Harmony 5000 Pivotal Trial Instructions For Use

CAUTION- Investigational Device. Limited by Federal law for investigational use only.

1.0 DEFINITIONS

1.1 EPISODE Study - Clinical study that is testing the use of the Harmony headset

1.2 Study Kit – box that houses the Harmony 5000 headset and accessories.

1.3 Jotform Survey – online survey required on every study enrollment to document the subject's run information.

2.0 STUDY ENROLLMENT CRITERIA

2.1 Inclusion Criteria (all must be met for inclusion)

2.1.1 The patient is being evaluated by a prehospital provider (i.e., Emergency Medical Technician or Paramedic) in an out-of-hospital setting.

2.1.2 The prehospital provider suspects that the patient is experiencing an acute stroke, based upon the provider's prior training and clinical experience.

2.1.3 The patient is aged 18 years or older.

2.1.4 The patient does not verbally decline to have the headset placed.

2.2 Exclusion Criteria (any single positive response will disqualify)

2.2.1 Has a scalp laceration or other evidence of head trauma.

2.2.2 Prehospital provider feels that placement of the headset might interfere with the patient's prehospital care.

2.2.3 Patient refuses to participate in the study.

2.2.4 Patient is a prisoner, mentally ill, or member of another vulnerable population as defined by the local IRB

3.0 Instructions for use

3.1 Initial Setup

3.1.1 Begin by breaking the seal on the side of the cardboard box, the study kit. Retrieve the Harmony 5000 device

3.1.2 Uncoil the ECG cable attached to the bottom of the dongle, removing the purple tape securing it in the process.

3.1.3 Power on the device (using the central power button)

3.1.4 After device initiation, a screen displaying the MindRhythm logo will appear, and immediately proceed to a screen confirming the enrollment criteria.

3.1.5 If Criteria are met, select the Right arrow on the dongle to proceed.

3.1.6 Next, you will be presented with the clinical assessment questions.

3.1.6.1 Face Weak?
3.1.6.2 Arm Weak?
3.1.6.3 Grip Weak?

3.1.7 Using clinical judgement, answer the clinical assessment questions and proceed as indicated on screen. Use the right and left buttons to scroll through the options and the center button to select your preferred answer.

3.1.8 After answering the clinical assessment questions, a summary screen will appear, verify that answers are correct, and proceed as indicated (or go back to re-enter information if incorrect)

3.1.9 Device will proceed to ECG setup.

3.2 Patient Setup

3.2.1 Place ECG pads on patients:
- 3.2.1.1 Left Clavicle
- 3.2.1.2 Right Clavicle
- 3.2.1.3 Abdomen

3.2.2 Connect ECG leads to pad button connectors as indicated:
- 3.2.2.1 WHITE = Right Clavicle
- 3.2.2.2 BLACK = Left Clavicle
- 3.2.2.3 RED = Abdomen

3.2.3 Adjust the ECG cable or connections as needed, the device will indicate when a good connection is made. Cleaning the skin with an alcohol wipe will improve connectivity.

3.2.4 When a good connection is made, proceed by pressing the right arrow on the dongle.

3.2.5 Following on screen prompts, place headset on the patient. Cable from dongle to headset should be on patient's right hand side.

3.2.6 After the headset is placed, proceed using right arrow, this will initiate the recording.

NOTE:

The Device will continuously monitor the quality of the ECG connection and motion during the recording.Screens may appear during the recording indicating an ECG or movement failure. If these occur, please follow on screen prompts and resolve to continue recording.

3.3 In-recording operation and conclusion

3.3.1 Study will proceed for a minimum of 90 seconds, up to 180 seconds, dependent on data quality.

3.3.2 Once the recording has started and following a successful recording a 4 letter code will appear, note this code as it is required for the JotForm survey. This is called and “ID code.”

3.3.3 If a recording is not successful, the screen will display “INVALID". Use clinical judgement to either choose to attempt another recording, or proceed without a recording as per normal protocol.

3.3.4 Upon recording completion, proceed to scan QR code on device, which will link to the JotForm Survey, complete survey fully, including the 4 letter ID code. If recording was not successful, note in comment field.

3.3.5 When complete, place device into study kit box, and return completed kit to MindRhythm labeled boxes at each receiving hospital (refer to site specific materials for exact locations per region).