

Patient Monitoring Performance Comparison:

GE Healthcare CARESCAPE B850 v3.0 vs. Philips IntelliVue X3

ABSTRACT

GE Healthcare conducted a comparison study between the latest versions of Philips and GE Healthcare patient monitors to assess their ability to detect and alarm serious cardiac arrhythmias while minimizing false alarms. The study found that the two monitors had very similar performance in detecting real arrhythmias. The Philips monitor produced four times as many total false alarms as the GE Healthcare monitor. Particularly it produced numerous false ventricular tachycardia alarms. The GE Healthcare monitor produced more false tachycardia alarms than the Philips monitor in cases with noisy signals.

1. Purpose

Accurate alarming of cardiac arrhythmias is essential to patient monitoring. Failure to detect arrhythmias can lead to severe adverse events, while false alarms can be a source of disruption in busy clinical settings. Too-frequent alarms that do not, in fact, signal serious conditions can be a nuisance and cause stress for caregivers and patients. Alarm fatigue may occur when the sheer number of monitor alarms overwhelms clinicians, possibly leading to alarms being disabled, silenced, or ignored.¹

With this in mind, GE Healthcare conducted a comparison study with expert analysis to document differences between two patient care monitoring products with respect to ECG monitoring:

- Latest-model Philips IntelliVue™ monitor X3 with the most recent software (Rev M.03.02-27)
- GE Healthcare's CARESCAPE™ B850 with the latest-release software (Version 3.0 with EK-Pro algorithm v14.12)

The study compared the performance of the two monitors in terms of detecting severe cardiac events including asystole (ASY), ventricular fibrillation (VF), ventricular tachycardia (VT), high heart rate (tachy) and low heart rate (brady).

2. Test setup

Performance testing was done by feeding pre-collected ECG waveforms in parallel to both monitors. Alarms were collected and compared to reference annotations made by cardiologists. The test was divided into two parts:

- Testing performance for detection of real events
- Evaluating false detection rates with challenging ECG waveforms, including those with difficult morphologies and artifacts.

Different databases were used for sensitivity and false alarm rate testing. Sensitivity was tested with data from 29 recordings that included 57 true annotated VT arrhythmias. Event annotation was done by cardiologists, and the waveforms were collected from different GE Healthcare hospital tests over the years. Data files were multi-lead ECG recordings collected from different ICUs in Europe and Canada.

False alarm performance was tested with waveforms including motion artifacts and challenging ECG morphologies and included 42 long-term post percutaneous coronary intervention (PCI) patients with histories of myocardial infarction (MI). The data originated from the Tampere University Hospital in Finland collected as part of the MADDEC study.² Both monitors were configured to default settings, and the arrhythmia criteria were set as close to identical as possible. For VT, the criteria were set identically to six premature ventricular contractions, with a heart rate of 100 BPM. For VF, no configurations were available, so both monitors used their usual default settings. For asystole, the GE Healthcare monitor uses a fixed five-second delay, while Philips monitor has a configurable delay from two to four seconds. In this test, a four-second delay was selected. The brady and tachy limit settings for both monitors were 40 and 150 BPM. Other configurations were kept at their respective default settings.

Table 1. Default settings for testing

Setting	Philips	GE
Measurement mode	Multi (lead 1 and lead 2)	Multi (I, II, III, V1)
Lead 1	II	NA
Lead 2	V1	NA
QRS threshold (mV)	0.15	Normal
ASY delay (seconds)	4	5
VT rate (BPM)	100	100
VT length (PVC's)	6	6
Tachy rate (BPM)	150	150
Brady rate (BPM)	40	40

For sensitivity testing of real arrhythmias, the same approach for default settings was used. In addition, because Philips has several options for configuring optimal leads for analyses, sensitivity was also tested with using such instructions. (See Appendix, Instructions to Select Leads for Philips).

Because Philips uses only two leads for monitoring arrhythmias and heart rate, those leads were selected as leads II and V1, as defined in the default settings. Because Philips has an adjustable setting for QRS sensitivity, 0.15 mV was chosen as that is default setting according to the user manual. Table 1 documents the default settings.

3. Test data

For testing sensitivity, ECG recordings including a total of 57 VT events were used. A total of 29 cases with five-lead ECG recordings were fed to monitors simultaneously. At the start of each test case, both monitors were “taught” a particular baseline ECG for a typical patient. Alarm notifications were collected and compared to the cardiologist annotations.

The false alarm rate comparison used a database of post-PCI patients. This group was selected because the patients had history of MI with significant changes in ECG morphology. They were also monitored in a stepdown unit, where patients are moving around and therefore subject to ECG artifacts. The selection of 90 such patients was reduced to include patients who had difficult morphology in ECG, such as small QRS, high T-wave or P-wave, conduction

abnormalities, significant damage caused by MI, or significantly noisy ECGs caused by patient movement. A total of 42 cases were included for testing. The original recordings were 24 hours long, but because of time limitations for testing, only the first five hours of data was used for testing. This resulted in a total of 210 hours of testing.

Table 2. Test set up and sample sizes

Test Setup	Sample Size	Sample specificities
True events	29 recordings that include >>	57 true annotated VT arrhythmias
False alarms	42 cases x 24 hours long, but because of testing time limitations only first five hours of data used. Total of 210 hours of testing	Selection of 90 patients reduced to include patients with difficult ECG morphology such as small QRS, high T-wave or P-wave, conduction abnormalities, significant damage caused by MI or noisy ECGs caused by patient movement

4. Results

True events

The results of detection of real arrhythmias were similar between the two monitors. With defaulted settings, out of 57 events in 29 cases, the GE monitor detected 47, while the Philips unit detected 46. In the second round of testing using recommended settings for Philips, the first monitoring lead on the Philips unit was switched from lead II to lead I, if the amplitude in lead II was weak while the amplitude of lead I was good. (See Appendix, Instructions to Select Leads for Philips). In nine cases, this switch was performed.

In this round of testing, the results in arrhythmia detection performance were essentially the same as in the first round. The difference between the monitors was still one more alarm detected by the GE Healthcare unit; however, the alarm count decreased by two for both monitors (from 47/46 to 45/44). The likely reason is that there were some borderline cases where performance could vary according to external artifacts, such as the exact time required for the algorithm to identify the patient’s normal ECG, environmental noise, or software details in the monitors.

False alarms

The Philips monitor had more false alarms than the GE monitor with the same set of data (Table 3). The Philips monitor generated a total of 203 false alarms, mainly from artifacts, the majority being false VT alarms (198). With same data, the GE Healthcare monitor generated 50 false alarms. Of those, 43 were tachy alarms, mainly due to artifacts. In two cases, the alarm history of the Philips monitor was full, and the oldest alarms were overwritten by the newest.

Table 3. False alarms by type

	Philips X3	GE B850 v3
Asystole	1	0
Vfib/Tach	3	0
Vtach	198	5
Tachy	1	43
Brady	0	2
Total	203	50

Figures 1 and 2 demonstrate the performance differences between the two monitors. Philips alarmed in 16 cases out of 42, while GE Healthcare alarmed in nine cases. GE Healthcare alarmed more than Philips in two cases.

Figure 1: False Alarms By Alarm Type

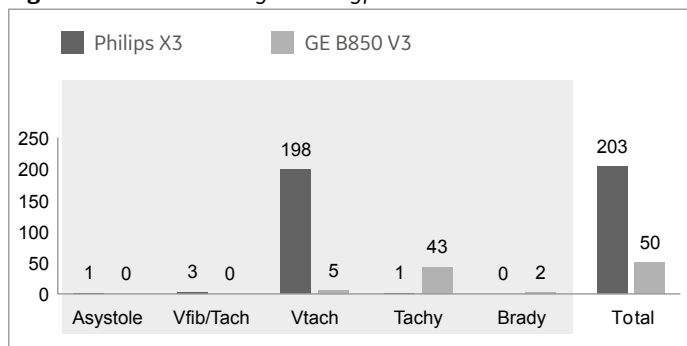
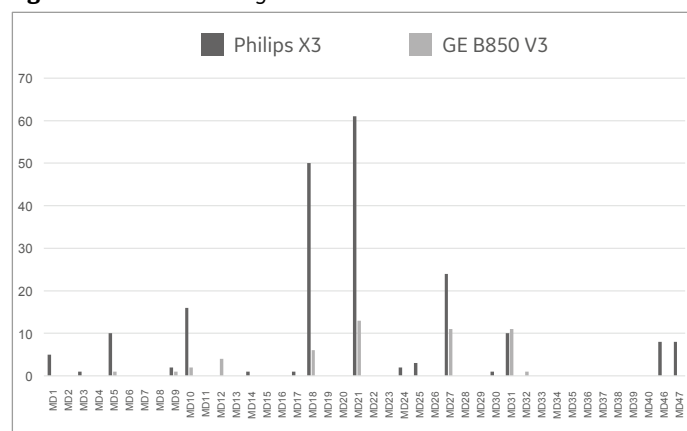


Figure 2: False Alarms By Case



5. Other observations

We observed a delay in ECG processing of 0.7 to 1.0 second with the Philips monitor. This provides a better and more stable ECG when displaying on the monitor screen, but the down side is that the Philips unit loses up to one second for the algorithm calculation, resulting in slower arrhythmia detection. This leads to two observations: The Philips monitor was alarming most real arrhythmias with a delay, and for VT events it alarmed a bit later than the GE Healthcare monitor.

The IEC 60601-2-27 Ed. 3.0 b:2011 standard (Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment) requires alarms for cardiac standstill to be provided within 10 seconds. If the monitor has external filtering delays before the algorithm, it needs to alarm with a shorter delay after last beat identified. This means the monitor needs to alarm with a shorter delay after last beat identified. The faster a monitor alarms asystole, the more irrelevant events (false alarms) are called. The GE Healthcare monitor waits five seconds to alarm after the last detected beat; it does not have any extra delay caused by front-end filtering and meets the 10-second standard. Philips has a filtering delay of about one second and waits up to four seconds to alarm; as such it also meets the 10-second standard. However, while they both alarm at the same time after cardiac standstill, internally the Philips unit waits less time to alarm than the GE Healthcare unit.

This is a potential trigger for false/irrelevant asystole alarms. In this study, we observed one false asystole alarm for 210 monitoring hours was triggered by the Philips unit, while the GE Healthcare unit did not produce any false asystole alarms.

There was one case in which a likely inferior MI caused a morphological abnormality to a lead II, associated with atrial flutter and uneven conduction between the atrium and ventricle. This resulted in variation in the QRS shape, especially in lead II, which was the primary lead for the Philips monitor. That variation was relatively small, but the Philips monitor started to trigger PVC detection on it. Philips has configured the PVC detection algorithm to be more sensitive than the GE Healthcare algorithm to morphological changes. It is well known that some arrhythmias are not very clearly visible in all of the leads: they may look similar to normal rhythm in some leads, while clear morphology differences can be seen in other leads. Because the Philips monitor uses only two leads for analysis, it must use very sensitive PVC detection. On the other hand, the GE Healthcare unit has more flexibility by using four parallel ECG leads for analysis. (A previous white paper provides case examples.)³

6. Conclusions and discussions

The Philips monitor produced 198 false ventricular tachycardia alarms in 210 hours, while GE Healthcare monitor produced five. The Philips monitor's issue is due to the use of only two ECG leads for arrhythmia analysis. Such limitation is compensated by setting a higher sensitivity to small morphology changes. This leads to more frequent false alarms in cases with artifacts and shape differences in QRS morphology.

The other limitation in the Philips monitor is related to the asystole alarm, as it can only be configured for up to four seconds, while the GE Healthcare monitor alarms asystole when five seconds have passed since last QRS. This limitation is also related to the design detail of having a delay in the signal going to the algorithm, requiring the algorithm to wait less time after the last detected QRS in order to meet the 10-second standard for detection of cardiac standstill.

The GE Healthcare monitor's performance limitation seems to be false tachy alarms caused by noisy signals. The difference from the Philips monitor in this category is clear, as the GE Healthcare unit falsely alarmed 43 times, while the Philips unit falsely alarmed only once in the 210 hours. The data set was selected to include a challenging subset of mobile (also out of hospital) patients to emphasize potential differences. This, therefore, does not accurately represent a normal distribution of mobile patients in a normal ward. Further evaluation is needed if this is to be an area for further development.



APPENDIX

Instructions to select leads for Philips

Lead 1 and lead 2 for multi lead analysis should be selected such that

1. QRS in lead is either 100% upwards or downwards; it should not be two directional.
2. QRS should be high amplitude (> 0.5 mV)
3. QRS should be narrow
4. T-wave should be less than $1/3$ of QRS amplitude
5. P-wave should be less than $1/5$ of QRS amplitude
6. If only one lead is good, monitoring should be done using the single-lead mode with that good lead
7. P- and T-wave in leads 1 and 2 should be less than 0.15 mV.

More details in Philips manual.

REFERENCES

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3. EK-Pro: The choice for quality ECG arrhythmia monitoring; David A. Sitzman, MSEE. Mikko Kaski, MSAM. Ian Rowlandson, MSBE. Tarja Sivonen, RN. Olli Väisänen, MD, PhD. ©2015, General Electric Company,

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