



Form 391 – Bolus Compatibility Evaluation Report

1 Purpose

- 1.1 The purpose of this evaluation is to determine whether the bolus material provided by 3rd party vendor is compatible with AlignRT.
- 1.2 This evaluation does not aim to investigate, comment on, or make claims on immobilization rigidity or patient alignment reproducibility.

2 Bolus Type Under Evaluation

Vendor:	<i>Innovative Oncology Solutions</i>
Bolus Name:	<i>Clearsight Bolus</i>
Ordering Info:	<i>Ref B-05-18-01</i>
Bolus Thickness:	<i>0.57cm (equivalent of 0.50cm of water)</i>
Color:	<i>Clear</i>
Material:	<i>Polymer Gel</i>
Vision RT Employee:	<i>Vicky Howard, Clinical Physicist, MS, MBA, DABR</i>
Date of Evaluation:	<i>18 February 2020</i>
Vision RT Camera Gen:	<i>Gen 4</i>

3 Special Instructions

Cleaning Instructions: Wash with soap and water, or use hospital approved non-alcohol based disinfectant and rinse thoroughly with water to remove residue of cleaner.

4 Training Techniques that Customers Receive

See attached Clearsight Bolus datasheet.



Clearsight Bolus

REF

B-05-18-01

QTY 1

[1] Reusable, non-sterile, polymer gel bolus sheet.

Thickness:
0.57cm (equivalent to 0.50cm of water)
Density:
0.87±0.02 g / cm³


Rx only

Manufactured for:



Clearsight RT LLC
P.O. Box 62612
Durham NC 27715

LOT 2018-001

 Polygel LLC
30 Leslie Court
Whippany, NJ 07981

General Instructions & Information:

Highly transparent, reusable polymer gel bolus. Product is non-sterile.

Bolus thickness:

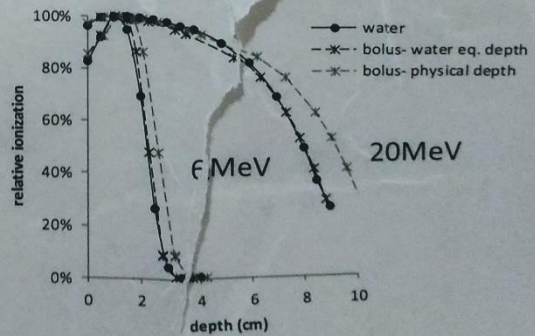
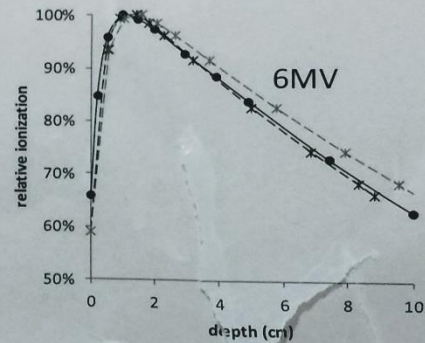
0.5cm water equivalent
(0.57±0.05cm physical thickness)

Features:

- Washable & reusable
- Conforms to patient contour
- High transparency for visualization through bolus of treatment field alignment to light field, crosshairs, and bolus adherence to skin.

Density: 0.87±0.03 g/cm³

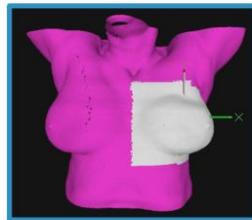
Attenuation: Bolus sheets have a "water equivalent" thicknesses, which is the product of the physical thickness and the bolus / water density ratio. When using water equivalent thickness, depth dose curves of bolus align within 2% or <1mm of the depth ionization curves of water for 6MV photons, 6MeV electrons, and 20MeV electrons. Hence the "water equivalent" thickness should be utilized when electron density is not accounted for in the dose calculation.



Cleaning Instructions: Wash with soap and water, or use hospital approved non-alcohol based disinfectant and rinse thoroughly with water to remove residue of cleaner. Gas sterilization, autoclaving, and use with automatic washing machines and dryers are NOT recommended.

5 AlignRT ROI Instructions for Breast

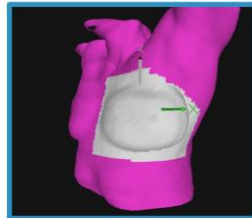
0004-1027 Flipbook Drawing an Isocenter Region of Interest for Tangent breast and Chest wall:



Include:

- Breast tissue and chest wall
- Stable surface such as mid-sternum and upper ribs
- Lateral aspect of the breast tissue extending to the midcoronal plane

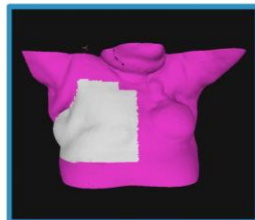
NOTE: THIS IS AN APPROPRIATE ROI FOR A TANGENT DEEP INSPIRATION BREATH HOLD. THE FREE BREATHING AND BREATH HOLD SURFACES SHOULD HAVE SIMILAR ROI'S.



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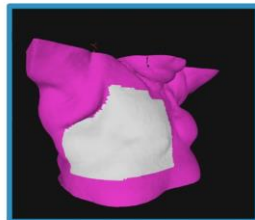
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Include:

- Breast or chest wall
- Lateral aspect of breast/ chest wall tissue to the midcoronal plane



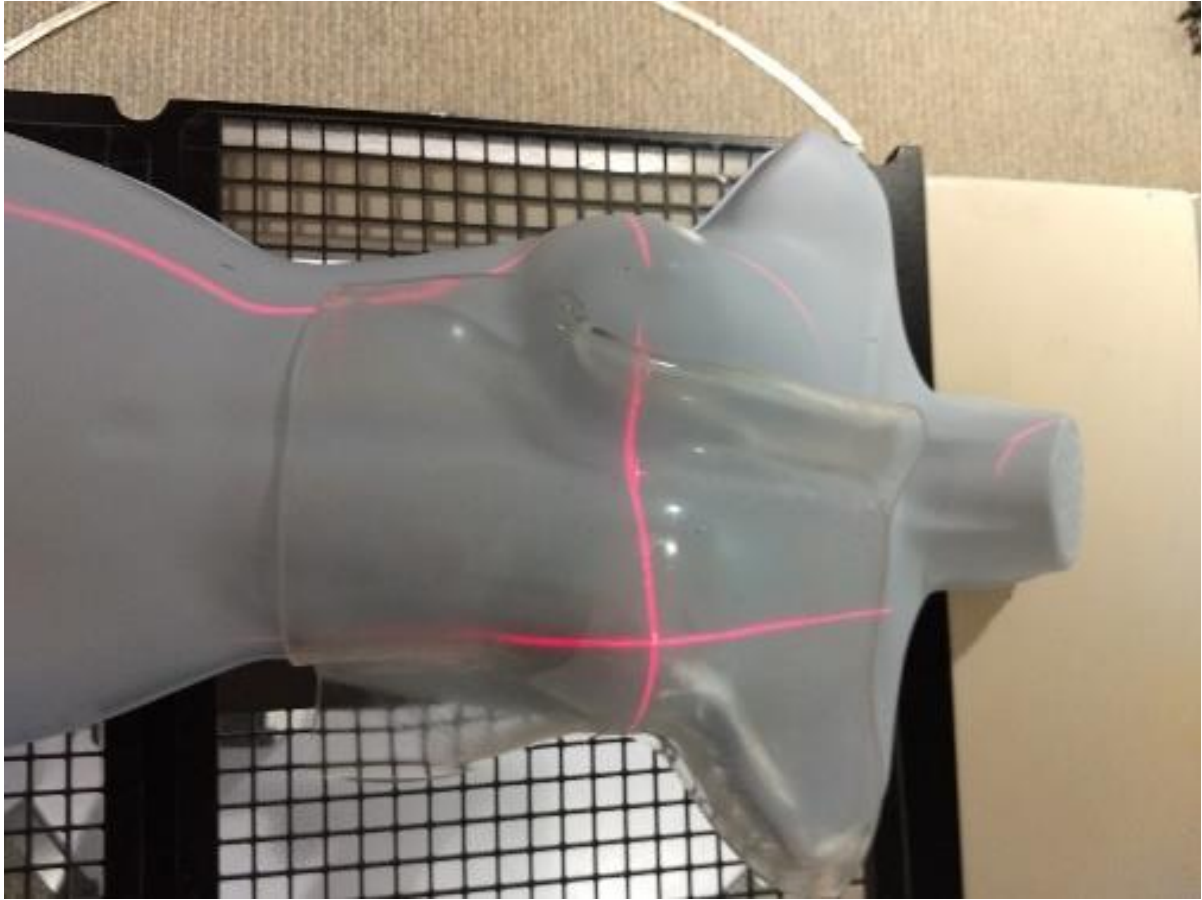
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6 Evaluation

Photos of the bolus material placed on the test phantom:



[Insert photo(s) here]

6.1 Results

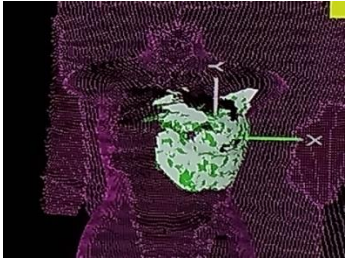

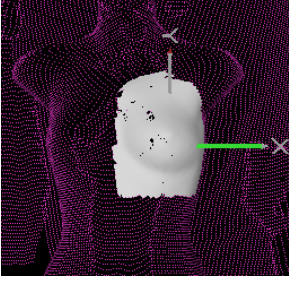
To determine the compatibility of bolus with Vision RT SGRT surface reconstruction, we shall capture a Reference Surface of the phantom without the bolus and a second Reference Surface with the bolus and visually compare the amount of data that is reconstructed.

We will also look at how ambient room lighting typical to clinical environments impacts these results including:

- dark room lighting (lights off with minor background lighting from computer screens)
- medium room lighting (recessed lighting only)
- bright room lighting

Skin tone used for this study will reflect the properties of the bolus rather than skin tone of patient

Data is captured in the chart below.

Room lighting	SGRT Reference without Bolus	SGRT Reference with Bolus	Pass?
Dark			Yes
Medium			Yes
Bright			Yes

Additional Comments if applicable:

The AlignRT system was able to capture an acceptable reference surface with the bolus placed and the ROI was adequately propagated onto the captured surface.

An additional evaluation was performed to investigate the impact the transparent properties of this material has on our surface reconstruction depth. We placed the bolus material on a flat surface and using the SSD measurement tool in AlignRT, we measured depth of surface reconstruction following AlignRT surface captures with and without a thin piece of paper tape on the outer surface.





Scenario	Result (AP SSD (CM))
Calibration plate surface (no bolus)	92.54
Plate + bolus (no tape)	92.31
Difference to plate	0.23
Plate + bolus + tape	92.08
Difference to plate	0.46
Difference with and without tape	0.23

Conclusion: For translucent bolus types such as this, AlignRT projects about 0.23cm into the surface when generating the surface used for reconstruction. If the customer wants to measure SSD to the surface of the bolus with greater accuracy than 2mm, they should be trained to use paper tape or other suitable material on the surface.

7 Recommendations to Bolus Vendor

N/A



8 Summary

Does the surface of the bolus material work suitably well with Vision RT SGRT surface reconstruction?

YES **NO**


If no, please elaborate under which conditions the bolus fails to meet ROI requirements below:

[Detail fail criteria]

9 Approvals

Completed by [To be signed by evaluator]

Vicky Howard
(Name) Clinical Physicist
(Job Title) 28 April 2020
(Date)

DocuSigned by:

 Signer Name: Vicky Howard
 Signing Reason: I approve this document
 Signing Time: 28 April 2020 | 10:39:13 AM PDT
 4298BAA5ACEF4C7B89B8CC81AFF3FF38

Reviewed and Approved by [To be signed by Senior Director of Product Management]

Ben Waghorn
(Name) Sr. Director of Product Management
(Job Title) 28 April 2020
(Date)

DocuSigned by:

 Signer Name: Ben Waghorn
 Signing Reason: I approve this document
 Signing Time: 28 April 2020 | 10:51:47 AM PDT
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