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

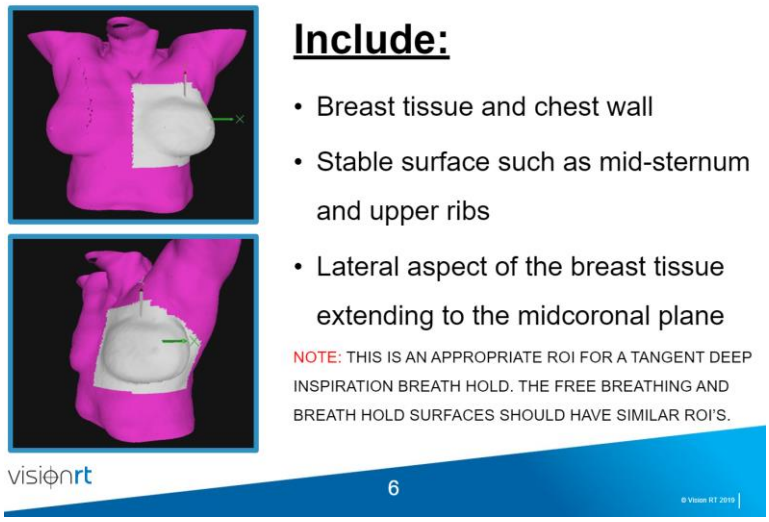
Vendor:	
Bolus Name:	*Mesh Bolus*
Ordering Info:	*n/a*
Bolus Thickness:	
Color:	*white*
Material:	*Brass mesh*
Vision RT Employee:	*Vicky Howard, Clinical Physicist, MS, MBA, DABR*
Date of Evaluation:	*18 February 2020*
Vision RT Camera Gen:	*Gen 4*

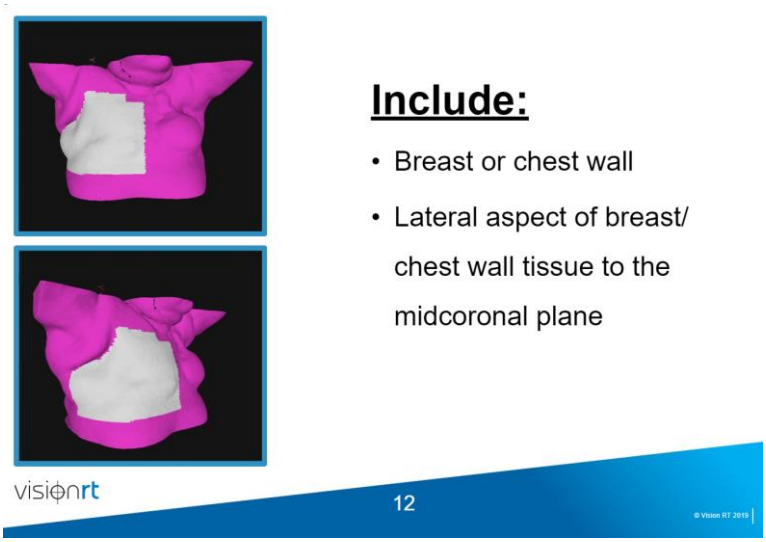
3 Special Instructions

4 Training Techniques that Customers Receive

5 AlignRT ROI Instructions for Breast

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





6 Evaluation

Photos of the bolus material placed on the test phantom:

[Insert photo(s) here]

6.1 Results

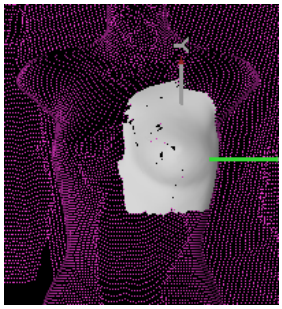
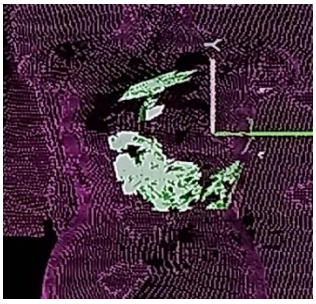
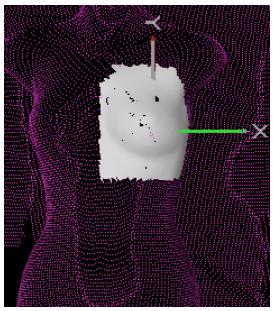
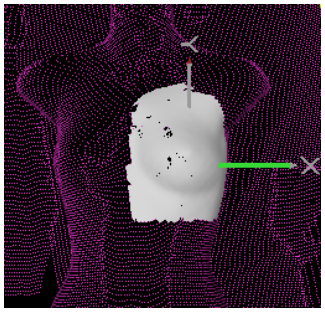
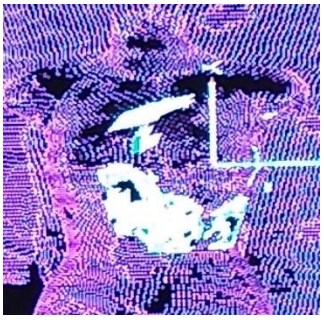
To determine the compatibility of bolus with Vision RT SGRT surface reconstruction, we shall capture a Reference Surface of the phantom without the bolus and a second Reference Surface with the bolus and visually compare the amount of data that is reconstructed.

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	ROI Propagation pass at 80% threshold?
Dark			**No**
Medium			**No**
Bright			**No**

Additional Comments if applicable:

7 Recommendations to Bolus Vendor

Although the ROI did not fully propagate onto the captured surface, the AlignRT cameras were able to see the majority of the surface for the medium and bright light settings as depicted by the wireframe screenshots above. In this case, the customer could modify the ROI to fill in the missing reconstructed sections of the ROI propagation on the bolus surface capture for more accurate patient monitoring with bolus.

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)		
08 April 2020		
(Date)	(Signature)	DocuSigned by: Vicky Howard Signer Name: Vicky Howard Signing Reason: I approve this document Signing Time: 08 April 2020 | 1:37:19 PM 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)		
08 April 2020		
(Date)	(Signature)	DocuSigned by: Ben Waghorn Signer Name: Ben Waghorn Signing Reason: I approve this document Signing Time: 08 April 2020 | 4:05:52 PM EDT *Add/remove signature blocks as required* 57F2C8AC76754E57AB7266B01DFC029D