TR522 – PD055 Forearm Pad vs Gel Pad Aluminium Equivalence Verification

PD055 – Adept Forearm Pad

Document Details

Current Version	6.0
Approved Version	6.0
Approval Date	8/02/2022 8:12:00 AM
Approved By	Matt Lazenby

ADEPT Medical Supporting you

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Abstract: This report verifies PD055 – Adept Forearm Pad Aluminium Equivalence data in comparison with another typical industry Gel Pad, measured at 100KvP. It identified the following aluminium equivalence values:

Item	***Aluminium Equivalence (mm) @ 100 kV***
Typical Medical Gel Pad - 10mm Thick	1.21 mm**
Adept Medical Forearm Pad - Rev A (M3335)	0.22 mm

Current Version	9.0
Approved Version	6.0
Approval Date	10/12/2020 10:11:00 AM
Print Date	Tuesday, 08 February 2022

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Contents

Current Version	3.0
Approved Version	3.0
Approval Date	20/05/2020 12:14:14 p.m.
Print Date	Tuesday, 08 February 2022

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1. Title

Product Verification Report – PD055 – Adept Forearm Pad

2. Product Development Number

PD055 – Adept Forearm Pad

3. Name of Person Responsible for Document Preparation

Matt Lazenby

4. Scope & Objective

This report describes the lab test taken by an independent medical physicist with analysis and interpretation to the show aluminium equivalence of PD055 – Adept Forearm Pad in comparison to a typical industry standard Gel pad. Both of which can be used for managing pressure injury to the Forearm during radial artery access procedures.

The independent report by the medical physicist is stored on Adept Medicals document database and has the internal reference 'Test report 22-01-13 Al equivalence with narrow beam geometry'.

The intent of this report is to present Aluminium Equivalence data measured by an independent medical physicist on the Adept Forearm Pad and another typical medical industry 'gel' pad. It presents the aluminium equivalence of 2 solutions for patient pressure injury management of a forearm when resting in a medical arm support used for radial artery access.

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5. Product Details

1. Medical Forearm Gel Pad*

Materials: Polyurethane low durometer core with outer foil.

Dimensions: 380mm x 150mm x 10mm Thickness

Supplier: Undisclosed

2. Adept Medical - Forearm Pad – Rev A

Materials: Polyurethane upper foil with Viscoelastic polyurethane memory foam core and Polyethylene lower layer.

Dimensions: 300mm x 150 x 16mm Thickness
Part No#: M3335

Supplier: Adept Medical Ltd, New Zealand

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6. Verification Method

Testing was conducted by an independent Medical Physicist in New Zealand, full report available or request. **

Test method:

The test method used here follows general guidance provided in IEC 61331-1 (2014) for determination of aluminium equivalence using a narrow beam geometry. The narrow beam set-up used had the following dimensions:

- X-ray tube focus – detector distance set to 80 cm.
- Sample – detector face distance of 30 cm.
- X-ray beam collimated to 2.5 cm x 2.5 cm in the sample plane.

Sample measurements were made at approximately central positions on each of the samples supplied.

Test equipment:

X-ray system used:

Philips Optimus 50 x-ray generator S/N 0801237 connected to a Philips SRO 2550 x-ray tube S/N 260925, with a total filtration of 2.9 mm Al equivalent.

The test kilovoltage used in this report was within 5 % of the nominal kilovoltage of 100 kV specified in IEC 60601-2-54, and the beam quality measured was 3.6 mm Al HVL. This was measured with an RTI Piranha model 657 x-ray meter (details provided below).

Radiation detector used:

Attenuation measurements were performed with an RTI dose probe S/N 1902053 connected to an RTI Piranha model 657 x-ray meter S/N CB2-19050128. This equipment was calibrated on 11 July 2021.

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Traceability: Aluminium equivalence for the test samples is determined by comparison of measured air kerma attenuation data against that of reference aluminium foils. The reference aluminium foils were manufactured by PTW-Freiburg, Germany, and have a purity of at least 99.5 %. Filter details are summarised below:

PTW filter ID	Serial number	Thickness (mm)
T43026.1.002	000141	0.096
T43026.1.003	000299	0.203
T43026.1.003	000300	0.203
T43026.1.004	000150	0.511
T43026.1.005	000141	0.997
T43026.1.006	000349	2.010
T43026.1.006	000350	2.018

The thickness of the aluminium foils is stated by the manufacturer and has been independently verified with the use of calibrated digital calipers which were manufacturer calibrated in October 2018.

7. Measurement Instrument Used

Test equipment: X-ray system used:

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8. Justification of Sample Size

Only one sample of each part was supplied for testing. Multiple readings were taken of each sample forearm pad and the mean value calculated where different results were observed.

- Controlled dimensions and visual requirements.
- The risk associated with the presentation of the results.

9. Results

The table below gives the measured Aluminium Equivalence for each item and material description tested at 100kVp using test equipment specified in section 8 and methodology in section 7.

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$$Material\ Sample\ thickness\ x\ Gradient = \ Aluminium\ Equivalence$$

Item	***Material***	***Location***	***Material Thickness***	***Gradient***	***Aluminium Equivalence @ 100 kVp***
Typical Medical Gel Pad*	Polyurethane low durometer core with outer foil.	Measurement taken at 2 locations central to the pad width at each end.	10mm	0.121	1.21 mm**
Adept Medical - Forearm Pad – Rev A (Part No#: M3335)	Polyurethane upper foil with Viscoelastic polyurethane memory foam core and Polyethylene lower layer.	Measurement taken at 2 locations central to the forearm rest channel.	16mm	0.0138	0.22 mm**

10. Comments & Analysis

Aluminium Equivalence values are used to describe radiolucency when referencing medical equipment used with X-ray imaging.

The 16mm thick foam based Forearm Pad was 18% of the Aluminium Equivalence value of the 10mm thick polyurethane medical Gel Pad.

11. Conclusion

Based on the comment and analysis in section 11, the measured Aluminium Equivalence for the Adept Medical Forearm Pad (Rev A) is 0.22mm, and significantly better for medical X-ray imaging when considering artefact, compared to the polyurethane Gel pads, typically ~10mm thick.

* Supplier details of Medical Gel pad available on request.

** Full report by independent physicist is available on request.

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