. Device

The device used in this investigation will be a modified LIFEPAK® 6s defibrillator. The modified unit, relabeled "LIFEPAK 7BI", is capable of producing either the standard monophasic Edmark defibrillation pulse or the new biphasic Gurvitch waveform. The LIFEPAK 7BI defibrillator is an investigational device and is limited by federal law to investigational use only. In addition, the device should only be used by qualified medical personnel familiar with its operation and under the authority and supervision of the investigators involved in this study. The monitor / recorder used will be a LIFEPAK 7 monitor/recorder relabeled "LIFEPAK 7BI" for study purposes.

C. Study Objectives

The primary objective of this investigation is to collect clinical safety and efficacy data on the Gurvitch (biphasic) defibrillating pulse waveform in humans, including but not limited to the following:

1) demonstration of a statistically significant difference,if any, in first shock defibrillation effectiveness between Gurvitch and Edmark waveforms;

2) characterization of patient parameters over which the Gurvitch and Edmark waveforms are effective; and

3) Assessment of the effect of using Gurvitch and Edmark waveforms on post-shock 12 lead electrocardiographic (ECG) patterns.

D. Clinical Investigation Phases

The clinical study of the Gurvitch defibrillating waveform will include two investigation phases.

1) Phase I: a local preliminary EP Lab study to assess the safety and feasibility of the data collection protocol;

2) Phase II: an independent, multi-center EP Lab clinical trial.

E. Duration of the Investigation

The clinical evaluation (Phases I and II) of the Gurvitch defibrillating waveform is estimated to require twenty months for completion. Physio-Control estimates that between 300 and 350 patients will be required to evaluate the safety and efficacy of this therapy.

F. Revision

This protocol is subject to revision based upon experience in the study. However, any changes to the protocol, or the device, should neither alter the fundamental operation of the device, nor increase the risk exposure of the study patient.

II. Protocol

A. General

1. Preface

The main objective of this investigation is to collect clinical safety and efficacy data on the biphasic Gurvitch pulse defibrillation waveform as delivered by a modified Physio-Control LIFEPAK 6s defibrillator (relabeled as "LIFEPAK 7BI"). Comparative efficacy is to be determined by comparing first shock defibrillation/cardioversion success rate of a 200J biphasic Gurvitch pulse to that of a conventional 200J monophasic Edmark pulse. The protocol has been designed to limit experimental variability by utilizing a device capable of producing either waveform, with the type of waveform being blind to the user. Only the first shock waveform is randomized. In the event the first shock delivered fails to defibrillate or convert the patient, all subsequent shocks are of the standard Edmark type.

This investigation is designed to minimize the number of patients involved and at the same time expose the defibrillating waveforms to a sufficiently large patient population to provide a representative and statistically meaningful sample.

2. Patient Population and Selection

The investigator has the responsibility of screening all potential patients and selecting those who are appropriate for study inclusion. Patients selected for this study will be adults (age 18 and over) of either sex who are judged by the investigator to be candidates for electrophysiological testing and may require defibrillation with at least a 200J pulse. The investigator will attempt to enroll all patients in the study to avoid preselection bias. Patients who are induced into a shockable rhythm requiring at least a 200J defibrillation pulse more than once may be used again as study subjects. However, repeat patient episodes are to be treated separately and a new data collection form is to be completed for each episode.

Data on all study patients who are cardioverted/defibrillated will be submitted to Physio-Control. This includes first shocks with the randomized 200J waveform and first shocks at 360J. First shocks with an energy other than the randomized 200J waveform should include a statement explaining the reason for the selection.

Patients under the age of 18 will be excluded from the investigation. Patients for whom defibrillation at 200J is not clinically indicated, e.g. those with excessive body mass, will be, at the discretion of the clinical investigator, excluded from the study. Patients with automatic implantable cardioverter/defibrillator (AICD) electrodes/patches in place shall be excluded from the investigation. The silicone backing present on AICD electrodes acts as an insulator and may disrupt the electric field of defibrillation thus making the energy required for success less predictable.

3. Patient Consent

Informed consent will be obtained from all patients (or their legal representatives) prior to their participation in the investigation. A copy of the signed consent form must be returned to Physio-Control Corporation.

4. Patient Data Confidentiality
   All information and data sent to Physio-Control concerning patients or their participation in this investigation will be considered confidential by Physio-Control. Only authorized Physio-Control personnel will have access to these confidential files. Authorized FDA personnel have the right to inspect and copy all records pertinent to this investigation. All data used in the analysis and summary of this investigation will be without identifiable reference to specific patient names.

5. Medical Discretion
   In the interest of patient safety and protection, all study procedures are subject to the medical discretion of the investigator. If a specific study procedure is contraindicated for a patient, the investigator should so state on the data collection form and omit the procedure.

6. Emergency
   In an emergency situation where steps must be taken to protect the life and physical well-being of a patient, the medical judgement of the investigator has priority over the requirement for study compliance.

B. Test Procedure

1. General
   During electrophysiological (EP) studies in which the patient has given consent to participate in the Gurvitch defibrillation waveform clinical trial, a LIFEPAK 7BI monitor/defibrillator, supplied by Physio-Control, will be used as the primary monitor/defibrillator for resuscitation. Prior to testing the patient, a diagnostic quality 12-lead ECG will be recorded as a baseline measurement. Physio-Control FAST-PATCH® disposable defibrillation/electrocardiogram (ECG) electrodes shall be accurately and consistently attached to the patient in the anteriolateral positions (see application instructions on package). The FAST-PATCH disposable defibrillation/ECG electrodes are connected to the defibrillation electrode cable and this cable is connected to the paddle extension cable. Electric counter-shock discharge will be accomplished by depressing the "AUX PADDLE DISCH" button located on the front control panel. A Physio-Control Patient Data Collection Form shall be completed for each patient participating in the study, and marked with a Patient Study Identification (ID) Number utilizing the pre-numbered, self adhesive labels provided.

   If during the course of EP testing, the investigator deems it necessary to cardiovert/defibrillate the patient, the first shock shall be 200J. This defines the beginning of an episode. During the cardioversion/ defibrillation event, the patient ECG will be documented on the LIFEPAK 7BI monitor strip chart recorder via the FAST PATCH electrodes, and on a multi-channel physiological recorder via intracardiac leads. After an electric counter-shock is delivered, a code number will appear on the ECG strip near the tracings associated with the shock delivered. The code number must be recorded on the corresponding episode shock number line of the patient data collection form. If defibrillation is achieved (i.e. indicated by a non-ventricular tachycardia (VT) or non-ventricular fibrillation (VF) rhythm), the shock shall be recorded as a success. If

defibrillation is not achieved, the shock shall be recorded as a failure, and subsequent shocks (default Edmark pulse type) of 200J and 360J will be administered as required, or follow-up care will be instituted as prescribed by the investigator. As soon as the charge button on the defibrillator is depressed the recorder will begin recording the ECG and will continue to record until 10 seconds after the shock has been delivered. The shock tracings will be annotated with the corresponding code numbers until the patient is effectively resuscitated, or the patient electrodes are removed. The patient's return to a hemodynamically stable rhythm, or the removal of patient electrodes, defines the end of an episode.

A diagnostic quality 12 lead ECG will be recorded 30 seconds after each shock occurs. The LIFEPAK 7 BI monitor will emit a tone 30 seconds after a shock has been delivered, to cue the investigator that it is time to obtain the 12 lead ECG. In addition, upon completion of the study a diagnostic quality 12 lead ECG will be recorded for post-test comparison to both baseline ECG and post-shock ECGs. All ECG data including the strip from the monitor recorder, a copy of the intracardiac lead tracing of each event (i.e. from 3 seconds prior to shock and 6 seconds of post shock recording), and the pre-test , post-shock and post-test 12 lead recordings shall be labeled with the patient study ID number on the corresponding patient data form using the pre-numbered, self-adhesive labels. All ECG documentation, along with the patient data form, shall be enclosed in a data collection envelope (also labeled with patient study ID number) provided.

2. Monitor/Defibrillator Operation

A complete description of the LIFEPAK 7 monitor and the LIFEPAK 6s defibrillator are given in their respective Operating and Service Manuals available through Physio-Control. The monitor/defibrillator used in this study is similar in operation to these with the following exceptions,which are described in greater detail in the modified instruction manual provided with the study materials.

a. Energy selection is limited to two settings, 200J and 360J. At 200J, the waveform type (biphasic Gurvitch pulse or standard monophasic Edmark pulse) delivered on the first shock of a sequence is randomly selected by the device. All subsequent shocks in a sequence are the conventional Edmark type. At 360J, any shock, including the first, will be an Edmark defibrillation waveform. (ref. Appendix A)

b. The available defibrillation energy measurements will not be displayed. The LIFEPAK 7BI monitor will automatically annotate on the ECG tracing a coded number that incorporates the type of waveform, energy level, peak current, and the sequence number of the shock in the episode.

c. The recorder on the LIFEPAK 7BI monitor will turn on automatically when the charge button is pushed on the defibrillator. It will continuously record the ECG until 10 seconds after the shock is delivered, at which time it will automatically stop. The strip obtained will be annotated with the date, time, and code number.

d. An indicator lamp has been added to the left side of the paddle well for testing defibrillation energy available with external paddles. The indicator flashes when 200J or greater is discharged into the test load.

e. An internal system reset will automatically occur 5 minutes after the last shock delivered in a sequence. This guarantees the random generation of the first shock waveform between the biphasic Gurvitch pulse and the standard monophasic Edmark pulse for each new episode. (ref. Appendix A)

f. To use the FAST-PATCH defibrillation/ECG electrodes, attach the electrodes to the disposable defibrillation cable and connect this cable to the paddle extension cable. Electric counter-shock discharge is accomplished by depressing the " AUX PADDLE DISCH" button located on the front control panel.

g. Although normal operation is via AC line power, for emergency back-up there is battery capacity, limited to six (6) 360J Edmark shocks at 25°C.

3. Patient Preparation

After obtaining patient consent from a selected candidate, the patient is situated in the study room. The FAST-PATCH disposable defibrillation/ECG electrodes should be placed on the patient in the anteriolateral positions, i.e one to the right of the upper sternum just below the right clavicle, and the other, just to the left of left nipple in the midaxillary line. The defibrillation electrode cable is attached to the electrodes and then connected to the paddle extension cable. In addition to providing a means for electric shock delivery, the electrodes will also be used for electrocardiogram and heart rate monitoring.

4. Data Collection

At the beginning of each operating day, the LIFEPAK 7BI monitor/defibrillator should be tested using the Physio-Control Patient Simulator. Attach the defibrillation electrode cable from the LIFEPAK 7BI defibrillator to the Physio-Control Patient Simulator and turn both devices on. Verify the presence of normal sinus rhythm on the cardioscope. Select 360J and depress the "CHARGE" button. Verify that the recorder comes on at this time. Simulate ventricular fibrillation and discharge the defibrillator into the Patient Simulator. Verify the annotation on the ECG recording and the return of normal sinus rhythm. ECG recording should cease 10 seconds after discharge. Be sure the 12 lead ECG reminder tone sounds 30 seconds after discharge. Reset the energy selection to 200J.

Prior to beginning the test, record a diagnostic quality 12 lead ECG as a baseline measurement. The patient's medical profile is recorded on the patient data collection form provided. This includes standard demographic information, current diagnosis, and any patient medication(s).

When a patient is induced into an arrhythmia, indicate the method of induction by checking the appropriate box on the patient data collection form. Record the nature of arrhythmia by selecting the appropriate number from the rhythm table provided. Note the time of onset of arrhythmia. If the patient subsequently requires electric counter-shock,

depress the amber "CHARGE" button on the defibrillator front control panel. At this time the LIFEPAK 7BI monitor strip recorder should automatically begin to record the event. If R-wave synchronization is desired, depress the white "SYNC" button on the front control panel. Discharge defibrillator by depressing the "AUX PADDLE DISCH" button. Record the pre-shock rhythm, if different from that initially induced, and the approximate duration of arrhythmia from induction to shock by checking one of the time span boxes on the data collection form.

After a shock is delivered, the code number will be annotated on the tracing obtained from the LIFEPAK 7BI monitor / recorder. This number must be recorded on the line provided on the data collection form. Mark the selected energy level and whether or not it was synchronized. Indicate whether the shock was successful or not. A successful shock is one that produces any non-VT/non-VF rhythm. Indicate the post-shock rhythm using a correspondingly appropriate number from the rhythm table on the data collection form.

The recorder will automatically turn off 10 seconds after the shock has been delivered. If the shock is successful, when the patient recovers, estimate the time from delivery of shock to the return of a hemodynamically stable rhythm and fill in the space provided. Attach the strip chart recording of the episode to the patient data collection form. Copy the portion of the multi-channel physiological recorder output containing the intracardiac lead tracing from 3 seconds prior to shock and 6 seconds after the shock. Label all channels on the hardcopy of the multi-channel recording and tag each copy with the patient study ID number labels provided.

If the shock is unsuccessful,the recorder will still turn off 10 seconds after the shock has been delivered. It will begin recording again as soon as the charge button is depressed for subsequent shocks. Continue to record the second and third subsequent shock information as above. Past three shocks, only the energy delivered and the success data need be collected.

At the conclusion of a shockable episode, record another diagnostic 12 lead ECG for post-test comparison to baseline ECG. Enclose all ECG data (i.e. strip chart, intracardiac lead tracings, pre-test, post-shock and post-test 12 lead recordings) with the data collection form in the data collection envelope provided.

5. Data Analysis

The data collected will be analyzed independently by the principal investigators and by Physio-Control. The analysis of the data in support of the investigation objectives will include, but not be limited to the following. Relative effectiveness of the Gurvitch and Edmark waveforms will be evaluated by comparing first shock effectiveness, peak current, and the first shock effectiveness versus ease of inducement as measured by the method of arrhythmia induction. The range of effective defibrillation for both waveforms will be characterized by the parameters of first shock effectiveness versus patient impedance, patient weight, pre-shock rhythm, duration of arrhythmia, patient age, patient gender and medication. The relative performance of the two different waveforms will be assessed using the following indicators: duration of post-shock

recovery time (time to return of a hemodynamically stable rhythm), post - shock rhythm, frequency and type of ECG changes immediately following defibrillation (e.g. A-V block, ST-elevation/depression, inverted T-wave). Physio-Control will provide for the blinded analysis of these ECG tracings. The goal of the analysis is to establish the safety and efficacy of the biphasic Gurvitch defibrillation waveform compared to the monophasic Edmark defibrillation pulse.

III. Risks and Benefits

A. Risks

The major risks associated with this clinical investigation include those related to cardiac catheterization procedures and electrophysiological test protocols for induction of arrhythmias. The patients selected for this investigation will be candidates for electrophysiological study, and therefore, would normally undergo these treatments as part of the routine diagnostic process.

Additional risks include delay of conventional therapy and the unknown response to the energy being delivered to the patient. The first risk is minimized by the immediate (10 seconds or less) availability of conventional therapy should the therapy under study prove ineffective. In a recent study, Fujimura et. al. found that delay of defibrillation therapy to 90 seconds has no significant effect on the ability to defibrillate. Conventional back-up units will also be ready in case of failure or other emergency. The second risk is minimized by the controlled setting of the investigation, which is capable of responding to the critical care needs of a patient, if necessary. The probability of risk is further reduced by past biphasic waveform research in a variety of animal models with favorable results. In another recent study- Bardy et. al. evaluated biphasic waveforms in epicardial defibrillation of 22 human subjects without incident, and in fact, found the current and energy required for defibrillation to be significantly less with biphasic pulses.

B. Benefits

Although no direct benefit to the patient can be guaranteed from this investigation, there is benefit to be gained in the development of a technology and therapy which could lead to instruments capable of providing more rapid and effective defibrillation with a safety equivalent to current practice.

C. Justification

The main objective of this investigation is to collect comparative clinical safety and efficacy data on the Gurvitch (biphasic) defibrillation waveform as delivered by a modified Physio-Control LIFEPAK 6s Defibrillator (relabeled as LIFEPAK 681). If this objective is satisfied, the data may be used to comply with FDA requirements for market release of the devices incorporating this electrical therapy in the United States.

In order to adequately substantiate the overall safety and efficacy of the devices in a clinical environment, a controlled study in humans is required. No other effective way exists for gathering this information.

IV. References

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Gurvitch NL, Tabak VY, Bogushevich MS, Venin IV, Makarychev VA: Defibrillation of the heart with a biphasic impulse in experimental and clinical conditions. *Kardiologia (USSR)*. Aug 1971; 11(8): 126-130.

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Jones JL, Jones RE: Improved defibrillator waveform safety factor with biphasic waveforms. *Am J Physiol*. 1983; 245(14): H60-H65.

Schuder JC, McDaniel WC, Stoeckle H, Yerkovich D: Comparison of effectiveness of relay-switched, one-cycle quasi-sinusoidal waveform with critically damped sinusoid waveform in transthoracic defibrillation of 100kg calves. 1988; In press.

Schuder JC, McDaniel WC, Stoeckle H: Defibrillation of 100kg calves with asymmetrical, bidirectional rectangular pulses. *Cardiovasc Res*. July 1984; 18(7): 419-426.

Study ID # _____

Biphasic Defibrillation Waveform Study

Patient Data Collection Form

Date _____

Site: University Hospital

Date of Birth _____/_____/_____

Gender: ☐ Male ☐ Female

Height _____ Weight _____

Cardiac Disease Diagnosis:

Etiological:

- ☐ Ischemia
- ☐ Dilated Cardiomyopathy
- ☐ Hypertrophic Cardiomyopathy
- ☐ Congenital
- ☐ Hypertensive
- ☐ Valvular
- ☐ Infectious/Parasitic
- ☐ Systemic Disease
- ☐ Pulmonary Disease
- ☐ Cardiac Tumor
- ☐ Cardiac Trauma
- ☐ Prolapse
- ☐ Long QT Syndrome
- ☐ Toxic
- ☐ Idiopathic
- ☐ Other: _____

Functional:

- ☐ Supraventricular Arrhythmia
  - ☐ Atrial Fibrillation
  - ☐ Atrial Flutter
  - ☐ Paroxysmal SVT
  - ☐ Pre-Excitation
  - ☐ Other: _____
- ☐ Ventricular Arrhythmia
  - ☐ Nonsustained VT
  - ☐ Sustained VT
  - ☐ VF
  - ☐ Ectopy only

Medication:

Antiarrhythmic Agents:

- ☐ Amiodarone
- ☐ Bretylium
- ☐ Digoxin
- ☐ Disopyramide
- ☐ Encainide
- ☐ Flecainide
- ☐ Imipramine
- ☐ Indecainide
- ☐ Lidocaine
- ☐ Mexiletine
- ☐ Moricizine
- ☐ Phenytoin
- ☐ Procainamide
- ☐ Propafenone
- ☐ Quinidine
- ☐ Recainam
- ☐ Sotalol
- ☐ Tocainide
- ☐ Other

☐ Beta Blocker ☐ Ca Channel Blocker ☐ Bronchiodilator

☐ Other Specify _____

Comments / Reason for Exclusion: _____

_____

_____

Study ID # _____

(1) First Shock

Method of Induction: ☐ S2 ☐ S3 ☐ S4 ☐ Other

Pre-shock Rhythm _____ (from table at right)

Duration of Arrhythmia:

☐ <10sec ☐ 10-30s ☐ 30-60s
☐ 1-2min ☐ 2-5min ☐ >5min

1st Shock Coded Event Number: _____

Energy Delivered: ☐ 200J ☐ 360J

Synchronized: ☐ YES ☐ NO

1st Shock Success (Non-VT/Non-VF):

☐ YES ☐ NO

Post-shock Rhythm _____ (from table at right)

Time from 1st Shock to Recovery of Original (Pre-Study) or Hemodynamically Stable Rhythm: _____

Rhythms as indicated in Lead II:

1. Asystole (Ampl <80μV, ≥5 sec)
2. Fine VF (Ampl <200μV & >80μV)
3. Coarse VF (Ampl >200μV)
4. Ventricular Tachycardia
5. Supraventricular Tachycardia
6. Sinus Tachycardia
7. Idioventricular (<100 bpm, QRS >120ms)
8. Normal Sinus Rhythm

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(2) Second Shock

Method of Induction: ☐ S2 ☐ S3 ☐ S4 ☐ Other

Pre-shock Rhythm _____ (from table at right)

Duration of Arrhythmia:

☐ <10sec ☐ 10-30s ☐ 30-60s
☐ 1-2min ☐ 2-5min ☐ >5min

2nd Shock Coded Event Number: _____

Energy Delivered: ☐ 200J ☐ 360J

Synchronized: ☐ YES ☐ NO

2nd Shock Success (Non-VT/Non-VF):

☐ YES ☐ NO

Post-shock Rhythm _____ (from table at right)

Time from 2nd Shock to Recovery of Original (Pre-Study) or Hemodynamically Stable Rhythm: _____

Rhythms as indicated in Lead II:

1. Asystole (Ampl <80μV, ≥5 sec)
2. Fine VF (Ampl <200μV & >80μV)
3. Coarse VF (Ampl >200μV)
4. Ventricular Tachycardia
5. Supraventricular Tachycardia
6. Sinus Tachycardia
7. Idioventricular (<100 bpm, QRS >120ms)
8. Normal Sinus Rhythm

Study ID # _____

(3) Third Shock

Method of Induction: ☐ S2 ☐ S3 ☐ S4 ☐ Other

Pre-shock Rhythm _____ (from table at right)

Duration of Arrhythmia:

☐ <10sec ☐ 10-30s ☐ 30-60s
☐ 1-2min ☐ 2-5min ☐ >5min

3rd Shock Coded Event Number: _____

Energy Delivered: ☐ 200J ☐ 360J

Synchronized: ☐ YES ☐ NO

3rd Shock Success (Non-VT/Non-VF):

☐ YES ☐ NO

Post-shock Rhythm _____ (from table at right)

Time from 3rd Shock to Recovery of Original (Pre-Study) or Hemodynamically Stable Rhythm: _____

Rhythms as indicated in Lead II:

1. Asystole (Ampl <80μV, ≥5 sec)
2. Fine VF (Ampl <200μV & >80μV)
3. Coarse VF (Ampl >200μV)
4. Ventricular Tachycardia
5. Supraventricular Tachycardia
6. Sinus Tachycardia
7. Idioventricular (<100 bpm, QRS >120ms)
8. Normal Sinus Rhythm

Subsequent Shocks:	Energy Delivered		Success (Non-VT/Non-VF)	
#4	☐ 200J	☐ 360J	☐ YES	☐ NO
#5	☐ 200J	☐ 360J	☐ YES	☐ NO
#6	☐ 200J	☐ 360J	☐ YES	☐ NO
#7	☐ 200J	☐ 360J	☐ YES	☐ NO
#8	☐ 200J	☐ 360J	☐ YES	☐ NO

Total Elapsed Time of Episode _____
(from induction to return of pre-study or hemodynamically stable rhythm)

ECG Recordings: Please attach to the Patient Data Collection form the entire LP7BI Monitor strip chart recording; the pre-study, post-shock and post-study 12 lead ECG recordings; and the segments of the intracardiac lead recording, from 3 seconds prior to shock delivery until six seconds post shock.

APPENDIX A

LIFEPAK 7BI Waveform Selection Algorithm