

Innovation, tested and proved:

Reproducibility and standardization

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Introduction

JAMES is a patented device that supports an optimal position of a patient's knee during standing knee acquisitions. It applies not only for joint space analyses but also for visual assessments.



ISO 13485 certified

The reproducibility is essential for follow-up studies. If the correct and consistent acquisition perspective isn't granted for two or more images, the likelihood for wrong analysis results or misinterpretations is significantly increased. Therefore the joint space analysis isn't such a reproducible tool in the medical world these days as it could be with JAMES.

James Mono & Duo

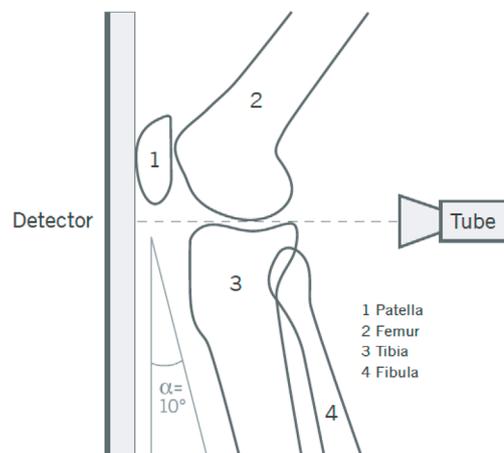
The foundation of the device is the ground plate. The foot element can be docked-in to be able to perform single knee captures. The foot elements can be easily adjusted.

foot element adjustments:

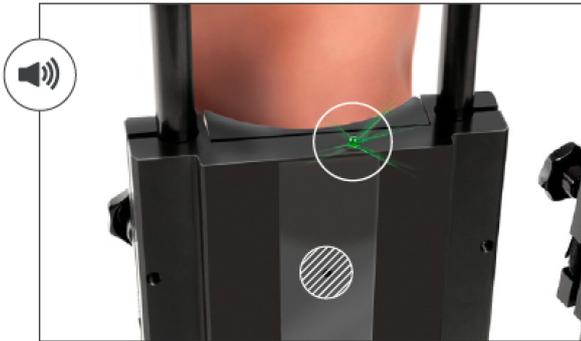
- foot rotation angle: -15° to 15° in 5° steps
- tibia inclination angle: 0° , 10° and 15°
- sensor module height: 27 to 42 cm to upper edge

The foot rotation angle ensures an individually natural standing position for the patient. Most people have an outward rotation of 5° while standing.

The correct tibia inclination angle is essential for an image acquisition that is parallel to the tibia plateau. The human tibia plateau has a standard slope of 10° .



The sensor module height can be adjusted, relative to the patient's body height. It features two tactile sensors which only activate the module when the patient is in the correct position.



If activated, acoustical (pulsed beep sound) and visual (colored LED light) feedback is perceptible. The two foot elements have a different pitch level and LED color to be able to tell if one or both legs are correctly positioned.

Proved reproducibility

To collect data for an improved reproducibility, clinical investigations were performed in the orthopedic office of the CORPUS clinic, Vienna. 10 different sets of test subjects were included. Each knee was examined two times with JAMES and two times without JAMES. Between the acquisitions, short pauses were included. The test subjects had to walk a few steps after each examination. The measurement setup was rearranged every time, to ensure realistic daily routine.

The basis parameter for the evaluation was the JSA (joint space area), which was determined using the i3A-JSX software. The JSA is very sensitive against perspective changes and therefore best suited for a comparison of capturing methods.

The results

The result clearly endorse the use of JAMES:

examination errors	
without JAMES	with JAMES
28,18 % (maximum)	2,73 % (maximum)
6,19 % (average)	0,83 % (average)

As mentioned, JAMES ensures a position that is best for an objective visual and computed JSA analysis. The optimal position is concluded from international studies [1, 2, 3]. The investigation also shows that free standing knee acquisitions can lead to results that vary approximately 30% to the results from the correct position.

JAMES grants a reproducibility rate accuracy of 99,17 % on average. The progression of Osteoarthritis is so rapid in most cases, that the 0,83 % of uncertainty hardly interferes with follow-up studies. The 6,29 % without JAMES does potentially falsify the assessment.

Data overview

mono:

Weight: appr. 6 kg (13,2 lb)
Dimensions (WxHxD): 240 x 440 x 500 mm
Side plate (WxD): 200 x 400 mm

duo:

Weight: appr. 9,8 kg (21,6 lb)
Dimensions (WxHxD): 440 x 440 x 500 mm

References

- [1] B.C. Didia, B.N.R. Jaja; "Posterior Slope of Tibial Plateau in Adult Nigerian Subjects" (2009)
- [2] U.Malzer P.Schuler; "Die Komponentenausrichtung beim Oberflächenersatz des Kniegelenkes" (1998)
- [3] S. Şenışık, C. Özgürbüz; „POSTERIOR TIBIAL SLOPE AS A RISK FACTOR FOR ANTERIOR CRUCIATE LIGAMENT RUPTURE IN SOCCER PLAYERS" (Dec 2011)

