KOELIS

User Manual

MR DRAW®

KMAN-4000/EN/1.6/ 2018.06.26

I, the undersigned, ……

hereby certify that I have received and read the user manual for MR DRAW medical device. I have received initial training delivered by KOELIS personnel. I am qualified to use this product and will ensure that my colleagues receiving training before using it themselves.

Date : ……

Place : ……..

Signature :

Manufactured by:

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CE 0459
Année du marquage CE : 2016

Name of Product:	**MR DRAW®**
Name of software suite:	**3D PROSTATE SUITE**
Name of software:	**PROMAP 4.1.x**
Product reference (REF):	**KURO-4000** **KSOF-2602**

Declaration of CE conformity (for Europe primarily)
KSOF 2602

With reference to directive 93/42/EEC concerning medical devices amended by directive 2007/47/EC (hereinafer referred to as "the Directive"), the device "KOELIS PROMAP – 3D PROSTATE SUITE", identified by reference KSOF-2602, meets the essential requirements of Annex I of the Directive, and is a class I medical device with a measuring function, according to Annex IX of the Directive.

KURO-4000

With reference to directive 93/42/EEC concerning medical devices amended by directive 2007/47/EC (hereinafter referred to as "the Directive"), the device "MR DRAW®", identified by reference KURO-4000, is placed on the market as a system that complies to the article 12 of the directive.

Indications for use:

MR DRAW® is a deployment system which integrates software features of PROMAP – 3D PROSTATE SUITE.

PROMAP – 3D PROSTATE SUITE with the option fusion MR, TEP, Second look 3DTRUS and the measuring option VM are intended to be used by clinicians qualified to realize prostate gland biopsy.
It allows the 2D and 3D prostate visualization and the multimodal image fusion with the transrectal 3D ultrasound to map the prostate gland.
Software additional functions allow the management of the patients' data, the communication of multimodal data, the reconstitution multi-plans, volume and surface rendered, the organ contouring, the definition of the region of interest, the offset of 3D images and the saving of the data.

Description of the device:

MR DRAW® is intended for organ contouring, and identification of region of interest on prostate MRI. These MR images can be exported for a 3D TRUS fusion realized during prostate biopsy on a compatible device.

Hardware platform and operating system
The application operates on a standard computer using the Microsoft Windows® (version 7 or greater) operating system, supplied by KOELIS.

Peripheral devices and accessories
The application is controlled by a control pedal and input devices (mouse, keyboard).

Trade marks
KOELIS AUGMENTED SURGERY®, UROSTATION®, ORGAN BASED TRACKING®, PROSTATE MORPHING® and MR DRAW® are trademarks filed by KOELIS.

Patents
KOELIS has filed several patents and is the exclusive international holder of patents filed by its partners in the field of computer-assisted medical and surgical procedures. The system described in this document is based on some of these patents.

Licenses
License held by Université Joseph Fourier TIMC/IMAG – Grenoble – France.

Modifications and updates
The information contained in this document may be modified without prior warning. Maximum efforts have been made to ensure the accuracy of this information. Updates will be supplied with future versions of MR DRAW.

License, maintenance and warranty contract
Refer to the General Terms and Conditions of Sale.

Extracts:
- "KOELIS grants the Customer the right to use the Licensed Software for recording and control purposes for diagnostic or therapeutic use."
- "KOELIS provides a warranty against all manufacturing defects for a period of twelve months from the date of acceptance by the Customer."

Performance and accuracy:

The volume of the prostate is calculated according to the contour defined by the user. The accuracy of this volume may vary depending on the resolution of the image, pixel size, or human errors.

Measure accuracy:

	System tolerance
Distance: lateral physical accuracy	<± 5%
Distance : Axial physical accuracy	<± 5%
Distance : Display accuracy	0.1mm
Angle : Physical accuracy	<±4%
Angle : Display accuracy	0.1 degree
DICOM data: Rule accuracy	0.1 mm

Calculation of SUV body weight (PET Image), according to the DICOM standard:

Definition of variables:

Symbols	**Values** (*DICOM*)	**Definition**	**Units**
SUV bw	*Standard Uptake Value body weight*	Normalized fixation value in relation to patient's body's weight	Gram / milliliter (g/ml)
P_x	Pixel value		Without unit
R_s	*Rescale slope*	Rescale slope	Without unit
R_i	*Rescale intercept*	Rescale intercept	Without unit
D_{inj}	*Injected Dose*	Injected Dose	Milliliter (ml)
D_{decay}	*Decay correction*	Corrective time of decay	Without unit
w	Patient's total weight		Gram (g)
S_{time}	*Series time*	Exam time	Seconds (s)
Rd_{time}	*Radio-Pharmaceutical start time*	Injection time	Seconds (s)
Rd_{HL}	*Radio-nuclide Half Life*	Half-life radioactive radionuclide	Seconds (s)

Formulas:

$$SUV_{bw} = \frac{(P_x \times R_s + R_i)}{D_{inj} \times D_{decay}} \times w \qquad D_{decay} = 2^{\frac{-(S_{time} - Rd_{time})}{Rd_{HL}}}$$

Units are defined in accordance with the DICOM standard (http://dicom.nema.org/standard.html).

CONTENT

1 – GENERAL INFORMATION

1.1 – DOCUMENT PURPOSE

This document provides a set of instructions for use of Mr DRAW® and facilitates routine use of the system.
The present manual does not provide any training in ultrasonography or clinical practices.
Before using MR DRAW, the operator must have received training in medical imaging.

1.2 - SUGGESTIONS AND REQUESTS

Customer service/Technical Support	Information/ Suggestions / Comments
+33 (0)4.58.17.68.17 service@koelis.com	**KOELIS** 16 Chemin du Vieux Chêne 38240 Meylan, France Postbox : CS10036 +33 (0)4.58.17.68.10 +33 (0)4.58.17.68.24 service@koelis.com

1.3 – CONVENTIONS

In the rest of the document:
The terms "software" or "application" refer to the **PROMAP** software.
The terms "system", "station" or "device" refer to the **Mr DRAW** computer panel.

WARNING

This symbol precedes a warning concerning a situation that may result in defective operation of the software or jeopardize the health or safety of users, patients or the environment.

RECOMMENDATION

This symbol precedes advice on the use of the system, with no impact on the health or safety of users, patients or the environment.

1.4- IMPORTANT INFORMATION

WARNING

Access to the station's computer system is strictly reserved for personnel approved by KOELIS.

WARNING

MR DRAW is intended for the described use only.

RECOMMENDATION

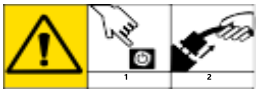
Read the user manual in its entirety before using the software.

RECOMMENDATION

This user manual must be kept throughout the product's service life.

1.5 - MEANING OF SYMBOLS

	Serial number
	Product reference
	WARNING, Refer to the instructions for use
	Manufacturer
	Disposal
	Consult the user manual

CE 0459	CE marking assigned by a notified body
	Caution! Do not unplug before power of the storage system
	Consult instructions for use
QTY	Quantity
	Manufacturing date

1.6- COMPATIBILITY

Mr DRAW® receives DICOM images from remote devices (CD-ROM or USB) or from the network (See appendix 1 about compatibility).
Exported data from Mr DRAW are intended to be read by the KOELIS systems: UROSTATION TOUCH ® and TRINITY®.

1.7- DELIVERY

KOELIS personnel perform on-site installation and check the good condition of the equipment on delivery.
The software is delivered installed on a computer specially configured by the KOELIS application system. Its technical characteristics enable its smooth use, with the accessories required for easy, ergonomic use.

WARNING

Only KOELIS representatives are qualified to perform installation of the software and assembly and initial configuration of the system.

2 – GENERAL DESCRIPTION

2.1 – INTENDED USE

MR DRAW® is a developed system based on the PROMAP – 3D Prostate Suite range intended to define prostate contour and targets the region of interest on a prostate gland image in anticipation of a fusion with a system compatible with a 3D echography image realized as part of a targeted prostate gland biopsy.

2.2 - PERSONNEL REQUIRED

No additional personnel are required compared to a conventional procedure.

- The personnel that may be required to use the system include: urologists, radiologists or physicians qualified to treat medical images.
- Any personnel using Mr DRAW must have received prior training.
- Patients are not authorized to handle the system.

2.3 – SAFETY INSTRUCTION

2.3.1 – General point

WARNING

Mr DRAW is intended for use in a clinical environment, in non-sterile conditions.

WARNING

The station's computer hardware (computer, monitor, peripheral devices, etc.) may not be used for any use other than the one described.

WARNING

Access to the closed parts of the computer, is prohibited.

2.3.2 - Installation

Installation of the station is performed by KOELIS or his representative on receipt of the equipment.

3 – DESCRIPTION OF THE SYSTEM

3.1- COMPONENTS

The system consists of:

- PROMAP – 3D PROSTATE SUITE software installed on a computer with a performance and compatibility validated by KOELIS
- an integrated tactile keyboard
- a keyboard and a mouse

More information about the system (characteristics, connectors, cleaning) are available in the user manual of the computer provided by KOELIS.

4 – SWITCHING ON AND SHUT DOWN

4.1- CONNECT AND START THE COMPUTER

1 – Plug the power unit into a main socket
2 – Press the button  on the side of the computer, this starts the application.

WARNING

To avoid any risk of electric shocks, the hardware must only be connected to a power supply equipped with a protective earthing system.

The system starts and display the three available sessions:
- Admin
- Mr DRAW
- Remote Control

Select Mr DRAW account to start the application.

4.2 – SHUT DOWN

WARNING

Take care to follow the steps for switching of or disconnecting the machines.
Disconnecting the system during use could lead to data loss.

-Quit the software 

-Switch off Mr DRAW with the button 

-If it is necessary to move the machines, disconnect the computer and then disconnect the network cable(s).

5 – PRESENTATION OF MR DRAW

5.1 – SOFTWARE FUNCTIONS:

Mr DRAW is a software application. Its different functions are presented in this document:
Mr DRAW enables to import images, to define prostate contour and targets. It also enables to export modified images, to the network or a peripheral device in a KOELIS format.
This format is readable by the UROSTATION TOUCH and TRINITY products and can be used for a fusion with 3D TRUS images.
The following modalities can be imported on Mr DRAW:

- MRI
- PET
- CT
- Enhanced US
- KOELIS Cartography.

SGx Option: Enable to export the KOELIS cartography elements (meshes) in DICOM Surface segmentation format.

Note: Mr DRAW can accept enhanced MRI format containing colours and contour. The Appendix 1 gives more information about this option.

The **"Volume Measurement"** option is used to calculate and display the prostate volume based on meshing, and hence the contour, of images. For each image mode where the prostate is contoured, a volume is defined. This option display the volume of the targets, and other measures based on image data (Ex: "Standardized Uptake Value" for PET images).

Note: the volume and measure precision depends on the precision of the acquisition system used to generate the image.

5.2 – GRAPHIC INTERFACE:

5.2.1 • Configuration Button:

- Enable the setting of general parameters: sequences link, virtual keyboard activation, and language.
- Connectivity settings: concern remote devices, reception setting and institution data.
- Update.

5.2.2 - Help

An help is available on each page to guide the user.

5.2.3 - Quit application

Quit the application from the home page or from the import page. Press the « Quit » button.

5.2.4- Export:

Images can be exported to the network, the PACS or a USB stick.

5.2.5- Image preparation:

Activate image preparation after series selection: contour and targets definition.

WARNING

Please make sure you quit the application as described above and then shut down the computer using the "shut down" button before switching of the power supply to the station. If these instructions are not followed, the integrity of the computer system may be affected and data lost.

5.3- SYSTEM MESSAGE

The system communicates with the user via messages. The purpose of these messages is to inform the user about progress of certain steps and sometimes request validation of previous steps.
There are three types of messages.

5.3.1- Information message

These messages:
- Allow the user to confirm certain steps in the protocol, before continuing.
- Indicate a protocol status or the result of a completed operation.

5.3.2 – Wait message

This message is displayed during a calculation operation temporarily preventing interactions with the user.

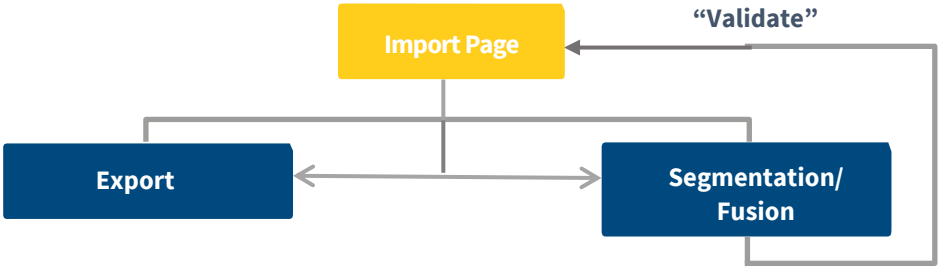
5.3.3 – Error Message

There are 2 types of error message:
- For a non-critical error, the user may opt to close the application or attempt the operation having triggered the error again.
- If system integrity is no longer guaranteed, a message warns the user that the application will be closed. In this case, it is essential to redirect the intervention towards a conventional protocol.

6 – PROTOCOL DESCRIPTION

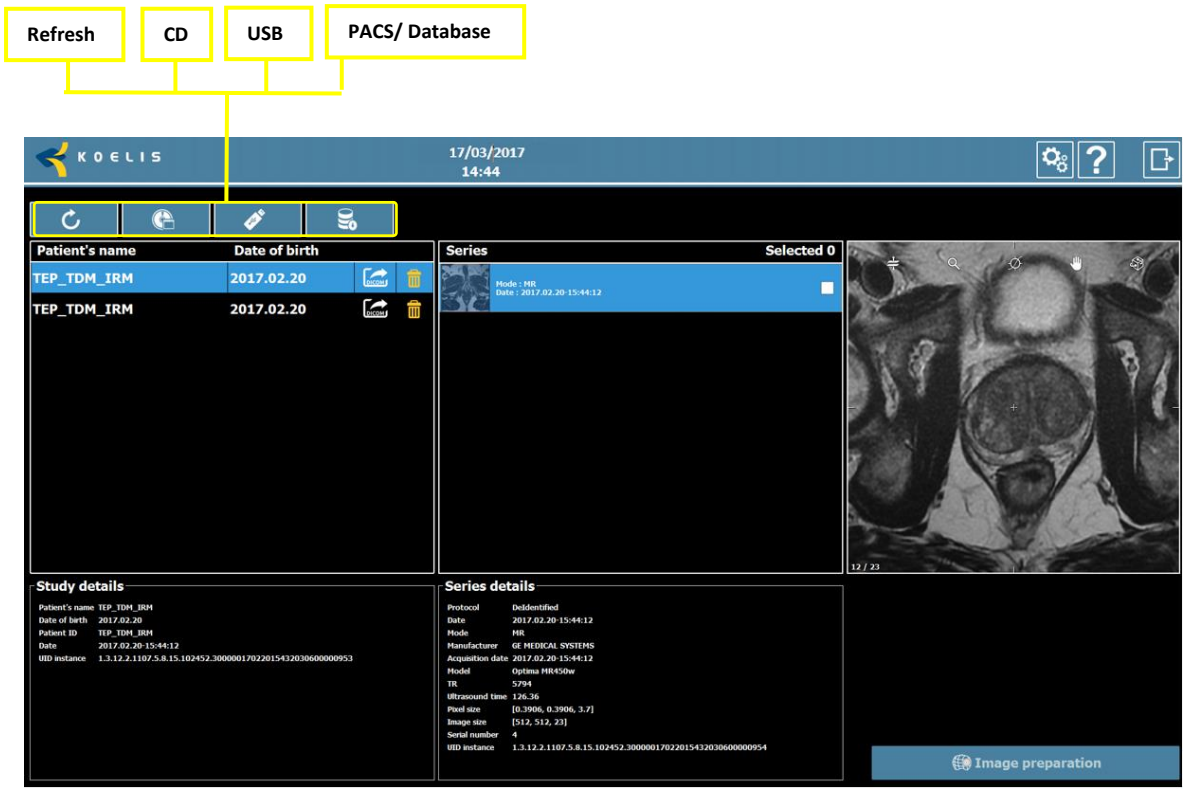
6.1 - OVERVIEW

The following diagram shows the computerized surgical protocol of **PROMAP** for MR DRAW.



6.2 – IMPORT

Images for a patient can be imported. To import images, the user may use an external device (CD or USB), to 'push' the images into MR DRAW from the PACS or to retrieve images directly on the PACS (Query/Retrieve).



6.2.1. Importing from an external support

The support may be a CD-ROM or a USB device. Connect it to the station then press the correct button (CD or USB) to launch images import. After exploration, the patients present on the external support are displayed on the interface. The process may take a few minutes, depending on the number of patients.

6.2.2. Sending image from a PACS

DICOM images can be pushed from a PACS via the clinical center's network. When images are sent by PACS, the application detects the arrival of new images. If they are not displayed, click the **"Refresh"** button.
Once the images have all been received, the visual interface is automatically updated.

6.2.3. Importing from a PACS: QUERY/RETRIEVE

From the home page, the **PACS/Database** button can be used to import images from a PACS.
It is possible to **search** for a study on the PACS using the following fields:

- Patient's name
- Patient's gender
- Study date
- Modality
- Patient ID

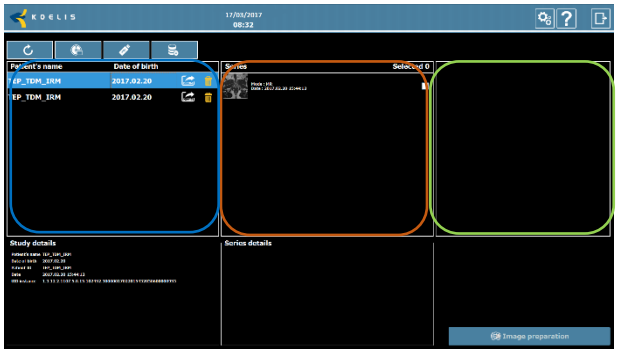
N.B.: At least the “name of the patient” has to be filled to make a research.
Click "Search" to run the search on the PACS. The **study list** searched is displayed.
Click a study to display the series. To download a series, click the **download** button: 

The downloaded images are displayed on the import page.

To preview images and choose the image(s) to be imported, select a patient in the **exam window**.

The images of the patient selected are automatically loaded and displayed in the **sequence window**.

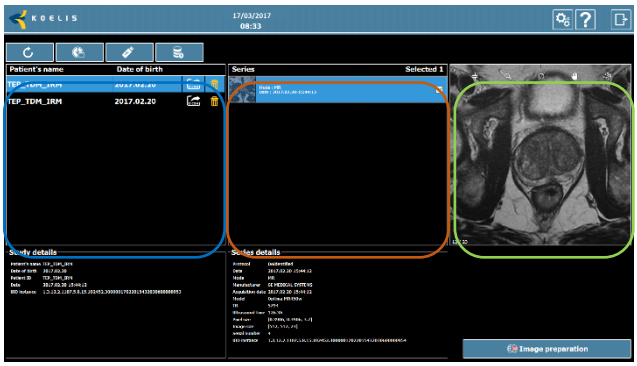
N.B.: When a series is displayed in the **preview window** on the right, it is possible to adjust image parameters and the window display, depending on the selected tool, by moving the cursor on the right-hand image. The window display is then retained.



Repeat for all the sequences to be imported:

- Select the sequence from the **sequence window** by ticking the check box. The preview images are displayed on the right according to the highlighted sequence line.

Several sequences can be selected for segmentation.
Untick the check box in the selection window in order to delete the image to import. Press the **“IMAGE PREPARATION”** button to go to the segmentation and target definition page.



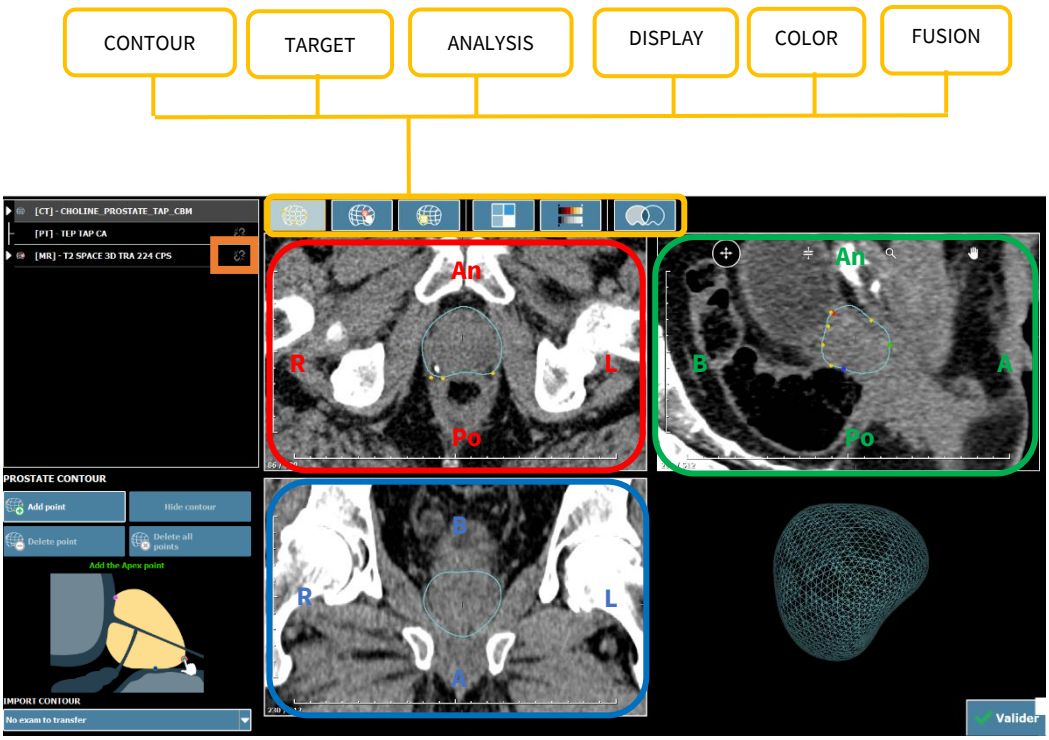
N.B.: Images stored on the system and not imported into a patient file are automatically deleted from the system

after a certain number of days (3 by default, to be configured in the maintenance account). Images that are not compatible with the Dicom standard 3.0 (version 2011) format and rejected by the system are shown in the sequence window with information on the reason for rejection in red.

Parameters: Refer to Appendix 1 of Volume 4 at the end of the manual for compatibility of DICOM parameters.
Declaration of DICOM compliance: Refer to the specific document entitled “Declaration of DICOM compliance” (available on request from KOELIS).

6.3- Image preparation

6.3.1 - Presentation of the interface and views



The diagram opposite shows how the different prostate views should be represented (**axial view**, **coronal view** and **sagittal view**) as well as their orientation:

- An=Anterior,
- Po=Posterior,
- B=Base
- A=Apex,
- R=Right,
- L=Left

The slice's number is displayed for each image view.
The thumbnail at the bottom left models the prostate in sagittal view mode.

The tool buttons around each view are used to navigate through the slices, move the image, and zoom in. To activate a tool, click the corresponding button. The button will be highlighted. To deactivate the tool, click the button a second time.

Move tool:
Select the Hand button to move the image

Zoom tool:
To zoom in, select the magnifying glass button and move the cursor over the image.

Navigation tool:
To navigate around the view, select the button opposite and move the cursor over the image.

Inter-slice tool:
To navigate between slices, select the button opposite and move the cursor over the view.

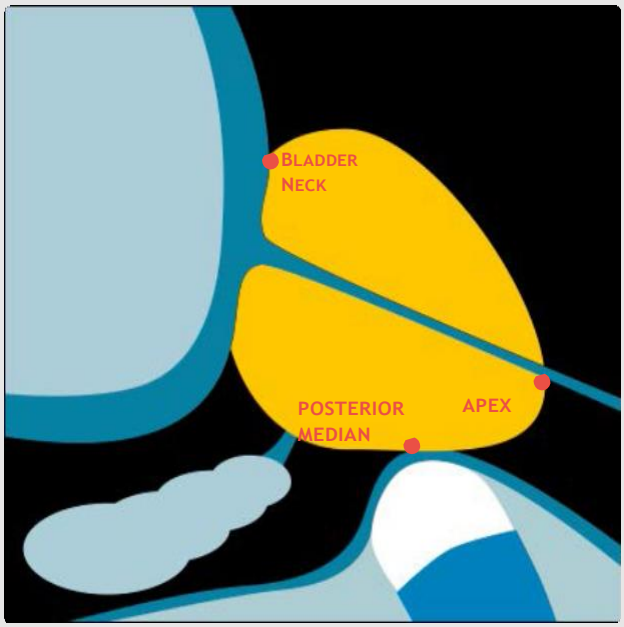
RECOMMENDATION

Be careful to check the correct orientation of images (right/left, anterior/posterior, head/foot).

RECOMMENDATION

It should be specified that the terms below - "bladder neck", "apex", "posterior median" - are indicative and only partially relate to radiological or urological conventions. It is recommended that the points be positioned on the sagittal slice (green box) of the interface, in this order:

- "APEX" point: this is the apex of the prostate, at the urethra exit.
- "BLADDER NECK" point: this is the point diagonally opposite the apex, close to the bladder neck.
- "POSTERIOR MEDIAN" point: this is the posterior prostate capsule point located in the middle of the left-right and bladder neck-apex axes.
- The triangle obtained should ideally cover a maximum surface area.



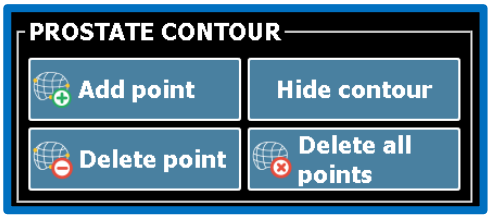
WARNING

The quality of the future 3D ULTRASOUND fusion is directly dependent on the quality of prostate contouring. It is therefore essential to pay particularly careful attention to each contouring step.

6.3.2 – Contour

A • POSITIONNING OF THE 3 REFERENCE POINTS

Select the mode desired in the left-hand box.
It is necessary to place the 3 apex, bladder neck and posterior median points to place the 3D prostate contour in the initial position.



In "Contour tab" use the prostate contour zone. Navigating around the slices, as explained above, Click **"Add point"**:

- On the sagittal view, place the cursor at the apical end of the prostate and click. The apex is then defined.
- Define the bladder neck in the same way, positioning the cursor then clicking the bladder neck.
- On the median transverse slice, position the posterior point in the same way on the posterior capsule.

A blue 3D contour of the prostate is automatically generated and adjusted on the basis of these 3 reference points. This contour corresponds to an average prostate shape and must be fine-tuned by navigating in the slices and adding points on the real prostate contour.

WARNING

Since the basic 3D contour of the prostate is automatically generated and adjusted on the basis of the 3 apex, bladder neck and posterior reference points, it is important to position them in accordance with the diagram displayed in the view on the bottom right of the screen.

B • FINE-TUNNING THE CONTOUR

It is necessary to fine-tune the prostate envelope, defining contour points in the different slices. To do this, with the **« Add point »** button still selected:

- Position the cursor at the desired place to add a contour point, then click.

The position of a contour point can be adjusted by moving it.
A contour point can be deleted by clicking the **"Delete Point"** button then clicking the point to be deleted.
All the contour points can be deleted by clicking the **"Delete all points"** button.
The contour can be shown or hidden by clicking the **"Hide Contour / Show Contour"** button.
N.B.: Each time a point is added or deleted, the contour and volumetric rendering are automatically updated by the application and displayed on the screen.
The contours are automatically saved after each modification. Confirm by pressing the **"Confirm button".**

WARNING

To ensure optimum precision in the elastic ultrasound fusion, it is important to be careful to adjust the contour points to the prostate.

WARNING

Contours imported from enhanced DICOM MRI images cannot be modified. However, the 3 key reference points (apex, bladder neck, posterior) can be moved on the contours to improve the original fusion. If in doubt, delete the contours and define them again using the MR DRAW's contour process.

6.3.3 – Image overlay

Two image sequences can be fused together. For this purpose:

- Select a reference sequence in the left-hand box
- Click on the “Fusion” button (§6.3.1) on the same line of the sequence to be fused.

ATTENTION

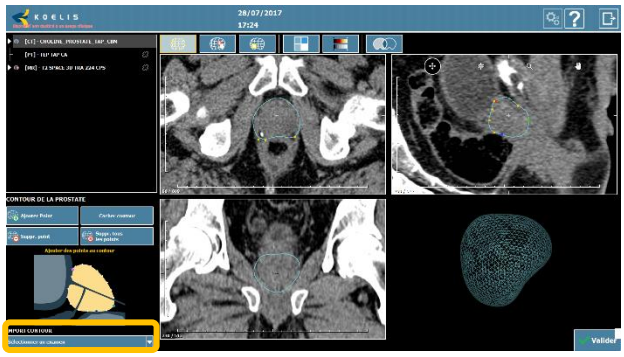
To have a correct images overlay, both images must have the same special reference.

6.3.4 – Transfer of contour

Once a sequence is contoured, it is possible to automatically transfer this contour to the other sequences imported.

To do this, simply go to the sequence without a contour and select a sequence already contoured in the **TRANSFER OF CONTOURS** tab.

The contour will then be automatically transferred.



WARNING

For a successful contour transfer, both sequences must have the same spatial origin.

6.3.5 – Volume Measures (VM Option)

When the option is activated, this volume is displayed beside the image name in the box where the available modalities are listed. The volume is calculated using the contour defined by the user.

WARNING

The volume accuracy depends on the acquisition system which generates the image.

6.3.6 - Definition of zones of interest (targets)

If a zone appears to be suspect on a sequence imported, this zone can be marked so that it is displayed in 3D in the biopsy mapping.

In this way, it is possible to:

- Try to position biopsies in the zone of interest.
- Or Check that that zone of interest has been reached.

A • ADDING A ZONE OF INTEREST

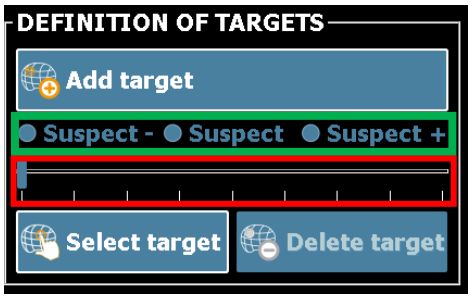
In the "Target tab", use the **target definition zone**. Navigating around the slices:

- Click the **"Add target "**button in the **target definition** zone
- Position the cursor in the center of the zone and click.

B • MODIFYING A ZONE OF INTEREST

Use "Target tab", target definition zone.

- Select the target to be modified using the **"Select target"** button.
- Check the relevant box to indicate **the degree of Suspicion** of the target (suspect, by default, or suspect- or suspect+). The target will then be shown as yellow, orange or red.
- The size of the zone of interest can be adjusted by the **slider.**



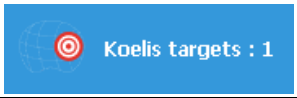
C • DELETING A ZONE OF INTEREST

To delete a target, use the setting box, target definition zone.

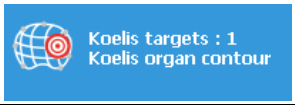
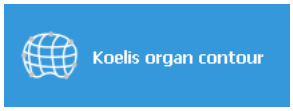
- Select the target to be modified using the **"Select target"** selection button.
- Then use the target deletion button. **"Delete target"**

N.B.: Once contours and/or targets are defined save with the **« Validate »** button. The import page appears.

These logos appear next to the modified sequence:

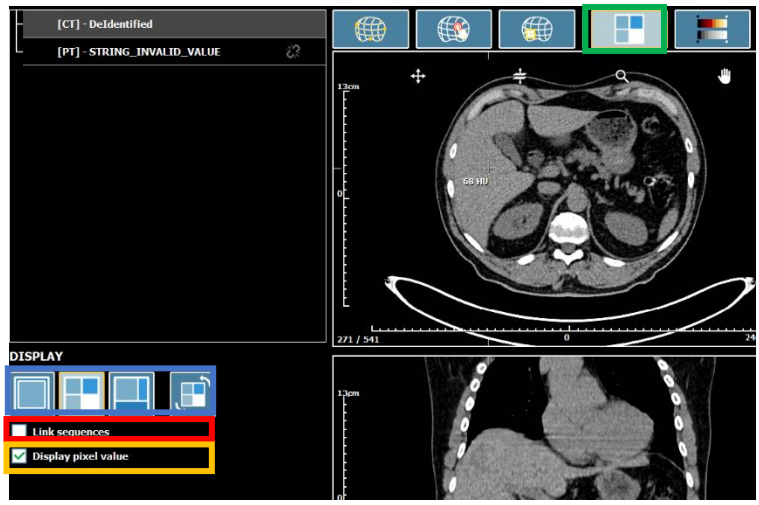


One or several targets added. The number of target is displayed next to the sequence.

	One or several target and a contour added.
	One contour added.

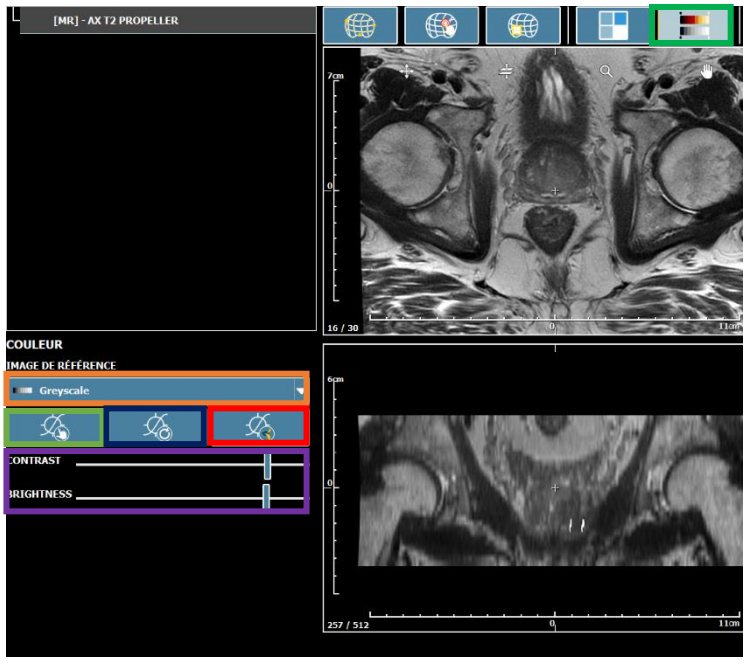
6.3.7 – Display

Use the "Display tab" to modify the display of the views of the selected sequence, to link two sequences or to display the pixel physical value (HU for CT images, SUV for PET images…).



6.3.8 – Color

Use the "Color tab"to modify the color of the selected sequences.
It is possible to apply different colors to fused sequences.
When two sequences are fused, it is possible to adjust the transparency of the fused sequence.



Color settings:

- Select the color palette
- Adjust the color contrast and brightness: manually, come back to inital settings, apply the preset optimized by KOELIS, adjustment thanks to sliders.

6.3.9 – Fusion

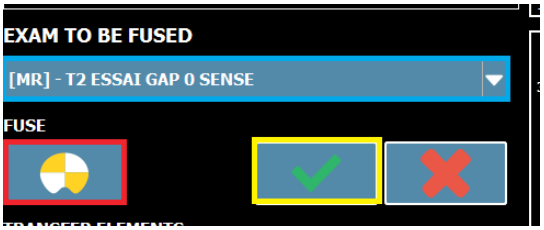
Prerequisites: This merge can be done between 2 sequences previously contoured. These images can be of different modalities (MRI, PET, CT ...)

Once these two contours are made:

• Click on the fusion tab 

• Firstly select the image that will become the reference for the fusion and only after that to select the **exam to be fused.**

• Click on the **« fusion »** button



A registration page appears:

• Check fusion's quality (coherence of borders…)

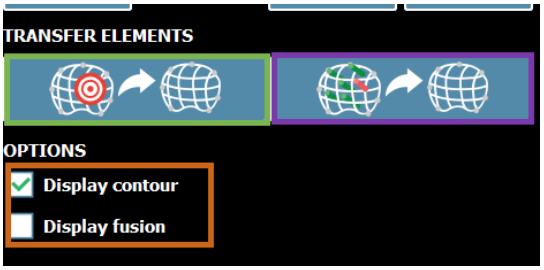
• Validate the fusion by clicking on **«Validate»**

Transfer the elements:

• Once this fusion is done, it is possible to transfer the elements (**targets**, **biopsies …)** from one image to the other one.

• Select the type of item you want to transfer

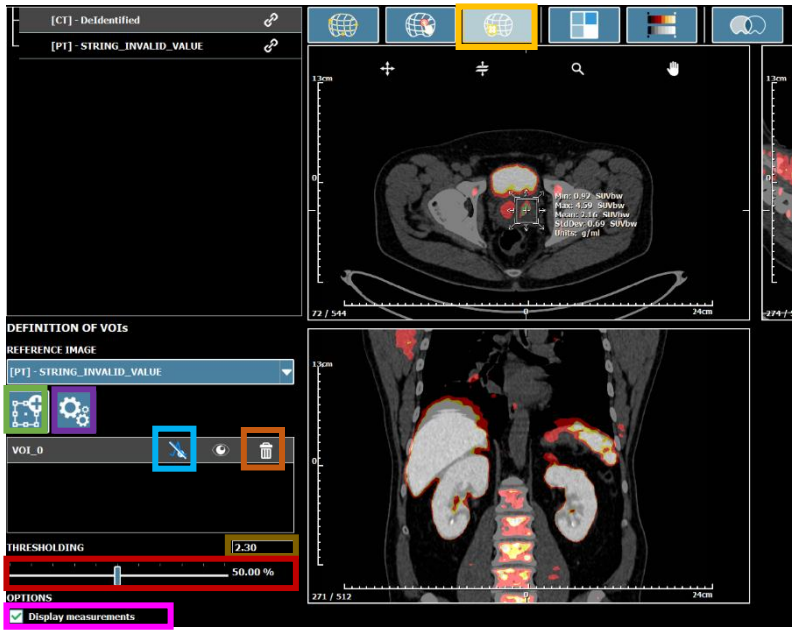
It is also possible to display or hide the contours and the fusion by **checking and unchecking the boxes.**



6.3.10 - Quantitative description (Option VM)

A. Calculation of SUV for PET images

This feature is accessible only on PET images. It highlights the inhomogeneities of fixing markers by indicating of the maximum SUV, minimum SUV, peak, volume and the standard deviation for this.



• Click on the "Analysis" tab

• Complete the information useful for calculating the SUV by clicking on the configuration icon

• Select the "volume of interest (VOI) button" and place the VOI on the image

• Adjust the volume to the study area by dragging the VOI arrows

•The threshold areas highlighted in green will correspond to the parts of the image with an SUV greater than:

- X% of the SUVmax, adjust the thresholding with the slicer

Or

- the SUV absolute value that is indicated in the editable text box

• Display the peak value (1 ml centered on the SUVmax) by clicking on the peak icon.

Result: The threshold zone appears in green, the peak value in blue and the maximum, minimum and average SUV of the VOI will be displayed.

It is possible to position several VOI, to manage their removal click on the trash icon.

It is also possible to display and hide the information by checking or unchecking the option button.

B. Quantitative analysis of images

A quantitative analysis is also available for all other modalities.

• Go to the "Analysis" tab

• Select the "volume of interest button"

• Adjust the volume of the study area by dragging the VOI arrows.

Result: The maximum, minimum and average intensity of the pixels present in the VOI will be displayed.

WARNING

If the image contains overlays, the anatomical information of the volume can be hidden and the calculation of the SUV wrong.

6.4 DATA EXPORT

After being treated or not, sequences can be exported to a USB stick, the PACS, or the network . Select the sequences to export and click on the **« Export »** button.
A pop-up appears and the network or a USB stick can be selected.

N.B: If the USB stick or the useful remote devices are not present, press « Update » button.
To cancel the export, press the **« Cancel »** button on this same popup.

N.B to export on the PACS: PROMAP makes an automatic research of the study to export on the PACS. If the patient is unknown of the PACS, the export can fail. It is recommended to link it to a WORKLIST patient by clicking on the "WORKLIST" button.

ANNEX 1: COMPATIBILITY

MR DRAW can receive MRI, PET, CT, US enhanced images and KOELIS cartography from an external support (CD-ROM or USB) or from the PACS network, as long as the DICOM 3.0 standard protocol is used. To transfer images to MR DRAW via the network, it is necessary to configure the following parameters on the console station:

Name of export target:	**MR DRAW®**
AETITLE:	**KOELIS_MDxx (xx: System number)**
TCP/IPport:	**11112**
IP Adress:	**adress assigned to the MR DRAW system**

N.B. : MR DRAW only accepts :

- DICOM images and DICOM compressed images, including at least the following information: patient's name, patient's date of birth, patient's position.
- Axial, coronal, sagittal images.
- Image series containing only one 3D image. No dynamic image sequences or interlacing of two images (case of DCE sometimes).
- MRI images with the following parameters: TR>1 and TE>0
- Grayscale images

« ENHANCED MRI » OPTION

MR DRAW's « PROMAP » software is capable of importing certain "enhanced" MRI images in standard DICOM format, containing, for example:

- Color images
- Prostate contours
- Lesion contours

MR DRAW 's software is also compatible with enhanced images from iCAD Versuave 3.2.1.

ANNEX 2 : MAINTENANCE AND CONFIGURATION

Remote control

Teamviewer is pre-installed on the system to allow KOELIS to have remote access.

To activate remote control, simply select the Remote Control account when the computer start.

A Teamviewer QS pop-up appears, with an ID and a 4-digit password.

These 2 items of information must be supplied to KOELIS so it can take over remote control of the station.

SYSTEM CONFIGURATION

System configuration is accessible from the MR DRAW application: « Configuration » button.

PRESENTATION OF THE INTERFACE

GENERAL TAB:

Language of the application and the virtual keyboard:

- Select the language of the application and the language of the virtual keybord among those available
- Click on the **« Save »** button to save modification.

Link sequence option:

- Check or uncheck the box **"Link sequence"**
- Click on the **« Save »** button to save modification.

Virtual keyboard activation.

- In the « Virtual keyboard »tab, choose ON to activate the virtual keyboard.
- Click on the **« Save »** button to save modification.

CONNECTIONS TAB:

Changing the Inbound parameters

- Enter the AETITLE and the port number for multi-modalities data in the 'Inbound parameters' box
- Select the storage duration for images in the station (in days)
- Click the "**Save**" button to save changes.

Remote devices:

- To add a new device, click **"New"** and complete the following fields: AETitle, port, IP address, then check the box corresponding to the type of device: Storage (for export), Q/R (for a PACS, for example), or WORKLIST.
- Click "Test" to test an existing device.
- Click the "**Save**" button to save changes.

Institution:

- Must be filled by the institution.
- Click on each empty field to fill the information: Name and address of the institution, department name, clinician name, and the number of days to keep created images.

ATTENTION

Connect the system to the network or modify the system (configuration change, other systems connection, other connected systems update), can introduce new unidentified risks for patients, users or third parties.
It is the responsibility of the clinical site to identify, evaluate and control these risks.

UPDATE TAB:

Update is made by Koelis remotely or from an external peripheral.

QUIT:

To quit the configuration page and return to the home page.

ANNEX 3: SOFTWARE UPDATE AND OPTION INSTALLATION

You just received an USB stick containing different setups. In order to install these setups, please follow the following steps.

WARNING

Depending on your product, the USB stick contains one or several setups.

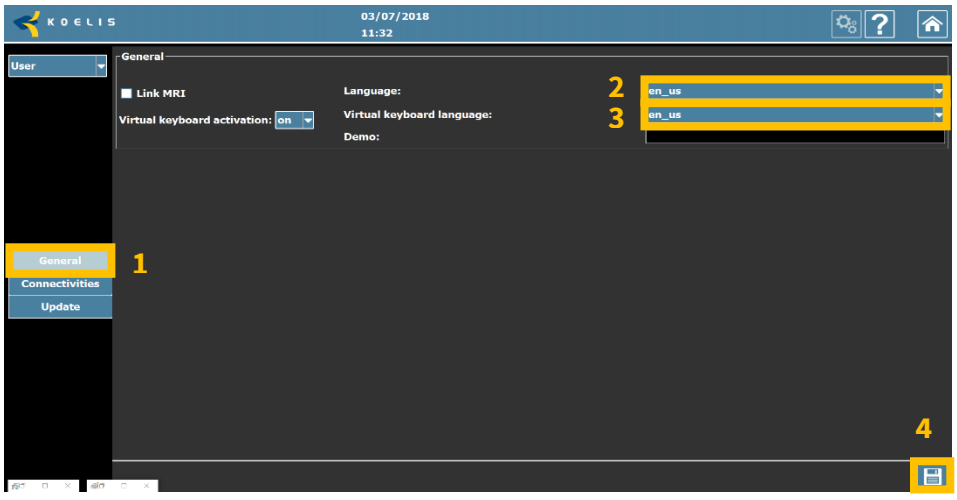
It is **mandatory** to install these setups with respect to their numbering:

KOELIS_**01**_Setup_Update...
KOELIS_**02**_OptionMaker...
KOELIS_**03**_Setup_Lanuagepackage...

1) Launch the Maintenance account.
2) Plug the USB stick in one of the USB ports of the TRINITY system.
3) Click on the button “Update software”.
4) A pop-up Windows explorer appears, select the USB stick containing the setups.
5) Select the setup to install then click on “Open” to begin the installation.

Note: it is mandatory to install the setups with respect to their numbering.
Note: numberous interactions pop-ups can appear during the installation, always click on “Next”, “Install” and then “Finish”.

6) Restart the system.
7) If the USB stick embedds several setups, repeat steps 1 to 6 for each setup.
8) Launch the Maintenance account.
9) Click on the button “General”
10) Successively click on the keys framed below in order to change of language



11) Restart the system
12) Installation is finished

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