PHILIPS

Image guided therapy

Hemo system

Monitor - measure - record

User study to evaluate **multi-user design**

of the Philips Interventional Hemodynamic system

Around the world healthcare systems are struggling with rising costs and maintaining quality standards [1]. Interventional therapy procedures also face these challenges. A study performed in cardiac surgery [2] revealed over 800 human errors in 40 cases observed. These ranged from errors in teamwork and communication and inconsistent adherence to clinical protocols to poorly organized work space. Improving the efficiency and quality of interventional procedures have been key drivers for Philips since it began developing interventional suites. This driver was also the starting position for developing the Philips Interventional Hemodynamic Monitoring system (hereafter referred to as the system).

This white paper highlights findings from a study that evaluated the multi-user design of the Philips Interventional Hemodynamic system. The study was performed at two different locations in the US by 33 clinical users in a realistic setting* using a Philips interventional x-ray system and the Philips Interventional Hemodynamic system.

* In a simulated environment

Hemo system

Monitor - measure - record

Hemodynamic monitoring provides essential information regarding a patient's cardiovascular and pulmonary status, during an interventional procedure. Multidisciplinary teams, performing these interventional procedures, interact with the hemo monitoring system as part of their daily tasks to ensure the patient remains stable throughout the procedure. These systems need to be easy to use and understandable by all team members.
The Philips Interventional Hemodynamic system design supports this multi-disciplinary team approach during cardiac catheterization procedures.

Key findings

Communication and workflow efficiency

- 100% of the users believe that visualization of analyses in the exam room improves communication with the control room.
- 85% of the users believe control of visualization and adaptation of the measurement using the Touch Screen Module helps to improve the workflow.
- 91% of the users believe displaying performed calculations in the exam room helps users to stay focused on the task at hand.

Integration of functional measurements

- 91% of the users believe the system provides an enhanced workflow due to the integration of instant wave-Free Ratio (iFR) functionality.

Intuitive user interaction design

- 97% of the users believe all vital signals regarding patient status can directly and easily be monitored during a procedure.
- 100% of the users believe the system allows for a straightforward assessment of hemodynamic parameters.
- 88% of the users believe the system can be confidently used by all staff members with minimal training.

Scope of the user tests

To objectively evaluate the benefits of the multi-user capabilities of the new system design and user satisfaction, its design was tested by participants that had relevant working experience in the interventional lab and who had not previously used the system. The main conclusions of this study are presented in the Results and Conclusions section of this white paper.

The system was designed to efficiently support workflow by allowing multiple users to interact with the system at any point during the procedure. One area of focus in the design process was to facilitate communication between the exam room and the control room.

Another was to seamlessly integrate functional measurements into the new multi-user design to enhance workflow. The purpose of this study was to evaluate the benefits of the multi-user design of the system based on simulated use by a clinical team in a realistic test environment.

Design of Philips Interventional

Hemodynamic monitoring system

The system consists of the following components:

- Exam room user interface: The hemodynamics exam room user interface is displayed on the ceiling suspended monitor.
- Control room workspot: A dual monitor set-up in the control room displays the hemodynamic user interface for the control room and for the Philips Xper Information Management system.
- Touch screen module (TSM) workspot: all hemodynamic functions can be controlled at a touch screen module located at table side in the exam room.
- Nurse station workspot: A remote station is connected to the main system in the control room and can also be used to control the patient monitoring device.
- Patient monitoring device (Philips FC2010): This device captures vital signs and hemodynamic waveforms.

To efficiently support workflow during cardiac catheterization procedures the design of the new system focused on three key areas:

- Communication and workflow efficiency
- Integration of functional measurements
- Enhancing user interaction

The new system was developed using an iterative approach. Philips developers tested the user interface with clinical users at different stages during the development process to ensure that the user interface would be easy to learn, use and remember.

The different workspots of the system are shown above.

1. Control room set-up with two monitors
2. TSM workspot in the exam room to control the new system
3. The exam room user interface on a ceiling suspended monitor.

Communication and workflow efficiency

Clear communication among team members is fundamental in hemodynamic monitoring, especially under critical portions of the procedure [3]. Two functions were introduced in the system to promote better communication between staff in the control and exam room: a shared screen between the exam and control room and table side control.
Both features aim to reduce the necessity of team members moving in and out of the sterile area during a procedure. Microbes in the air of the operating room or interventional lab can be an important source of pathogens for causing wound infections. Limiting traffic in the treatment area is essential to reducing airborne bacteria. [4,5]

Shared screen

The shared screen option is a novel feature designed to improve communication between the exam and control room. This option allows a user in the control room to visualize the analysis directly in the exam room. It also allows the operator to directly work with the hemo data.

Interaction with touch screen module and flexible workspot

The interventional team can control the new system via the TSM which allows the technologists to assist the procedure from the control room and the physician to take over control at table side if needed. This allows team members to carry out a broad range of tasks, including performing essential steps at the table, such as zeroing the pressure channels, starting and stopping recordings, initiating monitoring of vital signs and reviewing recorded measurements. This flexible control was designed to make workflow more efficient and help the operator at the table stay focused on the task at hand.

The TSM was redesigned to add a new dimension to using hemo data during interventional cases. With the new system it's now possible for the operator at the table to directly work with recorded signals or analyses performed in the control room.

Integration of functional measurements

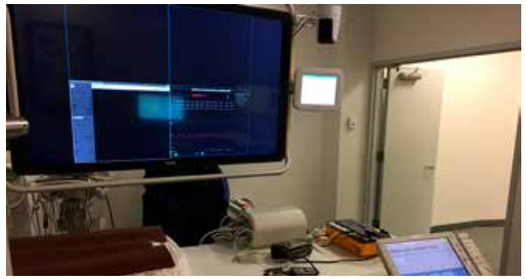
Functional measurements have become a proven method to assess the severity of coronary artery lesions. [6,7,8] and instant wave-free ratio (iFR) measurements are fully integrated with the system. These measurements can be controlled from both the exam and control room at any time during the measurement. This allows for a seamless connection without requiring additional consoles and displays.

User Interaction design

Several studies have documented the adverse impact that poor usability, design and ergonomics can have on medical procedures and patient safety. [9,10,11] An extensive user-centric design process was carried out for the system. During this iterative process, Philips team tested the user interface with clinical users at different stages during development to ensure that the user interface would be easy to learn, use and remember. The design process focused on providing a user interface where vital signs could be easily monitored, hemodynamic measurements could be assessed in a straightforward manner and the system could be confidently used after minimal training.

Design of the **multi-user test**

The study carried out a multi-user test in a realistic setting to simulate how the system will be used in clinical practice. During the study, the participants received training and hands-on practice with the system before performing the tests.



Test set-up in an exam room showing the exam room user interface, TSM workspot, FC2010 monitoring device and Fluke Vital Signs patient simulator.

Participant profile and training

The test was conducted by participants that had experience using other hemodynamic systems to ensure that they had an understanding of the clinical concepts of interventional cardiology. The participant sample included participants from the US from two user groups: 16 interventional cardiologists and 17 monitoring nurses/technicians.
To simulate a typical training the participants received the following training that lasted approximately 45 minutes:
1. High level explanation
2. Hands on demonstration

Study environment and set-up

The test was performed at two different locations in the US in a realistic setting with a control and exam room equipped with a Philips interventional X-ray system and the Philips Interventional Hemodynamic Monitoring system.The system was configured as follows:

- Exam room user interface, control room workspot, TSM workspot and nurse station workspot.
- The patient monitoring device was used as the physical patient monitor and was connected with an external Fluke Vital Signs Patient simulator to generate realistic vital signs.
- Instructions for Use were available in printed form and electronically under the system help.

This set-up represented how the system would be used in clinical practice. Participants could walk around freely between the control room and exam room during the test and use the workspot of their preference for specific tasks. Several tasks could be performed in three different workspots: the control room workspot, the nurse station workspot, and the TSM workspot. All workspots were covered in this evaluation.

Multi-user test protocols

The key feature of this study is that it tested the system in a multi-user set-up, meaning participants worked in teams of one cardiologist and one monitoring nurse/technician to complete two scenarios and they could use different workspots to complete tasks. This set-up was created to present a fair evaluation of how the multi-user design would perform in use scenarios that are representative for the system in clinical practice. The scenarios covered all hemodynamic monitoring functions used in clinical monitoring, including monitoring of vital signs, monitoring of invasive pressures, capturing and reviewing samples, performing calculations based on waveforms and reacting to an emergency situation purposely initiated by the Fluke Vital Signs Patient simulator. Evaluating the system in this format provided the opportunity to identify adverse issues caused by team interaction/communication.

Test evaluation

After the scenarios the participants were asked to fill out a questionnaire. Participants were asked to indicate their level of agreement with multiple statements around the topics of:

- Communication and workflow efficiency with the system
- Integration of functional measurements
- Design of the user interface

The questionnaire provided pre-defined statements and users were asked to answer the statements on the Likert scale of 1 to 5, with 1 representing the lowest level of agreement and 5 representing the highest level of agreement. With a score of 4 or higher it was considered that the participant agreed with the statement.

Results

The study evaluated a number of aspects of the multi-user design of the Philips Interventional Hemodynamic Monitoring system. This section highlights the results from the study that represent the most impactful learnings from the study. An overview of the specific data for these results is shown in Figure 1.

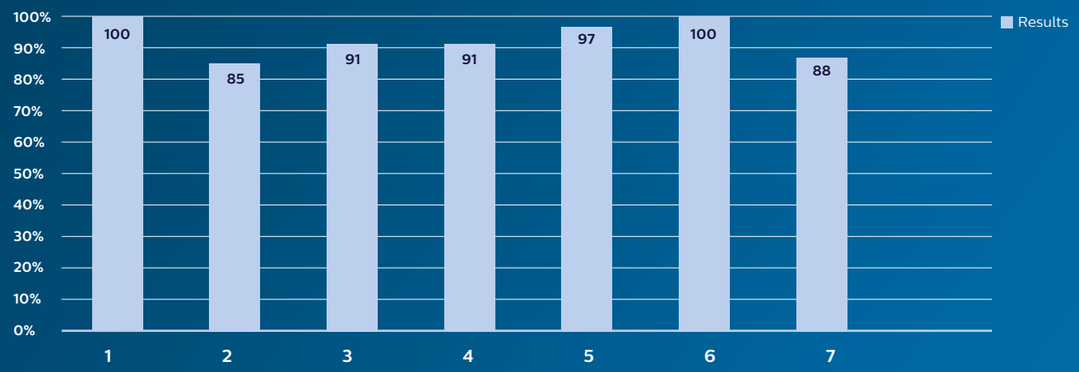


Figure 1

No. Statement

1. **100%** of the users believe that visualization of analyses in the exam room improves communication with the control room.
2. **85%** of the users believe control of visualization and adaptation of the measurement using the touch screen module helps to improve the workflow.
3. **91%** of the users believe displaying performed calculations in the exam room helps users to stay focused on the task at hand.
4. **91%** of the users believe the system provides an enhanced workflow due to the integration of instant wave-free ratio (iFR) functionality.
5. **97%** of the users believe all vital signals regarding patient status can directly and easily be monitored during a procedure.
6. **100%** of the users believe the system allows for a straightforward assessment of hemodynamic parameters.
7. **88%** of the users believe the system can be confidently used by all staff members with minimal training.

System Usability Scale

The SUS (System Usability Scale) is a ten item attitude scale that provides a global view of subjective assessments of usability, and yields a score between 0 and 100 [12]. Fifty percent of the SUS questions are positively phrased and fifty percent are negatively phrased. The mean SUS score in this multi-user study was 83.3. This is within the acceptable range and is considered “good” and almost “excellent” usability. See Figure 2.

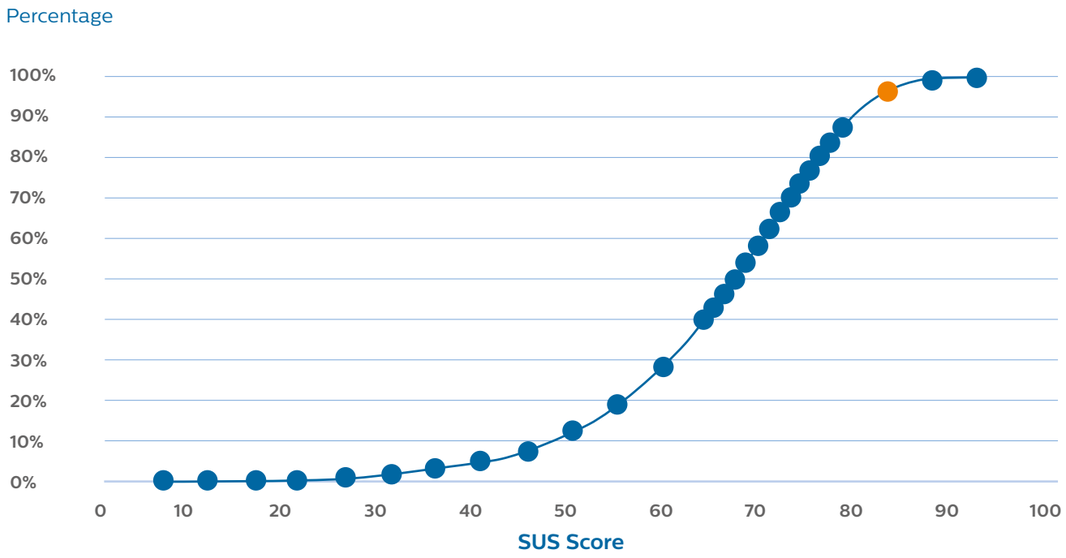


Figure 2 shows the percentile rank of the SUS based on a study carried out by Jeff Sauro.

Net promoter score

The Net Promoter Score (NPS) is a tool for measuring loyalty and is based on the question “How likely is it you would recommend our company/product/service to a friend or colleague?” For this specific product, the question asked was “How likely is it you would recommend this system to a friend or colleague?”

The NPS was a positive 79%. A score of a positive 100% would mean all the users would actively promote a product, and a score of a negative 100% would mean all the users would actively speak negatively about a product and discourage others from purchasing. 0% would mean the group had an equal amount of promoters and detractors. A positive 79% is thus a positive indication for the product.

Conclusion

This study aimed to evaluate how the multi-user design of the system benefits multiple users during simulated interventional cases. To gather input from a broad population of participants, the study involved 33 participants. Participants were spread evenly over technologists/nurses and physicians. These scenarios covered all functions of hemodynamic monitoring common in the clinical practice of interventional cardiology.

By using pre-defined statements and providing an answer scale, the data gathered were easy to compare and delivered valuable insights in the perception of the intended user group. The results show a positive validation of the envisioned benefits of the system.

Communication and workflow efficiency

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- 91% of the users believe displaying performed calculations in the exam room helps users to stay focused on the task at hand.
- 85% of the users believe control of visualization and adaptation of the measurement using the touch screen module helps to improve the workflow.

Integration of functional measurements

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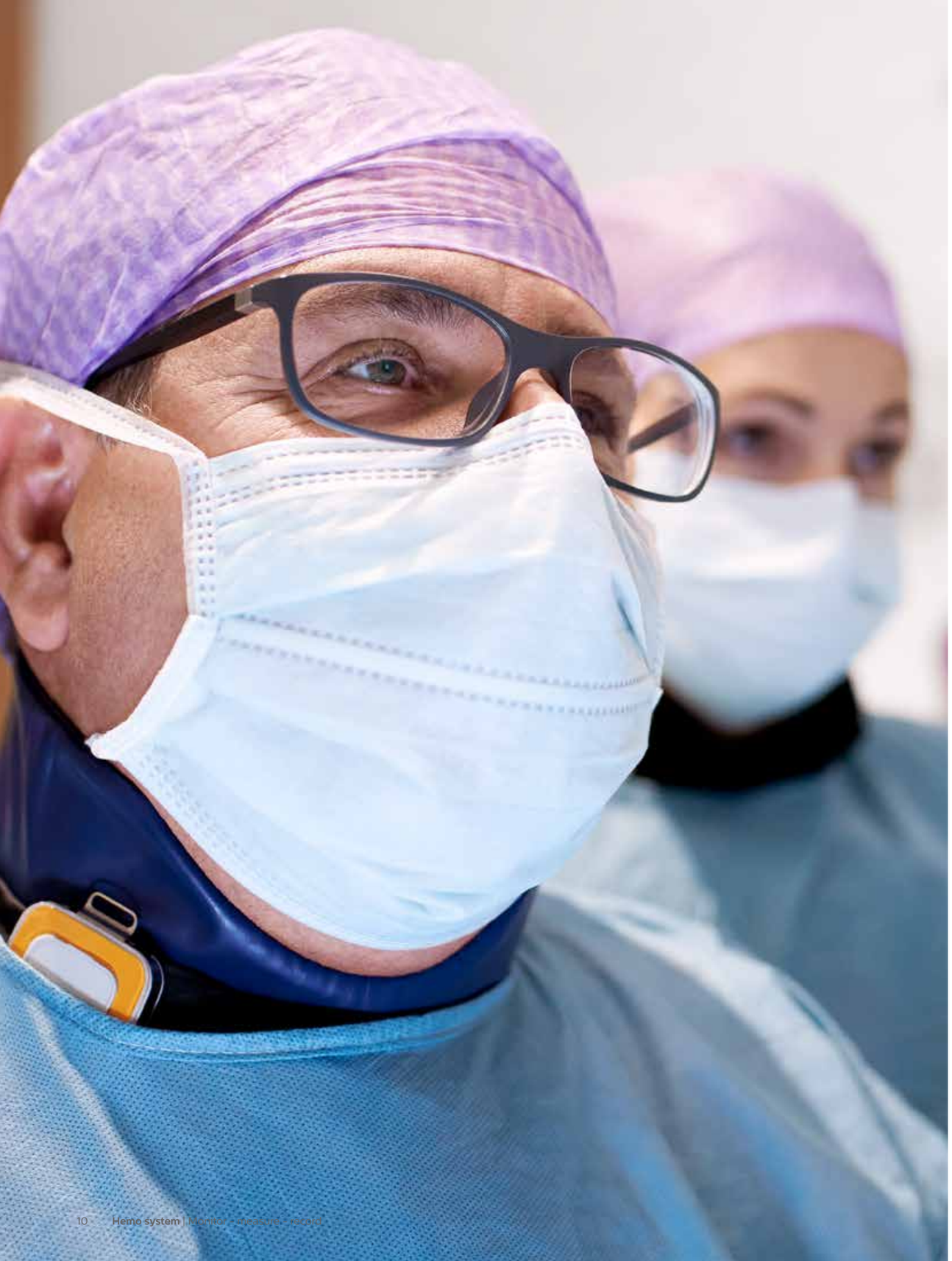
Optimizing user interaction design

- 97% of the users believe all vital signals regarding patient status can directly and easily be monitored during a procedure.
- 100% of the users believe the system allows for a straightforward assessment of hemodynamic parameters.
- 88% of the users believe the system can be confidently used by all staff members with minimal training.
- With an SUS score of 83.3 the usability of the system can be considered “good” and almost “excellent” regarding usability.



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