PHYSICIAN’S
OPERATION MANUAL

KING OF HEARTS
EXPRESS® +

CARDIAC EVENT RECORDER

Instromedix®
A Card Guard Company
SAN DIEGO, CA 92121 USA
CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Note: Operation of this device near sources of electromagnetic interference (such as, radio transmitters) may adversely affect the quality of the recorded ECG signal. This device complies with AAMI EC38–94 applicable specifications regarding electromagnetic compatibility.

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INTRODUCTION

The King of Hearts Express® + is a patient-activated recorder designed for diagnostic evaluation of transient symptoms; such as, dizziness, palpitations, syncope, and chest pain. The recorder provides single lead ECG morphology which may be used to visualize arrhythmias. The recorder may also provide automatic recording for detected bradycardia or tachycardia rhythms.

Although pacemaker spikes are sometimes visible on the ECG recordings, this recorder has no special provision for pacer spike detection or display.

Using looping memory, the King of Hearts Express® + recorder captures ECG data, both before and after the patient experiences a cardiac symptom and the recording is activated. The frequency response is .05 to 40 Hz and the memory capacity is 10 minutes. The patient wears the King of Hearts Express® + recorder day and night while it continuously scans ECG activity. Upon activation, a cardiac event is recorded and stored in solid-state memory.

With a sampling rate of 218 measurements per second, the recorder produces good amplitude and resolution with the very fast QRS complexes seen in some pediatric patients.

Used in conjunction with an Instromedix® telephonic ECG receiver, the King of Hearts Express® + recorder provides a practical and convenient method for collecting diagnostic ECGs over an extended period of time for patients with symptoms suggesting a cardiac arrhythmia.

The built-in LCD display enables you to easily control a variety of functions, so that the operation of the recorder is tailored to the needs of the patient and the clinician.
WARNING: Do not use the King of Hearts Express® + recorder in combination with an external cardiac defibrillator or high frequency surgical equipment. Disconnect the patient leads from the electrodes prior to performing external defibrillation or using electrosurgical equipment. There are no known safety hazards due to the use and operation of a cardiac pacemaker or other electrical cardiac stimulator with the King of Hearts Express® + recorder.
FEATURES

Easy to Use

The **King of Hearts Express**® + recorder is designed to be both comfortable and easy to use for cardiac patients needing long-term ambulatory monitoring. The recorder may be clipped to a belt, slipped into a shirt pocket, or worn around the neck like a pendant.

The small, portable **King of Hearts Express**® + recorder is worn with two electrodes. When the patient feels a symptom, a simple press of a button records and stores the ECG surrounding the event.

Following your defined protocol, the patient sends the stored data to a telephonic ECG receiver in your office or to a receiving service. The patient may bring the recorder directly to your office for ECG download, diagnosis and follow-up.

The **King of Hearts Express**® + recorder will also transmit ECG data using the high speed Accelerated Transmission Protocol™ (ATP). Facilities equipped with a LifeSigns™ Receiving Center 2000 (LRC 2000™), or a similar ATP compatible receiver, may activate ATP and receive data at three times the normal rate.

The **King of Hearts Express**® + recorder may be programmed to automatically record an ECG when the heart rate rises above a preset tachycardia value or falls below a preset bradycardia value. The physician may adjust these settings in the automatic-rate-trigger feature.
**Easy to Maintain**

A fresh set of AAA alkaline batteries typically powers the *King of Hearts Express® +* recorder for seven days. Additionally, the memory is protected by an internal lithium battery.

**Flexible Programming**

You may program the *King of Hearts Express® +* recorder to fit the patient’s condition and your own preferences, as follows:

- Define the time frame for which the ECG is captured and stored in memory by setting the **BEfore-event** and **AFter-event** storage times. This determines the total number of events that may be recorded before the 10 minutes of memory is full.

- Limit the maximum number of recorded events to fewer than the recorder’s capacity.

- Program the **SPeaker** to remain on or off during recording.

- Program the heart rate display **On** or **OFF**.

- Program the automatic rate trigger **On** or **OFF**.

- Set minimum heart rate for tachycardia detection when automatic rate trigger is on.

- Set maximum heart rate for bradycardia detection when automatic rate trigger is on.

- Set maximum number of events which may be recorded using the automatic rate trigger.

- Program the accelerated transmission function **On** or **OFF**.

- Program the recorder to transmit its recorder Identification number.
PHYSICAL FEATURES

On the Recorder

- Two control buttons:
  - Send
  - Record

- An internal speaker for telephonic data transmission.

- A lead set/programming jack.

- A clip for attaching the recorder to a belt or to undergarments.

- The status message display window. The status message may take the following forms:

  - Numerals representing heart rate, battery life, and/or number of events available to record.
  - An alphabetic feature identifier (such as, bE).

  Symbols describing current recorder status:

  - low battery
  - memory full
  - scanning/recording
  - transmitting
Separate Items

- A two electrode single channel lead set is included with the King of Hearts Express® + recorder. The lead set plugs into the lead set jack on the top end of the recorder.

- A programming key. When inserted into the programming jack on the top end of the recorder, this key enables access to the programming mode.

- A lanyard (cord), which may be used to wear the recorder around the neck. A belt clip, storage bag and spare batteries are also included.


OPERATION

The following describes the essential elements of patient hookup and the operation of the King of Hearts Express® + cardiac event recorder. If you have questions, please call Instromedix®.

**Note:** It is recommended that the King of Hearts Express® + recorder be demonstrated on each patient for proper operation and to verify the lead wire connections.

PATIENT HOOKUP

Electrodes

Good electrical contact between the electrodes, lead set and the skin is essential for a high quality ECG signal. The skin surface should be cleansed, abraded and wiped with alcohol according to standard Holter or stress-testing methods. Electrodes designed for long-term monitoring are recommended (similar to those used in a Holter procedure).

**Note:** Instromedix® recommends the use of low impedance Holter electrodes; such as, Lead-Lok® Pre-Gelled Electrodes. Typically, these will need to be changed every 3-4 days. If an electrode becomes loose, it should be replaced immediately with a new electrode.

**Note:** Use only the lead set supplied with the King of Hearts Express® + recorder.

Determine Electrode Placement

Any standard lead configuration may be used with the King of Hearts Express® + recorder. The diagram on the Page 8 shows an electrode placement that typically achieves good results; however, optimum electrode placement varies according to patient body shape, size and the desired view of ECG.

Prepare Placement Sites

- Clean the skin at the placement sites with alcohol. Abrade the skin slightly.
- Allow the skin to dry.
Apply Electrodes

- Remove an electrode from its sealed package and peel off the protective back cover.
- Discard any electrode having dry gel.
- Press the electrode firmly onto the prepared site. Replace any electrode which does not adhere securely.

Connect Lead Wires

- Snap the lead wires onto the electrodes.
- Make sure the electrode/lead wire connections are properly stabilized to prevent movement. Use a “service loop” below the electrode/lead wire snap to provide strain relief.
- Lead wire lengths may be adjusted by moistening the clear plastic slide and gently moving it, taking care not to stretch the lead wires.

Note: Instromedix recommends that an electrical confidence check be performed each time electrodes are connected. See Page 11.

Note: Conductive parts of the electrodes and associated connectors for this recorder, should not contact other conductive parts, including earth.

ELECTRODE PLACEMENT
ACTIVATE SCANNING MODE

After the electrodes are connected to the lead wires, insert the lead set plug into the jack on the top end of the King of Hearts Express® + recorder.

After a pause lasting up to 75 seconds you will hear a distinctive double beep, which signals that the King of Hearts Express® + recorder has completed a start-up check and is scanning the ECG activity. The recorder does not scan during the start-up check.
Status Message Display During Start-Up

During the start-up check the status window displays two numbers and/or letters.

- The number of events available to be recorded with the current programmed settings.
- The estimated number of days of battery life remaining.

**Note:** An F will appear in the status window rather than a number when the memory is full. After ten seconds the status window will go blank and scanning will terminate.

**Note:** An additional low battery indicator is provided during operation. If the battery is low, BAT will appear in the status window. Please refer to page 38 for a more complete description of the low battery indicators.

Status Window When Scanning Begins

Once start-up is complete and the King of Hearts Express® + recorder begins to scan the patient’s ECG activity, it will indicate scanning with a double beep. A new display will appear in the status window.

- This flashing symbol indicates that the King of Hearts Express® + recorder has started to scan the patient’s ECG activity.
- The number of events available to be recorded with current programmed settings.
- If the heart rate display has been programmed On, the current heart rate appears here.
ELECTRICAL CONFIDENCE CHECK

It is good practice to perform an electrical confidence check each time the King of Hearts Express® + recorder is connected to a patient or when a lead wire is reattached to an electrode.

- Place the recorder in scanning mode (lead set plugged into the recorder’s jack).
- Press and hold Send.
- Verify that the audible tone modulates with the patient’s heartbeat. If the ECG signal is not clear, perform the steps listed below in the order shown. Check the results after each step.
- Test each electrode by watching the heart rate display while tapping lightly on the electrode with your finger. Replace any electrode that causes a drastic change in heart rate when tapped.

If ECG Signal is Not Clear

1. Verify that the King of Hearts Express® + recorder is not operating near a source of electromagnetic interference; such as, fluorescent lights, computer monitors or household appliances. Verify the same for the telephonic ECG receiver, if applicable.
2. Reinsert the lead set plug into the jack.
3. Repress the electrodes to the skin. Be sure the snap attachments are secure. Electrodes which do not adhere securely must be replaced.
4. Replace electrodes (reprep the skin area, if necessary). Move the electrodes slightly to the right or left of the original sites.
5. Use a new lead set. Discard the old lead set.
6. Call Instromedix®.
If the heart rate display (rd) has been programmed On, the heart rate should appear within 20 seconds after start-up and remain on the display during scanning. This verifies that the King of Hearts Express® + recorder is functioning properly and that it is receiving the ECG data.

**RECORD AN ECG**

While the King of Hearts Express® + recorder is scanning the patient’s ECG, it is placing the data in an electronic memory loop, which holds up to 600 seconds of recorded ECG. New ECG activity replaces oldest ECG activity.

Your patient should use the following procedure as soon as symptoms occur:

- Press and release the Record button.
- Relax and remain still.

The King of Hearts Express® + recorder will capture the ongoing ECG as well as the previous ECG segment from the memory loop (the length of the before-event and after-event segments that have been programmed).

**Automatic Recording**

If automatic rate triggering has been programmed On, the recorder will record an ECG when the heart rate exceeds the preset tachycardia or bradycardia limit. Whether auto triggering is On or Off, the patient may record an ECG at any time by pressing the Record button.
Display and Tone

During ECG recording and storing, the Record symbol $\bigcirc\bigcirc$ stops flashing. If the speaker (SP) has been programmed On, the patient will hear a tone, pulsing rhythmically with the detected heartbeat. If the SPeker has been programmed OFF, the King of Hearts Express® + recorder will record silently.

If the heart rate display has been programmed On, the patient’s heart rate will appear in the status window.

At any given time, the number of events remaining can be observed in the status window while the recorder is scanning. When recording is completed, if there is sufficient memory to record another event, the King of Hearts Express® + recorder emits a double beep and automatically restarts normal scanning mode. The number of events will decrease by one. If the memory is full, an F will appear on the display.

Full Memory

When an F is displayed, indicating that the memory is full, the recorder will emit a series of five single beeps every three minutes. The beeps may be silenced by removing the lead set jack to stop scanning.

Note: If the length of before-event + after-event capture times exceeds the available memory, an F is displayed before any recordings have been made.

The memory is full.

The number of events that can be recorded before the memory is full.

heart rate
Number of Recorded Events

The King of King of Hearts Express® + can store up to 60 ECGs for transmission. The actual number depends on the programmed duration of the recorded segments.

TURN OFF SCANNING MODE

It is necessary to turn off scanning mode:

- before transmitting the stored ECGs over the telephone
- to silence the “memory full” or “low battery” indicators
- before bathing or showering
- before changing the batteries
- before programming
- when not in use

To turn off scanning mode, remove the lead set plug from the recorder jack. King of Hearts Express® + recorder will beep once, then turn off.
SEND RECORDED DATA

The patient may transmit the stored data after each recording or when the memory is full. Transmissions are sent either to a telephonic ECG receiver in your office or to a receiving service.

You determine the transmission speed by setting the accelerated transmission option On or OFF. Use the optional accelerated transmission only when sending to a compatible receiver. For all other receivers, use standard transmission.

**Note:** If you have a question regarding compatibility of your receiver, call Instromedix Technical Support at 1-800-237-4500.

All ECGs are sent in sequential order. See Appendix C for samples of ECG strips.

**Note:** The telephone used for data transmission must have a handset which will rest reasonably flat over the face of the recorder. Some telephones may not be suitable for use; such as, telephones that disconnect when placed on a flat surface.
To Send Recorded Data

- Unplug the lead set from the jack.
- Place the **King of Hearts Express® +** recorder face up on a flat surface near a telephone.
- Call the receiving service (the telephone number provided by the physician).
- When instructed by the technician, press and hold the **Send** button until the recorder emits a steady tone and 📡 appears in the status window.
- Release the **Send** button.
- **Quickly** place the mouthpiece of the telephone over the **Record** button.

The **King of Hearts Express® +** recorder then transmits all stored ECG data in the order in which it was recorded.

Total transmission time depends on the amount of data stored and the transmission speed. Using accelerated transmission, 600 seconds or 10 minutes of recorded ECG will take slightly over 3 minutes to transmit. Using standard transmission, 10 minutes of data will take approximately 10 minutes to transmit.

Audible Signals During Transmission

The patient should hear the following sequence of tones if accelerated transmission and **Id** transmission are both set to **On**.

- When the Send button is pressed and held, the **King of Hearts Express® +** recorder will emit a beep, then a steady tone. The 📡 symbol will appear in the status window.
- After approximately five seconds, the **King of Hearts Express® +** recorder will emit three clicks, indicating the start of ATP mode.
- The recorder will then emit three static-like bursts, which is the recorder **Id** being transmitted.
- When all the data has been sent, the recorder will emit a series of three clicks indicating that accelerated data transmission has been completed.
If accelerated transmission and \textbf{Id} transmission are both \textbf{OFF}.

- When the Send button is pressed and held, the \textbf{King of Hearts Express}® + recorder will emit a beep, then a steady tone. The \(\text{}\) symbol will appear in the status window.

- After approximately five seconds, the \textbf{King of Hearts Express}® + recorder will emit a single beep, followed by the ECG.

- When all the data has been sent, the recorder will emit a single beep, indicating that transmission is complete.

\begin{quote}
\textbf{Note:} If the recorder transmits using accelerated transmission (ATP) and you do not have an ATP compatible receiver, you will receive a time and amplitude distorted ECG, preceded by a noise burst. Retrieve the recorder and reprogram for standard transmission speed.
\end{quote}
Display During Transmission

When the tone stops and the status window is blank, the transmission is complete.

The telephone symbol indicates that transmission is in progress.

The number of recorded events remaining to be transmitted.

The recorded heart rate currently being transmitted will appear only if the heart rate display has been programmed On.

Transmission Can Be Interrupted

The transmission can be interrupted at any time by pressing and holding the **Send** button until the tone stops. When the **Send** button is pressed again, the transmission starts at the beginning.

Transmission Can Be Repeated

A transmission can be repeated as many times as necessary, **until the lead set is reinserted into the recorder**.

Transmission may need to be repeated because of a bad recording. Ask the patient to record and transmit another ECG. If this does not correct the problem, retrieve the recorder from the patient and call Instromedix.

**Note:** A 0.5mV, 300mSec square wave pattern at the beginning of a transmission indicates that the scanning memory was not full before the recording was started. This is not a problem condition. See Appendix C for samples of both types of square waves.
IN-OFFICE DOWNLOADING

Download patient data in your office by acoustical transfer. You or your staff will use a similar procedure to receive and process the data as a transtelephonic transmission; only the means of connection differs.

Unlike the patient, who transmits the audible signal into his or her telephone, you must manually direct the audible signal into your ECG receiver. In order to do this, you will need either an acoustic coupler attached to the receiver or a receiver that is equipped with a built-in acoustic coupler.

- Unplug the lead set from the jack.
- Place the King of Hearts Express® + recorder on its side facing the acoustic coupler, as shown below. Make sure the Send button faces up.
- Prepare the receiver to record the ECG data via the acoustic coupler. Refer to the instruction manual for your receiver.
- Press and hold the Send button on the King of Hearts Express® + recorder until it emits a steady tone and a symbol appears in the status window.
- Release the Send button.
- Leave the recorder in this position until the audible signal stops.
- Operate the appropriate controls on the receiver to complete and save the received transmission.

Stand the recorder on its side, facing the acoustic coupler.
ERASE MEMORY

The ECG data will be held in memory UNTIL all recordings have been transmitted and scanning has been restarted. When the lead set is reinserted into the jack, the memory is automatically erased.

The recorded ECGs are automatically erased ONLY under the following conditions:

1. All recordings have been completely transmitted.
2. The lead set plug is reinserted into the recorder to start scanning.

The memory will otherwise remain intact and any new recordings will be added to those already stored (if memory is available).
Programming options allow you to program the King of Hearts Express® + recorder to suit the patient’s condition and according to your own preferences. These options are summarized below. Default settings are circled.

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<th>AVAILABLE SETTINGS</th>
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<td>bE</td>
<td>Number of seconds of pre-event memory captured. (ECG bEfore Record is pressed)</td>
<td>5-600 seconds (five second increments)</td>
</tr>
<tr>
<td>AF</td>
<td>Number of seconds of post-event memory to be captured. (ongoing ECG AFter Record is pressed)</td>
<td>0-595 seconds (five second increments)</td>
</tr>
<tr>
<td>nE</td>
<td>Maximum number of events that can be stored.</td>
<td>Limited by 10 sec minimum bE + AF setting. 60 max.</td>
</tr>
<tr>
<td>SP</td>
<td>SPeaker emits an audible tone/heartbeat during recording. Option code is displayed in the status window.</td>
<td>SP On or OFF</td>
</tr>
<tr>
<td>rd</td>
<td>Heart rate will be displayed in the status window.</td>
<td>rd On or OFF</td>
</tr>
<tr>
<td>Ad</td>
<td>Turns automatic rate trigger On or OFF.</td>
<td>Ad On or OFF</td>
</tr>
<tr>
<td>dH</td>
<td>Set minimum heart rate for tachycardia detection when auto trigger is on.</td>
<td>Range = 120-250</td>
</tr>
<tr>
<td>dL</td>
<td>Set maximum heart rate for bradycardia detection when auto trigger is on.</td>
<td>Range = 30-65</td>
</tr>
<tr>
<td>nA</td>
<td>Number of events that may be recorded by the automatic rate trigger.</td>
<td>Range = 0 to value set for nE-1</td>
</tr>
<tr>
<td>AP</td>
<td>Turns accelerated transmission protocol On or OFF.</td>
<td>AP On or OFF</td>
</tr>
<tr>
<td>nH</td>
<td>First four digits of recorder Identification. (LRC™ 2000 required)</td>
<td>Display only; cannot be modified</td>
</tr>
<tr>
<td>nL</td>
<td>Last four digits of recorder Identification. (LRC™ 2000 required)</td>
<td>Display only; cannot be modified</td>
</tr>
<tr>
<td>Id</td>
<td>Recorder Identification number sent before each transmitted event.(LRC™ 2000 required)</td>
<td>Id On or OFF</td>
</tr>
</tbody>
</table>
Factory Programming

The King of Hearts Express® + recorder is factory programmed to capture 45 seconds of ECG before the Record button is pressed and 15 seconds after. This allows 10 single lead events to be recorded.

Factory defaults are shown on the previous page.

**CAUTION:** When a before- or after-event length is changed, the memory is erased and any stored data is lost.

**TO PROGRAM KING OF HEARTS EXPRESS® + RECORDER**

1. Fully insert the programming key into the smaller jack.

2. Press Send to scroll through the possible settings for the displayed program option.

3. Press Record to accept the displayed setting and automatically move to the next program option.
PROGRAM PROCEDURES

With the lead set plug removed from the jack:

To Enter Program Mode

Fully insert the programming key into the smaller of the two holes on the top end of the recorder. The recorder will display the \textit{bE} (bEfore-event) program option and the current value.

To Set Before-Event Interval

\begin{itemize}
  \item Press the \textbf{Send} button to scroll through the bEfore-event time settings until the desired value is displayed. (Repeatedly pressing the \textbf{Send} button advances the displayed time by five second increments. Press and hold the \textbf{Send} button to rapidly advance.)
  \item Press the \textbf{Record} button to accept the displayed time setting and to advance to the next program option.
\end{itemize}

To Set After-Event Interval

\begin{itemize}
  \item Press the \textbf{Send} button to scroll through the aFter-event time settings until the desired value is displayed. (Repeatedly pressing the \textbf{Send} button advances the displayed time by five second increments. Press and hold the \textbf{Send} button to rapidly advance.)
  \item Press the \textbf{Record} button to accept the displayed aFter-event setting and to advance to the next program option.
\end{itemize}
To Limit Maximum Number of Events
You may limit the maximum number of events that a patient may record by adjusting this setting.

- Press the Send button to set the number of events to be recorded.
- Press the Record button to accept the setting and to advance to the next program option.

To Turn Speaker On/OFF
- Press the Send button to toggle between On and Off.
- Press the Record button to accept the displayed setting and to advance to the next program option.

To Turn Heart Rate Display On/OFF
- Press the Send button to toggle between On and Off.
- Press the Record button to accept the displayed setting and to advance to the next program option.
To Set Minimum Heart Rate for Tachycardia Detection

- Press the **Send** button to scroll through the available settings. Set to highest available number to effectively disable Tachycardia detection only.
- Press the **Record** button to accept the displayed setting and to advance to the next program option.

**Note:** If the Automatic Rate Trigger is set to OFF the following three program settings become unavailable.

To Set Maximum Heart Rate for Bradycardia Detection

- Press the **Send** button to scroll through the available settings. Set to lowest available number to effectively disable Bradycardia detection only.
- Press the **Record** button to accept the displayed setting and to advance to the next program option.

To Turn Automatic Rate Trigger On/OFF

- Press the **Send** button to toggle between **On** and **OFF**.
- Press the **Record** button to accept the displayed setting and to advance to the next program option.
**To Set Maximum Number of Automatically Triggered Events**

- Press the **Send** button to scroll through the available settings.
- Press the **Record** button to accept the displayed setting and to advance to the next program option.

**To Turn Accelerated Transmission Protocol On/OFF**

The **King of Hearts Express**® + recorder offers the option of transmitting its ECG data in standard mode, which is suitable for a wide range of receivers, or accelerated mode. Use the optional accelerated transmission only when sending to a compatible receiver. For all other receivers, use standard transmission.

**Note:** If you have a question regarding compatibility of your receiver, call Instromedix Technical Support at 1-800-237-4500.

- Press the **Send** button to toggle between **On** and **OFF**.
- Press the **Record** button to advance to the next program option.
To Display Recorder Identification Number

The King of Hearts Express® + recorder displays a unique recorder Identification number which can be logged into the patient’s file. The recorder Identification number is displayed as two sets of four digits and is preset at the factory. The high digits and the low digits are displayed as shown:

The $n_H$ indicates that the four highest digits of the recorder Identification number are displayed in the status window.

The $n_L$ indicates that the four lowest digits of the recorder Identification number are displayed in the status window.

- Press the Record button to advance from the first half (or higher four digits) to the second half (or lower four digits) of the recorder Identification number.
- Press the Record button to advance to the next program option.

**Note:** The complete Identification number begins with a 76, which is not visible on the display above. When the Id number is printed on the ECG strip, the 76 indicates that the recorder is a King of Hearts Express® + recorder.
To Turn recorder Id Number Transmission On/OFF

The King of Hearts Express® + recorder offers the option of transmitting its identification (Id) number. When transmitting to a compatible receiver, the complete ten digit Id number will be edge-printed on the ECG strip.

- Press the Send button to toggle between On and Off.
- Press the Record button to advance to the first program option.

**Note:** If the recorder Identification number transmission is selected On and the ECG receiver is not recorder Id compatible, the strip will indicate a “noise burst” instead of the recorder Identification number.

To Leave Programming Mode

- Remove the programming key. The King of Hearts Express® + recorder automatically turns off. You may now activate scanning mode as described on Page 9.

**Note:** Removing the programming key accepts the displayed setting as well as any other modified program settings.

- Store the programming key in a safe place.
PATIENT INSTRUCTION

Successful operation of the King of Hearts Express® + recorder depends on thorough patient instruction. Instromedix® recommends that you walk through the following steps with each patient.

PREPARE RECORDER

- Prior to the patient’s visit, check battery life and, if necessary, install a fresh set of batteries (see Page 38).
- Verify that the desired bEfore- and AFter-event time settings are correct and that the desired SPeaker and heart rate display options are selected.

DISCUSS SYMPTOMS YOUR PATIENT MAY EXPERIENCE

Because the King of Hearts Express® + recorder is patient activated, you should discuss with the patient the possible symptoms that may be experienced. Discuss when to activate the recorder.

Typical symptoms include:

- syncope
- unexplained chest pain (angina)
- intermittent heart palpitations
- transient dizziness or light-headedness
- episodic nausea
- intermittent shortness of breath or breathlessness
POSITION ELECTRODES

Good electrical contact between the electrodes, lead set and the skin is essential for a high quality ECG signal. Electrodes designed for long-term monitoring are recommended (similar to those used in a Holter procedure).

Note: Instromedix® recommends the use of low impedance Holter electrodes; such as, Lead-Lok® Pre-Gelled Electrodes. Typically, these will need to be changed every 3-4 days. If an electrode becomes loose, it should be replaced immediately with a new electrode.

Determine Electrode Placement

Any standard lead configuration may be used with the King of Hearts Express® + recorder. The diagram below shows an electrode placement that typically achieves good results; however, optimum electrode placement varies according to patient body shape, size and the desired view of ECG.
Prepare Placement Sites

- Clean the skin at the placement sites with alcohol. Abrade the skin slightly.
- Allow the skin to dry.

Apply Electrodes

- Remove an electrode from its sealed package and peel off the protective back cover.
- Discard any electrode having dry gel.
- Press the electrode firmly onto the prepared site. Replace any electrode which does not adhere securely. Suggested placements are shown on the following page.

Connect Lead Wires

- Snap the lead wires onto the electrodes.
- Make sure the electrode/lead wire connections are properly stabilized to prevent movement. Use a “service loop” below the electrode/lead wire snap to provide strain relief.
- Lead wire lengths may be adjusted by moistening the clear plastic slide and gently moving the slide, taking care not to stretch the lead wires.

**Note:** Instruct the patient to use only the lead set that is supplied with the King of Hearts Express® + recorder.
Discuss Electrodes

Explain site preparation and the position for electrode placement.

- The skin surface should be cleansed with alcohol, allowed to dry, and abraded according to standard Holter or stress-testing methods.

- Explain that the adhesive electrodes may be worn in the shower or bath but they should not get soaked. The skin around the electrodes should be gently washed and the electrodes repressed to the skin after drying.

- Explain that any electrode which loosens during the monitoring period must be replaced.

- Explain that electrodes having dried gel should not be used.

- Explain reattachment of the lead wires to the electrodes. Show the patient how to connect the lead wires and secure the lead wires with service loops.

- Explain how to perform an electrical confidence check (see the next page) to verify good electrical contact.
PERFORM ELECTRICAL CONFIDENCE CHECK

It is good practice to perform an electrical confidence check each time the **King of Hearts Express**® + recorder is connected to a patient or when a lead wire is reattached to an electrode.

- Place the recorder in scanning mode (lead set plugged into the recorder’s jack).
- Press and hold *Send*.
- Verify that the audible tone modulates with the patient’s heartbeat. To troubleshoot a poor signal, perform the steps listed below in the order shown. Check the results after each step.
- Test each electrode by watching the heart rate display while tapping lightly on the electrode with your finger. Replace any electrode that causes a drastic change in heart rate when tapped.

**To Troubleshoot a Poor Signal**

1. Verify that the **King of Hearts Express**® + recorder is not operating near a source of electromagnetic interference; such as, fluorescent lights, computer monitors or household appliances.

2. Reinsert the lead set plug into the jack.

3. Repress the electrodes to the skin. Be sure the snap attachments are secure. Electrodes which do not adhere securely must be replaced.

4. Replace electrodes (reprep the skin area, if necessary). Move the electrodes slightly to the right or left of the original sites.

5. Use a new lead set. Discard the old lead set.

6. Call Instromedix®.
EXPLAIN BASIC OPERATION OF RECORDER

- Give the patient a copy of all King of Hearts Express® + recorder patient literature and review it together.

- Record an ECG to demonstrate proper operation. If the SPeaker is programmed On, demonstrate the sound of a good signal. A wildly fluctuating tone indicates interference. The patient should stop all movement in order to eliminate mechanical and body noise in the signal.

- Discuss the messages that appear in the status window and the beep patterns that may be heard when the batteries are low or when the memory is full. Explain the steps to be followed as a result.

- Give the patient the Patient Diary. Explain the format and request that the patient complete an entry after recording each ECG.

**Note:** The Patient Diary should contain 1) the phone number of your office or the receiving service to which the ECG data is to be transmitted and 2) your designated transmission schedule, if other than when the memory is full. Additional diaries and patient guides are available through Instromedix®.

- Show the patient how to contact your office or receiving service.

- Familiarize the patient with the routine questions that may be asked.

- Show the patient how to Send the data and restart scanning mode.

It is recommended that the patient repeat the steps of operation while you observe.
DISCUSS WEARING KING OF HEARTS EXPRESS® + RECORDER

- Explain that the King of Hearts Express® + recorder must be worn at all times to be useful. If the recorder is taken off and symptoms occur, the event will not be recorded.

- Discuss the patient’s daily schedule and activities. Review tasks; such as, bathing and dressing. Discuss proper wearing of the King of Hearts Express® + recorder. Answer questions that may arise.

EXPLAIN WHERE TO GO FOR HELP

- Be sure the patient has copies of all patient literature.

- Encourage the patient to call your office if there are any questions.
MAINTENANCE AND SERVICE

The King of Hearts Express® + recorder requires no regular maintenance (other than electrode and alkaline battery replacement) and has no user serviceable parts. Do not remove the cover or attempt to service any internal components.

Contact Instromedix® for service. If the user wishes to have the recorder serviced by a local service technician, Instromedix® will provide service documentation upon request.

SUPPLIES

The following supplies may be ordered through Instromedix®.

<table>
<thead>
<tr>
<th>PRODUCT DESCRIPTION</th>
<th>PART NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead-Lok® Pre Gelled Electrodes (case of 50)</td>
<td>010-0027-00</td>
</tr>
<tr>
<td>Two Electrode Lead Set</td>
<td>420-0073-00</td>
</tr>
<tr>
<td>Belt Clip</td>
<td>665-0226-01</td>
</tr>
<tr>
<td>38” Neck Lanyard (cord)</td>
<td>010-0067-00</td>
</tr>
<tr>
<td>Programming Key</td>
<td>406-0029-00</td>
</tr>
<tr>
<td>1.5V AAA Battery</td>
<td>410-0010-00</td>
</tr>
<tr>
<td>King of Hearts® Patient Diary</td>
<td>061-0114-03</td>
</tr>
<tr>
<td>King of Hearts Express® + “. . . I’m Glad You Asked That!” Patient Guide</td>
<td>061-0505-00</td>
</tr>
<tr>
<td>King of Hearts Express® + Quick Reference Card</td>
<td>061-0506-00</td>
</tr>
<tr>
<td>King of Hearts Express® + Physician’s Operation Manual</td>
<td>061-0507-00</td>
</tr>
</tbody>
</table>
BATTERIES

The King of Hearts Express® + recorder automatically checks its own batteries. A fresh set of AAA alkaline batteries typically powers the recorder for seven days. The batteries must be replaced when any of the following occurs:

- The low battery symbol \[\text{BAT}\] appears in the display (see below). This symbol will flash on and off during operation. (low battery)
- Low battery indications appear in the ECG chart strip. See Appendix C. (low battery)
- The low battery symbol remains on constantly and the recorder emits a series of five double beeps every three minutes. (dead battery)
- The batteries have discharged to the point that scanning stops or the recorder ceases to function entirely. (dead battery)
- The indicated number of days of battery life is less than the number of days of patient assignment. Estimated battery life displays briefly when the lead set is first inserted.

**Note:** The displayed days of battery life remaining is only an estimate based on use of fresh Eveready® alkaline batteries. Use of non-standard or old batteries may result in an erroneous value. The King of Hearts Express® + recorder will operate within specifications in a “low battery” condition. It will stop recording when batteries are too low to enable operation within specifications, a “dead battery” condition.
To Replace Batteries

- Remove the lead set plug from the jack. Remove the belt clip, if being used. Place the recorder face down on a flat surface.
- Slide the battery compartment door off the back of the recorder.

- Carefully remove the old batteries from the compartment. A blunt, flat object (such as, a coin) may be used to dislodge the batteries.
- Insert two new AAA alkaline batteries. Position the batteries as shown on the floor of the battery compartment.
- Replace the compartment door by sliding it into place. Be sure the door snaps shut.

**CAUTION:** Use only good quality AAA alkaline batteries; such as, Eveready® E92 (recommended). DO NOT replace just one of the batteries.
Note: The King of Hearts Express® + recorder memory is protected by an internal lithium battery, so that any stored data is retained when the main batteries die or are removed for replacement. This lithium battery, which typically lasts 1.3 to 10 years (depending on whether alkaline batteries are kept in the recorder), must be replaced by Instromedix. To extend the life of this battery, keep AAA batteries in the recorder at all times.

Note: If the King of Hearts Express® + recorder is to be stored for a long period (greater than a year), put in fresh AAA batteries before storing and replace the batteries annually.

HANDLING PRECAUTIONS

The King of Hearts Express® + recorder is a valuable medical instrument and must be treated with care.

- Do not drop the King of Hearts Express® + recorder.
- Do not dangle the King of Hearts Express® + recorder by the lead set wires.
- Do not expose the King of Hearts Express® + recorder to excessive dust or to extreme temperatures. In cold weather, wear the recorder under protective clothing.
- Do not immerse the King of Hearts Express® + recorder in any liquid. The case may be wiped clean with a soft cloth dampened with an antibacterial soap and water.

Note: If the King of Hearts Express® + recorder carries an Ingress Protection (IP) rating of 20, which means that the design precludes hazardous access by fingers but is not water tight.
## APPENDIX A

### SPECIFICATIONS*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Minimum</th>
<th>Typical</th>
<th>Maximum</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>3.38</td>
<td></td>
<td></td>
<td>inches</td>
</tr>
<tr>
<td>Width</td>
<td>2.13</td>
<td></td>
<td></td>
<td>inches</td>
</tr>
<tr>
<td>Thickness</td>
<td>0.7</td>
<td></td>
<td></td>
<td>inches</td>
</tr>
<tr>
<td>Weight (with batteries)</td>
<td>100</td>
<td></td>
<td></td>
<td>gm</td>
</tr>
<tr>
<td><strong>Environmental</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>10</td>
<td>50</td>
<td></td>
<td>°C</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>-10</td>
<td>60</td>
<td></td>
<td>°C</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>10</td>
<td>95</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td><strong>Electrical</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Input Impedance (with supplied leads)</td>
<td>3</td>
<td></td>
<td></td>
<td>Mohm</td>
</tr>
<tr>
<td>CMR Ratio (at 60Hz)</td>
<td>60</td>
<td></td>
<td></td>
<td>dB</td>
</tr>
<tr>
<td>Common Mode Range (AC + DC)</td>
<td>±0.5</td>
<td></td>
<td></td>
<td>V</td>
</tr>
<tr>
<td>Differential Range (ECG input range @ 5Hz)</td>
<td>±2</td>
<td></td>
<td>±250</td>
<td>mV</td>
</tr>
<tr>
<td>Baseline Reset Time</td>
<td>1</td>
<td></td>
<td></td>
<td>sec</td>
</tr>
<tr>
<td>Bandwidth (+1db –3db ref to 5Hz)</td>
<td>0.05</td>
<td>40</td>
<td></td>
<td>Hz</td>
</tr>
<tr>
<td>Resolution (calculated)</td>
<td>15.6</td>
<td></td>
<td></td>
<td>µV</td>
</tr>
<tr>
<td>Elapsed Timer Resolution</td>
<td>1</td>
<td></td>
<td></td>
<td>sec</td>
</tr>
<tr>
<td>Elapsed Timer Accuracy</td>
<td>300</td>
<td></td>
<td></td>
<td>sec/mo</td>
</tr>
<tr>
<td>Heart Rate Range</td>
<td>28</td>
<td>255</td>
<td></td>
<td>BPM</td>
</tr>
<tr>
<td>Heart Rate Accuracy</td>
<td>±1</td>
<td></td>
<td></td>
<td>BPM</td>
</tr>
</tbody>
</table>

### Telemetry Specifications

Transmission Test Condition: FM modulated, ECG, FSK data, Standard and ATP mode

<table>
<thead>
<tr>
<th>Center Frequency</th>
<th>1850</th>
<th>1900</th>
<th>1950</th>
<th>Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deviation (modulated with 1 mV p-p 5Hz)</td>
<td>90</td>
<td>100</td>
<td>110</td>
<td>Hz/mV</td>
</tr>
<tr>
<td>FSK0</td>
<td>1850</td>
<td>1900</td>
<td>1950</td>
<td>Hz</td>
</tr>
<tr>
<td>FSK1</td>
<td>2400</td>
<td>2450</td>
<td>2590</td>
<td>Hz</td>
</tr>
</tbody>
</table>
### Battery Specifications

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Minimum</th>
<th>Typical</th>
<th>Maximum</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alkaline Battery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 AAA Eveready® E92, or equivalent)</td>
<td>3.0</td>
<td>7</td>
<td>V</td>
<td>days</td>
</tr>
<tr>
<td>Life</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Fresh batteries, loop recording, transmit once a day)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lithium Battery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(not user replaceable)</td>
<td>3.6</td>
<td>10</td>
<td>V</td>
<td>years</td>
</tr>
<tr>
<td>Life (with alkaline batteries in)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life (with alkaline batteries out)</td>
<td>1.3</td>
<td>1.5</td>
<td>10</td>
<td>years</td>
</tr>
</tbody>
</table>

### Memory Specifications

<table>
<thead>
<tr>
<th>Characteristic</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Memory Hold Time</td>
<td></td>
<td></td>
<td></td>
<td>days</td>
</tr>
<tr>
<td>Elapsed Time (since first recording)</td>
<td></td>
<td></td>
<td></td>
<td>days</td>
</tr>
<tr>
<td>Recording Period (sampling rate of 218Hz)</td>
<td>128</td>
<td>31</td>
<td>600</td>
<td>sec</td>
</tr>
</tbody>
</table>

### Auto Trigger

<table>
<thead>
<tr>
<th>Characteristic</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bradycardia trigger range</td>
<td>30</td>
<td>65</td>
</tr>
<tr>
<td>Tachycardia trigger range</td>
<td>120</td>
<td>250</td>
</tr>
</tbody>
</table>

### Telephone System Minimum Performance Parameters

- 30dB signal to noise ratio
- -15dBm signal power (within a frequency range of 1,000 to 3,000 Hz)

### QRS Detection

<table>
<thead>
<tr>
<th>Characteristic</th>
<th></th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHA, MIT &amp; NST databases combined results.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive Predictivity</td>
<td>97.3</td>
<td>%</td>
</tr>
<tr>
<td>QRS Sensitivity</td>
<td>91.4</td>
<td>%</td>
</tr>
</tbody>
</table>

**Note:** No “Low battery” or no “Dead battery” indication and no recorder operation are indications of a fully depleted battery or a missing battery.

**Recorder Classification**

Type 3 per the AAMI EC38-94 standard.

* Specification change privileges reserved.
APPENDIX B

SYMBOLS

Type BF (European Designation)

Refer to accompanying documentation
APPENDIX C

TRANSMITTED DATA

ECG recordings transmitted from the King of Hearts Express® + cardiac event recorder contain distinctive waveforms, which serve a variety of purposes. Some of these waveforms act as markers to help you interpret the resulting ECG strips, while other waveforms identify certain operating states of the recorder and do not directly influence a successfully recorded and transmitted ECG. Recordings may also contain abnormal waveforms due to physical movement or electrical noise. Please review the chart strips on the following pages.

**Note:** If the recorder transmits using accelerated transmission (ATP) and you do not have an ATP compatible receiver, you will receive a time and amplitude distorted ECG, preceded by a noise burst. Retrieve the recorder and reprogram for standard transmission speed.
Transmitting to a Standard LRC™

INITIAL CALIBRATION PULSE: A 1.0mV, 200mSec pulse marks the beginning of each transmitted ECG.

DIGITAL DATA TRANSMISSION: When transmitting to a standard LRC™, if the recorder Id transmission is set On, the digital data will appear as a noise burst and will not print on the strip in alphanumeric characters.

ELAPSED TIME: This mark indicates the length of time between recording and transmission.

RECORD BUTTON PRESSED INDICATOR: A 5mV, 100mSec spike marks the point that the patient initiated the event recording. It separates bEfore-event waveforms (history) from AFter-event waveforms.

DO NOT USE ACCELERATED TRANSMISSION WHEN SENDING TO A NON-ATP-MODE RECEIVING CENTER.
Transmitting to a Standard LRC™

HEART RATE: The heart rate is averaged and printed every seven seconds. Standard transmission mode is required for proper heart rate.

FINAL CALIBRATION PULSE and END OF RECORDING INDICATOR: These marks show that all ECG data stored in the recorder memory has been transmitted.
Transmitting to an LRC™ 2000

Indicates data sent from Instromedix®
cardiac event recorder using ATP mode.

Initial calibration pulse.

Accelerated transmission (ATP) indicator pulses.

Gain and chart speed settings.

Event recorder Id number.

Start of recording indicator,

Date and time recording was taken.

Event recorder Id transmission.

Time printed.
Transmitting to an LRC™ 2000

INITIAL CALIBRATION PULSE, RECORD BUTTON PRESSED, HEART RATE and FINAL CALIBRATION PULSE: Same as on previous pages.

ATP INDICATOR PULSES: These spikes show that the recorder is transmitting in Accelerated Transmission Protocol at three times the normal speed.

EVENT RECORDER Id TRANSMISSION: If Id transmission is set ON, the alphanumeric recorder identification number is sent in a data stream and printed as a specific 10 digit number.

Note: If the recorder transmits using accelerated transmission (ATP) and you do not have an ATP compatible receiver, you will receive a time and amplitude distorted ECG, preceded by a noise burst. Retrieve the recorder and reprogram for standard transmission speed.
Motion Artifact

Motion artifact results when there is a poor connection between the patient’s skin and the King of Hearts Express® + recorder, and the electrode is stressed by physical movement during recording. See “If ECG Signal is Not Clear”, on page 11, which describes how to remedy a faulty connection. Additionally, the patient should be advised to remain still and quiet during the recording cycle.
Electrical Noise

Electrical Noise refers to additional electrical signals that distort the ECG. The intruding signals may be generated, for example, by machinery operated in the vicinity of the King of Hearts Express® + recorder during transmission, by the telephone, or even by fluorescent lighting at the receiving location. The LifeSigns™ Receiving Center and the LRC™ 2000 receivers are each equipped with two filters: LINE (for 50-60Hz power line noise) and 40Hz (for nonspecific noise and artifact). Use of these will minimize the effect of “noise”.

Square Wave A

If the Record button is pressed before the before-event memory is filled, the unused part of the before-event memory is indicated with a 0.5mV, 300mSec square wave. This will occur whenever the time period between events is shorter than the programmed before-event time setting.

ECG recordings can not overlap, so if Record is pressed again soon after a recording is made, the second ECG will begin with square waves representing any time period captured in the previous ECG recording.
Low Battery Indications

Transmitting to Standard LRC™

Spikes indicate a low battery condition. Two spikes indicate a low main battery. Four spikes indicate a low backup battery. Six spikes indicate low main and backup batteries.

Transmitting to LRC™ 2000

Narrow square waves indicate a low battery condition. Two square waves indicate a low main battery. Four square waves indicate a low backup battery. Six square waves indicate low main and backup batteries.

The LRC™ 2000 prints whether the low battery condition applies to the main, the backup or to both main and backup batteries.
APPENDIX D

Per definitions published in the AAMI standard EC38-94, the King of Hearts Express® + recorder does not perform analysis.

AUTO TRIGGERING

The heart rate detector in the King of Hearts Express® + recorder averages three valid and consecutive QRS intervals to calculate a heart rate reading. Three of these heart rate readings (each calculated from 3 QRS intervals) are processed to detect Bradycardia and Tachycardia and to trigger the recorder to record an event; therefore, for detection, the Tachycardia or the Bradycardia event must be sustained for at least three heart rate readings or 10 heart beats. Events shorter than 10 heart beats will be ignored and will not trigger the recorder.

The Tachycardia/Bradycardia algorithm detects an event and initiates an automatic recording if either one of the following conditions are satisfied:

1. If three heart rate readings in a row exceed the programmed limits of Tachycardia or Bradycardia. These limits are programmed using the programming key and are set to default values of 200bpm and 30bpm for Tachycardia and Bradycardia, respectively. The range for Tachycardia trigger is 120-250 at 10bpm intervals. The range for Bradycardia trigger is 30-65 at 5bpm intervals.

2. If the three most recent heart rate readings are outside the 66 to 100 bpm range and exceed the previous normal readings by 37%.

The heart rate detector algorithm was tested on the AHA, MIT, and NST ECG databases. The AHA and MIT databases are real ECGs. The NST database has added artificial noise. The results show that the King of Hearts Express® + recorder performs better when noise levels are low; therefore, to avoid triggering on noise, good skin preparation techniques and high quality electrodes must be used.
After an event is detected and automatically recorded, the algorithm waits for the triggering condition to be removed (heart rate to return to normal) before it will start looking for more events.

The recorder calculates heart rate by measuring the interval between four consecutive heart beats. Occasionally, due to noise or weak signal strength, the recorder will register a “false positive” or a “false negative” heart beat. When this happens, the calculated heart rate will likely be 33% higher or lower than the true heart rate.
APPENDIX E

LIMITED WARRANTY

This Instromedix® (“Instromedix”) product is warrantied against defective material and workmanship (excluding batteries and connecting cables) for two years following delivery of this product to the original purchaser.

If this product or any part thereof, in the judgement of Instromedix, is proven to be defective in material or workmanship within two years from date of original purchase, such defects will be repaired or replaced (at Instromedix’s option) free of charge for parts or labor.

This warranty does not apply to any product which has been damaged by accident or which has been misused, abused, altered or repaired by anyone other than Instromedix or its representatives.

Instromedix shall not be liable to any person for any direct or consequential damages resulting from or caused by any defect, failure or malfunction of this product.

This warranty is in lieu of all other warranties expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose, and no person is authorized to assume for Instromedix any other liability in connection with the sale of this product.

To obtain factory service, this product should be shipped prepaid to Instromedix at the address shown below. In–warranty product will be returned postage prepaid.

In the USA contact:
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A Card Guard Company
6779 Mesa Ridge Road, Suite 200
San Diego, California 92121-2909