Quantitative Analysis for Pivotal Study: AutoEF

# Purpose

The purpose of this document is to provide Bay Labs’ request for data tables and to solicit input from Hogan Lovells. The expected activities to follow include:

* Review of proposed data tables by Doug and Hogan Lovells
* Doug creates mock tables for review based on this request
* Bay Labs provides final data format for Doug to begin programming

# Output Data Table for REDCap (In Progress - Not Final Format)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Subject ID** | **Clip\_Selector\_Pass\_N**  **(Y/N)** | **Clip\_Selector\_Pass\_S**  **(Y/N)** | **AEF\_N(%)** | **AEF\_S (%)** | **IQS\_AP2\_N (1-5)** | **IQS\_AP4\_N (1-5)** | **IQS\_AP2\_S (1-5)** | **IQS\_AP4\_S (1-5)** | **RPM\_N** | **RPM\_S** |
| 1001 | TRUE | FALSE | 64.60712433 |  | 2.987132788 | 4.378159523 |  |  | -0.05192572251 |  |
| 1002 | TRUE | TRUE | 55.83360672 | 63.00717545 | 3.580712795 | 3.731759548 | 2.996183395 | 3.637342215 | 0.03958718106 | -0.06465864182 |
| 1003 | FALSE | TRUE |  | 55.71757126 |  |  | 4.038502216 | 3.448086262 |  | 0.05562833697 |

*\*Note: This is meant to illustrate the data that will be presented. Final variable names and order will be provided separately. Do not use as a basis for programming.*

# Description of Variables

|  |  |  |
| --- | --- | --- |
| **Variable** | **Definition** | **Data Processing Required** |
| Clip\_Selector\_Pass\_N  Clip\_Selector\_Pass\_S | The “Clip Selector” component of AutoEF assesses the suitability of the AP2 and AP4 clips for EF calculation. If both the AP2 and AP4 clips are deemed acceptable by the Clip Selector, the system moves onto the second stage and computes an ejection fraction for each individual view.  “TRUE” means that the Clip Selector has deemed the clips suitable for EF measurement. “FALSE” means the clips have been rejected and no EF measurement will be returned. | N/A |
| AEF\_N  AEF\_S | These variables represent the nurse and sonographer AutoEF measurement for a particular patient. | EF is returned by the algorithm in its raw format as a long decimal number (e.g., “55.83360672”). However, it is presented to the user in AutoEF as an integer (e.g., “56”). Thus the data should be rounded to the nearest integer. |
| IQS\_AP2\_N  IQS\_AP4\_N  IQS\_AP2\_S  IQS\_AP4\_S | Image Quality Scoring System (IQS) is an algorithm that estimates the ACEP score for clips. To develop IQS, Bay Labs trained the algorithm separately per view (i.e., AP2 and AP4) on ACEP IQS from in-house data (i.e., data gathered internally at Bay Labs with help from expert sonographers for the purpose of EchoGPS data collection) labeled with ACEP scores. | “IQS\_AP#\_#” is reported as a long decimal (e.g., “3.637342215”). However, in AutoEF it is displayed to the user via a three-bar icon that has three outputs (shown in table below).   |  |  | | --- | --- | | **IQS Value** | **IQS Category** | | 1 < IQS ≤ 2.5 | Poor | | 2 < IQS ≤ 3.5 | Satisfactory | | 2.5 < IQS ≤ 5 | Good | |
| RPM\_N  RPM\_S | In addition to the qualitative Image Quality Score, a further guide to assist in interpreting AutoEF results is a quantitative index, the Relative Performance Metric (RPM).  Analysis of AutoEF results has demonstrated that there is a range of performance that is correlated with the image quality of the clips used to calculate EF as measured by the Image Quality Score (IQS). As described in the original 510(k), the pivotal validation study demonstrated an average RMSD of 8.290% as compared to physician readers. Studies with better image quality clips have better agreement (RMSD values) with physician readers than the pivotal study average of 8.290%. Studies with lower image quality clips will have RMSD values that are not as good as the pivotal study average of 8.290%.  The Relative Performance Metric is a measure of the percentage difference of a particular study’s predicted RMSD compared to the average Auto EF RMSD in the pivotal study.    There are three possible RPM outputs:   * “Based on the image quality, AutoEF has [X]% better than average performance” * “Based on the image quality, AutoEF is equal to average performance” * “Based on the image quality, AutoEF has [X]% lower than average performance” * These are displayed on the EF results screen. “Equal to average performance” is defined as plus or minus 5% of the average performance. | N/A. Not requested for any data tables. Included for completeness. |

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