PHILIPS

Image guided therapy

Azurion

User study to evaluate new **workflow approach**[1]

including 61 clinical users from Europe and USA

Around the world healthcare systems are struggling with rising costs and maintaining quality standards[2]. Interventional therapy procedures also face these challenges. A study performed in cardiac surgery[3] revealed over 800 human errors in 40 cases observed. These ranged from 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 white paper highlights the findings from a study carried out with clinical users on Philips Azurion in 2015/2016 to evaluate its new, more flexible workflow approach. The study was conducted in a simulated lab environment, and was designed and supervised by Use-Lab GmbH, an independent and objective usability engineering consultancy and user interface design company. Use–Lab also analyzed the study results and documented the conclusions.

Azurion image guided therapy platform

Azurion is a highly-advanced interventional suite for image guided therapies. It offers a state-of-the-art hardware platform and software architecture based on Philips leading technologies. The new workflow approach of the Azurion platform was designed to support interventional teams in carrying out a high number of procedures and help them increase the consistency and efficiency of procedures while reducing complications. Azurion offers several advanced workflow features that are explained in detail in the section "Scope of the user tests".

1. Intuitive user interface
2. ProcedureCards
3. FlexSpot

4. FlexVision Pro
5. TSM Pro
6. Instant parallel working

Key findings

Workflow consistency
- 100% of the users believe that the possibility to access and control more applications at tableside, will reduce the need to walk between exam and control room
- 100% of the users believe that the possibility to display Checklists & Protocols on Azurion will help minimize preparation errors
- 91% of the users believe that the concept of using ProcedureCards helps standardize the way of working during an interventional procedure
- 87% of the users believe that the possibility to access and control more applications at tableside will lead to less miscommunication

Workflow efficiency
- 91% of the users believe that Azurion will help reduce procedure time
- 93% of the users believe that Azurion can help them make more efficient use of their time spent in the lab

Intuitive user interaction
- 96% of the users are satisfied with how easy it is to use Azurion
- During the study Azurion scored 87 on the System Usability Scale, which is in the top 10% of the scale[16]

Scope of the user tests

To evaluate the benefits of the new Azurion workflow approach and user satisfaction in an objective way, its novel design was put through a set of independent user tests in 2015/2016. These tests were designed and supervised by Use-Lab GmbH, an independent and objective usability engineering consultancy and user interface design company. Use-Lab also analyzed the study results and documented the conclusions. The main conclusions of this study are presented in the "Key results" section of this white paper.

The goal of the study was to evaluate improvements in workflow based on the participant's experience with Azurion in a simulated use environment. For the purpose of the study, the Azurion was referred to as "the system".

The following aspects of the new workflow approach were tested during the study and are explained in more detail in the following section "Azurion workflow approach".
- New user interface on all displays and control screens
- ProcedureCards with hospital specific documents to streamline and standardize system operation and reduce unintentional actions
- FlexSpot for seamless access to multiple imaging modalities and applications in the control room
- Instant Parallel Working to increase productivity by allowing team members to work on two different activities at the same time
- FlexVision Pro to control multiple imaging modalities and applications at tableside
- Touch screen module (TSM) Pro to support the procedure from tableside

Azurion
workflow approach

The new workflow approach aims to improve three aspects of interventional workflow:

· Workflow efficiency

· Workflow consistency

· Intuitive user interaction

Improving workflow efficiency
Hospitals are increasingly focused on improving efficiency and Azurion provides a number of features to support these efforts.

ProcedureCards
To standardize system set-up in both mixed and dedicated labs, Azurion provides ProcedureCards which offer one-click presets to enter the settings for an examination. These can be customized at examination, physician and department levels. With ProcedureCards, the user can pre-set the suitable X-ray protocols, relevant screen layout and content on the FlexVision in the exam room and on the FlexSpot monitors in the control room. The system will automatically select the appropriate ProcedureCard(s) based on the scheduled procedure code provided by RIS.

Flexible work spots
The flexibility of the Azurion concept allows facilities to customize the way of working for different teams:
· TSM Pro: Touch screen control of applications complemented by tableside control of X-ray images
· FlexVision Pro: Viewing and control of applications via a single wireless mouse
· FlexSpot: Integrated work spot in the control room to view, control and manipulate multiple applications from a single view, spread over one or two widescreen monitors, using one mouse and keyboard
· Instant Parallel Working: Ability to use fluoroscopy/ exposure and at the same time review, analyze and process images of current/previous exams or perform Quantitative Analysis

Improving workflow consistency
Azurion aims to improve the consistency of examinations to promote better care. The article Human Error in Medicine says, "Human error in medicine is a significant cause of

patient mortality."[4] It describes the Flawless Operative Cardiovascular Unified Systems initiative (FOCUS), a multi-year study/intervention to learn about and to reduce human error in cardiac surgery. Some of the categories used in the FOCUS analysis include: teamwork and communication, compliance with existing protocols and poor operating room design/ergonomics. According to a study done by McKinsey&Company, almost half of in-hospital adverse events are related to invasive procedures such as surgical procedures, endoscopy, or radiological interventions.[5] Several studies show that the need to improve the quality and patient safety in interventional radiology is increasingly being recognized.[6,7,8,9]

It is important that interventions are performed in a consistent manner. For example, during preparation, the room needs to be set-up with the required materials and with access to the different imaging modalities that will be used. Each manual task brings with it the potential for inconsistency and use errors. Azurion promotes consistency in several ways.

Task standardization
Azurion uses a range of ProcedureCards to help standardize routine tasks. Only the relevant system functionality and information is shown to simplify set-up and operation. Hospital specific clinical protocols, room preparation protocols and/or checklists can be added to the ProcedureCards and displayed on screen in the exam or control room to further standardize workflow and manage process quality.

FlexVision Pro and TSM Pro
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.[10,11]

The interventional team can control the relevant imaging modalities and applications, and operate the system at tableside via the FlexVision Pro and TSM Pro. The range of applications is broad, including multi-modality imaging, interventional and analytic applications and PACS from Philips and other vendors. Even the hospital PC is accessible to control for example Microsoft Office® programs. Control can be switched back and forth between exam and control room for further efficiency. This reduces the necessity of team members moving in and out of the sterile area during a procedure.

Flexible control
Clear communication among team members is important, especially during critical portions of the procedure.[12]

To promote better communication between the control and exam room, Azurion functionality can be controlled

from both rooms, allowing the technologists to assist the procedure from the control room and the physician to take over control at tableside if needed. A large mouse pointer can be controlled from the touch screen module to indicate the area of interest to the staff in the exam room and control room.

Designing for intuitive interaction
Several studies have documented the adverse impact that poor usability, design and ergonomics can have on medical procedures and patient safety.[13,14,15]

An extensive user-centric design process was carried out for Azurion. During this iterative process, 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.

Design of the **user tests**

The study was conducted with participants that had relevant working experience in the interventional lab. During the study, the participants received training and hands-on practice with the Azurion system, and questionnaires were administered. In these questionnaires, participants were asked to indicate their level of agreement with multiple statements around the topics of workflow efficiency, workflow consistency and intuitive user interaction.

Figure 2
Study environment (examination room) in the USA (top) and Europe (bottom)

The study was performed in Cleveland, Ohio, USA in November and December 2015 with 16 physicians and 15 technologists. In Best, the Netherlands, the study was performed in January and February 2016 with 15 physicians and 15 technologists. The European study was based on the training script used in the USA to assure that the European and USA participants received the same information and impression of the Azurion system. During the training sessions the users got hands-on experience by following a sequence of tasks representative for a clinical procedure. The physician or technologist was asked to perform typical tasks in the clinical procedure according to their role. The questionnaires were also tailored to the roles, meaning certain questions were only asked of physicians or technologists. The study was completed after finishing the training session and the questionnaires. Each participant was asked to fill out a separate questionnaire at the end about the perceived usability.

Based on this, the System Usability Scale (SUS) score was calculated. The SUS measures the subjective assessment of the usability of a system.[16.]

Participant profile and recruiting
All participants were currently working in the hospital environment and had experience with interventional X-ray systems. A variety of functions were represented in the study. These included: interventional radiologists, interventional cardiologists, pediatric interventional radiologists, medical department managers, hybrid OR managers, cath lab managers, cath lab technologists and vascular technologists. The age distribution of the participants ranged between 20 and 59 years whereby every participant had at least one year of relevant clinical experience in an interventional lab. The participants had experience using various brands of X-ray systems.

Study environment and set-up
The USA part of this study was conducted in the Philips facilities in Cleveland, OH. The simulated lab environment consisted of a control room and examination room equipped with a completely functional Azurion system, including a FlexVision Pro, TSM Pro and FlexSpot. The participants were able to use the full functionality of the system in both rooms. The European part of this study was conducted in a simulated lab environment with the same equipment at the Philips facilities in Best, the Netherlands. Figure 1 shows the examination room in both locations. All activities, such as training and questionnaires, took place in these environments.

To be able to combine the results of the sessions in the USA and Europe, it was important that all users had a similar experience. Therefore, a predefined script was used for all activities (introduction to the study, briefings, training and questionnaires). No significant difference was found in the results according to the location of the participants or their level of experience with previous usability tests within Philips.

See the Appendix for a description of the specific activities involved in the simulation study.

Results

The study evaluated a number of aspects of the Azurion system and workflow approach. 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 3.

100% of the users believe that the possibility to display Checklists & Protocols on Azurion will help minimize preparation errors
Each ProcedureCard can contain a hospital specific set of documents that can be displayed in the exam and control room. During the study, the technologists and physicians experienced the possibility to display a hospital specific document from a ProcedureCard to guide the preparation of the room or as guidance to explain the procedure to the patient.

Questionnaire statement
1. I feel the possibility to display our Checklists & Protocols on the Azurion system will help minimize errors during the preparation of the procedure.

Physician: "Documents in ProcedureCards can really help during complex procedures. For example nurses can lay out the necessary materials beforehand."

100% of the users believe that the possibility to access and control more applications at tableside, will reduce the need to walk between exam and control room
During the study, there were various moments when a task could entail walking from the exam room to the control room and vice versa. For instance, when the physician wanted to compare the current image with images from an earlier exam in PACS.

Questionnaire statement
2. I think that the possibility to access and control more applications at tableside will reduce the need to walk between the examination room and the control room.

Physician: "This system allows me to perform every task and get all the information I want on tableside. I never have to go to the control room anymore. I don't need a sterility break during procedures anymore."

87% of the users believe that the possibility to access and control more applications at tableside will lead to less miscommunication.
Certain features introduced on Azurion were expected to decrease miscommunication, such as the possibility of switching control over an application between the control and exam room. The tech in the control room would perform a Quantitative Analysis, and at the end the physician in the exam room would take over control to check the analysis and confirm the results.

Questionnaire statement
3. I think having the possibility to access and control more applications tableside will lead to less miscommunication.

Physician: "This system enables me to work more in sync with my technologists."

96% of the users think that standardization of best practices improves the quality of their services

91% of the users believe that the concept of using ProcedureCards helps standardize the way of working during an interventional procedure
During the training the technologist used the ProcedureCards to set up the system for the procedure, giving the user the suitable X-ray protocols for the specific procedure, the predefined screen layout and content on the FlexVision Pro and FlexSpot monitors, and the hospital specific documents that were uploaded under the selected ProcedureCard.
Each participant also created their own ProcedureCard to understand all of its attributes.

Questionnaire statement
The level of agreement ranges between 91% and 96% for the individual statements, 88% of the participants agreed to both:
4.1 I think that standardization of best practices improves the quality of our services.
4.2 From my point of view, the concept of using ProcedureCards helps standardize the way of working during an interventional procedure.

Physician: "The documents in the ProcedureCards can really help me viewing my standard operating procedures and this will improve safety."

93% of the users believe that Azurion can help them make more efficient use of their time spent in the lab
During the study, the technologist or physician experienced the possibility to review images and perform Quantitative Analysis during fluoroscopy and acquisition, to review images from the PACS at table side and to work on activities for different patients in the control room, while image acquisition was performed in the exam room.

Questionnaire statement
5. I believe that by using the Azurion system I can make more efficient use of my time spent in the lab.

Technologist: "Working on an old case at the same time as working on a fresh case can save so much time."

91% of the users believe that Azurion will help reduce procedure time
As described in the previous result, several possibilities enabled by Instant Parallel Working were experienced by the technologist or physician during the study. For example, the physician accessed the connected ultrasound application during the procedure and reviewed previous images from the PACS, both while standing at tableside in the exam room.

Questionnaire statement
6. I think using this system reduces the time needed for a procedure.

Physician: "If you reduce time through the applications, you also reduce dose for the patient and the staff."

96% of the users are satisfied with how easy it is to use Azurion
During the training the users got hands-on experience on the main functionality of all the different user interface modules. Step-by-step user guidance was experienced when participants performed Quantitative Analysis during the study. At the end of the procedure, the participants had to store images from the performed examination to a USB stick in their preferred format, such as mp4, jpg or DICOM. Another aspect that participants experienced when post-processing images was that controls only appear when hovering with the mouse over the toolbar. Even though several participants in the study had never used a Philips system before, 96% were satisfied with how easy it was to use.
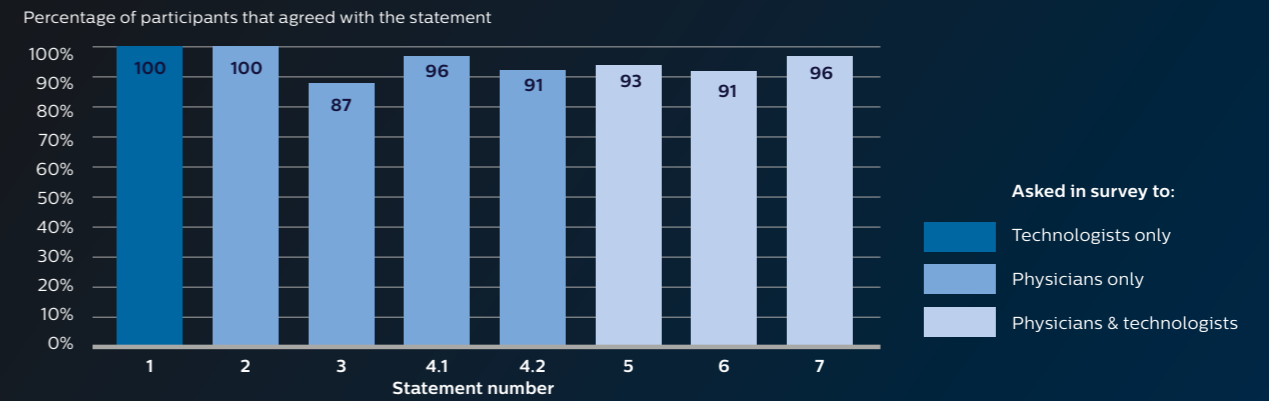
Technologist: "Even though I'm used to operating a system from another company, I find this system extremely easy to operate."

Questionnaire statement
7. Overall, I am satisfied with how easy it is to use this system.

Physician: "The system is very easy to use, after using it a few times it feels like second nature.
I don't have to search for applications, I now can have my key monitors on the FlexVision, and easily maximize and minimize them the way I need."

Figure 3: Overview of results from simulation study

Percentage of participants that agreed with the statement

Asked in survey to:
■ Technologists only
■ Physicians only
■ Physicians & technologists

No.	Statement
1	I feel the possibility to display our Checklists & Protocols on this system will help minimize errors during the preparation of the procedure
2	I think that the possibility to access and control more applications at tableside will reduce the need to walk between the examination room and the control room
3	I think having the possibility to access and control more applications at tableside will lead to less miscommunication
4.1	I think that standardization of best practices improves the quality of our services
4.2	From my point of view, the concept of using ProcedureCards helps standardize the way of working during an interventional procedure
5	I believe that by using the system I can make more efficient use of my time spent in the lab
6	I think using this system reduces the time needed for a procedure
7	Overall, I am satisfied with how easy it is to use this system

Figure 3 shows the percentile rank of the SUS based on a study carried out by Jeff Sauro.

Percentile rank
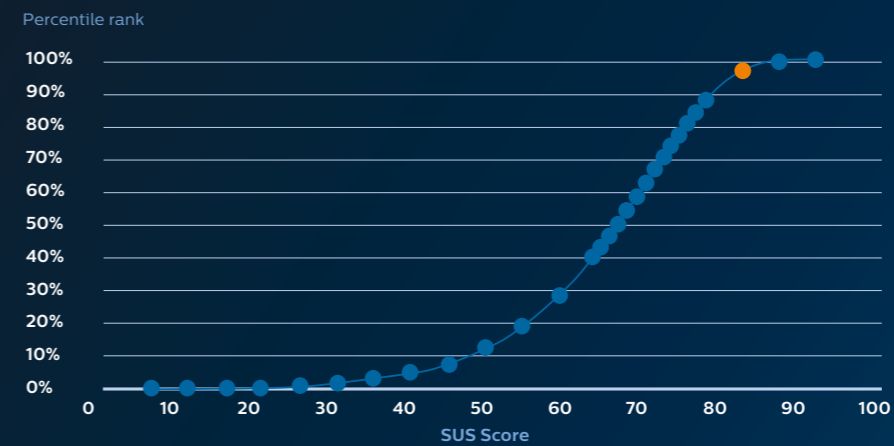
Azurion has a SUS score of 87
After the final questionnaire, participants were asked to complete the System Usability Scale (SUS) questionnaire to rate the system on its usability and learnability. The SUS is a standardized, industry-wide, ten-item Likert-Scale which yields a score between 0 and 100. The questions for the SUS can be found in the Appendix.

One multi-site study of cardiovascular operating rooms on patient safety hazards[13] identified a number of hazards related to the use of tools and technologies.

These include poor usability, such as non-intuitive interface design, inconsistency in design and poor visibility of system status. To ensure an intuitive user interaction, Philips applied a methodical and user-centric design process in designing the user interface of the Azurion system. The Philips developers carried out extensive usability testing during development with real users in different regions and adjusted the design based on their feedback.

Results of SUS questionnaire
The SUS questionnaire was completed by 61 participants. A SUS score above 68 would be considered above average and anything below 68 is below average. As shown in Figure 3, Azurion scored 87 on the System Usability Scale, which means the usability of this system is better than 90% of the 500 systems on which the scale is based.[16]

Conclusion

To gather input from a broad population of participants, the study involved 61 participants from Europe and USA. Participants were spread evenly over technologists and physicians. A variety of functions were represented in the study. These included: interventional radiologists, interventional cardiologists, pediatric interventional radiologists, medical department managers, hybrid OR managers, cath lab managers, cath lab technologists and vascular technologists.

The questionnaires included 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. This study can be seen as providing reliable and objective data, even though mainly subjective data were gathered. 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.

Workflow consistency
- 100% of the users believe that the possibility to access and control more applications at tableside, will reduce the need to walk between exam and control room
- 100% of the users believe that the possibility to display Checklists & Protocols on Azurion will help minimize preparation errors
- 91% of the users believe that the concept of using ProcedureCards helps standardize the way of working during an interventional procedure
- 87% of the users believe that the possibility to access and control more applications at tableside will lead to less miscommunication.

Workflow efficiency
- 91% of the users believe that Azurion will help reduce procedure time
- 93% of the users believe that Azurion can help them make more efficient use of their time spent in the lab

Intuitive user interaction
- 96% of the users are satisfied with how easy it is to use Azurion
- Azurion has a score of 87 on the System Usability Scale[16]

Appendix

Study set-up
The study set-up as shown in Figure 4 was followed for the USA study. For the European study, step 5 was not performed and questionnaire B and C were combined. The USA study lasted 4 hours per participant, the European study 3 hours per participant.

Figure 4: Study set-up

1. Introduction and welcome

   The participants received a brief overview of Use-Lab's background and the general goal of the study.

2. Completion of demographic form and questionnaire A

   The participants were asked to complete a pre-test questionnaire, questionnaire A, related to the participant's professional background and experience with interventional X-ray systems. Furthermore the participants were asked to complete the first questionnaire regarding their opinion on general topics related to the interventional lab and its system.

3. Training

   The participants received hands-on training on the device, covering the major aspects of the system and new key features. The training was performed based on a pre-defined script and covered the parts necessary for the simulation study as well as the feature related topics, providing the participants with a broad and realistic use experience.

4. Completion of questionnaire B

   After receiving the hands-on training, the participants were asked to complete the second questionnaire, questionnaire B. This questionnaire contained most statements regarding the actual system specific features and was meant to be answered at a point when the participants had the strongest experience of using the Azurion system.

5. Break and simulated procedure

   Subsequently the participants in the USA had a break of approximately 60 minutes. Afterwards the participants were asked to perform several tasks in a simulated use environment.

6. Final interview and completion of questionnaire C

   After completing the simulated procedure session, the participants were asked to complete several questionnaires including the third questionnaire about the features and usability of the system, questionnaire C.

The System Usability Scale

The SUS is a 10 item questionnaire with 5 response options.

1. I think that I would like to use this system frequently.
2. I found the system unnecessarily complex.
3. I thought the system was easy to use.
4. I think that I would need the support of a technical person to be able to use this system.
5. I found the various functions in this system were well integrated.
6. I thought there was too much inconsistency in this system.
7. I would imagine that most people would learn to use this system very quickly.
8. I found the system very cumbersome to use.
9. I felt very confident using the system.
10. I needed to learn a lot of things before I could get going with this system.

The SUS uses the following response format:

Strongly Disagree 1	2	3	4	Strongly Agree 5
●	●	●	●	●

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