



March 19, 2026

Radformation, Inc.
Jennifer Wampler
Senior Regulatory Affairs Specialist
261 Madison Ave.
9th Floor
New York, New York 10016

Re: K260509
Trade/Device Name: AutoContour Model RADAC V5
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: February 13, 2026
Received: February 17, 2026

Dear Jennifer Wampler:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, reading "Lora D. Weidner". The signature is fluid and cursive. A large, light blue "FDA" watermark is visible in the background behind the signature.

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260509

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Please provide the device trade name(s).

?

AutoContour Model RADAC V5

Please provide your Indications for Use below.

?

AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) Summary - AutoContour Model RADAC V5

This 510(k) Summary has been created per the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR Part 807.92.

1. Submitter's Information

Table 1: Submitter's Information	
Submitter's Name:	Kevin Robinson
Company:	Radformation, Inc.
Address:	261 Madison Avenue, 9th Floor New York, NY 10016
Contact Person:	Kevin Robinson VP of Regulatory Affairs, Radformation
Phone:	585-500-6996
Fax:	—
Email:	regulatory@radformation.com
Date of Summary Preparation	2/13/2026

2. Device Information

Table 2 : Device Information	
Trade Name:	AutoContour Model RADAC V5
Common Name:	AutoContour, AutoContouring, AutoContour Agent, AutoContour Cloud Server
Classification Name:	Class II
Classification:	Medical image management and processing system
Regulation Number:	892.2050
Product Code:	QKB
Classification Panel:	Radiology

3. Predicate Device Information

Predicate Device

AutoContour Model RADAC V5 (Subject Device) makes use of its prior submissions - AutoContour Model RADAC V4 (K242729) as the Predicate Device. The Indications for Use, patient population, functionality and technical components of this Predicate Device remain unchanged in AutoContour Model RADAC V5. This submission is intended to build on the functionality and technological components of the 510(k) cleared AutoContour Model RADAC V4.

Reference Device

AutoContour Model RADAC V5 also makes use of Limbus Contour (K241837) as a reference device for the new structure models from Limbus Contour that have been integrated into this version. Limbus Contour is a Radformation product.

4. Device Description

As with AutoContour Model RADAC V4, the AutoContour Model RADAC V5 device is software that uses DICOM-compliant image data (CT or MR) as input to: (1) automatically contour various structures of interest for radiation therapy treatment planning using machine learning based contouring. The deep-learning-based structure models are trained using imaging datasets consisting of anatomical organs of the head and neck, thorax, abdomen, and pelvis for adult male and female patients, (2) allow the user to review and modify the resulting contours, and (3) generate DICOM-compliant structure set data that can be imported into a radiation therapy treatment planning system.

AutoContour Model RADAC V5 consists of 3 main components:

1. A .NET client application designed to run on the Windows Operating System, allowing the user to load image and structure sets for upload to the cloud-based server for automatic contouring, perform registration with other image sets, as well as review, edit, and export the structure set.
2. A local “agent” service designed to run on the Windows Operating System that is configured by the user to monitor a network storage location for new CT and MR datasets that are to be automatically contoured.
3. A cloud-based automatic contouring service that produces initial contours based on image sets sent by the user from the .NET client application.

5. Indications for Use

AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.

6. Technological Characteristics

AutoContour RADAC V5 (Subject Device) makes use of its prior submission - AutoContour RADCC V2 (K242729), a Predicate Device. The Indications for Use, patient population, functionality, and technical components of this Predicate Device remain unchanged in AutoContour RADAC V5. The main UI outputs are equivalent to the Predicate Device as well, allowing the user to properly visualize and analyze the calculations. This submission is intended to build on the functionality and technological components of the 510(k) cleared AutoContour RADAC V4.

Table 11: Substantial Equivalence AutoContour Model RADAC V5 vs. AutoContour Model RADAC V4 (K242729)			
Characteristic	Subject Device: AutoContour Model RADAC V5	Predicate Device: AutoContour Model RADAC V4 (K242729)	Reference Device Limbus Contour (K241837) Used for Verification
AutoContour vs. Predicate Devices: Technological Characteristics			
Indications for Use	AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning	AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning	Limbus Contour is a software-only medical device intended for use by trained radiation oncologists, dosimetrists, and physicists to derive optimal contours for input to radiation treatment planning.
Target Population	Any patient type for whom relevant modality scan data is available.	Any patient type for whom relevant modality scan data is available.	Any patient type for whom relevant modality scan data is available.
Energy Used and/or Delivered	None – software-only application. The software application does not deliver or depend on energy delivered to or from patients	None – software-only application. The software application does not deliver or depend on energy delivered to or from patients	None – software-only application. The software application does not deliver or depend on energy delivered to or from patients
Intended users	Trained radiation oncology personnel	Trained radiation oncology personnel	Trained radiation oncology personnel
Design: Data Visualization/Graphical User Interface	Contains both an automated processing component and Data Visualization / Graphical User Interface	Contains both an automated processing component and Data Visualization / Graphical User Interface	Contains an automated processing component.
Design: View manipulation and Volume rendering	Window and level, pan, zoom, cross-hairs, slice navigation, fused views.	Window and level, pan, zoom, cross-hairs, slice navigation, fused views.	None

Design: Image registration	Manual and Automatic Rigid registration. Automatic Deformable Registration	Manual and Automatic Rigid registration. Automatic Deformable Registration	None
AutoContour vs. Predicate and Reference: Model Comparison			
Regions and Volumes of interest (ROI)	CT or MR input for contouring of anatomical regions: Head and Neck, Thorax, Abdomen and Pelvis. Machine learning based contouring of 420 CT-based and 62 MR-based models and manual ROI manipulation CT Models: • A_Aorta • A_Aorta_Asc • A_Aorta_Dsc • A_Brachiocephls • A_Carotid_L • A_Carotid_R • A_Celiac* • A_Circumflex_L • A_Coronary_2d_R • A_Coronary_L • A_Coronary_R • A_LAD • A_Mesenteric_S* • A_Pulmonary* • A_Subclavian_L • A_Subclavian_R • Atrium_L* • Atrium_R* • AV_Node • Barrigel™ • BileDuct_Common • Bladder* • Bladder_CBCT* • Bladder_F* • Body* • Body+Mask* • Bone_Hyoid* • Bone_Ilium* • Bone_Ilium_L* • Bone_Ilium_R* • Bone_Ischium_L* • Bone_Ischium_R* • Bone_Mandible* • Bone_Pelvic* • Bone_Pterygoid_L • Bone_Pterygoid_R	CT or MR input for contouring of anatomical regions: Head and Neck, Thorax, Abdomen and Pelvis. Machine learning based contouring of 260 CT-based and 35 MR-based models and manual ROI manipulation CT Models: • A_Aorta • A_Aorta_Asc • A_Aorta_Dsc • A_Brachiocephls • A_Carotid_L • A_Carotid_R • A_Coronary • A_LAD • A_Pulmonary • A_Subclavian_L • A_Subclavian_R • Atrium_L • Atrium_R • Bladder • Bladder_F • Bone_Hyoid • Bone_Ilium_L • Bone_Ilium_R • Bone_Mandible • Bone_Pelvic • Bone_Skull • Bone_Sternum • Bone_Teeth • Bowel • Bowel_Bag • Bowel_Large • Bowel_Small • BrachialPlex_L • BrachialPlex_R • Brain • Brainstem • Breast_L • Breast_R • Breast_Prone • Bronchus • BuccalMucosa	CT or MR input for contouring of anatomical regions: Head and Neck, Thorax, Abdomen and Pelvis. CT Models • A_Aorta • A_Aorta_Base • A_Aorta_I • A_Aorta_I • A_Celiac • A_LAD • A_Mesenteric_S • A_Pulmonary • Atrium_L • Atrium_R • Bag_Bowel • Bag_Bowel_Extend • Bag_Bowel_Full • Bag_Bowel_S • Bladder • Bladder_CBCT • Bladder_HDR • Body • Body+Mask • Bone_Hyoid • Bone_Hyoid • Bone_Ilium_L • Bone_Ilium • Bone_Ilium_L • Bone_Ilium_R • Bone_Ischium_L • Bone_Ischium_R • Bone_Mandible • Bone_Pelvic • BoneMarrow_Pelvic • Bowel • Bowel_Bag • Bowel_Bag_Extend • Bowel_Bag_Full • Bowel_Bag_Superior • Bowel_Extend • Bowel_Full • Bowel_HDR • Bowel_S • Bowel_Superior • BrachialPlex_L • BrachialPlex_R • BrachialPlexs • Brain • Brainstem • Breast_Implant_L • Breast_Implant_R • Breast_L

• Bone_PubicSymphys* • Bone_Sacrum* • Bone_Skull • Bone_Sternum* • Bone_Teeth • Bowel • Bowel_Bag* • Bowel_Bag_F • Bowel_F • Bowel_Large • Bowel_Large_F • Bowel_Small • Bowel_Small_F • BrachialPlex_L • BrachialPlex_R • BrachialPlexs • Brain • Brainstem • Breast_Implant_L* • Breast_Implant_R* • Breast_L • Breast_Prone • Breast_R • Breast_RTOG_L* • Breast_RTOG_R* • Breast_Wire_L* • Breast_Wire_R* • Breasts_RTOG* • Bronchus • BuccalMucosa • Canal_Anal* • Canal_Anal_F* • Cardiac_Avoidance_Area • Carina • CaudaEquina • Cavity_Oral* • Cavity_Oral_Ext • Cerebellum* • Chestwall_2cm_L* • Chestwall_2cm_R* • Chestwall_Anat* • Chestwall_Anat_L* • Chestwall_Anat_R* • Chestwall_ESTRO_L • Chestwall_ESTRO_R • Chestwall_L • Chestwall_OAR • Chestwall_R • Chestwall_RC_L • Chestwall_RC_R • Clavicle_L* • Clavicle_R* • Cochlea_L • Cochlea_R • Colon_Sigmoid	• Carina • CaudaEquina • Cavity_Oral • Cavity_Oral_Ext • Chestwall_L • Chestwall_OAR • Chestwall_R • Chestwall_RC_L • Chestwall_RC_R • Clavicle_L • Clavicle_R • Cochlea_L • Cochlea_R • Colon_Sigmoid • Cornea_L • Cornea_R • Dental_Artifact • Duodenum • Ear_Internal_L • Ear_Internal_R • Esophagus • External • Eye_L • Eye_R • Femur_Head_L • Femur_Head_R • Femur_L • Femur_R • Femur_RTOG_L • Femur_RTOG_R • Foley_Balloon • GallBladder • Genitals_F • Genitals_M • GInd_Lacrimal_L • GInd_Lacrimal_R • GInd_Submand_L • GInd_Submand_R • GInd_Thyroid • HDR_Bladder • HDR_Bowel • HDR_Cylinder • HDR_Rectum • Heart • Heart_Prone • Hippocampus_L • Hippocampus_R • Humerus_L • Humerus_R • Iliac_Int_L • Iliac_Int_R • Iliac_L • Iliac_R • Kidney_L • Kidney_R	• Breast_R • Breasts • Bronchus • Canal_Anal • Canal_Anal_HDR • Carina • CaudaEquina • Cavity_Oral • Cerebellum • Chestwall • Chestwall_L • Chestwall_R • Chestwalls • Clavicle_L • Clavicle_R • Cochlea_L • Cochlea_R • Colon_Sigmoid • Colon_Sigmoid_HDR • Cornea_L • Cornea_R • Duodenum • Esophagus • Eye_L • Eye_R • Eyes • Femur_Head_L • Femur_Head_L_CBCT • Femur_Head_R • Femur_Head_R_CBCT • Femur_Heads • Gallbladder • GInd_Lacrimal_L • GInd_Lacrimal_R • GInd_Submand_L • GInd_Submand_R • GInd_Thyroid • GreatVes • Heart • Heart+A_Pulm • Hippocampus_L • Hippocampus_R • Humerus_L • Humerus_R • InternalAuditoryCanal_L • InternalAuditoryCanal_R • Kidney_L • Kidney_R • Kidneys • Larynx • Lens_L • Lens_R • Lips • Liver • LN_Ax_L1_L • LN_Ax_L1_R • LN_Ax_L2_L • LN_Ax_L2_R • LN_Ax_L3_L • LN_Ax_L3_R • LN_Ax_Sclav_L • LN_Ax_Sclav_R • LN_IMN_L
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• Colon_Sigmoid_F • Cornea_2d_L* • Cornea_2d_R* • Cornea_L • Cornea_R • CorpusCallosum • Cribriform • Dental_Artifact • Duodenum • Ear_Internal_L • Ear_Internal_R • Esophagus • External • Eye_L • Eye_R • Eyes* • Falx • Femur_Head_L • Femur_Head_R • Femur_L • Femur_L_CBCT* • Femur_R • Femur_R_CBCT* • Femur_RTOG_L* • Femur_RTOG_R* • Femurs_RTOG* • Foley_Balloon • GallBladder • Genitals • GInd_Lacrimal_L* • GInd_Lacrimal_R* • GInd_Submand_L • GInd_Submand_R • GInd_Thyroid* • GreatVessels* • HDR_Bladder • HDR_Bowel • HDR_Canal_Anal* • HDR_Colon_Sigmoid* • HDR_Cylinder* • HDR_Rec-Canal_MR • HDR_Rectum • HDR_Ring* • HDR_Urethra* • Heart* • Heart_Prone • Heart+A_Pulm* • Hippocampus_L • Hippocampus_R • Humerus_L • Humerus_R • Iliac_Int_L • Iliac_Int_R • Iliac_L • Iliac_R	• Kidney_Outer_L • Kidney_Outer_R • Larynx • Larynx_Glottic • Larynx_NRG • Larynx_SG • Lens_L • Lens_R • Lips • Liver • LN_Ax_L • LN_Ax_L1_ESTRO_L • LN_Ax_L1_ESTRO_R • LN_Ax_L1_L • LN_Ax_L1_R • LN_Ax_L2_ESTRO_L • LN_Ax_L2_ESTRO_R • LN_Ax_L2_L • LN_Ax_L2_L3_L • LN_Ax_L2_L3_R • LN_Ax_L2_R • LN_Ax_L3_ESTRO_L • LN_Ax_L3_ESTRO_R • LN_Ax_L3_L • LN_Ax_L3_R • LN_Ax_R • LN_IMN_L • LN_IMN_R • LN_IMN_RC_L • LN_IMN_RC_R • LN_Inguinofem_L • LN_Inguinofem_R • LN_InPec_ESTRO_L • LN_InPec_ESTRO_R • LN_Neck_IA • LN_Neck_IB_L • LN_Neck_IB_R • LN_Neck_IB-V_L • LN_Neck_IB-V_R • LN_Neck_II_L • LN_Neck_II_R • LN_Neck_II-IV_L • LN_Neck_II-IV_R • LN_Neck_II-V_L • LN_Neck_II-V_R • LN_Neck_III_L • LN_Neck_III_R • LN_Neck_IV_L • LN_Neck_IV_R • LN_Neck_V_L • LN_Neck_V_R • LN_Neck_VIA	• LN_IMN_R • LN_Neck_234_L • LN_Neck_234_R • LN_Neck_2347AB_L • LN_Neck_2347AB_R • LN_Neck_IA • LN_Neck_IA6 • LN_Neck_IB_L • LN_Neck_IB_R • LN_Neck_II_L • LN_Neck_II_R • LN_Neck_III_L • LN_Neck_III_R • LN_Neck_IV_L • LN_Neck_IV_R • LN_Neck_L • LN_Neck_R • LN_Neck_V_L • LN_Neck_V_R • LN_Neck_VI • LN_Neck_VIIAB_L • LN_Neck_VIIAB_R • LN_Pelvics_CBCT • LN_Pelvis • LN_Sclav_L • LN_Sclav_R • Lung_L • Lung_R • Lungs • Mesorectum • Musc_Constrict • Musc_PecMinor_L • Musc_PecMinor_R • Musc_Sclmast_L • Musc_Sclmast_R • OpticChiasm • OpticNrv_L • OpticNrv_R • Optics • Pancreas • Parotid_L • Parotid_R • PelvisVessels • PenileBulb • Pericardium • Pericardium+A_Pulm • Pituitary • Prostate • Prostate_CBCT • Prostate+SeminalVes • ProstateBed • PubicSymphys • Rectum • Rectum_CBCT • Rectum_HDR • Retina_L • Retina_R • Ribs • Ribs Sacrum • Ribs_L • Ribs_R • Sacrum • SeminalVes
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• InternalAuditoryCanal_L* • InternalAuditoryCanal_R* • Kidney_L • Kidney_Outer_L* • Kidney_Outer_R* • Kidney_R* • Kidneys • Kidneys_Outer • Larynx • Larynx_Glottic • Larynx_NRG • Larynx_SG • Lens_L • Lens_R • Lips* • Liver • LN_Ax_L • LN_Ax_L1_2d_L* • LN_Ax_L1_2d_R* • LN_Ax_L1_ESTRO_2d_L • LN_Ax_L1_ESTRO_2d_R • LN_Ax_L1_ESTRO_L • LN_Ax_L1_ESTRO_R • LN_Ax_L1_L • LN_Ax_L1_R • LN_Ax_L2_2d_L* • LN_Ax_L2_2d_R* • LN_Ax_L2_ESTRO_2d_L* • LN_Ax_L2_ESTRO_2d_R* • LN_Ax_L2_ESTRO_L • LN_Ax_L2_ESTRO_R • • LN_Ax_L2_InPec_ESTRO_2d_L* • • LN_Ax_L2_InPec_ESTRO_2d_R* • LN_Ax_L2_L • LN_Ax_L2_L3_L • LN_Ax_L2_L3_R • LN_Ax_L2_R • LN_Ax_L3_2d_L* • LN_Ax_L3_2d_R* • LN_Ax_L3_ESTRO_2d_L* • LN_Ax_L3_ESTRO_2d_R* • LN_Ax_L3_ESTRO_L • LN_Ax_L3_ESTRO_R • LN_Ax_L3_L • LN_Ax_L3_R • LN_Ax_R • LN_Ax_Sclav_2d_L* • LN_Ax_Sclav_2d_R* • LN_IMN_2d_L* • LN_IMN_2d_R* • LN_IMN_ESTRO_2d_L*	• LN_Neck_VIIA_L • LN_Neck_VIIA_R • LN_Neck_VIIB_L • LN_Neck_VIIB_R • LN_Paraaortic • LN_Pelvics_F • LN_Pelvics • LN_Pelvic_NRG • LN_Post_Neck_L • LN_Post_Neck_R • LN_Presacral • LN_Sclav_ESTRO_L • LN_Sclav_ESTRO_R • LN_Sclav_L • LN_Sclav_R • LN_Sclav_RADCOM_P_L • LN_Sclav_RADCOM_P_R • Lobe_Temporal_L • Lobe_Temporal_R • Lung_L • Lung_R • Macula_L • Macula_R • Marrow_Ilium_L • Marrow_Ilium_R • Musc_Constrict • Musc_Iliopsoas_L • Musc_Iliopsoas_R • Myocardium • Nipple_L • Nipple_Prone • Nipple_R • OpticChiasm • OpticNrv_L • OpticNrv_R • Pancreas • Parotid_L • Parotid_R • PenileBulb • Pericardium • Pharynx • Pituitary • Prostate • ProstateBed • Rectum • Rectum_F • Retina_L • Retina_R • Rib • Rib01_L • Rib01_R • Rib02_L • Rib02_R	• SeminalVes_CBCT • Skin • SpinalCanal • SpinalCord • Spleen • Sternum • Stomach • Trachea • Urethra_HDR • Uterus_Cervix • Uterus+Cervix • V_Venacava_I • V_Venacava_S • Vagina • VB_C1 • VB_C2 • VB_C3 • VB_C4 • VB_C5 • VB_C6 • VB_C7 • VB_L1 • VB_L2 • VB_L3 • VB_L4 • VB_L5 • VB_T01 • VB_T02 • VB_T03 • VB_T04 • VB_T05 • VB_T06 • VB_T07 • VB_T08 • VB_T09 • VB_T10 • VB_T11 • VB_T12 • VBs • Ventricle_L • Ventricle_R MR Models: • Bladder • Bladder_HDR • Bowel_HDR • Brainstem • Canal_Anal_HDR • Colon_Sigmoid_HDR • Cornea_L • Cornea_R • Eye_L • Eye_R • Femur_Head_L • Femur_Head_R • Hippocampus_L • Hippocampus_R • Optics • PenileBulb • Prostate • PubicSymphys
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• LN_IMN_ESTRO_2d_R* • LN_IMN_Expand_2d_L* • LN_IMN_Expand_2d_R* • LN_IMN_Expand_ESTRO_2d_L* • LN_IMN_Expand_ESTRO_2d_R* • LN_IMN_L • LN_IMN_R • LN_IMN_RC_L • LN_IMN_RC_R • LN_Inguinofem_L* • LN_Inguinofem_R* • LN_InPec_ESTRO_2d_L* • LN_InPec_ESTRO_2d_R* • LN_InPec_ESTRO_L • LN_InPec_ESTRO_R • LN_Mesorectum* • LN_Neck_2d_L • LN_Neck_2d_R • LN_Neck_CerVII_2d_L • LN_Neck_CerVII_2d_R • LN_Neck_IA • LN_Neck_IA_2d* • LN_Neck_IA_VI_2d* • LN_Neck_IB_2d_L* • LN_Neck_IB_2d_R* • LN_Neck_IB_L • LN_Neck_IB_R • LN_Neck_IB-V_L • LN_Neck_IB-V_R • LN_Neck_II_2d_L* • LN_Neck_II_2d_R* • LN_Neck_II_L • LN_Neck_II_R • LN_Neck_III_2d_L* • LN_Neck_III_2d_R* • LN_Neck_III_L • LN_Neck_III_R • LN_Neck_II-IV_2d_L* • LN_Neck_II-IV_2d_R* • LN_Neck_II-IV_L • LN_Neck_II-IV_R • LN_Neck_II-V_L • LN_Neck_II-V_R • LN_Neck_IV_2d_L* • LN_Neck_IV_2d_R* • LN_Neck_IV_L • LN_Neck_IV_R • LN_Neck_V_2d_L* • LN_Neck_V_2d_R* • LN_Neck_V_L • LN_Neck_V_R	• Rib03_L • Rib03_R • Rib04_L • Rib04_R • Rib05_L • Rib05_R • Rib06_L • Rib06_R • Rib07_L • Rib07_R • Rib08_L • Rib08_R • Rib09_L • Rib09_R • Rib10_L • Rib10_R • Rib11_L • Rib11_R • Rib12_L • Rib12_R • Rib_L • Rib_R • SacralPlex_L • SacralPlex_R • SeminalVes • SpinalCanal • SpinalCord • Spleen • Stomach • Trachea • UteroCervix • V_Brachioceph_L • V_Brachioceph_R • V_Jugular_L • V_Jugular_R • V_Venacava_I • V_Venacava_S • VB • VB_C1 • VB_C2 • VB_C3 • VB_C4 • VB_C5 • VB_C6 • VB_C7 • VB_L1 • VB_L2 • VB_L3 • VB_L4 • VB_L5 • VB_T01 • VB_T02 • VB_T03 • VB_T04 • VB_T05	• Rectum • Rectum_HDR • Retina_L • Retina_R • Sacrum • SeminalVes • Urethra_HDR
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	• LN_Neck_VI_2d* • LN_Neck_VIA • LN_Neck_VII_2d_L* • LN_Neck_VII_2d_R* • LN_Neck_VIIA_2d_L* • LN_Neck_VIIA_2d_R* • LN_Neck_VIIA_L • LN_Neck_VIIA_R • LN_Neck_VIIB_2d_L* • LN_Neck_VIIB_2d_R* • LN_Neck_VIIB_L • LN_Neck_VIIB_R • LN_Paraaortic • LN_Pelvics • LN_Pelvics_CBCT* • LN_Pelvics_F • LN_Pelvics_NRG* • LN_Post_Neck_L • LN_Post_Neck_R • LN_Presacral • LN_Sclav_2d_L* • LN_Sclav_2d_R* • LN_Sclav_ESTRO_2d_L* • LN_Sclav_ESTRO_2d_R* • LN_Sclav_ESTRO_L • LN_Sclav_ESTRO_R • LN_Sclav_L • LN_Sclav_R • LN_Sclav_RC_L • LN_Sclav_RC_R • Lobe_Temporal_L* • Lobe_Temporal_R* • Lung_L • Lung_R • Lungs • Macula_L • Macula_R • Marrow_Ilium_L • Marrow_Ilium_R • Marrow_Pelvis* • Medulla • Midbrain • Musc_Constrict_2d* • Musc_Constrict • Musc_Iliopsoas_L • Musc_Iliopsoas_R • Musc_PecMinor_L* • Musc_PecMinor_R* • Musc_Sclmast_L* • Musc_Sclmast_R* • Myocardium • Nipple_L • Nipple_Prone • Nipple_R • OpticChiasm*	• VB_T06 • VB_T07 • VB_T08 • VB_T09 • VB_T10 • VB_T11 • VB_T12 • Ventricle_L • Ventricle_R MR Models: • A_Pud_Int_L • A_Pud_Int_R • Bladder • Bladder_Trigone • Brain • Brainstem • Cerebellum • Colon_Sigmoid • External_Pelvis • Eye_L • Eye_R • Femur_L • Femur_R • GInd_Prostate • Hippocampus_L • Hippocampus_R • Hypo_True • Hypothalamus • Lens_L • Lens_R • NVB_L • NVB_R • OpticChiasm • OpticNrv_L • OpticNrv_R • OpticTract_L • OpticTract_R • PenileBulb • Pituitary • Prostate • Rectal_Spacer • Rectum • SeminalVes • SpinalCord_Cerv • Urethra	
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	• OpticNrv_L* • OpticNrv_R* • Optics* • Pancreas* • Parametrium • Parotid_Glnd_L • Parotid_Glnd_R • Parotid_L • Parotid_R • PenileBulb • Pericardium • Pericardium_Inf* • Pericardium_Inf+A_Pulm* • Pharynx • Pituitary* • Pituitary_3d • Pons • Prostate* • Prostate_CBCT* • Prostate+SeminalVes* • Prostate+SV-Spacergel* • ProstateBed • ProstateFiducials* • Prostate-Gel_Fiducials* • Prostate-Spacergel_Vue* • Rectum • Rectum_CBCT* • Rectum_F • Rectum-Spacergel_Vue* • Retina_2d_L* • Retina_2d_R* • Retina_L • Retina_R • Rib* • Rib_L* • Rib_R* • Rib01_L • Rib01_R • Rib02_L • Rib02_R • Rib03_L • Rib03_R • Rib04_L • Rib04_R • Rib05_L • Rib05_R • Rib06_L • Rib06_R • Rib07_L • Rib07_R • Rib08_L • Rib08_R • Rib09_L • Rib09_R • Rib10_L		
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	• Rib10_R • Rib11_L • Rib11_R • Rib12_L • Rib12_R • SacralPlex_L • SacralPlex_R • SeminalVes* • SeminalVes_CBCT* • Sinuses • Skin* • SpaceOAR™Vue* • SpinalCanal • SpinalCord* • Spleen • Stomach • Tentorium • Trachea* • UteroCervix • V_Brachioceph_L • V_Brachioceph_R • V_Jugular_L • V_Jugular_R • V_Pulmonary • V_Venacava_I* • V_Venacava_I_UKSABR • V_Venacava_S • V_Venacava_S_UKSABR • Vagina* • Valve_Aortic • Valve_Mitral • Valve_Pulmonic • Valve_Tricuspid • VB • VB_C1 • VB_C2 • VB_C3 • VB_C4 • VB_C5 • VB_C6 • VB_C7 • VB_L1 • VB_L2 • VB_L3 • VB_L4 • VB_L5 • VB_T01 • VB_T02 • VB_T03 • VB_T04 • VB_T05 • VB_T06 • VB_T07 • VB_T08 • VB_T09		
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	• VB_T10 • VB_T11 • VB_T12 • Ventricle_Brain • Ventricle_L* • Ventricle_R* • Vessels_Pelvis* MR Models: • A_Pud_Int_L • A_Pud_Int_R • Amygdala_L • Amygdala_R • Bladder* • Bladder_Trigone • Bladder_TRUFI • Bone_PubicSymphys* • Bone_Sacrum* • Brain • Brainstem • Cerebellum • Colon_Sigmoid • Cornea_L* • Cornea_R* • CorpusCallosum • External_Pelvis • Eye_L* • Eye_R* • Falx • Femur_L* • Femur_R* • GInd_Prostate • HDR_Bladder* • HDR_Bowel* • HDR_Canal_Anal* • HDR_Colon_Sigmoid* • HDR_Rec-Canal* • HDR_Rectum* • HDR_Urethra* • Hippocampus_L* • Hippocampus_R* • Hypo_True • Hypothalamus • Lens_L • Lens_R • Medulla • Midbrain • NVB_L • NVB_R • OpticChiasm • OpticNrv_L • OpticNrv_R • Optics* • OpticTract_L		
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	• OpticTract_R • PenileBulb* • PenileBulb_TRUFI • Pituitary • Pons • Prostate* • Rectal_Spacer • Rectum* • Retina_L* • Retina_R* • SeminalVes* • Sinuses • SpinalCord_Cerv • Tentorium • Thalamus • Urethra • Ventricle_Brain		
Design: Region/volume of interest measurements and size measurements	None – not applicable	None – not applicable	None – not applicable
Design: Region/Volume Quantification	None – not applicable	None – not applicable	None – not applicable
Design: Supported modalities	CT or MR input for contouring or registration/fusion. PET/CT input for registration/fusion only. DICOM RTSTRUCT and REGISTRATION for input	CT or MR input for contouring or registration/fusion. PET/CT input for registration/fusion only. DICOM RTSTRUCT and REGISTRATION for input	CT or MR input for contouring.
Design: Reporting and data routing	No built-in reporting, supports exporting DICOM RTSTRUCT, REGISTRATION and DOSE files for output.	No built-in reporting, supports exporting DICOM RTSTRUCT, REGISTRATION and DOSE files for output.	No built-in reporting, supports exporting DICOM RTSTRUCT files for output
Compatibility with the environment and other devices	Compatible with data from any DICOM compliant scanners for the applicable modalities. Agent Uploader component compatible with Microsoft Windows. Cloud-based automatic contouring service compatible with Linux.	Compatible with data from any DICOM compliant scanners for the applicable modalities. Agent Uploader component compatible with Microsoft Windows. Cloud-based automatic contouring service compatible with Linux.	No Limitation on scanner model, DICOM 3.0 compliance required.

	Web application server-based application compatible with Linux.	Web application server-based application compatible with Linux.	
Communications/ Networking	TCP/IP	TCP/IP	N/A
Computer platform & Operating System	Windows Operating System	Windows Operating System	Operating System Windows 10 / Windows Server 2016 and Above

7. Performance

Verification testing confirmed that RADAC V5 features and functionality met predefined acceptance criteria consistent with the predicate device. RADAC models were divided into 4 categories and tested using protocols consistent with the category, while applying consistent acceptance criteria across each. Models were classified as 1) New Models that did not exist in the predicate or reference device, 2) Models that did not exist in the predicate, but were unchanged from the reference device, 3) Models that previously existed in the predicate or reference device but were changed in RADAC V5, and 4) Models that previously existed in the predicate device (AC V4) and are unchanged.

Model Verification Categories and Acceptance Criteria *, **, ***, and **** refer to specified acceptance criteria.			
New Models - Not previously in AC or LC	Models unchanged from LC 1.8	Updated Models Regardless of source (AC or LC)	Unchanged Models From AC 2.6
New Structure Model Validation: - Training DSC Evaluation* - External Dataset DSC Evaluation* - Internal Likert Qualitative Review** - External Likert Qualitative Review**	Existing Structure Model Tests: - DSC Comparison between Limbus v1.8 and AutoContour v2.7.*** - Hausdorff Distance between Limbus v1.8 and Autocontour v2.7.****	Existing Structure Model Tests: - DSC Comparison between Limbus v1.8 and AutoContour v2.7 or between AutoContour v2.6 and AutoContour v2.7.*** - Hausdorff Distance between Limbus v1.8 and AutoContour v2.7 or between AutoContour v2.6 and AutoContour v2.7.**** New Structure Model Validation: - Training DSC Evaluation* - External Dataset DSC Evaluation* - Internal Likert Qualitative Review** - External Likert Qualitative Review**	Existing Structure Model Tests: - DSC Comparison between AutoContour v2.6 and AutoContour v2.7.*** - Hausdorff Distance between AutoContour v2.6 and AutoContour v2.7.****

Model Acceptance testing utilized the following predefined acceptance criteria.

- * Training DSC and External Dataset DSC Evaluations: Mean DSC threshold for passing Large Structures: 0.80, Medium Structures: 0.65, and Small Structures: 0.50
- ** Internal and External Likert Qualitative Review: Each structure model was determined to pass if the average grade exceeded 3 across all external image sets reviewed.
- *** Existing Structure Model DSC Evaluation: The DSC threshold for passing Large Structures: >0.99, Medium Structures >0.98, and Small Structures: >0.95.
- **** Existing Structure Model Hausdorff Distance Evaluation: Hausdorff Distance threshold for passing structures is $\leq 3\text{mm}$.

Performance Data

Testing was performed according to Radformation's AutoContour Validation Test Protocol and Report, which demonstrates that AutoContour Model RADAC V5 performs as intended per its indications for use. Further tests were performed on independent datasets from those included in training and validation sets in order to validate the generalizability of the machine learning model.

Description of Changes to Test Protocol

Changes to the test protocol include an update to the existing structure model tests to include Hausdorff Distance as an additional metric for regression testing of existing model output changes, and the inclusion of a comparison to Limbus v1.8. There were no changes to the new and updated structure model testing protocol between AutoContour RADAC V4 and RADAC V5.

Testing Summary

Mean Dice Similarity Coefficient (DSC) was used to validate the accuracy of structure model outputs when tested on image data sequestered from the original training data population. The test datasets were independent from those used for training and consisted of approximately 10% of the number of training image sets used as input for the model. For CT structure models there were an average of 459 training and 49 testing image sets. CT training images were gathered from several institutions, in several different countries.

Ground truthing of each test data set were generated manually using consensus (NRG/RTOG/ESTRO) guidelines as appropriate by six clinically experienced experts consisting of 2 radiation therapy physicists, 1 radiation dosimetrist, and 3 radiation therapists with specialized training in radiation therapy contouring.

Structure models were categorized into three size categories as DSC metrics can be sensitive to structure volume. A structure would pass initial validation if the mean DSC exceeded 0.8 for Large volume structures (eg. Bladder, Spleen) 0.65 for Medium volume structures (eg. Gallbladder, Duodenum) and 0.5 for Small structures (eg. Cornea, Retina). For CT Structure models large, medium and small structures resulted in a mean DSC of 0.91 ± 0.14 , 0.86 ± 0.13 , and 0.75 ± 0.20 respectively. A full summary of the CT structure DSC is available below:

Table 4: CT Training Data Results for AutoContour Model RADAC V5

CT Structure	Size	Pass Criteria	# of Training Sets	# of Testing Sets	DSC (Avg)	DSC Std Dev	Lower Bound 95% Confidence Interval
A_Aorta** (Update)	Large	0.80	N/A	N/A	N/A	N/A	N/A
A_Aorta_Asc** (Update)	Medium	0.65	240	60	0.92	0.02	0.91
A_Carotid_L** (Update)	Medium	0.65	328	83	0.79	0.13	0.58
A_Carotid_R** (Update)	Medium	0.65	328	83	0.79	0.13	0.58
A_Celiac	Small	0.50	435	44	0.87	0.24	0.47
A_Circumflex_L	Small	0.50	415	45	0.52	0.36	-0.08
A_Coronary_2d_R	Small	0.50	415	45	0.83	0.26	0.41
A_Coronary_L	Small	0.50	415	45	0.50	0.36	-0.11
A_Coronary_R** (Update)	Small	0.50	408	103	0.56	0.09	0.41
A_Mesenteric_S	Small	0.50	428	43	0.79	0.28	0.33
A_Pulmonary** (Update)	Medium	0.65	1338	50	0.91	0.18	0.60
Atrium_L** (Update)	Medium	0.65	398	45	0.82	0.19	0.51
Atrium_R** (Update)	Medium	0.65	398	45	0.82	0.20	0.50
AV_Node	Medium	0.65	398	45	0.87	0.20	0.53
Barrigel	Medium	0.65	111	28	0.77	0.06	0.66
BileDuct_Common	Small	0.50	643	162	0.57	0.20	0.24
Bladder** (Update)	Large	0.80	1105	50	0.93	0.18	0.63
Body+Mask*	Large	0.80	N/A	N/A	N/A	N/A	N/A
Bone_Ischium_L	Large	0.80	521	50	0.92	0.15	0.68
Bone_Ischium_R	Large	0.80	35	4	0.92	0.15	0.68
Bone_Mandible** (Update)	Medium	0.65	234	25	0.88	0.16	0.62
Bone_Pelvic** (Update)	Large	0.80	234	25	0.94	0.12	0.74
Bone_Pterygoid_L	Small	0.50	308	36	0.73	0.29	0.26
Bone_Pterygoid_R	Small	0.50	308	36	0.73	0.29	0.26
Bone_Skull** (Update)	Large	0.80	80	20	0.92	0.01	0.90
Bone_Teeth** (Update)	Medium	0.65	340	76	0.88	0.02	0.84
Bowel** (Update)	Medium	0.65	221	13	0.78	0.03	0.72
Bowel_Bag** (Update)	Large	0.80	454	48	0.95	0.05	0.87
Bowel_Bag_F*	Large	0.80	N/A	N/A	N/A	N/A	N/A
Bowel_F*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
Bowel_Large** (Update)	Medium	0.65	805	52	0.89	0.17	0.61
Bowel_Large_F*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
Bowel_Small** (Update)	Medium	0.65	705	45	0.93	0.05	0.85

Bowel_Small_F*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
BrachialPlex_L** (Update)	Medium	0.65	527	132	0.73	0.08	0.61
BrachialPlex_R** (Update)	Medium	0.65	527	132	0.73	0.08	0.61
BrachialPlexs*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
Brain** (Update)	Large	0.80	1033	50	0.95	0.14	0.71
Brainstem** (Update)	Medium	0.65	614	50	0.90	0.14	0.67
Breast_RTOG_L	Large	0.80	660	50	0.88	0.25	0.46
Breast_RTOG_R	Large	0.80	660	50	0.88	0.25	0.46
Breasts_RTOG*	Large	0.80	N/A	N/A	N/A	N/A	N/A
BuccalMucosa** (Update)	Medium	0.65	392	98	0.70	0.05	0.61
Canal_Anal*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
Canal_Anal_F*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
InternalAuditoryCanal_L	Small	0.50	253	27	0.76	0.34	0.19
CaudaEquina** (Update)	Medium	0.65	N/A	N/A	N/A	N/A	N/A
Cavity_Oral_Ext** (Update)	Medium	0.65	392	98	0.94	0.02	0.90
Chestwall_2cm_L	Large	0.80	223	25	0.92	0.11	0.74
Chestwall_2cm_R	Large	0.80	223	25	0.92	0.11	0.74
Chestwall_ESTRO_L	Large	0.80	223	20	0.87	0.21	0.52
Chestwall_ESTRO_R	Large	0.80	223	20	0.87	0.21	0.52
Cochlea_L** (Update)	Small	0.50	106	26	0.65	0.10	0.49
Cochlea_R** (Update)	Small	0.50	106	26	0.65	0.10	0.49
Cornea_2d_L	Small	0.50	729	50	0.90	0.17	0.62
Cornea_2d_R	Small	0.50	729	50	0.90	0.17	0.62
CorpusCallosum	Medium	0.65	58	15	0.76	0.07	0.64
Cribriform	Medium	0.65	361	41	0.74	0.30	0.24
Dental_Artifact** (Update)	Medium	0.65	342	86	0.76	0.10	0.60
Ear_Internal_L** (Update)	Small	0.50	580	146	0.64	0.21	0.29
Ear_Internal_R** (Update)	Small	0.50	580	146	0.64	0.21	0.29
Esophagus** (Update)	Medium	0.65	1116	279	0.76	0.13	0.55
Eyes*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
Falx	Medium	0.65	177	48	0.76	0.06	0.66
HDR_Canal_Anal*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
GreatVessels*	Large	0.80	N/A	N/A	N/A	N/A	N/A
HDR_Colon_Sigmoid	Medium	0.65	494	48	0.83	0.22	0.48
Heart** (Update)	Large	0.80	1000	50	0.81	0.31	0.30
Heart+A_Pulm	Large	0.80	33	4	0.96	0.11	0.78

Hippocampus_L** (Update)	Medium	0.65	226	57	0.67	0.10	0.51
Hippocampus_R** (Update)	Medium	0.65	226	57	0.67	0.10	0.51
Iliac_Int_L** (Update)	Medium	0.65	160	40	0.66	0.28	0.19
Iliac_Int_R**(Update)	Medium	0.65	160	40	0.66	0.28	0.19
Iliac_L** (Update)	Medium	0.65	162	82	0.83	0.07	0.71
Iliac_R** (Update)	Medium	0.65	162	82	0.83	0.07	0.71
Kidneys*	Large	0.80	N/A	N/A	N/A	N/A	N/A
Larynx** (Update)	Medium	0.65	172	43	0.85	0.05	0.77
LN_Ax_L1_ESTRO_2d_L	Medium	0.65	395	44	0.88	0.21	0.53
LN_Ax_L1_ESTRO_2d_R	Medium	0.65	395	44	0.88	0.21	0.53
LN_Ax_L2_ESTRO_2d_L	Medium	0.65	404	45	0.89	0.21	0.54
LN_Ax_L2_ESTRO_2d_R	Medium	0.65	404	45	0.89	0.21	0.54
LN_Ax_L3_ESTRO_2d_L	Medium	0.65	404	45	0.89	0.21	0.54
LN_Ax_L3_ESTRO_2d_R	Medium	0.65	404	45	0.89	0.21	0.54
LN_InPec_ESTRO_2d_L	Medium	0.65	404	45	0.89	0.21	0.54
LN_InPec_ESTRO_2d_R	Medium	0.65	404	45	0.89	0.21	0.54
LN_Ax_L2_InPec_ESTRO_2d_L	Medium	0.65	404	45	0.89	0.21	0.54
LN_Ax_L2_InPec_ESTRO_2d_R	Medium	0.65	404	45	0.89	0.21	0.54
LN_Mesorectum	Large	0.80	302	33	0.86	0.27	0.42
LN_Neck_2d_L	Large	0.80	672	50	0.85	0.18	0.55
LN_Neck_2d_R	Large	0.80	672	50	0.85	0.18	0.55
LN_Neck_CerVII_2d_L	Large	0.80	672	50	0.85	0.18	0.55
LN_Neck_CerVII_2d_R	Large	0.80	672	50	0.85	0.18	0.55
LN_Neck_IB_2d_L	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_IB_2d_R	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_II_2d_L	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_II_2d_R	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_II-IV_2d_L	Large	0.80	672	50	0.85	0.18	0.55
LN_Neck_II-IV_2d_R	Large	0.80	672	50	0.85	0.18	0.55
LN_Neck_III_2d_L	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_III_2d_R	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_IV_2d_L	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_IV_2d_R	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_VII_2d_L	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_VII_2d_R	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_VIIA_2d_L	Medium	0.65	672	50	0.85	0.18	0.55

LN_Neck_VIIA_2d_R	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_VIIB_2d_L	Medium	0.65	672	50	0.85	0.18	0.55
LN_Neck_VIIB_2d_L	Medium	0.65	672	50	0.85	0.18	0.55
LN_Pelvics_NRG** (Update)	Large	0.80	921	50	0.89	0.16	0.63
LN_Presacral** (Update)	Medium	0.65	191	48	0.78	0.16	0.52
Lobe_Temporal_L** (Update)	Large	0.80	211	23	0.81	0.27	0.37
Lobe_Temporal_R** (Update)	Large	0.80	211	23	0.81	0.27	0.37
Lungs*	Large	0.80	N/A	N/A	N/A	N/A	N/A
Marrow_Pelvis	Medium	0.65	35	4	0.94	0.12	0.74
Medulla	Medium	0.65	614	50	0.90	0.14	0.67
Midbrain	Medium	0.65	614	50	0.906	0.14	0.67
Musc_Iliopsoas_L** (Update)	Large	0.80	1082	65	0.94	0.08	0.81
Musc_Iliopsoas_R** (Update)	Large	0.80	1082	65	0.94	0.14	0.71
Musc_PecMinor_L	Medium	0.65	398	42	0.83	0.22	0.48
Myocardium** (Update)	Medium	0.65	1082	65	0.90	0.05	0.82
Pancreas** (Update)	Medium	0.65	765	50	0.82	0.15	0.57
Parametrium	Medium	0.65	1095	50	0.85	0.19	0.54
Parotid_L** (Update)	Medium	0.65	787	197	0.88	0.051	0.80
Parotid_R** (Update)	Medium	0.65	787	197	0.88	0.051	0.80
Pericardium** (Update)	Large	0.80	160	41	0.94	0.02	0.91
Pericardium_Inf	Large	0.80	734	50	0.94	0.165	0.68
Pericardium_Inf+A_Pulm	Large	0.80	1000	50	0.81	0.31	0.30
Pharynx** (Update)	Medium	0.65	57	15	0.90	0.02	0.87
Pituitary** (Update)	Small	0.50	295	33	0.83	0.27	0.40
Pituitary_3d	Small	0.50	373	41	0.68	0.09	0.53
Pons	Medium	0.65	614	50	0.90	0.14	0.67
ProstateBed** (Update)	Medium	0.65	133	34	0.87	0.04	0.79
ProstateFiducials	Small	0.50	888	50	0.88	0.20	0.55
Rectum-Spacergel_VUE*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
Retina_2d_L	Small	0.50	729	50	0.90	0.17	0.62
Retina_2d_R	Small	0.50	729	50	0.90	0.17	0.62
Rib01_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib01_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib02_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib02_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib03_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76

Rib03_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib04_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib04_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib05_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib05_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib06_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib06_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib07_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib07_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib08_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib08_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib09_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib09_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib10_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib10_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib11_L** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib11_R** (Update)	Medium	0.65	148	37	0.90	0.09	0.76
Rib12_L** (Update)	Small	0.50	148	37	0.90	0.09	0.76
Rib12_R** (Update)	Small	0.50	148	37	0.90	0.09	0.76
Rib** (Update)	Large	0.80	84	11	0.91	0.10	0.74
Rib_R** (Update)	Large	0.80	84	11	0.91	0.10	0.74
SacralPlex_L** (Update)	Medium	0.65	326	83	0.75	0.06	0.66
SacralPlex_R** (Update)	Medium	0.65	326	83	0.75	0.06	0.66
Sinuses	Medium	0.65	177	48	0.78	0.07	0.67
SpinalCanal** (Update)	Large	0.80	87	22	0.90	0.02	0.87
SpinalCord** (Update)	Medium	0.65	1000	49	0.91	0.07	0.79
Spleen** (Update)	Large	0.80	765	70	0.94	0.14	0.71
Tentorium	Medium	0.65	177	48	0.70	0.10	0.55
Trachea** (Update)	Medium	0.65	865	50	0.90	0.17	0.63
UteroCervix** (Update)	Medium	0.65	594	50	0.92	0.20	0.61
V_Jugular_L** (Update)	Medium	0.65	264	68	0.78	0.18	0.48
V_Jugular_R** (Update)	Medium	0.65	264	68	0.78	0.18	0.48
V_Pulmonary	Medium	0.65	398	45	0.68	0.21	0.34
V_Venacava_I** (Update)	Medium	0.65	1000	50	0.88	0.16	0.62
V_Venacava_I_UKSABR	Medium	0.65	627	49	0.91	0.11	0.72
V_Venacava_S** (Update)	Medium	0.65	168	26	0.83	0.08	0.69

V_Venacava_S_UKSABR	Medium	0.65	619	48	0.89	0.16	0.63
Vagina	Medium	0.65	446	50	0.85	0.21	0.51
Valve_Aortic	Medium	0.65	398	45	0.88	0.20	0.57
Valve_Mitral	Medium	0.65	398	45	0.85	0.21	0.50
Valve_Pulmonic	Medium	0.65	398	45	0.91	0.17	0.63
Valve_Tricuspid	Medium	0.65	398	45	0.88	0.21	0.54
VB** (Update)	Large	0.80	1051	64	0.99	0.01	0.97
VB_C1** (Update)	Medium	0.65	196	14	0.90	0.25	0.49
VB_C2** (Update)	Medium	0.65	202	13	0.99	0.01	0.97
VB_C3** (Update)	Medium	0.65	214	14	0.97	0.03	0.92
VB_C4** (Update)	Medium	0.65	234	15	0.90	0.24	0.51
VB_C5** (Update)	Medium	0.65	328	20	0.89	0.21	0.54
VB_C6** (Update)	Medium	0.65	520	33	0.87	0.24	0.48
VB_C7** (Update)	Medium	0.65	651	36	0.98	0.01	0.96
VB_L1** (Update)	Large	0.80	731	49	0.97	0.09	0.82
VB_L2** (Update)	Large	0.80	650	44	0.99	0.03	0.94
VB_L3** (Update)	Large	0.80	582	44	0.99	0.03	0.94
VB_L4** (Update)	Large	0.80	569	44	0.99	0.01	0.97
VB_L5** (Update)	Large	0.80	550	43	0.99	0.02	0.96
VB_T01** (Update)	Medium	0.65	663	37	0.98	0.01	0.96
VB_T02** (Update)	Medium	0.65	682	38	0.96	0.12	0.76
VB_T03** (Update)	Medium	0.65	700	38	0.96	0.14	0.73
VB_T04** (Update)	Medium	0.65	695	39	0.95	0.16	0.69
VB_T05** (Update)	Medium	0.65	687	39	0.97	0.08	0.84
VB_T06** (Update)	Medium	0.65	682	36	0.97	0.06	0.87
VB_T07** (Update)	Medium	0.65	686	39	0.94	0.16	0.68
VB_T08** (Update)	Medium	0.65	729	45	0.96	0.14	0.73
VB_T09** (Update)	Medium	0.65	778	49	0.98	0.04	0.91
VB_T10** (Update)	Medium	0.65	803	49	0.97	0.09	0.82
VB_T11** (Update)	Medium	0.65	814	48	0.98	0.07	0.86
VB_T12** (Update)	Medium	0.65	795	50	0.97	0.13	0.76
Ventricle_Brain	Medium	0.65	177	48	0.84	0.05	0.75
Ventricle_L** (Update)	Medium	0.65	398	45	0.72	0.27	0.28
Ventricle_R** (Update)	Medium	0.65	398	45	0.84	0.23	0.45
Vessels_Pelvis	Medium	0.65	921	50	0.892	0.16	0.63

*N/A: Structures are generated based on a post-processing/boolean operation from previously released structure models (Eye, Rib) rather than generated from a CNN model. Quantitative and Qualitative testing for these structures is still performed in the following sections in order to validate appropriate contour generation and clinical acceptability.

** A_Aorta, A_Aorta_Asc, A_Carotid_L, A_Carotid_R, A_Coronary_R, A_Pulmonary, Atrium_L, Atrium_R, Bladder, Bone_Skull, Bone_Teeth, Bone_Mandible, Bone_Pelvic, Bowel, Bowel_Bag, Bowel_Large, Bowel_Small, BrachialPlex_L, BrachialPlex_R, Brain, Brainstem, BuccalMucosa, CaudaEquina, Cavity_Oral_Ext, Cochlea_L, Cochlea_R, Dental_Artifact, Ear_Internal_L, Ear_Internal_R, Esophagus, Heart, Hippocampus_L, Hippocampus_R, Iliac_Int_L, Iliac_Int_R, Iliac_L, Iliac_R, Kidneys, Larynx, LN_Pelvics_NRG, LN_Presacral, Lobe_Temporal_L, Lobe_Temporal_R, Musc_Iliopsoas_L, Musc_Iliopsoas_R, Myocardium, Parotid_L, Parotid_R, Pancreas, Pericardium, Pharynx, Pituitary, ProstateBed, Rib01_L, Rib01_R, Rib02_L, Rib02_R, Rib03_L, Rib03_R, Rib04_L, Rib04_R, Rib05_L, Rib05_R, Rib06_L, Rib06_R, Rib07_L, Rib07_R, Rib08_L, Rib08_R, Rib09_L, Rib09_R, Rib10_L, Rib10_R, Rib11_L, Rib11_R, Rib12_L, Rib12_R, Rib, Rib_R, SacralPlex_L, SacralPlex_R, SpinalCanal, SpinalCord, Spleen, Trachea, UteroCervix, V_Jugular_L, V_Jugular_R, V_Venacava_L, V_Venacava_S, VB, VB_C1, VB_C2, VB_C3, VB_C4, VB_C5, VB_C6, VB_C7, VB_L1, VB_L2, VB_L3, VB_L4, VB_L5, VB_T01, VB_T02, VB_T03, VB_T04, VB_T05, VB_T06, VB_T07, VB_T08, VB_T09, VB_T10, VB_T11, VB_T12, Ventricle_L, and Ventricle_R models were previously released/tested, but updates to the training datasets and contour output necessitated additional release testing for these models.

Additional external clinical testing was performed in order to validate the accuracy of the models on image sets acquired that were unique to the training datasets. Both AutoContour and manually added ground truth contours following the same structure guidelines used for structure model training were added to the image sets.

Table 5: CT External Clinical Dataset References

Model Group	Data Source ID	Data Citation
CT Pelvis	TCIA - Pelvic-Ref	Afua A. Yorke, Gary C. McDonald, David Solis Jr., Thomas Guerrero. (2019) Pelvic Reference Data. The Cancer Imaging Archive. DOI: 10.7937/TCIA.2019.woskq5oo
CT Head and Neck	TCIA - Head-Neck-PET-CT	Martin Vallières, Emily Kay-Rivest, Léo Jean Perrin, Xavier Liem, Christophe Furstoss, Nader Khaouam, Phuc Félix Nguyen-Tan, Chang-Shu Wang, Khalil Sultanem. (2017). Data from Head-Neck-PET-CT. The Cancer Imaging Archive. doi: 10.7937/K9/TCIA.2017.8oje5q00
CT Abdomen	TCIA - Pancreas-CT-CB	Hong, J., Reyngold, M., Crane, C., Cuaron, J., Hajj, C., Mann, J., Zinovoy, M., Yorke, E., LoCastro, E., Apte, A. P., & Mageras, G. (2021). Breath-hold CT and cone-beam CT images with expert manual organ-at-risk segmentations from radiation treatments of locally advanced pancreatic cancer [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/TCIA.ESHQ-4D90
CT Thorax:	TCIA - NSCLC	Aerts, H. J. W. L., Wee, L., Rios Velazquez, E., Leijenaar, R. T. H., Parmar, C., Grossmann, P., Carvalho, S., Bussink, J., Monshouwer, R., Haibe-Kains, B., Rietveld, D., Hoebers, F., Rietbergen, M. M., Leemans, C. R., Dekker, A., Quackenbush, J., Gillies, R. J., Lambin, P. (2019). Data From

		NSCLC-Radiomics [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/K9/TCIA.2015.PF0M9REI
CT Thorax	TCIA - LCTSC	Yang, J., Sharp, G., Veeraraghavan, H., Van Elmpt, W., Dekker, A., Lustberg, T., & Gooding, M. (2017). Data from Lung CT Segmentation Challenge (Version 3) [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/K9/TCIA.2017.3R3FVZ08
CT Thorax Prone Female	TCIA- QIN-BREAST and Prone Thorax	Li, X., Abramson, R. G., Arlinghaus, L. R., Chakravarthy, A. B., Abramson, V. G., Sanders, M., & Yankeelov, T. E. (2016). Data From QIN-BREAST (Version 2) [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/K9/TCIA.2016.21JUEBH0 N/A- Testing data was shared from several institutions
CT HDR Female	Female HDR Pelvis	N/A- Testing data was shared from 2 different institutions based in the United States.
CT Prostatectomy	Pelvis ProstateBed	N/A- Testing data was shared from 1 institution based in the United States
CT Pelvis Barrigel	Barrigel™	N/A- Testing data was shared from several institutions in Australia
CT Pelvis SpaceOARVUE	SpaceOAR™_VUE	N/A- Testing data was shared from several institutions

DSC values were calculated between ground truth contour data and AutoContour structures and rated on the same DSC passing criteria used for the Training DSC validation. All structures passed the minimum DSC criteria for small, medium and large structures with a mean DSC of 0.73 ± 0.11 , 0.84 ± 0.09 , and 0.93 ± 0.05 respectively: Additionally, the qualitative clinical appropriateness of AutoContour structures generated on these scans was graded by clinical experts. Autocontour structures were graded on a scale from 1 to 5 where 5 refers to contour requiring no additional edits, and 1 refers to a score in which full manual re-contour of the structure would be required. An average score ≥ 3 was used to determine whether a structure model would ultimately be beneficial clinically. An average rating of 4.37 was found across all CT structure models demonstrating that only minor edits would be required in order to make the structure models acceptable for clinical use.

Table 6: CT External Reviewer Results for AutoContour Model RADAC V5

CT Structure	Size	Pass Criteria	# Testings Sets	Average DSC	Average DSC Std. Dev	Lower Bound 95% Confidence Interval	External Reviewer Average Rating (1-5)
A_Aorta (Update)	Large	0.80	20	0.94	0.02	0.91	4.80
A_Aorta_Asc (Update)	Medium	0.65	20	0.91	0.03	0.86	4.40
A_Carotid_L (Update)	Medium	0.65	37	0.79	0.06	0.68	4.30
A_Carotid_R (Update)	Medium	0.65	37	0.78	0.05	0.69	4.20
A_Celiac	Small	0.50	24	0.78	0.22	0.41	4.40
A_Circumflex_L	Small	0.50	40	0.56	0.16	0.30	4.25

A_Coronary_2d_R	Small	0.50	39	0.65	0.21	0.31	3.60
A_Coronary_L	Small	0.50	18	0.69	0.22	0.33	4.35
A_Coronary_R (Update)	Small	0.50	40	0.55	0.13	0.33	4.25
A_Mesenteric_S	Small	0.50	25	0.78	0.13	0.57	4.50
A_Pulmonary (Update)	Medium	0.65	20	0.89	0.02	0.85	4.50
Atrium_L (Update)	Medium	0.65	20	0.87	0.02	0.85	4.50
Atrium_R (Update)	Medium	0.65	20	0.85	0.06	0.75	4.50
AV_Node	Medium	0.65	40	0.87	0.12	0.67	4.45
Barrigel	Medium	0.65	14	0.79	0.03	0.74	4.30
BileDuct_Common	Small	0.50	25	0.66	0.11	0.47	4.55
Bladder (Update)	Large	0.80	20	0.96	0.02	0.94	4.60
Body+Mask	Large	0.80	22	0.99	0.01	0.98	4.50
Bone_Ischium_L	Large	0.80	41	0.98	0.02	0.94	4.20
Bone_Ischium_R	Large	0.80	41	0.98	0.03	0.94	4.20
Bone_Mandible (Update)	Medium	0.65	22	0.88	0.02	0.84	4.40
Bone_Pelvic (Update)	Large	0.80	41	0.91	0.01	0.89	4.25
Bone_Pterygoid_L	Small	0.50	22	0.81	0.03	0.77	4.20
Bone_Pterygoid_R	Small	0.50	22	0.81	0.03	0.76	4.30
Bone_Skull (Update)	Large	0.80	22	0.94	0.01	0.92	4
Bone_Teeth (Update)	Medium	0.65	9	0.87	0.02	0.84	4.20
Bowel (Update)	Medium	0.65	46	0.87	0.03	0.82	3.50
Bowel_Bag (Update)	Large	0.80	46	0.91	0.05	0.83	4.40
Bowel_Bag_F	Large	0.80	20	0.89	0.05	0.81	4.40
Bowel_F	Medium	0.65	20	0.91	0.04	0.84	4.40
Bowel_Large (Update)	Medium	0.65	46	0.84	0.08	0.71	4.20
Bowel_Large_F	Medium	0.65	20	0.79	0.20	0.47	4.40
Bowel_Small (Update)	Medium	0.65	46	0.83	0.06	0.73	4.10
Bowel_Small_F	Medium	0.65	20	0.87	0.10	0.70	4.30
BrachialPlex_L (Update)	Medium	0.65	22	0.91	0.03	0.87	4.50
BrachialPlex_R (Update)	Medium	0.65	22	0.90	0.03	0.86	4.40
BrachialPlexs	Medium	0.65	22	0.91	0.03	0.87	4.40
Brain (Update)	Large	0.80	22	0.97	0.00	0.97	4.70
Brainstem (Update)	Medium	0.65	22	0.87	0.02	0.84	4.60
Breast_RTOG_L	Large	0.80	20	0.99	0.01	0.97	5
Breast_RTOG_R	Large	0.80	20	0.99	0.02	0.95	4.90
Breasts_RTOG	Large	0.80	20	0.99	0.02	0.96	4.95

BuccalMucosa (Update)	Medium	0.65	22	0.66	0.09	0.51	4.40
Canal_Anal	Medium	0.65	20	0.72	0.17	0.44	4.70
Canal_Anal_F	Medium	0.65	20	0.75	0.21	0.40	4.30
InternalAuditoryCanal_L	Small	0.50	20	0.88	0.10	0.72	4.40
CaudaEquina (Update)	Medium	0.65	41	0.80	0.08	0.66	4.40
Cavity_Oral_Ext (Update)	Medium	0.65	22	0.95	0.01	0.94	4.10
Chestwall_2cm_L	Large	0.80	20	0.99	0.002	0.99	4.80
Chestwall_2cm_R	Large	0.80	20	0.99	0.003	0.99	5
Chestwall_ESTRO_L	Large	0.80	18	0.90	0.04	0.83	4.20
Chestwall_ESTRO_R	Large	0.80	18	0.89	0.03	0.84	4.20
Cochlea_L (Update)	Small	0.50	22	0.70	0.12	0.51	4.50
Cochlea_R (Update)	Small	0.50	22	0.80	0.13	0.59	4.50
Cornea_2d_L	Small	0.50	22	0.80	0.05	0.73	4.40
Cornea_2d_R	Small	0.50	22	0.78	0.06	0.69	4.40
CorpusCallosum	Medium	0.65	22	0.75	0.05	0.67	4.20
Cribriform	Medium	0.65	22	0.74	0.11	0.55	4.10
Dental_Artifact (Update)	Medium	0.65	20	0.89	0.10	0.73	4.10
Ear_Internal_L (Update)	Small	0.50	22	0.72	0.09	0.58	4
Ear_Internal_R (Update)	Small	0.50	22	0.73	0.08	0.60	4.10
Esophagus (Update)	Medium	0.65	40	0.83	0.04	0.78	4.75
Eyes	Medium	0.65	21	0.97	0.01	0.96	4.50
Falx	Medium	0.65	22	0.79	0.04	0.73	4.40
GreatVessels	Medium	0.65	20	0.92	0.02	0.89	4.30
HDR_Canal_Anal	Large	0.80	20	0.79	0.10	0.62	4.30
HDR_Colon_Sigmoid	Medium	0.65	20	0.70	0.20	0.38	4.10
Heart (Update)	Large	0.80	20	0.97	0.04	0.91	5
Heart+A_Pulm	Large	0.80	20	0.98	0.01	0.96	4.50
Hippocampus_L (Update)	Medium	0.65	22	0.77	0.11	0.59	4.50
Hippocampus_R (Update)	Medium	0.65	22	0.81	0.06	0.71	4.50
Iliac_Int_L (Update)	Medium	0.65	41	0.80	0.05	0.72	4.45
Iliac_Int_R (Update)	Medium	0.65	41	0.80	0.06	0.69	4.45
Iliac_L (Update)	Medium	0.65	41	0.88	0.06	0.79	4.50
Iliac_R (Update)	Medium	0.65	41	0.84	0.06	0.74	4.50
Kidneys	Large	0.80	25	0.99	0.03	0.94	4.80
Larynx (Update)	Medium	0.65	22	0.88	0.10	0.72	4.40
LN_Ax_L1_ESTRO_2d_L	Medium	0.65	20	0.95	0.05	0.87	4.50

LN_Ax_L1_ESTRO_2d_R	Medium	0.65	20	0.94	0.05	0.87	4.50
LN_Ax_L2_ESTRO_2d_L	Medium	0.65	20	0.92	0.04	0.85	4.50
LN_Ax_L2_ESTRO_2d_R	Medium	0.65	20	0.93	0.04	0.86	4.60
LN_Ax_L3_ESTRO_2d_L	Medium	0.65	18	0.69	0.13	0.48	4.50
LN_Ax_L3_ESTRO_2d_R	Medium	0.65	18	0.67	0.14	0.44	4.50
LN_InPec_ESTRO_2d_L	Medium	0.65	20	0.90	0.07	0.78	4.60
LN_InPec_ESTRO_2d_R	Medium	0.65	19	0.902	0.09	0.76	4.50
LN_Ax_L2_InPec_ESTRO_2d_L	Medium	0.65	20	0.93	0.04	0.86	4.50
LN_Ax_L2_InPec_ESTRO_2d_R	Medium	0.65	20	0.93	0.05	0.86	4.50
LN_Mesorectum	Large	0.80	41	0.93	0.03	0.88	4.50
LN_Neck_2d_L	Large	0.80	22	0.90	0.02	0.86	4.50
LN_Neck_2d_R	Large	0.80	22	0.90	0.03	0.86	4.50
LN_Neck_CerVII_2d_L	Large	0.80	22	0.94	0.04	0.87	4.20
LN_Neck_CerVII_2d_R	Large	0.80	22	0.94	0.03	0.89	4.20
LN_Neck_IB_2d_L	Medium	0.65	22	0.79	0.05	0.71	4.30
LN_Neck_IB_2d_R	Medium	0.65	22	0.82	0.03	0.76	4.50
LN_Neck_II_2d_L	Medium	0.65	21	0.75	0.04	0.68	4.50
LN_Neck_II_2d_R	Medium	0.65	21	0.77	0.05	0.68	4.50
LN_Neck_II-IV_2d_L	Large	0.80	22	0.94	0.05	0.87	4.40
LN_Neck_II-IV_2d_R	Large	0.80	22	0.94	0.04	0.89	4.40
LN_Neck_III_2L	Medium	0.65	22	0.74	0.06	0.65	4.40
LN_Neck_III_2R	Medium	0.65	22	0.72	0.06	0.61	4.40
LN_Neck_IV_2L	Medium	0.65	22	0.94	0.04	0.87	4.30
LN_Neck_IV_2R	Medium	0.65	22	0.93	0.04	0.86	4.30
LN_Neck_VII_2d_L	Medium	0.65	22	0.75	0.10	0.58	4
LN_Neck_VII_2d_R	Medium	0.65	22	0.72	0.09	0.58	4
LN_Neck_VIIA_2d_L	Medium	0.65	22	0.85	0.07	0.74	4.20
LN_Neck_VIIA_2d_R	Medium	0.65	22	0.82	0.10	0.66	4.20
LN_Neck_VIIB_2d_L	Medium	0.65	22	0.69	0.13	0.48	4
LN_Neck_VIIB_2d_R	Medium	0.65	22	0.68	0.12	0.49	4
LN_Pelvics_NRG (Update)	Large	0.80	41	0.82	0.03	0.77	4.50
LN_Presacral (Update)	Medium	0.65	41	0.81	0.07	0.70	4.45
Lobe_Temporal_L (Update)	Large	0.80	22	0.95	0.07	0.84	4.50
Lobe_Temporal_R (Update)	Large	0.80	22	0.95	0.08	0.83	4.50

Lungs	Large	0.80	20	0.98	0.01	0.97	5
Marrow_Pelvis	Medium	0.65	21	0.94	0.01	0.93	4.45
Medulla	Medium	0.65	22	0.76	0.06	0.67	4.50
Midbrain	Medium	0.65	22	0.75	0.13	0.55	4.50
Musc_Iliopsoas_L (Update)	Large	0.80	41	0.92	0.02	0.88	4.90
Musc_Iliopsoas_R (Update)	Large	0.80	41	0.92	0.02	0.88	4.90
Musc_PecMinor_L	Medium	0.65	18	0.89	0.04	0.82	4.50
Myocardium (Update)	Medium	0.65	20	0.91	0.02	0.87	4.40
Pancreas (Update)	Medium	0.65	25	0.73	0.13	0.52	4.20
Parametrium	Medium	0.65	19	0.77	0.11	0.59	4.70
Parotid_L (Update)	Medium	0.65	22	0.90	0.03	0.86	4.20
Parotid_R (Update)	Medium	0.65	22	0.91	0.02	0.87	4.10
Pericardium (Update)	Large	0.80	20	0.98	0.02	0.95	4.30
Pericardium_Inf	Large	0.80	20	0.98	0.01	0.96	4.40
Pericardium_Inf+A_Pulm	Large	0.80	20	0.98	0.01	0.97	4.30
Pharynx (Update)	Medium	0.65	22	0.84	0.04	0.77	4.30
Pituitary (Update)	Small	0.50	18	0.60	0.29	0.13	3.10
Pituitary_3d	Small	0.50	20	0.63	0.10	0.47	4.50
Pons	Medium	0.65	22	0.85	0.03	0.80	4.50
ProstateBed (Update)	Medium	0.65	20	0.89	0.05	0.80	4.40
ProstateFiducials	Small	0.50	10	0.52	0.09	0.37	3.80
Rectum-Spacergel_VUE	Medium	0.65	5	0.95	0.02	0.92	3.90
Retina_2d_L	Small	0.50	22	0.88	0.03	0.83	4.40
Retina_2d_R	Small	0.50	22	0.88	0.03	0.83	4.40
Rib01_L (Update)	Medium	0.65	40	0.84	0.08	0.72	4.20
Rib01_R (Update)	Medium	0.65	40	0.85	0.08	0.71	4.15
Rib02_L (Update)	Medium	0.65	40	0.84	0.08	0.71	4.15
Rib02_R (Update)	Medium	0.65	39	0.82	0.12	0.63	4.30
Rib03_L (Update)	Medium	0.65	40	0.84	0.09	0.69	4.15
Rib03_R (Update)	Medium	0.65	39	0.85	0.11	0.67	4.20
Rib04_L (Update)	Medium	0.65	38	0.85	0.06	0.76	4.25
Rib04_R (Update)	Medium	0.65	39	0.82	0.12	0.61	4.30
Rib05_L (Update)	Medium	0.65	37	0.85	0.09	0.70	4.20
Rib05_R (Update)	Medium	0.65	33	0.86	0.09	0.70	3.95
Rib06_L (Update)	Medium	0.65	40	0.85	0.11	0.68	4.30
Rib06_R (Update)	Medium	0.65	40	0.82	0.15	0.57	4.35

Rib07_L (Update)	Medium	0.65	40	0.86	0.07	0.75	4.40
Rib07_R (Update)	Medium	0.65	40	0.84	0.13	0.62	4.35
Rib08_L (Update)	Medium	0.65	40	0.87	0.02	0.83	4.35
Rib08_R (Update)	Medium	0.65	40	0.83	0.15	0.59	4.20
Rib09_L (Update)	Medium	0.65	40	0.87	0.03	0.82	4.30
Rib09_R (Update)	Medium	0.65	40	0.81	0.20	0.48	4.20
Rib10_L (Update)	Medium	0.65	40	0.85	0.11	0.67	4.35
Rib10_R (Update)	Medium	0.65	40	0.77	0.26	0.35	4.40
Rib11_L (Update)	Medium	0.65	40	0.83	0.11	0.65	4.40
Rib11_R (Update)	Medium	0.65	40	0.76	0.27	0.32	4.40
Rib12_L (Update)	Small	0.50	30	0.79	0.12	0.59	4.35
Rib12_R (Update)	Small	0.50	27	0.81	0.06	0.71	4.30
Rib (Update)	Large	0.80	20	0.81	0.02	0.79	4.50
Rib_R (Update)	Large	0.80	20	0.81	0.02	0.79	4.60
SacralPlex_L (Update)	Medium	0.65	41	0.67	0.04	0.60	4.45
SacralPlex_R (Update)	Medium	0.65	41	0.69	0.05	0.61	4.45
Sinuses	Medium	0.65	22	0.71	0.04	0.63	4.10
SpinalCanal (Update)	Large	0.80	25	0.93	0.05	0.84	4.50
SpinalCord (Update)	Medium	0.65	45	0.89	0.04	0.82	4.50
Spleen (Update)	Large	0.80	24	0.97	0.10	0.96	4.50
Tentorium	Medium	0.65	22	0.61	0.07	0.48	4.30
Trachea (Update)	Medium	0.65	22	0.84	0.04	0.78	4.40
UteroCervix (Update)	Medium	0.65	12	0.85	0.06	0.76	4.50
V_Jugular_L (update)	Medium	0.65	37	0.76	0.13	0.55	3.90
V_Jugular_R (update)	Medium	0.65	36	0.81	0.06	0.71	4.10
V_Pulmonary	Medium	0.65	40	0.89	0.09	0.74	4.35
V_Venacava_I (Update)	Medium	0.65	11	0.80	0.09	0.65	4.65
V_Venacava_I_UKSABR	Medium	0.65	18	0.97	0.06	0.87	4.50
V_Venacava_S (Update)	Medium	0.65	20	0.88	0.02	0.85	4.50
V_Venacava_S_UKSABR	Medium	0.65	18	0.95	0.08	0.83	4.40
Vagina	Medium	0.65	20	0.89	0.05	0.81	4.50
Valve_Aortic	Medium	0.65	36	0.82	0.18	0.52	4.45
Valve_Mitral	Medium	0.65	40	0.91	0.10	0.75	4.45
Valve_Pulmonic	Medium	0.65	39	0.81	0.18	0.52	4.35
Valve_Tricuspid	Medium	0.65	40	0.91	0.09	0.77	4.45
VB (Update)	Large	0.80	62	0.94	0.02	0.91	4.125

VB_C1 (Update)	Medium	0.65	22	0.89	0.02	0.86	4.10
VB_C2 (Update)	Medium	0.65	22	0.91	0.01	0.89	4.30
VB_C3 (Update)	Medium	0.65	22	0.88	0.02	0.85	4.30
VB_C4 (Update)	Medium	0.65	22	0.88	0.02	0.85	4.40
VB_C5 (Update)	Medium	0.65	22	0.87	0.02	0.84	4.30
VB_C6 (Update)	Medium	0.65	22	0.88	0.02	0.85	4
VB_C7 (Update)	Medium	0.65	22	0.90	0.01	0.88	4.30
VB_L1 (Update)	Large	0.80	19	0.89	0.21	0.54	4.40
VB_L2 (Update)	Large	0.80	19	0.88	0.21	0.53	4.50
VB_L3 (Update)	Large	0.80	20	0.90	0.19	0.58	4.50
VB_L4 (Update)	Large	0.80	20	0.90	0.21	0.56	4.50
VB_L5 (Update)	Large	0.80	20	0.90	0.19	0.58	4.30
VB_T01 (Update)	Medium	0.65	20	0.95	0.13	0.73	4.50
VB_T02 (Update)	Medium	0.65	20	0.96	0.07	0.85	4.50
VB_T03 (Update)	Medium	0.65	20	0.93	0.18	0.63	4.50
VB_T04 (Update)	Medium	0.65	20	0.92	0.21	0.57	4.30
VB_T05 (Update)	Medium	0.65	20	0.91	0.21	0.57	4.40
VB_T06 (Update)	Medium	0.65	20	0.87	0.23	0.49	4.40
VB_T07 (Update)	Medium	0.65	20	0.82	0.32	0.28	4.10
VB_T08 (Update)	Medium	0.65	20	0.82	0.34	0.26	4.40
VB_T09 (Update)	Medium	0.65	20	0.82	0.34	0.26	4.20
VB_T10 (Update)	Medium	0.65	20	0.82	0.34	0.26	4.10
VB_T11 (Update)	Medium	0.65	20	0.81	0.34	0.24	4
VB_T12 (Update)	Medium	0.65	17	0.89	0.23	0.52	4.40
Ventricle_Brain	Medium	0.65	22	0.85	0.06	0.76	4.30
Ventricle_L (Update)	Medium	0.65	20	0.93	0.10	0.92	4.50
Ventricle_R (Update)	Medium	0.65	20	0.84	0.03	0.78	4.50
Vessels_Pelvis	Medium	0.65	41	0.93	0.05	0.85	4

The MR training data set used for initial testing of the Brain models (Amygdala_L/R, CorpusCallosum, Cornea_L/R, Falx, Retina_L/R, Tentorium, Sinuses, Thalamus and Ventricle_Brain) had an average of 259 training image sets and 58 testing image sets and were acquired from several different institutions in several countries.

The MR training data used for initial testing of the MR Pelvis models (Rectal_Spacer) had an average of 243 training image sets and 50 testing image sets and were taken from 2 open source datasets, and several institutions within several countries, such as the United States,

Canada, and Spain. Datasets used for testing were removed from the training dataset pool before model training began, and used exclusively for testing.

Ground truthing of each test data set was generated manually using consensus (NRG/RTOG) guidelines as appropriate by six clinically experienced experts consisting of 2 radiation therapy physicists, 1 radiation dosimetrist, and 3 radiation therapists with specialized training in radiation therapy contouring. For MR Structure models, a mean training DSC of 0.82+/-0.12 for medium models, and 0.72+/- 0.09 for small models.

Table 8: MR Training Data Results for AutoContour Model RADAC V5							
MR Models	Size	Pass Criteria	# of Training Sets	# of Testing Sets	DSC (Avg)	DSC Std Dev (Avg)	Lower Bound 95% Confidence Interval
A_Pud_Int_L** (Update)	Small	0.50	221	56	0.69	0.08	0.56
A_Pud_Int_R** (Update)	Small	0.50	221	56	0.69	0.08	0.56
Amygdala_L	Small	0.50	493	133	0.73	0.07	0.61
Amygdala_R	Small	0.50	493	133	0.73	0.07	0.61
Bladder_Trigone** (Update)	Medium	0.65	256	65	0.72	0.05	0.64
Brainstem** (Update)	Medium	0.65	422	50	0.88	0.16	0.62
CorpusCallosum	Medium	0.65	56	15	0.72	0.25	0.31
Falx	Medium	0.65	178	45	0.83	0.03	0.78
HDR_Bowel	Medium	0.65	307	37	0.83	0.19	0.51
HDR_Colon_Sigmoid	Medium	0.65	240	24	0.81	0.21	0.46
Lens_L** (Update)	Small	0.50	208	52	0.81	0.09	0.66
Lens_R** (Update)	Small	0.50	208	52	0.81	0.09	0.66
Medulla*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
Midbrain*	Medium	0.65	N/A	N/A	N/A	N/A	N/A
NVB_L** (Update)	Small	0.50	167	43	0.61	0.08	0.48
NVB_R** (Update)	Small	0.50	167	43	0.61	0.08	0.48
OpticNrv_L** (Update)	Small	0.50	164	32	0.64	0.08	0.51
OpticNrv_R** (Update)	Small	0.50	164	32	0.64	0.08	0.51
OpticTract_L** (Update)	Small	0.50	304	76	0.72	0.08	0.59
OpticTract_R** (Update)	Small	0.50	304	76	0.72	0.08	0.59
PenileBulb_TRUFI	Small	0.50	228	58	0.79	0.12	0.59
Pons *	Medium	0.65	N/A	N/A	N/A	N/A	N/A
Rectal_Spacer** (Update)	Small	0.50	233	26	0.82	0.24	0.43
Sinuses	Medium	0.65	178	45	0.83	0.04	0.762

Tentorium	Small	0.50	180	46	0.77	0.05	0.69
Thalamus	Medium	0.65	361	40	0.83	0.13	0.62
Urethra** (Update)	Small	0.50	390	100	0.68	0.09	0.53
Ventricle_Brain	Medium	0.65	182	47	0.90	0.04	0.8342

*These structures were generated from post-processing operations from previously released or re-tested models, Brainstem, rather than from a CNN model. Qualitative and Quantitative analysis of these structures is still performed.

**A_Pud_Int_L, A_Pud_Int_R, Bladder_Trigone, Brainstem, Lens_L, Lens_R, NVB_L, NVB_R, OpticNrv_L, OpticNrv_R, OpticTract_L, OpticTract_R, Rectal_Spacer, and Urethra models were previously released/tested, but updates to the training datasets and contour output necessitated additional release testing for these models.

Additional external clinical testing was performed in order to validate the accuracy of the models on image sets acquired that were unique to the training datasets.

Table 9: MR External Clinical Dataset References		
Model Group	Data Source ID	Data Citation
MR Brain	MR - Renown	N/A
MR Pelvis	Gold Atlas Pelvis	Nyholm, Tufve, Stina Svensson, Sebastian Andersson, Joakim Jonsson, Maja Sohlén, Christian Gustafsson, Elisabeth Kjellén, et al. 2018. "MR and CT Data with Multi Observer Delineations of Organs in the Pelvic Area - Part of the Gold Atlas Project." <i>Medical Physics</i> 12 (10): 3218–21. doi:10.1002/mp.12748.
MR Pelvis_2	SynthRad	Thummerer A, van der Bijl E, Galapon Jr A, Verhoeff JJ, Langendijk JA, Both S, van den Berg CAT, Maspero M. 2023. SynthRAD2023 Grand Challenge dataset: Generating synthetic CT for radiotherapy. <i>Medical Physics</i> , 50(7), 4664-4674. https://doi.org/10.1002/mp.16529
MRLinac Pelvis	MR Linac	N/A- Testing data was shared by 2 institutions utilizing MR Linacs for image acquisitions.
MR Female HDR Brachy	Female HDR MR Pelvis	N/A- Testing data was shared by 1 institution in Canada
MR Pelvis Barrigel	Barrigel	N/A- Testing data was shared by several institutions in Australia.

For the Brain models, datasets acquired via data-use agreement from a clinical partner were acquired containing 20 MR T1 Ax post (BRAVO) image scans acquired with a GE MR750w scanner. Images had an average slice thickness of 1.6mm, In-plane resolution between 0.94 mm, and acquisition parameters of TR=5.98ms, TE=96.8s. Data for testing of the MR Pelvis structure models were acquired from 2 publicly available datasets, which contained images of patients with prostate or rectal cancer, as well as 1 dataset shared from 2 institutions utilizing an MR Linac. Various scanner models and acquisition settings were used. Data for testing of the MR Pelvis HDR structure models were acquired from 1 institution using two different slice thicknesses, 1mm and 4mm, and two different in-plane resolutions, 1mm and .72mm.

DSC values were calculated between ground truth contour data and AutoContour structures and rated on the same DSC passing criteria as was used for the training DSC validation. All structures, but one passed the minimum DSC criteria for small, and medium structures with a

mean DSC of 0.71+/-0.13, and 0.78+/-0.09 respectively. Additionally, the qualitative clinical appropriateness of AutoContour structures generated on these scans was graded by clinical experts. Autocontour structures were graded on a scale from 1 to 5 where 5 refers to contour requiring no additional edits, and 1 refers to a score in which full manual re-contour of the structure would be required. An average score ≥ 3 was used to determine whether a structure model would ultimately be beneficial clinically. An average rating of 4.3 was found across all MR structure models demonstrating that only minor edits would be required in order to make the structure models acceptable for clinical use. The single structure that did not pass the minimum DSC criteria was also evaluated by clinical experts and scored an average of 3.90, which demonstrates the clinical effectiveness of this model.

Table 10: MR External Reviewer Results for AutoContour Model RADAC V5

MR Models	Size	Pass Criteria	# External Test Data Sets	Average DSC	Average DSC Std. Dev	Lower Bound 95% Confidence Interval	External Reviewer Average Rating (1-5)
A_Pud_Int_L (Update)	Small	0.50	39	0.57	0.11	0.39	4.30
A_Pud_Int_R (Update)	Small	0.50	39	0.59	0.07	0.48	4.40
Amygdala_L	Small	0.50	20	0.65	0.17	0.37	4.30
Amygdala_R	Small	0.50	19	0.66	0.17	0.48	4.10
Bladder_Trigone (Update)	Medium	0.65	45	0.56	0.17	0.28	4.20
Brainstem (Update)	Medium	0.65	20	0.93	0.02	0.90	4.80
CorpusCallosum	Medium	0.65	20	0.76	0.08	0.63	4.80
Falx	Medium	0.65	20	0.79	0.09	0.64	4.50
HDR_Bowel	Medium	0.65	7	0.50	0.14	0.26	3.90
HDR_Colon_Sigmoid	Medium	0.65	8	0.80	0.12	0.60	4.40
Lens_L (Update)	Small	0.50	18	0.74	0.13	0.53	4.80
Lens_R (Update)	Small	0.50	19	0.68	0.16	0.41	4.80
Medulla	Medium	0.65	19	0.82	0.09	0.67	4.40
Midbrain	Medium	0.65	20	0.84	0.06	0.74	4.40
NVB_L (Update)	Small	0.50	6	0.81	0.09	0.66	4.20
NVB_R (Update)	Small	0.50	6	0.83	0.04	0.76	4.10
OpticNrv_L (Update)	Small	0.50	20	0.75	0.17	0.47	4.20
OpticNrv_R (Update)	Small	0.50	20	0.70	0.17	0.42	4.40
OpticTract_L (Update)	Small	0.50	20	0.78	0.18	0.49	4.20
OpticTract_R (Update)	Small	0.50	20	0.80	0.16	0.54	4.10
PenileBulb_TRUFI	Small	0.50	39	0.74	0.09	0.59	4.40
Pons	Medium	0.65	20	0.90	0.04	0.83	4.40

Rectal_Spacer (Update)	Small	0.50	18	0.80	0.09	0.65	4
Sinuses	Medium	0.65	20	0.79	0.18	0.49	4.30
Tentorium	Small	0.50	20	0.67	0.18	0.37	4.30
Thalamus	Medium	0.65	20	0.81	0.08	0.68	4.50
Urethra (Update)	Small	0.50	39	0.55	0.13	0.33	4.50
Ventricle_Brain	Medium	0.65	20	0.91	0.03	0.86	4.30

Validation testing of the AutoContour application demonstrated that the software meets user needs and intended uses of the application.

8. Conclusion

AutoContour RADAC V5 is deemed substantially equivalent to the primary Predicate Device AutoContour RADAC V4 (K242729). Verification tests were performed to ensure that the software works as intended, and pass/fail criteria were used to verify requirements. Validation testing was performed to ensure that the software was behaving as intended, and output results from AutoContour were validated against accepted results for known planning parameters from clinically-utilized treatment planning systems. All tests passed regression testing. Verification and validation testing, and the risk documentation demonstrate that AutoContour is as safe and effective as the Predicate Device. The minor technological differences between AutoContour Model RADAC V5 and the Predicate Device do not raise any significant questions on the safety and effectiveness of the Subject Device.