ACCURAY ACCURAY ACCURAY Radixact® System, the Most Comprehensive Breast Cancer Radiation Therapy System



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Safety Statement

Most side effects of radiotherapy, including radiotherapy delivered with Accuray systems, are mild and temporary, often involving fatigue, nausea, and skin irritation. Side effects can be severe, however, leading to pain, alterations in normal body functions (for example, urinary or salivary function), deterioration of quality of life, permanent injury and even death. Side effects can occur during or shortly after radiation treatment or in the months and years following radiation. The nature and severity of side effects depend on many factors, including the size and location of the treated tumor, the treatment technique (for example, the radiation dose), the patient's general medical condition, to name a few. For more details about the side effects of your radiation therapy, and if treatment with an Accuray product is right for you, ask your doctor.

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Overview Focus on breast cancer treatments

Radixact[®] System Overview THE LATEST GENERATION TOMOTHERAPY[®] SYSTEM



Radixact® System Benefits for Breast Cancer Treatments

Tools to treat breast cancer cases with accuracy, precision, and with high patient throughput









TomoHelical™

- Treat complex irradiation volumes (bilateral breast, breast with lymph nodes, breast cases not suited for breath hold)
- Treat Partial Breast Irradiation (PBI) cases with Synchrony® for real-time target tracking with dynamic delivery

- Simplified and automated VOLO™ Ultra planning
- Treat tangential beams' breast cancer cases fast (10 min treatment time slots with typical 2 min beam-on times)
- Fast pause/resume enabling higher breast cancer patient throughput

*VitalHold™

- Cardiac and lung sparing for left breast cancer with TomoDirect and DIBH with automated beam gating using SGRT
- Easy setup; tattoo-free
- Confident Monitoring
- Fast delivery

Radixact® System Most comprehensive breast cancer treatment system

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Use of efficient TomoDirect treatments for other indications. Use of SGRT for patient positioning.

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TomoHelical™ Treatments

Delivers beamlets in 360^o helical pattern providing precise dose painting and homogeneous coverage

Clinical Applications

- Highly conformal dose distributions for complex shaped target volumes
- Organ-at-risk (OAR) dose minimization
- Simultaneous irradiation of multiple target volumes

TomoHelical breast with lymph nodes, surgical site boost and intermammary node boost plan

TomoHelical[™] bilateral breast plan

50 Gy in 25 fractions



Left breast with 46 Gy, surgical site boost with 59 Gy, intermammary node boost with 61 Gy in 23 fractions



Cardiac Sparing with Personalized Treatment Planning for Early-stage Left Breast Cancer

Helical TomoTherapy[®] is a cardiac sparing alternative to deep inspiration breath-hold (DIBH)

Study Design

- Retrospective planning study with 23 patients
- 42.5 Gy in 16 fractions
- Comparison of plans to analyze cardiac sparing optimization:
 - a) Free-breathing (FB) with tangential technique
 - b) DIBH with tangential technique
 - c) Tomo 1: free breathing plan optimized to limit contralateral dose to breast to 3.1 Gy
 - d) Tomo 2: free breathing plan optimized to reduce heart dose without controlling dose to contralateral breast

Outcomes

Helical TomoTherapy® provides excellent conformity and dose distribution

Helical TomoTherapy resulted in significant cardiac sparing





(a) FB WH: 3.9 Gy; LAD: 27.0 Gy

(b) DIBH WH: 0.8 Gy; LAD: 2.9 Gy



Mathieu D, Bedwani S, Mascolo-Fortin J, Côté N, Bernard AA, Roberge D, Yassa M, Bahig H, Vu T. Cardiac Sparing with Personalized Treatment Planning for Early-stage Left Breast Cancer. Cureus. 2020 Mar Proprietory and Confidential Property of Accuray 7 12;12(3):e7247. doi: 10.7759/cureus.7247. PMID: 32292662; PMCID: PMC7152579.

Cardiopulmonary related patient-reported outcomes in a randomized clinical trial of radiation therapy for breast cancer

Helical TomoTherapy[®] demonstrates superior preservation of long-term heart and lung function when compared to conventional radiotherapy

Study Design

- Phase III randomized control trial highlighted patient-reported outcomes at 10 years follow-u
- 123 patients (64 conventional radiotherapy versus 59 helical TomoTherapy®)
- 42 Gy in 15 fractions

Outcomes

Patient reported outcomes showed 10-year survival free of heart and lung deterioration was 84.5% with helical TomoTherapy- a significant improvement above the 66.9% achieved with conventional radiotherapy (p=0.029)

Helical TomoTherapy can significantly improve patient reported outcomes

Helical TomoTherapy allows highly conformal shaping of dose distribution

Integrated imaging improves the accuracy of the treatment

Lung toxicity is detectable early on and is affected by the choice of radiation technique



Fig. 3 Patient reported outcome (PRO) specific survival free from deterioration in any of dyspnea, fatigue, pain, or physical functioning scales, by randomization arm. TT: tomotherapy. CR: conventional radiotherapy

TomoDirect™ Treatments

3DCRT or IMRT treatments delivered at discrete beam angles with fixed gantry positions

Radixact® Treatment Delivery System capabilities

- Fast pause of beam in < 100 milliseconds
- Fast resume of beam in < 1 second
- 10-minute treatment time slots with typical total 2-minute beam-on-time



TomoDirect[™] planning capabilities with VOLO[™] Ultra

- Automated beam angle selection
- Opposing beam with divergence
- Beam weighting and balancing to reduce hot spots
- Beam on time displayed for each beam



TomoDirect™ Treatments

3D-CRT or IMRT treatments delivered at discrete beam angles with fixed gantry positions

Left breast DIBH 3DCRT treatment plans created using VOLO™ Ultra on Accuray Precision®

Plan Highlights

- Homogeneous dose coverage of left breast
- Low mean heart dose of 0.91 Gy
- 50 Gy in 25 fractions (94.5 seconds beam on time)



Plan Highlights

- Homogeneous dose coverage of left breast
- Low mean heart dose of 0.76 Gy
- 42.4 Gy in 16 fractions (128.4 seconds beam on time)



Static Beam TomoTherapy® as an Optimization Method in Whole-Breast Radiation Therapy (WBRT)

TomoDirect[™] represents a suitable WBRT alternative treatment approach

Study Design

Outcomes

- A study of 27 patients was planned to evaluate TomoDirect[™] with 2 beams against inverse planned intensity modulated radiation therapy (IP-IMRT) with 4 beams
- Comparisons included:
 - Target and organ at risk (OAR) doses
 - Planning efficiency by measuring optimization times



OAR Dosimetric Comparisons

PTV dose metrics were similar between modalities and met ICRU50 goals

TomoDirect plans produced a statistically significant reduction in V₅ ipsilateral lung doses

TomoDirect reduced planning time and optimization compared to IP-IMRT

Squires M, Hu Y, Byrne M, Archibald-Heeren B, Cheers S, Bosco B, Teh A, Fong A. Static beam tomotherapy as an optimisation method in whole-breast radiation therapy (WBRT). J Med Radiat Sci. 2017 Dec;64(4):281-289. doi: 10.1002/jmrs.232. Epub 2017 Jun 4. PMID: 28580762; PMCID: PMC5715293.

Clinical Evidence with TomoDirect[™] Techniques

TomoDirect provides consistent clinical results

Ultra hypofractionated radiotherapy in 271 elderly patients with T1-T3 disease¹

TomoDirect[™] IMRT reduces the occurrence of severe toxicities

 Dosimetry was superior in reducing dose to the contralateral breast and to the heart compared to conventional 3D-CRT

A comparison of TomoDirect IMRT, TomoDirect **3D--CRT** and conventional linac **3D-CRT** all using 2 beams in 20 of 152 patients with TI-T3 disease ²

- OAR dosimetry was superior with TomoDirect IMRT when compared to conventional 3D-CRT
- Late skin toxicity was reduced with TomoDirect IMRT when compared to conventional 3D-CRT
- TomoDirect IMRT provided good coverage of the whole breast with reduced high doses to the target and low doses to the contralateral tissues
- 152 patients were treated with TomoDirect IMRT with a local control rate of 99.1% at 3 years

1. Zerella MA et al (2022) Ultra-hypofractionated whole breast adjuvant radiotherapy in the real-world setting: single experience with 271 elderly/frail patients treated with 3D and IMRT technique. J Cancer Res Clin Oncol. 2022 Apr;148(4):823-835. doi: 10.1007/s00432-021-03907-w. Epub 2022 Jan 6. PMID: 34989858; PMCID: PMC8733799.

 Nagai A, Shibamoto Y, Yoshida M, Inoda K, Kikuchi Y. Intensity-modulated radiotherapy using two static ports of tomotherapy for breast cancer after conservative surgery: dosimetric comparison with other treatment methods and 3-year clinical results. J Radiat Res. 2017 Jul 1;58(4):529-536. doi: 10.1093/jrr/rrw132. PMID: 28339844; PMCID: PMC5570131.

VitalHold[™] Solution*

SGRT and DIBH on Radixact System with Accuray and C-RAD partnership

Accuray & C-RAD Partnership

effective patient set-up

- Catalyst⁺ HD integration with Radixact[®] System
- Tattoo-free, non-ionizing patient setup
- Patient monitoring during DIBH treatments



ACCURAY



FAST DELIVERY Treat precisely in as little as 2 minutes with added patient comfort *VitalHold™ is 510(k) Pending. VitalHold is not available for sale in the USA. It is not CE-marked and availability is subject to regulatory clearance or approval in some markets. Proprietary and Confidential Property of Accuray 13

CATALYST





Radixact[®] VitalHold[™] with Catalyst⁺ HD

SGRT Overview DIBH with SGRT (integrated & automated)



- Founded in 2003 to advance precision and safety in cancer care
- Product conception based on research from

Professor Anders Brahme, Head of Medical Radiation Physics, Karolinska Institute, Stockholm

- Global HQ: Uppsala, Sweden
- Offices in USA, Germany, France and China
- Listed on Nasdaq First North (2007) Listed on NASDAQ Stock Exchange (2014)







C-RAD SGRT TECHNOLOGY

Three Catalyst⁺ HD scanners







High Resolution Cameras

Structured Light Projectors

High Resolution surface





Clinical advantages



Dose free - Less side effects



Non-invasive - Ease of use

Marker less





Less impact on daily workflow

- Usability advantages



Patient compliance - Standardized workflows

Catalyst⁺ HD to treat breast cancer on Radixact[®] System

C-RAD SGRT use the surface to:

- Setup the patient
 - According to the planned treatment position

Monitor the patient in real-time

According to verified setup and hold treatment if patient moves out of tolerance

Perform breath hold treatments

According to planned respiratory gating window and allow gated treatment only when patient is holding their breath





Easy Setup Workflow

- Large patient surface is compared to reference CT structure
- Patient posture errors are shown onto the patient by projected light for an easy chin and arm correction
- Calculated 6 Degrees of Freedom (DOF) couch shifts are presented to the user and with a • single click automatically sent to the couch for instant position correction

Benefits

- Color map projection & tattoo-free Efficiency •
- Direct communication with Accuray Radixact® System - Efficiency and Safety
- Reproducibility Precision ۲
- User comfort Patient-centric



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CALCULATED RRECTIO

POSTURE

0 +

Left Camera

Mid Camera **Right Camera** Reference im

Live imag

ID zzzmall2018_TD_Tang_mam--zzz_mall2018_TD_Tang_mam 40Gy_11

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For all patients

- Favourable cases
 - Left Breast DIBH: Isocenter, arm • and chin
 - Extremity: Time-saving •
 - TBI ٠



Real-Time Motion Monitoring during TomoHelical™ treatments

- Snapshot reference from setup verification to monitor the patient position throughout the treatment
- Tracking patient posture position withing prescribed tolerance
- Tracking patient isocentric position within prescribed tolerances
- Automatic pause of beam if needed

Benefits

- Real-time SGRT with TomoHelical– Efficiency
 and Confidence
- Direct communication with Accuray Radixact[®] Linac - Efficiency and Safety
- No fiducial Efficiency



For all patients

- Favourable cases
 - Radical or involuntary
 movement cases





Easy and Reproducible DIBH gating

- Prescribed gating parameters with dual tracking points and a 2-4mm gating window, only to account for a daily baseline correction
- Tracking the dynamic respiratory breathing
- Visual coaching to let the patient breathe as planned
- Allow treatment only at the prescribed gating window at breath hold in combination with the breath hold patient position
- Automatic beam hold and resume

Benefits

- No blocker Efficiency
- Reproducibility Precision
- Visual coaching Ease of use
- Multiple respiration tracking points Confidence
- Direct communication with Accuray Radixact[®] System Efficiency and Safety



DIBH Gating

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1 2 3 4

Reference image

- Favourable cases
 - Left Breast DIBH
 - Lung SBRT

The Radixact® System: The Most Comprehensive Breast Cancer Treatment System

TomoHelical™ TomoDirect™ VitalHold™*

Demos Available:

Accuray Booth #2586 C-RAD Booth #2923

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