

Implementation of proactive risk analysis in radiotherapy with myQA PROactive. Case study: surface guided DIBH breast radiotherapy

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Background

RT clinic in a public community hospital (S. Maria Annunziata Hospital, Florence)

- 2 LINACs
- Risk analysis performed since 2010
- Investigated workflows: 3D CRT, IMRT, VMAT, SGRT
DIBH, SBRT (in progress)
- Methods: FMEA, 3 parameters, scales 1-5 (local guidelines)
- Tools: Word\Excel

“Home made” FMEA Analysis SGRT DIBH

AZIONI	RESPONSABILI LITA'	DOCUMENTI DI SUPPORTO	RISCHI	CAUSE	EFFETTI	G	F	R	IPR	Barriere
TC Breast Hold (BH):										
La paziente indossa gli occhiali per la visualizzazione del proprio respiro	TSRM	Procedura interne	POSIZIONE NON CORRETTA	scarica compilata paziente	NON CORRETTA VISUALIZZAZIONE SCHERMO	2	2	1	6	Verifica della visualizzazione dello schermo

ELABORAZIONE PIANO TRATTAMENTO CORPO MAMMARIO BH

AZIONI	RESPONSABILI LITA'	DOCUMENTI DI SUPPORTO	RISCHI	CAUSE	EFFETTI	G	F	R	IPR	Barriere
			Individuazione lito/ Errore nella	sulla cartella di	DTF e frazionamento					Verifica durante approvazione del

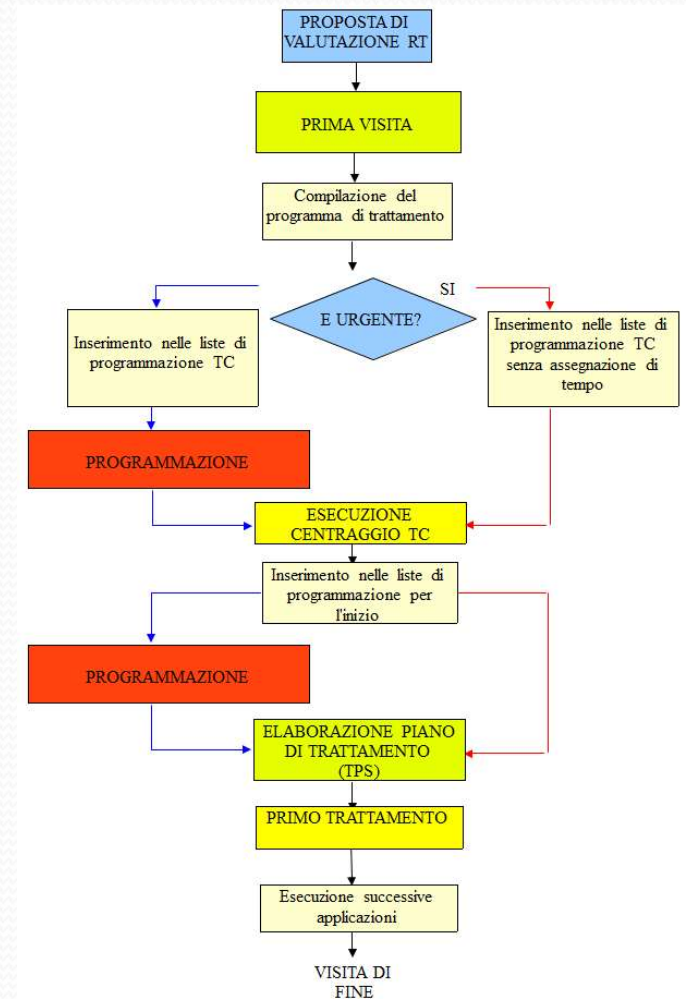
ELABORAZIONE PIANO TRATTAMENTO CORPO MAMMARIO BH

AZIONI	RESPONSABILI LITA'	DOCUMENTI DI SUPPORTO	RISCHI	CAUSE	EFFETTI	G	F	R	IPR	Barriere
Elaborazione ed invio DRR	FISICO	TPS	Errato/assente invio delle DRR non ottimali	Mancato/Errato invio DRR Non impiego del giusto filtro	DRR non idonea alla verifica con IP in fase di trattamento	3	3	2	18	importazione e verifica DRR il giorno precedente a quello di trattamento

PRIMA SEDUTA TRATTAMENTO BH / SEDUTE SUCCESSIVE - III

CENTRAGGI - III

PRIMA SEDUTA TRATTAMENTO BH / SEDUTE SUCCESSIVE - IV											
AZIONI	AZIONI	RESPONSABILI LITA'	DOCUMENTI DI SUPPORTO	RISCHI	CAUSE	EFFETTI	G	F	R	IPR	Barriere
Effettuazione foto di ri	Acquisizione la base-line giornaliera	TSRM	Catalyst	Base line non corretta	Posizione punto di riferimento non ottimale / Movimenti paziente	Mancata riproducibilità apnea	3	2	1	6	Training paziente / Ottimizzazione parametri di acquisizione telecamera
	Esecuzione apnea per verificare la correttezza del respiro nei confronti delle soglie	TSRM	Catalyst	Soglie non valide	Incapacità paziente a raggiungere soglie / Scarza compliance paziente / Apnea	Mancata riproducibilità apnea / Eccessiva durata seduta	3	2	1	6	Training paziente
Positionamer	Valutazione dei parametri di riferimento del segnale respiratorio ed eventuale modifica	MEDICO/FISICO	Catalyst	Soglie non valide	Variazione della posizione del punto di riferimento per il controllo del respiro	Possibile variazione apnea rispetto a centraggio TC	3	2	3	10	Verifica con Portal/Immagi / Mantenimento della stessa differenza tra soglia inferiore e base line ed ampiezza della
	Apertura fascio Rte e Ric riferimento in BH in Catal	TSRM	View	Esecuzione dell'immagine portale in apnea non corretta / Filardo partenza fascio	Mancato collegamento / errata selezione parametri di acquisizione	Ripetizione dell'acquisizione dell'immagine portale	3	3	2	10	Presenza di 2 TSRM e medico
Esecuzione spostamenti si durante l'apnea per ripro	Valutazione immagini portali	MEDICO	TPS / View	Errata valutazione	Bassa qualità dell'immagine portale/DRR	Il volume irradiato può essere diverso da quello pianificato	4	2	1	8	Manutenzione pannello View/ Consulenza fisico
	Firma in cartella IP e accordo con il sistema ottico	MEDICO	Cartella trattamento	Mancanza firma e valutazione accordo	Dimenticanza / carico di lavoro	Mancato passaggio informazioni	3	2	2	12	Presenza di 2 TSRM e medico
Passaggio in modalità Mot	Erogazione trattamento BH	TSRM	Mosaik / Catalyst	Difficoltà di erogazione	Mancato collegamento / Scarza compliance paziente	Mancato avvio del fascio	3	3	1	9	Presenza di piano a RL approvato per back up
	Congedo paziente	TSRM		Caduta dal letto di trattamento / Utro con la testata	Il paziente si alza troppo presto	Danno accidentale	5	1	1	5	Istruzione del paziente/Controllo di 2 TSRM con sistema telecamera /
Variazione/conferma del pur il controllo del respiro se n	Firma della seduta in cartella di trattamento	TSRM	Cartella di trattamento	Mancato conteggio seduta	Carico di lavoro / Dimenticanza Cartella presa per visita	Errore nel conteggio della dose e del numero di sedute	2	3	1	6	Registrazione sedute effettuate su mosaik / Revisione cartelle
	Rendicontazione prestazioni mosaik	TSRM	Mosaik	Mancata/errata rendicontazione	Carico di lavoro / Dimenticanza	Errata rendicontazione	3	2	1	4	Presenza pacchetti di attività / Verifica a fine turno TSRM



Flowchart

ESTRO 2023

Automated tools for clinical risk management

myQA PROactive

- Dedicated to prospective risk analysis
- Optimized for clinical applications
- Prototype tested by >20 clinical partners worldwide

BIA Dosimetry > Product > myQA® PROactive

myQA® PROactive

The only commercial prospective risk management solution for radiation oncology

Unlock the power of risk analysis and transform it into value!

With myQA PROactive, you will:

- ✓ Achieve higher safety levels
- ✓ Perform objective risk evaluation
- ✓ Strengthen compliance and follow best practice, efficiently

Category	Value	Unit
Risk Index	10	
Overall Risk	10,000	€
Overall Risk	10,000	€
Overall Risk	10,000	€

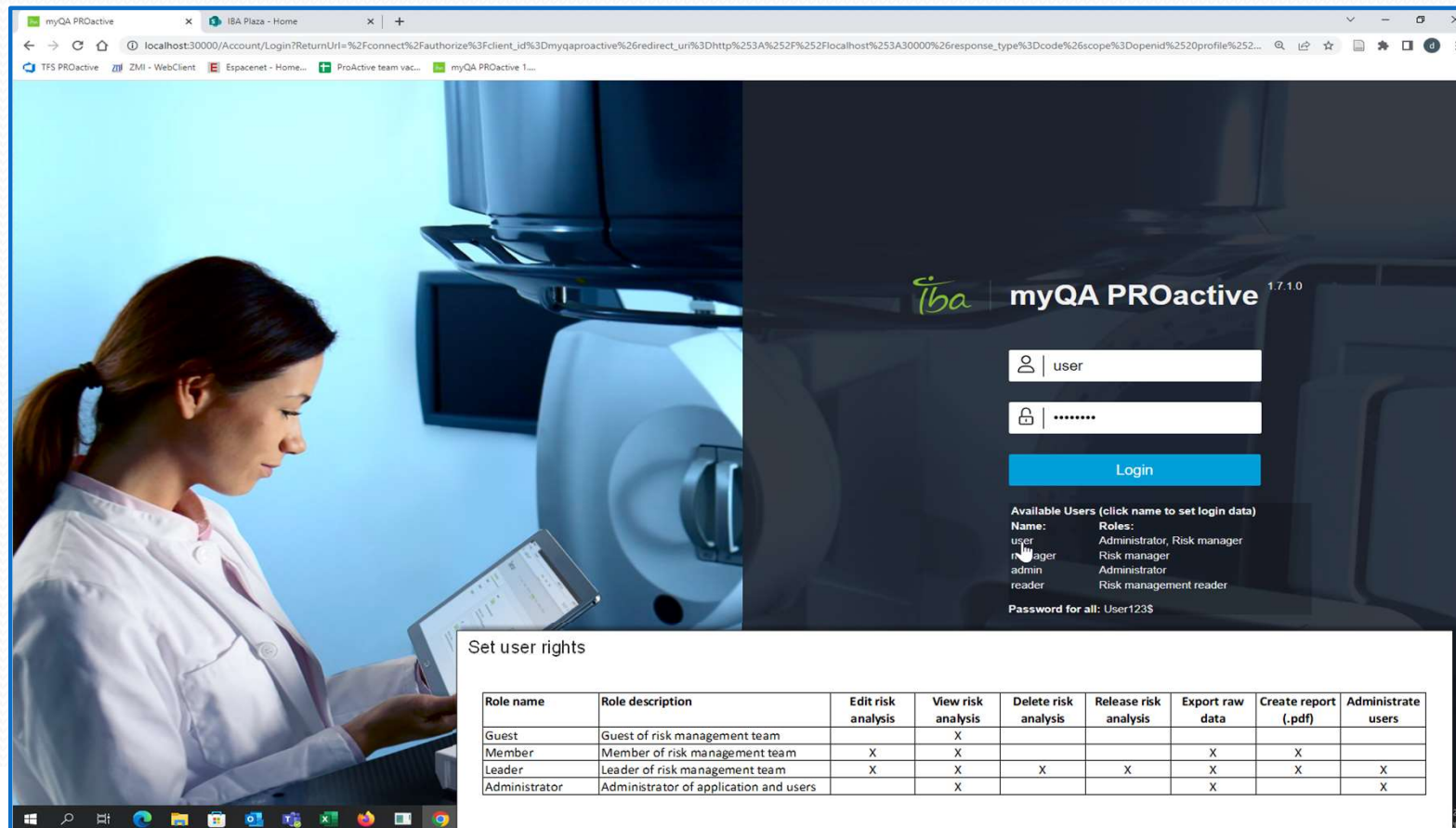
89
18
1

High Risk
Medium Risk
Low Risk

Automated tools for clinical risk management

myQA PROactive

- Browser based
- Local installation (PC or server)
- Multi-user access with personal credentials



myQA PROactive 1.7.1.0

user

.....

Login

Available Users (click name to set login data)

Name:	Roles:
user	Administrator, Risk manager
manager	Risk manager
admin	Administrator
reader	Risk management reader

Password for all: User123\$

Set user rights

Role name	Role description	Edit risk analysis	View risk analysis	Delete risk analysis	Release risk analysis	Export raw data	Create report (.pdf)	Administrate users
Guest	Guest of risk management team		X					
Member	Member of risk management team	X	X			X	X	
Leader	Leader of risk management team	X	X	X	X	X	X	X
Administrator	Administrator of application and users		X			X		X

Automated tools for clinical risk management

myQA PROactive

- **Templates** fully editable elaborated by clinical partners
- FMEA excel spreadsheet can be imported with few formatting steps

myQA PROactive 1.71.0 | Licensed to: D. Marchetti, IBA Dosimetry | v08 Aug 31, 2023

Risk analyses

+ Create new | Import

Name	Failure Modes			Neff	Version	Last updated	Status		
	Total	●	●						●
VMAT & SBRT	303	270	32	1	334.04	3	9/1/22, 3:23 PM	Pending	View Edit Version
Teletherapy	10	6	3	1	51.90	2	5/4/22, 10:45 AM	Pending	View Edit Version
Lutetium-177-PSMA	3	1	2	0	210.00	1	9/15/22, 11:38 AM	Pending	View Edit Version
SGRT Breast BH	48	39	8	1	1.98	1	9/15/22, 10:01 AM	Pending	View Edit Version

myQA PROactive
Risk management for radiation oncology
From burden to value

Automated tools for clinical risk management

myQA PROactive Templates

Templates include a typical description of:

- Workflow (step list and flowchart)
- Failure modes
- Examples of Failure mode evaluation (O, S, D): provided, with context (the clinical setting in which they have been generated)
- Risk reduction measures in place by-default in most clinics
- Example of quality measures which can be added

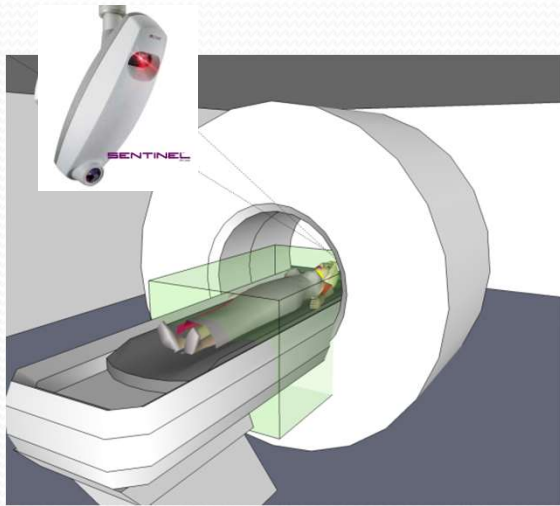
Risk analyses

+ Create new Import

Name	Failure Modes				Neff	Version	Last updated	Status	View Edit Version
	Total	O	S	D					
VMAT & SBRT	303	270	32	1	334.04	3	9/7/22, 3:23 PM	Pending	View Edit Version
Teletherapy	10	6	3	1	51.90	2	5/4/22, 10:45 AM	Pending	View Edit Version
Lutetium-177-PSMA	3	1	2	0	210.00	1	9/15/22, 11:38 AM	Pending	View Edit Version
SGRT Breast BH	48	39	8	1	1.98	1	9/15/22, 10:01 AM	Pending	View Edit Version

Library dashboard

Surface guided DIBH breast radiotherapy



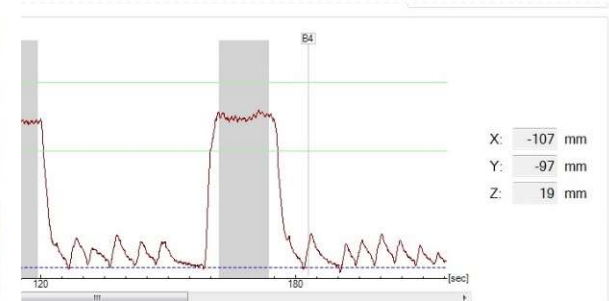
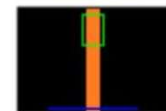
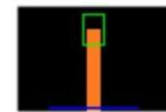
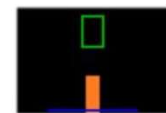
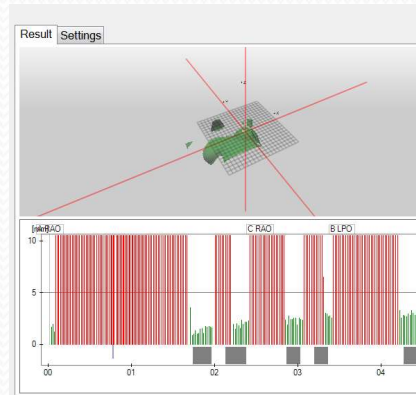
CATALYST HD



*Posture adjustment
Patient Setup*

*Intrafraction
Monitoring*

Respiratory Gating



Visual Coaching Systems

SGRT DIBH Template

Select language

Tiba myQA PROactive 19.0.

Process view Cost/benefit view Effect view Report

Settings Cancel edit Export

Selected risk analysis: SGRT Breast BH Version: 1 Change

Settings Cancel edit Export

+ Step Show Flowchart >>

+ Failure Mode

Filter Show All

Step	Step / Failure Mode ↑	Cause	Effect ↑	Severity (S) ↑	Occurrence (O) ↑	Detectability (D) ↑	RPN ↑	Event rate neff (patients/y) ↑	
> 1. CT simulation	1.1.Patient acceptance Wrong patient identification (patients mix-up)	Cause	Wrong volume	7.00	5.00	5.00	175.00	<0.01	(0) ...
> 2. Planning	1.1.Patient acceptance Informed consent not received from the patient	Cause	Legal liability	4.00	8.00	3.00	96.00	0.01	(1) ...
> 3. Data transfer	1.2.Patient positioning FB Wrong positioning because lasers are not well aligned	Cause	Suboptimal plan	5.00	5.00	4.00	100.00	<0.01	(0) ...
> 4. Treatment	1.2.Patient positioning FB Wrong positioning because of wrong choice of immobilization system	Cause	Inconvenience	5.00	4.00	4.00	80.00	<0.01	(0) ...
	1.2.Patient positioning FB Wrong positioning because patient moves during definition of reference points	Cause	Suboptimal plan	5.00	7.00	5.00	175.00	0.02	(0) ...
	1.3.CT system settings FB Wrong CT volume because of not proper selection/setting of CT protocol	Cause	Suboptimal plan	5.00	4.00	6.00	120.00	<0.01	(0) ...
	1.4.Export FB CT data to TPS CT scan is not sent to TPS	Cause	Suboptimal plan	3.00	8.00	2.00	48.00	<0.01	(0) ...
	1.5.Virtual simulation & identification of isocenter Wrong identification of treatment isocenter	Cause	Suboptimal plan	6.00	5.00	4.00	120.00	<0.01	(0) ...
	1.5.Virtual simulation & identification of isocenter Wrong tattoos position because of patient movement	Cause	Suboptimal plan	6.00	6.00	4.00	144.00	<0.01	(0) ...
	1.5.Virtual simulation & identification of isocenter Patient CT settings not documented	Cause	not specified	4.00	7.00	6.00	168.00		

Show step details >>

FMEA analysis according to AAPM TG100

SGRT DIBH Template elaborated with AUSL TC Radiotherapy of Florence - Italy



SGRT DIBH Template

Process view Cost/benefit view Effect view Report

change Version 1 Release Settings Cancel edit Export Import

+ Failure mode

Status	Step / Failure mode	Cause	Severity	RPN	Event rate neff (patients/y)	Comments				
✓	Wrong positioning because patient moves during definition of reference points	Cause	(1)	175.00	0.02	(0)				
✓	1.3. CT system settings FB Wrong CT volume because of not proper selection/setting of CT protocol	Cause	(1)	120.00	<0.01	(0)				
✓	1.4. Export FB CT data to TPS CT scan is not sent to TPS	Cause	(1)	48.00	<0.01	(0)				
✓	1.5. Virtual simulation & identification of isocenter Wrong identification of treatment isocenter	Cause	(1)	120.00	<0.01	(0)				
✓	1.5. Virtual simulation & identification of isocenter Wrong tattoos position because of patient movement	Cause	(1)	144.00	<0.01	(0)				
✓	1.5. Virtual simulation & identification of isocenter Patient CT setup not documented	Cause	(1)	168.00	0.05	(0)				
✓	1.6. BH preparation Wrong definition of gating window	Cause	(1)	150.00	0.01	(0)				
✓	1.7. CT system settings BH Wrong CT volume because of not proper selection/setting of CT protocol	Cause	Suboptimal plan 6.00	4.00	(1)	5.00	(1)	120.00	<0.01	(0)
✓	1.8. BH CT execution Not reproducible BH	Cause	Suboptimal plan 5.00	5.00	(1)	5.00	(1)	125.00	<0.01	(0)

Edit failure mode

Description *
Patient CT setup not documented

Cause *
Workload

Step *
Virtual simulation & identification of isocenter

Create new Effect

Select an existing Effect

None

Occurrence (O) 7 Severity (S) * 4 Detectability (D) 6

Cancel Edit

Show step details >>

1 25 items per page

1 - 13 of 13 items

SGRT DIBH Template

Process view Cost/benefit view Effect view Report

1:3 Change

+ Failure Mode

Show step details

New Failure Mode

Name *

This field is required.

Cause *

Step/Substep *

- Create new Effect
- Select an existing Effect
- None



Occurrence (O) *

Severity (S) *

Detectability (D) *

Cancel

Create

Step / Failure Mode Cause Effect Severity (S) Occurrence (O) Detectability (D)

	Occurrence	Severity of effect	Detectability
Rank	Pocc [%]*	Qualitative description	Pmiss [%]**
1	0.01	No effect	0.01
2	0.02	Inconvenience	0.2
3	0.05	Inconvenience	0.5
4	0.1	Minor dosimetric error	1
5	0.2	Limited toxicity or tumor underdose	2
6	0.5	Limited toxicity or tumor underdose	5
7	1	Potential serious toxicity or tumor underdose	10
8	2	Potential serious toxicity or tumor underdose	20
9	5	Possible very serious toxicity or tumor underdose	50
10	100	Catastrophic	100

Adapted from Huq et al.: TG 100 report

*Probability that the failure mode occurs. Pocc=1% means it occurs on the average once every 100patients.

**Probability that the failure mode occurs and remain undetected. Pmiss=10% means that out of 100 failures, 90 are detected and 10 hit the patient.

SGRT DIBH Template

Process view Cost/benefit view Effect view Report

Version 1 Release Settings Cancel edit Export Import

+ Failure mode Clear filters Show all

Status	Step / Failure mode	Cause	Effect	Severity (S)	Occurrence (O)	Detectability (D)	RPN	Event rate neff (patients/y)
✓	isocenter Wrong tattoos position because of patient movement	Cause	Suboptimal plan	6.00	6.00	4.00	144.00	<0.01
✓	1.5. Virtual simulation & identification of isocenter Patient CT setup not documented	Cause	not specified	4.00	7.00	6.00	168.00	0.05
✓	1.6. BH preparation Wrong definition of gating window	Cause	Suboptimal plan	5.00	6.00	5.00	150.00	0.01
✓	1.7. CT system settings BH Wrong CT volume because of not proper selection/setting of CT protocol	Cause	Suboptimal plan	6.00	4.00	5.00	120.00	<0.01

Cause Preventions Barriers

Cause/Initial prevention	Pocc, i (%)	Oi
Lapse, possibly due to heavy workload Double check with 2 RTAs	1	7

Added preventions	Pmiss (%)	Status	Fixed cost (€)	Recurrent cost (€)	Key/Note
No added preventions					

Pocc (%) 0

Mitigated Occurrence	Pocc (%)	O
Mitigated Occurrence	1	7.00

1 25 items per page

SGRT DIBH Template

Process view Cost/benefit view Effect view Report



Change Version 1 Release

Settings Cancel edit Export Import

+ Failure mode

Clear filters

Show all

Status	Step / Failure mode	Cause	Effect	Severity (S)	Occurrence (O)	Detectability (D)	RPN	Event rate neff (patients/y)
✓	isocenter Wrong tattoos position because of patient movement	Cause	Suboptimal plan	6.00	6.00	4.00	144.00	<0.01
✓	1.5. Virtual simulation & identification of isocenter Patient CT setup not documented	Cause	not specified	4.00	7.00	6.00	168.00	0.05
✓	1.6. BH preparation Wrong definition of gating window	Cause	Suboptimal plan	5.00	6.00	5.00	150.00	0.01
✓	1.7. CT system settings BH Wrong CT volume because of not proper selection/setting of CT protocol	Cause	Suboptimal plan	6.00	4.00	5.00	120.00	<0.01

Cause Preventions Barriers

Initial barrier	Pmiss, I (%)	Di
Review patient record before the patient leaves	5	6

Added barriers	Pmiss (%)	Status	Fixed cost (€)	Recurrent cost (€)	Key/Note
No added barrier					

	Pmiss (%)	D
Mitigated Occurence	5	6.00

Show step details



SGRT DIBH Dashboard

+ Step Show flowchart

Step	Order steps	F (% of patients through the step)	R (step repetitions per patient)	Failure Modes			Event rate Neff (patients/y)	Note	
				Total	✓	!			✗
>	1. CT simulation	100	1	13	13	0	0	0.12	...
>	2. Planning	100	1	9	2	7	0	2.01 → 0.05	...
>	3. Data transfer	100	1	17	17 → 1	0	0	0.05 → 0.04	...
>	4. Treatment	100	1-20	9	8	1	0	0.06	...

Expected event rate:
affected patients number per year is automatically evaluated

$$N_{pt}/year \times F \times R \times P_{occ} (O) \times P_{miss} (D)$$

SGRT DIBH Risk matrix

- Set tolerances with a risk-matrix approach
- Tolerance based on: Event rate
Occurrence and Detectability

General **Tolerances** Report Version Management

Acceptance Criteria

Acceptance criteria are used to determine whether the risk associated with a failure mode is acceptable, tolerable or not acceptable.

Event rate neff (patients/y) Occurrence x Detectability Alternative, less realistic

		Severity					
		1	2.8	4.6	6.4	8.2	10
Event rate neff (patients/y)	25	Yellow	Yellow	Red	Red	Red	Red
	20	Green	Yellow	Yellow	Red	Red	Red
	15	Green	Green	Yellow	Yellow	Red	Red
	10	Green	Green	Green	Yellow	Red	Red
	5	Green	Green	Green	Green	Yellow	Yellow
	0	Green	Green	Green	Green	Green	Yellow

Click into cells to toggle between
Green Acceptable
Yellow Tolerable
Red Not acceptable

Save acceptance criteria

Definition of preventions

+ Failure Mode

Step / F

- 2.1.Con Guidelin
- 2.1.Con Guidelin
- 2.1.Con Wrong c
- 2.1.Con Guidelin
- 2.2.Trea Wrong t
- → ● 2.2.Trea Wrong c
- → ● 2.2.Treatment planning Wrong absolute calibration of the LINAC
- → ● 2.2.Treatment planning Use of a wrong LINAC beam fitting

Close

Causes and preventions for failure mode Wrong absolute calibration of the LINAC

Cause

Wrong use of dosimetric protocols; wrong use of instrumentation

Initial Preventions	$P_{occ, i} (%)$	O_i
training	5	9

Added Prevention	$P_{miss} (%)$	Status
Use of multiple dosimeters	4	Potential

Mitigated Occurrence

$P_{occ} (%)$	O
5.00	9.00
5.00	5.00

Detectability (D) ↑	RPN ↑	Event rate neff (patients/y) ↑
4.00 ▮▮▮▮ (1)	144.00	<0.01
6.00 ▮▮▮▮ (1)	288.00	0.03
6.00 ▮▮▮▮ (1)	216.00	<0.01
5.00 ▮▮▮▮ (1)	270.00	0.01
5.00 ▮▮▮▮ (1)	200.00	<0.01
3.00 ▮▮▮▮ (2)	27.00	<0.01
6.00 ▮▮▮▮ (2)	270.00	0.01
4.00 ▮▮▮▮ (2)	200.00	<0.01
9.00 ▮▮▮▮ (2)	810.00	2.50
2.00 ▮▮▮▮ (2)	103.33	<0.01
7.00 ▮▮▮▮ (2)	630.00	0.50

Definition of barriers

+ Failure Mode

i

Step / Failure Mode ↑

i	2.1.Contouring (target and OAR) Guidelines for OAR->PRV expansion are not followed			144.00	<0.01
✓	2.1.Contouring (target and OAR) Guidelines are not followed for OAR contouring			288.00	0.03
i	2.1.Contouring (target and OAR) Wrong CTV->PTV expansion			216.00	<0.01
i	2.1.Contouring (target and OAR) Guidelines are not followed for CTV contouring			270.00	0.01
✓	2.2.Treatment planning Wrong beam setting			200.00	<0.01
i → i	2.2.Treatment planning Wrong dose prescription			27.00	<0.01
i → i	2.2.Treatment planning Wrong absolute calibration of the LINAC			200.00	<0.01
i → i	2.2.Treatment planning Use of a wrong LINAC beam fitting			103.33	<0.01

Barriers for failure mode

Wrong absolute calibration of the LINAC

Initial Barriers

Double calculation review	Pmiss, i (%)	Di			
	50	9	...	144.00	<0.01

Added Barrier

	Pmiss (%)	Status			
Dosimetric Audit	2	Potential	...	216.00	<0.01

Mitigated Detectability

	Pmiss (%)	D			
	50	9.00 4.00		200.00	<0.01

Close

+ Barrier

	Cause	Pmiss (%)	D	Pmiss (%)	D	RPN	Event rate neff (patients/y)
	Wrong dose	10.00	5.00 9.00	4.00 9.00	P (2)	200.00 810.00	<0.01 2.50
	Wrong dose distribution	10.00	5.17 9.00	2.00 7.00	P (2)	103.33 630.00	<0.01 0.50

The SW automatically calculates the „benefit“ of a mitigation:
 neff(with)-neff(wihtout)

Cost-benefit analysis of mitigation actions

Drag a column header and drop it here to group by that column

Context			Mitigations					Cost/Benefit i			
Step	Failure Mode	Effect	Description	Type	Status	Pmiss	Benefit Δ_{neff} (patients/y)	Fixed cost (€)	Recurrent Ct (€)	Total @5y (€)	
22. Treatment planning	Wrong absolute calibration of the LINAC	Wrong dose	Dosimetric Audit	Barrier	Potential	2.00 %	1.42	5,000	1,000	10,000	
22. Treatment planning	Use of a wrong LINAC beam fitting	Wrong dose distribution	Dosimetric audit	Barrier	Potential	2.00 %	0.49	5,000	1,000	10,000	
22. Treatment planning	Wrong dose prescription	Wrong dose	Verification of availability of printed dose prescription	Barrier	Potential	10.00 %	<0.01	1,000	1,000	6,000	
22. Treatment planning	Wrong dose prescription	Wrong dose	Printed form to confirm dose prescription	Prevention	Potential	5.00 %	<0.01	1,000	1,000	6,000	
22. Treatment planning	Use of a wrong LINAC beam fitting	Wrong dose distribution	pre-clinical dosimetric verifications	Prevention	Potential	5.00 %	0.48	100,000	8,000	140,000	
22. Treatment planning	Wrong absolute calibration of the LINAC	Wrong dose	Use of multiple dosimeters	Prevention	Potential	4.00 %	1.39	10,000	1,000	15,000	
31. Export/Import plan and body contours to SGRT system (FB)	Wrong definition of ROI (FB) in SGRT system	Inconvenience	Check settings before first fraction	Barrier	Potential	20.00 %	<0.01	1,000	1,000	6,000	

SGRT DIBH Flowchart

Selected risk analysis: Change | Version: 1 Change | Status: Pending Change

+ Step **Hide Flowchart** **>>**

Step	
> 1. CT simulation	...
> 2. Planning	...
> 3. Data transfer	...
> 4. Treatment	...
4.1. Patient identification	...
4.2. Patient set up	...
4.3. DIBH instructions	...
4.4. X-ray target localization [e.g. kV/MV por...	...
4.5. BH radiation delivery	...
4.6. Reporting	...

FLOWCHART SHAPES

- Process
- Predefin ed ...
- Deci...
- Decision
- Input/ Output
- Database
- Document
- Multiple documents
- Manual operation
- Manual input
- Preparati on

OTHER FLOWCHART SHAPES

- Text
- Annotation
- Circle

SGRT Breast BH v241022

Start of workflow

Create SGRT-friendly immobilization

with content

1. CT simulation

F: 100% R: 1
 FMs: 13 0 0 0
 Neff: 0.12

with content

2. Planning

F: 100% R: 1
 FMs: 2 7 0 0
 Neff: 2.01 0.05

with content

3. Data transfer

F: 100% R: 1
 FMs: 17 0 0 0
 Neff: 0.95 0.04

with content

4. Treatment

F: 100% R: 1-20
 FMs: 8 1 0 0
 Neff: 0.10

End of treatment course

Return To Parent Flowchart

Export SVG

Export PNG

Show step details >>

sub-Flowchart

iba myQA PROactive

Process view Cost/benefit view Effect view Report

Selected risk analysis: SGRT Breast BH Version: 1 Change

+ Step Hide Flowchart >>

Step

+ 1. CT simulation	...
+ 2. Planning	...
+ 3. Data transfer	...
- 4. Treatment	...
4.1. Patient identification	...
4.2. Patient set up	...
4.3. DIBH instructions	...
4.4. X-ray target localization [e.g. kV/MV ports...]	...
4.5. BH radiation delivery	...
4.6. Reporting	...

▼ FLOWCHART SHAPES

Process Predefin ed ...

Deci... Decision

Input/ Output Database

Document Multiple documents

Manual operation Manual input

Preparati on

▼ OTHER FLOWCHART SHAPES

Text Annotation

Circle }

SGRT Breast BH > 4. Treatment

LEGEND

1st day only

1st day & subsequent days

4.1. Patient identification F: 100% R: 20 FMc: 0 0 0 0 Neff: 0.01

4.2. Patient set up F: 100% R: 20 FMc: 2 0 0 0 Neff: 0.04

4.3. DIBH instructions F: 100% R: 20 FMc: 1 0 0 0 Neff: 0.02

4.4. X-ray target localization [e.g. kV/MV ports] to confirm DIBH F: 100% R: 1 FMc: 3 0 0 0 Neff: <0.01

4.5. BH radiation delivery F: 100% R: 20 FMc: 1 0 0 0 Neff: <0.01

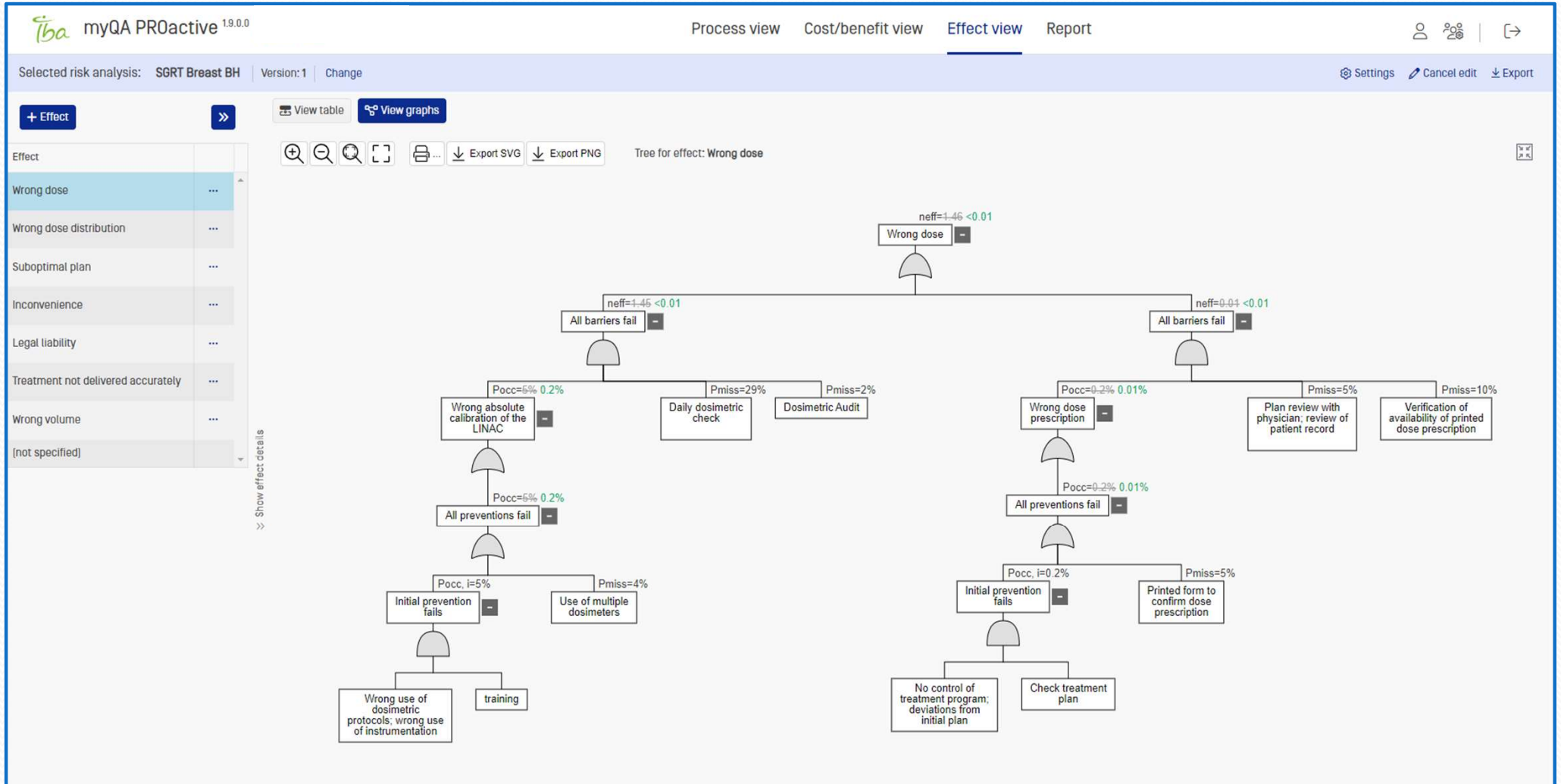
4.6. Reporting F: 100% R: 20 FMc: 1 0 0 0 Neff: 0.02

Page physics/physician and troubleshoot


Patient aligned to surface within thresholds? Yes

-Set up immobilization devices and other devices according to setup instructions;
-Setup with lasers at free breathing
-Posture verification FB with SGRT
-Fine-tune positioning set up with BH SGRT

Fault Tree Analysis



Report Generation



Selected risk analysis: SGRT Breast BH

Version 1 Release

Process view

Cost/benefit view

Effectiveness

Risk analysis for radiation therapy new treatment performed according to regulation xyz no. 126. Version 1.23 | Released | 01.01.2022

University clinic of Postbauer-Heng Radiation oncology department

3 CONCLUSIONS

2.5 Cost/benefit analysis of quality management tools

2.5.1 Cost/benefit summary table

Quality management tool				Cost/benefit analysis			
	Benefit (1/yr)	Fixed cost (€)	Recurrent cost (€)	Total cost (€)	Benefit (1/yr)	Fixed cost (€)	Recurrent cost (€)
	16.80	50,000	5,000	75,000			
	3.60	200,000	20,000	300,000			
	5.76	300,000	30,000	450,000			
	0.25	5,000	15,000	80,000			

2.4 FMEA table-failure modes details

Step/substep	Failure mode	Initial		Current		Description	S	O	D	RPN	eff	Risk	
		RPN	Risk	RPN	Risk								
[3.3] Patient preparation for imaging session (bladder/bowel)	Name of the failure mode. Usually it is concise, but we have verbose examples in literature: Blocks used in addition to MLC are not placed.	600	Unacc	500	Tol.	in place at the at the time or				10.0	10.0	1000	14.0
[3.11] Immobilized patient set up on CT	Name of the failure mode. Usually it is concise, but we have verbose examples in literature: Blocks	599	Unacc	499	Tol.	as a result of the of the risk				6.0	8.0	480	1.0
		598	Unacc	498	Tol.	in place at the at the time or				10.0	10.0	1000	14.0
		597	Unacc	497	Tol.	as a result of the of the risk				10.0	10.0	1000	14.0
		596	Unacc	496	Tol.	as a result of the of the risk				10.0	10.0	1000	14.0
		595	Unacc	495	Tol.	in place at the at the time or				10.0	10.0	1000	14.0
		594	Unacc	494	Tol.	in place at the at the time or				10.0	10.0	1000	14.0
		593	Unacc	493	Tol.	in place at the at the time or				10.0	10.0	1000	14.0
		592	Unacc	492	Tol.	as a result of the of the risk				10.0	10.0	1000	14.0
		591	Unacc	491	Tol.	as a result of the of the risk				4.0	4.0	160	0.1
		590	Unacc	490	Tol.								
		589	Unacc	489	Tol.								
		588	Unacc	488	Tol.								
		587	Unacc	487	Tol.								
		586	Unacc	486	Tol.								
		585	Unacc	485	Tol.								

2 RESULTS

2.1 Remarks of the risk management team:

Risks have been initially evaluated using a fault tree analysis, to quickly identify the failure modes which could lead to know severe adverse effect for the patients. Subsequently, the analysis has been refined with a FMECA analysis of the most risky process steps.

1 RISK MANAGEMENT PLAN

1.1 Team Members, roles and responsibilities

Dr. Francesca Caccini, chief medical physicist (risk manager)
 Dr. Wolfgang A. Mozart, radiation oncologist
 Mrs. Fanny Mendelsohn, dosimetrist
 Mr. Johannes Brahms, healthcare assistant
 Mrs. Amy Beach, RTT
 Mrs. Barbara Storz, administrative assistant

Risk analysis for radiation therapy new treatment performed according to regulation xyz no. 126.

University clinic of Postbauer-Heng Radiation oncology department
 Centrum ID 92339 Postbauer-Heng
 Managing director: Mr. L. v. Beethoven

Summary table:

Risks in various risk classes and active added mitigations		Total No.
Unacceptable		
0	2	
0	5	
0	16	
0	7	
0	10	
0	11	
0	31	
0	18	
0	16	
0	22	
0	169	

Status: Version 1.23 | Released

Released by: Dr. Francesca Caccini, chief medical physicist

Released on: 2.8.2022

Next review due by: 2.8.2025

Analysed process: Release of normo-fractionated radiotherapy treatments.
 Treatment unit: ELEKTA Versa HD.
 TPS: Monaco
 R&V system: MOSAIQ

QR code: [QR Code]

Risk analysis URL: [Link]

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Save

Status: Version 1 | Pending
 Released by: n/a
 Released on: n/a
 Next review due by: n/a

Conclusions

myQA PROactive SW for risk management allows:

- Efficient FMEA analysis
- Agile FMEA analysis review
- Facilitates periodic updating of FMEA analysis
- Comparison of risk reduction measures through cost/benefit analyses
- Documentation of the risk analysis



**THANKS FOR
YOUR ATTENTION !!**

12° Congresso Nazionale
AIFM2023
Firenze
LA FISICA MEDICA
AL SERVIZIO DELLA SALUTE

 ASSOCIAZIONE ITALIANA
di FISICA MEDICA e SANITARIA

FIRENZE • 8-11 giugno 2023
Palazzo dei Congressi

Presidente del Congresso:
Carlo Cavedon

The poster features a blue background with a faint image of Michelangelo's David. The text is white and yellow, providing details about the congress, including the dates and location.