ziehm imaging

Dose comparison between Ziehm Vision RFD 3D, Medtronic O-arm® O2 and Samsung NeuroLogica BodyTom

Discover significantly lower dose levels for the Ziehm Vision RFD 3D.

Today, intraoperative 3D imaging is regarded as the gold standard in complex, minimally invasive surgeries. Especially in sensitive areas such as the cervical spine, or even in complex orthopedic and trauma surgeries, reliable intraoperative imaging is essential for the safe placement of implants and the immediate control of results. As a flexible, space-saving and cost-effective alternative to fixed installed 3D scanners, mobile 3D imaging systems are gaining in relevance in this clinical area of interest, which is why various medical device companies offer alternative mobile 3D imaging systems to fulfill the market's requirements.

At the same time, dose exposure is being increasingly discussed in our industry and in daily communication with customers and healthcare professionals. Organizations such as the International Commission on Radiology Protection (ICRP), the European ALARA Network, the American Association of Physicists in Medicine (AAPM) and Image Gently are instrumental in recognizing the importance of dose management and appropriate treatment.

This paper is a compilation of dosimetry measurements on major current mobile 3D imaging technologies.

Current situation

For more than four decades, OR planning and control has been based on CT scans to display anatomical structures not only in 2D, but also in 3D. This is why they were recognized as the imaging standard for years.

With the trend toward minimally invasive surgeries, the demand for intraoperative 3D imaging has gained relevance during the last decade to enable real-time imaging information within the operating theater and to be able to refer to the current anatomical situation. It has also become more important to control the placements of implants intraoperatively to reduce the need for revision surgeries.

Data acquisition method

The following comparison of the Ziehm Vision RFD 3D, the enhanced Ziehm Vision RFD 3D CMOSline[1], Samsung NeuroLogica BodyTom and Medtronic O-arm® O2 provides dose values for equivalent applications of leading intraoperative mobile 3D imaging technologies. There were also plans to measure the Siemens Healthineers ARCARDIS Orbic 3D, but it was excluded from the evaluation process, as its X-ray beam and the resulting 3D volume (12 cm x 12 cm x 12 cm) were too small compared with the other imaging modalities, in particular when considering that the CTDI phantom has a diameter of 32 cm.

Comparable CTDI measurements were performed together by Stryker and Ziehm Imaging for the Ziehm Vision RFD 3D and BodyTom. The Ziehm Vision RFD 3D CMOSline is an advanced version of the established Ziehm Vision RFD 3D. Measurements on the latter system were performed in-house at Ziehm Imaging under identical conditions. The CTDI values from the Medtronic O-arm® O2 refer to a reference document provided by Medtronic (BI-160-00227 Rev 1, O-arm® O2 Imaging System Version 4.0 Dosimetry Report March 2015). All further measurements are either on file at Ziehm Imaging or publicly available.

Measurement procedure setup

For each measurement with the Ziehm Vision RFD 3D and the Ziehm Vision RFD 3D CMOSline and Samsung NeuroLogica BodyTom, the same carbon fiber OR table from Stille (STILLE imagiQ2) was used. The carbon fiber OR table ensured that no metal parts were attached or part of the radiation field to avoid modified dose levels due to metal in the field of view. The measurements were done under realistic and maximally comparable conditions with the same experimental setup and comparable positioning of the phantom (PMMA) at the center of the 3D scan.

As the measuring points (positioning of the measuring probe) were located in the center and at 3, 6, 9 and 12 o'clock positions on the PMMA phantom just below the surface, the influence of the specific self-absorption and scattering of the mounting plate were taken into account.

Measurement equipment

The American College of Radiology (ACR) utilizes the parameter CTDIvol to specify acceptance criteria for its CT Accreditation program. While the Ziehm Vision RFD 3D and Medtronic O-arm® O2 are currently not considered a CT modality, the information is presented for comparative purposes only. The CTDI values were measured/calculated with the cylindrical PMMA phantom with three different diameters (32 cm, 16 cm, 10 cm) known as the "3-part CT phantom: Adult Head & Body/Pediatric Head & Body" by IBA (Figure 1). This phantom is designed to image the pediatric and adult head and body in accordance with the FDA performance standard for diagnostic X-ray systems. The ionization chamber DCT10-RS Lemo[2] by IBA with an active length of 100 mm and the software MagicMaX Universal version 2.1.2 were used.

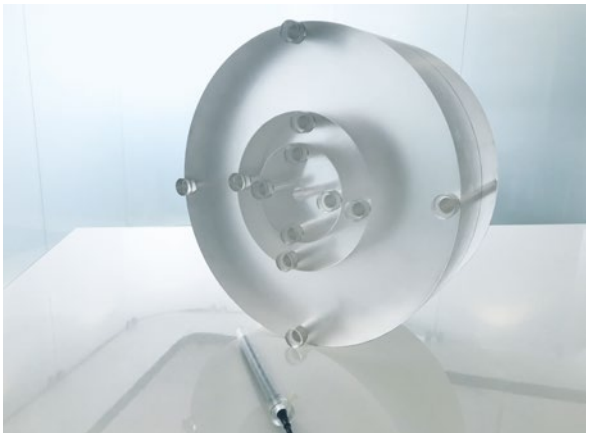


Fig. 1: 3-part CT phantom

The dose length product was measured with a probe at the 3, 6, 9 and 12 o'clock positions and in the center of the phantom. After performing the five measurements, the CTDI values were calculated by the MagicMaX software. This is a standard procedure that is well-known and regularly performed in CTs to confirm the system's stability and conduct other tests.

Scans were made for the following applications: head, cervical spine, thoracic spine/chest, shoulder, lumbar spine/pelvis and extremities under Pediatric/Low Dose, Adult and Obese patient modifiers. 3D imaging was performed "live" for all anatomical regions. Due to the different size of the anatomical regions, the phantom diameters are listed in table 1.

Application	Diameter of CTDI phantom
Head	16 cm
Cervical spine	16 cm
Thoracic spine/ chest	32 cm
Lumbar spine/ pelvis	32 cm
Shoulder	32 cm
Extremities	16 cm

Table 1: Application referenced to diameter CTDI phantom

Pediatric/Low Dose is used for pediatric patients and smaller adults up to 60 kg, Adult mode is used for adults from 61 kg up to 130 kg, and the Obese patient modifier is used for adults weighing more than 130 kg. The following programs were measured:

Application	Ziehm Vision RFD 3D program
Head	Pediatric/Low Dose: head Adult: head Obese patient: head
Cervical spine	Pediatric/Low Dose: cervical spine Adult: cervical spine Obese patient: cervical spine
Thoracic spine/ chest	Pediatric/Low Dose: spine Adult: spine Obese patient: spine
Lumbar spine/ pelvis	Pediatric/Low Dose: spine Adult: spine Obese patient: spine
Shoulder	Pediatric/Low Dose: shoulder Adult: shoulder Obese patient: shoulder
Extremities	Pediatric/Low Dose: hand Adult: hand Obese patient: hand

Table 2: Application referenced to the Ziehm Vision RFD 3D program

a. Ziehm Vision RFD 3D (CMOSline)

For the measurements, a Ziehm Vision RFD 3D with software version 6.07[3] was used. For in-house measurements with the Ziehm Vision RFD 3D CMOSline, software version 7.03[3] was used.

The Ziehm Vision RFD 3D has three different modes for the patient size: Pediatric/Low Dose, Adult, and Obese patients.

b. Samsung NeuroLogica BodyTom

The measurement took place in July 2017 at Baptist Health Medical Center in Little Rock, Arkansas, USA. The CTDI values were measured with Samsung NeuroLogica BodyTom[3] and software version 1.08. The measurements were performed with the helical settings according to the manufacturer's recommendations for the specific application.

The Samsung NeuroLogica BodyTom is designed with different modes for the patient size and application. The following modes were selected for the comparison, according to the respective manufacturer's recommendations: Adult, Pediatric (60 kg+), Pediatric (30 - 60 kg) and Pediatric (14 years+). As there was no Obese patient mode or HQ mode available, only Pediatric and Adult patient modes were measured. Table 3 shows the protocols used for the examined body regions.

Application	Samsung NeuroLogica BodyTom protocol
Head	Adult: helical head Pediatric: helical head (14 yrs.+)
Cervical spine	Adult: helical cervical spine Pediatric: helical cervical spine (14 yrs.+)
Thoracic spine/ chest	Adult: helical chest Pediatric: helical chest (60+kg) Pediatric: helical chest (30 - 60 kg)
Lumbar spine/ pelvis	Adult: helical lumbar spine Pediatric: TL spine (60+kg) Pediatric: TL spine (30 - 60 kg)
Shoulder	Adult: helical shoulder Pediatric: helical shoulder
Extremities	Adult: helical lower extremities Pediatric: helical lower extremities

Table 3: Application referenced to the BodyTom protocol

c. Medtronic O-arm® O2

As described in the reference document "O-arm® O2 Imaging System, Version 4.0, Dosimetry Report March 2015", the dose measurements were performed for the following anatomical sections with a field of view of 20 cm^4: abdomen, chest, head and extremities. Besides the anatomical selection, the settings are also defined by the 3D mode (standard 3D, HD3D, Low Dose 3D, enhanced 3D) and the patient size (small, medium, large, and extra large). Table 4 shows the available 3D image information and available patient sizes.

3D mode	Patient size
Low Dose	Small/medium/large/extra large
Standard	Small/medium/large/extra large
HD3D	Small/medium/large/extra large
Enhanced 3D (for anatomical section head only)	Small/medium/large/extra large

Table 4: Medtronic O-arm® O2 3D mode according to patient size

The following programs were used for the examined applications:

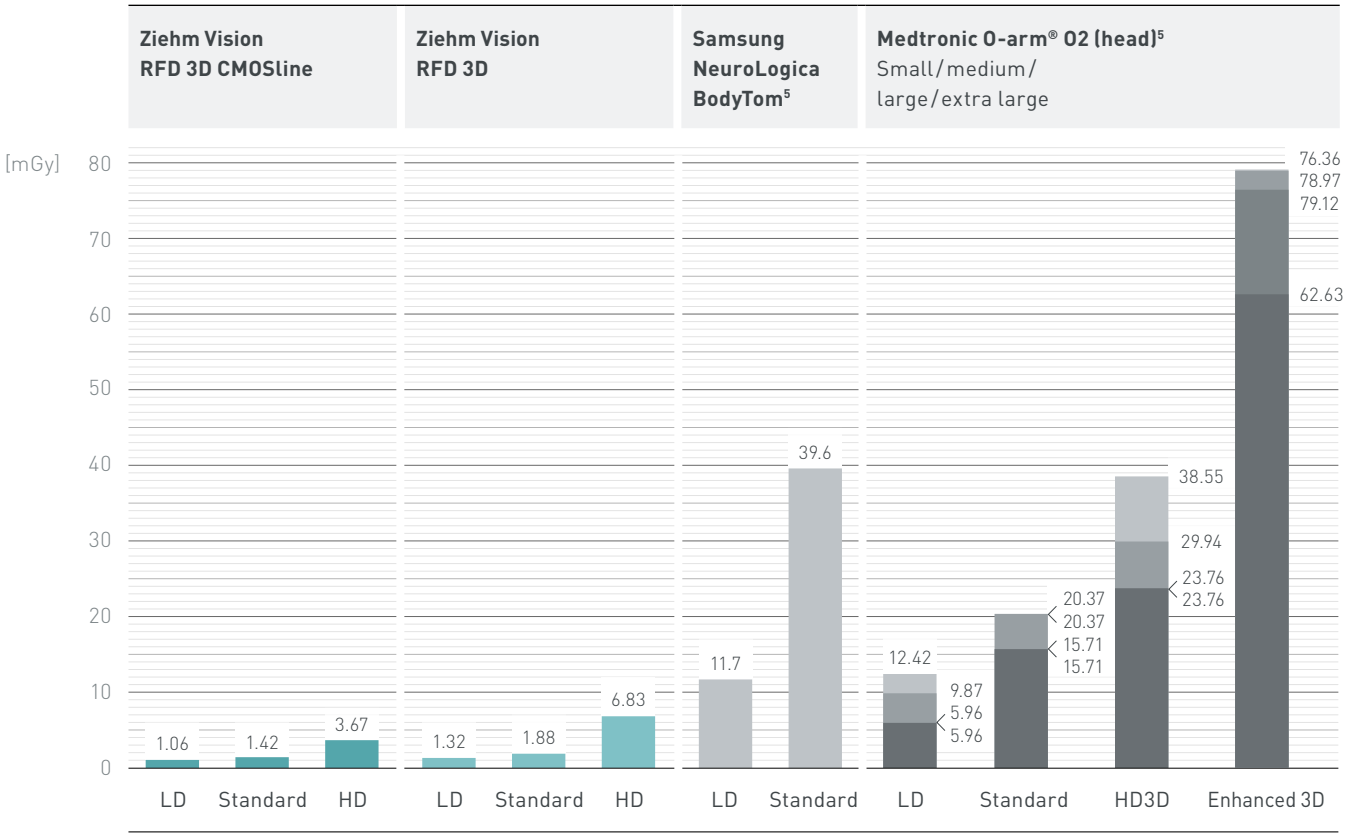
Application	Medtronic O-arm® O2 anatomical section
Head	Head
Cervical spine	Chest
Thoracic spine/ chest	Chest
Lumbar spine/ pelvis	Abdomen
Shoulder	Chest
Extremities	Extremities

Table 5: Application referenced to O-arm® O2 program

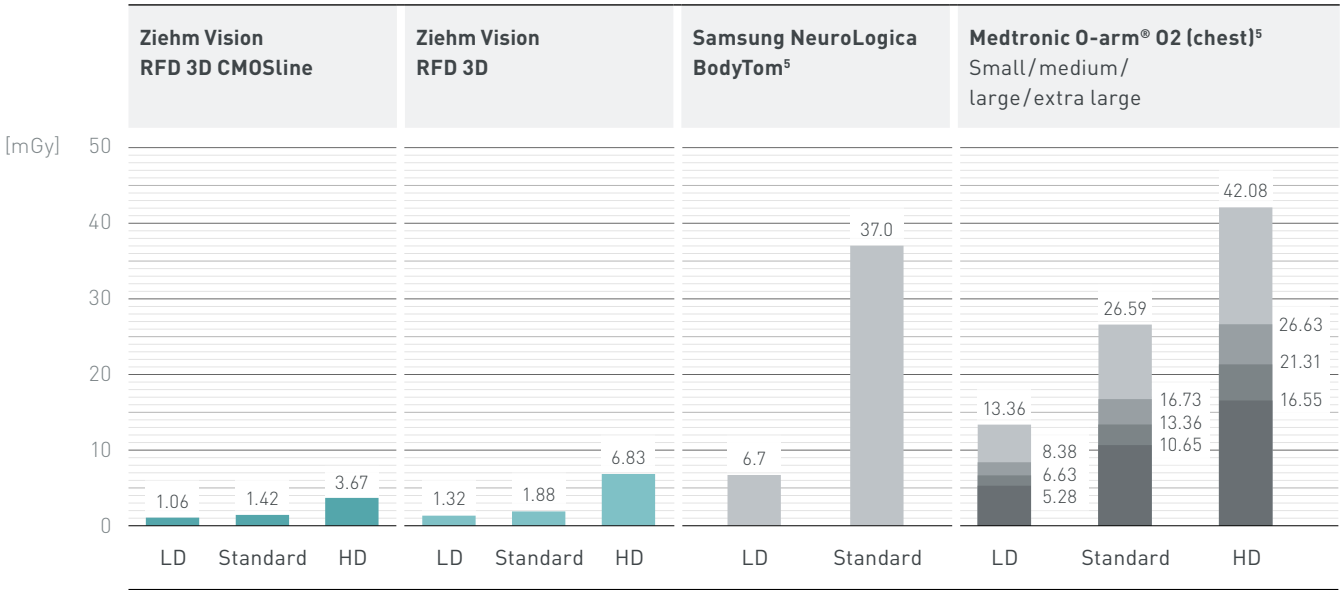
Dosimetry Results

The following tables show the CTDI in mGy for the different applications named in each headline.

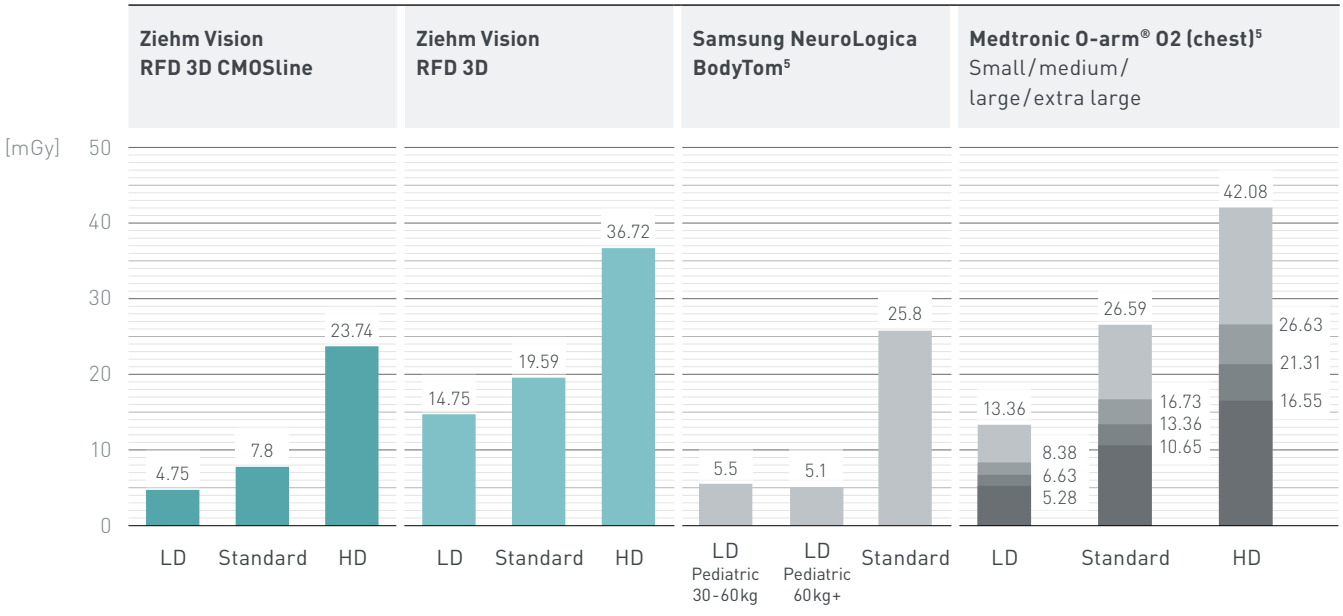
a. Dosimetry data for head protocols



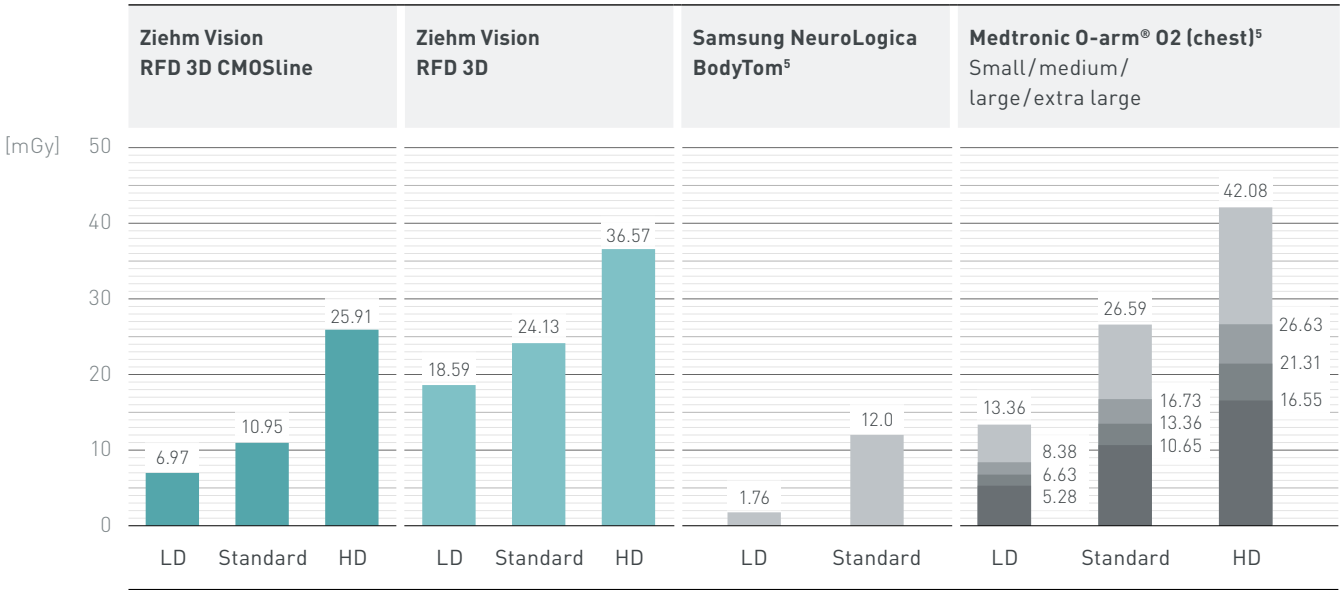
b. Dosimetry data for cervical spine



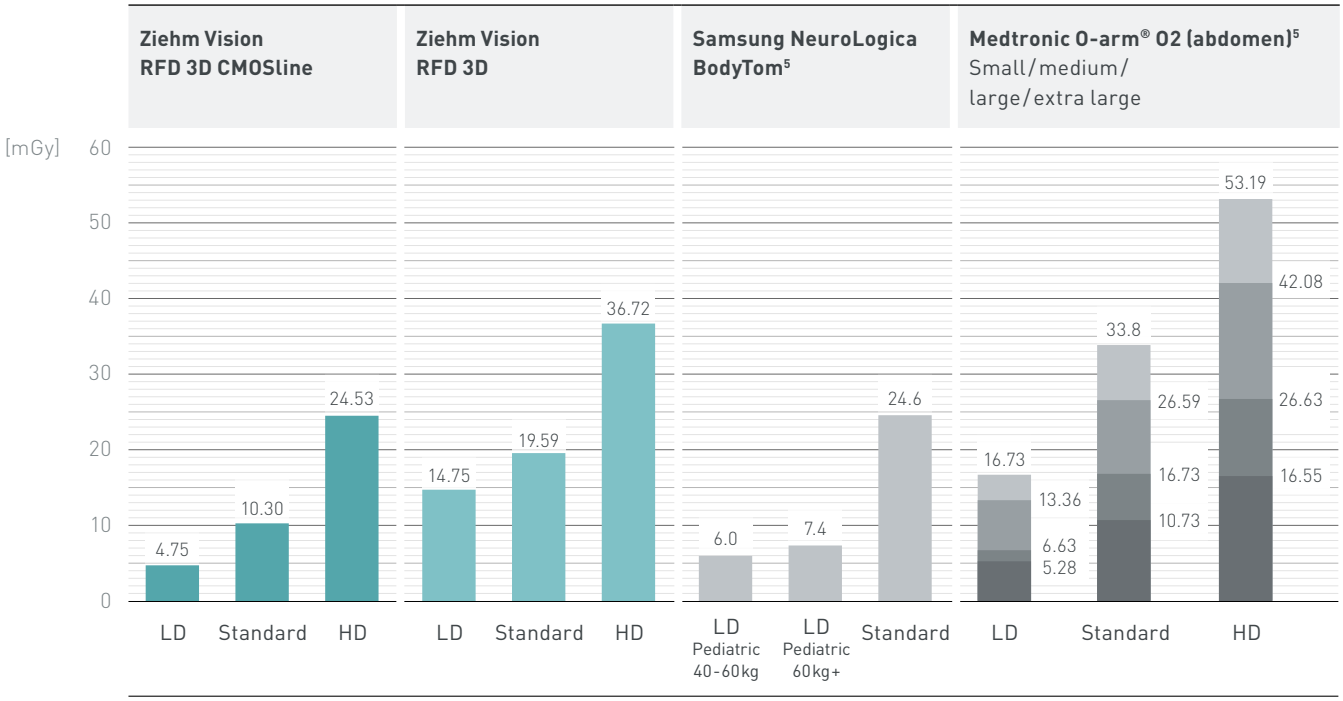
c. Dosimetry data for chest/thoracic spine protocols



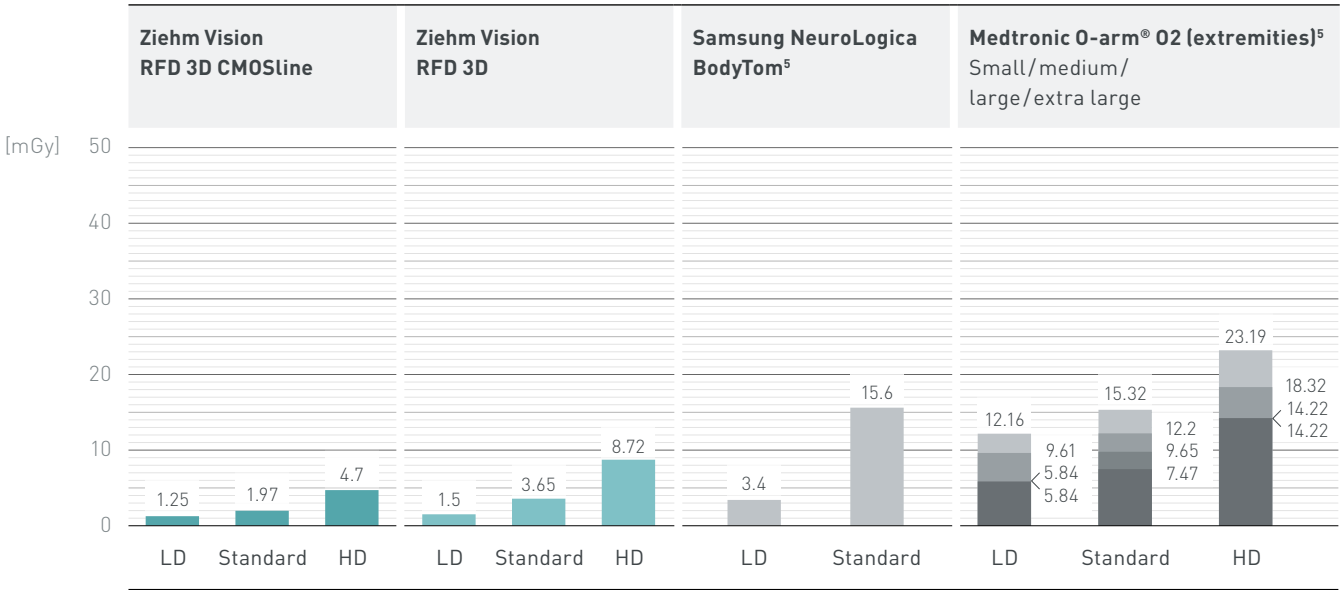
d. Dosimetry data for shoulder protocols



e. Dosimetry data for lumbar spine/pelvis protocols



f. Dosimetry data for extremities



Dosimetry comparison

For the first time, we are able to compare standardized measurements with the PMMA phantom and standardized measurement setups for the Ziehm Vision RFD 3D and the Ziehm Vision RFD 3D CMOSline, Samsung NeuroLogica BodyTom and Medtronic O-arm® O2. This makes it possible to eliminate patient variability, which usually influences dose levels the most. The systems from Ziehm Imaging in particular offer an intelligent, real-time dose regulation that is influenced by different patient anatomy and constitution. The setup with a standardized PMMA phantom makes a real comparison possible.

1. The dose measurements comparing the four different systems clearly depict the profound advantage the Ziehm Vision RFD 3D has over the other systems. Ziehm Imaging is strongly driving the awareness of ALARA principles in the industry and among customers. That is why the Low Dose mode is set as the default mode for all Ziehm Imaging systems. In addition, the CMOSline achieves higher spatial resolution due to smaller pixel sizes combined with lower noise levels. This makes interpolation unnecessary, especially in the magnification modes. Therefore, the Ziehm Vision RFD 3D CMOSline offers not only minimal dose levels but also exceptional image quality[6].

2. Especially in the anatomical programs for head, cervical spine and extremities, the Ziehm Vision RFD 3D in its enhanced CMOSline version shows by far the best results with better dose values in all different patient modifiers compared with the other systems.

3. Comparing the Ziehm Vision RFD 3D CMOSline with Samsung's NeuroLogica BodyTom, the Ziehm Imaging system shows better results in all compared cases except one (shoulder LD).[7]

4. The Ziehm Vision RFD 3D shows advantages in CTDI values in all cases compared with Medtronic's O-arm® O2 depending on the specialized patient program of the O-arm® O2. By comparing only the lowest-possible CTDI values in each program of Medtronic with the CTDI values of the Ziehm Vision RFD 3D, the C-arm shows better results in 67 of 76 available cases.[8]

5. In those programs where the Ziehm Vision RFD 3D shows higher CTDI values, the values are comparable to those values of the other systems. Especially in the critical trunk area, the Ziehm Vision RFD 3D is able to invest higher dose values for obese patients to provide an optimized penetration and therefore improved image quality. Further, to fulfill the need of sufficient image quality at the lowest-possible dose in obese patients, Ziehm Imaging offers additional dose levels for those challenging patient anatomies. But here as well, the intelligent dose regulation algorithms ensure optimized dose levels for each individual anatomy, depending on patient size, weight, constitution and scanned area as well as scan projections (AP or lateral projection). This is made possible by the real-time, patient-unique regulation strategy that allows different mA levels within one modifier (Pediatric/Low Dose, Adult, Obese patient). This is why the Ziehm Vision RFD 3D manages with only three different modifiers, as mA levels will be adapted to the optimum automatically and in a manner unique to the patient. As this is done automatically by the system and does not have to be set by the user, it provides a profound advantage compared with other intraoperative 3D imaging solutions in which staff variability complicates the correct use of the system and therefore the correct dose.

Image quality results

In addition to the dosimetry comparisons based on physical conditions, we also managed to achieve an exemplary image quality comparison with an anthropomorphic X-ray head phantom for high-contrast imaging on all three systems. For those high-contrast procedures, the differentiation between metal, bone and soft tissue is pivotal. The following images show the image quality of the three different systems. Image captures show the dose results of the measurements for the 16 cm CTDI phantom.

Ziehm Vision RFD 3D CMOSline (head, resolution 512^3 voxel)

Low Dose, $CTDI_{vol16}$ 1.06 mGy

Standard, $CTDI_{vol16}$ 1.42 mGy

HD, $CTDI_{vol16}$ 3.67 mGy

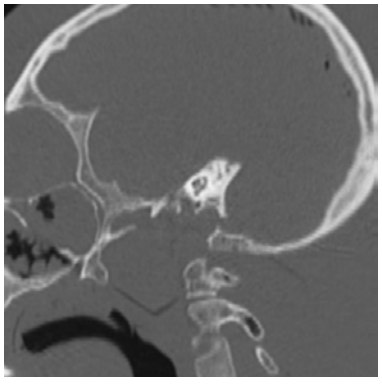
Medtronic O-arm® O2 (head, resolution 512 x 512 x 192 voxel)

Low Dose, small, $CTDI_{vol16}$ 5.96 mGy

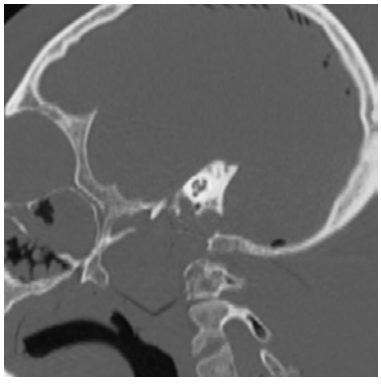
Standard, medium, $CTDI_{vol16}$ 15.71 mGy

HD 3D, medium, $CTDI_{vol16}$ 23.79 mGy

Samsung NeuroLogica BodyTom (head, resolution: LD Pediatric 512 x 512 x 208 voxel, Standard 512 x 512 x 400 voxel)



Low Dose, (14 yrs.+), $CTDI_{vol16}$ 11.7 mGy



Standard, $CTDI_{vol16}$ 39.6 mGy

Image quality comparison

The images show clearly that all three systems offer a comparable image quality and allow a clear differentiation of finest bone structures and soft tissue in the head. Furthermore, boundaries between cortical bone structures and the cancellous bone can also be differentiated as well as hollow spaces in the sinus cavity.

The high-contrast characteristic is provided by all three different systems but variations between image impression and homogeneity arise from different dose levels. Comparing the dose levels of those three exemplary phantom images ($CTDI_{vol16}$ value for standard 3D mode[9]: Ziehm Vision RFD 3D CMOSline: 1.42 mGy; Medtronic O-arm O2: 15.71 mGy; Samsung NeuroLogica BodyTom: 39.6 mGy), the data shows that comparable image quality does not result in comparable dose levels. As a result, the conclusion can be drawn that the Ziehm Vision RFD 3D CMOSline works strictly according to ALARA principles, offering sufficient image quality at the lowest-possible dose.

Conclusion

The Ziehm Vision RFD 3D offers unprecedented performance across the most varied and challenging application spectrum and can be seen as one of the most important and dose-saving alternatives in the field of mobile intraoperative 3D imaging systems. In addition, the Ziehm Vision RFD 3D CMOSline comes with an enhanced version of our comprehensive SmartDose concept. A newly developed dose-saving technology called Beam Filtration[10] supports the latest improvements in our enhanced CMOS imaging chain, thus enabling an exceptional reduction in the skin entrance dose. As a result, the Ziehm Vision RFD 3D CMOSline delivers excellent image quality with a lower dose, which is also confirmed by our customers:

"Compared with systems with comparable image quality such as Medtronic's O-arm, the Ziehm Vision RFD 3D has superior OR usability and advanced radiation dose control, which benefits patients, surgeons and staff alike. The excellent image quality results in increased patient safety. In addition, the ideal usability gives improved surgical efficiency. Ziehm Imaging's dramatically superior price-performance ratio allows radiology purchasing decision-makers to get this technology in the hands of doctors and realize immediate return on investment," said S. Raymond Golish, MD PhD MBA, Chief Quality Officer at Jupiter Medical Center in Palm Beach, Florida, USA.

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[1] CMOSline represents a system configuration that is based on a Ziehm Imaging CMOS flat-panel detector.
[2] Information on calibration is available on request.
[3] Serial number is traceable and available on request.
[4] For 20 cm field of view, the cylinder has a diameter of 212 ± 1 mm and a length of 160 ± 1 mm
[5] The programs and settings used were in accordance with the respective manufacturer's recommendations regarding the applied applications.
[6] Based on a clinical evaluation for the anatomical program Head, see chapter "Image quality results". Data on file, results may vary.
[7] Case means patient modifier in a protocol; 4 protocols including 2 modifier comparing LD and Standard and 2 protocols including 3 modifier comparing LD of Ziehm Vision RFD 3D with LD 30-60 kg and LD 60 kg+ of Samsung's NeuroLogica BodyTom.
[8] Case means patient modifier in a protocol with different patient size; 5 protocols including 3 modifier à 4 patient sizes (cervical spine protocol, chest/thoracic spine protocol, shoulder protocol, spine/pelvis protocol, extremities protocol with modifier Low Dose, Standard, HD in the patient sizes small, medium, large and extra large) and 1 protocol including 4 modifier à 4 patient sizes (head protocol with modifier Low Dose, Standard, HD3D and Enhanced 3D in the patient sizes small, medium, large and extra large) result in 76 cases.
[9] It can be assumed that the absorption with a 16 cm PMMA CTDI phantom adequately represents the head phantom.
[10] The technology Beam Filtration reduces dose exposure for all CMOSline systems in comparison with conventional filtration techniques (status before September 2017). Data on file. Results may vary.