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1 Scope

1.1 Scope

This document contains software requirements for the TheraSphere 360 Medical Device Functions. Medical Device Functions include functionality associated with the Treatment Draft and Written Directive / Post Treatment worksheet documents.

At a high level, the following functionality is covered: Case Details, Treatment Date, Single Compartment Dosimetry, Post Treatment Analysis, Vial Selector, Review and Submit, Written Directive and Post Treatment draft and worksheet, security requirements as they relate to the medical device functions specifically. Non-medical device functions and their associated requirements are not in scope of this requirements document.

Relevant Formula, GUI messages, Field Limits, Warning, and Parameters defined within the software requirements are located in the appendix to this document.

1.2 Product Description

TheraSphere 360 is an end to end, browser-based platform that will host a wide range of resources (e.g. radioembolization activity calculations, ordering, tracking, and education) that support authorized users of TheraSphere Microspheres. TheraSphere 360 will include multiple functions, some of which are non-medical device functions and some of which are medical device functions.

TheraSphere 360 includes treatment planning functionality, activity calculation functionality and post-treatment analysis functionality which are the device functions of the platform.

The treatment planning functionality and the activity calculation functionality include an interactive tool intended for calculating the activity of TheraSphere Microspheres required at the treatment time based upon the desired dose, lung shunt fraction, anticipated residual waste, and liver mass. These device functionalities also include features to aid in TheraSphere Microspheres dose vial selection.

The post-treatment analysis functionality is intended as an optional tool for post-treatment evaluation following TheraSphere Microspheres treatment.

1.3 Indication/Intended Use:

TheraSphere 360 includes Treatment Planning and Activity Calculation functionalities as optional interactive tools intended for calculating the activity of TheraSphere Microspheres required at treatment time based upon the desired dose, lung shunt fraction, anticipated residual waste, and target liver mass.

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The Treatment Planning and Activity Calculation functionalities includes features to aid in TheraSphere Microspheres dose vial selection. Additionally, TheraSphere 360 includes optional post-treatment analysis functionalities to be used following treatment by TheraSphere Microspheres.

For post-TheraSphere Microspheres treatment, TheraSphere 360 should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for pre-Treatment Planning when there is a need for retreatment using TheraSphere Microspheres.

2 Terminology, Acronyms, and Applicable Documents

2.1 Applicable Documents

1. Global Documents

Number	Title
92047866	Device Software Development and Validation
90751626	Global SOP for Device Software Development and Validation
90575423	Global WI Design Review

2. Project Specific Documents

Number	Document Title
97170016	TheraSphere360 Medical Functions User Needs
97170022	TheraSphere360 Medical Functions Design Requirements
97169458	TheraSphere360 Medical Functions Hazard Analysis
97170054	TheraSphere360 Medical Functions Task Analysis
97170218	TheraSphere360 Medical Functions D and D Plan
97170048	TheraSphere360 Medical Functions SW Development Plan
97173192	TheraSphere360 Medical Functions Device SW Architecture
97169448	TheraSphere360 Medical Functions SW RMP
97169475	TheraSphere360 Medical Functions SAMD Privacy Impact Assessment
97286748	TS360 Input Limits Technical Report

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2.2 Terms & Definitions

Term	Abbreviations/Definition
TS	TheraSphere
VOC/VOB	Voice of Customer / Voice of Business
AU	Authorized User
IR	Interventional Radiology
SIRT	Selective Internal Radiation Therapy
Y90	Yttrium 90
HCC	Hepatocellular Carcinoma
SAB/MAB	Strategic Advisory Board / Medical Advisory Board
NG	Next Generation
IFU	Instructions for Use
IR	Interventional Radiologist
GUI	Graphical User Interface
SW	Software
PC	Personal Computer
Gy	SI Unit for Absorbed Dose (Gray)
mCi	Unit of radioactivity (millicuries) - Common fractions of the curie are the millicurie (1 mCi = 1/1,000 Ci)
GBq	SI unit for the measurement of radioactivity. (Gigabecquerel))

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LSF	Lung shunt fraction (F) - the fraction of injected radioactivity expected to localize in the lungs
R	Anticipated Residual Waste
SCD	Single Compartment Dosimetry
MCD	Multi-compartment (post treatment analysis) Dosimetry
CDL	Cumulative Dose to Lungs - the total amount of a drug or radiation given to a patient over time; for example, the total dose of radiation given in a series of radiation treatments.
WD	Written Directive
TNR [T/N]	Tumor to normal tissue ratio of the liver
NRC	Nuclear Regulatory Commission
AU	Authorized user who is listed on the institution's radioactive materials license and meets the requirements stipulated by the Nuclear Regulatory Commission (NRC) or Agreement States. This is often a board-certified radiation oncologist, a board-certified interventional radiologist, or a board-certified nuclear medicine physician.
PHI	Protected Health Information is defined as information collected by a healthcare professional that is used to identify an individual and/or determine appropriate care.
PII	Personal Identifiable Information is defined as any information that allows the identity of an individual for which the information pertains to be indirectly or directly inferred.
UDI	Unique Device Identification - An identifier that adequately identifies a device through its distribution and use.
onblur	The onblur event occurs when an object loses focus.
MDDS	Medical Device Data System
TOP	Inventory System

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Authorized User	An Authorized user is a user who is authorized to have access to particular settings and functionalities. Authorization is typically controlled by user type
Labeling	The label (medical device or accessory), instructions for use (e.g., User Manual), and any other information that is related to identification, technical description, intended purpose, and proper use of the medical device, but excluding shipping documents.
Medical Device Regulators	Regulatory bodies, their employees, and authorized agents are responsible for protecting and promoting public health through the control and oversight of medical devices. Regulatory bodies include the United States Food and Drug Administration (FDA), China's National Medical Products Administration (NMPA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), etc.
Medical Device Manufacturer	Medical device manufacturers are the entities responsible for developing, manufacturing, or maintaining the medical device. In the context of this document, medical device manufacturer refers to Boston Scientific and any third-party manufacturers contracted by Boston Scientific.
Medical Device Beneficiary	Medical device beneficiaries are individuals who benefit from a medical device, even if the individuals themselves do not operate or interact with the medical device. Examples include patients and their caregivers.
Record	Data stored in the MDDS for a Patient/Procedure

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3 Software Design Requirements

The tables below represent the formatted export from the Jama database for TheraSphere 360 System Requirements. (See TheraSphere 360 Requirements & Test Management Guidelines 97404206 for further details)

3.1 Functional

3.1.1 General

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-1	1. Functional	Dosimetry Selection	The software shall provide the selection for the following types of dosimetry: • Single Compartment (selected by default) • Multi-compartment (post treatment)	User wants to be able to select the dosimetry method of their choice.
TS360-SWR-2	1. Functional	SCD and MCD mutually exclusive	The software shall support calculations of only one dosimetry method (SCD or MCD) at a time.	The software prevents calculations for both MCD and SCD in the same treatment draft.
TS360-SWR-3	1. Functional	Another Dosimetry Selected in the session	If dosimetry is started and another dosimetry method is selected, the software shall display a confirmation message, M42 in TS360-TXT-49, to the user and delete Calculator inputs and results as well as previously selected vials upon confirmation.	User should only perform one dosimetry per patient in one session.
TS360-SWR-6	1. Functional	Treatment Time Format	The software shall present time format as follows and indicate the time zone: • HH:MM AM or PM	User should be guided on the time format. Example: 03:00 PM CST
TS360-SWR-9	1. Functional	Target Name	The software shall adhere to the defined Target Name input ranges and warnings as defined in the TS360-TXT-42	User should be able to name their target.
TS360-SWR-13	1. Functional	Software Version Nomenclature	The software shall display current Software version in the XX.YY.ZZ format where: - XX is the major version - YY is the minor version - ZZ is the patch	User needs to confirm/verify they are using the right version of software.
TS360-SWR-18	1. Functional	Lung Mass	The software shall provide the means to enter Lung Mass (kg), with a default provided value of 1 kg.	User needs to enter parameter to perform calculations.
TS360-SWR-19	1. Functional	Recalculate on Constants update	The software shall provide the means to recalculate the results if any of the constants are updated.	User needs to be able to recalculate the results.
TS360-SWR-20	1. Functional	Recalculate on Target update	The software shall provide the means to recalculate the results if any of the target attributes are updated.	User needs to be able to recalculate the results for a target.
TS360-SWR-21	1. Functional	Calculate and Recalculate operations	The software shall calculate the results only when Calculate or Recalculate button is pressed.	User needs to be able to recalculate the results
TS360-SWR-22	1. Functional	Correct Calculations Results	The software shall correctly display the Calculate and Recalculate Results.	User needs to be able to view the results.
TS360-SWR-380	1. Functional	Unable to Calculate Indication	The software shall display a visual indicator for targets that were unable to be calculated due to invalid input.	The user needs to know which targets need to be updated for a calculation to occur for that target.
TS360-SWR-23	1. Functional	Clearing Results	The software shall clear the Calculator Results on the screen If any numeric constant values, or any Target values are modified.	User needs to be able to recalculate the results and appropriate data is cleared when recalculating the MCD or SCD values.

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TS360-SWR-24	1. Functional	Activity Units in GBq and mCi	The software shall convert between GBq and mCi and between mCi and GBq using the following formulas: •1 GBq = 27.027027027 mCi •1 mCi = 0.037 GBq	Source # 1 User needs to see appropriate units, expressed in SI units as specified in ISO 80000-1 Therasphere IFU.
TS360-SWR-25	1. Functional	Time zone with Time	The software shall display the time zone for all time selections based on the time zone of the Treatment Facility selected.	Source #1 User needs to see time zone of a treating facility for decay calculations.
TS360-SWR-328	1. Functional	Warning message - Blank Field	The SW shall display a warning message if the user leaves any of the required fields blank onblur.	The user needs the sw to display a message if any required fields are blank when user clicks away from input field.
TS360-SWR-357	1. Functional	Warning message - Invalid Field	The software shall display a warning message if the user leaves invalid input in a field onblur.	The user needs the software to display a message if any required fields are invalid when user clicks away from input field.
TS360-SWR-291	1. Functional	Mass Conversion - Formula	The software shall convert the below inputs from cc into Kg as per the formula defined in TS360-TXT-38 and display both the units - Perfused Volume (cc) converted to Calculated Perfused Mass (Kg) - Tumor Volume (cc) to Calculated Tumor Mass (Kg) - Normal Tissue Volume (cc) to Calculated Normal Tumor Mass (Kg) - Target Volume (cc) to Calculated Target Liver Mass (Kg) - Whole Liver Volume (cc) to Calculated Whole Liver Mass (Kg)	The user needs to know the Volumes in Kilograms as well. This formula is the same for all scenarios where cc to kg conversion occurs. Therasphere IFU
TS360-SWR-35	1. Functional	Calculated Dose to Lungs Formula	The software shall provide the means to calculate Dose to Lungs for each target using the formula in TS360-TXT-18	Source # 1 User needs to view Dose To Lungs. Formula is for SCD and MCD calculations.
TS360-SWR-297	1. Functional	Absorbed Dose formula	The software shall provide the means to calculate and display Absorbed Dose for each vial using the formula in TS360-TXT-58.	User needs to be able to see the Absorbed Dose for each vial.
TS360-SWR-298	1. Functional	Activity at Treatment formula	The software shall provide the means to calculate and display Activity at Treatment for each vial using the formula in TS360-TXT-57.	The user needs to be able to see Activity at Treatment.
TS360-SWR-28	1. Functional	Non-Linear Workflow	The software shall support non-linear workflow as specified in the TS360-TXT-36.	User needs flexibility to navigate to different tabs
TS360-SWR-8	1. Functional	Browser Support	The software shall run on the following web browsers: Chrome (134 or later), Firefox (135 or later), Safari (18 or later), MS Edge (133 or later).	User should have flexibility on using several browsers. The sw application should maintain its functionality and aesthetics across different screen resolutions and sizes, for desktops.
TS360-SWR-211	1. Functional	Editable and non-editable	The software shall provide the means to differentiate between editable and non-editable fields.	User needs to see which fields editable and which ones are not
TS360-SWR-338	1. Functional	Total Dose To Lungs Formula	The Software shall display a Total Dose to Lungs (Gy) using the following formula: TDL = Sum of Calculated Dose to Lungs for all Targets	User needs a formula calculation of Total Dose to Lungs.
TS360-SWR-15	1. Functional	Cumulative Dose to Lungs Formula	The Software shall display a Cumulative Dose to Lungs (Gy) using the following formula: CDL = Previous Dose to Lungs + Sum of Calculated Dose to Lungs for all Targets	User needs a formula calculation of Cumulative Dose to Lungs. Therashpere IFU
TS360-SWR-256	1. Functional	Total Dose to Lungs Notification	The software shall display message, M39 in TS360-TXT-49, if the dose to lungs equals or exceeds 30 Gy in the following screens: - SCD - MCD - Vial Selector - Review and Submit	The user needs to know if the lung dose exceeds 30 Gy.

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TS360-SWR-232	1. Functional	Cumulative Dose to Lungs Notification	The software shall display message, M40 in TS360-TXT-49, if the cumulative dose to lungs equals or exceeds 50 Gy in the following screens: - SCD - MCD - Vial Selector - Review and Submit	The user needs to know if the cumulative lung dose exceeds 50 Gy.
TS360-SWR-331	1. Functional	Delete Target Message	The software shall display a confirmation message, M44 in TS360-TXT-49, when targets are deleted that contain user entered information.	The user needs to confirm the delete action as the software will delete the inputs, results, and selected vials
TS360-SWR-270	1. Functional	Previously Selected Vials Cleared if calculator used for the first time	The software shall remove selected vials after user confirmation if vials were selected prior to using Calculator and then the Calculator was used for the first time. • M41 in TS360-TXT-49 if SCD calculator was used • M77 in TS360-TXT-49 if MCD calculator was used	The vials that were preselected upfront, they are independent of targets. So, the decision of what vials should go to which targets, as well as if more vials than allowed per target cant be made when navigated to the calculator. So the vials preselected need to be cleared. Example: up to 4 vials can be selected without using Calculator. But with the calculator, only 3 vials are allowed per target. No activity calculation is done. The user goes back to MCD & calculates dose, vials will clear. This behavior aligns with SCD.
TS360-SWR-385	1. Functional	Finish Calculation notification	The software shall notify the user of an unfinished calculation with M70 in TS360-TXT-49 when the user tries to leave the activity calculator after deleting a target without recalculating.	The user needs to be informed of unfinished calculations
TS360-SWR-315	1. Functional	Loading Time - Message	The software shall display message M136 in TS360-TXT-49 for data loading failures.	The user needs to know if there are any system connection error while performing the treatment planning.
TS360-SWR-271	1. Functional	Previously Selected Vials Not Cleared on Recalculate Operation	The software shall maintain the selected vials when activity is recalculated, if the previously selected dosimetry method is used.	The user may want to keep the vials selected for the same dosimetry method.
TS360-SWR-342	1. Functional	Additional contextual information	The software shall display additional contextual information upon user request for the following: • SCD ◦ Target Name (M21 in TS360-TXT-49) ◦ Target Volume (M22 in TS360-TXT-49) ◦ Residual Waste (%) (M23 in TS360-TXT-49) ◦ Total Dose To Lungs (M25 in TS360-TXT-49) ◦ Cumulative Dose To Lungs (M24 in TS360-TXT-49) • MCD ◦ Target Name (M21 in TS360-TXT-49) ◦ Residual Waste (%) (M50 in TS360-TXT-49) ◦ Whole Liver Volume (M46 in TS360-TXT-49) ◦ Tumor Volume (M47 in TS360-TXT-49) ◦ Normal Tissue Volume (M48 in TS360-TXT-49) ◦ Activity and Absorbed Dose (M49 in TS360-TXT-49) ◦ Total Dose To Lungs (M25 in TS360-TXT-49) ◦ Cumulative Dose To Lungs (M24 in TS360-TXT-49) • Prescribing Information ◦ Activity of Vial(s) (M140 in TS360-TXT-49) ◦ Prescribed Activity (M115 in TS360-TXT-49) ◦ Desired Dose (M117 in TS360-TXT-49) • Post Treatment Worksheet - Treatment Information ◦ Target Volume (if field is editable) (M22 in TS360-TXT-49)	User needs to understand application, which might include additional information for some users. Additional contextual information is hidden in a tool tip to not clutter screen for power users.
TS360-SWR-389	1. Functional	Autocomplete and Autofill	The software shall disable the browser's autocompletion and autofill features for input fields in the following screens: • Case Details • Activity Calculator	

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TS360-SWR-381	1. Functional	Treatment Draft- Patient Information on left-hand side panel	The software shall provide the following information on the left-hand side panel of the Treatment Draft: - Last Name, First Name - Patient Reference ID	The user needs to know which patient they are creating a treatment draft for.
TS360-SWR-386	1. Functional	Target Navigation	The software shall allow navigation between targets.	The user needs to be able to switch between targets.

3.1.2 Save, Delete, Email and Exit

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-273	1. Functional	Save current content	The software shall save the current unsaved valid content on all screens and shall exit the application when the Save and Exit button is pressed.	The user needs to save the information for future retrieval. The user can save and exit the application at any time of creating the treatment plan and treatment documents.
TS360-SWR-274	1. Functional	Previously stored data	The software shall load the previously stored data for all available screens.	The user needs to be able to retrieve the information when entering treatment documents, previously started draft, or when switching between draft sections. Switching between draft sections utilizes data saved to state. Loading previously started draft or treatment documents utilizes data saved to the record.
TS360-SWR-276	1. Functional	Save Calculator inputs and outputs	The software shall save valid Calculator inputs and outputs if Calculator results are successful when Calculate and Recalculate operations on the Activity Calculator screen are performed.	The user needs to be able to save the calculator results.
TS360-SWR-278	1. Functional	Save Calculator Inputs and Outputs and Vials details when recalculate	The software shall save valid Calculator Inputs and Outputs and Vials details when recalculate operation on the Vial Screen is performed.	The user needs to save all the inputs and the outputs of the calculation and vial details
TS360-SWR-279	1. Functional	Vials information when Add / Remove operations	The software shall save selected vials information when successful Add / Remove operations on the Vials screen are performed.	The user needs to save the vials information at any point of time during the treatment planning process
TS360-SWR-280	1. Functional	Save order information	The software shall save order information when Submit Order on the Review Order screen is performed.	The user needs to save order information when the user submits order, so the users can retrieve for later review.
TS360-SWR-281	1. Functional	Save Prescribing Information Section	The software shall save the Prescribing Information Section when Lock operation performed.	The user needs to save the data from the Prescribing Information Section, so the information can be passed down to create PDF reports.
TS360-SWR-282	1. Functional	Save Post Treatment Information on Lock operation	The software shall save valid Post Treatment information when Lock operation on Post Treatment work sheet is performed	User needs to be able to save post treatment information for future retrieval. There are two places where Lock operation is performed on the Post Treatment / Prescribing Information Section
TS360-SWR-283	1. Functional	Save valid data on the Post Treatment worksheet	The software shall save all valid data on the Post Treatment worksheet when successful calculate or recalculate operations are performed on Post Treatment work sheet.	User needs to have calculations results saved. The Post Treatment content is saved when calculate and recalculate buttons are pressed. Calculation is successful if calculation produced valid result without warnings.
TS360-SWR-186	1. Functional	Delete Treatment Draft	The software shall provide the means to delete the Treatment draft with confirmation modal M102 in TS360-TXT-49	User needs to be able to delete treatment draft
TS360-SWR-187	1. Functional	Email Draft	The software shall provide the means to initiate the email of the Treatment Draft with inputs and warnings as defined in TS360-TXT-50 and confirmation message M101 in TS360-TXT-49.	User needs to be able to email treatment draft. Note: the actual emailing occurs outside of the medical device application.

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TS360-SWR-284	1. Functional	Unsaved data Notification	The software shall provide a confirmation message that data will be lost upon user confirmation for the below user actions: - When user attempts to navigate away from the Treatment Date screen without re-confirming (M20 in TS360-TXT-49) - When user attempts to navigate away from the Calculator screen without re-calculating (M43 in TS360-TXT-49) - When user attempts to leave the application without saving data	The user needs the data to be saved to the record upon a qualified action, so they won't lose the entered data.
TS360-SWR-275	1. Functional	Save treatment date and time	The software shall save Treatment Date and Time when Confirm operation on Treatment Date screen is performed.	The user needs to be able to save Treatment Date and Time. User needs to confirm their time and date selected.

3.1.3 Record Locking Mechanism - Treatment Draft & Post Treatment Document

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-179	1. Functional	Locking of Patient Record	The software shall lock the Treatment Draft record or Post Treatment worksheets record upon opening and prevent another user from opening it.	The treatment draft record means anything prior to the submission of the record. Post Treatment Worksheets Record means anything after target selection. The record is still available for the same user but cannot be edited by multiple users at the same time. Record locking is to prevent multiple users from updating the same data simultaneously, which could lead to corrupted or inconsistent information.
TS360-SWR-180	1. Functional	Unlock Patient Record when closed	The software shall unlock a Treatment Draft record or Post Treatment worksheets record when Save and Exit is pressed.	User needs to be able to lock and unlock the treatment draft record and Post Treatment worksheets so no other clinician can update it concurrently
TS360-SWR-182	1. Functional	Unlock Patient Record Due to Inactivity	The software shall automatically unlock a Treatment Draft record or Post Treatment worksheets record if an inactivity logout has occurred.	User needs the Patient Record to unlock after inactivity
TS360-SWR-286	1. Functional	Patient Record Lock Notification	The software shall display a notification message that includes the patient name and user name that another user is editing the record when a direct link to the draft or treatment document is used.	Only one user can edit the patient record at a a time. The user unable to edit the record will receive the message.
TS360-SWR-377	1. Functional	Patient Record not Found	The software shall display a message with a link to portal when a user tries to access a treatment draft or treatment document that does not exist.	The user needs to be notified when a direct link to treatment draft or document does not work. User needs to be directed to a portal when a direct link to treatment draft or document does not work. The Treatment Document is only created once the treatment draft is submitted.
TS360-SWR-378	1. Functional	Patient Record already submitted	The software shall redirect the user to the treatment details page when a user tries to access a treatment draft that has already been submitted.	The user needs to access relevant and valid parts of the application. User needs to be redirected when attempting to access an invalid portion of the application.

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3.1.4 Case Details Requirements

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-85	1. Functional	Treatment Planning and Case Details Required Fields	The software shall confirm that all required fields are entered. •Referring Physician (optional) •Treating Physician •Consult Date (optional) •Disease Type •Treatment Goal •Treatment Approach •Mapping Date	User needs software confirmation on which fields are required.
TS360-SWR-87	1. Functional	Case Details Limits and Warnings	The software shall adhere to the defined case details input ranges and warnings as defined in the TS360-TXT-41	The software needs to check if the user inputs are within the defined ranges. The user needs to know if the input is outside the range and the trouble shooting guidance to correct. IEC 62304: 2015 Multiple Function Device Products FDA Guidance: July 2020 92047866 Device SW development process
TS360-SWR-88	1. Functional	Date Format on Case Details screens	The software shall provide the means for entering Consult Date and Mapping Date in the following format: “mm/dd/yyyy”	User needs to be able to enter consult date and mapping date
TS360-SWR-89	1. Functional	Display Contextual Studies	The software shall display text and functional external hyperlinks within the clinical context section based on the following logic: - always show: o TheraSphere™ Instructions for Use (plaintext, not a hyperlink) - If Disease Type = “Hepatocellular Carcinoma (HCC)” and Treatment Approach = “Radiation Segmentectomy” then show: o Legacy Study o Raser Study - If Disease Type = “Hepatocellular Carcinoma (HCC)” and Treatment Approach = “Multifocal - Unilobar” then show: o DOSISPHERE-01 Trial - If Disease Type = “Hepatocellular Carcinoma (HCC)” and Treatment Approach = “MVI/PVT - Macrovascular Invasion” then show: o DOSISPHERE-01 Trial	User needs to have access to clinical studies.
TS360-SWR-90	1. Functional	Disease Type	The software shall provide the following disease types options - Hepatocellular Carcinoma (HCC) - Intrahepatic Cholangiocarcinoma (ICCA) - Metastatic Colorectal Cancer (mCRC) - Neuroendocrine Tumors (NETs) - Metastatic Breast Cancer - Not Specified	User needs to see disease type options.
TS360-SWR-91	1. Functional	Treatment Approach Options	The software shall provide the following treatment approach options: - Radiation Segmentectomy - Radiation Lobectomy - Multifocal – Unilobar - Multifocal – Bilobar - MVI/PVT - Macrovascular Invasion - Not Specified	User needs to view treatment approach options.
TS360-SWR-93	1. Functional	Treatment Goal Options	The software shall provide the following Treatment Goal options: • Curative • Palliative • Not Specified	User needs to view treatment goals
TS360-SWR-92	1. Functional	Disease Type Contraindication	The software shall provide a visual indication for off-label use if the Disease Type selected is not Hepatocellular Carcinoma (HCC), M10 in TS360-TXT-49, and/or if the Treatment Approach selected is MVI/PVT - Macrovascular Invasion, M11 in TS360-TXT-49.	User needs to view the informational message for contraindication.

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TS360-SWR-349	1. Functional	Treatment Draft Modal	The software shall display a modal upon entering a treatment draft for the first time to collect the following: - Patient First Name - Patient Last Name - Patient Reference Number (optional) - Treatment Facility	User needs to enter basic information when starting a treatment draft
TS360-SWR-352	1. Functional	Treatment Draft Modal Limits and Warnings	The software shall adhere to the defined treatment draft modal input ranges and warnings as defined in the TS360-TXT-40	The software needs to check if the user inputs are within the defined ranges. The user needs to know if the input is outside the range and the trouble shooting guidance to correct. IEC 62304: 2015 Multiple Function Device Products FDA Guidance: July 2020 92047866 Device SW development process
TS360-SWR-350	1. Functional	Treatment Draft Modal Options - Treatment Identifier	The software shall provide options on the treatment draft modal to either return to portal or create a treatment identifier and enter the treatment draft for that treatment identifier.	User needs to be able to create treatment identifier for the treatment draft. User also needs the option to leave if accidental entry to treatment draft. User can either press start (create treatment identifier) or cancel (go to portal) on the modal.
TS360-SWR-387	1. Functional	Treatment Facility	The software shall provide a list of all treatment facilities assigned to the user under Treatment Facility. If the user is assigned to only one facility, the Treatment Facility field shall be automatically populated with that facility.	User wants the Treatment Facility field to be automatically populated with that facility if they are only assigned to one facility.

3.1.5 Treatment Date

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-94	1. Functional	Treatment Date Selection	The software shall provide the means to select Treatment Date between Monday and Friday.	User needs to be able to select treatment date. Vials cannot be ordered for weekend treatment.
TS360-SWR-382	1. Functional	Treatment Date Range	The software shall support treatment date range from the current month to 12 months out in increments of 1 month.	User needs to be able to select a treatment date and see specific date ranges.
TS360-SWR-95	1. Functional	Treatment Time Selection	The software shall provide the means to select Treatment Time.	User needs to select Treatment Time
TS360-SWR-96	1. Functional	Treatment Time Range	The software shall support Treatment Time Range from 8 AM to 6 PM in the increments of 1 hour.	User needs to see hourly increments and specific time ranges.
TS360-SWR-239	1. Functional	First Available Date	The software shall provide the means to display first available date on the Treatment Date and Time screen based on Inventory.	The user needs to be able to select dates that are available.
TS360-SWR-102	1. Functional	Treatment Date and Time based on Inventory	The software shall display dates available based on inventory status	User needs to view inventory status (available or not).
TS360-SWR-100	1. Functional	Treatment Date and Time - TOP inventory rules	The software shall provide the means to select dates if inventory is available based on inventory management rules (if Treatment Date is after first available date and is within 12 days of Order Date)	User needs to view current inventory. Only inventory within 12 days will be analyzed for date availability
TS360-SWR-101	1. Functional	Treatment Date and Time within 12 days	The software shall provide the means to select dates when Inventory is available (for the first 12 days) if vials have been previously selected by the user. The software shall not check inventory if vials were not previously selected.	User needs to be able to select the date if inventory is available.

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TS360-SWR-103	1. Functional	Treatment Date and Time beyond 12 days	The software shall provide the means to select dates beyond 12 days without inventory check.	User needs to be able to view and select dates beyond 12 day inventory lookup.
TS360-SWR-230	1. Functional	Update/Edit Treatment data and Time	The software shall provide the means to update the date and time.	The user needs the functionality to update or edit the treatment date and time
TS360-SWR-104	1. Functional	Updated Date and Time results in clearing of vials	The software shall delete previous vials if treatment day of week or treatment time are updated to no longer match the day of week or time of previously selected vials, and user agreed to proceed via M15 in TS360-TXT-49.	User needs to have current vials selection associated with the selected day of week and time.
TS360-SWR-98	1. Functional	Treatment Date and Time Summary	The software shall provide a summary on the treatment date screen with the following items: • Treatment Facility • Day of week of selected vials (if vials selected) • Time of selected vials (if vials selected) • Selected treatment date (if selected) • Selected treatment Time (if selected) • Ability to confirm the date and time, or M13 in TS360-TXT-49 if data and time are confirmed	User needs to see summary of their time and date selection. User needs to see visual feedback on whether time and date are confirmed.
TS360-SWR-361	1. Functional	Treatment Date and Time unable to Confirm	The software shall display the following messages on the treatment date summary upon attempt to confirm if the treatment date and time are unable to be confirmed: • M16 in TS360-TXT-49 if date and time are not selected • M17 in TS360-TXT-49 if time is not selected • M18 in TS360-TXT-49 if date is not selected • M14 in TS360-TXT-49 if no vials are available for the selected date and time • M71 in TS360-TXT-49 if selected vial(s) are not available for the selected date and time	The user needs to know why the treatment date and time cannot be confirmed.
TS360-SWR-240	1. Functional	Treatment Date selected not valid or Not available	The software shall display notification to the user, M19 in TS360-TXT-49, if Treatment Date selected is no longer available.	The user needs to be notified when the Treatment Date is before First Available Date

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3.1.6 Single Compartment Dosimetry

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-33	1. Functional	SCD Constants and Target Information	The software shall provide the means to enter the following SCD constants and target information: • Constants ◦ Lung Mass (kg) ◦ Previous Dose to Lungs (Gy) ◦ Lung Shunt Fraction (%) ◦ Anticipated Residual Waste (%) • Target Information ◦ Target Name ◦ Target Volume (cc) ◦ Desired Dose (Gy)	Source # 1 User needs to be able to enter SCD inputs to calculate results.
TS360-SWR-257	1. Functional	SCD Input Limits and Warnings	The software shall allow the user to enter SCD input between the ranges defined in the TS360-TXT-14	The software needs to check if the user inputs are within the defined ranges. The user needs to know if the input is outside the range and the trouble shooting guidance to correct. IEC 62304: 2015 Multiple Function Device Products FDA Guidance: July 2020 92047866 Device SW development process
TS360-SWR-34	1. Functional	SCD Dosimetry Targets Total	The software shall provide the means to add up to four targets in SCD with a minimum of one target.	User needs to receive total for all targets in Single compartment Dosimetry.
TS360-SWR-31	1. Functional	Single Compartment Dosimetry Outputs	The software shall display the following SCD calculator output: • Target Name (per target) • Activity Required at Treatment (GBq and mCi) (per target) • Calculated Dose to Lungs (Gy) (per target) • Total Dose to Lungs (Gy) • Cumulative Dose to Lungs (Gy)	Source # 1 User needs to see Single Compartment Dosimetry results.
TS360-SWR-258	1. Functional	SCD Output Limits and Messages	The software shall adhere to the defined SCD output ranges and message as defined in the TS360-TXT-27	The user needs to ensure that the software has ranges for outputs. The user needs to know if output goes out of the ranges and the trouble shooting guidance.
TS360-SWR-30	1. Functional	Activity Required At Treatment Formula	The Software shall use the following formula in TS360-TXT-17 for Single Compartment Dosimetry to calculate Required Activity At Treatment	Source #1 User needs to be able to calculate the results using MIRD formula.
TS360-SWR-383	1. Functional	SCD- Nonoverlapping Volumes	The software shall display "Additional targets are intended to be non-overlapping volumes" on additional targets.	Additional SCD targets are for non-overlapping volumes.

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3.1.7 Post Treatment Analysis / Multi-Compartment Dosimetry

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-36	1. Functional	Multiple Compartment Dosimetry Targets	The software shall provide the means to calculate the MCD outputs for up to two targets with a minimum of one target.	User needs to be able to perform post-treatment analysis.
TS360-SWR-49	1. Functional	MCD Constants and Target Information	The software shall provide the means to enter the following MCD constants and target information: • Constants ◦ Lung Mass (kg) ◦ Previous Dose to Lungs (Gy) ◦ Lung Shunt Fraction (%) ◦ Residual Waste (%) ◦ Whole Liver Volume (cc) • Target Information ◦ Target Name ◦ Perfused Volume (cc) ◦ Perfused Counts ◦ Tumor Volume (cc) ◦ Tumor Counts ◦ Normal Tissue Volume (cc) ◦ Normal Tissue Counts ◦ One of the four parameters below: ▪ Perfused Volume Absorbed Dose (Gy) ▪ Normal Tissue Absorbed Dose (Gy) ▪ Tumor Absorbed Dose (Gy) ▪ Activity At Treatment (GBq)	User needs to enter parameters to perform post-treatment analysis.
TS360-SWR-39	1. Functional	Calculate By Option	The software shall provide the means to select one of the four parameters as listed below in order to enter the appropriate value for the option selected: The value field shall be updated based on the newly selected option. • Activity At Treatment (GBq) • Perfused Volume Absorbed Dose (Gy) • Tumor Absorbed Dose (Gy) • Normal Tissue Absorbed Dose (Gy)	User needs to perform post-treatment analysis based on an option elected.
TS360-SWR-40	1. Functional	Activity At treatment Selected	The software shall provide the means to calculate the below if Activity At Treatment is selected: • Perfused Volume Absorbed Dose • Normal Tissue Absorbed Dose • Tumor Absorbed Dose	User needs to perform post-treatment analysis based on an option elected.
TS360-SWR-41	1. Functional	Tumor Absorbed Dose is Selected	The software shall provide the means to calculate the below if Tumor Absorbed Dose is selected: • Activity At Treatment • Normal Tissue Absorbed Dose • Perfused Volume Absorbed Dose	User needs to perform post-treatment analysis based on an option elected.
TS360-SWR-42	1. Functional	Normal Tissue Absorbed Dose is Selected	The software shall provide the means to calculate the below if Normal Tissue Absorbed Dose is selected: • Tumor Absorbed Dose • Activity At Treatment • Perfused Volume Absorbed Dose	User needs to perform post-treatment analysis based on an option elected.
TS360-SWR-43	1. Functional	Perfused Volume Absorbed Dose is selected	The software shall provide the means to calculate the below if Perfused Volume Absorbed Dose is selected: • Tumor Absorbed Dose • Activity At Treatment • Normal Tissue Absorbed Dose	User needs to perform post-treatment analysis based on an option elected.
TS360-SWR-188	1. Functional	MCD Input limits and warnings	The software shall adhere to the defined MCD input ranges and warnings as defined in the ID:TS360-TXT-15	The software needs to check if the user inputs are within the defined ranges. The user needs to know if the input is outside the range and the trouble shooting guidance to correct. IEC 62304: 2015 Multiple Function Device Products FDA Guidance: July 2020 92047866 Device SW development process

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TS360-SWR-38	1. Functional	Multi-compartment Dosimetry Results	The software shall provide the following MCD results for display: • Target Name (per target) • Activity At Treatment (GBq and mCi) (per target) • Perfused Volume Absorbed Dose (Gy) (per target) • Tumor Absorbed Dose (Gy) (per target) • Normal Tissue Absorbed Dose (Gy) (per target) • Calculated Dose to Lungs (Gy) (per target) • Total Dose to Lungs (Gy) • Cumulative Dose to Lungs (Gy) • Whole Liver Dose (Gy)	User needs to be able to perform post-treatment analysis and view results
TS360-SWR-259	1. Functional	MCD Output Limits and Warnings	The software shall adhere to the defined MCD output ranges and warnings as defined in the TS360-TXT-35	The user needs to ensure that the software has ranges for outputs and the needs to know if output goes out of the ranges.
TS360-SWR-46	1. Functional	Tumor Absorbed Dose Formula	The Tumor Absorbed dose is calculated based on the formula in TS360-TXT-11	User needs to perform post-treatment analysis. Source 3
TS360-SWR-45	1. Functional	Normal Tissue Absorbed Dose Formula	The Normal Tissue Absorbed dose is calculated based on the formula in TS360-TXT-20	User needs to perform post-treatment analysis Source 3
TS360-SWR-47	1. Functional	Whole Liver Absorbed Dose Formula	The Whole Liver dose is calculated based on the formula TS360-TXT-12	User needs to perform post-treatment analysis. Source 3
TS360-SWR-48	1. Functional	Activity at Treatment using Perfused Volume Absorbed Dose Formula	Activity at treatment is calculated based on the equations in TS360-TXT-13	User needs to perform post-treatment analysis. Source 3
TS360-SWR-237	1. Functional	MCD count overlap	The software shall provide a notification if the combined MCD normal count and MCD tumor count is greater than perfused count with M69 in TS360-TXT-49	The user needs to know if the combined MCD normal count and MCD tumor count is greater than perfused count
TS360-SWR-238	1. Functional	MCD volume overlap	The software shall provide a notification if the combined MCD normal volume and MCD tumor volume is greater than perfused volume with M68 in TS360-TXT-49.	The user needs to know if the combined MCD normal volume and MCD tumor volume is greater than perfused volume.
TS360-SWR-261	1. Functional	Perfused Volume (cc) Warning Messages	The software shall provide a warning message if MCD perfused volume is greater than the whole liver volume with M66 in TS360-TXT-49.	The perfused volume is a subset of Whole liver volume, and it cannot be greater than the whole liver volume.
TS360-SWR-290	1. Functional	Generate electronic copy - MCD	The Software shall provide the option to generate an electronic copy of the Post treatment Analysis/MCD when MCD calculations have successfully been completed.	The user needs to generate the record for the Post treatment Analysis/MCD calculations.
TS360-SWR-362	1. Functional	MCD Alert	The software shall display message M45 in TS360-TXT-49 on the Activity Calculator screen while MCD is selected.	The user needs to be informed that MCD is intended for post-treatment evaluation.
TS360-SWR-384	1. Functional	MCD- non-overlapping VOIs	The software shall display "Overlapping VOIs are invalid for dosimetry purposes, ensure there are no overlapping VOIs before proceeding" when Multi-Compartment Dosimetry is selected.	MCD is intended to use for non-overlapping VOIs.

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3.1.8 Vial Selector

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-80	1. Functional	Two Vial Selection Views	The software shall provide two Vial selection views: Week View and Day View with default of Day view	User needs to be able to view vials via weekly view or daily view. The user needs an option to view the vial selection table. The Week View and Day View give the user flexibility to select the vials that suits them best for treatment planning.
TS360-SWR-54	1. Functional	Vial Selector Load Activity from SCD	The software shall display the following Calculator Results on the Vial Selector screen from the SCD Calculator if the results exist: Shown by Default: • Target Name • Target Volume (cc, kg) • Activity Required at Treatment (GBq, mCi) • Desired Dose (Gy) Shown when Expand Target Details is selected: • Lung Mass (kg) • Previous Dose to Lungs (Gy) • Lung Shunt Fraction (%) • Anticipated Residual Waste (%) • Calculated Dose to Lungs (Gy) • Total Dose to Lungs (Gy) • Cumulative Dose to Lungs (Gy)	Flows 1, 2, and 3. User needs to view vials based on previously ported results. User needs to enter vials independent of the MCD (post treatment analysis) calculations. MCD calculations are not indicated for pre-treatment. Some of these will only display when view is expanded.
TS360-SWR-56	1. Functional	Flows 1 & 2 - Vial Selector Day View Table	The software shall produce a Vial Selector Day View Table with filters and headers below when Treatment Date / Time, and SCD Calculator Results are available. • Filters ◦ Calibration Week ◦ Vial Size (GBq) • Table Headers ◦ Vial Size (Data displayed in GBq) ◦ Activity at Treatment (Data displayed in GBq) ◦ Estimated RPM * (Data displayed in Bq) ◦ % of Desired Dose (Data displayed in %) ◦ Absorbed Dose (Data displayed in Gy)	Screen Flows 1 & 2 Activity Calculation was calculated, and Date and Time were selected. User needs to select vials based on the previously selected treatment date and calculator results.
TS360-SWR-340	1. Functional	Flows 1 & 2 - Vial Selector Week View Table	The software shall produce a Vial Selector Week View Table with filters, headers, and cells below when Treatment Date / Time, and SCD Calculator Results are available. • Filters ◦ Calibration Week ◦ Vial Size (GBq) • Table Headers ◦ Day of Week (Mon - Fri) ◦ Time (8:00 AM - 6:00PM) • Table Cells ◦ Absorbed Dose (Gy) ◦ Activity at Treatment (GBq)	Flows 1 & 2 - User needs to be able select vials where activity/dose was previously calculated and treatment date was selected. User needs to be able to view weekly view of vial options. The weekly view will have the same units and contents but different representation. The user also needs the flexibility to select the vials that are appropriate for the treatment planning.
TS360-SWR-65	1. Functional	Flow 3 - Vial Selector Day View Table	The software shall produce a Vial Selector Day View Table with filters and headers below when SCD Calculator Results are available. • Filters ◦ Calibration Week ◦ Treatment Day of Week ◦ Vial Size (GBq) • Table Headers ◦ Treatment Time ◦ Activity at Treatment (Data displayed in GBq) ◦ Estimated RPM * (Data displayed in Bq) ◦ % of Desired Dose (Data displayed in %) ◦ Absorbed Dose (Data displayed in Gy)	Screen Flow 3. User needs to land in Day of the week view to be able to view vials and desired dose/activity was previously calculated (using the calculator)
TS360-SWR-339	1. Functional	Flow 3 - Vial Selector Week View Table	The software shall produce a Vial Selector Week View Table with filters, headers, and cells below when SCD Calculator Results are Available • Filters ◦ Calibration Week ◦ Vial Size (GBq) • Table Headers ◦ Day of Week (Mon - Fri) ◦ Time (8:00 AM - 6:00PM) • Table Cells ◦ Absorbed Dose (Gy) ◦ Activity at Treatment (GBq)	Flow 3 - User needs to be able select vials where activity/dose was previously calculated, but treatment date was not selected. User needs to be able to view weekly view of vial options. The weekly view will have the same units and contents but different representation. The user also needs the flexibility to select the vials that are appropriate for the treatment planning.

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TS360-SWR-57	1. Functional	Flow 4 - Vial Selector Day View Table	The software shall produce a Vial Selector Day View Table with filters and headers below when treatment Date and Time are available. • Filters ◦ Calibration Week ◦ Vial Size (GBq) • Table Headers ◦ Vial Size (Data displayed in GBq) ◦ Estimated RPM * (Data displayed in Bq) ◦ % of Vial Activity (Data displayed in %) ◦ Activity at Treatment (Data displayed in GBq)	User needs to select vials based on the previously selected treatment date, even if calculator results were not previously calculated. The user needs to enter the Desired Activity at Treatment to see the % of Vial Activity for each vial so the user could select the appropriate vial for the treatment. Flow 4 - Activity Calculation was Not calculated, and Date and Time are available.
TS360-SWR-59	1. Functional	Flow 4 - Vial Selector Week View Table	The software shall produce a Vial Selector Week View Table with filters and headers below when treatment Date and Time are available. • Filters ◦ Calibration Week ◦ Vial Size (GBq) • Table Headers ◦ Day of Week (Mon - Fri) ◦ Time (8:00 AM - 6:00PM) • Table Cells ◦ Activity at Treatment (GBq)	Flow 4 - User needs to be able select vials where treatment date is available, but no activity/dose was previously calculated. The user needs the flexibility to select the vials that are appropriate for the treatment planning.
TS360-SWR-63	1. Functional	Flow 5 - Vial Selector Day View Table	The software shall produce a Vial Selector Day View Table with filters and headers below when nothing is available. • Filters ◦ Calibration Week ◦ Treatment Day of Week ◦ Vial Size (GBq) • Table Headers ◦ Treatment Time ◦ Estimated RPM * (Data displayed in Bq) ◦ % of Vial Activity (Data displayed in %) ◦ Activity at Treatment (Data displayed in GBq)	User needs to be able to select vials if user has not previously entered the date and time or activity calculator. Screen Flow #5
TS360-SWR-66	1. Functional	Flow 5 - Vial Selector Week View Table	The software shall produce a Vial Selector Week View Table with filters, headers, and Data below when nothing is available. • Filters ◦ Calibration Week ◦ Vial Size (GBq) • Table Headers ◦ Day of Week (Mon - Fri) ◦ Time (8:00 AM - 6:00PM) • Table Cells ◦ Activity at Treatment (GBq)	User needs to be able to select vials if user has not previously entered the date and time or activity calculator. The user needs the flexibility to select the vials that are appropriate for the treatment planning. Screen Flow #5
TS360-SWR-304	1. Functional	Treatment Day of Week Filter	The software shall provide a means to filter Vial Selector for Day of the week if Date and time were not previously selected where Monday-Friday are supported and default to Wednesday.	The user needs to be able to select the day of week of the vials. Flows 3 and 5.
TS360-SWR-58	1. Functional	Calibration Week Filter	The software shall provide a means to filter Vial Selector for Week 1 and Week 2 calibrations with a default of Week 1.	User needs to see vials for week 1 and week 2.
TS360-SWR-60	1. Functional	Vial Size Filter	The software shall provide a means to filter Vial Selector for Vial Size where vials sizes from 3-20 GBq in 0.5 GBq increments and "All Available" are supported.	User needs to filter vials selection. User needs to select different vial sizes.
TS360-SWR-300	1. Functional	Vial Size Filter - Day view defaults	The software, while showing day view, shall default the vial size filter to 3 GBq if treatment date/time has not been selected and "All Available" if treatment date/time has been selected.	user needs to have default filters for vial sizes.
TS360-SWR-379	1. Functional	Vial Size Filter - Week view defaults	The software, while showing week view, shall default the vial size filter to 3 GBq.	user needs to have default filters for vial sizes.
TS360-SWR-61	1. Functional	Vial Selector Repopulate if SCD Recalculate	The software shall repopulate the Vial Selector Table if SCD is recalculated.	User needs the updated vials if SCD was recalculated. The vial table gets refreshed when the recalculation happens. Recalculation can occur on Vial Selector screen or Activity Calculator. Flows 1, 2 and 3.

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TS360-SWR-70	1. Functional	Vial Selector Repopulate if Date or Time Change	The software shall repopulate Vial Selector Table if Treatment Date and/or Time have been changed	User needs the most recent vial selection options after treatment date and/or time were updated.
TS360-SWR-64	1. Functional	Ability to Enter Desired Activity At Treatment	The software shall provide the means to enter Desired Activity at Treatment and select vials based on it if SCD has not been calculated.	User needs to be able to select vials if user has not previously entered activity. This allows the user to select the vials based on the % of Vial Activity for each vial calculated after entering the Desired Activity At Treatment Flows 4, 5, and 6.
TS360-SWR-83	1. Functional	Vial Selector Repopulate if Desired Activity At Treatment Update	The software shall repopulate the Vial Selection table upon Desired Activity At Treatment Update.	User needs to be able to view updated vials if Desired Activity at Treatment was updated. SCD has not been calculated. Flows 4, 5, and 6.
TS360-SWR-67	1. Functional	Vial Selector Table when Desired Activity entered	The SW shall display the percent of Desired Activity when the Desired Activity at Treatment is entered.	User needs to be able to view percentage of required activity compared to activity at treatment, if SCD calculations were previously not entered. Flows 4, 5, and 6.
TS360-SWR-363	1. Functional	Ability to Enter Desired Dose	The software shall provide the means to change Desired Dose on the vial selector screen and select vials based on percentage of Desired Dose if SCD has been calculated.	User needs to be able to select vials based on Desired Dose. This allows the user to select the vials based on the % of absorbed dose for each vial calculated after entering the Desired Dose. Flows 1, 2, and 3.
TS360-SWR-68	1. Functional	Vial Selector Visual Indicator for Activity Within Range	The software shall provide the visual indicator for vial selections which fall in the range of +/- 10% of Desired Dose or +/-10% Activity at Treatment, where 10% is included into the visual indicator. % Desired Dose is calculated based on Desired Dose verses Absorbed Dose if Calculator was used. % Activity at Treatment is calculated based on Desired Activity at Treatment versus Activity at Treatment if Calculator was not used.	User needs to be able to see which vials are optimal for selection (if they fall within 10%)
TS360-SWR-76	1. Functional	Vials Selection Add and Remove	The software shall provide the means to add and remove vials.	User needs to be able to add and remove vials.
TS360-SWR-329	1. Functional	Add Vials - Same day of the week and time	The software shall allow the user to select only vials that are associated with the same day of the week and same time.	The user wants to software to prevent selecting vials that are associated with a different day of the week or time.
TS360-SWR-330	1. Functional	Add Vials - Same day of the week and time Notification	The software shall notify the user why some vials are unable to be selected by displaying M80 in TS360-TXT-49 in week view if treatment time and date has been selected, and M81 in TS360-TXT-49 in week view and day view if treatment time and date has not been selected but vial(s) have been selected.	User can see that only vials on my previously chosen day of week and time are selectable And can see an information message, indicating that only vials on my previously chosen date and time will be selectable
TS360-SWR-75	1. Functional	Vials Selection - per Target	The software shall provide the means to select up to three vials per target up to a max of 6 vials per order.	User needs to be able to select between 1-3 vials per target. SCD has been calculated, so targets are available. Flows 1, 2, and 3.
TS360-SWR-77	1. Functional	Vials Selection - no Targets	The software shall provide the means to select up to 4 vials if SCD was not calculated	The user needs the SW to provide the flexibility to select the vials without performing the calculations. Targets are not available since SCD was not calculated. Flows 4, 5, and 6.

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TS360-SWR-71	1. Functional	Selected Vial Details if Desired Dose available.	The software shall provide a means to display the selected vial(s) details for Each Target as follows if Desired Dose is available: • Calibration week • Vial size (GBq) • Activity At treatment (GBq) • Absorbed Dose (Gy) • Dose To lungs (Gy) • Total activity at treatment for all target vials (GBq) • Total absorbed dose for all target vials (Gy) • Total dose to lungs for all vials (Gy) • Total cumulative dose to lungs for all vials (Gy)	Flows 1, 2, and 3.User needs to see selected vials per target if desired dose is available. User needs to see vial summary for each target and for treatment. Source 1
TS360-SWR-72	1. Functional	Selected Vial Details if Desired Dose not available	The software shall provide a means to display selected vial(s) details as follows if Desired Dose is not available: • Calibration week • Vial size (GBq) • Activity at treatment (GBq) • Activity at treatment for all vials (GBq)	Flows 4, 5, and 6. User needs to be able to see selected vials if desired dose is not available. SCD is not performed.
TS360-SWR-285	1. Functional	Vial selection Visual Indicator for outside of 10% range	The software shall provide a message on the Vial Screen for the range outside of +/- 10% of Desired Dose or +/-10% Activity at Treatment for single or multiple vial selections, as shown below: - % Desired Dose is calculated based on Desired Dose versus Absorbed Dose calculations if Calculator was used (M78 in TS360-TXT-49). - % Activity at Treatment is calculated based on Desired Activity at Treatment versus Activity At Treatment if Calculator was not used (M84 in TS360-TXT-49).	The user needs to know if the dose is outside desired ranges
TS360-SWR-296	1. Functional	Estimated RPM (Bq/Sphere) Formula	The software shall provide the means to calculate and display Estimated RPM for each vial using the formula in TS360-TXT-56	User needs to be able to see Bq per sphere for each vial.
TS360-SWR-372	1. Functional	Percent Desired Dose Formula	The software shall provide the means to calculate and display Percent Desired Dose for each vial using the formula in TS360-TXT-60.	User needs to be able to see % Desired Dose. The % Desired dose is calculated to display the % off from desired. (e.g. user desires a dose of 50 Gy, a vial with a dose of 50 Gy is 0% off from the desired dose)
TS360-SWR-373	1. Functional	Percent of Vial Activity Formula	The software shall provide the means to calculate and display Percent of Vial Activity for each vial using the formula in TS360-TXT-61.	User needs to be able to see % of Vial Activity. The % of Vial Activity is calculated to display the % off from of desired Vial Activity. (e.g. user desires an activity of 5GBq, a vial with an activity of 5GBq is 0% off from the desired Vial Activity)
TS360-SWR-7	1. Functional	Date Format	The software shall present the date format as follows: • Day of the week, • Month (spelled), Date, and Year	User should be guided on the date format. Example: "Thursday, May 30th, 2024"
TS360-SWR-341	1. Functional	No Vials Available Notification	The software shall display a notification, M83 in TS360-TXT-49, if there are no available vials to display in the Vial Selection Table based on the user's selections.	User needs to know why there are no vials to select.
TS360-SWR-353	1. Functional	Vial Display Parameters	The software shall adhere to the defined display rules defined in the TS360-TXT-43	The user needs to view readable vial information.
TS360-SWR-364	1. Functional	Vial Selector Table when Desired Dose changed	The software shall display message M85 in TS360-TXT-49 instead of available vials while the user is changing the Desired Dose.	User needs to be able to view percentage of required activity compared to activity at treatment, if SCD calculations were previously not entered. Flows 1, 2, and 3.

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TS360-SWR-375	1. Functional	Vial Selection Input Limits and Warnings	The software shall allow the user to enter Vial Selection input between the ranges defined in the TS360-TXT-64	The software needs to check if the user inputs are within the defined ranges. The user needs to know if the input is outside the range and the trouble shooting guidance to correct.
TS360-SWR-376	1. Functional	No Vials Selected	The software shall show message M79 in TS360-TXT-49 when the user attempts to submit an order without adding vials to a target or order.	The user needs to be informed why they were unable to submit an order.

3.1.9 Review and Submit

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-105	1. Functional	Review and Submit Content Overview	The software shall provide the means to display the following content on the Review and Submit screen: - Case Details - Activity Calculator details if MCD was not chosen - Vial Selection details - Order Summary	User needs to be able to see order details before submitting the order, so the user can review and make changes as required.
TS360-SWR-308	1. Functional	Review and Submit - Case Details	The software shall display the following content for the Case Details in the Review and Submit Screen. - Patient Name - Patient ID - Treating Physician - Disease Type	The user needs to view the case details on the Review and Submit screen before confirming the order.
TS360-SWR-106	1. Functional	Review and Submit - Calculator performed	The software shall provide the Activity Calculation summary containing the following items if SCD calculation was performed - Target Name - each target - Desired Dose (Gy) - each target - Activity Required at treatment (Gbq and mCi) - each target - Calculated Dose to Lungs (Gy) - each target - Total Dose to Lungs (Gy) - all targets - Cumulative dose to Lungs (Gy) - all targets	User needs to be able to view the calculator results if calculator was previously used.
TS360-SWR-107	1. Functional	Review and Submit - Calculator not performed	The software shall provide a notification and the means to navigate to the Calculator function if the calculations have not been previously performed and MCD was not chosen.	User needs to be able to navigate to the calculator if calculations have not been previously performed.
TS360-SWR-309	1. Functional	Review and Submit - Vial selection SCD performed	The software shall display the below content in the selected vials section of the Review and Submit screen if the vial selection and SCD were previously completed. • Each Vial ◦ Vial Size (GBq) ◦ Activity at Treatment (GBq, mCi) ◦ Absorbed Dose (Gy) ◦ Calculated Dose to Lungs (Gy) • Target Totals ◦ Absorbed Dose (Gy) ◦ Activity at Treatment (GBq, mCi) • All Vial Totals ◦ Total Dose to Lungs (Gy) ◦ Cumulative Dose to Lungs (Gy)	The user needs to know the vial details if the vials were previously selected and SCD was calculated.
TS360-SWR-269	1. Functional	Review and Submit - Vial selection SCD not performed	The software shall display the below content in the selected vials section of the Review and Submit screen if the vial selection and was previously completed, but SCD was not completed. • Each Vial ◦ Vial Size (GBq) ◦ Activity at Treatment (GBq, mCi) • All Vial Totals ◦ Activity at Treatment (GBq, mCi)	This is the scenario when either MCD or no SCD calculations took place.

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TS360-SWR-311	1. Functional	Review and Submit - Order Summary	The software shall display the below content for the Order Summary section in the Review and Submit screen. - Treatment Facility - Treatment Date and Time (if selected), - Delivery Charge (if date/time and vial(s) selected) - Number of Selected vials per each target if multiple targets OR Number of Selected vials if no targets (if vials selected)	The user needs to know the Order summary before submitting the order
TS360-SWR-245	1. Functional	Standard or Expedited Delivery	The software shall display Standard or Expedited Delivery status and charge based on the Rush order status.	The user needs to be informed about the associated delivery charge upfront when an order is placed.
TS360-SWR-246	1. Functional	Expedited Delivery Message	The software shall, in the event of an expedited order, display message M97 in TS360-TXT-49 notifying the user of the expedited order.	The user needs to know the if the order would have expedited shipping.
TS360-SWR-370	1. Functional	Short Shipping Message	The software shall, in a short shipping event, display a message corresponding to the number of days available to ship. • 1 day - M86 in TS360-TXT-49 • 2 days - M87 in TS360-TXT-49 • 3 days - M88 in TS360-TXT-49	The user needs to know if the vial will have to be shipped quickly after being manufactured.
TS360-SWR-108	1. Functional	Optional Tubing	The software shall provide the means to add optional Tubing Sets in quantities of 5, 10, 15, 20.	User needs to be able to order tubing sets in preset amounts so the user can have the necessary accessories available for the treatment
TS360-SWR-114	1. Functional	Review and Submit PO Number	The software shall adhere to the defined PO Number input ranges and warnings as defined in the TS360-TXT-44	User needs to be able to enter PO number.
TS360-SWR-255	1. Functional	Review Order screen - Visual Indicator for Activity or Dose Outside of 10% Range	The software shall provide a visual indicator for Review and Submit screen, if selected vials produce a % Desired Dose or % Activity at Treatment that falls outside the range of +/- 10%. -% Desired Dose is calculated based on Desired Dose verses Absorbed Dose if Calculator was used (M78 in TS360-TXT-49). -% Activity at Treatment is calculated based on Desired Activity at Treatment versus Activity at Treatment if Calculator was not used (M89 in TS360-TXT-49).	The user needs to know if the selected vials are outside the desired range
TS360-SWR-336	1. Functional	Review and Approve Order	The software shall display a confirmation message that the order has been reviewed and approved that needs to be confirmed before order can be placed; if message not confirmed before user attempts to submit order, M94 in TS360-TXT-49 will be displayed.	User must acknowledge that they have reviewed and approved the order.
TS360-SWR-115	1. Functional	Review and Submit – Submit Order	The software shall provide the means to Submit Order if all required data is filled out.	User needs to be able to submit the order.
TS360-SWR-292	1. Functional	Review and Submit - No Case Details	The software shall provide means to navigate to the Case Details section if required case details were not added, and add a notification, M91 in TS360-TXT-49, upon attempt to submit the order without case details.	The user needs to add the mandatory case details [Treating Physician, Disease Type, Treatment Goal, Treatment Approach and Mapping date] to submit the order. User needs to be able to view feedback and reasons why order cannot be submitted

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TS360-SWR-109	1. Functional	Review and Submit - No Vials	The software shall provide means to navigate to the Vial Selector section if any target(s) do not have vial(s) associated with them, and add a notification, M92 in TS360-TXT-49, upon attempt to submit the order while target(s) do not have vial(s) associated with them.	User needs to be able to navigate to the Vial Selector screen if no prior vials were selected. User needs to be able to view feedback and reasons why order cannot be submitted
TS360-SWR-112	1. Functional	Review and Submit Vials No Longer Available message	The software shall provide a visual indicator for vials that are no longer available for order • M95 in TS360-TXT-49 in the vial selection details • M96 in TS360-TXT-49 in the order summary details	User needs to view the most recent vial feedback based on inventory status. User needs to be able to view feedback and reasons why order cannot be submitted
TS360-SWR-294	1. Functional	Review and Submit - No Treatment Date and Time	The software shall provide means to navigate to the Treatment Date and Time, if the treatment date and time have not been previously selected, and add a notification, M93 in TS360-TXT-49, upon attempt to submit the order without treatment date and time.	The user needs to select the treatment date and time before confirming the order, so the SW displays a panel to click to get redirected to the Treatment Date and Time. User needs to be able to view feedback and reasons why order cannot be submitted
TS360-SWR-365	1. Functional	Review and Submit Date No Longer Available message	The software shall provide message M19 in TS360-TXT-49 if the date is no longer available.	User needs to be informed if their previously selected date is no longer available. User needs to be able to view feedback and reasons why order cannot be submitted
TS360-SWR-118	1. Functional	Review Order Confirmation	The software shall display the Review Order Confirmation if order placement was successful that contains the below • Patient Name • Patient ID • Treatment Facility • Treating Physician • Order Number(s) • Quantity of vials • PO Number (if available) • Number of Administration Sets (if available)	User needs to be able to review order confirmation details.
TS360-SWR-119	1. Functional	Review and Submit – Navigate to the Treatment Details	The software shall provide the means to navigate to the Treatment Details or main portal after order placement.	User needs to be able to navigate to treatment details after order is placed. Treatment Details is part of the portal.

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3.1.10 Treatment Documents (Prescribing Information, Pre-Treatment / Post Treatment)

3.1.10.1 General

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-120	1. Functional	Treatment Documents	The software shall provide the means to produce the following treatment documents per target: - Written Directive - Post Treatment Worksheet	Source 8 User needs to be able to produce Written Directive and Post Treatment documents. The NRC written directive is a document that Hospitals use as the formal documentation of the treatment plan. The post-treatment worksheet is a document that the Nuclear Medicine department uses to calculate the activity & absorbed dose delivered to a target for a particular treatment. The final calculations consist of total activity delivered to the patient at time of treatment (GBq/mCi), activity delivered to target (GBq/mCi), dose to target (Gy), activity delivered to Lungs (GBq/mCi), dose to lungs (Gy) and cumulative dose to lungs (Gy). The primary output for the AU is the Actual Radiation Dose to Target Tissue vs. Desired Dose measured in percentage which determines whether a medical event has, or has not, occurred
TS360-SWR-121	1. Functional	Treatment Documents - upon entry	The software shall display the below upon entering the Treatment Documents section. - Left-hand Side Panel - Step 1: Prescribing Information - Target Tabs - Available Documents Nuclear Medicine Worksheet TheraSphere Checklist - Step 2: Post Treatment Worksheet (unavailable)	User needs to be able to view the Prescribing Information
TS360-SWR-268	1. Functional	Patient Information on left-hand side panel	The software shall provide the following information on the left-hand side panel: - Patient Reference ID - Treating Physician - Last Name, First Name - Disease Type - Treatment Facility - Treatment Date	The patient information is displayed on the left-hand side panel. This information was previously entered by the clinician as follows: - Patient Reference ID (from user input on a treatment draft) - Treating Physician (from user input on a treatment draft) - Disease Type (from user input on a treatment draft) - Treatment Facility (from user input on a treatment draft) - Treatment Date (from user input on a treatment draft)
TS360-SWR-128	1. Functional	Post Treatment After Prescribing Information section Lock	The software shall prevent the user from entering the Post Treatment Worksheet until the Prescribing Information Section status is Locked.	The lock mechanism prevents the user from editing the Post Treatment Worksheet until after the Prescribing Information Section is locked.
TS360-SWR-132	1. Functional	Generate electronic copy	The software shall provide the means to generate electronic copy for: Written Directive and Post Treatment Worksheet once data for that document is locked.	User needs to be able to generate electronic record (pdf). The software sends a request to microservices to generate a pdf record from the existing parameters.

3.1.10.2 Pre-Screens - No SCD

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-316	1. Functional	Pre-Screens - Targets	The software shall allow the user to select up to 4 targets when the SCD calculator data is unavailable.	When the user has not used the SCD calculator, in order to generate a Post treatment documents (WD &Post Treatment worksheet), the number of targets needed to be captured.

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TS360-SWR-344	1. Functional	Pre-Screens - Targets notification	The software shall display a notification, M104 in TS360-TXT-49, if the user tries to continue without selecting Number of Targets when the SCD calculator data is unavailable.	The user has to select the number of targets
TS360-SWR-176	1. Functional	Pre-Screens - Assign Ordered Vials to Targets	The software shall provide the means to assign ordered vials to each target if SCD calculator data is unavailable.	User needs to be able to assign vials to targets manually.
TS360-SWR-345	1. Functional	Pre-Screens - Assign Ordered Vials to Targets notification	The software shall display notification, M105 in TS360-TXT-49, if the user tries to confirm without assigning vials to targets when the SCD calculator data is unavailable.	The user has to assign ordered vials to targets
TS360-SWR-346	1. Functional	Pre-Screens - Target/Vial mismatch	The software shall display message M106 in TS360-TXT-49 if a target is not assigned a vial, and M107 in TS360-TXT-49 if a vial is not assigned to target when the SCD calculator data is unavailable.	The user needs to associate vials to targets correctly.
TS360-SWR-366	1. Functional	Pre-Screens - Successful selection	The software shall display M108 in TS360-TXT-49 when the user successfully confirms the vials to targets.	The user needs to know that their selections were accepted.

3.1.10.3 Prescribing Information

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-122	1. Functional	Prescribing Information Content	The software shall display the following content on the Prescribing Information: - Patient Name - Treatment Site (Liver) - Treatment Date - Treatment Time with time zone - Device - Contract Manufacturer - Anticipated Residual Waste (%) - Activity of Vial(s) (GBq) - Calculated Absorbed Dose (Gy) - Prescribed Activity (GBq) - Desired Dose (Gy) - Number of vials administered	User needs to be able to view content on the Prescribing Information
TS360-SWR-247	1. Functional	Prescribing Information Section- Data Elements per target	The software shall pre-populate the data elements captured in TS360-TXT-28	The Prescribing Information Section where the prescriptions for the treatment can be captured
TS360-SWR-319	1. Functional	Assign vials - Manual Override	The software shall provide the means to override/update the assigned vials manually.	The user needs to have an option to manually override/update the assigned vials, so the Prescribing Information section can be updated to reflect the treatment plan.
TS360-SWR-317	1. Functional	Assign vials - Visual Notification	The software shall provide message M118 in TS360-TXT-49 if required vials are not assigned to the target.	The user needs to know if any vials are not assigned to the target. The warning message helps the user to adjust the vial quantity.
TS360-SWR-323	1. Functional	Update Calculated Absorbed Dose	The software shall update the Calculated Absorbed Dose using the formula defined in TS360-TXT-58 when the Prescribed Activity is updated and SCD was calculated in treatment draft.	The user needs to have an updated Calculated Absorbed Dose

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TS360-SWR-321	1. Functional	Update Activity of Vial(s)	If the user has not modified the Activity of Vial(s), the software shall update the Activity of Vial(s) based on the sum of the Decay formula in TS360-TXT-57 for all vials on target when the Treatment time and or Number of vials are updated.	The user needs to have the flexibility to update the inputs in Prescribing Information section to adjust to the prescription and user needs the updated Activity of Vial(s) based on the updates. Activity of Vial(s) is based on decay calculation of the vials ordered. The user needs to know the Activity of Vial(s) at Treatment for the chosen vials accounting the decay factor, unless the user has overridden with a manual entry.
TS360-SWR-131	1. Functional	Post Treatment Worksheet content recalculated	The software shall update Post Treatment worksheet if the user changes any of the following: • Treatment Time • Number of Vials • Anticipated Residual Waste (%) • Target Name	User needs to be able to recalculate Post Treatment content if user updates the fields. The user needs to know that the Prescribed Activity is updated based on the sum of the activity at treatment time for chosen/assigned vials when the calculator is not used.
TS360-SWR-267	1. Functional	Prescribing Information Section: Update Message	The software shall provide a message, M109 in TS360-TXT-49, to confirm the updated inputs prior locking the Prescribing Information Section when updates are made on any of the following in the Prescribing Information Section: • Treatment Time • Number of Vials • Anticipated Residual Waste (%) • Target Name	User needs to know that the changes will propagate into the Post treatment worksheet and to verify changes. The user needs to know that the Prescribed Activity is updated based on the sum of the activity at treatment time for chosen/assigned vials when the calculator is not used.
TS360-SWR-334	1. Functional	Activity of Vials +/-10% notification	The software shall display a notification, M116 in TS360-TXT-49, when the user changes the Activity of Vials to result in the Activity of Vials differing more than +/- 10% of the Activity at Treatment for the number of vials on the target.	The user needs to be notified if the Activity of Vials becomes greater than +/- 10% of the Activity at Treatment for the vials ordered.
TS360-SWR-337	1. Functional	Review and Approve Prescribing Information	The software shall display a confirmation message that the prescribing information has been reviewed and approved that needs to be confirmed before prescribing information can be locked; if message not confirmed before user attempts to lock prescribing information, M94 in TS360-TXT-49 will be displayed.	User must acknowledge that they have reviewed and approved the order.
TS360-SWR-127	1. Functional	Prescribing Information Lock Confirmation	The software shall provide the means to lock the Prescribing Information section.	User needs to lock Prescribing Information, so the Written Directive can be created
TS360-SWR-324	1. Functional	Lock- Visual Notification	The software shall provide a message, M114 in TS360-TXT-49, when the Prescribing Information Section is locked	The user needs to know when the Prescribing Information Section is locked
TS360-SWR-129	1. Functional	Prescribing Information: unlock	The software shall allow the user to unlock the Prescribing Information section for editing purposes.	Used needs to be able to unlock the Prescribing Information to edit the treatment plan.
TS360-SWR-244	1. Functional	Prescribing Information- Default State	The software shall persist the previous lock state of the Prescribing Information section when opening and will default to unlocked when opening for the first time.	Persistent state means the state that remains in the last time. For future retrievals, the state remains the same as it was previously saved.
TS360-SWR-374	1. Functional	Prescribed Activity Formula	The software shall provide the means to calculate Prescribed Activity for each target using the formula in TS360-TXT-62	The user needs to be able to see Prescribed Activity.

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3.1.10.4 Post Treatment Worksheet

ID	Category	Name	Design Requirement	Source/ Rationale (optional)

3.1.10.4.1 General Post Treatment Worksheet

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-145	1. Functional	Post Treatment worksheet consistent treatment dates	The software shall prepopulate as default all treatment dates fields in the Post Treatment worksheets for all targets upon manual entry.	User needs to be able to view prepopulated content whenever it was previously entered.
TS360-SWR-144	1. Functional	Post Treatment worksheet consistent manufacture and vial info	The software shall pre-populate the manufacturer lot & vial number across Post Treatment worksheet upon manual entry	User needs to view manufacturer and vial selection numbers across the document

3.1.10.4.2 Treatment Information

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-134	1. Functional	Treatment Information: Fields	The Treatment Information section shall populate the following un-editable fields if previously entered calculator and vial data is available: General • Lung Mass (kg) • Previous Dose to Lungs (Gy) • Lung Shunt Fraction (%) • Anticipated Residual Waste (%) • Target Name • Target Volume (cc & kg) For Each Vial (Total number of vials come from Written Directive) • Vial Size (GBq) • Calibration Date • Time from Calibration to Treatment (hours) (Calculated from the calibration date & time and Treatment Time) • Nominal Activity at Treatment (GBq & mCi) Totals Across Vials • Sum of Nominal Activity (GBq) • Calculated Absorbed Dose (Gy) • Calculated Dose to Lungs for Target (Gy) • Cumulative Dose to Lungs for Target (Gy)	User needs to be able to view pre-populated data the Post Treatment worksheet. The post-treatment worksheet is a document that the Nuclear Medicine department uses to calculate the activity & absorbed dose delivered to a target for a particular treatment. The primary output for the AU is the Actual Radiation Dose to Target Tissue vs. Desired Dose measured in percentage which determines whether a medical event has, or has not, occurred
TS360-SWR-136	1. Functional	Treatment Information: Required Fields - No SCD	If calculator data is unavailable, the software shall provide the means to input the following required inputs as defined in TS360-TXT-14 • Lung Mass (kg) • Previous Dose to Lungs (Gy) • Lung Shunt Fraction (%) • Target Volume (cc)	User needs to be able to enter data on the Post Treatment worksheet
TS360-SWR-354	1. Functional	Treatment Information: Calculate - No SCD	If calculator data is unavailable, the software shall provide the means to calculate the following and adhere to rules in TS360-TXT-27 and TS360-TXT-43 • Calculated Absorbed Dose • Calculated Dose to Lungs for Target • Cumulative Dose to Lungs for Target	User needs to be able to view calculated activity and doses.
TS360-SWR-254	1. Functional	Treatment Information - Inputs and Outputs	The software shall follow the rules for the input and output fields in Treatment Information - Post Treatment as per TS360-TXT-34	The user needs to ensure that the software has ranges for input/output and the needs to know if input goes out of the ranges.
TS360-SWR-146	1. Functional	Treatment Information: Time from calibration to Treatment	The software shall calculate and display the hours between calibration and time of treatment while taking into account the time zone of the Treatment Facility.	User needs to be able to calculate the hours between calibration and time of treatment on the Post Treatment worksheet.

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TS360-SWR-139	1. Functional	Post Treatment Worksheet Calculated Dose To Lungs at Treatment Time	If calculator data is unavailable, the software shall calculate the Calculated Dose to Lungs using the formula in TS360-TXT-18	User needs to be able to calculate Dose to Lungs on the Post Treatment worksheet
TS360-SWR-171	1. Functional	Treatment Information: Calculated Cumulative Dose to Lungs for the Target	The software shall calculate the Cumulative Dose to Lungs for Target based on the sum of Previous Dose to Lungs and current Dose to Lungs for the Target.	User needs to calculate the Cumulative Dose to Lungs Per target on the Post Treatment worksheet. The Cumulative Dose to Lungs is for all vials in that given Target.

3.1.10.4.3 Pre-Treatment Dose Calibrator Measurement

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-141	1. Functional	Pre-treatment Dose Calibrator Measurement: Required Input data	The software shall provide the means to input the following required Pre-treatment Dose Calibrator Measurement data, per each vial: - Manufacturer Lot Number - Vial Number - Date of Measurement - Time of Measurement - Dose Calibrator Measured Activity (mCi) - Manufacturer's Activity at Calibration (GBq)	User needs to be able to enter data on the Post Treatment worksheet
TS360-SWR-252	1. Functional	Pre-treatment Dose Calibrator Measurements - Input fields validation	The software shall display the fields and provide the input fields integrity check as per TS360-TXT-33	The user needs to ensure that the software has ranges for inputs and the needs to know if input goes out of the ranges.
TS360-SWR-147	1. Functional	Time from calibration to Measurement	The software shall calculate the Time from Calibration to Measurement by subtracting the calibration date and time (12pm EST) from the pre-treatment dose calibrator measurement date and time for each vial, taking into consideration the time zone of the Treatment Facility.	User needs to be able to see the hours between calibration date and time of vial measurement on the Post Treatment worksheet
TS360-SWR-148	1. Functional	Value to be used in Delivery calculations for Activity Administered per Vial at time of Treatment	The software shall provide the means to select one of the following options to produce the final calculations for Activity Administered per Vial at time of Treatment (GBq.) - Manufacturer's Activity at Calibration - Dose Calibrator Measurement - Nominal Dose Size	The user needs to be able to perform final calculations based on several options.
TS360-SWR-149	1. Functional	Manufacturer's Activity at Calibration Value to be used in Activity Administered per Vial at time of Treatment	If Manufacturer's Activity at Calibration option is selected, the software shall provide final calculations for Activity Administered per Vial at time of Treatment based on the Manufacturer's Activity at Calibration taking into account the time zone of the treatment facility, decay formula with calibration and date/time of treatment as shown in the formula in TS360-TXT-23	The user needs to be able to perform final calculations based on several options.
TS360-SWR-150	1. Functional	Nominal Dose Size Value to be used in Activity Administered per Vial at time of Treatment	If Nominal Dose Size option is selected, the software shall provide below as shown in the formula in TS360-TXT-23 -final calculations for Activity Administered per Vial at time of Treatment based on the Nominal Dose Size, decay formula with calibration and date/time of treatment	The user needs to be able to perform final calculations based on several options.
TS360-SWR-151	1. Functional	Dose Calibrator Measurement Value to be used in Activity Administered per Vial at time of Treatment	If Dose Calibrator Measurement option is selected, the software shall provide final calculations for Activity Administered per Vial at time of Treatment based on the Dose Calibrator Measurement, decay formula with calibration and date/time of treatment as shown in the formula in TS360-TXT-23	The user needs to be able to perform final calculations based on several options.

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TS360-SWR-152	1. Functional	Dose Calibrator Measured Activity at Treatment Formula	The software shall calculate and display the Dose Calibrator Measured Activity at Treatment based on the formula in TS360-TXT-55	The user needs to be able to see Dose Calibrator Measured Activity at time of treatment value. The true decay is calculated based on DC Measured activity and Date of Measurement from Pre-Treatment Dose Calibrator Measurement section.
TS360-SWR-367	1. Functional	DC Measured Activity at Treatment off by 10% or more from Activity of Vials	The software shall display M120 in TS360-TXT-49 when the Dose Calibrator Measured Activity at Treatment differs by 10% or more from the Activity of Vials.	The user needs to be informed when the measured Activity at Treatment is too far off from the Activity of Vials.

3.1.10.4.4 Pre-Treatment Template Measurement

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-249	1. Functional	Pre-treatment Template Measurement fields	The software shall incorporate the inputs values defined in TS360-TXT-30 for each vial	The user needs to ensure that the software has ranges for inputs and the needs to know if input goes out of the ranges.
TS360-SWR-153	1. Functional	Net rate of vial on template	The software shall display the "Net rate of vial on template" by calculating the difference between the vial measurement and background measurement, as shown below, if "Net rate of vial on template" is less than 0, '---' will display. Net rate of vial on template = Pre-treatment Measurement of Vial on Template (mr/h) - Pre-treatment Measurement of Background (mr/h)	The user needs to be able to perform "Net Rate of Vial on Template" calculation

3.1.10.4.5 Treatment / Administration Notes

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-251	1. Functional	Administration Notes - Inputs	The software shall follow the rules defined in TS360-TXT-32 for the Administration Notes section in the Post Treatment Worksheet	
TS360-SWR-157	1. Functional	Methods of Confirming Patient	The software shall provide the means to select from the following methods for confirming patient identity: - Name - Birth Date - Physician - Wrist Band	User needs to confirm patient identify.
TS360-SWR-158	1. Functional	Patient Identifiers	The software shall enforce that user selects at least two patient identifiers with message M131 in TS360-TXT-49.	User needs to select two identifiers to confirm patient identify
TS360-SWR-159	1. Functional	Confirm Vial Lot Number	The software shall require the user to confirm the lot & vial number for each vial with message M132 in TS360-TXT-49.	User needs to confirm the lot and vials

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3.1.10.4.6 Post Treatment Template Measurement

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-250	1. Functional	Post Treatment Template Measurement Fields per vial	The software shall incorporate the inputs values as per TS360-TXT-31 per vial	The user needs to ensure that the software has ranges for inputs and fields and the needs to know if input goes out of the ranges.
TS360-SWR-355	1. Functional	Calculate Post Treatment Template Measurements	The software shall provide a means to calculate/recalculate and display the following for each vial used on target: • Average of 4 Orientations minus background (mR/h) • Hours between Pre- and Post Treatment Measurements • Pre-treatment net rate decayed to post-treat time (mR/h) • Percentage of Vial Delivered • Hours between calibration and treatment • Activity in waste jar at time of treatment • Activity administered per vial at time of treatment	User needs to Post Treatment Template information.
TS360-SWR-162	1. Functional	Pre-Treatment Net Rate Decayed to Post-Treat Time (mR/h) Formula	The software shall perform Pre-Treatment Net Rate Decayed to Post-Treatment Time calculation per the formula in TS360-TXT-22	User needs to perform Pre-Treatment Net Rate Decayed to Post-Treat Time calculations on post treatment worksheet
TS360-SWR-163	1. Functional	Post Treatment Worksheet Formula for Activity Administered per Vial At Time of Treatment	The software shall calculate Activity Administered per Vial at Time of Treatment (GBq) per formula in TS360-TXT-23 and display on the post Treatment Template Measurement section.	User needs to perform Activity Administered per Vial at Time of Treatment calculations on post treatment worksheet
TS360-SWR-368	1. Functional	Activity in waste jar at time of treatment formula	The software shall perform Activity in Waste Jar at Time of Treatment calculation per the formula in TS360-TXT-51	User needs to see Activity in Waste Jar at Time of Treatment calculation on post treatment worksheet
TS360-SWR-369	1. Functional	Percentage of Vial Delivered Formula	The software shall perform Percentage of Vial Delivered calculation per the formula in TS360-TXT-52	User needs to see Percentage of Vial Delivered calculation on post treatment worksheet

3.1.10.4.7 Final Calculations

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-248	1. Functional	Final Calculations - Post Treatment Work sheet	The software shall calculate and display the values defined in TS360-TXT-29 for the target.	The user needs to ensure that the software provide the final calculation based on defined parameters
TS360-SWR-356	1. Functional	Calculate Final Measurements	The software shall provide a means to calculate/recalculate and display the following final calculations for the target: • Prescribed Activity vs. Delivered Activity • Total Activity Delivered to Patient at Time of Treatment • Activity Delivered to Perfused Liver Tissue • Dose to Perfused Liver Tissue • Activity Delivered to Lungs for Target • Dose Delivered to Lungs for Target	The user needs to be able to calculate and view final calculations
TS360-SWR-164	1. Functional	Prescribed Activity vs. Delivered Activity Formula	The software shall calculate Prescribed Activity vs. Delivered Activity based on the formula in TS360-TXT-24	User needs to see Prescribed Activity vs. Delivered Activity calculations on post treatment worksheet
TS360-SWR-165	1. Functional	Total Activity Delivered to Patient at Time of Treatment (GBq) Formula	The software shall calculate the Total Activity Delivered to Patient at Time of Treatment (GBq) based on the formula in TS360-TXT-25	User needs to perform Total Activity Delivered to Patient at Time of Treatment calculations on post treatment worksheet
TS360-SWR-166	1. Functional	Activity Delivered to Perfused Liver Tissue (GBq) Formula	The software shall calculate the Activity Delivered to Perfused Liver Tissue (GBq) based on the formula in TS360-TXT-26	User needs to perform Activity Delivered to Perfused Liver Tissue (GBq) calculations on post treatment worksheet.

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TS360-SWR-351	1. Functional	Dose to Perfused Liver Tissue Formula	The software shall perform the Dose to Perfused Liver Tissue calculation per the formula in TS360-TXT-53	user needs to see Dose to Perfused Liver Tissue in the final calculations
TS360-SWR-169	1. Functional	Activity Delivered to Lungs for Target Formula	The software shall calculate the Activity Delivered to Lungs for Target based on the Total Activity Delivered to Patient at Time of Treatment multiplied by the Lung Shunt Fraction.	User needs to calculate the Activity Delivered to Lungs for each target
TS360-SWR-170	1. Functional	Dose Delivered to Lungs for Target Formula	The software shall perform the Dose Delivered to Lungs for Target calculation per the formula in TS360-TXT-54	User needs to see the Dose Delivered to Lungs for Target.
TS360-SWR-172	1. Functional	Activity Delivered versus Prescribed 20% difference indicator	The software shall provide a message, M121 in TS360-TXT-49, when the Activity Delivered to Perfused Liver Tissue differs by 20% or more than the Prescribed Activity at Time of Treatment.	User needs to view the visual indicator if Activity Delivered versus Prescribed difference is greater than 20%
TS360-SWR-173	1. Functional	Lock Post Treatment Worksheet	The software shall provide the means to lock the post treatment worksheet and display message M119 in TS360-TXT-49 when post treatment worksheet is locked.	User needs to be able to lock the Post Treatment worksheet
TS360-SWR-174	1. Functional	Unlock Post Treatment Worksheet	The software shall provide the means to unlock the Post Treatment Worksheet	User needs to be able to unlock the Post Treatment worksheet

3.2 Performance

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-226	2. Performance	Calculation Performance	The software shall provide requested calculations upon receiving the command within 5 seconds or less.	User should be able to perform calculations in a reasonable amount of time. The software will display loading icon to let the user know. The calculation performance is specific to the back-end operation. Since it is not feasible to create performance requirements to communicate between front-end and back- end, which is dependent on the network and connection.

3.3 GUI, Usability, HFE

3.3.1 GUI, Usability, HFE

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-29	3. GUI, Usability, HFE	Status Checkbox	The software shall provide visual indicator for which sections of workflow have been completed in the treatment draft for the following: • Case Details • Treatment Date • Activity Calculator • Vial Selector • Review and Submit	User needs to see which tabs have been filled out in the treatment draft.
TS360-SWR-210	3. GUI, Usability, HFE	Language Display	The software shall display the content and accept user inputs in the following language(s): • US English	User should be able to view content in English. The software release is for US only
TS360-SWR-213	3. GUI, Usability, HFE	Software Version Consistency	The software shall display one Software Version for both software applications (the front end and the back end).	User needs to confirm/verify they are using the right version of software

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TS360-SWR-234	3. GUI, Usability, HFE	Browser Resolution	The system user interface shall be responsive to a minimum screen width of 768 px and a maximum of 1400 px.	The resolution needs to be compatible with desktops. Screen width can be smaller or bigger, but will stop being responsive outside of the stated range.
TS360-SWR-235	3. GUI, Usability, HFE	Global Footer	The Software application shall display the web application Footer that includes the below: - BSC Logo - Copyright that includes copyright year - Version number and a functional hyperlink to the SW Release Notes - Functional hyperlink to the Instructions for Use - Functional hyperlink to Legal Information - Functional hyperlink to Copyright Notice Additional Reference Documents for Treatment Draft Footer: - Functional hyperlink to the TheraSphere 360 Instructions for Use - Functional hyperlink to the Dosimetry Guidelines	The software needs to display the Footer in the Medical Device similar to the portal experience.
TS360-SWR-287	3. GUI, Usability, HFE	Global Header	The software shall display the Global Header that includes the below – Logo that is a hyperlink to portal - Icon - My account text	The software needs to display the Header in the Medical Device similar to the portal experience.
TS360-SWR-359	3. GUI, Usability, HFE	Alert and message types	The software shall adhere to the defined alert types and their display as defined in the TS360-TXT-48	The user needs to be able to see the difference between the different message types.
TS360-SWR-360	3. GUI, Usability, HFE	GUI Messages	The software shall display the GUI messages as defined in TS360-TXT-49.	The user needs to be able to view alerts, messages, tooltips, and modals with correct information.

3.4 Labeling, Packaging, Shipping

3.4.1 Labeling, Packaging, Shipping

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-241	4. Labeling, Packaging, Shipping	Instructions for Use	The software shall provide the ability to access the instructions for Use.	Product labeling contents shall comply to internal BSC's requirements and standards. All labeling shall comply with LBSC Create Labeling SOP 92757664. Instructions for Use is not part of SaMD application.

3.5 Environment

TS360-TSR-16	5. Environment	N/A	There are no environmental requirements for this software web application.	

3.6 Installation, Maintenance, PM

3.6.1 Installation, Maintenance, PM

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-208	6. Installation, Service, PM	Software Updatability and Patchability	The software shall have the ability to be updated and patched.	User needs the software to have the ability to be updated including the SW feature updates and patches.

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3.7 Cybersecurity

3.7.1 Cybersecurity

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-17	7. Cybersecurity	Boundary Checks Before Calculate Operation	The software shall provide boundary checks for all numeric values before Calculate operation is performed.	User needs to rely on the application to do integrity checks.
TS360-SWR-217	7. Cybersecurity	Pass Authorization/Authentication token	The software shall support token authorization/authentication interface where an authentication token is passed to the application from an external interface.	Only authorized users can access the software. The authentication token provides the means for the application to grant access for the authorized users.
TS360-SWR-218	7. Cybersecurity	CIA - Confidentiality, Integrity, Authorization	The software shall require secure communication for all external connections.	The software needs to be protected from unauthorized access that will have an impact on the confidentiality, integrity, or availability of an information system.
TS360-SWR-219	7. Cybersecurity	Logs - DataDog Format	The software shall generate logs in the DataDog format, such as API calls and log access.	User needs to be able to send logs for troubleshooting
TS360-SWR-220	7. Cybersecurity	Authentication token mechanism	The software shall support an authentication token mechanism.	User needs access controls, secure application.
TS360-SWR-222	7. Cybersecurity	Data Transmission	The software shall support secure transmission of patient data.	User needs patient data to remain secure.
TS360-SWR-223	7. Cybersecurity	Cross Site Request Forgery attacks	The software shall provide a mechanism for minimizing potential CSRF (Cross Site Request Forgery) attacks	User needs access controls. The software needs to be protected from CSRF that will have an impact on the confidentiality, integrity, or availability of an information system.
TS360-SWR-224	7. Cybersecurity	Authorization token	The software shall pass the user's authorization token when calling any external system via the API gateway	User needs secure application The API Gateway should always receive the user's authorization token to be able to introspect the token to ensure it is still valid. This should happen for the Inventory calls, database calls.
TS360-SWR-225	7. Cybersecurity	Input Data Validation	The system shall utilize input validation to ensure that inputs are properly formed and free of malicious patterns.	The user needs the software to have the data is in the correct format, within expected ranges, and logically consistent. Data validation acts as a safeguard against errors and inconsistencies that could corrupt data or compromise the security. Corrupted data due to validation failures can cause application crashes, incorrect calculations, or misleading results, significantly impacting system functionality and decision-making.
TS360-SWR-227	7. Cybersecurity	Session time out	The software shall have a session time out of 15 minutes of inactivity.	Session timeout helps protect against the system attacks and it helps prevent unauthorized access to sensitive information.
TS360-SWR-272	7. Cybersecurity	Five minute reminder before Session Time Out	The software shall provide a 5-minute reminder pop-up before session time out via M103 in TS360-TXT-49.	The pop up would remind the user about the session time out.

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TS360-SWR-326	7. Cybersecurity	Role-Based Access Controls	The software shall deny a user's access to order vials and accessories if the role of the user is not explicitly authorized to access the feature and notify the user via message M90 in TS360-TXT-49.	The user wants the SW to have access controls, Authorization is a basic security control. Employ an authorization model that incorporates the principle of least privileges by differentiating privileges based on the user role (e.g., caregiver, patient, healthcare provider, system administrator) or device functions. Require authentication, and authorization in certain instances, before permitting software or firmware updates, including those updates affecting the operating system, applications, and anti-malware functionality. Source: "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff"

3.9 Interfaces

ID	Category	Name	Design Requirement	Source/ Rationale (optional)
TS360-SWR-193	9. Interfaces	Communication Between External Interfaces	The software shall support defined input and output interfaces to facilitate exchange of data with external systems.	User needs to receive reliable information from the database and Inventory system.
TS360-SWR-190	9. Interfaces	External Output Interface Requirement	The software shall produce output data for the external interfaces such as inventory system and clinical data storage.	User should be able to store calculator results, vials, and other clinical data in database.
TS360-SWR-189	9. Interfaces	External Input Interface Requirement	The software shall support Input data from the external interface where MDDS clinical data is being retrieved by SAMD.	User should be able to retrieve calculator results and other clinical data from database. This data contains either SCD or MCD data inputs. The contract and Detailed design document contains the details of the data structure
TS360-SWR-191	9. Interfaces	Data Set for future retrieval	The software shall produce data sets for future retrieval containing details of the case.	User should be able to store data in the database for later retrieval. This data structures contains dosimetry type, parameters associated with the dosimetry selected, their associated values, selected vials, and other clinical data entered into the application.
TS360-SWR-78	9. Interfaces	Inventory Check If Treatment Date selected	The software shall call inventory system to determine inventory availability if Date and Time were previously selected.	User needs to have most current inventory vials data
TS360-SWR-305	9. Interfaces	Available vials display	The software shall display available vials based on the available inventory.	The user needs to select the available vials, so they can complete the treatment planning.
TS360-SWR-201	9. Interfaces	Vial Selector Data Transfer	The software shall provide the means to return the Vial Selector outputs to an external interface.	User needs to be able to store vials information in the MDDS data base for later retrieval. User needs to be able to access the most current inventory vials availability status.

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TS360-SWR-202	9. Interfaces	Treatment Planning and Case Details content	The software shall provide the means for entering the following Treatment Planning and Case Details: • Referring Physician (optional field) • Treating Physician (required field) • Consult Date (optional field) • Disease Type (required field) • Treatment Goal (required field) • Treatment Approach (required field) • Mapping Date (optional field)	User needs to be able to enter Case Details for a patient.
TS360-SWR-205	9. Interfaces	Treating Physician associated with User	The software shall display the list of treating physicians received.	User needs to view Treating physicians associated with the user. Note: this list can be variable. So different sizes need to be supported. This list arrives from an external interface (Microservices)
TS360-SWR-203	9. Interfaces	Treating Clinician Selection	The Software shall provide the means to select Treating Physician Name associated with the user.	User needs to select Treating clinician so the user can associate the correct physician with upcoming treatments.
TS360-SWR-206	9. Interfaces	Time Zone associated with Treatment Facility	The software shall display the time zone for Treatment Time based on the Treatment Facility.	User needs to see the time zone associated with the hospital.
TS360-SWR-243	9. Interfaces	Generate Nuclear Worksheet and TheraSphere checklist	The software shall initiate a request to generate the Nuclear Worksheet and TheraSphere checklist regardless of if the Prescribing Information is locked or not.	User needs the Nuclear Worksheet and TheraSphere checklist.
TS360-SWR-262	9. Interfaces	Treatment Draft Modal Required Fields	The software shall provide the means to collect the following information: - Patient First Name - Patient Last Name - Patient Reference Number (optional) - Treatment Facility.	The user needs to save the treatment draft specific to the patient record.
TS360-SWR-265	9. Interfaces	Interaction with MyAccount Menu	The software shall provide a means to interact with the MyAccount Menu.	This is needed if user is already in the software application.
TS360-SWR-314	9. Interfaces	Loading Time	The software shall load the information within 10 seconds upon the request of the user.	The SW responds for the API queries and backend in 10 seconds [Example: Calculating/Recalculating time for both Calculator Results and Desired Dose Calculation in vial selector screen, getting vials information from TOP, Loading vials etc]

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4 Appendices

4.9 Appendix: TheraSphere 360 Requirement Category Definitions

Requriement Category	Definition	WI 92265457 Category Name
Functional	Specify what the product does, focusing on the operational capabilities of the product and processing of inputs and the resultant outputs.	Functional/Performance
Performance	Specify how much or how well the product must perform (e.g. accuracy, trueness, latency).	Functional/Performance
GUI, Usability, HFE	Interface between the user and the product (HFE requirements, UI standards).	User Interface
Labeling, Packaging, Shipping	Labeling. Packaging and shipping standards and requirements. Specify labeling, packaging and shipping needs	Product Distribution, Service, and Maintenance
Environment	Related to the interaction between the product and the use environment (e.g., temperature, humidity, UV light exposure, noise, disposal).	Environmental, Sterilization
Installation, Service, PM	Installation, service, preventative maintenance	Product Distribution, Service, and Maintenance
Cybersecurity	Intrusion protection, network safeguards, industry and BSC standards.	Functional/Performance
Technical Standards, Regulatory	Regulatory requirements (60601, biocompatibility, sterilization, global geography standards).	Functional/Performance, Product Distribution, Service, and Maintenance
Interfaces	User Needs related to the interfaces of the product with other products, accessories, substances, or equipment.	Product Interface

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The category “Sterilization” is not covered in this project because the components are non-sterile.
The “Environment” section is not covered in this project because the product is used outside the sterile and it is a web based software application.
The category "Shipping" is not covered in this project as the product is a web-based application.

4.10 Appendix: Formulas

4.10.1 TS360-TXT-11 Tumor Absorbed Dose Formula

$$D_t = \frac{\left[\left(\frac{A_{pv1}}{C_{pv1}}\right)C_{t\cap pv1} + \left(\frac{A_{pv2}}{C_{pv2}}\right)C_{t\cap pv2} + \cdots + \left(\frac{A_{pvN}}{C_{pvN}}\right)C_{t\cap pvN}\right] \times 50 \times (1-F) \times (1-R)}{\rho V_t}$$

Where as:

- D_t is the tumor absorbed dose, in Gy.
- A_{pvi} is the injected activity, in GBq, of perfused volume *i*.
- *F* is the lung shunt fraction.
- *R* is the residual fraction.
- $C_{t\cap pvi}$ is the number of counts in the volume formed by the intersection of the tumor VOI and perfused volume *i*,
- C_{pvi} is the number of counts in perfused volume *i*.
- ρ is the liver tissue density in kg/cm³, assumed to be $1.03\text{x}10^{-3}$ kg/cm³.
- V_t is the volume of the normal tissue, in cm³.

4.10.2 TS360-TXT-12 Whole Liver Absorbed Dose Formula

$$D_{liver} = \frac{50 \times A \times (1-F) \times (1-R)}{M_{liver}}$$

Where as:

- D_{liver} is the dose that was or is to be delivered to the whole liver structure in Gy.
- A is the summed target activities of all perfused volumes in GBq.
- F is the lung shunt fraction.
- R is the residual fraction.
- M_{liver} is the whole liver mass in kg.
- the constant 50 is the dose in Gy delivered to 1 kg of mass by 1 GBq of 90Y.

The mass of the whole liver, Mliver, is calculated as:

$$M_{liver} = \frac{V_{liver} \times \rho_{liver}}{1000}$$

Where as:

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•M_{liver} is the whole liver mass in kg.
•V_{liver} is the volume of the liver in cm3.
• ρ_{liver} is the liver tissue density in g/ cm3, assumed to be 1.03 g/ cm3.

4.10.3 TS360-TXT-13 Activity at Treatment using Perfused Volume Absorbed Dose Formula

Using Perfused Volume Absorbed Dose:

$$A_{pv} = \frac{M_{pv} \times D_{pv}}{50 \times (1 - F) \times (1 - R)}$$

Where as:

• A_{pv} is the activity injected into the perfused volume selected for calculation, in GBq.
• D_{pv} is the dose for the perfused volume, in Gy.
• F is the lung shunt fraction as a percentage value.
• R is the residual fraction as a percentage value.
• The constant 50 is the dose in Gy delivered to 1 kg of mass by 1 GBq of 90Y.
• M_{pv} is the mass of the perfused volume in kg.

The mass of the perfused volume, Mpv, is calculated as:

$$M_{pv} = \frac{V_{pv} \times \rho_{liver}}{1000}$$

Where as:

• M_{pv} is the mass of the union of perfused volume in kg.
• V_{pv} is the volume of the union of perfused volumes in cm3.
• ρ_{liver} is the liver tissue density in kg/cm3.

Using Tumor Absorbed Dose:

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$$A_{pv} = \frac{D_t \times \rho V_t \times \sum_{\forall i} C_i}{50 \times (1 - F) \times (1 - R) \times C_t}$$

Where as:

- A_{pv} is the perfused volume's injected activity in GBq
- D_t is the tumor absorbed dose, in Gy.
- F is the lung shunt fraction.
- R is the residual fraction.
- C_t is the number of counts in the total tumor within the perfused volume,
- $\Sigma_{\forall i}Ci$ are the total counts in the perfused volume
- ρ is the liver tissue density in kg/cm3, assumed to be 1.03x10-3 kg/cm3.
- Vt is the volume of the total tumor within the perfused volume, in cm3.

Using Normal Tissue Absorbed Dose:

$$A_{pv} = \frac{D_{nt} \times \rho V_t \times \sum_{\forall i} C_i}{50 \times (1 - F) \times (1 - R) \times C_{nt}}$$

Where as:

- Apv is the perfused volume's injected activity in GBq
- Dnt is the normal tissue absorbed dose, in Gy.
- F is the lung shunt fraction.
- R is the residual fraction.
- $\Sigma_{\forall i}Ci$ are the total counts in the perfused volume
- C_{nt} is the number of counts in the total normal tissue within the perfused volume
- ρ is the liver tissue density in kg/cm3, assumed to be 1.03x10-3 kg/cm3.
- V_t is the volume of the total tumor within the perfused volume, in cm3.

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4.10.4 TS360-TXT-17 Activity Required At Treatment Formula

$$Activity\ Required\ (GBq) = \frac{[Desired\ Dose\ (Gy)][\ Liver\ Mass\ (kg)]}{50\ (Gy \cdot kg \cdot GBq^{-1})[1-F][1-R]}$$

Where:
- F is the lung shunt fraction.
- R is the residual fraction.
- The constant 50 is the dose in Gy delivered to 1 kg of mass by 1 GBq of 90Y.

4.10.5 TS360-TXT-18 Calculated Dose to Lungs Formula

$$D_{lung} = \frac{50 \times A \times F \times (1-R)}{M_{lung}}$$

Where:
- D_{lung} is the current lung absorbed dose in Gy.
- A is the total target activity in GBq.
- F is the lung shunt fraction.
- R is the residual fraction.
- 50 is the dose in Gy delivered to 1 kg of mass by 1 GBq of ^{90}Y.
- M_{lung} is the lung mass in kg.

4.10.6 TS360-TXT-20 Normal Tissue Absorbed Dose Formula

$$D_{nt} = \frac{\left[\left(\frac{A_{pv1}}{C_{pv1}}\right)C_{nt\cap pv1} + \left(\frac{A_{pv2}}{C_{pv2}}\right)C_{nt\cap pv2} + \cdots + \left(\frac{A_{pvN}}{C_{pvN}}\right)C_{nt\cap pvN}\right] \times 50 \times (1-F) \times (1-R)}{\rho V_{nt}}$$

Where as:

- Dnt is the normal tissue absorbed dose, in Gy.
- Apvi is the injected activity, in GBq, of perfused volume i.
- F is the lung shunt fraction.
- R is the residual fraction.
- $C_{nt\cap pvi}$ is the number of counts in the volume formed by the intersection of the normal tissue VOI and perfused volume i,
- C_{pvi} is the number of counts in perfused volume i
- ρ is the liver tissue density in kg/cm3, assumed to be 1.03x10-3 kg/cm3.
- Vnt is the volume of the normal tissue, in cm3.

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4.10.7 TS360-TXT-22 Pre-Treatment Net Rate Decayed to Post-Treat Time (mR/h) Formula

This equation takes the activity measured from the Pre-Treatment template measurement and calculates its current value based on the time between measurements.

$$T_{1/2} \text{ of Y-90} = 64.1 \textit{ hours}$$

$$[\text{Pre Treatment Net Rate Decayed to Post Treat Time}] = [\text{activity from the pretreatment template}] * e^{\frac{-\ln(2)*[\text{Time between measurements}]}{64.1}}$$

Where:
Time between measurements (hrs) = Hours between Pre- and Post Treatment Measurements
activity from the pretreatment template = Net Rate of Vial on Template

4.10.8 TS360-TXT-23 Post Treatment Worksheet Formula for Activity Administered per Vial At Time of Treatment

This equation takes the activity of the vial at calibration from the user's choice of the nominal (ordered) dose size, the Dose Calibration measured activity, or the manufacturer's activity and calculates the activity administered at time of treatment based on the % delivered and the time between calibration and treatment.

$$\text{Activity Administered per Vial at Time of Treatment (GBq)} = \%\text{ delivered per vial} * A_0 * e^{\frac{-\ln(2)*[\text{Time}]}{64.1}}$$

Where:

- For "Nominal(Ordered) Dose Size" and "Manufacturer's Activity at Cal", "Time" is the time between calibration and treatment
- For "Dose Calibrator Measured Activity", "Time" is the elapsed time from the Pre Treatment Dose Calibrator Measurement to the time of treatment

$$A_0 = \begin{cases} Nominal(ordered)\,DoseSize \\ \text{Dose Calibrator Measured Activity} \\ \text{Manufacturer's Activity at Cal} \end{cases}$$

4.10.9 TS360-TXT-24 Prescribed Activity vs. Delivered Activity Formula

$$Prescribed\ Activity\ vs\ Delivered\ Activity = \frac{Delivered\ Activity}{Prescribed\ Activity} * 100$$

Where:
Delivered Activity = Total Activity Delivered to Patient at Time of Treatment (GBq)

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Prescribed Activity = Prescribed Activity (GBq)

4.10.10 TS360-TXT-25 Total Activity Delivered to Patient at Time of Treatment (GBq) Formula

$$[\text{Total Activity Delivered at Time of Treatment (GBq)}] = \sum \text{Activity Administered per Vial at Time of Treatment (GBq)}$$

4.10.11 TS360-TXT-26 Activity Delivered to Perfused Liver Tissue (GBq) Formula

$$[\text{Activity Delivered to Perfused Liver Tissue (GBq)}] = \text{Total Activity Delivered (GBq)} * (1 - LSF)$$

Where:

LSF is lung shunt fraction

4.10.12 TS360-TXT-38 Mass Conversion - Formula

The software shall use the below formula for converting from a liver mass (kg) to a liver volume (cc).
Mass (kg) = Volume (cc) *1.03 / 1000

4.10.13 TS360-TXT-51 Activity in waste jar at time of treatment formula

$$\text{Activity in waste jar at time of treatment} = \frac{\text{Activity administered per vial at time of treatment in GBq)}}{\text{percentage of vial delivered}} * (100 - \text{Percentage of vial delivered})$$

Where:

Activity administered per vial at time of treatment in GBq = TS360-TXT-23

Note: "100-Percentage of vial delivered" is assuming "Percentage of vial delivered" is already multiplied by 100 for percentage display.

4.10.14 TS360-TXT-52 Percentage of Vial Delivered Formula

$$\text{Percentage of vial delivered} = \frac{(\text{I} - \text{b1}) - (W - b2)}{(\text{I} - \text{b1})} * 100$$

Where:

(I-b1) = pre-treatment net rate decayed to post treatment time

(W-b2) = Average of 4 Orientations minus background (mR/h) of waste

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4.10.15 TS360-TXT-53 Dose to Perfused Liver Tissue Formula

$$\text{Dose to perfused liver tissue (Gy)} = \frac{50 * \text{Activity to Delivered Perfused Liver tissue (GBq)}}{\text{mass of perfused liver tissue (kg)}}$$

Where:

Activity to Delivered Perfused Liver tissue (GBq) = result of equation in TS360-TXT-26

mass of perfused liver tissue (kg) = Target Volume measured in kg

4.10.16 TS360-TXT-54 Dose Delivered to Lungs for Target Formula

$$\text{Dose Delivered to Lungs for Target} = \frac{50 * \text{activity delivered to lungs for target}}{\text{lung mass in kg}}$$

4.10.17 TS360-TXT-55 Dose Calibrator Measured Activity at Treatment Formula

$$\text{Dose Calibration Measured Activity at Treatment} = [\text{Dose Calibrator Measured Activity}] * e^{\frac{-\ln(2)*[Time\ between\ measurements]}{64.1}}$$

Where:

Time between measurements (hrs) = Pre-treatment Dose Calibrator Measurement Section date and time - Prescribing Information date and time

Dose Calibrator Measured Activity = Dose Calibrator Measured Activity field value

4.10.18 TS360-TXT-56 Estimated RPM (Bq/Sphere) Formula

$$\text{Estimated RPM (Bq/Sphere)} = 4000 * e^{\frac{-\ln(2)*[Time\ between\ treatment\ and\ calibration]}{64.1}}$$

Where

"Time between treatment and calibration" (Hrs) takes into account the time zone of the treatment facility and the time zone of the calibration (EST)

"Estimated RPM (Bq/Sphere)" is rounded up to a whole number

4.10.19 TS360-TXT-57 Activity at Treatment formula

$$\text{Activity at Treatment} = [\text{Activity in Vial (GBq)}] * e^{\frac{-\ln(2)*[Time\ between\ calibration\ and\ treatment]}{64.1}}$$

Where

"Activity in Vial (GBq)" is the Vial Size

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"Time between calibration and treatment" (Hrs) takes into account the time zone of the treatment facility and the time zone of the calibration (EST)

4.10.20 TS360-TXT-58 Absorbed Dose formula

$$Absorbed\ Dose = \frac{50 * A * (1 - F) * (1 - R)}{M_{target}}$$

Where:

- *A* is the Activity at Treatment for the vial(s) in GBq
- *F* is the lung shunt fraction as a percentage value.
- *R* is the residual fraction as a percentage value.
- 50 is the dose in Gy delivered to 1 kg of mass by 1 GBq of ^{90}Y.
- M_{target} is the mass of the perfused target in kg.

4.10.21 TS360-TXT-60 Percent Desired Dose Formula

$$\%\ Desired\ Dose = \left(\frac{Absorbed\ Dose}{Desired\ Dose} - 1\right) * 100$$

4.10.22 TS360-TXT-61 Percent of Vial Activity Formula

$$\%\ of\ Vial\ Activity = \left(\frac{Activity\ at\ Treatment\ (GBq)}{Desired\ Activity\ at\ Treatment\ (GBq)} - 1\right) * 100$$

4.10.23 TS360-TXT-62 Prescribed Activity Formula

$$Prescribed\ Activity = (1 - R) * Activity\ of\ Vial(s)$$

where:

R = Anticipated Residual Waste fraction

4.10.24 TS360-TXT-36 Non-Linear Workflows

There are 6 workflows associated with the Vial selection. Depending on the workflow, the vial selection screen will look different. At a high level, the diagram below shows the overview of the flow

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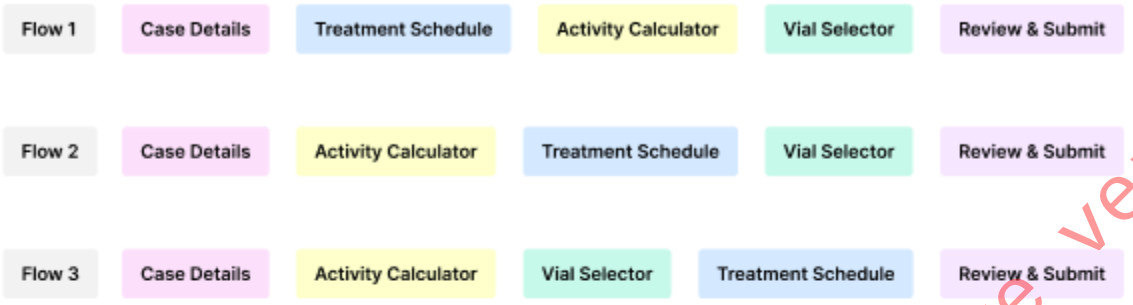
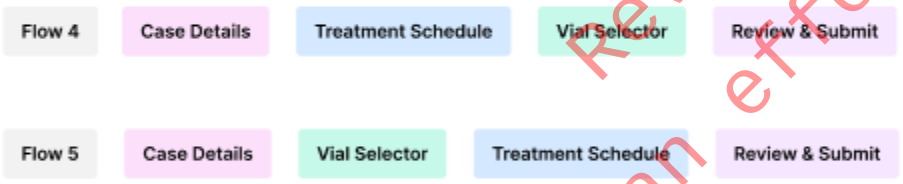
Non-Linear Flows

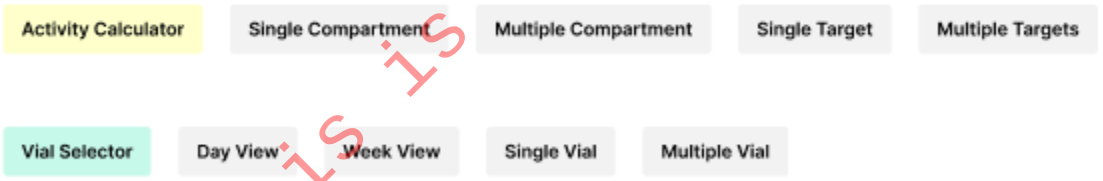
With Activity Calculator



Without Activity Calculator



Within Each Flow



MCD Variants

Review
(This is not an effective version)

4.10.25 TS360-TXT-48 Alert and message types

Message Type	Icon	Text Color	Background Color
Patient Safety Caution	Yellow triangle with a yellow exclamation point inside	Black	Yellow with a yellow border
Patient Safety Warning	Red triangle with a Red exclamation point inside	Black	Red with a red border
System Messaging Alert	Red Circle with a red exclamation point inside	Red	White with a red border
Form Validation Alert	Red Circle with a red exclamation point inside	Red	White with no border
Informational Message	Blue circle with a blue 'i' inside	Black	Blue with a blue border
Confirmation Message	Green circle with a green checkmark inside	Black	Green with a green border
Tooltip	Blue circle with a white 'i' inside	Black	White with a blue border
Delete Alert Modal	Red trashcan	Black	White modal, rest of screen is darkened
Information Alert Modal	Blue circle with a blue 'i' inside	Black	White modal, rest of screen is darkened
Form Validation Soft Limit	None	Grey	White with no border

4.10.26 TS360-TXT-49 GUI Messages

Message ID	Message Type	Text
M1	Form Validation Alert	Please limit special characters to the following: . - _ ( )
M2	Form Validation Alert	Please enter the patient first name.
M3	Form Validation Alert	Please enter the patient last name.
M4	Form Validation Alert	Please select the treatment facility.
M5	Form Validation Alert	Please select the treating physician.
M6	Form Validation Alert	Please select the disease type.
M7	Form Validation Alert	Please select the treatment goal.

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M8	Form Validation Alert	Please select the treatment approach.
M9	Form Validation Alert	Please enter the mapping date.
M10	Patient Safety Caution	The safety and effectiveness of TheraSphere has not been established for this treatment. Please refer to the TheraSphere IFU for the full indications for use.
M11	Patient Safety Warning	TheraSphere is contraindicated in patients with portal vein thrombosis (PVT) Type 4 involvement and lack of Tc-99m MAA deposition on the PVT seen on the Tc-99m MAA imaging. Please refer to the TheraSphere IFU for full indications for use.
M12	N/A - Unused	N/A - Unused
M13	Confirmation Message	Treatment Date Confirmed
M14	System Messaging Alert	There are no vials available. Please select a later treatment date or contact Customer Care for support.
M15	Delete Alert Modal	Title: "Are You Sure?" Body: "Updating your treatment date & time will remove all selected vials." Buttons: "Remove Vials", "Cancel"
M16	System Messaging Alert	Please select the treatment date and time.
M17	System Messaging Alert	Please select the treatment time.
M18	System Messaging Alert	Please select the treatment date.
M19	System Messaging Alert	The previously selected treatment date is no longer available. Please select a new treatment date.
M20	Information Alert Modal	Title: "Are You Sure?" Body: "You are about to leave this page. Any unconfirmed updates will be lost." Buttons: "Leave", "Stay"
M21	Tooltip	Title: "Target Name" Body: "Use this field to label your perfused volume target."
M22	Tooltip	Title: "Target Volume" Body: "Enter the perfused volume for this target."
M23	N/A - Unused	N/A - Unused
M24	Tooltip	Title: "Cumulative Lung Dose" Body: "This value is the sum of the patient's previous dose to lungs and all entered targets' calculated dose to lungs."

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(This is not an effective version)

M25	Tooltip	Title: "Total Dose to Lungs" Body: "This value is the sum of all entered targets' calculated dose to lungs."
M26	Form Validation Alert	Please enter the lung mass.
M27	Form Validation Alert	Please enter the previous dose to Lungs.
M28	Form Validation Alert	Please enter the lung shunt fraction.
M29	Form Validation Alert	Please enter the anticipated residual waste.
M30	Form Validation Alert	Please enter the target name.
M31	Form Validation Alert	Please enter the target volume.
M32	Form Validation Alert	Please enter the desired dose.
M33	Form Validation Alert	The lung mass must be 0.3 kg to 2.0 kg.
M34	Form Validation Alert	The previous dose to lungs must be 0 Gy to 50 Gy.
M35	Form Validation Alert	The lung shunt fraction must be 0% to 99.999%.
M36	Form Validation Alert	The anticipated residual waste must be 0% to 20%.
M37	Form Validation Alert	The target volume must be 1 cc to 8,000 cc.
M38	Form Validation Alert	The desired dose must be 1 Gy to 10,000 Gy.
M39	Patient Safety Warning	The dose to lungs for a single treatment should not exceed 30 Gy.
M40	Patient Safety Warning	The lifetime dose to lungs should not exceed 50 Gy.
M41	Delete Alert Modal	Title: "Are You Sure?" Body: "Calculating Single Compartment Dosimetry results will remove all selected vials." Buttons: "Remove Vials", "Cancel"
M42	Delete Alert Modal	Title: "Are You Sure?" Body: "Changing dosimetry methods will clear previous calculator results and remove any selected vials." Buttons: "Clear Results", "Cancel"
M43	Information Alert Modal	Title: "Are You Sure?" Body: "You are about to leave this page. All non-calculated updates will be lost." Buttons: "Leave", "Stay"
M44	Delete Alert Modal	Title: "Are You Sure?" Body: "Deleting the target will erase data any associated data." Buttons: "Delete Target", "Cancel"
M45	Patient Safety Caution	Multicompartment dosimetry is intended to be used as a post-treatment evaluation of absorbed dose to tumor and normal tissue.

(This is not an effective Review version)

M46	Tooltip	Title: "Whole Liver Volume" Body: "To calculate whole liver dose enter the whole liver volume."
M47	Tooltip	Title: "Tumor Volume" Body: "Tumor volume is defined as perfused tumor volume within the perfused volume."
M48	Tooltip	Title: "Normal Tissue Volume" Body: "The normal tissue volume is defined as perfused normal tissue within the perfused volume."
M49	Tooltip	Title: "Activity & Absorbed Dose" Body: "To calculate the absorbed doses, enter the activity delivered to the target at time of treatment. To calculate the activity at treatment, enter the absorbed dose at time of treatment."
M50	Tooltip	Title: "Residual Waste" Body: "Enter the residual waste from administration."
M51	Form Validation Alert	Please enter the residual waste.
M52	Form Validation Alert	Please enter the whole liver volume.
M53	Form Validation Alert	Please enter the perfused volume.
M54	Form Validation Alert	Please enter the perfused counts.
M55	Form Validation Alert	Please enter the tumor volume.
M56	Form Validation Alert	Please enter the tumor counts.
M57	Form Validation Alert	Please enter the normal tissue volume.
M58	Form Validation Alert	Please enter the normal tissue counts.
M59	Form Validation Alert	Please enter the activity at treatment.
M60	Form Validation Alert	Please enter the tumor absorbed dose.
M61	Form Validation Alert	Please enter the normal tissue absorbed dose.
M62	Form Validation Alert	Please enter the perfused volume absorbed dose.
M63	N/A - Unused	N/A - Unused
M64	Form Validation Alert	The residual waste must be 0% to 20%.
M65	Form Validation Alert	The whole liver volume must be 1 cc to 8,000 cc.
M66	Form Validation Alert	The perfused volume must be less than or equal to the whole liver volume.
M67	Form Validation Alert	The perfused counts must be 2 to 10,000,000.

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M68	Form Validation Alert	The sum of the values for the tumor volume and the normal tissue volume must be less than or equal to the perfused volume.
M69	Form Validation Alert	The sum of the values for the tumor counts and the normal counts must be less than or equal to the perfused counts.
M70	Information Alert Modal	Title: "Finish Calculation" Body: "After deleting a target, please finish updating the calculation by pressing the recalculate button." Buttons: "Return to Calculator"
M71	System Messaging Alert	One or more of the selected vials are not available. Please select a later treatment date or contact Customer Care for support.
M72	Form Validation Alert	The activity at treatment must be 0.01 GBq to 50 GBq.
M73	Form Validation Alert	The perfused volume absorbed dose must be 1 Gy to 10,000 Gy.
M74	Form Validation Alert	The tumor absorbed dose must be 1 Gy to 10,000 Gy.
M75	Form Validation Alert	The normal tissue absorbed dose must be 1 Gy to 10,000 Gy.
M76	Informational Message	The recommended absorbed dose to the liver is between 80 and 150 Gy. Please verify the entered values are accurate.
M77	Delete Alert Modal	Title: "Are You Sure?" Body: "Calculating Multi-Compartment Dosimetry results will remove all selected vials." Buttons: "Remove Vials", "Cancel"
M78	Patient Safety Caution	The selected vials will result in an Absorbed Dose that is not within +/- 10% of the Desired Dose.
M79	System Messaging Alert	Please select vials for this order.
M80	Informational Message	Only vials available on <day of week> at <time> will be selectable to match the confirmed Treatment Date.
M81	Informational Message	Only vials available on <day of week> at <time> will be selectable to match the previously selected vials.
M82	N/A - Unused	N/A - Unused
M83	Informational Message	There are no vials available based on the treatment date. Please try another calibration week or set a new treatment date. Contact your Sales Representative for further assistance.

(This is not an effective version) Review

M84	Patient Safety Caution	The selected vials will have an Activity at Treatment that is not within +/- 10% of the searched value in the Desired Activity at Treatment field.
M85	Informational Message	Please finish your calculation to view table of vials.
M86	Informational Message	This is a very short notice order. There is only 1 day available to ship your order. Please contact our Customer Care team.
M87	Informational Message	This is a very short notice order. There are only 2 days available to ship your order. Please contact our Customer Care team.
M88	Informational Message	There are only 3 days available to ship your order. We may contact you shortly.
M89	Patient Safety Caution	The selected vials will have an Activity at Treatment that is not within +/- 10% of the searched value in the Desired Activity at Treatment field during the vial selection step.
M90	Informational Message	You do not have permission to submit TheraSphere orders. Click here to notify to another user to submit the order.
M91	System Messaging Alert	Please enter all data in case details.
M92	System Messaging Alert	Please add vials to order.
M93	System Messaging Alert	Please select the treatment date and time.
M94	Form Validation Alert	Please review and complete this required step.
M95	System Messaging Alert	This vial is unavailable. Please reselect the vials or choose a later treatment date.
M96	System Messaging Alert	One or more of the selected vials are not available. Please reselect the vials or choose a later treatment date.
M97	Informational Message	Based on the treatment date selected, this is an expedited order. Please select a later treatment date or contact Customer Care for support.
M98	Form Validation Alert	The activity of vial(s) must be 0.1 GBq to 80 GBq.
M99	Form Validation Alert	Please select the user.
M100	Form Validation Alert	Please select the step.
M101	Confirmation Message	Email sent to <user>
M102	Delete Alert Modal	Title: "Are You Sure?" Body: "This Treatment Draft and associated data will be deleted permanently." Buttons: "Delete", "Cancel"

(This is not an effective version) Review

M103	Information Alert Modal - no icon	Title: "Do you want to continue your session?" Body: "For security, your session will time out in <min:sec> unless you continue." Buttons: "Continue Session"
M104	Form Validation Alert	Please select a number of targets.
M105	Form Validation Alert	Please select the associated vials for this target.
M106	System Messaging Alert	Each target requires one associated vial. Please deselect one or more vials or choose a different number of targets.
M107	System Messaging Alert	Every vial needs to be associated with a target. Vials can be removed from the target when editing the Treatment Documents.
M108	Confirmation Message	Treatment Sites saved.
M109	Informational Message	The Post Treatment worksheet for this target will reflect the updated inputs, please verify inputs prior to continuing.
M110	Form Validation Alert	Please select a number of vials administered.
M111	Form Validation Alert	Please select a treatment site.
M112	Form Validation Alert	Please select a treatment time.
M113	Form Validation Alert	Please enter the activity of vial(s).
M114	Confirmation Message	Section information locked.
M115	Tooltip	Title: "Prescribed Activity" Body: "The calculated total amount of activity (GBq) intended to be administered to this target (i.e. total Activity of Vial(s) minus the anticipated residual waste)."
M116	Patient Safety Caution	The Activity of Vials differs from +/- 10% of the activity at treatment for the vials ordered. Please update your treatment plan accordingly.
M117	Tooltip	Title: "Desired Dose" Body: "The desired dose value entered in the treatment activity calculator. This field is for reference purposes only."
M118	Form Validation Alert	Please select the vial for this target.
M119	Confirmation Message	Post Treatment Worksheet locked.
M120	Patient Safety Caution	The DC measured activity at treatment differs by 10% or more from the Activity in Vial(s). Please verify inputs.
M121	Patient Safety Caution	The Activity Delivered to Perfused Liver Tissue differs by 20% or more than the Prescribed Activity at Time of Treatment.

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M122	Form Validation Alert	Please enter the manufacturer lot number.
M123	Form Validation Alert	Please enter the vial number.
M124	Form Validation Alert	Please select the date of measurement.
M125	Form Validation Alert	Please enter the time of measurement.
M126	Form Validation Alert	Please enter the dose calibrator measured activity.
M127	Form Validation Alert	Please enter the manufacturer's activity at calibration.
M128	Form Validation Alert	Please select a value.
M129	Form Validation Alert	Please enter the background measurement.
M130	Form Validation Alert	Please enter the vial measurement on template.
M131	Form Validation Alert	Please select two methods.
M132	Form Validation Alert	Please confirm the vial.
M133	Form Validation Alert	Please select the administration start date.
M134	Form Validation Alert	Please enter the administration start time.
M135	Form Validation Alert	Please enter a value.
M136	Form Validation Alert	There was a system server error. Please press <button name> again.
M137	Form Validation Soft Limit	Please verify the entered values are accurate.
M138	Form Validation Soft Limit	Please verify that the value entered is accurate.
M139	N/A - Unused	N/A - Unused
M140	Tooltip	Title: "Activity of Vial(s)" Body: "The total amount of activity (GBq) in vial(s) intended to be used for this target at the time of treatment. Pre-populated based on vials ordered."
M141	Form Validation Alert	The dose calibrator measured activity must be 0 to [vial size in mCi].
M142	Form Validation Alert	The manufacturer's activity at calibration must be 0 to 22.
M143	Form Validation Alert	The Background Measurement must be 0 to 1000.
M144	Form Validation Alert	The Vial Measurement on Template must be 0 to 999.
M145	Form Validation Alert	The patient dose rate, maximum on contact must be 0 to 1000.
M146	Form Validation Alert	The patient dose rate, maximum at 1 meter must be 0 to [insert data input from Measurement of Dose Vial on Template].
M147	Form Validation Alert	The Background Measurement must be 0 to 1000.
M148	Form Validation Alert	The 0º (mR/h) must be 0 to [Vial Measurement on Template field value]

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M149	Form Validation Alert	The 90º (mR/h) must be 0 to [Vial Measurement on Template field value]
M150	Form Validation Alert	The 180º (mR/h) must be 0 to [Vial Measurement on Template field value]
M151	Form Validation Alert	The 270º (mR/h) must be 0 to [Vial Measurement on Template field value]
M152	Form Validation Alert	Please enter a time after the previously entered time
M153	Form Validation Alert	The perfused volume must be 2 cc to 8,000 cc.
M154	Form Validation Alert	The tumor volume must be 1 cc to 7,999 cc.
M155	Form Validation Alert	The tumor counts must be 1 to 9,999,999,999.
M156	Form Validation Alert	The normal tissue volume must be 1 cc to 7,999 cc.
M157	Form Validation Alert	The normal tissue counts must be 1 to 9,999,999,999.
M158	Form Validation Alert	The vial measurement must be greater than the background measurement.

4.11 Field Limits, Warnings, and Parameters

4.11.1 TS360-TXT-14 SCD Input Limits and Warnings

Input Field	Data Type	Significant Figures to Display (Input and Output)	Lower Limit (greater than or equal to)	Upper Limit (less than or equal to)	Limit Message	Soft Limit	Soft Limit Message	Empty Message
Desired Dose (Gy)	Positive whole number	No decimals, whole numbers only (ex: 20 Gy)	1 Gy	10,000 Gy	M38 in TS360-TXT-49	>2,000 Gy	M138 in TS360-TXT-49	M32 in TS360-TXT-49
Target Volume (cc)	Positive number	2 decimal places (ex: 800.15 cc or 7,000.21 cc)	1 cc	8,000 cc	M37 in TS360-TXT-49	>5,000cc	M138 in TS360-TXT-49	M31 in TS360-TXT-49
Lung Shunt Fraction (%)	Positive percentage	3 decimal places (ex: 4.512% or 0.523%)	0%	99.999%	M35 in TS360-TXT-49	N/A	N/A	M28 in TS360-TXT-49
Previous Dose to Lungs (Gy)	Positive number	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	0 Gy	50 Gy	M34 in TS360-TXT-49	N/A	N/A	M27 in TS360-TXT-49
Anticipated Residual Waste (%)	Positive percentage	No decimals, whole numbers only (ex: 25%)	0%	20%	M36 in TS360-TXT-49	>5%	M138 in TS360-TXT-49	M29 in TS360-TXT-49
Lung Mass (kg)	Positive number	3 decimal places (ex: 0.312 kg or 1.532 kg)	0.3 kg	2.0 kg	M33 in TS360-TXT-49	N/A	N/A	M26 in TS360-TXT-49

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4.11.2 TS360-TXT-15 MCD Input limits and warnings

Input Field	Data Type	Significant Figures to Display (Input and Output)	Lower Limit (greater than or equal to)	Upper Limit (less than or equal to)	Invalid Range Message (user not allowed to proceed until fixed)	Input Dependencies	Invalid Input Dependencies Message	Soft Limit (user allowed to proceed)	Soft Limit Message (user allowed to proceed)	Empty Message
Lung Shunt Fraction (%)	Positive percentage	3 decimal places (ex: 4.512% or 0.523%)	0%	99.999%	M35 in TS360-TXT-49	N/A	N/A	N/A	N/A	M28 in TS360-TXT-49
Previous Dose to Lungs (Gy)	Positive number	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	0 Gy	50 Gy	M34 in TS360-TXT-49	N/A	N/A	N/A	N/A	M27 in TS360-TXT-49
Residual Waste (%)	Positive percentage	No decimals, whole numbers only (ex: 25%)	0%	20%	M64 in TS360-TXT-49	N/A	N/A	>5%	M138 in TS360-TXT-49	M51 in TS360-TXT-49
Lung Mass (kg)	Positive number	3 decimal places (ex: 0.312 kg or 1.532 kg)	0.3 kg	2.0 kg	M33 in TS360-TXT-49	N/A	N/A	N/A	N/A	M26 in TS360-TXT-49
Whole Liver Volume (cc)	Positive number	2 decimal places (ex: 800.15 cc or 7,000.21 cc)	1 cc	8,000 cc	M65 in TS360-TXT-49	N/A	N/A	>5,000cc	M138 in TS360-TXT-49	M52 in TS360-TXT-49
Perfused Volume (cc)	Positive number	2 decimal places (ex: 800.15 cc or 7,000.21 cc)	2 cc	8,000 cc	M153 in TS360-TXT-49	Less than or equal to <whole liver volume input>	M66 in TS360-TXT-49	N/A	N/A	M53 in TS360-TXT-49
Perfused Counts	Positive whole number	No decimals, whole numbers only	2	10,000,000,000	M67 in TS360-TXT-49	N/A	N/A	N/A	N/A	M54 in TS360-TXT-49
Tumor Volume (cc)	Positive number	2 decimal places (ex: 800.15 cc or 7,000.21 cc)	1 cc	7,999 cc	M154 in TS360-TXT-49	Sum of input value + <normal tissue volume> must be less than or equal to <perfused volume>.	M68 in TS360-TXT-49	N/A	N/A	M55 in TS360-TXT-49
Tumor Counts	Positive whole number	No decimals, whole numbers only	1	9,999,999,999	M155 in TS360-TXT-49	Sum of input value + <normal counts> must be less than or equal to <perfused counts>.	M69 in TS360-TXT-49	N/A	N/A	M56 in TS360-TXT-49

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Normal Tissue Volume (cc)	Positive number	2 decimal places (ex: 800.15 cc or 7,000.21 cc)	1 cc	7,999 cc	M156 in TS360-TXT-49	Sum of input value + <tumor volume> must be less than or equal to <perfused volume>.	M68 in TS360-TXT-49	N/A	N/A	M57 in TS360-TXT-49
Normal Tissue Counts	Positive whole number	No decimals, whole numbers only	1	9,999,999,999	M157 in TS360-TXT-49	Sum of input value + <tumor counts> must be less than or equal to <perfused counts>.	M69 in TS360-TXT-49	N/A	N/A	M58 in TS360-TXT-49
Activity at Treatment (GBq)	Positive number	2 decimal places (ex: 5.53 GBq or 50.51 GBq)	0.01 GBq	50 GBq	M72 in TS360-TXT-49	N/A	N/A	N/A	N/A	M59 in TS360-TXT-49
Perfused Volume Absorbed Dose (Gy)	Positive number	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	1 Gy	10,000 Gy	M73 in TS360-TXT-49	N/A	N/A	N/A	N/A	M62 in TS360-TXT-49
Tumor Absorbed Dose (Gy)	Positive number	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	1 Gy	10,000 Gy	M74 in TS360-TXT-49	N/A	N/A	N/A	N/A	M60 in TS360-TXT-49
Normal Tissue Absorbed Dose (Gy)	Positive number	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	1 Gy	120 Gy	M75 in TS360-TXT-49	N/A	N/A	>150Gy	M138 in TS360-TXT-49	M61 in TS360-TXT-49

4.11.3 TS360-TXT-27 SCD Output Limits and Messages

Output Field	Data Type	Source	Significant Figures to Display (Input and Output)	Limit	Limit Message
Calculated Target Liver Mass (kg)	Positive number	Calculated using formula in TS360-TXT-38	3 decimal places (ex: 0.312 kg or 1.532 kg)	N/A	N/A
Activity Required at Treatment (GBq)	Positive number	Calculated using formula in TS360-TXT-17	2 decimal places (ex: 0.98 GBq or 4.26 Gbq)	N/A	N/A
Activity Required at Treatment (mCi)	Positive number	Calculated using Activity Required at Treatment (GBq) and formula in TS360-SWR-24	2 decimal places (ex: 133.06 mCi or 90.22 mCi)	N/A	N/A
Calculated dose to lungs (Gy)	Positive number	Calculated using formula in TS360-TXT-18	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	N/A	N/A

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Total dose to lungs (Gy)	Positive number	Calculated using formula in TS360-SWR-338	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	30 Gy	M39 in TS360-TXT-49
Cumulative dose to lungs (Gy)	Positive number	Calculated using formula in TS360-SWR-15	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	50 Gy	M40 in TS360-TXT-49

4.11.4 TS360-TXT-28 Prescribing Information Section - Data Elements per target

Data Element	System Generated	Data Type	Format Significant Figures	Source	Editable	Empty Message	Edit Description
Patient Name	Y	Alpha		Treatment Details (Portal)	N	N/A	
Treatment Site (Liver)	Y	both		Treatment Details (Portal) OR manual input	Y	M111 in TS360-TXT-49	User can select one of the following: Right Lobe Left Lobe Segment 1 Segment 2 Segment 3 Segment 4 Segment 5 Segment 6 Segment 7 Segment 8 Other If other, then the user can enter free form text according to TS360-TXT-42.
Treatment Date	Y	both	Month, dd, YYYY	Treatment Details (Portal)	N	N/A	
Treatment Time (Timezone)	Y	both	HH:MM AM/PM	Treatment Details (Portal) OR manual input	Y	M112 in TS360-TXT-49	User can adjust treatment time according to TS360-SWR-96
Device	Y	both	"TheraSphere Y-90 Glass Microspheres"	Hardcoded	N	N/A	

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Data Element	System Generated	Data Type	Format Significant Figures	Source	Editable	Empty Message	Edit Description
Contract Manufacturer	Y	both	"BWXT Medical (formerly Nordion)"	Hardcoded	N	N/A	
Anticipated Residual Waste (%)	Y	numeric	No decimals, whole numbers only (ex: 2%)	Treatment Details (Portal) OR manual input	Y	M29 in TS360-TXT-49	User can adjust the Anticipated Residual Waste % according to Anticipated Residual Waste in TS360-TXT-14.
Activity of Vial(s) (GBq)	Y	numeric	GBq 2 decimal places *system should also calculate the activity in mCi	Treatment Details (Portal) OR Summation of Activity at Treatment for all vials. Activity at Treatment is calculated by equation in TS360-TXT-57 OR manual input	Y	M113 in TS360-TXT-49	User can adjust the Activity of Vials between a minimum value of 0.1 GBq and a maximum value of 80 GBq. If the user enters a value outside that range, M98 in TS360-TXT-49 shall display. (This is to account for variations in manufacturing of vials)
Prescribed Activity	Y	numeric	GBq 2 decimal places *system should also calculate the activity in mCi	Calculated by using equation in TS360-TXT-62	N	N/A	
Calculated Absorbed Dose	Y, calculated	numeric	Gy 2 decimal places	Treatment Details (Portal) OR Calculated by using formula in TS360-TXT-58 If any of the inputs are changed. A=Activity of Vials	N	N/A	
Desired Dose	Y, if available	numeric	Gy whole numbers only	Treatment Details (Portal) OR "---" if not available	N	N/A	
Number of Vials Administered	Y	numeric	whole numbers only	Order Details - Sum of vials associated with target	Y	M110 in TS360-TXT-49	User can select from a list, starting at 1 up to the number of sum of vials associated with target

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4.11.5 TS360-TXT-29 Final Calculations - Post Treatment Work sheet

Data Element	Source	Data Type	Format Significant Figures	Editable
Prescribed Activity vs. Delivered Activity	Calculated by formula found in TS360-TXT-24	numeric	% 2 decimal places	N
Total Activity Delivered to Patient at time of Treatment	Calculated by formula found in TS360-TXT-25	numeric	GBq 2 decimal places *system should also calculate the activity in mCi	N
Activity Delivered to Perfused Liver Tissue	Calculated by formula found in TS360-TXT-26	numeric	GBq 2 decimal places *system should also calculate the activity in mCi	N
Dose to Perfused Liver Tissue	Calculated by formula found in TS360-TXT-53	numeric	Gy 2 decimal places	N
Lung Shunt Fraction	user entered into treatment draft or post treatment worksheet: Pre-treatment Plan	numeric	% 3 decimal places	N
Activity Delivered to Lungs for Target	Calculated by formula found in TS360-SWR-169	numeric	GBq 2 decimal places *system should also calculate the activity in mCi	N
Dose Delivered to Lungs for Target	Calculated by formula found in TS360-TXT-54	numeric	Gy 2 decimal places	N

(This is not an effective version) Review

4.11.6 TS360-TXT-30 Pre-treatment Template Measurement fields

Data Element	System Generated	Data Type	Format Significant Figures	Range	Invalid Value Message	Source	Editable	Empty Message
Vial Size	Y	numeric	N/A	N/A	N/A	Treatment Details (Portal)	N	N/A
Vial Lot Number	Y	numeric	N/A	N/A	N/A	Manufacturer Lot Number user entered into the Pre-treatment Dose Calibration Measurement Section	N	N/A
Vial Number	Y	numeric	N/A	N/A	N/A	Vial Number user entered into the Pre-treatment Dose Calibration Measurement Section	N	N/A
Date of Measurement	Y	numeric	mm/dd/yyyy		N/A	Defaulted from Date of Measurement entered earlier or Manual Entry	Y	M124 in TS360-TXT-49
Time of Measurement	N	numeric	HH:MM AM/PM (Timezone)	Input value must be > (Pre-treatment Dose Calibration Measurement Time of Measurement)	M152 in TS360-TXT-49	Manual Entry	Y	M125 in TS360-TXT-49
Background Measurement	N	numeric	3 decimal places	Input value must be 0-1000 and less than Vial Measurement on Template	M143 in TS360-TXT-49 If greater than 1000, and M158 in TS360-TXT-49 if greater than Vial Measurement on Template	Manual Entry	Y	M129 in TS360-TXT-49
Vial Measurement on Template	N	numeric	3 decimal places	Input value must be 0-999 and greater than Background Measurement	M144 in TS360-TXT-49 If greater than 999, and M158 in TS360-TXT-49 if less than Background Measurement	Manual Entry	Y	M130 in TS360-TXT-49
Net rate of vial on template	Y, calculated	numeric	3 decimal places	N/A	N/A	Calculated by formula in TS360-SWR-153	N	N/A

(This is not an effective version) Preview

Data Element	System Generated	Data Type	Format Significant Figures	Range	Invalid Value Message	Source	Editable	Empty Message
Vial Size (GBq)	Y	numeric	N/A	N/A	N/A	Treatment Details (Portal)	N	N/A
Vial Lot Number	Y	numeric	N/A	N/A	N/A	Manufacturer Lot Number user entered into the Pre-treatment Dose Calibration Measurement Section	N	N/A
Vial Number	Y	numeric	N/A	N/A	N/A	Vial Number user entered into the Pre-treatment Dose Calibration Measurement Section	N	N/A
Date of Measurement	Y	numeric	mm/dd/yyyy		N/A	Defaulted from Date of Measurement entered earlier or Manual Entry	Y	M124 in TS360-TXT-49
Time of Measurement	N	numeric	HH:MM AM/PM (Timezone)	Input value must be > (Admin Start Time)	M152 in TS360-TXT-49	Manual Entry	Y	M125 in TS360-TXT-49
Background Measurement (mR/h)	N	numeric	3 decimal places	Input value must be 0-1000.000	M147 in TS360-TXT-49	Manual Entry	Y	M129 in TS360-TXT-49
0º (mR/h)	N	numeric	3 decimal places	0-(value entered into the Vial Measurement on Template field)	M148 in TS360-TXT-49	Manual Entry	Y	M135 in TS360-TXT-49
90º (mR/h)	N	numeric	3 decimal places	0-(value entered into the Vial Measurement on Template field)	M149 in TS360-TXT-49	Manual Entry	Y	M135 in TS360-TXT-49
180º (mR/h)	N	numeric	3 decimal places	0-(value entered into the Vial Measurement on Template field)	M150 in TS360-TXT-49	Manual Entry	Y	M135 in TS360-TXT-49
270º (mR/h)	N	numeric	3 decimal places	0-(value entered into the Vial Measurement on Template field)	M151 in TS360-TXT-49	Manual Entry	Y	M135 in TS360-TXT-49

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Average of 4 Orientations minus background (mR/h)	Y, calculated	numeric	3 decimal places	N/A	N/A	Calculated based on average of the 4 cylinder orientations, with the Background Measurement subtracted. If Average is less than background, 0 will display.	N	N/A
Hours between Pre- and Post Treatment Measurements	Y, calculated	numeric	HHh MMm Where: HH is number of hours MM is number of minutes	N/A	N/A	Calculates the HH:MM difference between the Post-treatment Template measurement (date and time) and Pre-treatment Vial template measurement (date and time).	N	N/A
Pre-Treatment net rate decayed to Post-Treat time (mR/h)	Y, calculated	numeric	3 decimal places	N/A	N/A	Calculated by using formula in TS360-TXT-22	N	N/A
Percentage of Vial Delivered	Y, calculated	numeric	% 2 decimal places	N/A	N/A	Calculated by using formula in TS360-TXT-52	N	N/A
Hours between calibration and Treatment	Y, calculated	numeric	HHh MMm Where: HH is number of hours MM is number of minutes	N/A	N/A	Calculates the HH:MM difference between the calibration date/time & administration date/time taking into consideration the time zone of the treatment facility	N	N/A
Activity in waste jar at time of treatment	Y, calculated	numeric	GBq 3 decimal places *system also calculates the activity in mCi	N/A	N/A	Calculated by using formula in TS360-TXT-51	N	N/A
Activity Administered per Vial at time of Treatment	Y, calculated	numeric	GBq 3 decimal places *system also calculates the activity in mCi	N/A	N/A	Calculated by using formula in TS360-TXT-23	N	N/A

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(This is not an effective version)

4.11.7 TS360-TXT-32 Administration Notes - Inputs

Data Element	System Generated	Data Type	Format Significant Figures	Range	Invalid Value Message	Source	Editable	Empty Message	Notes
Vial Size	Y	numeric	N/A	N/A	N/A	Treatment Details (Portal)	N	N/A	Displayed per Vial
Vial Lot Number	Y	numeric	N/A	N/A	N/A	Manufacturer Lot Number user entered into the Pre-treatment Dose Calibration Measurement Section	N	N/A	Displayed per Vial
Vial Number	Y	numeric	N/A	N/A	N/A	Vial Number user entered into the Pre-treatment Dose Calibration Measurement Section	N	N/A	Displayed per Vial
Admin Start Date	Y	numeric	mm/dd/yyyy		N/A	Defaulted from Date of Measurement entered earlier or Manual Entry	Y	M133 in TS360-TXT-49	Displayed per Vial
Admin Start Time	N	numeric	HH:MM AM/PM (Timezone)	Input value must be > (Pre-treatment Template Time of Measurement)	M152 in TS360-TXT-49	Manual Entry	Y	M134 in TS360-TXT-49	Displayed per Vial
Patient dose rate, maximum on contact (mR/h)	N	numeric	2 decimal places	Input value must be 0-1000.00	M145 in TS360-TXT-49	Manual Entry OPTIONAL FIELD	Y	N/A	
Patient dose rate, maximum at 1 meter (mR/h)	N	numeric	2 decimal places	0-(data input from Measurement of Dose vial on Template)	M146 in TS360-TXT-49	Manual Entry OPTIONAL FIELD	Y	N/A	

4.11.8 TS360-TXT-33 Pre-treatment Dose Calibrator Measurements - Input fields validation

Data Element	System Generated	Data Type	Format Significant Figures	Range	Invalid Value Message	Source	Editable	Empty Message	Notes
Manufacturer Lot Number	N	numeric	whole numbers only	Character count: Max 25	N/A	Manual Entry	Y	M122 in TS360-TXT-49	
Vial Number	N	numeric	whole numbers only	Character count: Max 25	N/A	Manual Entry	Y	M123 in TS360-TXT-49	
Date of Measurement	N	numeric	mm/dd/yyyy		N/A	Manual Entry	Y	M124 in TS360-TXT-49	This date should be used as the default

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									to the remaining date collection
Time of Measurement	N	numeric	HH:MM AM/PM (Timezone)		N/A	Manual Entry	Y	M125 in TS360-TXT-49	
Time from Calibration to Measurement	Y, calculated	numeric	HHh MMm Where: HH is number of hours MM is number of minutes		N/A	Calculated by the difference in hours between the calibration date & measurement date/time	N	N/A	
Dose Calibrator Measured Activity	N	numeric	mCi 2 decimal places *system should also calculate the activity in GBq	Input value must be 0-(vial size in mCi).	M141 in TS360-TXT-49	Manual Entry	Y	M126 in TS360-TXT-49	
Manufacturer's Activity at Calibration	N	numeric	GBq 2 decimal places *system should also calculate the activity in mCi	Input value must be 0-22	M142 in TS360-TXT-49	Manual Entry	Y	M127 in TS360-TXT-49	This comes from the manufacturer's Calibration Data Sheet, in GBq.
Dose Calibrator Measured Activity at Treatment	Y, calculated	numeric	GBq 2 decimal places *system should also calculate the activity in mCi		N/A	Calculated by the formula in TS360-TXT-55	N	N/A	
Value to be used in final calculations	N	dropdown	N/A	N/A	N/A	N/A	Y	M128 in TS360-TXT-49	

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4.11.9 TS360-TXT-34 Treatment Information - Inputs and Outputs

Data Element	System Generated	Data Type	Format Significant Figures	Range	Source	Editable	Notes
Lung Mass (kg)	Y, if available	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14	Treatment Details (Portal) OR Manual Entry	Only if no SCD data	All limits and messages same as TS360-TXT-14
Target Volume (cc)	Y, if available	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14	Treatment Details (Portal) OR Manual Entry	Only if no SCD data	All limits and messages same as TS360-TXT-14

Previous Dose to Lungs (Gy)	Y, if available	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14	Treatment Details (Portal) OR Manual Entry	Only if no SCD data	All limits and messages same as TS360-TXT-14
Lung Shunt Fraction (%)	Y, if available	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14	Treatment Details (Portal) OR Manual Entry	Only if no SCD data	All limits and messages same as TS360-TXT-14
Anticipated Residual Waste (%)	Y	numeric	N/A	N/A	Written Directive - Anticipated Residual Waste	N	
Target Name	Y	String	N/A	N/A	Written Directive - Treatment Site	N	
Vial Size	Y	numeric	1 decimal place (e.g. 3.0 GBq)	N/A	Treatment Details (Portal)	N	Displayed Per Vial
Calibration Date	Y	numeric	Week [1 or 2] - MONTH DD(with suffix) YYYY (e.g. Week 1- June 2nd, 2024)	N/A	Treatment Details (Portal)	N	Displayed Per Vial
Time from Calibration to Treatment	Y, calculated	numeric	HHh MMm Where: HH is number of hours MM is number of minutes	N/A	Difference in hours between the calibration date & treatment date/time	N	Displayed Per Vial
Nominal Activity at Treatment (GBq)	Y, calculated	numeric	GBq 2 decimal places *system should also calculate the activity in mCi	N/A	Calculated using formula in TS360-TXT-57	N	Displayed Per Vial
Sum of Nominal Activity (GBq)	Y, calculated	numeric	GBq 2 decimal places *system should also calculate the activity in mCi	N/A	Calculated by summation of all nominal activity at treatments for the target.	N	
Calculated Absorbed Dose (Gy) (formally Dose to Target Volume at Treatment As Ordered)	Y, calculated	numeric	Gy 2 decimal places	N/A	Calculated using formula in TS360-TXT-58	N	

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Calculated Dose to Lungs for Target (Gy)	Y, calculated	numeric	Gy 2 decimal places	N/A	Calculated using formula in TS360-TXT-18	N	
Cumulative Dose to Lungs for Target (Gy)	Y, calculated	numeric	Gy 2 decimal places	N/A	Calculated by adding Previous Dose to Lungs (Gy) + Calculated dose to lungs for Target (Gy)	N	

4.11.10 TS360-TXT-35 MCD Output limits and Warnings

Output Field	Data Type	Source	Significant Figures to Display (Input and Output)	Limit	Limit Message
Calculated Whole Liver Mass (kg)	Positive Number	Calculated using formula in TS360-TXT-38	3 decimal places (ex: 0.312 kg or 1.532 kg)	N/A	N/A
Calculated Perfused Mass (kg)	Positive Number	Calculated using formula in TS360-TXT-38	3 decimal places (ex: 0.312 kg or 1.532 kg)	N/A	N/A
Calculated Tumor Mass (kg)	Positive Number	Calculated using formula in TS360-TXT-38	3 decimal places (ex: 0.312 kg or 1.532 kg)	N/A	N/A
Calculated Normal Tissue Mass (kg)	Positive Number	Calculated using formula in TS360-TXT-38	3 decimal places (ex: 0.312 kg or 1.532 kg)	N/A	N/A
Activity at Treatment (GBq)	Positive Number	Calculated using formula in TS360-TXT-13	2 decimal places (ex: 5.53 GBq or 50.51 GBq)	N/A	N/A
Activity at Treatment (mCi)	Positive Number	Calculated using Activity at Treatment (GBq) and formula in TS360-SWR-24	2 decimal places (ex: 149.45 mCi or 148.92 mCi)	N/A	N/A
Perfused Volume Absorbed Dose (Gy)	Positive number	Calculated using formula in TS360-TXT-58 Where A is Activity at Treatment for the target in GBq.	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	>2,000 Gy	M137 in TS360-TXT-49
Tumor Absorbed Dose (Gy)	Positive number	Calculated using formula in TS360-TXT-11	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	>2,000 Gy	M137 in TS360-TXT-49
Normal Tissue Absorbed Dose (Gy)	Positive number	Calculated using formula in TS360-TXT-20	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	N/A	N/A
Calculated dose to lungs (Gy)	Positive number	Calculated using formula in TS360-TXT-18	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	N/A	N/A

(This is not an effective version) Review

Total dose to lungs (Gy)	Positive number	Calculated using formula in TS360-SWR-338	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	30 Gy	M39 in TS360-TXT-49
Cumulative dose to lungs (Gy)	Positive number	Calculated using formula in TS360-SWR-15	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	50 Gy	M40 in TS360-TXT-49
Whole liver dose (Gy)	Positive number	Calculated using formula in TS360-TXT-12	2 decimal places (ex: 5.53 Gy or 50.51 Gy)	Outside of 80-150 Gy	M76 in TS360-TXT-49

4.11.11 TS360-TXT-40 Treatment Draft Modal Limits and Warnings

Input Field	Data Type	Max Length	Symbols	Invalid Symbol Warning Message	Empty Warning Message
Patient First Name	Text entry	50	ABC, abc, 0-9, Symbols: Space, Period, Dash, Underscore, Parathesis	M1 in TS360-TXT-49	M2 in TS360-TXT-49
Patient Last Name	Text entry	50	ABC, abc, 0-9, Symbols: Space, Period, Dash, Underscore, Parathesis	M1 in TS360-TXT-49	M3 in TS360-TXT-49
Patient Reference ID (optional)	Text entry	50	ABC, abc, 0-9, Symbols: Space, Period, Dash, Underscore, Parathesis	M1 in TS360-TXT-49	N/A
Treatment Facility	Dropdown	N/A	N/A	N/A	M4 in TS360-TXT-49

4.11.12 TS360-TXT-41 Case Details Limits and Warnings

Input Field	Data Type	Max Length	Symbols	Invalid Symbol Message	Empty Message
Referring Physician	Text entry	50	ABC, abc, 0-9, Symbols: Space, Period, Dash, Underscore, Parathesis	M1 in TS360-TXT-49	N/A
Treating Physician	Dropdown	N/A	N/A	N/A	M5 in TS360-TXT-49
Disease Type	Dropdown	N/A	N/A	N/A	M6 in TS360-TXT-49
Treatment Goal	Dropdown	N/A	N/A	N/A	M7 in TS360-TXT-49
Treatment Approach	Dropdown	N/A	N/A	N/A	M8 in TS360-TXT-49
Mapping Date	Date	N/A	N/A	N/A	M9 in TS360-TXT-49

Review (This is not an Effective version)

4.11.13 TS360-TXT-42 Target Name

Input Field	Data Type	Max Length	Symbols	Invalid Symbol Error Message	Empty Error Message
Target Name	Text entry	25	ABC, abc, 0-9, Symbols: Space, Period, Dash, Underscore, Parathesis	M1 in TS360-TXT-49	M30 in TS360-TXT-49

4.11.14 TS360-TXT-43 Vial Display Parameters

Output Field	Data Type	Source	Significant Figures to Display (Input and Output)
Vial Size	Positive number	Size of Vial in GBq	0-1 decimal places (ex: 3 GBq or 3.5 GBq)
Absorbed Dose (Gy)	Positive whole number	Calculated using formula in TS360-TXT-58	0 decimal places (ex: 150 Gy or 1500 Gy)
Activity at Treatment (GBq)	Positive number	Calculated using formula in TS360-TXT-57	2 decimal places (ex: 0.28 GBq or 1.28 GBq)
Estimated RPM* (Bq)	Positive whole number	Calculated using formula in TS360-TXT-56	0 decimal places (ex: 375 Bq or 1166 Bq)
% of Desired Dose	Positive or Negative Percentage	Calculated using formula in TS360-TXT-60	2 decimal places (ex: - 71.35 % or + 38.5 %)
% of Vial Activity	Positive or Negative Percentage	Calculated using formula in TS360-TXT-61	2 decimal places (ex: - 71.35 % or + 38.5 %)
Calculated Dose To Lungs (Gy)	Positive number	Calculated using formula in TS360-TXT-18	2 decimal places (ex: 2.15 Gy or + 10.15 Gy)
Total activity at treatment for all target vials (GBq)	Positive number	Calculated by summation of Activity at Treatment for all target vials.	2 decimal places (ex: 0.28 GBq or 1.28 GBq)
Total absorbed dose for all target vials (Gy)	Positive whole number	Calculated by summation of Absorbed Dose for all target vials.	0 decimal places (ex: 73 Gy or 473 Gy)

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(This is not an effective version)

Total dose to lungs for all vials (Gy)	Positive number	Calculated by summation in TS360-SWR-338	2 decimal places (ex: 2.15 Gy or + 10.15 Gy)
Total cumulative dose to lungs for all vials (Gy)	Positive number	Calculated by summation of TS360-SWR-15	2 decimal places (ex: 2.15 Gy or + 10.15 Gy)
Activity at treatment for all vials (GBq)	Positive number	Calculated by summation of Activity at Treatment for all vials.	2 decimal places (ex: 0.28 GBq or 1.28 GBq)

4.11.15 TS360-TXT-44 Review and Submit PO Number

Input Field	Data Type	Max Length	Symbols Allowed to be entered into field
PO Number (optional)	Text entry	50	ABC, abc, 0-9, Symbols: dash, space

4.11.16 TS360-TXT-50 Email Draft

Input Field	Data Type	Options	Empty Warning Message
Select User	Dropdown	Select User: list of TS360 users within the current user's Treatment Facility	M99 in TS360-TXT-49
Select Step	Dropdown	Select Step: Case Details, Treatment Date, Activity Calculator, Vial Selector, Review and Submit	M100 in TS360-TXT-49

4.11.17 TS360-TXT-64 Vial Selection Input Limits and Warnings

Input Field	Data Type	Significant Figures to Display (Input and Output)	Lower Limit (greater than or equal to)	Upper Limit (less than or equal to)	Limit Message	Soft Limit	Soft Limit Message	Empty Message
Desired Dose (Gy)	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14	Same as TS360-TXT-14
Desired Activity at Treatment (GBq)	Positive number	2 decimal places (ex: 0.98 GBq or 4.26 Gbq)	0.01 GBq	50 GBq	M72 in TS360-TXT-49	N/A	N/A	N/A

Review (This is not an effective version)