

NovoTAL™ flex

Version 1.0

Instructions For Use

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I. Software Description

NovoTAL™ flex is a software which is used to generate a transducer array layout mapping for Optune Gio patients.

The process includes generation of the array layouts by Novocure radiologists, after receiving patients' MRI images and entering morphological measurements of the head and a specific tumor location into the NovoTAL flex software. Generated layouts are then provided to prescribing physicians. It is an accessory of the Optune Gio treatment kit.

II. Intended Purpose

The NovoTAL flex software is intended to be used internally by trained radiologists to provide physicians prescribing Optune Gio with transducer array layout maps.

III. Intended Users, Use Environment, Contraindications, Warnings, Precautions and Notices

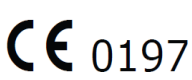
The NovoTAL flex software is not intended to treat patients directly. It serves as an accessory for Optune Gio medical device, used to treat patients with recurrent and newly diagnosed WHO grade 4 glioma.

IV. Mechanism of Action & Performance

The software, NovoTAL flex, is being used to plan the optimal transducer array layout (TAL) for each patient, based on the location of the tumor.

The NovoTAL flex software selects a transducer array layout based on the distribution of Tumor Treating Fields (TTFields) within the brain, morphological measurements of the head and a specific tumor location for the patient to be treated.

V. Glossary of Symbols

	Follow instructions for use
	Medical Device
	Manufacturer Information: Novocure GmbH, Neuhofstrasse 21, 6340 Baar, Switzerland
	Part number
	Unique Device Identifier Indicates a device carries Unique Device Identifying information.
	Caution Consult the instructions for use for important cautionary information such as warnings and precautions
	CE Mark with Notified Body Number
	European authorized representative MDSS GmbH Schiffgraben 41 30175 Hannover, Germany
	Importer details: Novocure Netherlands B.V., Ekkersrijt 2066, 5692 BA Son en Breugel, The Netherlands

VI. Before you begin

The NovoTAL flex software should be used by Novocure radiologists who have undergone training and certification by Novocure in the operation of the software.

Software setup and hardware requirements

The NovoTAL flex software is supplied to users already installed on a laptop that is managed according to Novocure Information Technology General Controls (ITGCs) and Policies, running Microsoft Windows. The computer is password protected and can only run software installed by Novocure.

In order to obtain a personal username and password the user should contact Novocure's technical support e-mail at novotal@novocure.com. Username and password will be supplied only to users who have been certified by Novocure.

The username and password are personal and should not be transferred to anyone who has not undergone formal training and certification by Novocure for the prescription and use of the Optune Gio system.

NovoTAL flex may include Protected Health Information (PHI). Care should be taken to protect the laptop computer from unauthorized access when not in use.

In case the username or password is lost or forgotten please contact Novocure's technical support to have a new password issued.

Network connectivity notices

The laptop on which NovoTAL flex is installed includes network connectivity, though NovoTAL flex does not require a network connection to function.

Execution of NovoTAL flex while the laptop is connected to a network could result in previously unidentified risks. The Novocure radiologists using NovoTAL flex are advised to identify, analyze, evaluate and control these risks. Subsequent changes to the network could introduce new risks and require additional analysis. Changes to the network could include network configuration, addition of software platforms or software applications, removal of items from the network, update of hardware and/or software platforms or software applications, and upgrades of hardware and/or software platforms or software applications.

VII. Directions For Use:

1. Running the NovoTAL flex application

From the desktop double click on the NovoTAL flex icon -



2. Logging in for the first time

Enter your username and password in the appropriate fields:

The screenshot shows a window titled 'Novocure Patient Transducer Array Layout (NovoTAL™ flex)'. The window has a dark green header bar with 'User Login' on the left and 'NovoTAL™ flex' on the right. The main area is white and contains the text 'Please enter your User ID and Password'. Below this are two input fields: 'User ID' and 'Password'. There is a checkbox labeled 'Select to update user information' and an 'OK' button at the bottom.

After clicking OK or pressing <Enter> the following screen will appear:

The screenshot shows a window titled 'Novocure Patient Transducer Array Layout (NovoTAL™ flex)'. The window has a dark green header bar with 'Update user personal information' on the left and 'NovoTAL™ flex' on the right. The main area is white and contains the text 'Please enter the following information'. Below this are five input fields: 'User ID' (containing 'Jane.Doe'), 'Password' (containing '*****'), 'First name', 'Last name', and 'Clinic/Hospital name'. There is an 'OK' button at the bottom.

Enter your first name, last name and institution name (hospital or clinic).

After clicking OK or pressing <enter> a list of existing measurement records will appear.

3. Subsequent use of the software – login:

You will be prompted to enter your username and password as in section VII.2 above, however you will not need to re-enter your name and institution. You can update this personal information at any subsequent login by checking the check box in the right lower corner of the login screen:

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

X

User Login

NovoTAL™ flex

Please enter your User ID and Password

User ID

Password

Select to update user information ☒

OK

4. Record management:

After logging in the following screen will appear:

QSD-QR-039 EU(EN) Rev 01.0 NovoTAL flex IFU
Issue Date : January 2026

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

Patient Records

NovoTAL™ flex

Physician name | Jane Doe

Patient Records

Patient Name	Patient ID	Report Date
--------------	------------	-------------

New Patient Record

Delete Patient Data

Load Patient Data

Close

Click the New Patient Record button to start entering measurements for a new transducer array layout. The measurement View Form will appear. Go to section VII.5 for instructions on completing this form.

Or

Select an existing record from the list and click Load Patient Data to review an existing set of measurements.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

Patient Records

NovoTAL™ flex

Physician name

Jane Doe

Patient Records

Patient Name	Patient ID	Report Date
John Doe	12345	Oct 25, 2022 01:51 PM

New Patient Record

Delete Patient Data

Load Patient Data

Close

Or

Select an existing record from the list and click Delete Patient Data to delete an existing set of measurements. If you choose this option a pop-up box will appear asking you to verify you wish to delete this record. The record will be deleted only if you click OK. If you change your mind, click Cancel.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

X

Patient Records

NovoTAL™ flex

Physician name

Jane Doe

Patient Records

Patient Name	Patient ID	Report Date
John Doe	12345	Oct 25, 2022 01:51 PM

Are you sure you want to delete the selected items?

OK

Cancel

New Patient Record

Delete Patient Data

Load Patient Data

Close

5. Entering head size measurements:

Step 1 – Enter patient identification details

Your name will appear automatically in the top left of the measurement View Form in the Planning Physician field and cannot be edited. The Ordering Physician field is defaulted to your name but can be edited.

Enter the patient name, patient identifier (ID), and select gender (defaulted to Male) in the appropriate fields. If you choose so, you can also add the patient date of birth and date of MRI in the appropriate fields. Note that the Patient Name, Patient ID and Gender are compulsory fields. You will not be able to proceed to the next screen until you have filled these fields. Date of birth and date of MRI may be entered after proceeding to the next screens as well.

Note – All measurements should be in millimeters. No decimal points are accepted.

Step 2 – Enter axial view head coordinates

The following measurements should be made on an axial T1 sequence MRI at the most superior image which still includes the orbits (uppermost edge of the orbits) or one image above the orbits:

- a. Maximal anterior-posterior (AP) size of the patient's head – this measurement should be entered in the field named "1. Front to Back (AP)".
- b. Maximal head width measured perpendicular to the AP midline of the head – this measurement should be entered in the field named "2. Right to Left (Lat)".
- c. Distance from right to midline measured perpendicular to the AP midline of the head – this measurement should be entered in the field named "3. Right to Midline".

A generic example of how to make these measurements is shown on the right hand side of the View Form screen.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

View Form

NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Description	Comment
Axial Head Coordinates	
Coronal Head Coordinates	
Axial Tumor Coordinates 1	
Coronal Tumor Coordinates 1	

View type
Axial Head Coordinates

1. Front to Back (AP) 183 mm
2. Right to Left (Lat) 143 mm
3. Right to Midline 70 mm

Sequence
Slice #

Comments

Add file ...

Axial head size:
Axial view
Uppermost level of orbits
Three measurement needed:
1. Front to back (AP)
2. Right to left (Lat)
3. Right to midline
All measurements should be in millimeters

Next
Cancel
Save

You may add information about the MRI sequence and slice on which measurements were performed in the appropriate fields. A text comment can also be added in the Comments field at your discretion.

You may attach a file (e.g. exported MRI image with measurements from your MRI viewer) by clicking the ... symbol on the right side of the Add File field.

At any stage you can:

- Click cancel and none of the information entered or modified for the current patient will be saved.
- Once measurements are entered correctly, you can click Next and move to the Coronal Head Coordinates screen for entering the next set of measurements.

If the Patient Name and Patient ID have not been entered, or if the measurements entered are invalid, then a text box with the message: “The data entered is invalid, you can’t continue until you fix it.” will appear. When you click on the OK button in the box, then you will return to the data entry screen, and the invalid fields will appear in red. If you move the mouse over one of the invalid fields, the limitations on the input in that field will appear in a text box.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

View Form NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Description	Comment
Axial Head Coordinates	
Coronal Head Coordinates	
Axial Tumor Coordinates 1	
Coronal Tumor Coordinates 1	

View type: Axial Head Coordinates

- Front to Back (AP)
- Right to Left (Lat)
- Right to Midline

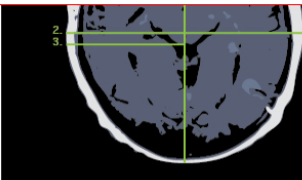
The data entered is invalid, you can't continue until you fix it.

OK

Sequence: Slice #: Comments: Add file: ...

Next Cancel Save

Axial head size:
Axial view
Uppermost level of orbits
Three measurement needed:
1. Front to back (AP)
2. Right to left (Lat)
3. Right to midline
All measurements should be in millimeters



Novocure Patient Transducer Array Layout (NovoTAL™ flex)

View Form NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Description	Comment
Axial Head Coordinates	
Coronal Head Coordinates	
Axial Tumor Coordinates 1	
Coronal Tumor Coordinates 1	

View type: Axial Head Coordinates

- Front to Back (AP)
- Right to Left (Lat)
- Right to Midline

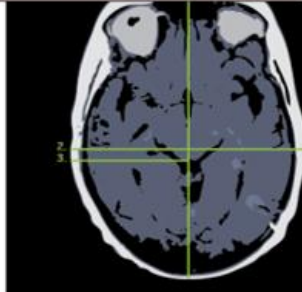
Right to left measurement should be smaller than front to back measurement

143 mm
70 mm

Sequence: Slice #: Comments: Add file: ...

Next Cancel Save

Axial head size:
Axial view
Uppermost level of orbits
Three measurement needed:
1. Front to back (AP)
2. Right to left (Lat)
3. Right to midline
All measurements should be in millimeters



Step 3 – Enter coronal view head coordinates

The following measurements should be made on coronal T1 sequence MRI at the level of the ear canal:

- Draw an imaginary line beneath the temporal lobes at the level of the tentorium (horizontal dashed line in the example below)
- Maximal apex to tentorium height of the patient's head (through the midline perpendicular to the line described in a.) – this measurement should be entered in the field named "1. Superior to Tentorium".
- Maximal head width (measured parallel to the line measured in a.) – this measurement should be entered in the field named "2. Right to Left (Lat)".
- Distance from right to midline (measured parallel to the line measured in a.) – this measurement should be entered in the field named "3. Right to Midline".

A generic example of how to make these measurements is shown on the right hand side of the View Form screen.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

View Form

NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Description	Comment
Axial Head Coordinates	
Coronal Head Coordinates	
Axial Tumor Coordinates 1	
Coronal Tumor Coordinates 1	

View type

Coronal Head Coordinates

1. Superior to Tentorium

190

mm

2. Right to Left (Lat)

150

mm

3. Right to Midline

65

mm

Sequence

Slice #

Comments

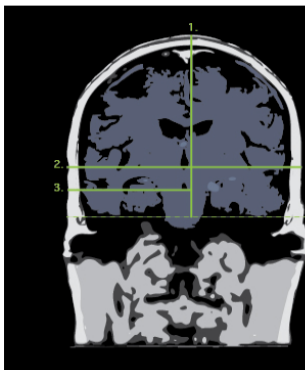
Add file

...

Next

Cancel

Save



Coronal head size:

Coronal view

Level of ear canals

Three measurement needed:

1. Superior to tentorium

2. Right to left (Lat)

3. Right to midline

All measurements should be in millimeters

You may add information about the MRI sequence and slice on which measurements were performed in the appropriate fields. A text comment can also be added in the Comments field at your discretion.

You may attach a file (e.g. exported MRI image with measurements from your MRI viewer) by clicking the ... symbol on the right side of the Add File field.

At any stage, you can:

- a. Click cancel and none of the information entered or modified for the current patient will be saved.
- b. Once all measurements are entered correctly, you can click Next and move to the Axial Tumor Coordinates screen for entering the next set of measurements.

If the measurements entered into the system are invalid, then a text box with the message: “The data entered is invalid, you can’t continue until you fix it” will appear. When you click on the OK button in the box, then you will return to the data entry screen, and the invalid fields will appear in red. If you move the mouse over one of the invalid fields, the limitations on the input in that field will appear in a text box.

6. Entering tumor coordinates:

After entering the head measurements as described in section **Error! Reference source not found..5** above, you will be asked to enter measurements of the tumor. For multiple tumors, this step can be repeated as often as needed (see section **Error! Reference source not found..7** below).

Step 1 – Enter axial view tumor measurements

The following measurements should be made on an axial T1 sequence MRI at the level of the maximal enhancing tumor diameter:

- a. Maximal anterior-posterior (AP) size of the patient’s head – this measurement should be made without the nose (see example below) and entered in the field named “1. Front to Back (AP) –w/o nose”.
- b. Maximal head width measured perpendicular to the AP midline of the head – this measurement should be entered in the field named “2. Right to Left (Lat)”.
- c. Distance from right to midline measured perpendicular to the AP midline of the head – this measurement should be entered in the field named “3. Right to Midline”.
- d. Distance from right to closest tumor margin measured perpendicular to the AP midline of the head – this measurement should be entered in the field named “4. Right to Close”.
- e. Distance from right to farthest tumor margin measured perpendicular to the AP midline of the head – this measurement should be entered in the field named “5. Right to Far”.
- f. Distance from front of head to the closest tumor margin measured parallel to the AP midline of the head – this measurement should be entered in the field named “6. Front to Close”.
- g. Distance from front of head to the farthest tumor margin measured parallel to the AP midline of the head – this measurement should be entered in the field named “7. Front to Far”.

A generic example of how to make these measurements is shown on the right hand side of the View Form screen.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

View Form

NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Description	Comment
Axial Head Coordinates	
Coronal Head Coordinates	
Axial Tumor Coordinates 1	
Coronal Tumor Coordinates 1	

View type

Axial Tumor Coordinates 1

1. Front to Back (AP) - w/o nose mm
2. Right to Left (Lat) mm
3. Right to Midline mm
4. Right to Close mm
5. Right to Far mm
6. Front to Close mm
7. Front to Far mm

Sequence
Slice #

Comments

Add file ...

Next

Preview

Cancel

Save

Axial tumor size:
Axial view
Level of maximal tumor diameter
Seven measurement needed:
1. Front to back (AP) - w/o nose
2. Right to left (Lat)
3. Right to midline
4. Right to close tumor margin
5. Right to far tumor margin
6. Front to close tumor margin
7. Front to far tumor margin
All measurements should be in millimeters

You may add information about the MRI sequence and slice on which measurements were performed in the appropriate fields. A text comment can also be added in the Comments field at your discretion.

You may attach a file (e.g. exported MRI image with measurements from your MRI viewer) by clicking the ... symbol on the right side of the Add File field.

At any stage, you can:

- Click Cancel and none of the information entered or modified for the current patient will be saved.
- Once all measurements are entered correctly, you can click Preview to view a schematic showing the approximate position and size of the tumor within the axial plane of the patient's head. The schematic will appear to the right of the measurements. The head volume is shown in grey, and the tumor in white. The tumor is approximated as an ellipsoid. The size of the head and the size and position of the tumor are deduced from all measurements entered into the software. You can close the schematic by clicking on the X to the top right of the schematic.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

View Form

NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Description	Comment
Axial Head Coordinates	
Coronal Head Coordinates	
Axial Tumor Coordinates 1	
Coronal Tumor Coordinates 1	

View type

Axial Tumor Coordinates 1

1. Front to Back (AP) - w/o nose

171

mm

2. Right to Left (Lat)

132

mm

3. Right to Midline

65

mm

4. Right to Close

50

mm

5. Right to Far

60

mm

6. Front to Close

50

mm

7. Front to Far

60

mm

Sequence

Slice #

Comments

Add file

...

X

Axial tumor size:

Axial view

Level of maximal tumor diameter

Seven measurement needed:

1. Front to back (AP) - w/o nose

2. Right to left (Lat)

3. Right to midline

4. Right to close tumor margin

5. Right to far tumor margin

6. Front to close tumor margin

7. Front to far tumor margin

All measurements should be in millimeters

Next

Preview

Cancel

Save

- c. Once measurements are entered correctly, you can click Next and move to the Coronal Tumor Coordinates screen for entering the next set of measurements.

If the measurements entered into the system are invalid, then a text box with the message: “The data entered is invalid, you can’t continue until you fix it” will appear. When you click on the OK button in the box, then you will return to the data entry screen, and the invalid fields will appear in red. If you move the mouse over one of the invalid fields, the limitations on the input in that field will appear in a text box.

Step 2 – Enter coronal view tumor coordinates

The following measurements should be made on a coronal T1 sequence MRI at the level of the maximal enhancing tumor diameter:

- Draw an imaginary line at the lowest level of the tentorium (horizontal dashed line in the example below)
- Maximal apex to tentorium height of the patient's head (through the midline perpendicular to the line described in a.) – this measurement should be entered in the field named "1. Superior to Tentorium".
- Maximal head width (measured parallel to the line measured in a.) – this measurement should be entered in the field named "2. Right to Left (Lat)".
- Distance from right to midline (measured parallel to the line measured in a.) – this measurement should be entered in the field named "3. Right to Midline".
- Distance from right to closest tumor margin (measured parallel to the line measured in a.) – this measurement should be entered in the field named "4. Right to Close".
- Distance from right to farthest tumor margin (measured parallel to the line measured in a.) – this measurement should be entered in the field named "5. Right to Far".
- Distance from top of head to the closest tumor margin (measured perpendicular to the line measured in a.) – this measurement should be entered in the field named "6. Superior to Close".
- Distance from top of head to the farthest tumor margin (measured perpendicular to the line measured in a.) – this measurement should be entered in the field named "7. Superior to Far".

A generic example of how to make these measurements is shown on the right hand side of the View Form screen.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

View Form

NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Description	Comment
Axial Head Coordinates	
Coronal Head Coordinates	
Axial Tumor Coordinates 1	
Coronal Tumor Coordinates 1	

View type: Coronal Tumor Coordinates 1

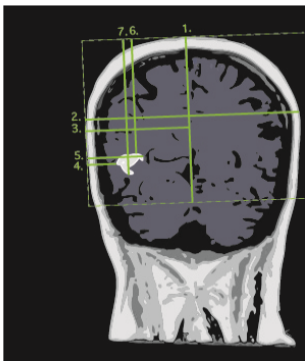
1. Superior to Tentorium	122	mm
2. Right to Left (Lat)	131	mm
3. Right to Midline	66	mm
4. Right to Close	50	mm
5. Right to Far	60	mm
6. Superior to Close	50	mm
7. Superior to Far	60	mm

Sequence: Slice #:

Comments:

Add file:

Next Preview Cancel Save



Coronal tumor size:
Coronal view
Level of maximal tumor diameter
Seven measurement needed:
1. Superior to tentorium
2. Right to left (Lat)
3. Right to midline
4. Right to close tumor margin
5. Right to far tumor margin
6. Superior to close tumor margin
7. Superior to far tumor margin
All measurements should be in millimeters

You may add information about the MRI sequence and slice on which measurements were performed in the appropriate fields. A text comment can also be added in the Comments field at your discretion.

You may attach a file (e.g. exported MRI image with measurements from your MRI viewer) by clicking the ... symbol on the right side of the Add File field.

At any stage, you can:

- Click Cancel and none of the information entered or modified for the current patient will be saved.
- Once all measurements are entered correctly, you can click Preview to view a schematic showing the approximate position and size of the tumor within the coronal plane of the patient's head. The schematic will appear to the right of the measurements. The head volume is shown in grey, and the tumor in white. The tumor is approximated as an ellipsoid. The size of the head and the size and position of the tumor are deduced from all measurements entered into the software. You can close the schematic by clicking on the X to the top right of the schematic.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

View Form NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Description	Comment
Axial Head Coordinates	
Coronal Head Coordinates	
Axial Tumor Coordinates 1	
Coronal Tumor Coordinates 1	

View type: Coronal Tumor Coordinates 1

- Superior to Tentorium: 122 mm
- Right to Left (Lat): 131 mm
- Right to Midline: 66 mm
- Right to Close: 50 mm
- Right to Far: 60 mm
- Superior to Close: 50 mm
- Superior to Far: 60 mm

Sequence: Slice #:

Comments:

Add file: ...

Next
Preview
Cancel
Save

Coronal tumor size:

Coronal view

Level of maximal tumor diameter

Seven measurement needed:

- Superior to tentorium
- Right to left (Lat)
- Right to midline
- Right to close tumor margin
- Right to far tumor margin
- Superior to close tumor margin
- Superior to far tumor margin

All measurements should be in millimeters

- Once measurements are entered correctly, you can click Next and move to the QA Form.

If the measurements entered into the system are invalid, then a text box with the message: “The data entered is invalid, you can’t continue until you fix it” will appear. When you click on the OK button in the box, then you will return to the data entry screen, and the invalid fields will appear in red. If you move the mouse over one of the invalid fields, the limitations on the input in that field will appear in a text box.

7. Entering coordinates for additional tumors:

Once you have completed the head and tumor measurements the QA Form screen will appear. You can now click More Tumors and repeat section **Error! Reference source not found..6** above. This step can be performed for as many tumors as needed.

8. The QA Form screen:

This screen displays all measurements entered into the system, along with schematic diagrams showing the approximate size and position of tumor in axial and coronal planes as described in section **Error! Reference source not found..6** above. The diagrams are found to the left of the corresponding set of measurements.

The screen allows you to manage the measurements you have entered using the following options:

- Edit – double click the measurement you want to edit. This measurement screen will open and allow you to make changes to the data entered. You can also edit a measurement by highlighting the measurement with a single click, and then clicking the Edit button.
- Delete – allows you to delete a specific tumor. Select one of the measurements of the tumor you want to delete and click the Delete button.
- More Tumors – add more tumors as described in section **Error! Reference source not found..7** above.
- Export – allows you to save the measurements, comments and attachments to an external flash drive and create a PDF file with the data.
- Save – saves all measurements to the local hard drive
- Back to Main – takes you to Patient Records screen. If data was not saved or exported this will erase all measurements made for this patient during this login session.
- Generate Transducer Array Layout – click this button for a transducer array layout to be generated based on the measurements made.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

QA Form

NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Description	Image	Measurements		Comment
Axial Head Coordinates		Front to Back (AP)	183 mm	
		Right to Left (Lat)	143 mm	
		Right to Midline	70 mm	
Coronal Head Coordinates		Superior to Tentorium	130 mm	
		Right to Left (Lat)	139 mm	
		Right to Midline	70 mm	
Axial Tumor Coordinates 1		Front to Back (AP) - w/o nose	171 mm	
		Right to Left (Lat)	132 mm	
		Right to Midline	65 mm	
		Right to Close	50 mm	
		Right to Far	60 mm	
		Front to Close	50 mm	
		Front to Far	60 mm	
Coronal Tumor Coordinates 1		Superior to Tentorium	122 mm	
		Right to Left (Lat)	131 mm	
		Right to Midline	66 mm	
		Right to Close	50 mm	
		Right to Far	60 mm	
		Superior to Close	50 mm	
		Superior to Far	60 mm	

Edit

Delete

More Tumors

Generate Transducer Array Layout

Export

Save

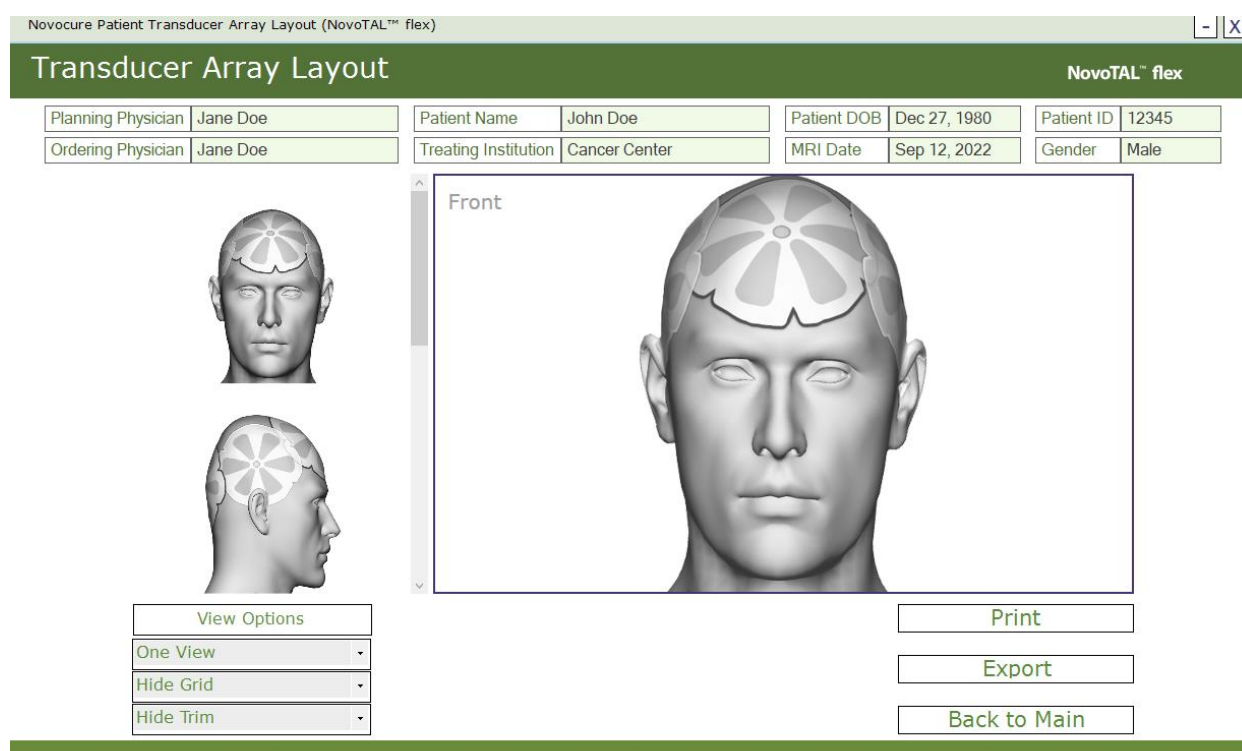
Back to Main

If you decide to edit tumor measurements, then when you return to the appropriate tumor measurement screen, you will see the schematic showing the position of the tumor to the right of the measurements. You can close this schematic by clicking on the X to the top right of the schematic.

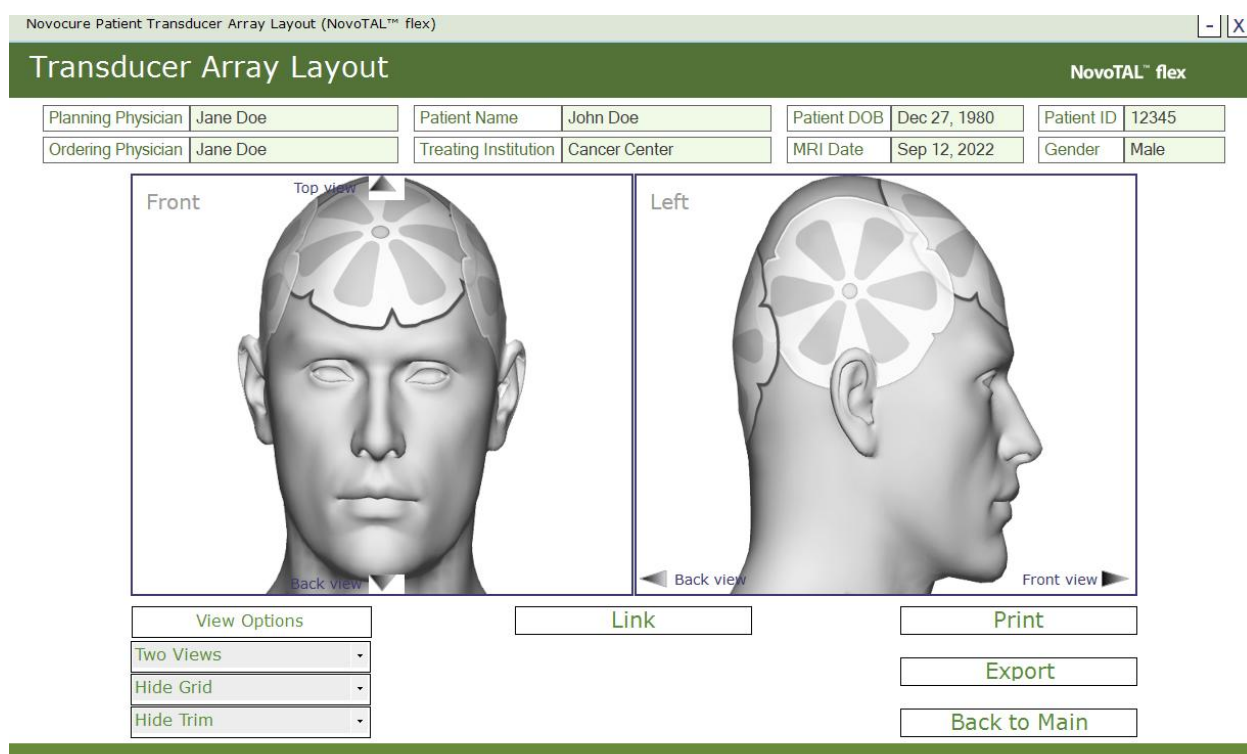
9. The Transducer Array Layout screen:

This screen allows you to view the transducer array layout for this patient using several different views:

- a. **Thumbnails** – This is the default screen which will appear first. You select this view by choosing the “One view” option in the bottom left of the screen. You can scroll through the thumbnails on the left using the vertical slider bar. Click the thumbnail you wish to view in the enlarged image box.



- b. **Two tiles** – You can select this view by choosing the “Two views” option in the bottom left of the screen. You can scroll vertically through different views on the left using the arrow buttons on the top and bottom of the left view. You can scroll horizontally through different views on the right using the arrow buttons on the left and right of the right view.



You can link the two images by toggling the Link/Unlink button in the center of the screen. When linked, the two views will scroll sequentially through the different head views when clicking the arrows on the right and left of the screen.

For both the Thumbnail view and the Two-tile view there are additional view options available:

- a. Show/hide grid – by selecting the Show Grid option from the pull down menu on the bottom left of the screen, a 1X1 cm grid will be overlaid on the image shown on the screen. Selecting Hide Grid removes this overlay.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

Transducer Array Layout

NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Front

Top view

Back view

Left

Back view

Front view

View Options

Two Views

Show Grid

Hide Trim

Link

Print

Export

Back to Main

- b. Show/hide trim lines – Selecting the Show Trim option from the pull down menu on the bottom left of the screen adds dotted trim lines to the arrays layout views showing where the medical tape surrounding the arrays could potentially be trimmed. Selecting Hide Trim removes these dotted lines.

Novocure Patient Transducer Array Layout (NovoTAL™ flex)

Transducer Array Layout

NovoTAL™ flex

Planning Physician	Jane Doe	Patient Name	John Doe	Patient DOB	Dec 27, 1980	Patient ID	12345
Ordering Physician	Jane Doe	Treating Institution	Cancer Center	MRI Date	Sep 12, 2022	Gender	Male

Front

Top view

Back view

Right

Front view

Back view

View Options

Two Views

Hide Grid

Show Trim

Link

Print

Export

Back to Main

10. Exporting, saving and printing Transducer Array Layouts:

Clicking the Print button will print a document with the following information to a local printer:

- Cover Sheet with identifying information and MRI information (if entered).
- Measurements report with all measurements entered into the software.
- 5 basic views of the transducer array layout (Right, Left, Front, Back, Top).

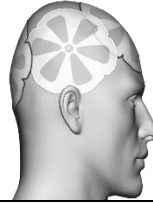
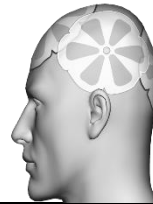
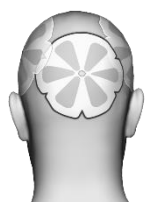
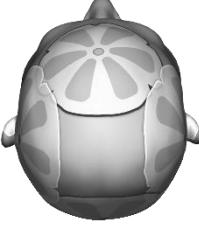
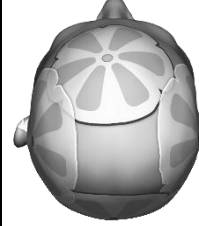
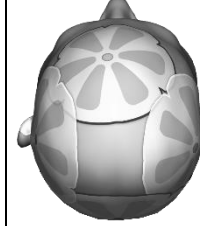
At the top of each sheet the identifying information will also appear.

Clicking the Export button will save the cover sheet measurements report and the 5 basic views of the transducer array layout (as a PDF file) to a flash drive. This will allow you to print these images from another computer, in case you do not have a printer connected to the laptop.

Clicking the “Back to Main” Button will take you back to the Patients Record screen.

11. Example library of available layouts

The NovoTAL flex software selects one of five transducer array layouts as described in section IV. The five transducer array layouts are shown below, each with the five basic views of the transducer array layout (Right, Left, Front, Back, Top).

View	Layout 1	Layout 2	Layout 3	Layout 4	Layout 5
Right					
Left					
Front					
Back					
Top					

12. Software Information

Clicking the right mouse button on an unused portion of the screen will reveal an “About” button. Clicking on the “About” button will display the software information screen below. To close the screen – click the OK button on the “About” screen.



VIII. Environmental Conditions for Normal Operation and Storage

Conditions for operation

The NovoTAL flex software is preinstalled on the laptop by Novocure. The laptop is for indoor use only.

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Issue Date : January 2026

The laptop should be stored in a dry location.

IX. Expected Life

The expected life of the software will be based on the expiry of the Windows 11 operating system. The expected date is no earlier than October 12, 2027.

X. Maintenance, Decommissioning and Disposal

The NovoTAL flex software cannot be updated by the end user. For all maintenance questions please contact Technical Support. (Contact information is provided in Section XI)

Please contact Novocure Technical Support to arrange for proper disposal of the laptop computer and/or software at the end of life.

XI. Assistance & Information

Technical Support

For technical support or the return of the laptop computer please contact novotal@novocure.com or call 1-855-281-9301 (toll free).

Reporting

If you experience a serious incident that occurs while using the NovoTAL flex software you should report it to the manufacturer (Novocure) and the competent authority of the Member State in which you reside.

XII. Glossary of Terms

WHO grade 4 Glioma – A type of brain cancer.

Transducer Array – Array of insulated transducers applied to the scalp to deliver the TTFields.

TTFields – Tumor Treating Fields: Alternating electric fields, delivered using HFE Transducer arrays to the part of the body with a solid tumor.

XIII. Applicable Standards

The NovoTAL flex Software complies with the latest editions of the following safety standards:

- EN 62304 – Medical device software. Software life-cycle processes
- EN 82304-1 – Health software – Part 1: General requirements for product safety

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