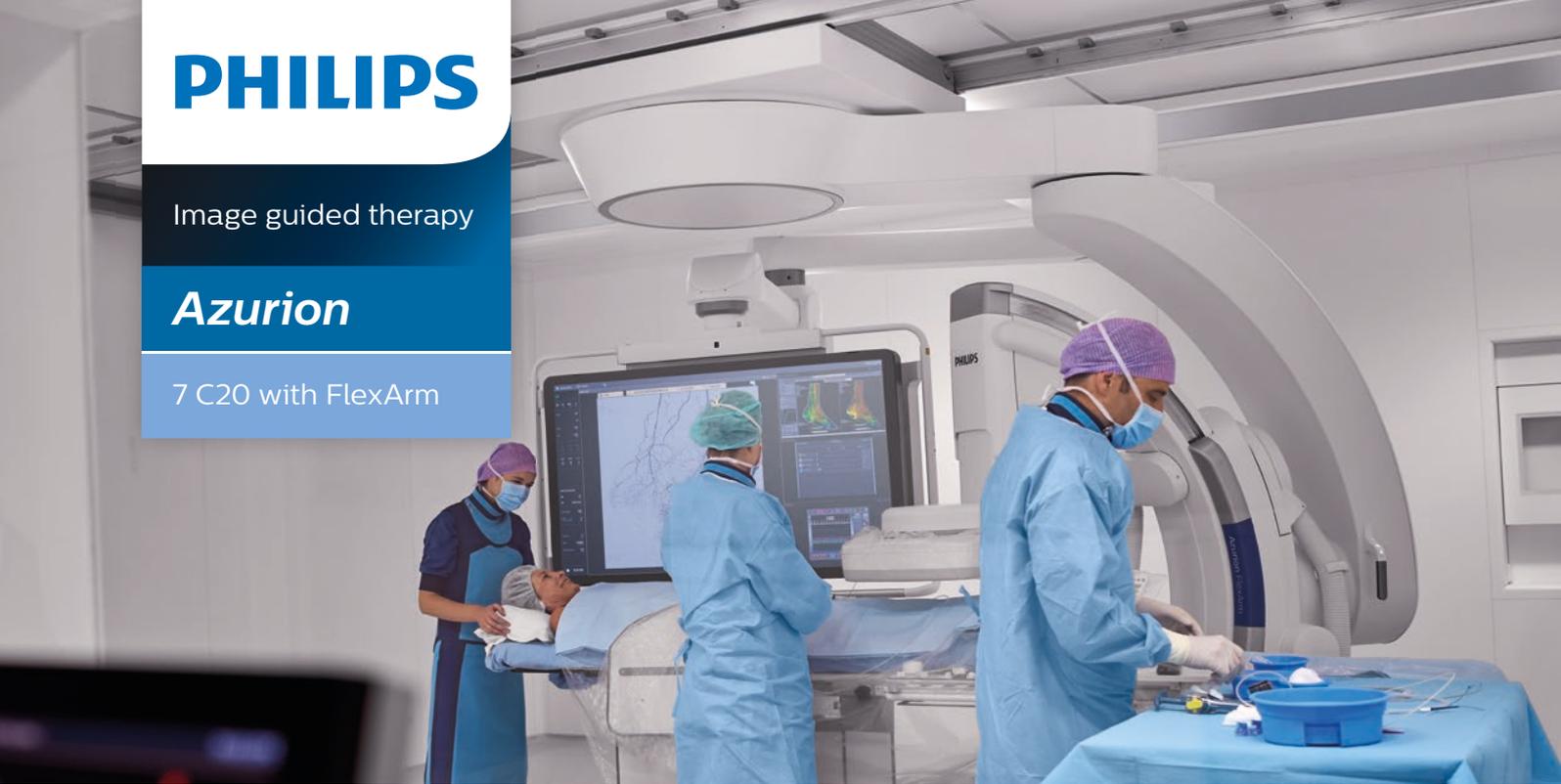


PHILIPS

Image guided therapy

Azurion

7 C20 with FlexArm



User study to evaluate **FlexArm flexibility and efficiency**

Including 17 clinical users from Europe and USA

Interventional suite requirements are a paradox. These rooms must have a solid infrastructure yet they need to be flexible enough to efficiently handle diverse patients, procedures and associated equipment over a long life span. "Unlike commercial or educational facilities, hospitals are routinely used for 50 years or more – but at the same time individual rooms may be changed or replaced after as few as seven years, as clinical methods and equipment change," says Richard Sprow, AIA at architectural firm Perkins Eastman.¹ That is why it is so important for hospitals to use their interventional imaging equipment as flexibly and efficiently as possible to make the most of their investment.

For decades, Philips has been evolving the design of interventional suites to help healthcare facilities meet their goals for improving the efficiency and quality of their interventional care. One of our latest key initiatives aims to significantly increase positioning flexibility for imaging and staff for standard sized suites and existing suites through a new 8-axis ceiling suspension called FlexArm on Philips Azurion 7 C20 interventional X-ray system.

This white paper highlights the findings from a study carried out with 17 physicians on Philips Azurion 7 C20 with FlexArm in 2017/2018 to evaluate the new 8-axis ceiling-mounted gantry. 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.

Philips Azurion with **FlexArm**

Philips Azurion with FlexArm – a revolutionary new approach to image guided therapy that gives you the freedom to improve and grow your minimally invasive care. This new ceiling-mounted system provides unlimited imaging flexibility for diverse procedures and exceptional positioning freedom for medical teams. With the full flexibility and compact set-up of the FlexArm stand you have a highly cost-effective environment ready for the procedures of the future.

By working around you, Philips Azurion with FlexArm helps you optimize your suite performance and deliver superior care.

Key findings^{*}

Workflow consistency by increasing positioning flexibility

- **100% of physicians** agreed that FlexArm would allow them to work with great flexibility
- **94% of physicians** agreed that FlexArm offers full body coverage without the need to move the patient
- **100% of physicians** agreed that FlexArm offered uncompromised access to the patient's head end
- **100% of physicians** agreed that the FlexArm system would reduce the need to move the table
- **88% of physicians** agreed that FlexArm would reduce staff and equipment movement in the suite

Workflow efficiency by reducing movement in the suite

- **27% average reduction in time** spent positioning the system in procedures that include table pivots, such as radial access procedures, compared to suites with standard ceiling mounted c-arms*
- **91% reduction in table positioning movements**, from 19.4 to 1.8 on average, in procedures that include table pivots, such as radial access procedures, compared to suites with

standard ceiling mounted c-arms*. Eight participants eliminated all movements

- **88% of physicians** agreed that FlexArm would help them save time. In addition, 76% agreed that the stand-by option in particular could help them save time
- **76% of physicians** agreed that by using FlexArm they could make more efficient use of their time spent in the suite

Intuitive user interaction

- **94% of physicians** agreed that with FlexArm more tasks could be done without assistance from others
- **100% of physicians** agreed that the FlexArm system was easy to control
- **The Azurion system with FlexArm scored 92** on the System Usability Scale, which is significantly higher than the industry average SUS score of 68
- **94% of physicians** agreed that FlexArm's flexibility is capable of supporting new procedures

* Compared to the suites with Azurion 7 C20. Evaluated with clinical users in a simulated lab environment after approximately 20 minutes of practicing C-arm and table positioning.

Scope of the **user tests**

To evaluate the benefits of the new FlexArm geometry in an objective way, its novel design was put through a set of independent user tests in 2017/2018. These tests were designed and supervised by Use-Lab GmbH, which 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.

FlexArm includes a new ceiling-mounted gantry for the X-ray geometry, Image Beam Rotation and an intuitive table side control. This combination offers a novel level of movement flexibility, which can have a positive influence on several aspects that are important during interventional X-ray cases, such as less movement of staff and equipment within the room, better ways to position the geometry and general time savings. These features are expected to have a very beneficial influence on the workflow for radial access procedures, in particular.

The goal of the usability testing was to validate improvements in performance based on the participant’s experience with FlexArm in a simulated use environment. For the purpose of the study Azurion 7 C20 with FlexArm was compared to standard Azurion 7 C20, and is referred to as “the FlexArm system”.

The following aspects of the new geometry were tested during the study and are explained in more detail in the following section “FlexArm positioning capabilities”:

- Time required to perform a radial access procedure
- Time required to position C-arm and/or table to display wire in subclavian/aortic arch region
- Time required to position C-arm and/or table to display wire in elbow region
- Time required to position C-arm to display wire in elbow region, so that elbow is displayed horizontally
- Time required to position C-arm to display wire in wrist region, so that arm is displayed horizontally
- Time required to move C-arm to foot level
- Time required to move C-arm to standby position and return to working position
- Number of table movements required to reach each position



Image 1: Radial access set up with partially extended arm.



Image 2: FlexArm system in stand by position

FlexArm **positioning capabilities**

The new FlexArm ceiling-mounted system includes four key components:

- Ceiling-mounted gantry
- 8-axis flexible arm
- Axsys motion control system
- Image beam rotation

Ceiling-mounted gantry

The Philips Azurion ceiling-mounted gantry provides an extremely strong and stable support for FlexArm – a flexible arm that rotates on 8 axis, and supports the C-arm. The FlexArm geometry consists of a ceiling-mounted carriage, a flexible geometry arm and a C-arm with a rotatable image beam.

This provides the following advantages:

- The ceiling carriage and flexible arm allow the system to be steered over the patient providing full body coverage
- The system offers various positions that can create space around the table. At any time during procedures the system can be easily moved out of the way and easily moved back into working position.
- When a minimally invasive procedure has to convert to open surgery, the system can be moved in a standby position or parking position away from the table, giving the clinical team more space around the patient.





8-axis flexible arm

The flexible arm can be rotated and moved longitudinally and laterally, allowing three-sided patient access and total body coverage from both sides of the table.

- L-arm rotation around the patient table: from +135 to -135 degrees
- FlexArm coverage: Y stroke: 285 (112.2 inch), 460 (181.1 inch) or 635 cm (250 inch) depending on the chosen rail length.
X-stroke: 236 cm (92.9 inch)

3D acquisitions can be made at the head of the table at 0 degrees (propeller rotation) and at the nurse/physician positions at +/- 90 degrees (roll rotation). The FlexArm roll rotation speed has been increased to provide 5.2 second rotational scans, which reduces artifacts from patient movements.



Image Beam Rotation

The Image Beam Rotation feature is part of the X-ray tube which continually aligns and rotates the image beam so it remains centered over the patient as the C-arm is angulated and rotated. This eliminates the need to re-adjust the position of the image to display it correctly.



Axsys motion control system

This system incorporates the newly developed Axsys motion control system and the intuitive Axsys controller, designed to provide predictable and precise system movements that promote less disturbance and greater staff concentration.

Design of the **user tests**

The study was conducted with 17 physicians from Europe and the USA who had relevant working experience in the interventional lab or hybrid OR. During the study, participants were trained and performed multiple scenarios to position the system – on the Azurion and on the FlexArm, 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.

The scenarios were conducted at a Philips test facility under the supervision of Use-Lab personnel. Participants were filmed during the tests, as they filled out the questionnaires to assure traceability between the participant's response behaviors, the completed paper based questionnaires and any digital format of the questionnaires.



Image 3: Standard system



Image 4: FlexArm system

Study environment and set-up

The study was conducted in Philips facilities in Best, the Netherlands. The study environment consisted of a fully equipped examination room equipped with a fixed interventional X-ray system for each system. Both training and the usability study took place in this environment. The participants were able to use actual X-ray and were appropriately protected.

The study consisted of the following sessions:

- Questionnaire A related to the participant's professional background and experience interventional X-ray
- Training on standard system – Philips Azurion 7 C20
- Usability session on standard system – Philips Azurion 7 C20
- Questionnaire B about their experience with the standard system
- Training on FlexArm system
- Usability session on FlexArm system
- Questionnaire C about their experience with the FlexArm system

Participant profile and recruiting

Participants were selected and profiled based on their years of experience using interventional X-ray systems and on the number of minimally invasive procedures they had performed. All participants had experience using various brands of X-ray systems. Seventeen physicians from Europe and the USA were recruited for the study.

Except for three participants, all were familiar with the Philips Allura X-ray system. Furthermore, thirteen participants were familiar with and regularly performed radial access procedures. On average, the participants had eleven years of work experience.

Prior to the test session the participants received training on the systems. The training covered the major aspects of the system and the new key features. The training focused on the overall use of the FlexArm system including the hardware and movement of the geometry.

Data collection

Based on statements about the benefits of the FlexArm system and its advantages over the standard system, statements and questions were developed and then organized into three questionnaires. Most items in the questionnaires are statements and were responded to on a 5-point agreement scale from "I disagree" to "I agree." In addition to the statements, participants also filled-out the System Usability Score (SUS) survey at the end of questionnaires B and C. The last questionnaire, questionnaire C, focused on the FlexArm system and comparison of the FlexArm and the standard system or the system participants usually used; it was given to participants after the usability test session.

Objective data about task completion times and table movements was gathered using the systems' log-files. When participants began a task, the moderator pressed a button on the remote control that set a specific tag in the log-files; he pressed this button again when participants had concluded the task. In addition, all test sessions were video-recorded to allow the data to be checked.

Results

The study evaluated a number of aspects of the FlexArm system and its positioning versatility. This section highlights the results that represent the most impactful learnings from the study.

Workflow consistency by increasing positioning flexibility

Frequent table movements during minimally invasive interventions can create stress for fragile patients, dislodge wires and tubes and disrupt the equipment and instrument set-up which can affect the consistency and quality of care. The FlexArm system gives medical teams the ability to handle cases requiring full body access with 2D or 3D imaging from three sides of the table without pivoting or panning the table. All 3D navigation tools can be used from seven positions around the table to support optimal staff positioning and patient access. This can enhance the patient experience and improve catheter control and intubation. It also supports consistent workflow by allowing teams to standardize their clinical set-up.

100% of physicians agreed that the FlexArm system would reduce the need to move the table

During the study, there were various moments when a task could entail moving the table to obtain the correct imaging position. For instance, when displaying a wire in the subclavian/aortic arch or elbow region. After using the second system, participants were asked to rate if they thought FlexArm would help reduce table movements, all participants agreed. Thirteen participants furthermore agreed that FlexArm would eliminate the need to pivot the table during procedures.

Questionnaire statements:

I believe that this system will reduce the need to move the table during procedures.

I believe that this system would eliminate the need to pivot the table during procedures.

88% of physicians agreed that FlexArm would reduce staff and equipment movement during procedures

FlexArm was also hypothesized to be advantageous for the suite and those working in the suite. Several of these advantages result from less movement in the suite. All seventeen participants agreed that staff would have to move around less.

Questionnaire statements:

I believe that equipment would have to be moved around less during procedures with this system than during procedures with my regular system.

I believe that staff would have to move around less during procedures with this system than during procedures with my regular system.

100% of physicians agreed that FlexArm would allow them to work with great flexibility

Flexibility is also an important aspect of usability. FlexArm increases positioning flexibility by X-stroke of 236cm lateral movement, 3D acquisition from 3 sides of the table, L-arm rotation from +135 to -135 degrees and Image Beam rotation.

Questionnaire statement:

I believe this system will allow me to work with great flexibility.

100% of physicians agreed that FlexArm offered uncompromised access to the patient's head end

Another advantage offered by the FlexArm system is access to patient's head.

Questionnaire statements:

I believe this system offers uncompromised access to the patient's head end.

94% of physicians agreed that FlexArm offers full body coverage without the need to move the patient

Questionnaire statement:

I believe that the patient would have to be moved less during procedures with this system than during procedures with my regular system.

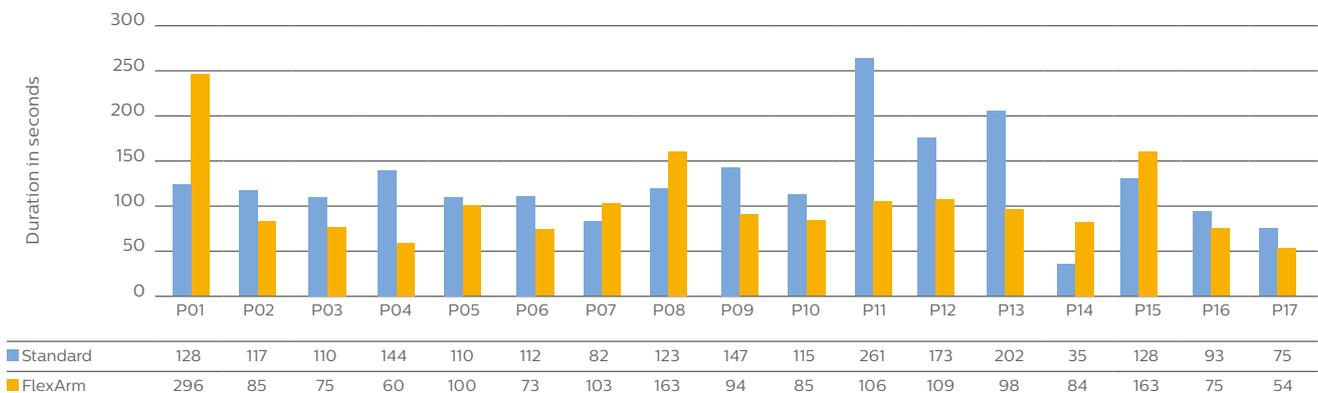
Workflow efficiency by reducing movement

Radial artery access procedures are being increasingly performed as an alternative to traditional femoral artery access procedures, but they can be very time-consuming because conventional X-ray systems are not designed to visualize fully extended arms. Each time the table is pivoted it can disturb wires and other equipment and adds extra time to the procedure. The FlexArm can be moved laterally along the table to provide off-center imaging along both sides of the table. This eliminates the need to pivot the table during radial access procedures in particular. The FlexArm system also provides a wide range of movement around the table to prevent having to repeatedly pivot the table during other procedures as well.

27% average reduction in time spent positioning the system in procedures that include table pivots, such as radial access procedures

As described above, times were taken to measure how long it took participants to perform a number of radial access procedures. Participants performed the same timed procedures with both systems. Graph 1 shows how long participants took to complete the second “forward” procedure with each system. Based on the log files, twelve of the seventeen participants performed the procedure with the FlexArm system faster than the procedure with the standard system. On average, participants were 27% faster with the FlexArm system than with the standard system.

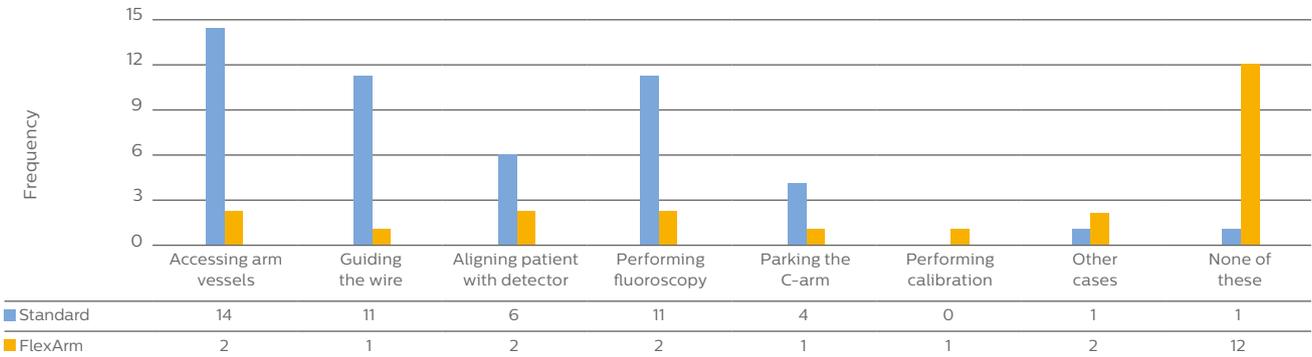
Task completion time: run 2



Graph 1: Task times for the second radial access procedure (wrist-elbow-subclavian) with both systems

The major advantage of the FlexArm system is that the table does not have to be pivoted (as often). To assess whether participants got this advantage, they were asked in which situations they would pivot the table during a procedure with each system. Graph 2 shows the results: Most notably ten of fifteen participants said they would not pivot the table at all using FlexArm, while only one said so about the standard system. The median number of situations marked for the standard system was three, for the FlexArm system it was zero.

In which cases would you pivot the table, if you were using this system?

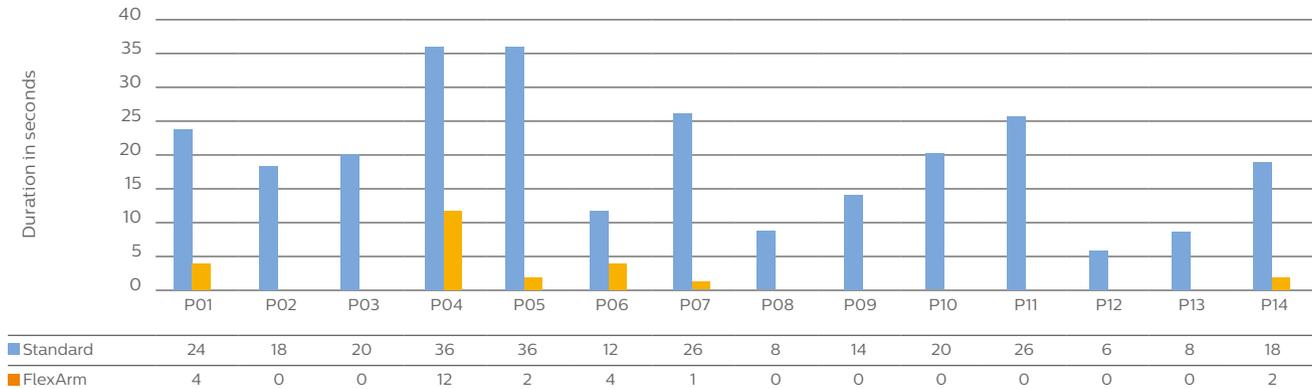


Graph 2

91% reduction in table positioning movements, from 19.4 to 1.8 on average, in procedures that include table pivots, such as radial access procedures, compared to the Philips Azurion 7 C20 system.² Eight participants eliminated all movements.

As with the time it took participants to complete the procedures, the number of table movements required to complete the procedures was tracked. Data from this study showed that table movements were completely eliminated compared to the standard system. Without training, 97% of all table movements were eliminated spontaneously.

Table movements: Run 2



Graph 3: Table movements for the second radial access procedure (wrist-elbow-subclavian) with both systems

88% of physicians agreed that FlexArm would help them save time. In addition, 76% agreed that the stand-by option in particular could help them save time

Reducing the need to pivot the table is not the only feature hypothesized to save time, the standby feature is as well.

Questionnaire statement:
I believe the standby option could help save time during procedures.

76% of physicians agreed that by using FlexArm they could make more efficient use of their time spent in the lab

Participants were presented with a statement about more efficient use of time following use of the system after each test session.

Questionnaire statement:
I believe using the system would allow me to make more efficient use of my time in the lab



Intuitive user **interaction**

Studies have documented the adverse impact that poor usability, design and ergonomics can have on medical procedures and patient safety.³ FlexArm offers many new innovations to help physicians and team members maintain their focus on the procedure including the Axsys motion control system, intuitive Axsys controller and patient oriented movement. Making system operations intuitive, predictable and comfortable to use, can improve patient care and staff satisfaction.

94% of physicians agreed that with FlexArm more tasks could be done without assistance from others

An important aspect of usability is to what extent the controls enable independent operation. Participants were asked to what extent they thought the FlexArm system would allow them to work more independently than their regular systems and whether they thought they would be able to do more tasks without assistance.

Questionnaire statements:

I believe that this system would allow me to work more independently than with my regular system.

I believe that this system would allow me to do more tasks without assistance from others.

100% of physicians agreed that the FlexArm system was easy to control

Attributes that users ascribe to systems affect the extent to which they are willing to rely on these systems and how much they like using them.

Questionnaire statement:

I found this system easy to control.

94% of physicians agreed that FlexArm's flexibility is capable of supporting new procedures²

The FlexArm system is a significant investment, so it needs to be future-proof.

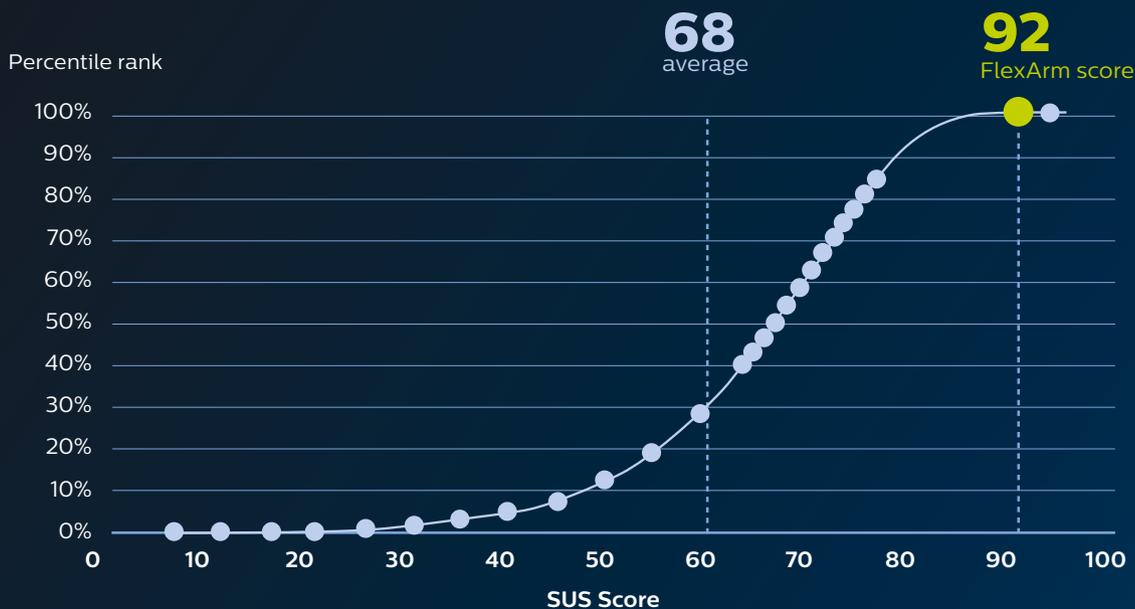
Questionnaire statement:

I believe that with this system my lab will be able to adapt to new procedures easily.

The Azurion system with FlexArm scored 92 on the System Usability Scale, which is significantly higher than the industry average SUS score of 68

One way to evaluate usability is with the System Usability Scale (SUS). The SUS is an independent, scientifically proven scale to assess the usability of technological systems, including household appliances, high-tech systems and health tech solutions. Users respond to 10 statements on a scale of 1 to 5 (Likert scale), where '1' means 'Strongly Disagree' and '5' means 'Strongly Agree'. Results are converted to an overall score between 0 and 100.

Participants were asked to respond to the SUS statements after each test session. Overall, the FlexArm system achieved an SUS score of 92, which is significantly higher than the industry average SUS score of 68.



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 | | | | Strongly agree |
| 1 | 2 | 3 | 4 | 5 |
| <input type="radio"/> |

Conclusion

To gather input from a broad population of participants, the study involved 17 participants from Europe and the USA. Participants represented a variety of functions in the study. These included: interventional radiologists, interventional cardiologists and vascular surgeons.

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 based on both subjective data and log-file times. 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.

The overall results from the study confirm that the increased positioning flexibility of FlexArm reduces staff movement and patient movement within the minimally invasive suite, which results in significant time savings during procedures. This can improve throughput and enhance patient care. Although FlexArm offers a very sophisticated range of movement capabilities, all physicians indicated the system is easy to use, which is an important consideration for busy treatment environments that involve diverse medical users.

References

- ¹ Sprow R. Planning Hospitals of the Future, White Paper, Perkins Eastman. Accessed 1 August 2018. <http://www.perkinseastman.com/dynamic/document/week/asset/download/3411781/3411781.pdf>
- ² Philips does not promote the use of its products in a manner not covered by the intended use.
- ³ Gurses A, Ozok AA, Pronovost PJ. Time to accelerate integration of human factors and ergonomics in patient safety. *BMJ Qual Saf.* 2012;21:347-51.

