Bay Labs, Inc. Protocol 1.0



Study for Point-of-Care Echocardiography with Assistance Technology

Table and Figure Mockups

Complete Set

Version 3.0

Date: 02Apr2019

[Table 1 Patient Enrollment and Accountability by Site 5](#_Toc5112530)

[Table 2 Patient Enrollment and Accountability by Nurse 7](#_Toc5112531)

[Table 3 Nurse User Training and Qualification for User Readiness by Site 9](#_Toc5112532)

[Table 4 Demographics of Enrolled Patients 10](#_Toc5112533)

[Table 5 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by BMI category 11](#_Toc5112534)

[Table 6 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Presence of Known Cardiac Abnormality 12](#_Toc5112535)

[Table 7 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Study Site 13](#_Toc5112536)

[Table 8 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Sex of Patient 14](#_Toc5112537)

[Table 9 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Age of Patient 15](#_Toc5112538)

[Table 10 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Number of Scans Completed by this Nurse prior to the Current Scan. 16](#_Toc5112539)

[Table 11 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Acquiring Nurse 17](#_Toc5112540)

[Table 12 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by BMI category 18](#_Toc5112541)

[Table 13 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by Presence of Known Cardiac Abnormalities 19](#_Toc5112542)

[Table 14 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by Study Site 20](#_Toc5112543)

[Table 15 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by Acquiring Nurse 21](#_Toc5112544)

[Table 16 Inter-User Variability of Nurse Performance Using EchoGPS to Acquire Scans of Acceptable Quality- Primary Clinical Parameters 22](#_Toc5112545)

[Table 17 Acquisition Time- Summary of Time to Acquire 10-view Echocardiogram by Nurse, Total and by View\* 23](#_Toc5112546)

[Table 18 Inter-User Variability of Acquisition Time among Nurses, Total and by View \* 25](#_Toc5112547)

[Table 19 Percent of Views that were Autocaptured by BMI category 26](#_Toc5112548)

[Table 20 Percent of Views that were Autocaptured by Presence of Known Cardiac Abnormalities 28](#_Toc5112549)

[Table 21 Percent of Views that were Autocaptured by Age of Patient 30](#_Toc5112550)

[Table 22 Percent of Views that were Autocaptured by Sex of Patient 32](#_Toc5112551)

[Table 23 Inter-User Variability of Percent of Scans Autocaptured among Nurses, Total and by View 35](#_Toc5112552)

[Table 24 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and BMI category 35](#_Toc5112553)

[Table 25 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Presence of Known Cardiac Abnormalities 37](#_Toc5112554)

[Table 26 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Study Site 40](#_Toc5112555)

[Table 27 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Sex of Patient 42](#_Toc5112556)

[Table 28 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Age of Patient 44](#_Toc5112557)

[Table 29 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Number of Scans Completed by this Nurse prior to the Current Scan 46](#_Toc5112558)

[Table 30 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Acquiring Nurse 48](#_Toc5112559)

[Table 31 Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by BMI category 50](#_Toc5112560)

[Table 32 Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by Presence of Known Cardiac Abnormalities 52](#_Toc5112561)

[Table 33 Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and BMI category 54](#_Toc5112562)

[Table 34 Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and Presence of Known Cardiac Abnormalities 56](#_Toc5112563)

[Table 35 Cross-Classification of Cardiologists’ Rating of Image Quality for Clinical Assessment of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by Clinical Parameter 58](#_Toc5112564)

[Table 36 Cross-Classification of Cardiologists’ Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View 61](#_Toc5112565)

[Table 37 Cross-Classification of Cardiologists’ Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Autocaptured Scans Only 64](#_Toc5112566)

[Table 38 Cross-Classification of Cardiologists’ Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Save-Best Scans Only 69](#_Toc5112567)

[Table 39 Cross-Classification of Cardiologists’ ACEP Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View 73](#_Toc5112568)

[Table 40 Cross-Classification of Cardiologists’ ACEP Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Autocaptured Scans Only 76](#_Toc5112569)

[Table 41 Cross-Classification of Cardiologists’ ACEP Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Save-Best Scans Only 78](#_Toc5112570)

[Table 42 Cross-Classification of Cardiologists’ Clinical Assessment Using Nurse-Acquired vs. Sonographer-Acquired Echocardiograms- Primary Endpoints among Patients for whom a Qualitative Assessment could be Made 81](#_Toc5112571)

[Table 43 Cross-Classification of Cardiologists’ Clinical Assessment Using Nurse-Acquired vs. Sonographer-Acquired Echocardiograms- Secondary Endpoints among Patients for whom a Qualitative Assessment could be Made 83](#_Toc5112572)

[Table 51 Panel Variability: Extent of Agreement among Cardiologists in Rating Acceptability of Echocardiography for Clinical Parameter Assessment- Primary Endpoints by Image Acquirer 86](#_Toc5112573)

[Table 52 Panel Variability: Extent of Agreement among Cardiologists in Rating Diagnostic Quality(ACEP 1-5) of Echocardiography by 2D View and Image Acquirer 87](#_Toc5112574)

Table Patient Enrollment and Accountability by Site

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Study Phase |  |  | Study Site | | All |
|  |  |  | Northwestern | Minneapolis |  |
|  | Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |  |
| Nurse Exam | Patients Undergoing Nurse-acquired EchoGPS echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patients Completing Nurse-acquired EchoGPS echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patients withdrawing early from Nurse-acquired EchoGPS echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | Withdrawal reason, n (%) |  |  |  |  |
|  |  | Patient withdrew consent | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Adverse Event | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Equipment Issue | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
| Sonographer Exam | Patients Undergoing Sonographer-acquired echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patients Completing Sonographer-acquired echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patients withdrawing early from Sonographer-acquired echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | Withdrawal reason, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Patient withdrew consent | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Adverse Event | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Equipment Issue | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
| Study Completion | Patients Completing both Nurse exam and Sonographer exam, n(%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Table Patient Enrollment and Accountability by Nurse

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Acquiring Nurse (last name) | | | | | | | |  |
| Study Phase |  |  | Alpha | Bravo | Charlie | Delta | Echo | Foxtrot | Golf | Hotel | All |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | Patients Enrolled, N |  |  |  |  |  |  |  |  |  | XX |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Nurse Exam | Patients Undergoing Nurse-acquired EchoGPS echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  | Patients Completing Nurse-acquired EchoGPS echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  | Patients withdrawing early from Nurse-acquired EchoGPS echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | Withdrawal reason, n (%) |  |  |  |  |  |  |  |  |  |  |
|  |  | Patient withdrew consent |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Adverse Event |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Equipment Issue |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Other |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Sonographer Exam | Patients Undergoing Sonographer-acquired echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  | Patients Completing Sonographer-acquired echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  | Patients withdrawing early from Sonographer-acquired echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | Withdrawal reason, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Patient withdrew consent |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Adverse Event |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Equipment Issue |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Other |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Study Completion | Patients Completing both Nurse exam and Sonographer exam, n(%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

Table Nurse User Training and Qualification for User Readiness by Site

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Nurses undergoing didactic training, guided EchoGPS training and hands-on practice, N |  | XX | XX | XX |
|  |  |  |  |  |
| Nurses approved as a User, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Nurses failed as a User, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Number of independent, hands-on practice scans necessary before User qualified, per nurse\* |  |  |  |  |
|  | mean (SD) |  |  |  |
|  | median |  |  |  |
|  | min, max |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

\*among nurses who were successfully qualified as users

Table Demographics of Enrolled Patients

|  |  |
| --- | --- |
|  |  |
|  | Total |
| Total Enrolled | XX |
|  |  |
| Sex, n (% of enrolled) |  |
| Female | XX(X.X%) |
| Male | XX(X.X%) |
|  |  |
| Ethnicity, n (% of enrolled) |  |
| Hispanic or Latino | XX(X.X%) |
| Not Hispanic or Latino | XX(X.X%) |
| Unknown/Not Reported | XX(X.X%) |
|  |  |
| Race, n(% of enrolled) |  |
| White | XX(X.X%) |
| Black/ African American | XX(X.X%) |
| Asian | XX(X.X%) |
| American Indian / Alaska Native |  |
| Native Hawaiian or other Pacific Islander | XX(X.X%) |
| Unknown/ Not Reported | XX(X.X%) |
| Other | XX(X.X%) |
|  |  |
| Age on day of first protocol-required scan  , years |  |
| n | XX |
| mean (SD) | XX.X(XX.XX) |
| median | XX.X |
| min, max | XX.X, XX.X |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by BMI category

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | BMI category of Patient | | | All | MRMC  conf. int. | Acceptance  Criterion | PASS or  FAIL­­ |
|  | Clinical Parameter |  | < 25 | 25- <30 | ≥30 |  |  |  |  |
| 1 | Qualitative Left Ventricular Size, Yes or no |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  | 80.0% |  |
|  |  |  |  |  |  |  |  |  |  |
| 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  | 80.0% |  |
|  |  |  |  |  |  |  |  |  |  |
| 3 | Qualitative Right Ventricular Size, Yes or no |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  | 80.0% |  |
|  |  |  |  |  |  |  |  |  |  |
| 4 | Pericardial Effusion, Yes or no |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  | 80.0% |  |

Table 6 Side-by-Side Comparison of Acceptability of Nurse-Acquired vs. Sonographer-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment-Primary Endpoints

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Nurse-Acquired Scan | |  | Sonographer-Acquired Scan | |  |
|  |  |  | Acceptability | MRMC  conf. int. |  | Acceptability | MRMC  conf. int. | MRMC  p-value |
|  | Clinical Parameter |  |  |  |  |  |  |  |
| 1 | Qualitative Left Ventricular Size, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers | X |  |  | X |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned | XXX |  |  | XXX |  |  |
|  |  | n (%) acceptable | XXX (XX.X%) | XX.X%, XX.X% |  | XXX (XX.X%) | XX.X%, XX.X% | 0.XXX |
|  |  |  |  |  |  |  |  |  |
| 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | Qualitative Right Ventricular Size, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | Pericardial Effusion, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Presence of Known Cardiac Abnormality

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Presence of Known Cardiac Abnormality | | All |
|  | Clinical Parameter |  | Present | Absent |  |
| 1 | Qualitative Left Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Right Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Pericardial Effusion, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Study Site

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Study Site | | All |
|  | Clinical Parameter |  | Northwestern | Minneapolis |  |
| 1 | Qualitative Left Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Right Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Pericardial Effusion, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Sex of Patient

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Sex | | All |
|  | Clinical Parameter |  | Male | Female |  |
| 1 | Qualitative Left Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Right Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Pericardial Effusion, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Age of Patient

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Age of Patient at Time of Scan | | All |
|  | Clinical Parameter |  | < 65 | ≥ 65 |  |
| 1 | Qualitative Left Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Right Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Pericardial Effusion, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Number of Scans Completed by this Nurse prior to the Current Scan.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Number of Scans Completed by this Nurse prior to the Current Scan | | |  |
|  |  |  |  |  |  | All |
|  |  |  | 0-9 | 10-19 | 20-29 |  |
|  | Clinical Parameter |  |  |  |  |  |
| 1 | Qual. LV Size, Yes or no |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 2 | Qual. LV Global Funct., Yes or no |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 3 | Qual. RV Size, Yes or no |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 4 | Peri. Effus., Yes or no |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Acquiring Nurse

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Acquiring Nurse (last name) | | | | | | | | All |
|  |  |  | Alpha | Bravo | Charlie | Delta | Echo | Foxtrot | Golf | Hotel |  |
|  | Clinical Parameter |  |  |  |  |  |  |  |  |  |  |
| 1 | Qual. LV Size, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8 |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | Qual. LV Global Funct., Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 3 | Qual. RV Size, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 4 | Peri. Effus., Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |

Table 13 Side-by-Side Comparison of Acceptability of Nurse-Acquired vs. Sonographer-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment-Secondary Endpoints

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Nurse-Acquired Scan | |  | Sonographer-Acquired Scan | |  |
|  |  |  | Acceptability | MRMC  conf. int. |  | Acceptability | MRMC  conf. int. | MRMC  p-value |
|  | Clinical Parameter |  |  |  |  |  |  |  |
| 1 | Qualitative Assessment of Inferior Vena Cava Size, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers | X |  |  | X |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned | XXX |  |  | XXX |  |  |
|  |  | n (%) acceptable | XXX (XX.X%) | XX.X%, XX.X% |  | XXX (XX.X%) | XX.X%, XX.X% | 0.XXX |
|  |  |  |  |  |  |  |  |  |
| 2 | Qualitative Assessment of Right Ventricular Function, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | Qualitative Assessment of Left Atrial Size, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | Qualitative Assessment of Aortic Valve, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | Qualitative Assessment of Mitral Valve, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | Qualitative Assessment of Tricuspid Valve, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by BMI category

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | BMI category of Patient | | | All | MRMC  conf. int. |
|  | Clinical Parameter |  | < 25 | 25- <30 | ≥30 |  |  |
| 1 | Qualitative IVC Size, Yes or no |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | Qualitative RV Function, Yes or no |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | Qualitative LA Size, Yes or no |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | Qualitative Valves, Yes or no |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by Presence of Known Cardiac Abnormalities

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Presence of Known Cardiac Abnormality | | All |
|  | Clinical Parameter |  | Present | Absent |  |
| 1 | Qualitative IVC Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative RV Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative LA Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Valves, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by Study Site

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Study Site | | All |
|  | Clinical Parameter |  | Northwestern | Minneapolis |  |
| 1 | Qualitative IVC Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative RV Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative LA Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Valves, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by Acquiring Nurse

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Acquiring Nurse (last name) | | | | | | | | All |
|  |  |  | Alpha | Bravo | Charlie | Delta | Echo | Foxtrot | Golf | Hotel |  |
|  | Clinical Parameter |  |  |  |  |  |  |  |  |  |  |
| 1 | Qualitative IVC Size, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8 |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | Qualitative RV Function, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 3 | Qualitative LA Size, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 4 | Qualitative Valves, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |

Table Inter-User Variability of Nurse Performance Using EchoGPS to Acquire Scans of Acceptable Quality- Primary Clinical Parameters

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Clinical Parameter | Number of Nurses Assessing this Parameter | Percent of Scans that were of Sufficient Image Quality  to Assess Clinical Parameter | | | | |
|  |  |  | Worst  Performance | Best  Performance | Range | Mean | %CV |
|  |  |  |  |  |  |  |  |
| 1 | Qual. LV Size | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | Qual. LV Global Func. | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | Qual. RV Size | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | Pericardial Effusion | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

Table Acquisition Time- Summary of Time to Acquire 10-view Echocardiogram by Nurse, Total and by View\*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| View | Acquisition Time (min) | Acquiring Nurse (last name) | | | | | | | | All |
|  |  | Alpha | Bravo | Charlie | Delta | Echo | Foxtrot | Golf | Hotel |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |  |  |  |  |  |  |
|  | n |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |

\*Failed attempts to acquire a view will have acquisition time imputed as XXX minutes

Table Inter-User Variability of Acquisition Time among Nurses, Total and by View \*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Mean Per-Nurse Acquisition Time | | | | | |
| View |  | Number of Nurses  Attempting this View | Shortest  Mean  Time | Longest  Mean  Time | Range | Mean  across  Nurses | SD  across  Nurses | %CV  across Nurses |
|  |  |  |  |  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |

\*Failed attempts to acquire a view will have acquisition time imputed as XXX minutes

Table Percent of Views that were Autocaptured by BMI category

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | BMI Category of Patient | | |  |
| View |  | < 25 | 25- <30 | ≥30 | All |
|  |  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |

Table Percent of Views that were Autocaptured by Presence of Known Cardiac Abnormalities

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Presence of Known Cardiac Abnormalities | |  |
| View |  | Present | Absent | All |
|  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 1 | PLAX |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 5 | AP4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 6 | AP5 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 7 | AP3 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 8 | AP2 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 9 | SubC4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 10 | SC-IVC |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |

Table Percent of Views that were Autocaptured by Age of Patient

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Age of Patient | |  |
| View |  | < 65 | ≥ 65 | All |
|  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 1 | PLAX |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 5 | AP4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 6 | AP5 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 7 | AP3 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 8 | AP2 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 9 | SubC4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 10 | SC-IVC |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |

Table Percent of Views that were Autocaptured by Sex of Patient

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Sex of Patient | |  |
| View |  | Male | Female | All |
|  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 1 | PLAX |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 5 | AP4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 6 | AP5 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 7 | AP3 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 8 | AP2 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 9 | SubC4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 10 | SC-IVC |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |

Table 25 Inter-User Variability of Percent of Scans Autocaptured among Nurses, Total and by View

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Percent of Scans Autocaptured | | | | | |
| View |  | Number of Nurses  Attempting this View | Lowest  Pct . Autocaptured among Nurses | Highest  Pct. Autocaptured among Nurses | Range | Mean  Pct. Autocaptured  among Nurses | SD  Pct. Autocaptured  among Nurses | %CV  Pct. Autocaptured  among Nurses |
|  |  |  |  |  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |

Table Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and BMI category

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | View |  | BMI category of Patient | | | All | MRMC  conf. int. |
|  |  |  | < 25 | 25- < 30 | ≥30 |  |  |
| 1 | PLAX |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 27 Side-by-Side Comparison of Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography vs. Sonographer –Acquired Echocardiography by 2-D View

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Nurse-Acquired Scans | |  | Sonographer-Acquired Scans | |  |
|  | View |  | Diagnostic  Quality  (ACEP ≥ 3) | MRMC  conf. int. |  | Diagnostic  Quality  (ACEP ≥ 3) | MRMC  conf. int. | MRMC  p-value |
|  |  |  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |

Table Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Presence of Known Cardiac Abnormalities

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Presence of Known Cardiac Abnormalities | | All |
|  |  |  | Present | Absent |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Study Site

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Study Site | | All |
|  |  |  | Northwestern | Minneapolis |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Sex of Patient

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Sex | | All |
|  |  |  | Male | Female |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Age of Patient

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Age of Patient at Time of Scan | | All |
|  |  |  | < 65 | ≥ 65 |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Number of Scans Completed by this Nurse prior to the Current Scan

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | View |  | Number of Scans Completed by this Nurse prior to the Current Scan | | | All |
|  |  |  | 0-9 | 10-19 | 20-29 |  |
| 1 | PLAX |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |
|  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Acquiring Nurse

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | View |  | Acquiring Nurse (last name) | | | | | | | |  |
|  |  |  | Alpha | Bravo | Charlie | Delta | Echo | Foxtrot | Golf | Hotel | All |
| 1 | PLAX |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by BMI category

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Clinical Parameter |  | BMI category of Patient | | | All | MRMC  conf. int. |
|  |  |  | < 25 | 25- <30 | ≥30 |  |  |
| 1 | Qualitative Left Ventricular Size |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | Qualitative Left Ventricular Global Function |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | Qualitative Right Ventricular Size |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | Pericardial Effusion |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 5 | Qualitative IVC Size |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 6 | Qualitative RV Function |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 7 | Qualitative LA Size |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 8 | Qualitative Valves |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |

Table Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by Presence of Known Cardiac Abnormalities

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Presence of Known Cardiac Abnormality | | All |
|  |  |  | Present | Absent |  |
| 1 | Qualitative Left Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Left Ventricular Global Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Right Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Pericardial Effusion |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 5 | Qualitative IVC Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 6 | Qualitative RV Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 7 | Qualitative LA Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 8 | Qualitative Valves |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and BMI category

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | View |  | BMI category of Patient | | | All | MRMC  conf. int. |
|  |  |  | < 25 | 25- < 30 | ≥30 |  |  |
| 1 | PLAX |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and Presence of Known Cardiac Abnormalities

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Presence of Known Cardiac Abnormalities | | All |
|  |  |  | Present | Absent |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-PM |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-MV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table Cross-Classification of Cardiologists’ Rating of Image Quality for Clinical Assessment of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by Clinical Parameter

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinical Parameter Assessed** |  |  |  | |  |  |  |
| 1. Qualitative Left Ventricular Size |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| 2. Qualitative Left Ventricular Global Function |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| 3. Qualitative Right Ventricular Size |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| 4. Pericardial Effusion |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **5.** Qualitative IVC Size |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| 6. Qualitative RV Function |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **7.** Qualitative LA Size |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| 8. Qualitative Valves |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |

Repeat for subgroups:

* + Results per BMI group (<25, 25-30, ≥30)
  + Sex (female, male)
  + Age (<65, ≥65)
  + Number of scans completed (split into thirds, i.e., 1-10, 11-20, 21-30 patients)
  + RN User
  + Investigative Site
  + Pathology

Table Cross-Classification of Cardiologists’ Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **3. View= PSAX-PM** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **4. View= PSAX-MV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |

Repeat for subgroups:

* + Results per BMI group (<25, 25-30, ≥30)
  + Sex (female, male)
  + Age (<65, ≥65)
  + Number of scans completed (split into thirds, i.e., 1-10, 11-20, 21-30 patients)
  + RN User
  + Investigative Site
  + Pathology

Table 40 Cross-Classification of Cardiologists’ Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Autocaptured Scans Only

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **3. View= PSAX-PM** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **4. View= PSAX-MV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |

Table 41 Cross-Classification of Cardiologists’ Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Save-Best Scans Only

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **3. View= PSAX-PM** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **4. View= PSAX-MV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |
|  |  |  | 215 | 25 | 240 |  |  |
|  |  |  |  |  |  |  |  |

Table 42 Cross-Classification of Cardiologists’ ACEP Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | ACEP Rating of  Sonographer-Acquired Echocardiograms, n(%) | | | | |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  |  |  | 1 | 2 | 3 | 4 | 5 |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  | XX.X % (XX.X, XX.X ) | 0.xxx |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **3. View= PSAX-PM** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **4. View= PSAX-MV** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |

Table 43 Cross-Classification of Cardiologists’ ACEP Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Autocaptured Scans Only

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | ACEP Rating of  Sonographer-Acquired Echocardiograms, n(%) | | | | |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  |  |  | 1 | 2 | 3 | 4 | 5 |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  | XX.X % (XX.X, XX.X ) | 0.xxx |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **3. View= PSAX-PM** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **4. View= PSAX-MV** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |

Table 44 Cross-Classification of Cardiologists’ ACEP Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Save-Best Scans Only

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | ACEP Rating of  Sonographer-Acquired Echocardiograms, n(%) | | | | |  | % Overall Agreement and c.i. | Cohen’s  Kappa |
|  |  |  | 1 | 2 | 3 | 4 | 5 |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  | XX.X % (XX.X, XX.X ) | 0.xxx |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **3. View= PSAX-PM** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **4. View= PSAX-MV** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |

Table Cross-Classification of Cardiologists’ Clinical Assessment Using Nurse-Acquired vs. Sonographer-Acquired Echocardiograms- Primary Endpoints among Patients for whom a Qualitative Assessment could be Made

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinical Parameter** |  |  |  | |  |  |  |
|  |  |  |  | |  |  |  |
| **1. Qualitative Visual Assessment of Left Ventricular Size** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Normal/Borderline | Abnormal/Enlarged |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Abnormal/Enlarged |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **2. Qualitative Visual Assessment of Global Left Ventricular Function** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Normal/Borderline | Reduced  (EF ≤ 50%) |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Reduced  (EF ≤ 50%) |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **3. Qualitative Visual Assessment of Right Ventricular Size** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Normal/Borderline | Abnormal/Enlarged |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Abnormal/Enlarged |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **4. Qualitative Visual Assessment of Non-Trivial Pericardial Effusion** |  |  |  |  |  |  |  |
|  |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Normal/Borderline | Reduced |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Reduced |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

|  |  |
| --- | --- |
|  |  |

Table 46 Cross-Classification of Cardiologists’ Clinical Assessment Using Nurse-Acquired vs. Sonographer-Acquired Echocardiograms- Secondary Endpoints among Patients for whom a Qualitative Assessment could be Made

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinical Parameter** |  |  |  | |  |  |  |
|  |  |  |  | |  |  |  |
| **1. Qualitative Visual Assessment of Inferior Vena Cava Size** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Normal | Dilated |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Dilated |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **2. Qualitative Visual Assessment of Right Ventricular Function** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Normal/Borderline | Reduced |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Reduced |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **3. Qualitative Visual Assessment of Left Atrial Size** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Normal | Enlarged |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Abnormal/Enlarged |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **4. Qualitative Visual Assessment of Aortic Valve** |  |  |  |  |  |  |  |
|  |  |  | Sonographer-acquired echo w/o platform | |  |  |  |
|  |  |  | Structurally normal | Structurally  abnormal |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Structurally normal |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  | Structurally  abnormal |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **5. Qualitative Visual Assessment of Mitral Valve** |  |  |  |  |  |  |  |
|  |  |  | Sonographer-acquired echo w/o platform |  |  |  |  |
|  |  |  | Structurally normal | Structurally  abnormal |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Structurally normal |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  |  | Structurally  abnormal |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **6. Qualitative Visual Assessment of Tricuspid Valve** |  |  |  |  |  |  |  |
|  |  |  | Sonographer-acquired echo w/o platform |  |  |  |  |
|  |  |  | Structurally normal | Structurally  abnormal |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |
|  | Nurse-acquired echo w/ EchoGPS platform | Structurally normal |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |
|  |  | Structurally  abnormal |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

Table 47 Panel Variability: Extent of Agreement among Cardiologists in Rating Acceptability of Echocardiography for Clinical Parameter Assessment- Primary Endpoints by Image Acquirer

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Image Acquirer |  | Clinical Parameter | %Overall Agreement | *p*-value |
|  |  |  |  |  |
| Nurse using EchoGPS |  |  |  |  |
|  |  |  |  |  |
|  | 1 | Qualitative Left Ventricular Size, Yes or no |  |  |
|  |  |  |  |  |
|  | 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |
|  |  |  |  |  |
|  | 3 | Qualitative Right Ventricular Size, Yes or no |  |  |
|  |  |  |  |  |
|  | 4 | Pericardial Effusion, Yes or no |  |  |
| Sonographer without EchoGPS |  |  |  |  |
|  |  |  |  |  |
|  | 1 | Qualitative Left Ventricular Size, Yes or no |  |  |
|  |  |  |  |  |
|  | 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |
|  |  |  |  |  |
|  | 3 | Qualitative Right Ventricular Size, Yes or no |  |  |
|  |  |  |  |  |
|  | 4 | Pericardial Effusion, Yes or no |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Table 48 Panel Variability: Extent of Agreement among Cardiologists in Rating Diagnostic Quality(ACEP 1-5) of Echocardiography by 2D View and Image Acquirer

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Image Acquirer | View |  | % Overall Agreement | *p*-value |
|  |  |  |  |  |
| Nurse using EchoGPS |  |  |  |  |
|  | 10-View Total | TOTAL |  |  |
|  |  |  |  |  |
|  | 1 | PLAX |  |  |
|  |  |  |  |  |
|  | 2 | PSAX-AV |  |  |
|  |  |  |  |  |
|  | 3 | PSAX-PM |  |  |
|  |  |  |  |  |
|  | 4 | PSAX-MV |  |  |
|  |  |  |  |  |
|  | 5 | AP4 |  |  |
|  |  |  |  |  |
|  | 6 | AP5 |  |  |
|  |  |  |  |  |
|  | 7 | AP3 |  |  |
|  |  |  |  |  |
|  | 8 | AP2 |  |  |
|  |  |  |  |  |
|  | 9 | SubC4 |  |  |
|  |  |  |  |  |
|  | 10 | SC-IVC |  |  |
|  |  |  |  |  |
| Sonographer w/o EchoGPS |  |  |  |  |
|  | 10-View Total | TOTAL |  |  |
|  |  |  |  |  |
|  | 1 | PLAX |  |  |
|  |  |  |  |  |
|  | 2 | PSAX-AV |  |  |
|  |  |  |  |  |
|  | 3 | PSAX-PM |  |  |
|  |  |  |  |  |
|  | 4 | PSAX-MV |  |  |
|  |  |  |  |  |
|  | 5 | AP4 |  |  |
|  |  |  |  |  |
|  | 6 | AP5 |  |  |
|  |  |  |  |  |
|  | 7 | AP3 |  |  |
|  |  |  |  |  |
|  | 8 | AP2 |  |  |
|  |  |  |  |  |
|  | 9 | SubC4 |  |  |
|  |  |  |  |  |
|  | 10 | SC-IVC |  |  |

{Repeat for other Quantitative metrics}

Table 49 Summary of Adverse Events by Study Period

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Study Period | | |
|  |  |  | Prior to either scan  (post- Informed Consent signature) | Study Exam  (Nurse-performed  echocardiogram) | Control Exam  (Sonographer-performed  echocardiogram) |
|  |  |  |  |  |  |
|  | N patients entering study period |  | XXX | XXX | XXX |
|  |  |  |  |  |  |
|  | n (%) experiencing any AE |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | n Events |  | XXX | XXX | XXX |
|  |  |  |  |  |  |
|  | n (%) experiencing any procedure-related AE |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | n (%) experiencing any SAE |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | n (%) experiencing any AE that caused withdrawal from study |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |

Table 50 Listing of Adverse Events

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Patient ID | Site | Nurse | Sonographer | Verbatim  Term | Body System | Study Period of onset | Severity | Relatedness to Procedure | Serious | Outcome | Action Taken |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |