

Business Rules for Defining Real Data versus Artifact from Time Series Vital Sign Data Streams

| Rule | Example of rule in Zoom video | | |
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| | Subject ID | Meeting date | Zoom video timestamp |
| <p>1. Ignore all alerts within the first 5 min of starting to record waveform data</p> <p><i>Rationale:</i> During the initial start or restart of continuous vital sign recording two things are occurring. First, the calculated variables are acquiring signals and averaging those signals over time. Second, a bedside clinician is already present and inspecting the quality of the signals and readjusting the sensors as needed to record non-invasive data. Thus, these initial readings can be inaccurate and if real already have a bedside clinician present.</p> | <p>1193704</p> <p>1633671</p> <p>1017281</p> | <p>09/29/20</p> <p>10/7/20</p> <p>10/8</p> | <p>15:11:19</p> <p>11:32:52</p> <p>14:20:59</p> |
| <p>2. For heart rate (HR) numeric to be accurate they must have a corresponding electrocardiographic (ECG) in any acquired lead with their respective primary harmonic by 1/RR interval or fast Fourier transform (FFT) averaged over 20-30 seconds equal to the subsequent reported HR.</p> <p><i>Rationale:</i> HR is derived from automatic sensing of the R wave from the ECG. R-R intervals define 1/frequency. Since multiple different ECG lead configurations may be used, the corollary of this is:</p> <p>2a. For HR to be deemed artifact, if the ECG RR interval or primary harmonic of a good signal does not equal the reported HR within 5%, the value is an artifact.</p> <p><i>Rationale:</i> Extraneous electrical activity, muscular contractions and poor electrode connectivity between the skin and sensing electrode can all lead to both poor and erratic ECG sensing.</p> <p>2b. Anytime an isolated HR Numeric recorded in advance of ECG waves being established is artifact.</p> <p><i>Rationale:</i> The HR numeric needs at least 30 seconds of waveform established before the isolated numeric can be contribute to the event. Similarly, for SpO₂ and RR, but covered in rule #1 above.</p> | <p>1212931</p> <p>1573490</p> | <p>09/29/20</p> <p>09/30/20</p> | <p>15:04:27</p> <p>15:32:45</p> |
| <p>3. For HR numeric to be considered accurate if no clear ECG electrode R wave is detected from any lead, or the electrical interference makes such FFT analysis not defining a primary harmonic, then if the HR is unchanging and a pulse oximeter plethysmographic (Pleth) or arterial pressure (ART) waveform signal is present with their primary harmonic by FFT averaged over 20-30 seconds equals the subsequent reported HR, then the HR is deemed accurate.</p> <p><i>Rationale:</i> Since both Pleth and ART are derived from the ventricular contraction, assuming no premature ventricular contractions, then the Pleth and ART will have the same beat frequency at HR.</p> | <p>1430807</p> | <p>10/29</p> | <p>13:20:02</p> |

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| <p>4a. For RR numeric to be accurate if no good ECG signal or respiratory impedance display are available, then either the Pleth or ART need to display a secondary harmonic by FFT equal to the RR.</p> <p><i>Rationale:</i> The act of breathing causes strong cyclic changes in Pleth and ART signals associated with left ventricular stroke volume variation. If present they will display a secondary harmonic equal to the RR. If the impedance amplitude is too low, it may falsely undercount true RR.</p> <p>4b. As a general rule for creating the initial reference real versus artifact, if no respiratory impedance signal is present, even if there is a good ECG signal, then the RR numeric cannot be used for training purposes. Potentially, if the arterial pressure or pleth oximeter waveforms are also visible and have a clear second harmonic equal to the RR then they can be used, but in the list of patients we reviewed so far that pleth or arterial pressure value was only available twice.</p> | 1017281 1633671 1927237 1283449 1430807 | 10/7/20 10/7/20 10/29 11/17/20 11/17/20 | 11:49:19 11:37:42 13:09:01 16:07:49 16:33:55 |
| <p>5. For the SpO₂ numeric to be accurate the associated Pleth must be visible and display a waveform variability whose primary harmonic by FFT is equal to HR.</p> <p><i>Rationale:</i> The SpO₂ reported by a pulse oximeter needs to see a variable Pleth to calculate arterial oxygen saturation as the difference between the maximum and minimum density for two separate waveform transmissions through the skin. If there is no pulsatility any reported SpO₂ numeric is artifact. The pulse oximeter requires ~20 seconds of readings of the Pleth signal to imitate a SpO₂ display (see Business Rule 1). So a Pleth signal that is intermittently pulsatile and at the same frequency as HR will be intermittently accurate during those times of sensing Pleth pulsation. (Note: pulse oximetry SpO₂ values of <70% may be inaccurate in their absolute values but still reflect real alert hypoxemia)</p> | 1017281 | 10/8 | 14:20:59 |
| <p>6. For the Blood Pressure (BP) numeric to be accurate, if derived from a non-invasive blood pressure cuff sphygmomanometer (NIBP), needs to have the higher BP value (called systolic BP) greater than the lower BP value (called diastolic BP) of > 10 mmHg. And if prior BP recordings show specific numeric values, onto which the next BP vales have a selective increase in diastolic BP, then the diastolic BP is an artifact.</p> <p><i>Rationale:</i> Automated sphygmomanometer recordings can cause the patient to tense their arm during inflation causing an artifactually high systolic and diastolic pressures and a very low difference between systolic and diastolic BP (called pulse pressure). If only causing arm muscle tensing post initial cuff inflation, the diastolic BP will be selectively elevated. The usual response of the bedside clinician is to recycle the automatic BP cuff and remeasure BP.</p> | | | |
| <p>7. For the Blood Pressure (BP) numeric to be accurate, if derived from an indwelling arterial catheter (ART), the associated ART needs to have a characteristic waveform which of FFT has a primary harmonic equal to HR and pressure profile associated with several secondary harmonics by FFT. Otherwise only the mean arterial pressure numeric is valid.</p> <p><i>Rationale:</i> Indwelling arterial pressure recordings often have blunted ART pressure transmission due to clot or catheter lumen partial obstruction making the pulse pressure and systolic and diastolic BP measures inaccurate. However, the mean arterial pressure value remains accurate. Since most hemodynamic management algorithms target mean arterial pressure (there are exceptions) reporting mean arterial pressure is usually enough to define</p> | | | |

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| cardiovascular instability triggering. | | | |
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