

VON NULL ZU DIGITAL

Erfahrungen aus 10 Jahren MedTech Startup

iThera Medical @ MedXD
September 2022



iTHERA MEDICAL: OPTOAKUSTISCHE BILDGEBUNG

iTheraMedical
Listening to Molecules



ITM entwickelt und
kommerzialisiert eine
neuartige Bildgebungs-
technologie

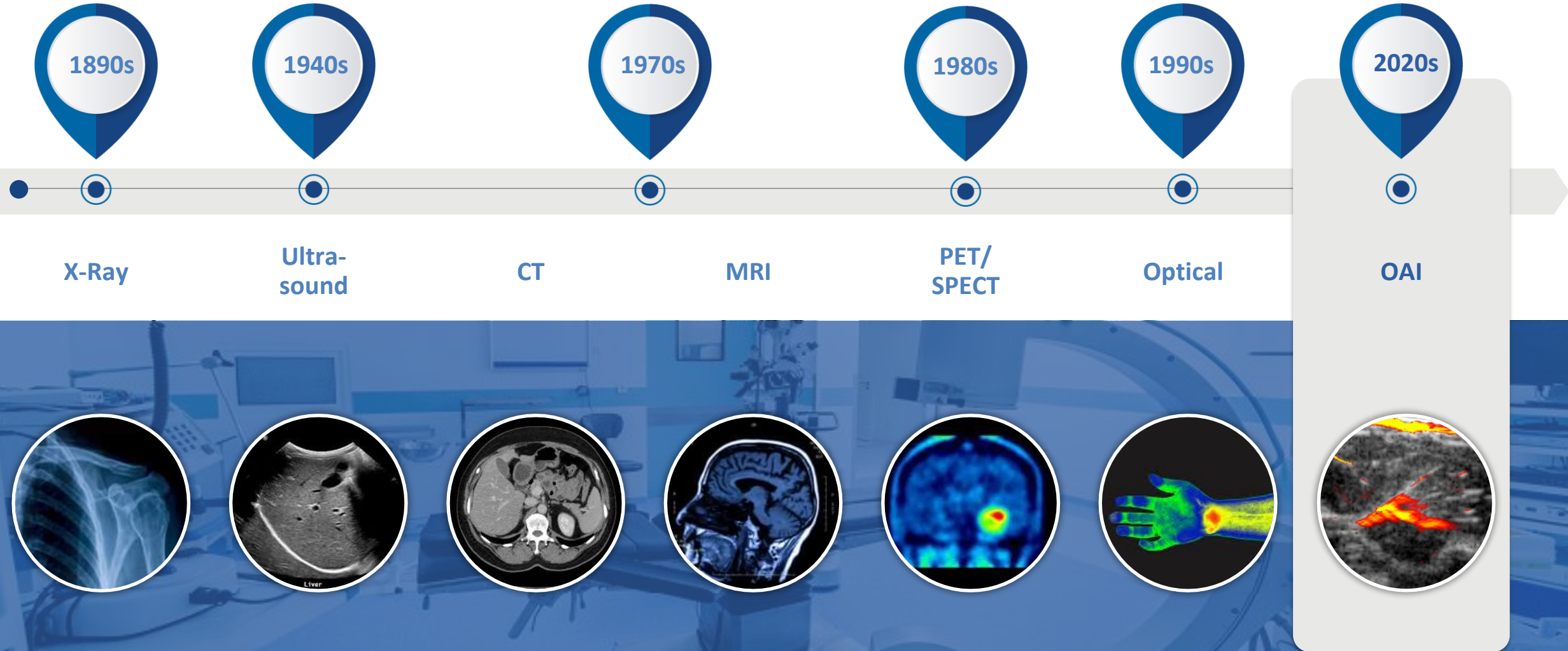


Globaler Technologie-
& Marktführer für die
optoakustische
Bildgebung (OAI)



Etabliert in der
Forschung und auf
dem Sprung in die
klinische Diagnostik

OAI: eine komplett neue Bildgebungstechnologie



2012 – erste Begegnung mit der ISO 13485

Entwicklung

HW/SW Entwicklung



Risikomanagement



Tools (TE, SW)



Klinische Bewertung



Usability



Change Mmgt



Markt-Feedback

Complaints



CAPA



Med Dev Report



PMS



Operations



Produktion



Service



Traceability



Employees



Support-Prozesse

Information Control



Training



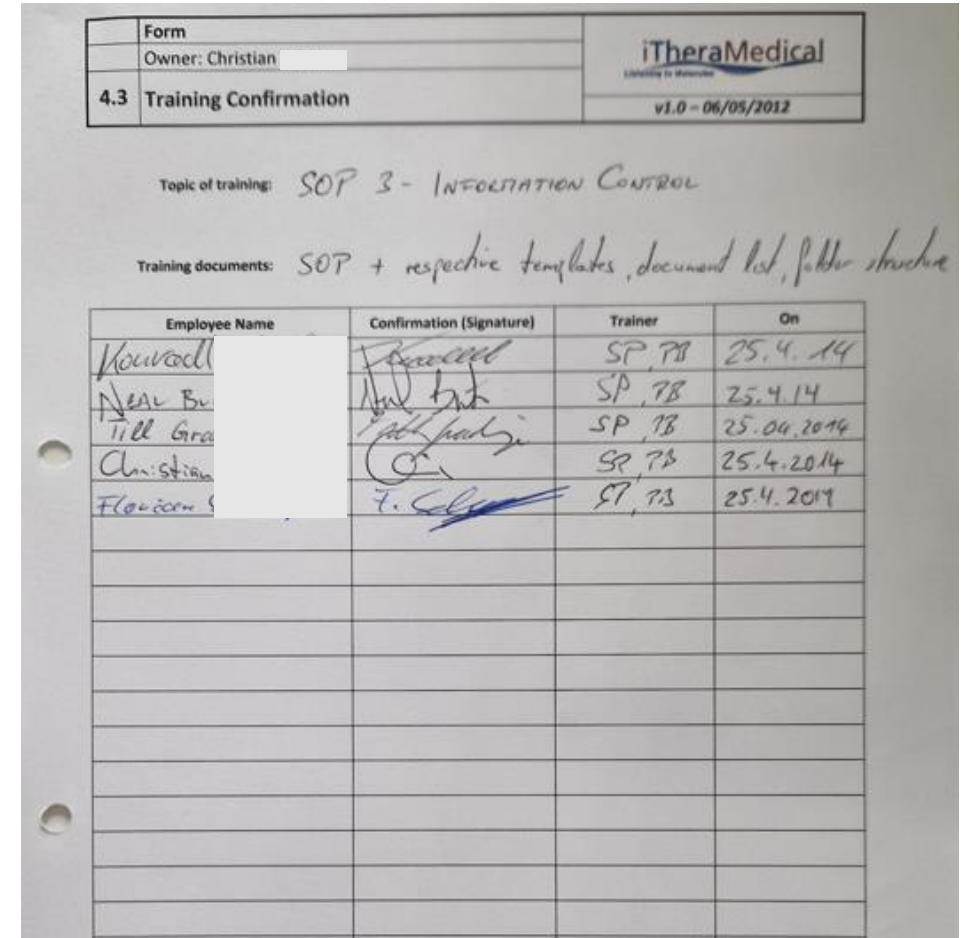
Mgmt Assessment



Internal Audits



Training



2014 - erste ,digitale' QM-Prozesse mit ERP System

Entwicklung

HW/SW Entwickl



Risikomanagem



Tools (TE, SW)



Klinische Bewertung



Usability



Change



Operations



Traceability



Markt-Feedback



Med Dev Report



PMS



Support-Prozesse

Information Com



Training



Mgmt Assessme



Internal Audit



Nachverfolgung von Complaints

Helpdesk Overview / Tickets / Crack on probe head (#1563)

EDIT

CREATE

Print

Action

ASSIGN TO ME

CANCEL

CREATE CHANGE

CREATE INCIDENT

DRAFT

EVALUATED

IMPLEMENTED

CLOSED

MORE

0

CAPA Ticket

0

FCOs

0

Quality Ticket

1

Service record

0

Incident Ticket

4

Documents

Crack on probe head

Inbox

3_External NCs

Last modified

2021-12-02 11:13:00

Next review on

1. Input

Assigned to	Philipp Bell	Related installed base	[2-21-03] DE - Erlangen (ITM Loan)
Feedback source	Customer	Contact	Universitätsklinikum Erlangen, Dr. med. [REDACTED]
Reference		Contact Email	[REDACTED]@uk-erlangen.de
Priority	★ ★ ★	Communication	Phone
Tags		Product Category	Acuity
Company	iThera Medical GmbH	Product	[SYS-MSOTACUITYechoCE2] MSOT Acuity Echo CE (660-1300nm)

Important: Check if the problem led to/or could potentially result in:

- Injury of a person, e.g. due to laser radiation, leakage current, chemical substances, moving parts, cross infection with germs, fire etc.
- Damage of other equipment/material, e.g. due to high temperature, fire, electromagnetic interference, chemicals
- Loss or mix up of data, e.g. due to unauthorized access, display of incorrect patient or imaging information, incorrect data storage

If yes, inform Medical Device Safety Officer IMMEDIATELY!

2022-09-14

Description

2016 – erste Digitalisierungsschritte in der Entwicklung

Entwicklung

HW/SW Entwicklung 

Risikomanagement 

Tools (TE, SW) 

Klinische Bewertung 

Usability 

Change Management 

Operations

Einkauf 

Produktion 

Vertrieb 

Service 

Traceability 

Employees 

Markt-Feedback

Complaints 

CA 

Med Dev Reports 

PMS 

Support-Prozesse

Information Control 

Training 

Mgmt Assessment 

Internal Audits 

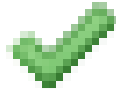
Traceability in der Entwicklung



  **MSOT-10989 - INTERFACE REQ: Fiber coupling efficiency**
The coupling efficiency for 730nm shall be >60% for a test fiber with the following properties:



  **MSOT-11093 - Fiber coupling efficiency**
Conditions: Final laser prototype available; test fiber as mentioned in  MSOT-10989 - INTERFACE REQ: Fiber coupling efficiency available .
 TE-106 - Coherent EM-USB J-50MB-YAG available



Test Result	Test Run
 Passed	 cMSOT2_LP_TR01 - cMSOT-2 Laser and PDU Verification - TR 01



Test Equipment ID & Name	Equipment Status	Equipment Type
 TE-106 - Coherent EM-USB J-50MB-YAG	 Qualified	Laser Energy Meter

Detailed Operations

Initial Demand	1.00 Units
Quantity Done	1.00 Units

To	Lot/Serial Number	Done
iThera-Medical/Stock	P1954	1.00

CONFIRM DISCARD

Product	Order description	Demand	Done	Unit of Measure
[IT-OPT-00114] SpitLight DPSS-OPO-MED OEM 25Hz, includ...	[IT-OPT-00114] SpitLight DPSS-OPO-MED OEM 25Hz,prepared for safety box and 1064nm access	1.00	1.00	Units

Traceability in den Operations

Wareneingang

Produktionsauftrag

Inventory

EDIT

QUALITY A

WH/

Receive F

Importer

Operation

Destinati

Back Ord

Operati

Product

[IT-OPT-00

Traceability

1 / 1 Work Orders

Product Moves

Valuation

Cost Analysis

Quality Checks

WH/MO/00525

Product

[SYS-MSOTACUITYechoCE2] MSOT Acuity Echo CE (660-1300nm)

Quantity To Produce

1.00 Units

Bill of Material

[SYS-MSOTACUITYechoCE] MSOT Acuity Echo CE

Routing

DMR-2.3-WI-6500_Assembly Instructions - Acuity Echo Final assembly

Deadline

2021-08-27 08:18:14

Planned Date

2021-08-28 14:54:47 to 2021-08-28 15:56:00

Responsible

Source

/

Original Source

Company

iThera Medical GmbH

Components

Finished Products

Miscellaneous

1-40 / 54

<

>

Product	Unit of Measure	Tracki...	Qty in sour...	Free to use Qty in Sour...	Quantity in Ha...	To Consume	Consumed
[IT-OPT-00114] SpitLight DPSS-OPO-MED OEM 25Hz, including spectrom...	Units	☒	0	0	N/A	1.00	1.00
[IT-SYS-00091] Acuity Echo - Base Frame and Rack	Units	☒	2.0	2.0	2.0	1.00	1.00
[IT-SYS-00118] Acuity Echo Screen Holder Assembly	Units	☒	2.0	2.0	2.0	1.00	1.00
[IT-SYS-00092] Acuity Echo - Laser Tray Assembly	Units	☐	1.0	1.0	1.0	1.00	1.00
[IT-SYS-00119] Acuity Echo Cable Holder Assembly	Units	☐	0	0	N/A	1.00	1.00
[IT-SYS-00094] Acuity Echo - front cover (top) incl. switches	Units	☒	2.0	2.0	2.0	1.00	1.00
[IT-SYS-00096] Acuity echo - Front (bottom) incl. paint and print	Units	☐	2.0	2.0	2.0	1.00	1.00
[IT-SYS-00116] Acuity Echo: Interface plate	Units	☒	2.0	2.0	2.0	1.00	1.00
[IT-SYS-00098] Acuity Echo - back cover incl. paint	Units	☐	2.0	2.0	2.0	1.00	1.00
[IT-SYS-00117] Acuity Echo: laser warning module	Units	☒	2.0	2.0	2.0	1.00	1.00
[IT-SYS-00106] Acuity Echo Front Panel Cable, Part B	Units	☐	2.0	2.0	2.0	1.00	1.00
[IT-SYS-00113] Acuity Echo: Out of Tolerance Warning Cable	Units	☐	7.0	7.0	7.0	1.00	1.00

one

1.00

Komponentenansicht

WH#

Product

Quantity

Bill of Materials

Routing

Component

Product

[IT-OPT-00114]

Product

[IT-OPT-00114] SpitLight DPSS-OPO-MED OEM
25Hz, including spectrometer, energy monitor,
type 1+, 680-980nm & 1064nm

Initial Demand

1.00 Units

Quantity Done

1.00 / 0.00

Lot/Serial Number

Finished Lot/Serial Number

Reserved

Done

:

P1954

2-21-05

0.00

1.00

[IT-SYS-00091] Acuity Echo - Base Frame and Rack

Units

☒

2.0

2.0

2.0

1.00

1.00

[IT-SYS-00118] Acuity Echo Screen Holder Assembly

Units

☒

2.0

2.0

2.0

1.00

1.00

[IT-SYS-00092] Acuity Echo - Laser Tray Assembly

Units

☐

1.0

1.0

1.0

1.00

1.00

[IT-SYS-00119] Acuity Echo Cable Holder Assembly

Units

☐

0

0

N/A

1.00

1.00

[IT-SYS-00094] Acuity Echo - front cover (top) incl. switches

Units

☒

2.0

2.0

2.0

1.00

1.00

[IT-SYS-00096] Acuity echo - Front (bottom) incl. paint and print

Units

☐

2.0

2.0

2.0

1.00

1.00

[IT-SYS-00116] Acuity Echo: Interface plate

Units

☒

2.0

2.0

2.0

1.00

1.00

[IT-SYS-00098] Acuity Echo - back cover incl. paint

Units

☐

2.0

2.0

2.0

1.00

1.00

[IT-SYS-00117] Acuity Echo: laser warning module

Units

☒

2.0

2.0

2.0

1.00

1.00

[IT-SYS-00106] Acuity Echo Front Panel Cable, Part B

Units

☐

2.0

2.0

2.0

1.00

1.00

[IT-SYS-00113] Acuity Echo: Out of Tolerance Warning Cable

Units

☐

7.0

7.0

7.0

1.00

1.00

</

Traceability in den Operations

Wareneingang

Produktionsauftrag

Komponentenansicht

Systemansicht

WH, [2-21-05] DE - Jena

Product

Quantity

Bill of Materials

Routing

Initial Description

Quantity

Lot/Serial

P1954

Component

Product

[IT-OPT-00114] SpitLight DPSS-OPO-MED OEM 25Hz, including...

[IT-SYS-00091] Acuity Echo - Base Frame and Rack

[IT-SYS-00092] Acuity Echo - V3 Computer assembly

[IT-SYS-00093] Acuity Echo - Screen Holder Assembly

[IT-SYS-00094] Acuity Echo - front cover (top) incl. switches

[IT-SYS-00095] Acuity Echo: Interface plate

[IT-SYS-00096] Acuity Echo: laser warning module

[IT-SYS-00097] Acuity Echo: RAB

[IT-SYS-00098] Acuity Echo: PT1000 sensor cable

Name

DE - Jena

Customer

Universitätsklinikum Jena

Product

[SYS-MSOTACUITYechoCE2] MSOT Acuity Echo CE (660-1300nm)

iThera Serial number

2-21-05

Region

Europe

Delivery date

2021-08-31 11:36:53

Status

Running

Days until service

-145

Service engineer

Application support

Sales rep

iThera Medical GmbH,

Customer Contact

Universitätsklinikum Jena,

Distributor contact

Universitätsklinikum Jena

Critical emails to

Laser Type

Laser Options

Second Fiber Port

No

Handheld probe

Access Data

Service Records

Helpdesk Tickets

Tasks

Traceability

Other Info

Manufacturing

[IT-SYS-00136] Acuity Echo: V3 Computer assembly

PCAC-20-05

1.00

i...

V...

2021-08-28 15:56:22

WH/MO/00525

Manufacturing

[IT-OPT-00114] SpitLight DPSS-OPO-MED OEM 25Hz, including...

P1954

1.00

i...

V...

2021-08-28 15:56:22

WH/MO/00525

Manufacturing

[IT-SYS-00091] Acuity Echo - Base Frame and Rack

0000903

1.00

i...

V...

2021-08-28 15:56:22

WH/MO/00525

Manufacturing

[IT-SYS-00118] Acuity Echo Screen Holder Assembly

0000923

1.00

i...

V...

2021-08-28 15:56:22

WH/MO/00525

Manufacturing

[IT-SYS-00094] Acuity Echo - front cover (top) incl. switches

0000898

1.00

i...

V...

2021-08-28 15:56:22

WH/MO/00525

Manufacturing

[IT-SYS-00116] Acuity Echo: Interface plate

0000905

1.00

i...

V...

2021-08-28 15:56:22

WH/MO/00525

Manufacturing

[IT-SYS-00117] Acuity Echo: laser warning module

0000846

1.00

i...

V...

2021-08-28 15:56:22

WH/MO/00525

Manufacturing

[IT-SYS-00106] Acuity Echo: RAB

0000935

1.00

i...

V...

2021-08-28 15:56:22

WH/MO/00525

Manufacturing

[IT-SYS-00121] Acuity Echo: PT1000 sensor cable

0000940

1.00

i...

V...

2021-08-28 15:56:22

WH/MO/00525

1.00

Traceability in den Operations

Inventory
1 / 1 Work Orders
Product Moves
Valuation
Cost Analysis
Quality Checks

WH, [2-10-2021]

Product

Quantity

Bill of Materials

Routing

Initial Date

Quantity

Lot/Serial

Component

Product

[IT-OPT-000001] Acuity Electronics

[IT-SYS-00091] Acuity Electronics

[IT-SYS-00118] Acuity Electronics

[IT-SYS-00092] Acuity Electronics

[IT-SYS-00119] Acuity Electronics

[IT-SYS-00094] Acuity Electronics

[IT-SYS-00096] Acuity Electronics

[IT-SYS-00116] Acuity Electronics

[IT-SYS-00098] Acuity Electronics

[IT-SYS-00117] Acuity Electronics

[IT-SYS-00106] Acuity Electronics

[IT-SYS-00113] Acuity Electronics

Service Record 5,790 - installation of type 2 laser

1. Overview

Customer and contact	Maren
Related installed base	[2-21-05] DE - Jena
Serial number	2-21-05

Created on	2021-10-08 19:08:51	Created by	
FCO		FCO number	
Responsible		Complaint	
Service Type	Hardware		

2. Details of Service Intervention

Description	2021-10-20 QB: Replacement of Type 1 laser with Type 2 laser.		
Parts exchanged?	Yes	Serial numbers	P1932 (new laser) P1954 (replaced)
Service Date	2021-10-11 12:51:13	Onsite visit?	Yes

Traceability in den Operations

Wareneingang

Produktionsauftrag

Komponentenansicht

Systemansicht

Serviceeinsatz

Neue Systemansicht

Inventory

EDIT

QUALITY A

WH

Product

Quantity

Bill of Ma

Routing

Initial De

Name

Customer

Product

Quantity

Lot/Seri

P1954

Compo

Product

[IT-OPT-0

[IT-SYS-00091] Acuity E

[IT-SYS-00118] Acuity E

[IT-SYS-00092] Acuity E

[IT-SYS-00119] Acuity E

[IT-SYS-00094] Acuity E

[IT-SYS-00096] Acuity e

[IT-SYS-00116] Acuity E

[IT-SYS-00098] Acuity E

[IT-SYS-00117] Acuity E

[IT-SYS-00106] Acuity E

[IT-SYS-00113] Acuity E

Access Da

Manufactur

Manufactur

Manufactur

Manufactur

Manufactur

Manufactur

Manufactur

Manufactur

Manufactur

Manufactur

Manufactur

1. Over

Customer

Related in

Serial num

Created o

FCO

Responsi

Service Ty

Name

DE - Jena

Customer

Universitätsklinikum Jena

Product

[SYS-MSOTACUITYechoCE2] MSOT Acuity Echo CE (660-1300nm)

iThera Serial number

2-21-05

Region

Europe

Delivery date

2021-08-31 11:36:53

Status

Running

Days until service

-145

Service engineer

Application support

Sales rep

iThera Medical GmbH,

Customer Contact

Universitätsklinikum Jena,

Distributor contact

Universitätsklinikum Jena

Critical emails to

@med.uni-jena.de

Laser Type

Laser Options

Second Fiber Port

No

Handheld probe

Total

Contacts

1

Access Data

Service Records

Helpdesk Tickets

Tasks

Traceability

Other Info

Service

Replace[Add]

[IT-OPT-00058] Safet

P1932SB

1.00

iThera-Medical/Stock

Virtual Locations/iT...

2021-10-20 17:23:51

installation of type...

Service

Replace[Add]

[IT-OPT-00056] SpitL...

P1932

1.00

iThera-Medical/Stock

Virtual Locations/iT...

2021-10-20 13:47:09

installation of type...

Service

Replace[Remove]

[IT-OPT-00058] Safet...

P1954SB

1.00

Virtual Locations/iT...

iThera-Medical/Stock

2021-10-20 17:23:51

installation of type...

Service

Replace[Remove]

[IT-OPT-00114] SpitL...

P1954

1.00

Virtual Locations/iT...

iThera-Medical/Stock

2021-10-20 13:47:09

installation of type...

Manufacturing

[IT-SYS-00136] Acuit...

PCAC-20-05

1.00

iThera-Medical/Stock

Virtual Locations/iT...

2021-08-28 15:56:22

WH/MO/00525

Manufacturing

[IT-OPT-00114] SpitL...

P1954

1.00

iThera-Medical/Stock

Virtual Locations/iT...

2021-08-28 15:56:22

WH/MO/00525

Product

[IT-OPT-00

Receive F

Importer

Operation

Destinati

Back Ord

Operati

Product

2022 – digital bis zur elektronischen Unterschrift

Entwicklung

HW/SW Entwicklun



Risikomanageme



Tools (TE, SW)



Klinische Bewertu



Usability



Change Manag



Markt-Feedback

Complaints



CA



Med Dev Reporting



PMS



Operations

Einkauf



Produktion



Vertrieb



Service



Traceability



Employees



Support-Prozesse

Information Contr



Training



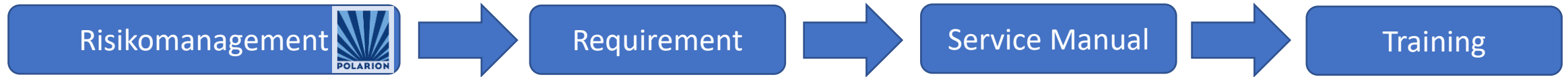
Mgmt Assessment



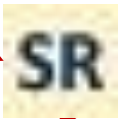
Internal Audits



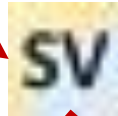
Darstellbare Traceability – Risikomanagement



 **Risk Control Measure, c1RM-926, ✓ Released - S&P Check: Check of wavelength accuracy during planned service.**
Extended Self-Test --> Check wavelength accuracy



SR, ✓, MSOT-13993 - The instructions for factory acceptance and service shall contain the following...
The instructions for factory acceptance and service shall contain the following information: c1RM-926 - S&P Check: Check of wavelength accuracy during planned service.



SV, ✓, MSOT-12862 - Service Documentation (Service Manual, Safety and Performance Checklist)
Conditions: -/-

-  QMS-6285 - Service Manual - MSOT Acuity Echo CE available.
-  QMS-6508 - Safety and Performance Checklist - MSOT Acuity Echo CE available.
-  QMS-6522 - Preventive service checklist - MSOT Acuity Echo CE available.

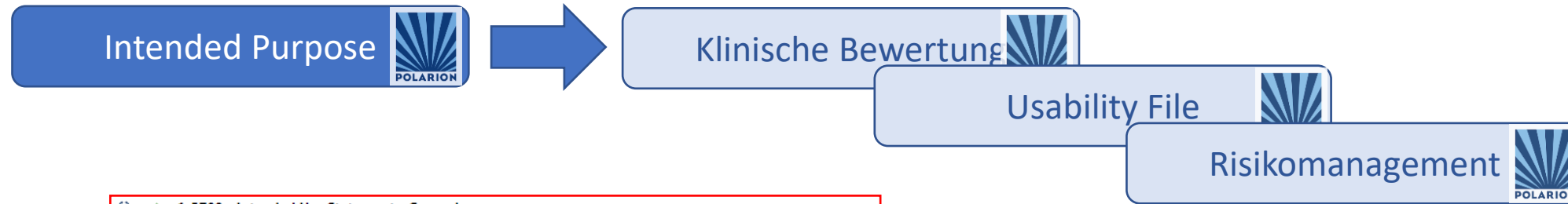


 **DMR-2.03-WI-6285, 2.1 - Service Manual - MSOT Acuity Echo CE**
Service Manual - MSOT Acuity Echo CE



 QMS-8940	QB Phantom calibration	 Assessed
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Darstellbare Traceability – Textbausteine



🔗, ✓, c1-5709 - Intended Use Statement - General
The cMSOT-2 system is an imaging tool used to detect and visualize photoabsorbers in soft tissue with optical and acoustic properties similar to breast tissue or tissue of regions as defined by specific indications below.

- Open in Document
- Open in Intended Purpose cMSOT-2 - General OA Imaging
- Open in MSOT-13920 - cMSOT-2 Clinical Evaluation Report General OAI
- Open in MSOT-13123 - Clinical Evaluation Plan
- Open in cMSOT-2_Stakeholder Requirements
- Open in 10-FS-01_Usability File Summary
- Open in Risk Management Plan

2 Intended Purpose

🔗, ✓, c1-5709 - Intended Use Statement - General
The cMSOT-2 system is an imaging tool used to detect and visualize photoabsorbers in soft tissue with optical and acoustic properties similar to breast tissue or tissue of regions as defined by specific indications below.

4.3 Intended Purpose

The intended use is defined in detail in the separate document (📄 MSOT-20548 - Intended Purpose cMOST-2 General OAI), including description of the medical purpose, patient population, user groups and user profiles as well as conditions of use. Only the intended use statement (📄 MSOT-20548 - Intended Purpose cMOST-2 General OAI, chapter 2) has been copied to the clinical evaluation report and a summary of the defined user group is provided below (📄 MSOT-20548 - Intended Purpose cMOST-2 General OAI, chapter 2.6). For other information, please see the respective chapters in the intended use document.

Intended Use Statement

🔗, 📄, c1-5709 - Intended Use Statement - General
The cMSOT-2 system is an imaging tool used to detect and visualize photoabsorbers in soft tissue with optical and acoustic properties similar to breast tissue or tissue of regions as defined by specific indications below.

2.2 Intended Purpose

🔗, ✓, c1-5709 - Intended Use Statement - General
The cMSOT-2 system is an imaging tool used to detect and visualize photoabsorbers in soft tissue with optical and acoustic properties similar to breast tissue or tissue of regions as defined by specific indications below.

Training documentation today

👤 QMS-13236 🕒 QMS-1430 🕒 QMS-1431 🕒 QMS-1438 🕒 QMS-1458 🕒 👤 QMS-8958

↑ 👤 QMS-13436 - Admin Onboarding Training
↑

Status: 🚨 **Needed**

Type of training: **Presentation**
Self-study

Training Effectiveness: **Discussion**

Training date: **2022-08-11**

Training valid until:

Duration (e.g. 1h, 1/h): **1h**

Planned Role: **Company (all)**

Type: 👤 **Training**

Project: **Control of Approved Docs**

Document:

Participants

Rutra

Approvals

Approving User: State

Rutra Waiting

Linked Work Items

Suspect	Role	Title
	relates to	👤 QMS-13236 - Admin Onboarding Training
	training for	📄 QMS-1430 - QMH
	training for	📄 QMS-1431 - Company Structure
	training for	📄 QMS-1438 - Information Control
	training for	📄 QMS-1458 - Complaint Handling
	training for	👤 QMS-8958 - General work safety training - Munich HQ

Details about trained Documents

🕒 📄 QMS-1430 - QMH

Document ID	00	Valid Version	2.5	Release date	2022-02-28	Owner	
Document Type	Quality Management Handbook	Status	✅ Approved	Need for training	Training required for last major version (G)		

Description

Provides an introduction, overview and structure of the quality management system implemented at iThera Medical.

Attachments

📄 v2.5: 00_QMH v2.5.pdf

Applicable departments

Company (all)

🕒 📄 QMS-1431 - Company Structure

Document ID	01-SOP	Valid Version	2.2	Release date	2021-01-25	Owner	
Document Type	SOP (Process)	Status	✅ Approved	Need for training	No training (see justification) (G)		

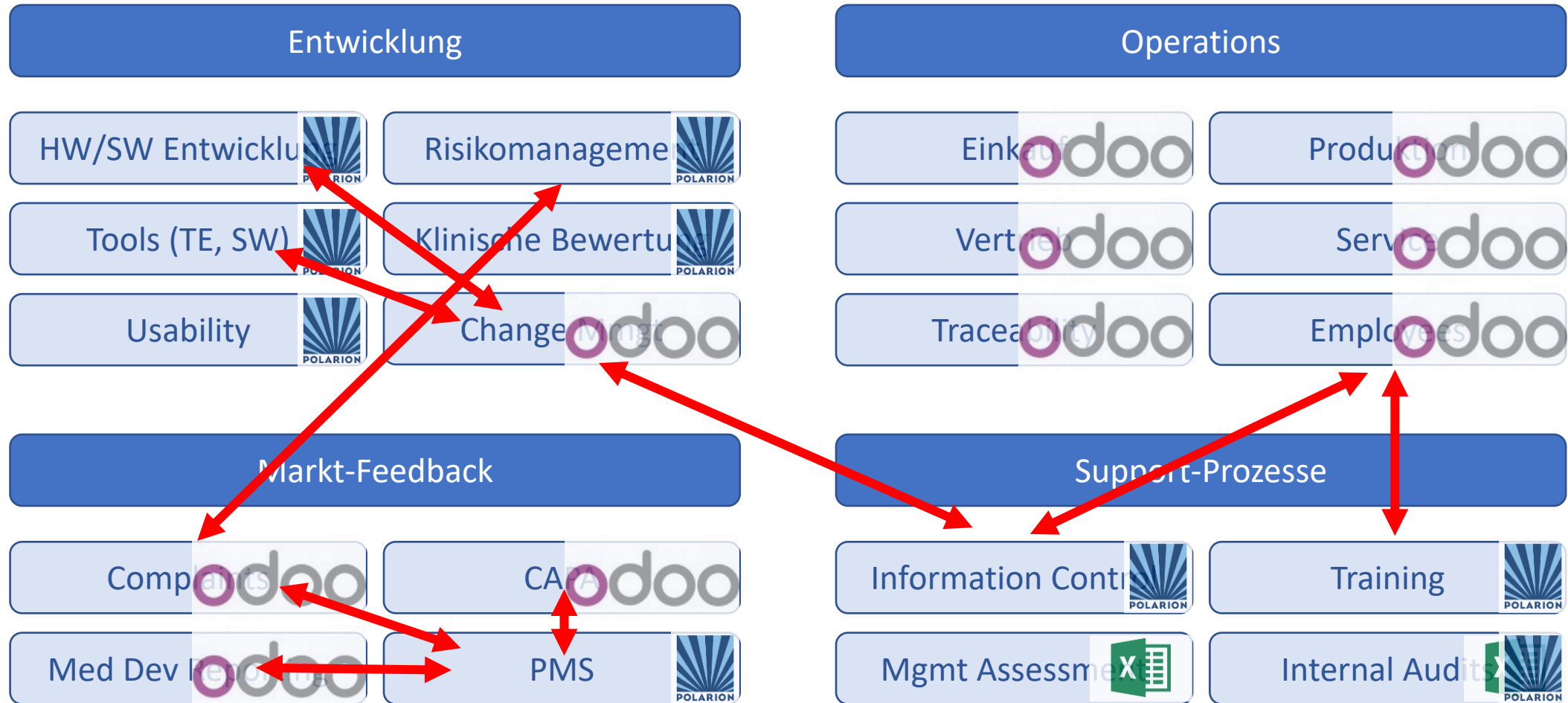
Description

Definition of responsibilities within iThera and of iThera Medical Management regarding the company in general and specifically the Quality Management System.

Attachments

📄 v2.2: 1-SOP_Company Structure.pdf

Die Zukunft – Weitere Integration



-
- Nimm eine Software, die flexibel anpassbar ist, aber limitiere die Anpassungen auf das tatsächlich Notwendige.
 - Nimm lieber ein in der Firma existierendes Tool, das nicht 100% passt, als ein neues einzuführen.
 - Verstehe das Tool und verlass dich nicht nur auf Berater.
 - Gehe bei der Entwicklung des Tools immer in kleinen Schritten vor.
 - Involviere die Mitarbeiter bei der Entwicklung der Tools, schreibe kurze Work-Instructions und trainiere, so oft es geht.
-

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Optoacoustics, the next generation in biomedical imaging.

