

DSG Connect - Tutorial

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Dynamic Surgical Guidance (DSG[®]) Technology

The DSG Technology is based on the principle that the electrical conductivity of tissue varies by the type of tissue.

Electrical conductivity is the property of a material to conduct an electrical current. e.g.:



- Cortical bone has low conductivity.
- Cancellous bone has medium conductivity.
- Periosteum and blood have high conductivity.

The varying conductivity, is a parameter that can be very helpful in differentiating between various tissue types while drilling a pedicle prior to screw placement.

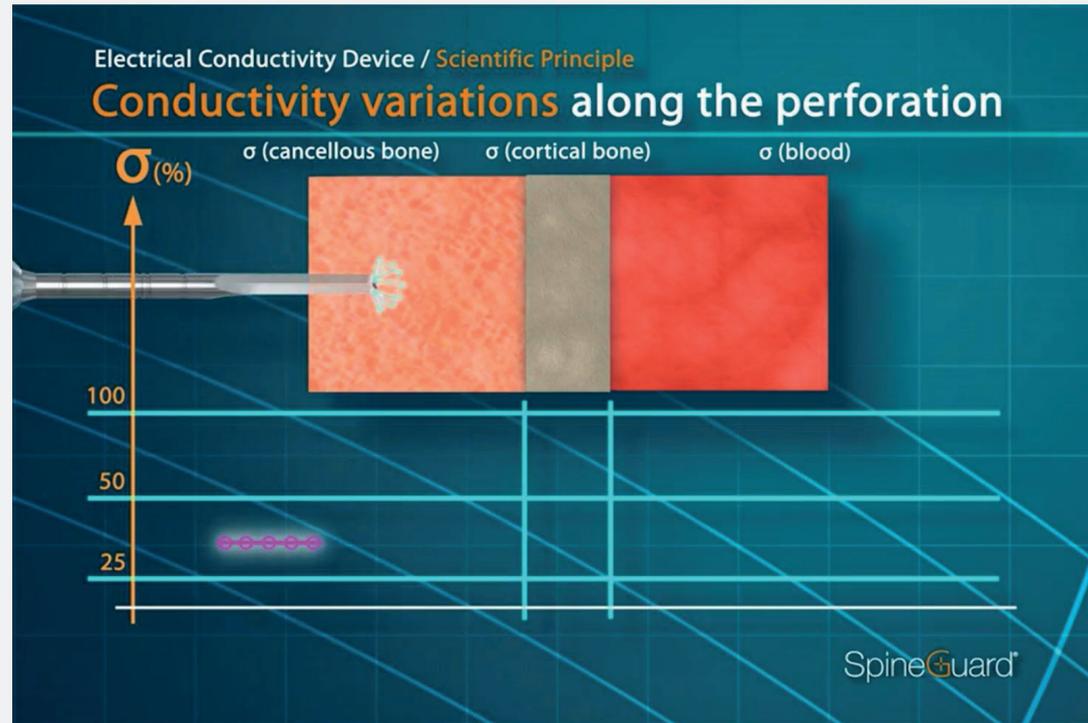
How does the DSG Connect device work?

A bipolar sensor is embedded at the tip of each DSG Connect device probe. A current is pulsed through two electrodes in the probe. Based on the local conductivity, the sensor can accurately inform the surgeon of the type of tissue the tip is in. This in turn can alert the surgeon prior to an imminent cortical breach during pedicle preparation. The surgeon is informed in real time of the tissue type by changes in the pitch and cadence of an audio signal and a flashing LED light.

The sound signal will change depending whether the surgeon is in the cancellous bone, cortical bone or blood.

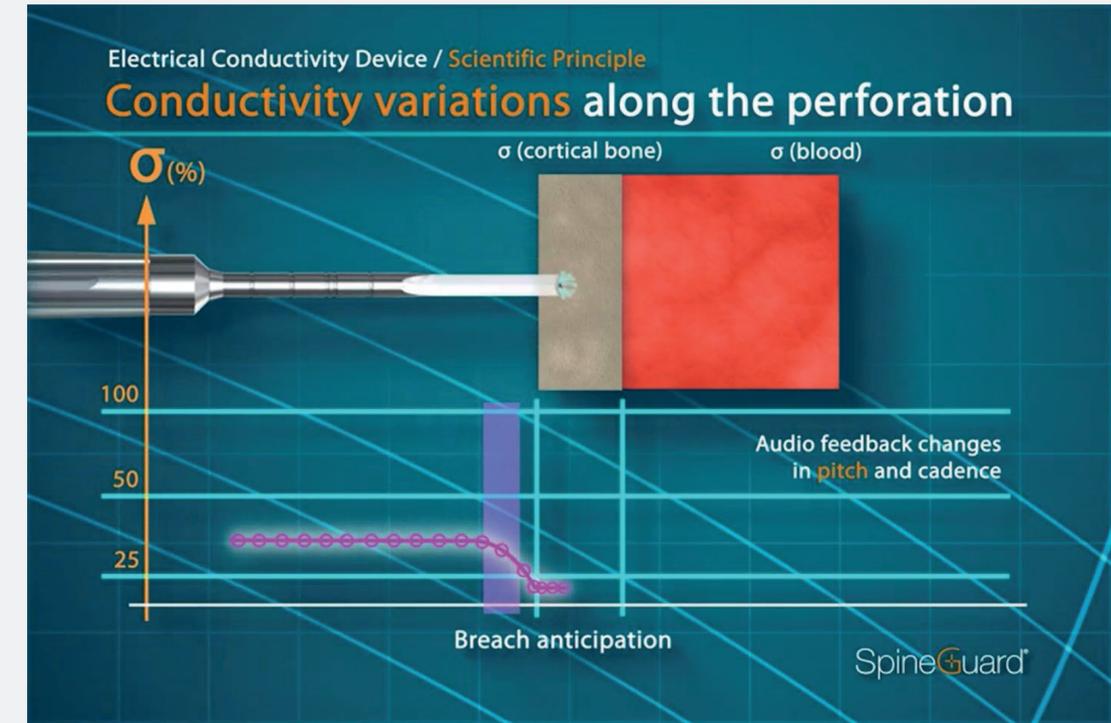
What is DSG?

Tip in cancellous bone



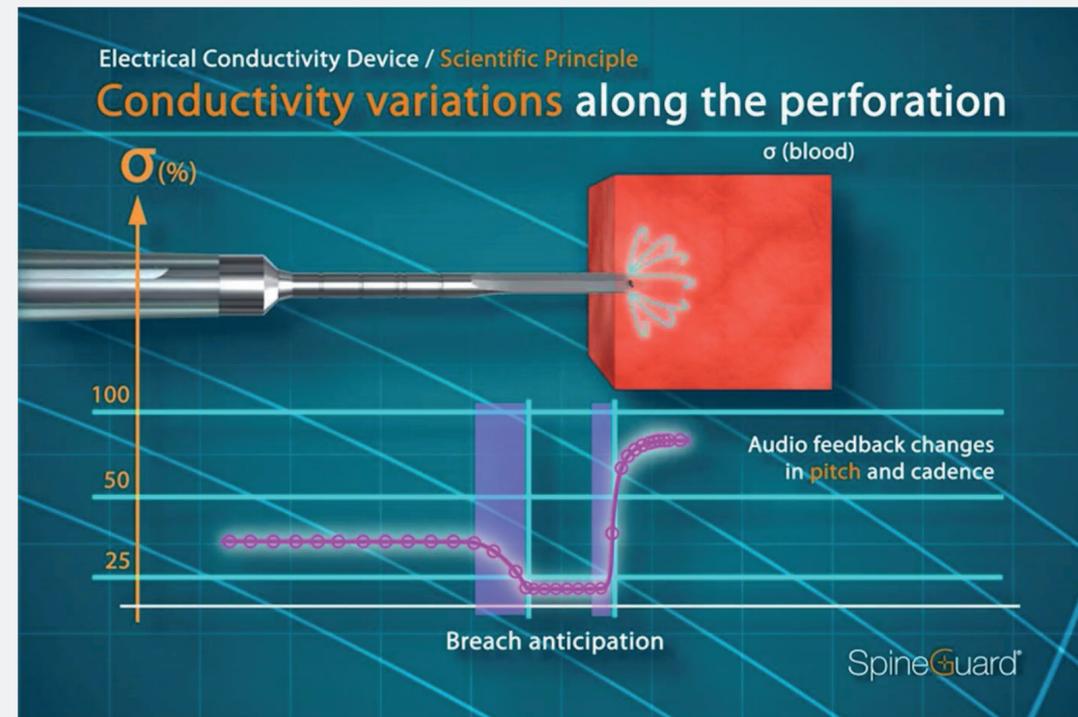
Medium pitch, medium cadence

Tip in cortical bone



Low pitch, low cadence

Tip in soft tissue/blood



High pitch, high cadence

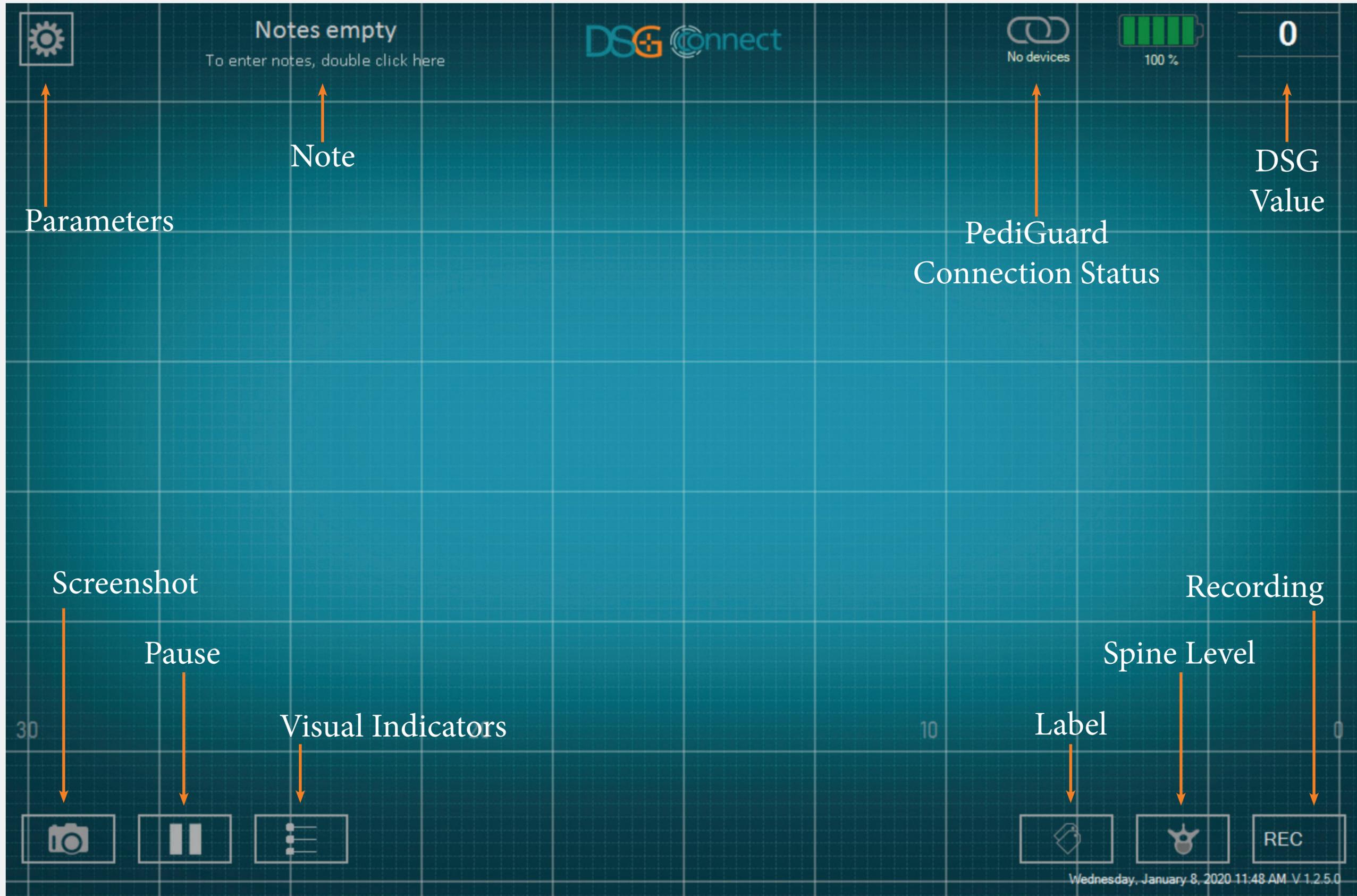
DSG Connect App objective

SpineGuard developed the DSG Connect App for surgeons to have a visualization of the audio feedback from the DSG technology during pedicle drillings.

The DSG Connect App allows collection and visualization of the signal measured at the tip of DSG Connect devices. The digital data from the DSG devices, allows for the data to be recorded, extracted and analyzed.

Note : The DSG Connect App is not intended for medical decision making.

Interface Global Overview

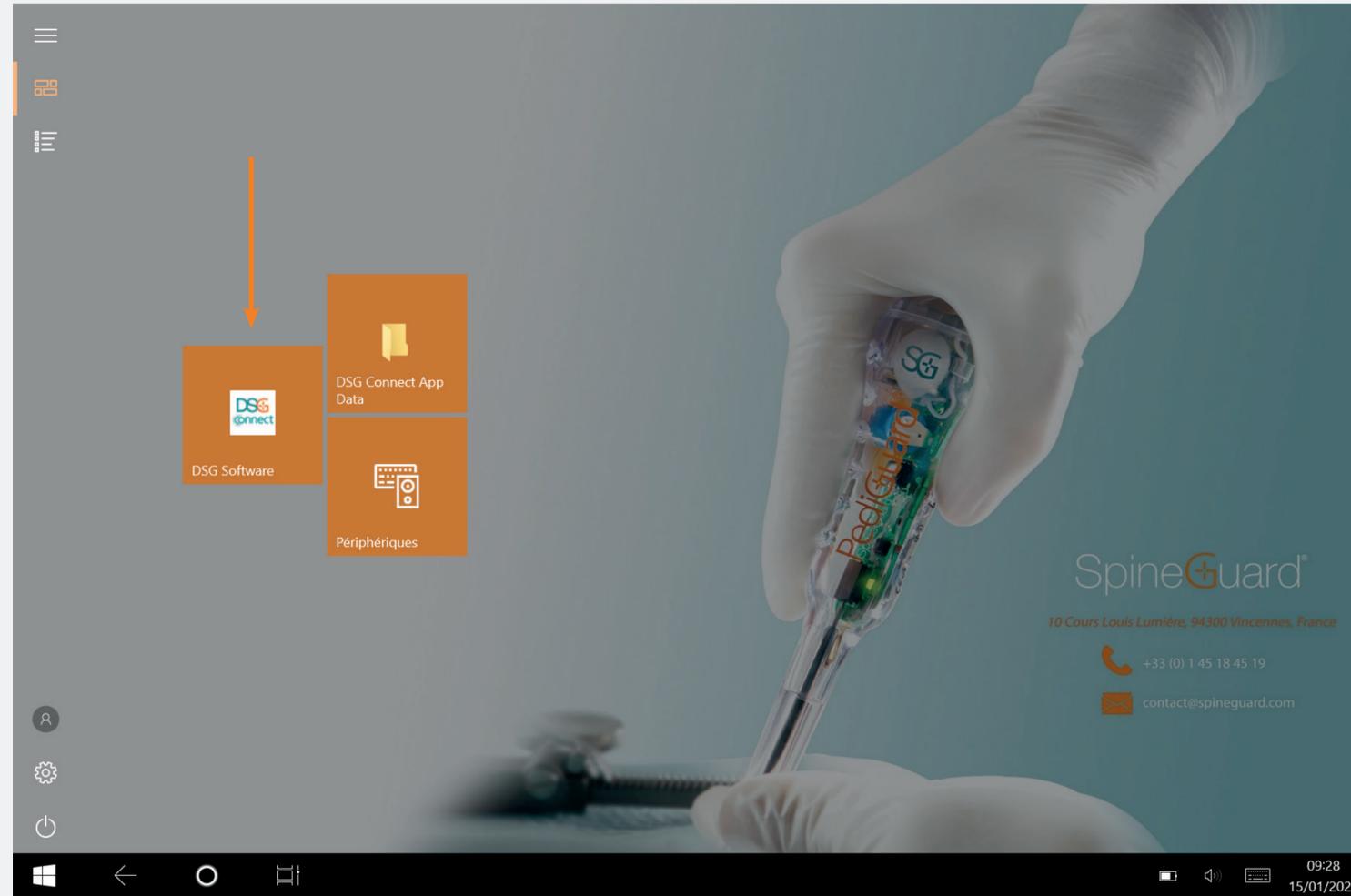


Information area

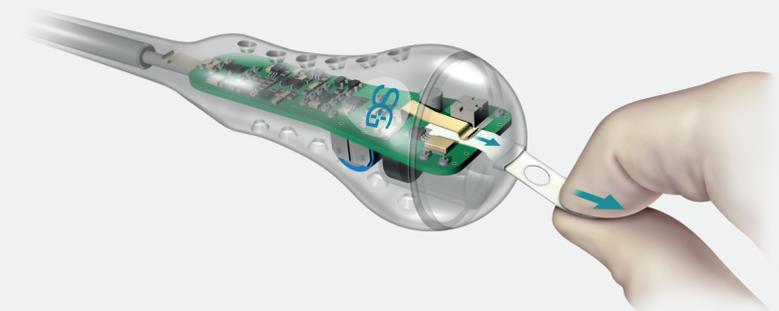
Graph area

Feature Control area

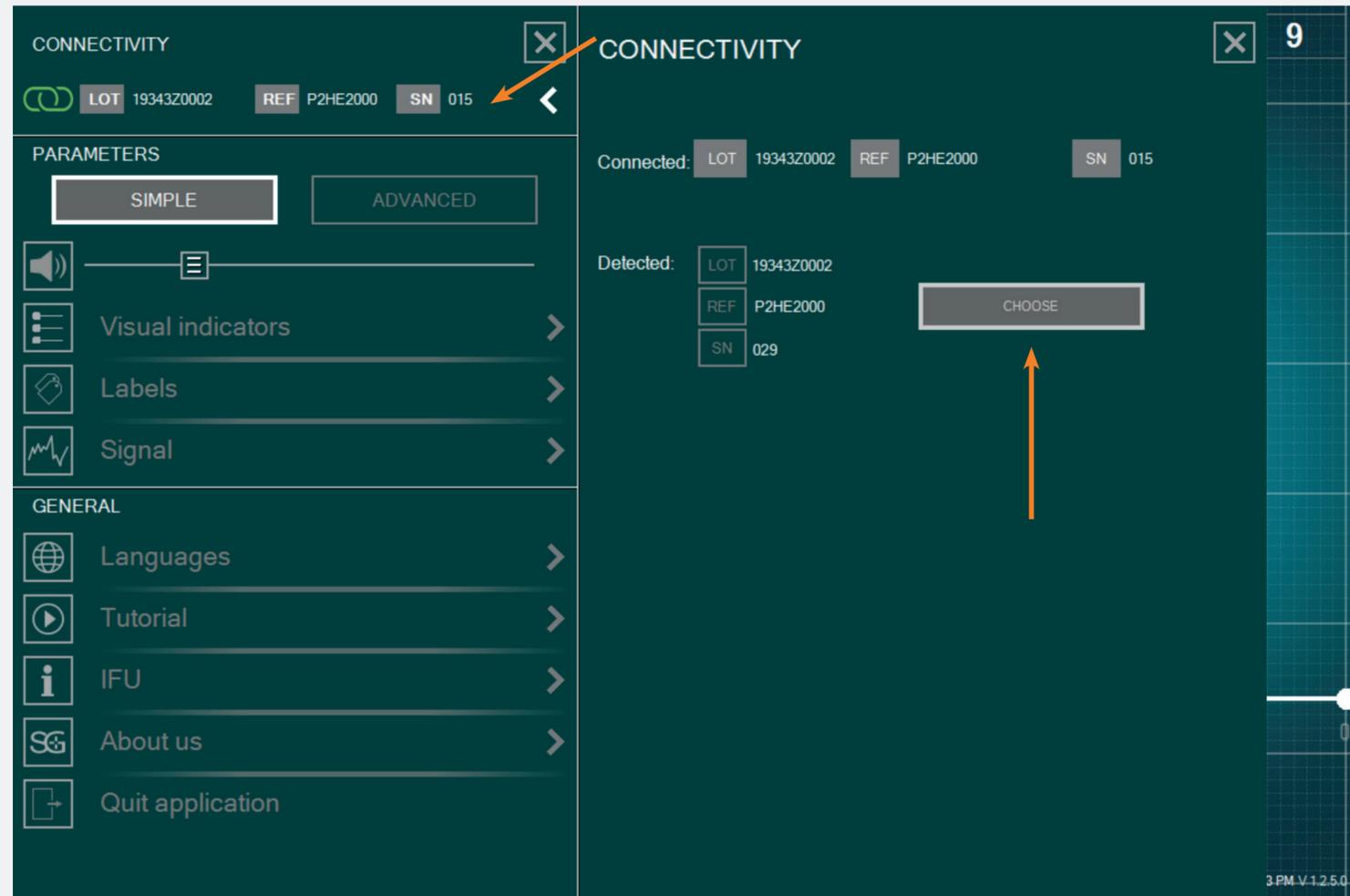
How to connect the DSG Connect device to the tablet?



- Turn the tablet on and launch the DSG App.
- Then, pull out the activation tab of the DSG Connect device. This will activate the device and the automatic connection between the DSG Connect device and the tablet.
- The graph should start to stream and the DSG value should appear in the top right corner of the screen.



What if the connection fails?



- Go to the window connection in the parameters menu, and choose one of the detected DSG Connect device you would like to be connected with.

The Simple Mode is a core function in which the evolution of the conductivity data along time is graphically represented by a curve on the screen. It allows you to have a visual feedback with basic features (visual indicators, pause mode and screenshots). You can also personalize the Empty Field “Note”.

Signal (Graph)

What does the graph represent?



- While drilling, you will be able to visualize the data collected by the DSG Connect device.
- The conductivity data are graphically represented by the white curve on the screen.

How to understand the visual signal?



- The comprehension of the signal should be made as follow: the higher the signal, the higher the conductivity and the lower the signal, the lower the conductivity.
- The light point represents the live measurement by the DSG Connect device. The number on top right represents the conductivity measured at the instrument's tip.
- The graph will start generating from left to right and once the full screen is filled, the entire curve will move from right to left
- You can adjust the width of the time window in the parameters menu (p. 20).

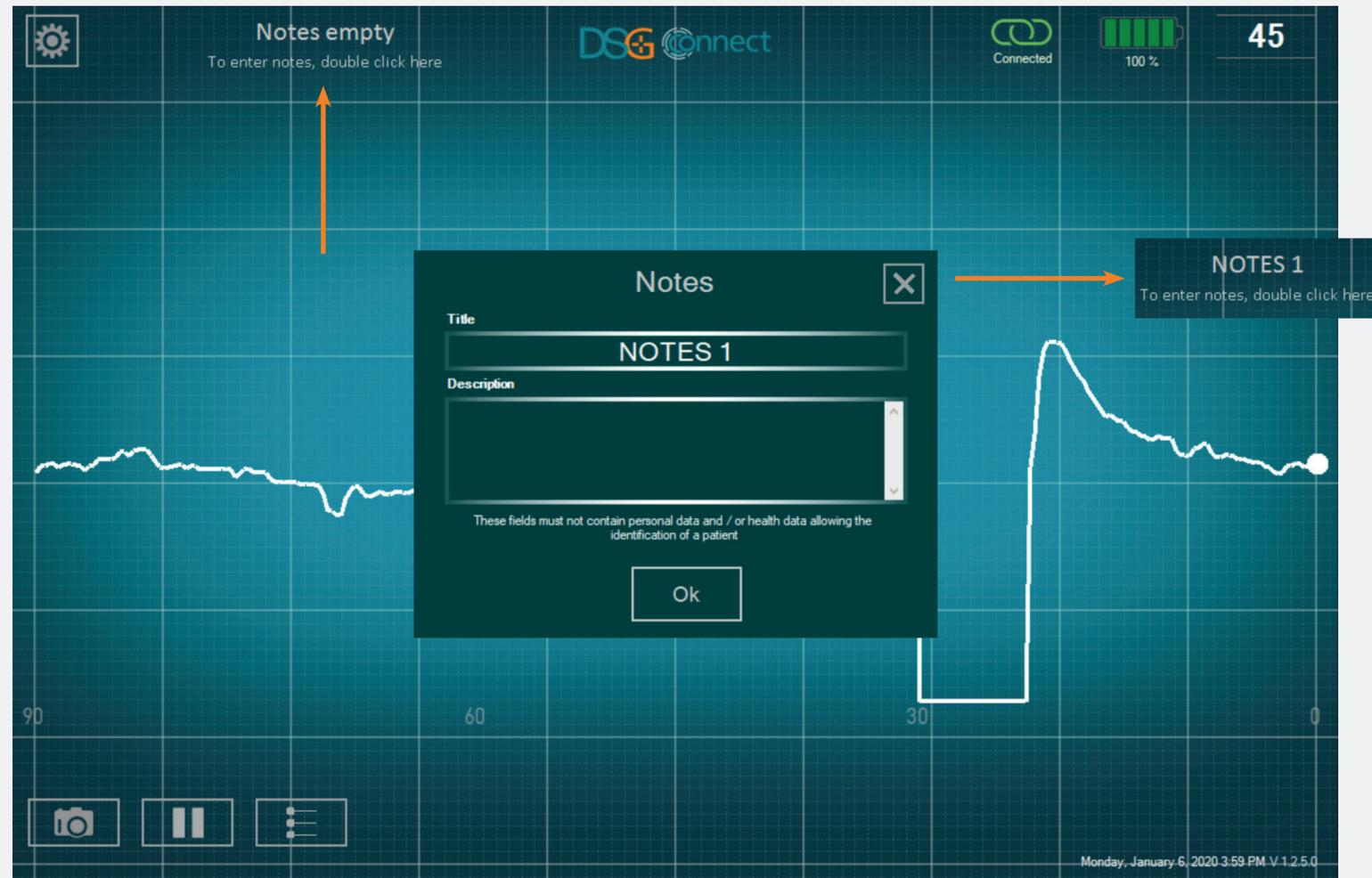
Empty Field - Notes

What is the Notes feature?



- This feature allows you to enter any information deemed necessary.
- It is optional, the app can be used and data can be recorded even if no Notes are filed.
- However, if you enter a Note in the Empty Field, the report at the end of your surgery will be named as such (see p. 31).
- This text field must not contain personal data and/or health data allowing patient identification.

How to add Notes?



- Double click on “Notes empty”.
- Fill in the corresponding empty boxes.

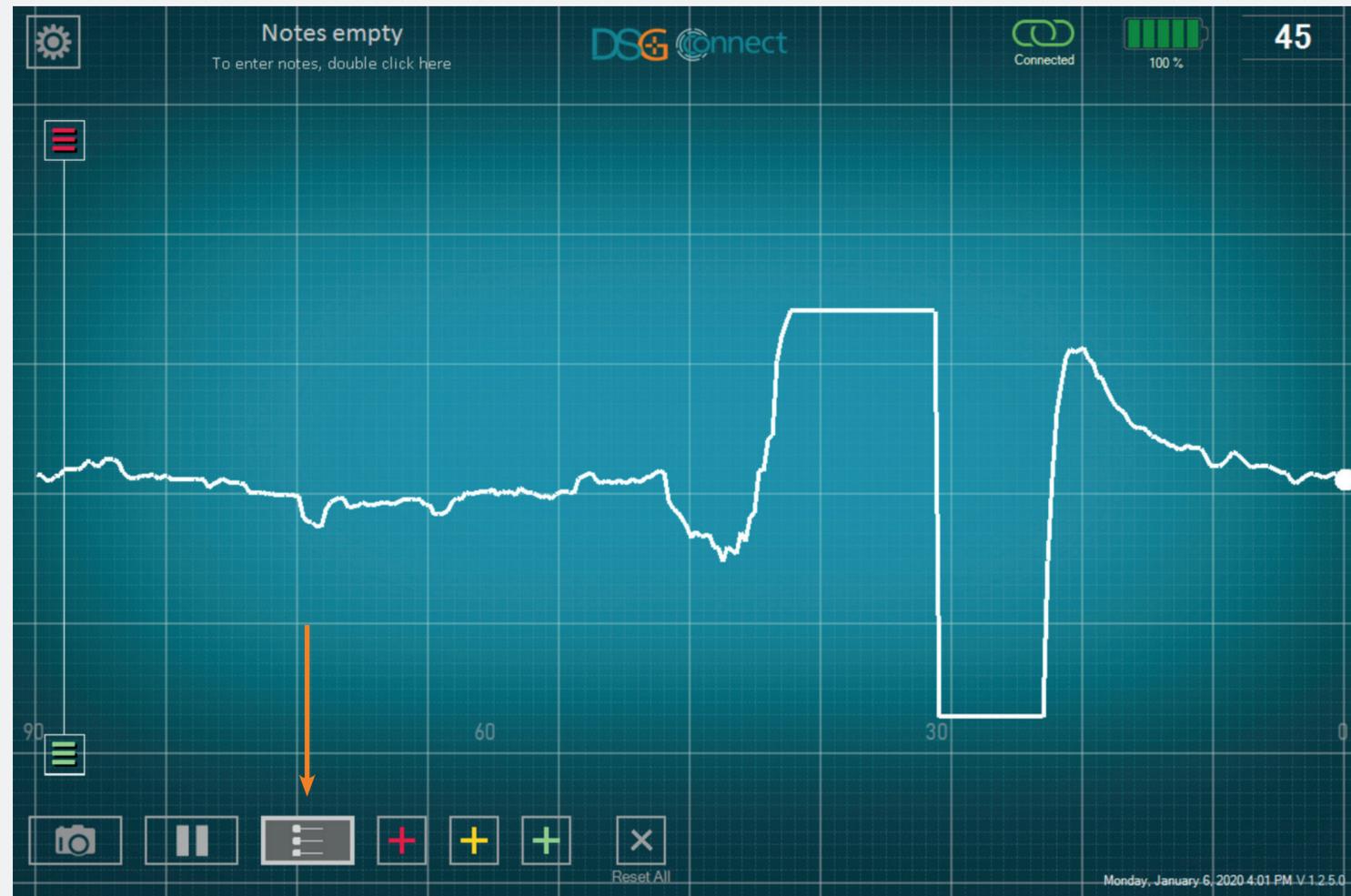
Visual Indicators

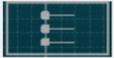
What is the visual indicator feature?



- The visual indicator feature allows you to position a landmark on the graph which you can adjust according to your drilling.

How to activate the visual indicator?



- To activate the visual indicator feature, click on the button: .
- When the feature is active and during use, the button will become bright.
- You can position visual indicators.

How to add visual indicators on the screen?



- You have 2 options to add visual indicators:
 - Option #1: click on any of the buttons at the bottom of the screen . The visual indicator will be positioned automatically at the level of the live DSG value.
 - Option #2:  drag one of the buttons on the left panel (on top or bottom), and position the visual indicator where you want on the scale.
- You can add up to 6 visual indicators on the screen (see p. 36).

How to change visual indicators position?



- Drag one of the buttons  at the expected location.
- The value of the visual indicator is viewable at the bottom of the screen. It is also visible directly next to the buttons but only during the adjustment of the the visual indicator for visibility reasons



How to delete visual indicators?



- You have the possibility to hide or remove the visual indicators individually.
- You have 2 options to remove a visual indicator:
 - Option #1: Click on the corresponding button .
 - Option #2: Slide the corresponding button  up or down the scale until the end of the selection zone.
- If you want to remove all the visual indicators, click on the cross «Reset All»



How to deactivate the visual indicator feature?



- If you want to deactivate the visual indicator feature, click on the button  to automatically hide the use of the feature.
- In that case, the visual indicators, the scale on the left and the  buttons will no longer be showed.
- If you want to reactivate the feature, click once again on the visual indicator button: . It will come-back as it was before the deactivation.

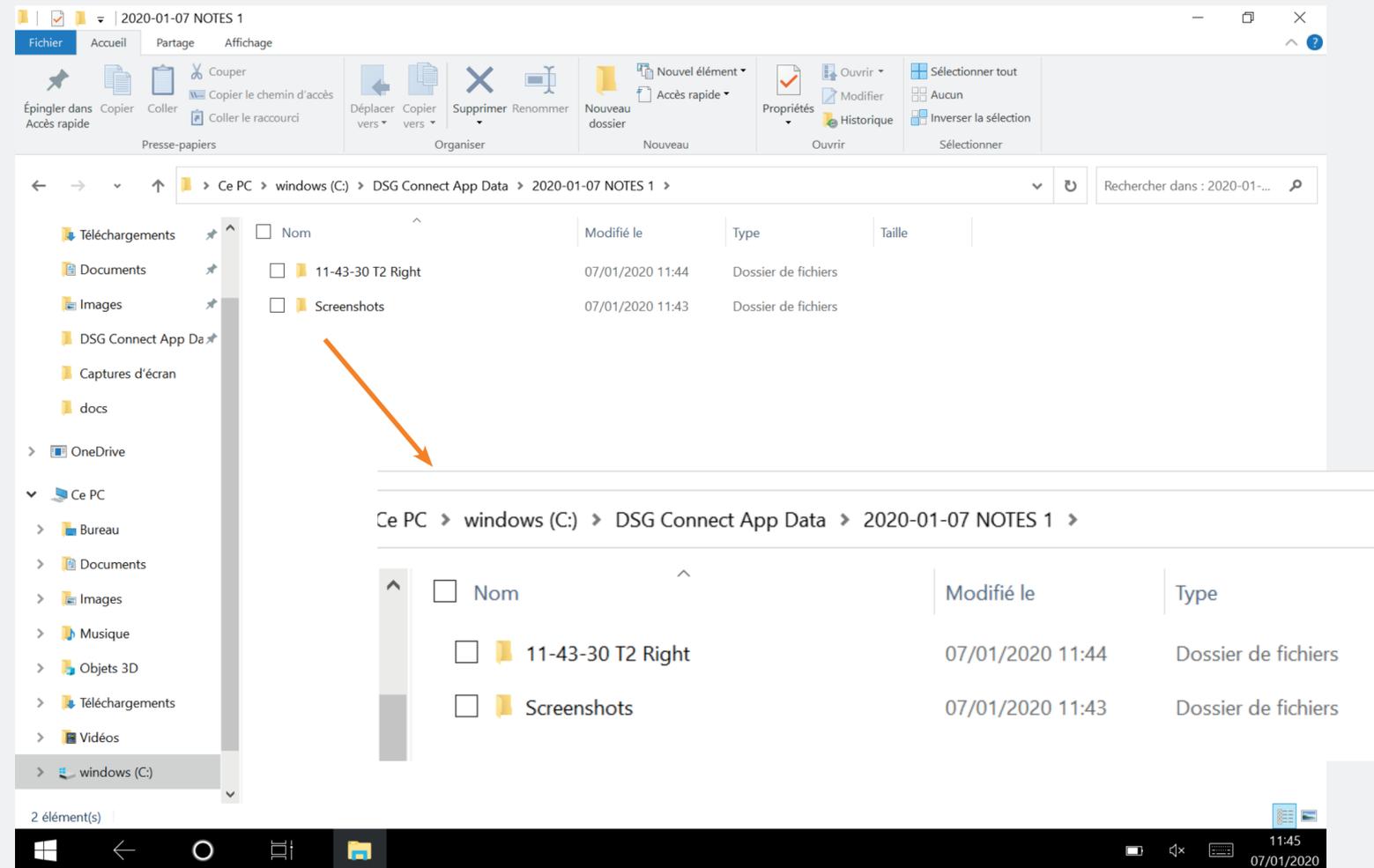
Screenshots

How to use the Screenshot feature?



- You can take screenshots at any moment of the surgery.
- Screenshot your graph if needed by clicking on the screenshot button.

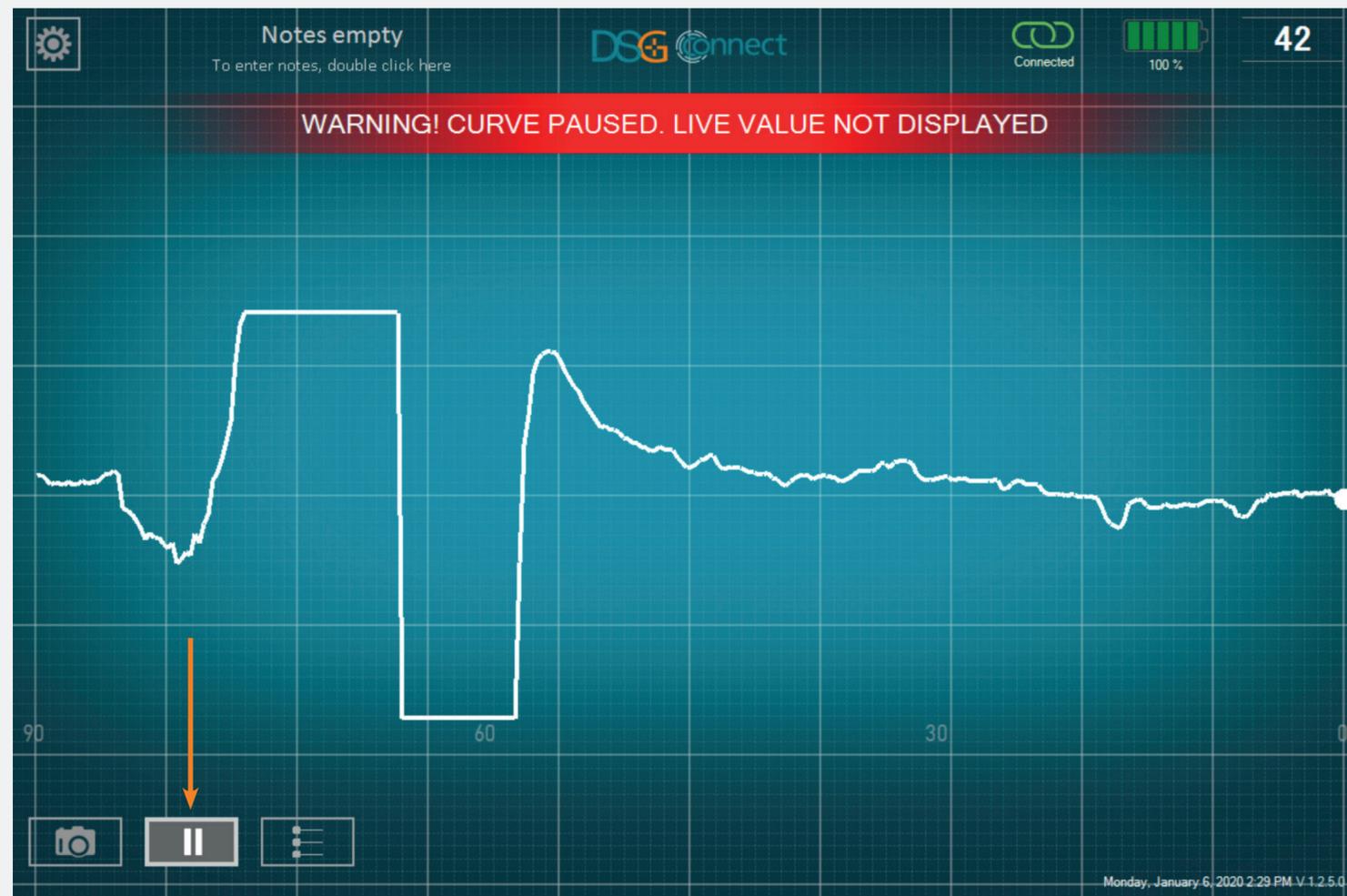
Where can I find the screenshots I took?



- You can see your screenshots at the end of the surgery in a dedicated folder (see p. 31).

Pause

How to use the Pause feature?

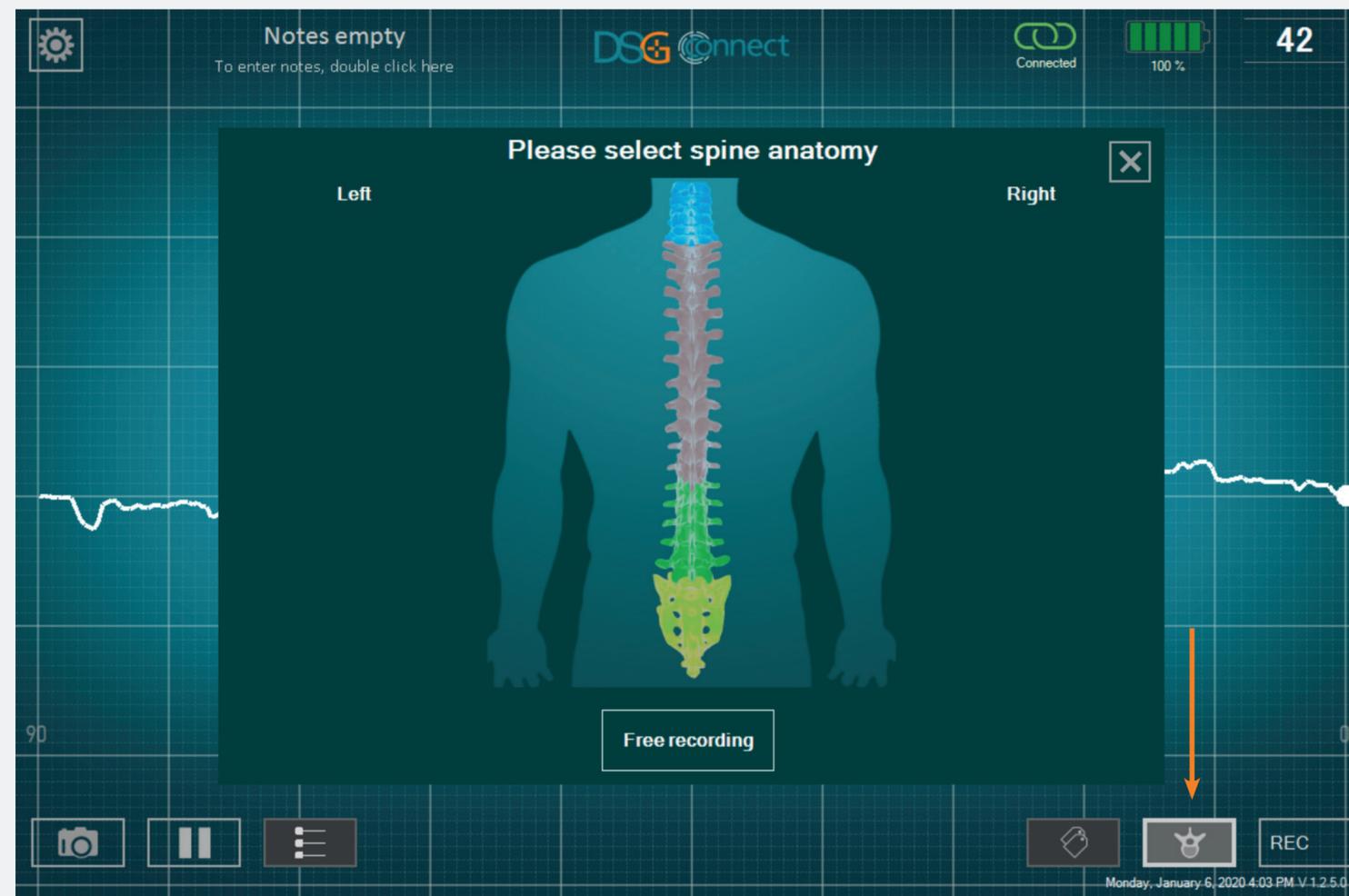


- Click on the Pause button: .
 - The screen will freeze and a notification will appear.
- To go back to normal, click once again on the Pause button: .

The Advanced Mode is mainly used for data recording purposes. It has additional features compared to the Simple Mode such as Spine Level Selection, Recording, Labels.

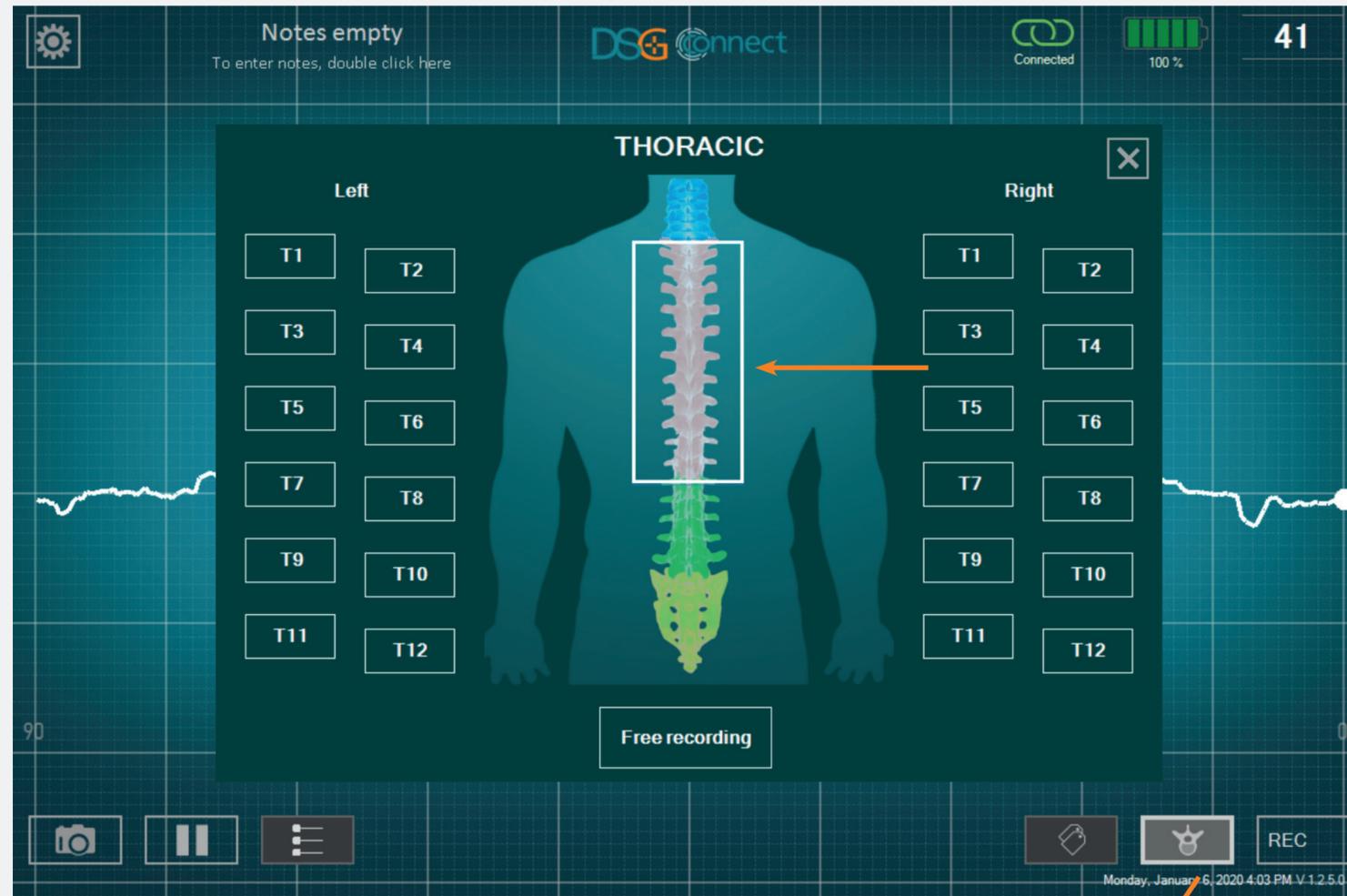
Pedicle Selection

What is the “Pedicle Selection” feature?



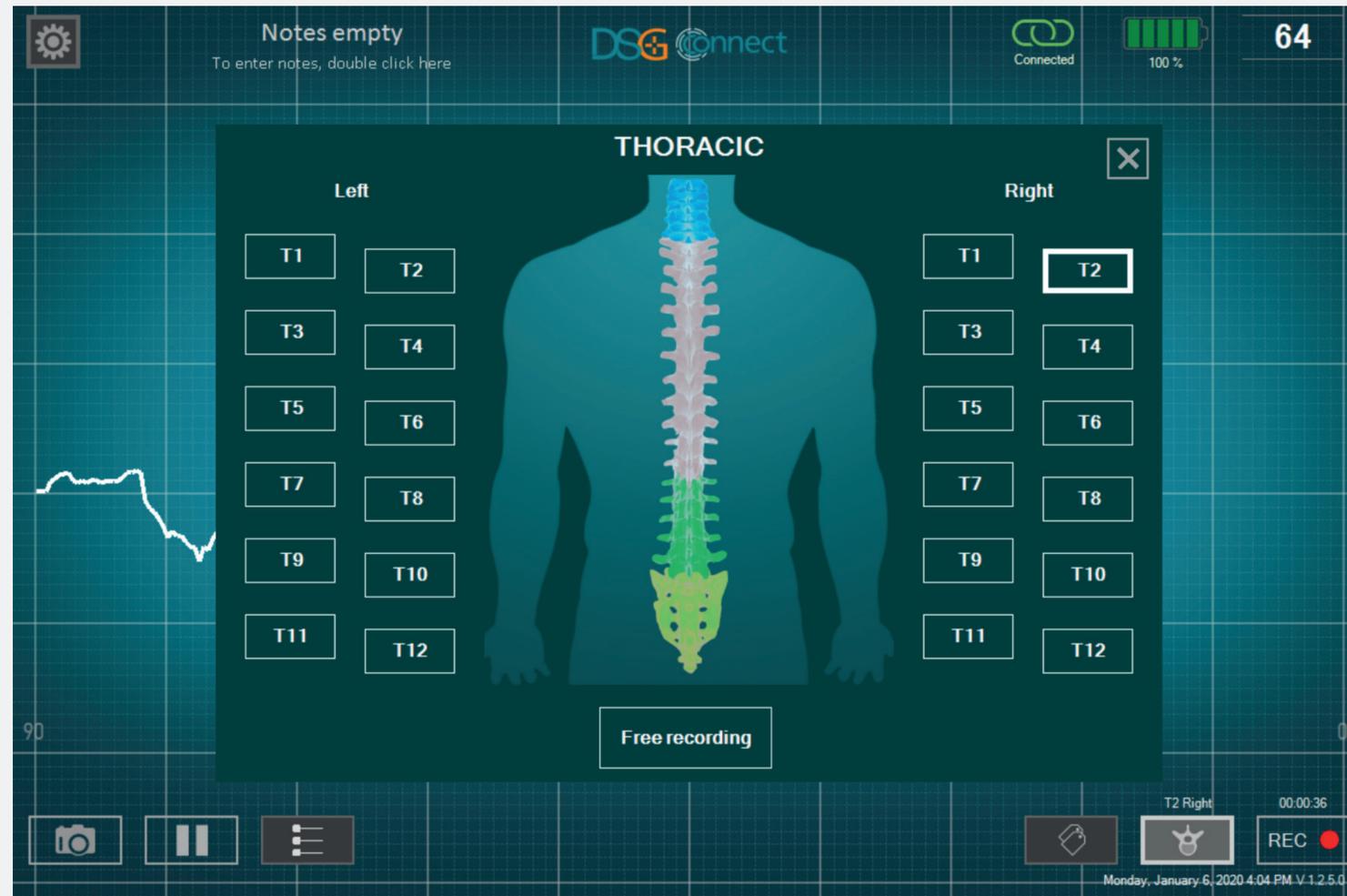
- The Pedicle Selection feature allows identification of the pedicle for each drilling record.
- You have to select your pedicles to be able to use the record mode.
- The data are recorded by pedicle drillings to facilitate the review at the end of the surgery.

How to use it?



- Click on the Spine Level button:  . A window with a spine appears.
- Select the level of the spine you want to drill.
- Then, select the corresponding pedicle. The state of the button will change from  to .
- After having selected your pedicle, the window automatically closes.
- The pedicle you selected is indicated on top of the Spine Selection button.

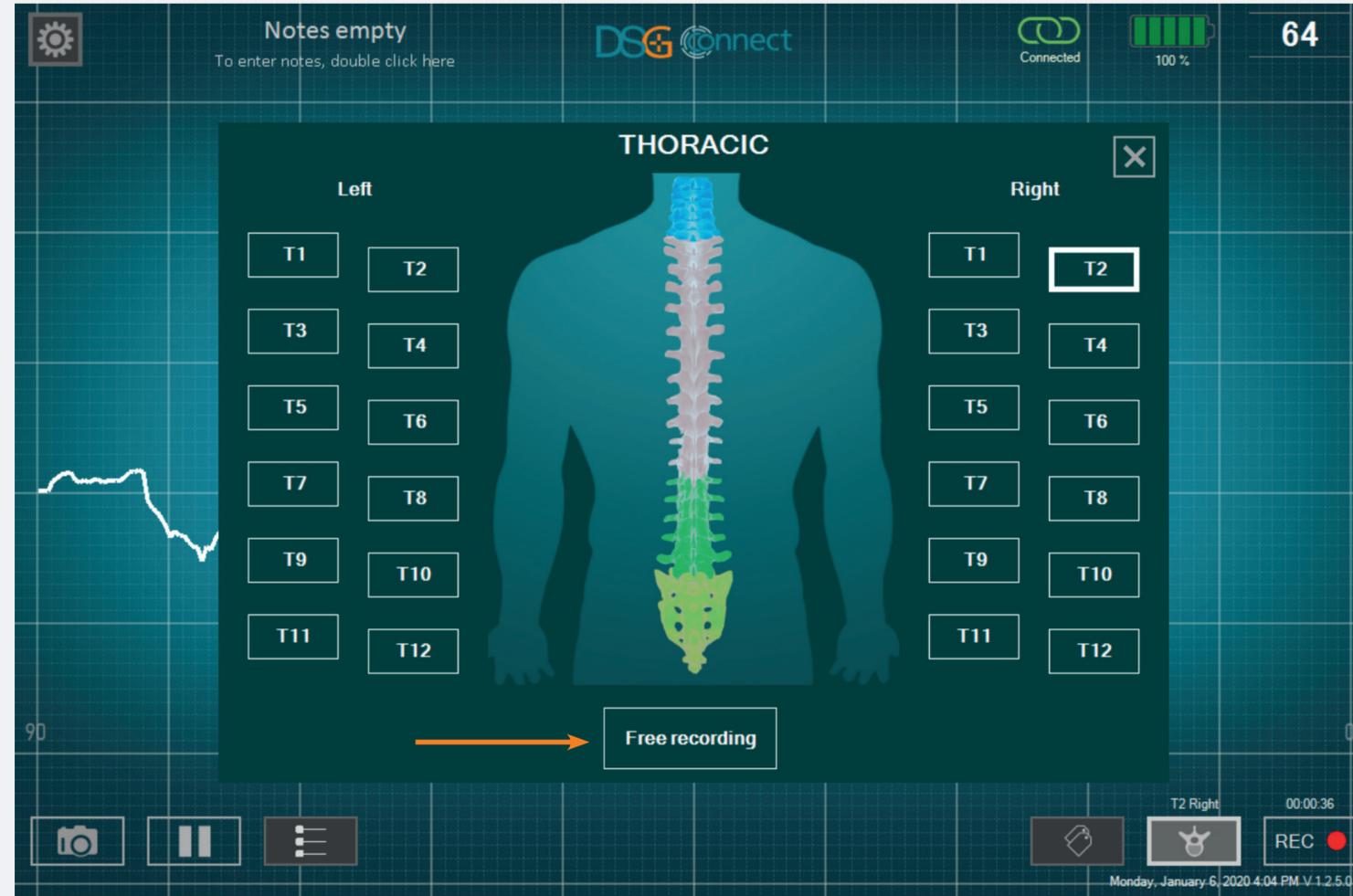
What if I want to select a pedicle I have already selected, and already recorded the drilling?



- Click a second time on the corresponding button. The button (as it has already been selected) will be shaded:



What is “Free Recording”?

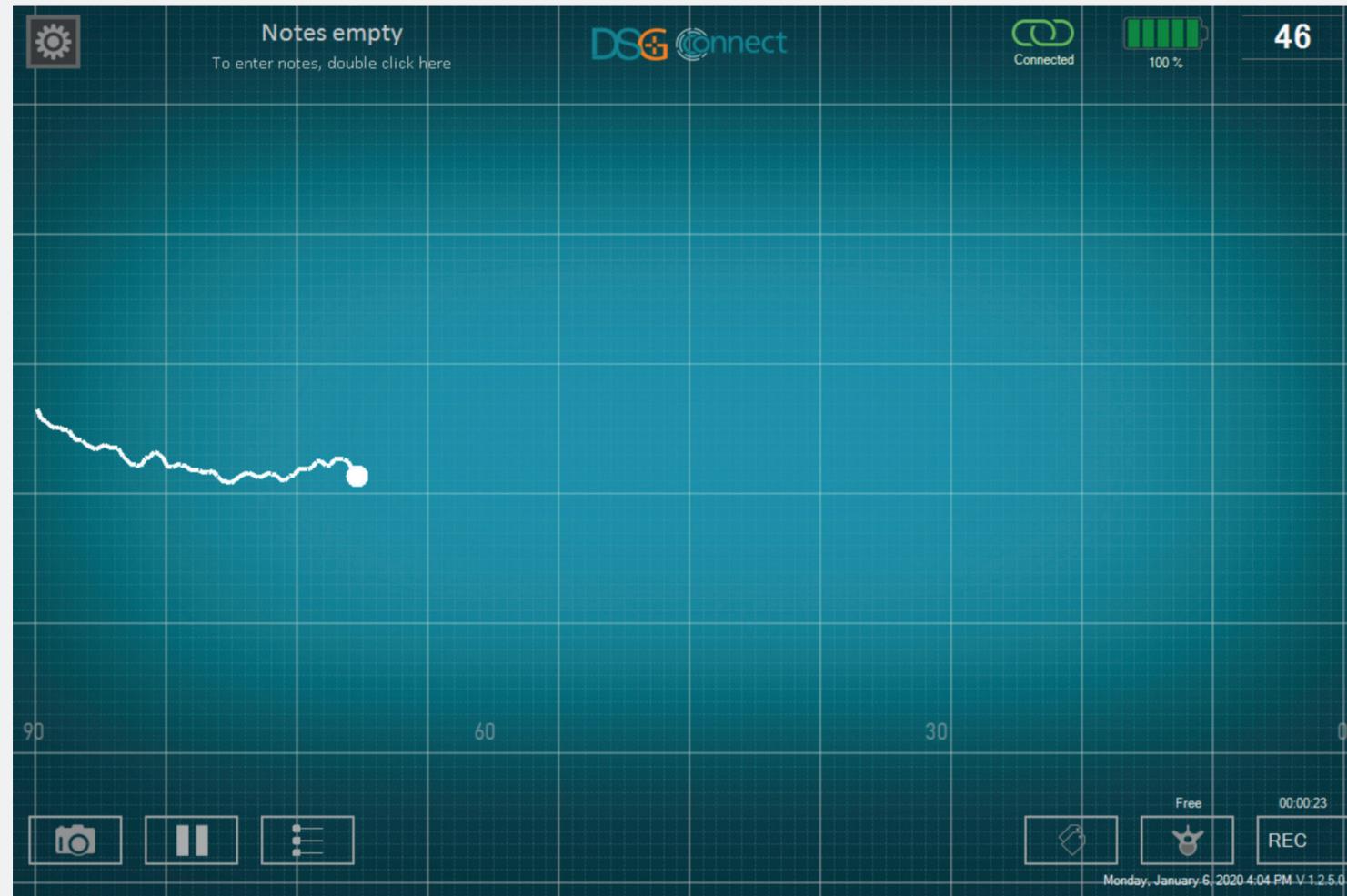


- If you do not want to record the data per pedicle, you can select “Free Recording”. It works the same way as the pedicle selection.

Note: Recording is only possible if a spine level or free recording is selected.

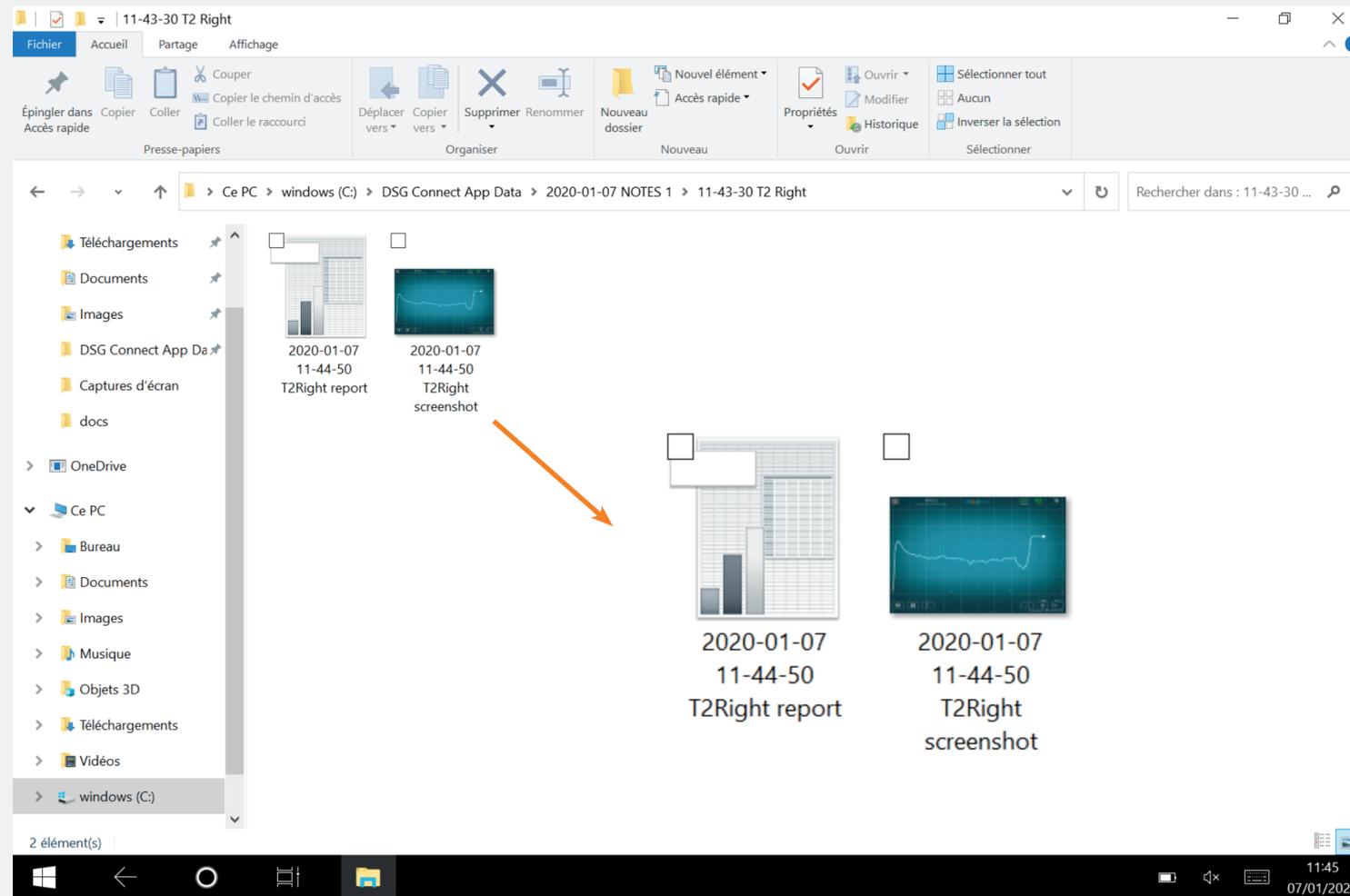
Recording

How to use it?



- After having selected your pedicle or Free recording, a grey circle in the REC button will appear: . It means you can start to record your drilling.
- Click on that button to record. The grey circle will turn red and will blink, it means that you are recording: . The time-indicator will inform you of the duration of the recording.
- If you want to stop your recording, click once again on the button.

Where can I find my recordings?



- You can see your recordings at the end of the surgery in a dedicated folder (see p. 31). One spreadsheet file and one screenshot of the curve are generated for each recording done.

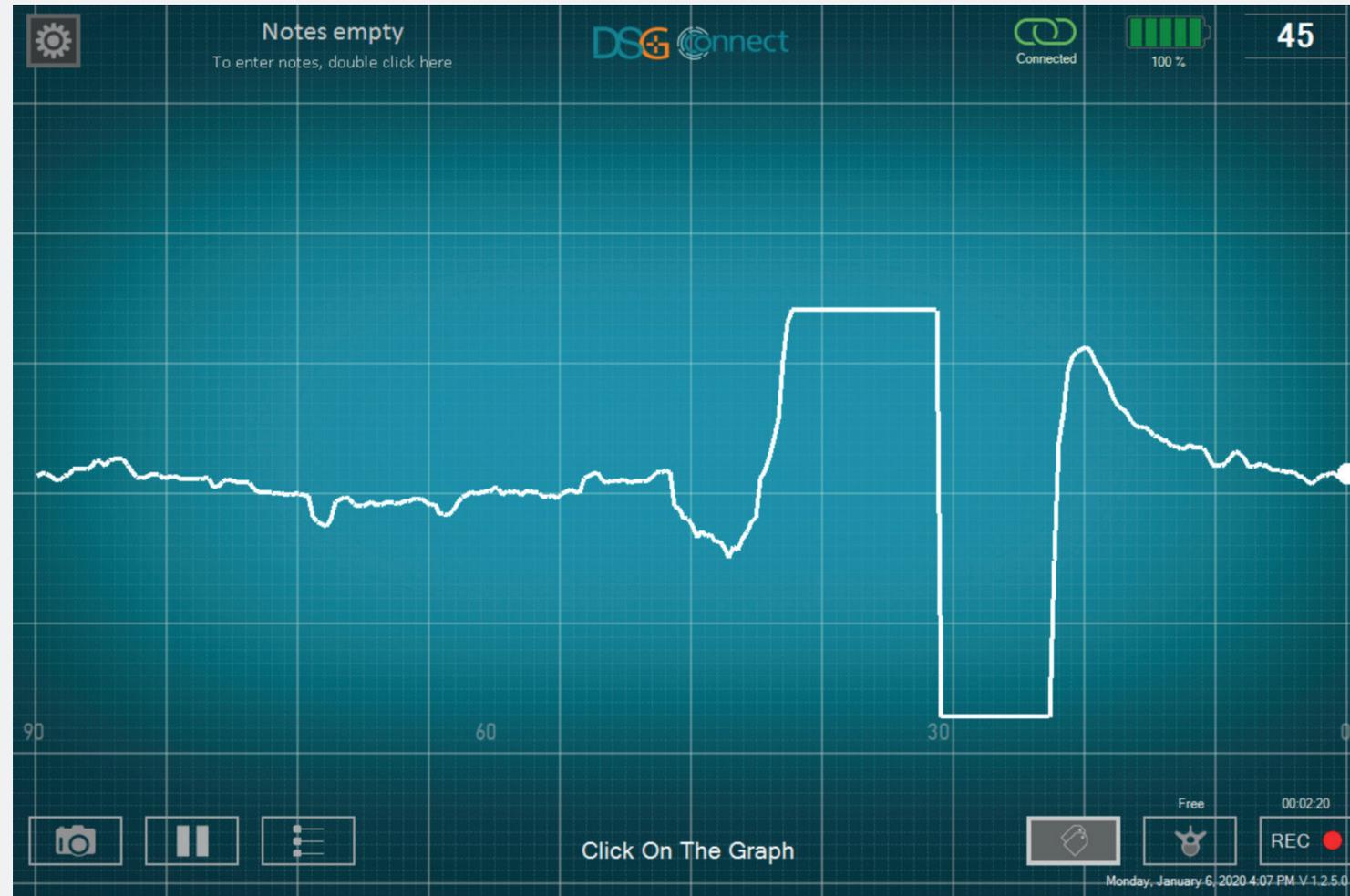
Label

What is the “Label” feature?



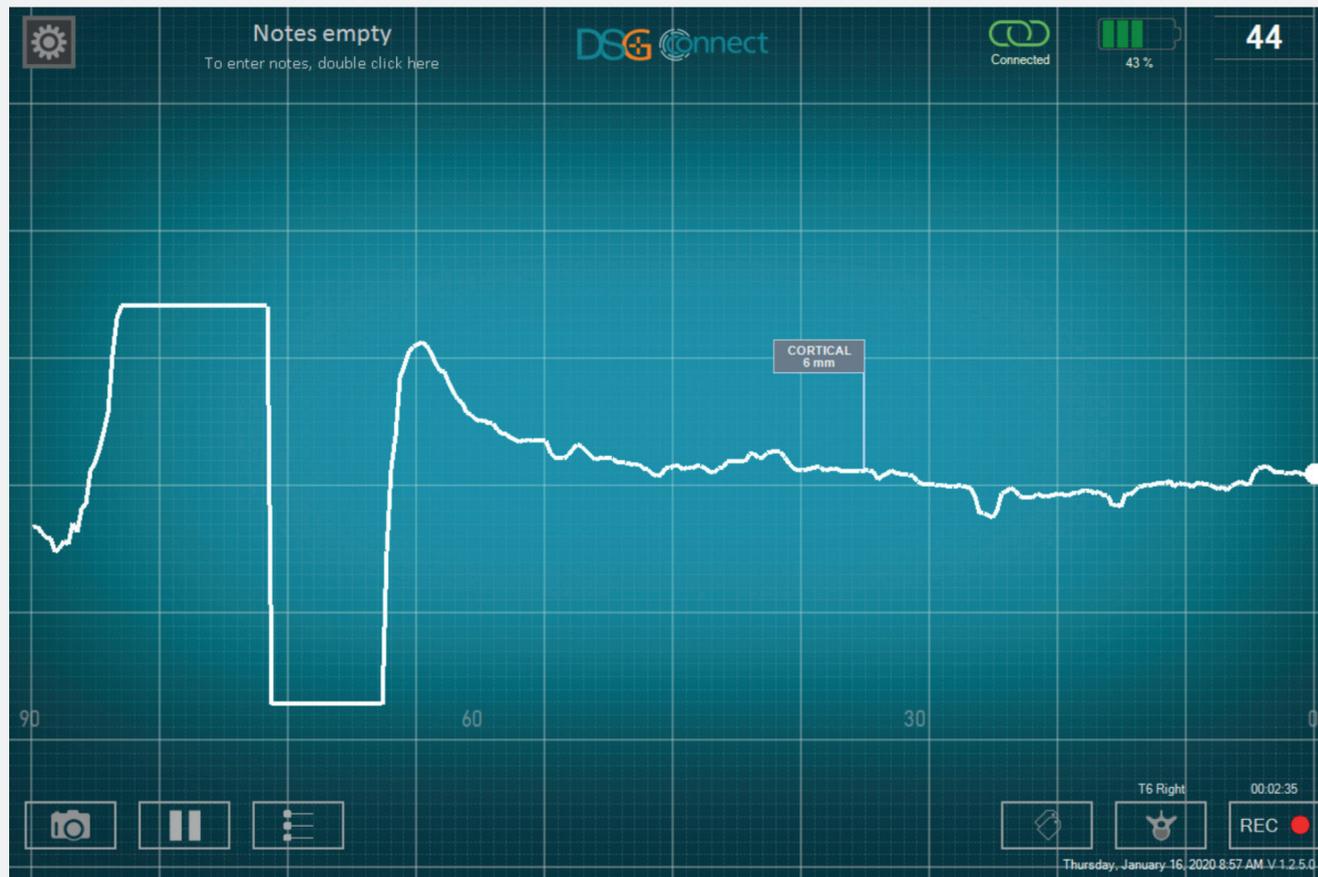
- It allows you to identify a specific event during the surgery by putting a tag on the screen.

How to use it?



- When you click on the Label button: , the sentence “Click on the Graph” appears.
- Then, you can click on the curve to add a tag.

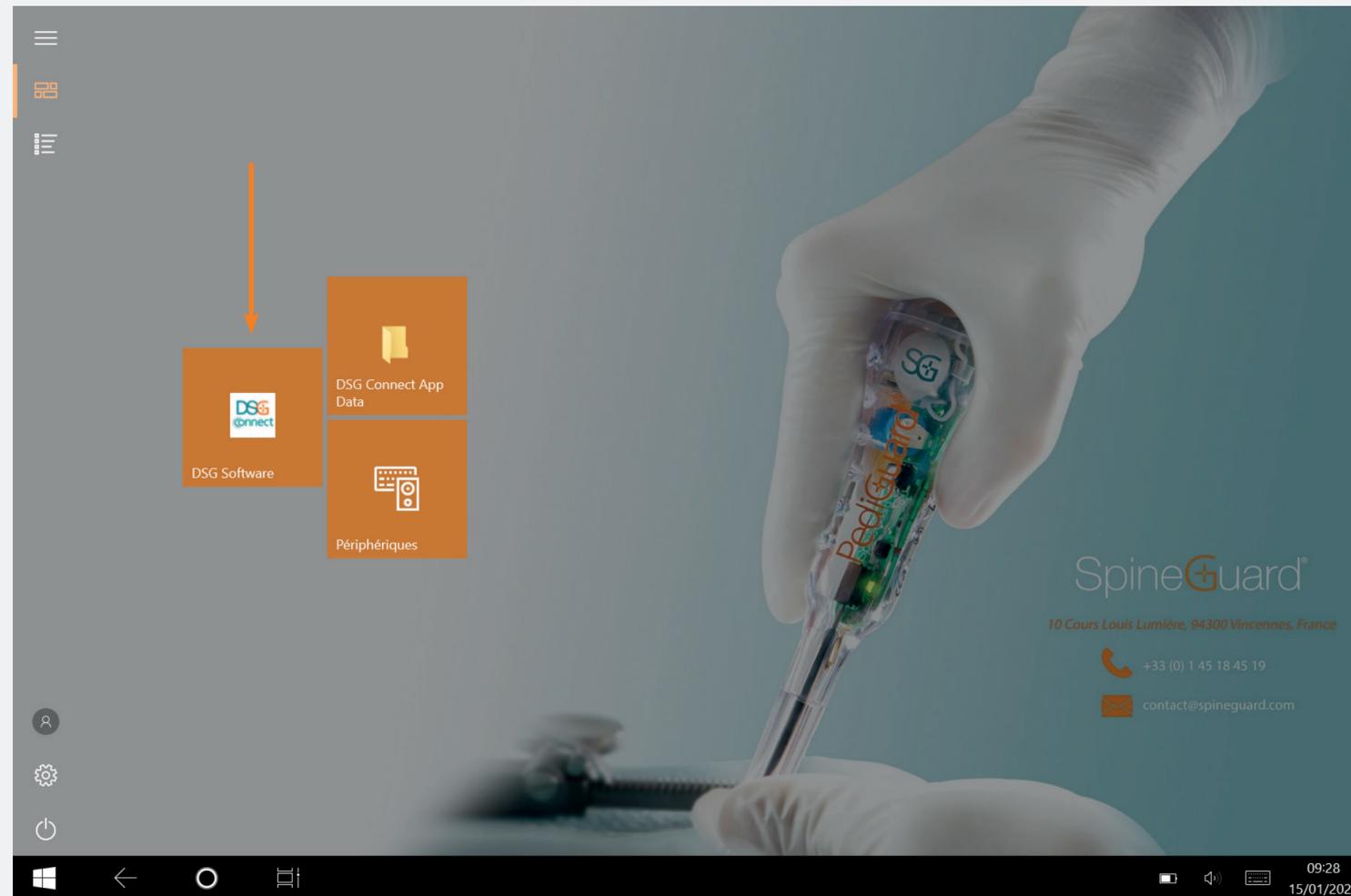
Advanced Mode



- Choose a nature from the pre-selected list (for example a tissue type or an event) and/or a depth for your tag by dropping down the setting wheel, then click on the button OK.
- A flag will appear with the information of the tag you selected.
- The flag will be following the graph horizontal scrolling.
- If you want to add another tag, repeat the process.

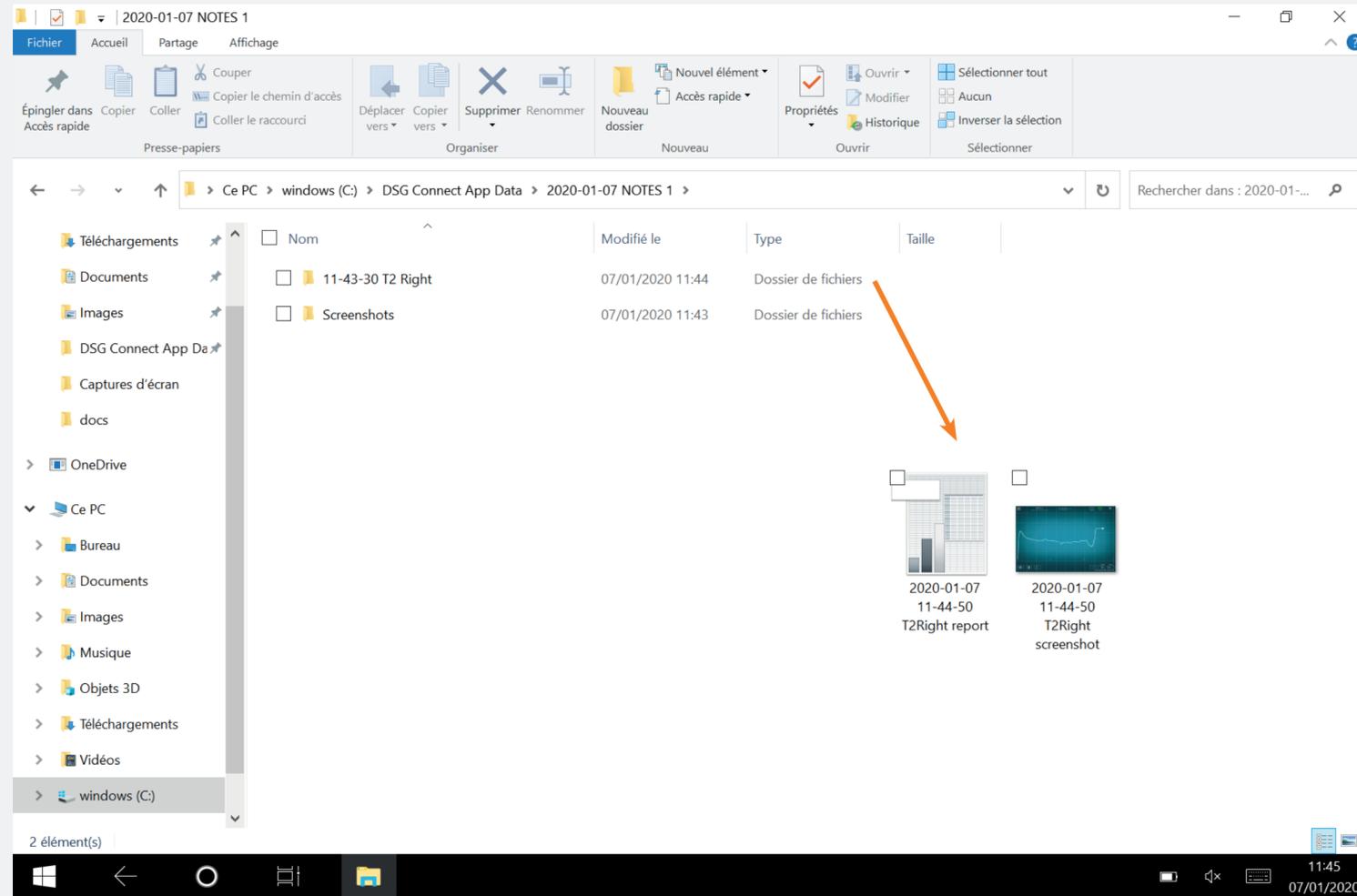
Export-Report (data review)

Where to find my screenshots and my recordings?



- Your screenshots and recordings are available after the surgery and are stored in a separate folder named as follow:
 - Name: YYYY-MM-DD
 - Example: 2020-01-07
- If you entered a Note, the folder will be named as such:
 - Name: YYYY-MM-DD Note
 - Example: 2020-01-07 NOTES 1
- Manuel Screenshot:
 - Format: JPG
 - Name: YYYY-MM-DD HH-MM-SS
 - Example: 2020-01-07 11-43-24

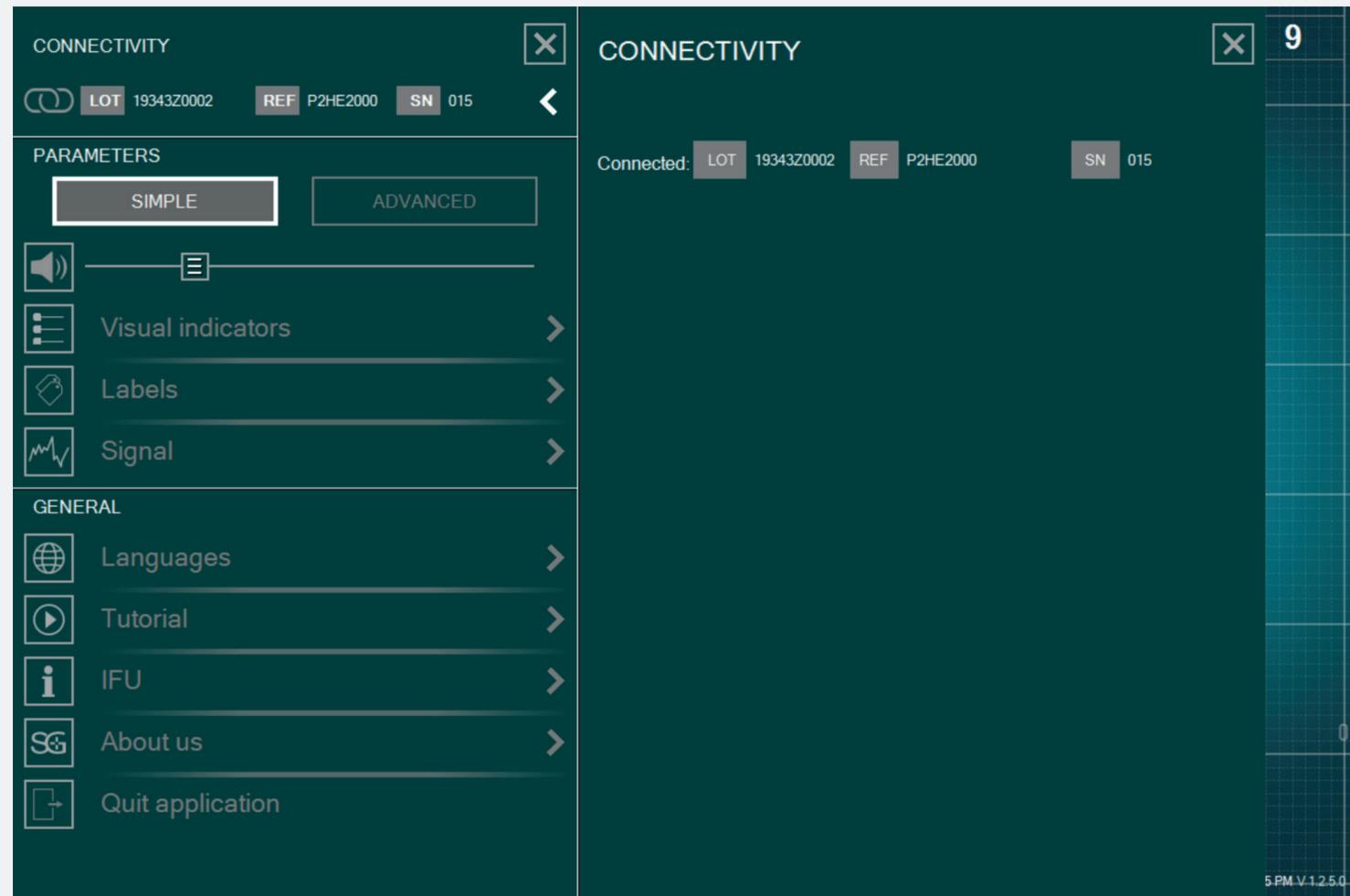
Advanced Mode



- Automatic Screenshot:
 - Format: JPG
 - Name: YYYY-MM-DD HH-MM-SS Selected_Pedicle screenshot
 - Example: 2020-01-07 11-44-50 T2 Right screenshot
- Recording:
 - Format: CSV
 - Name: YYYY-MM-DD HH-MM-SS Selected_Pedicle report
 - Example: 2020-01-07 11-44-50 T2Right report

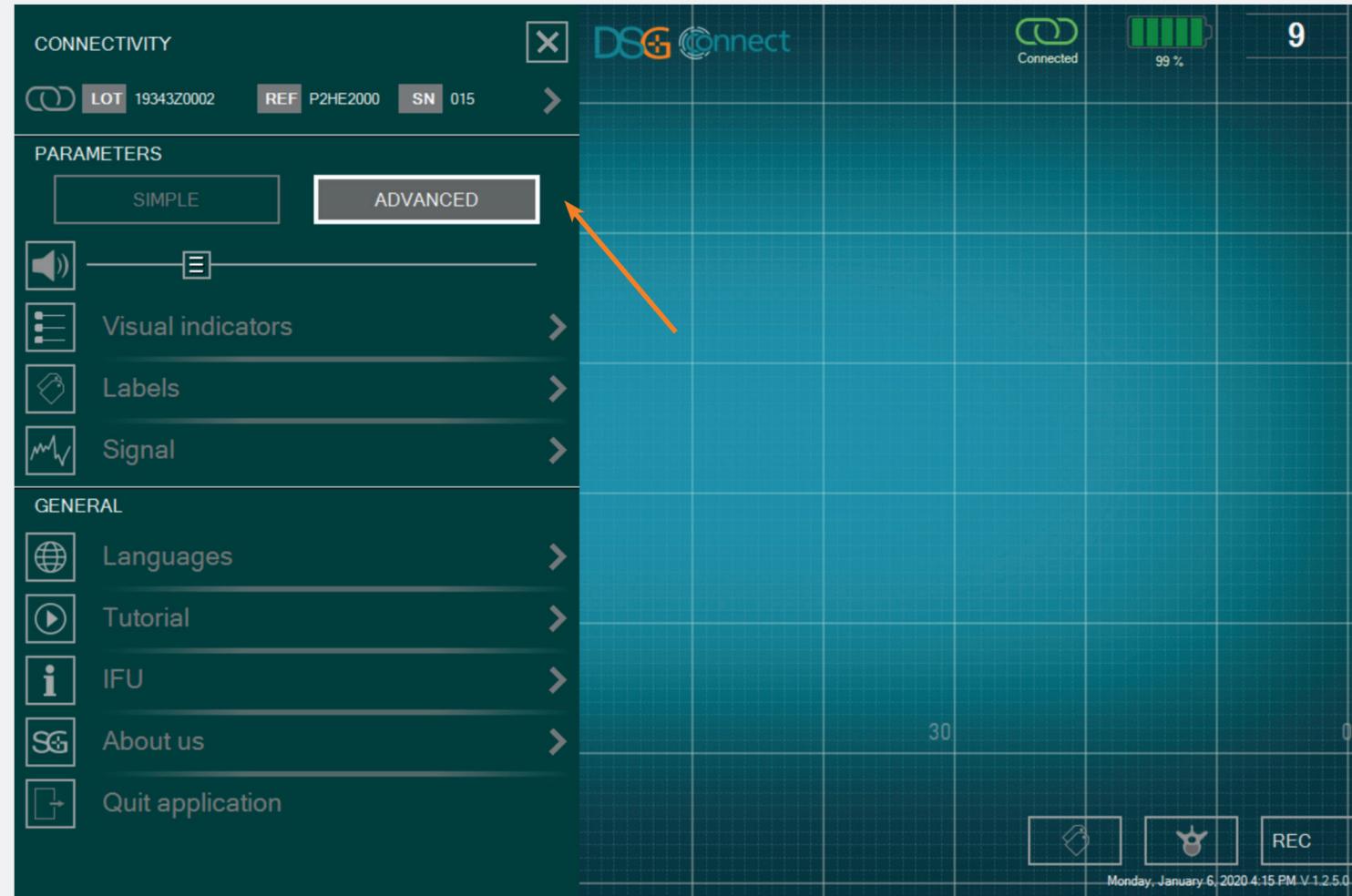
DSG Device Connection

How to know if the DSG Connect device I want to use is connected?



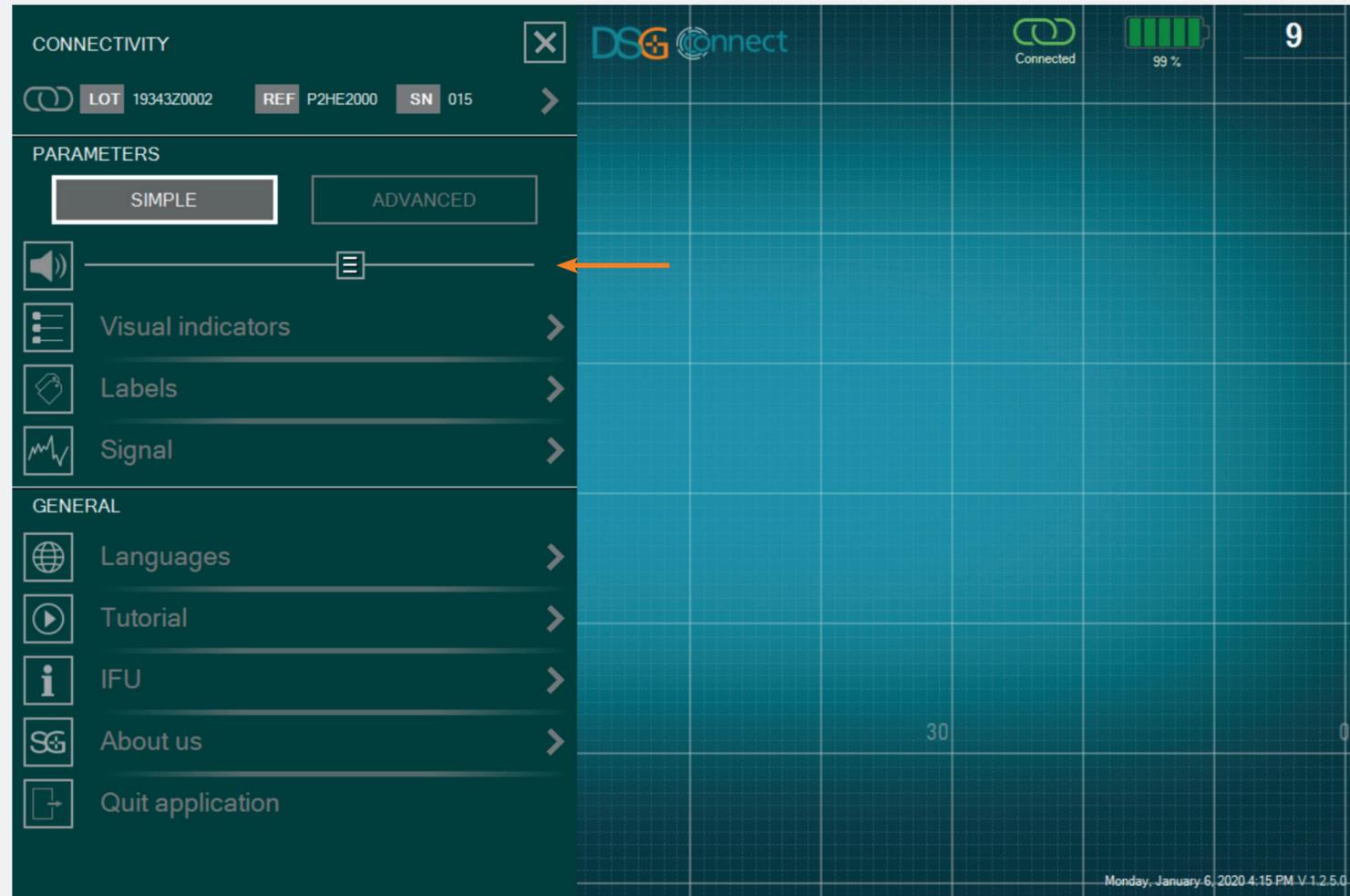
- The green connected icon means one DSG Connect device is connected to the tablet: .
- The traceability information of the device (reference, lot number and serial number) is indicated in the connection window.
- If there is no DSG Connect device Connected: .

Simple and Advanced Modes



- You can select either the Simple mode or Advanced mode, depending on your needs during surgery.

Volume



- The sound notification volume can be modified by sliding the corresponding bar from left to right.

- The sound notification will indicate:
 - Low battery,
 - Connection loss,
 - Full Memory,
 - Pause,
 - Screenshot.

Visual Indicators

The screenshot shows a software interface with a dark green background. On the left, there is a 'PARAMETERS' menu with options: 'SIMPLE' (selected), 'ADVANCED', 'Visual indicators' (highlighted with an orange arrow), 'Labels', and 'Signal'. Below this is a 'GENERAL' menu with options: 'Languages', 'Tutorial', 'IFU', 'About us', and 'Quit application'. The main area is titled 'VISUAL INDICATORS' and contains a small graph showing a signal waveform. Below the graph, there are settings for 'Number of visual indicators on the screen' (a row of buttons from 1 to 6, with 6 selected) and 'Color of the visual indicators:' (a grid of 6 rows and 6 columns of color swatches, with the top-left swatch in the first row highlighted).

- You can personalize the visual indicators feature by choosing:
 - the number of the visual indicators viewable on the screen (by default 3 – maximum 6),
 - the color for each visual indicator (2 cannot be of the same color).

Label

CONNECTIVITY

LOT 19343Z0002 REF P2HE2000 SN 015

PARAMETERS

SIMPLE ADVANCED

Visual indicators

Labels

Signal

GENERAL

Languages

Tutorial

IFU

About us

Quit application

LABELS

Available label(s)

Nature Depth

Labels' name:

#01: CANCELLOUS - #06: REDIRECTION -

#02: CORTICAL - #07: END OF DRILL -

#03: BLOOD - #08: +

#04: ENTRY POINT -

#05: BREACH -

Depth interval (mm):

1 2 3 4 5

5 PM V.1.2.5.0

- You can choose your default label type: Nature or Depth, or both.
- There are several natures (or pre-filled label names) by default. You can edit these tags by clicking on the following button **+** (10 tags at maximum).
- If you want to remove one label, click on the button **-**.
- You can also choose your depth interval from 1 to 5mm.

Signal

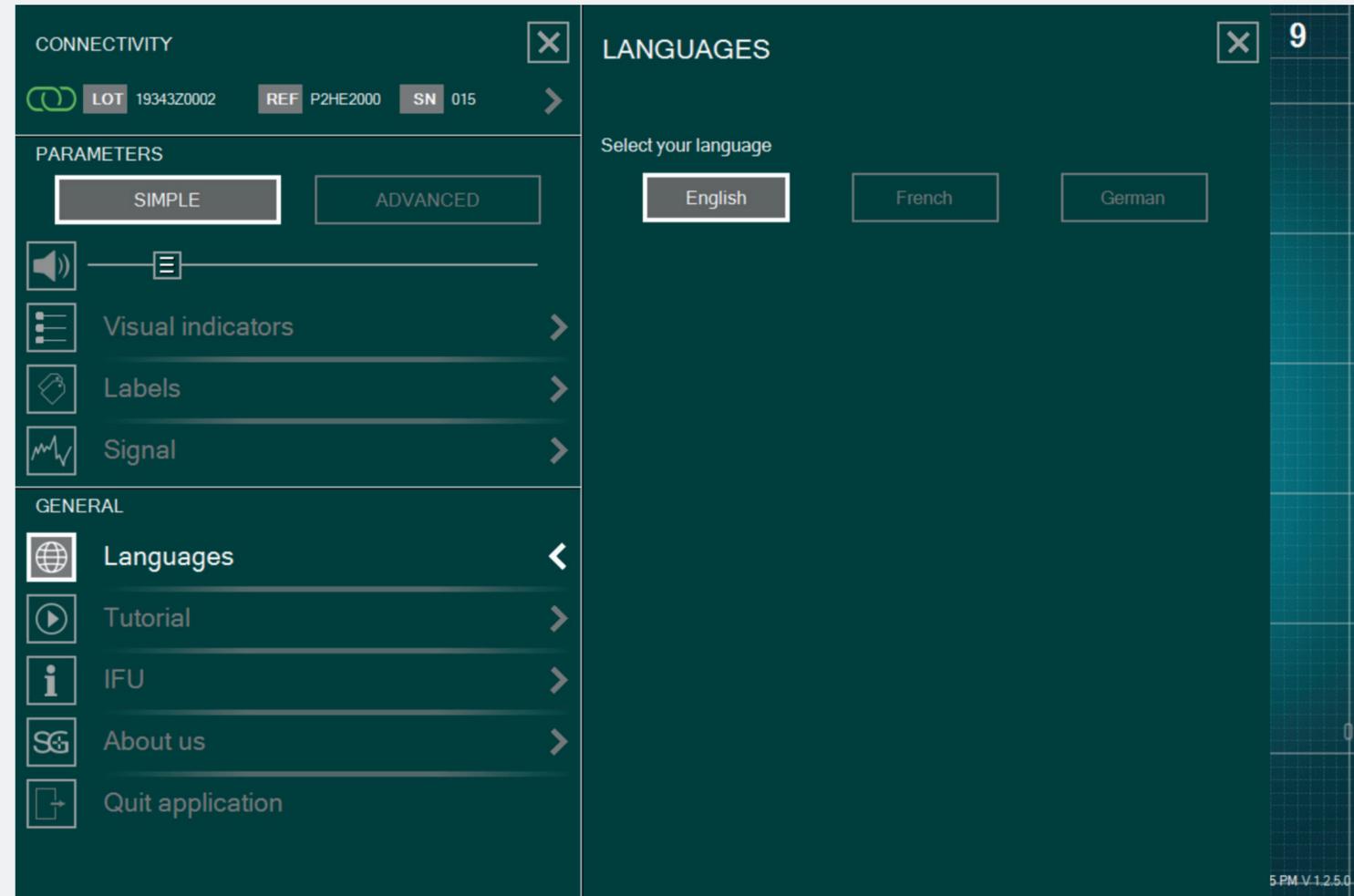
The screenshot shows a software interface with a dark teal background. On the left, a sidebar menu is visible with an orange arrow pointing to the 'Signal' option. The main window is titled 'SIGNAL' and contains the following settings:

- CONNECTIVITY:** Includes fields for 'LOT' (1934320002), 'REF' (P2HE2000), and 'SN' (015).
- PARAMETERS:** Features two buttons, 'SIMPLE' (selected) and 'ADVANCED'.
- Grid on the curve window:** A checkbox labeled 'Yes' is checked, and a 'No' option is also present.
- Time scale of the curve window:** Four buttons are shown: '30', '60', '90' (selected), and '120'.

The bottom right corner of the window displays the version number '5 PM V.1.2.5.0'.

- You can choose the width of the time window to be 30s, 60s, 90s (by default) or 120s.
- If you do not want to have the grid background on the main screen, select “No” for the option “grid on the curve window”.

Languages



- Select your language.

The screenshot displays the DSG Connect App interface. On the left, a sidebar menu is visible with the following sections and items:

- CONNECTIVITY**: Includes fields for LOT (19343Z0002), REF (P2HE2000), and SN (015).
- PARAMETERS**: Contains two tabs, 'SIMPLE' (selected) and 'ADVANCED'. Below the tabs are icons for 'Visual indicators', 'Labels', and 'Signal'.
- GENERAL**: Contains icons for 'Languages', 'Tutorial', 'IFU' (highlighted with an orange arrow), 'About us', and 'Quit application'.

The main content area on the right is titled 'IFU' and displays the 'USER MANUAL (EN)'. The text reads:

In no case can the DSG® Connect App replace the surgeon's experience or knowledge of anatomic structures. It is intended to be used by the operating room staff in a clinical environment. The DSG Connect App visually provides the same information as the DSG Connect PediGuard® devices provide audibly. The LED and audio outputs from the DSG Connect PediGuard® device are the primary output of the DSG Connect device and should remain the basis for clinical decision-making. THE DSG CONNECT APP IS NOT INTENDED FOR MEDICAL DECISION MAKING.

1. INTRODUCTION
The DSG Connect App is part of a system involving a DSG Connect PediGuard® device and a tablet. The DSG Connect App is used to collect, display and potentially record the signal provided by the DSG Connect PediGuard® devices, representative of the electrical conductivity measured at the tip of the instrument.

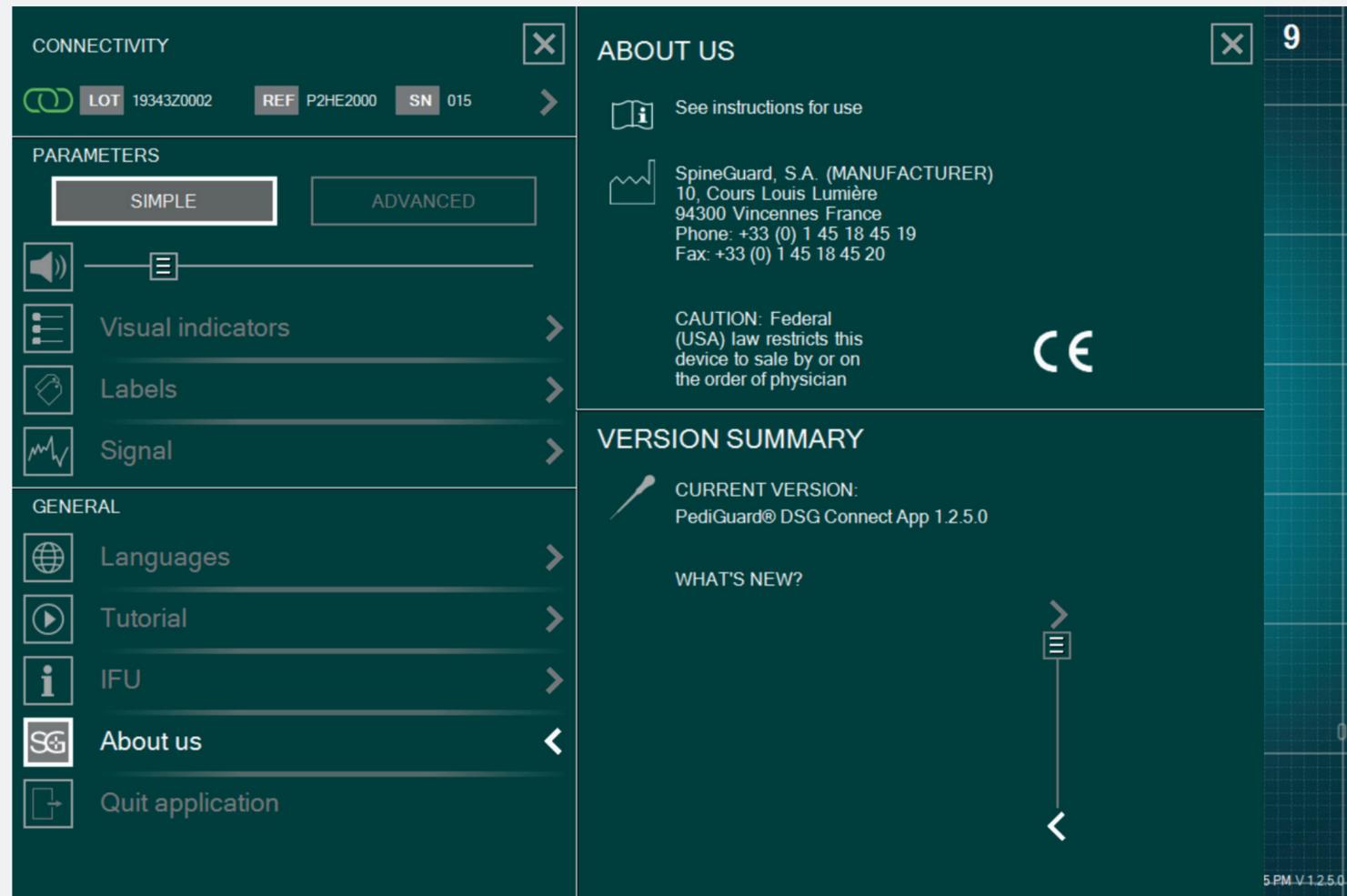
The data transmission with the DSG Connect devices occurs via radio frequency (RF) communication (2.40 to 2.48 GHz, GFSK modulation and maximum RF output power of 9.9 dBm).

2. DSG CONNECT APP TECHNICAL DESCRIPTION
The DSG Connect App is an optional accessory of the DSG Connect devices. It allows the surgeon to collect, display and

At the bottom right of the screen, the version number '5.PM.V.1.2.5.0' is visible.

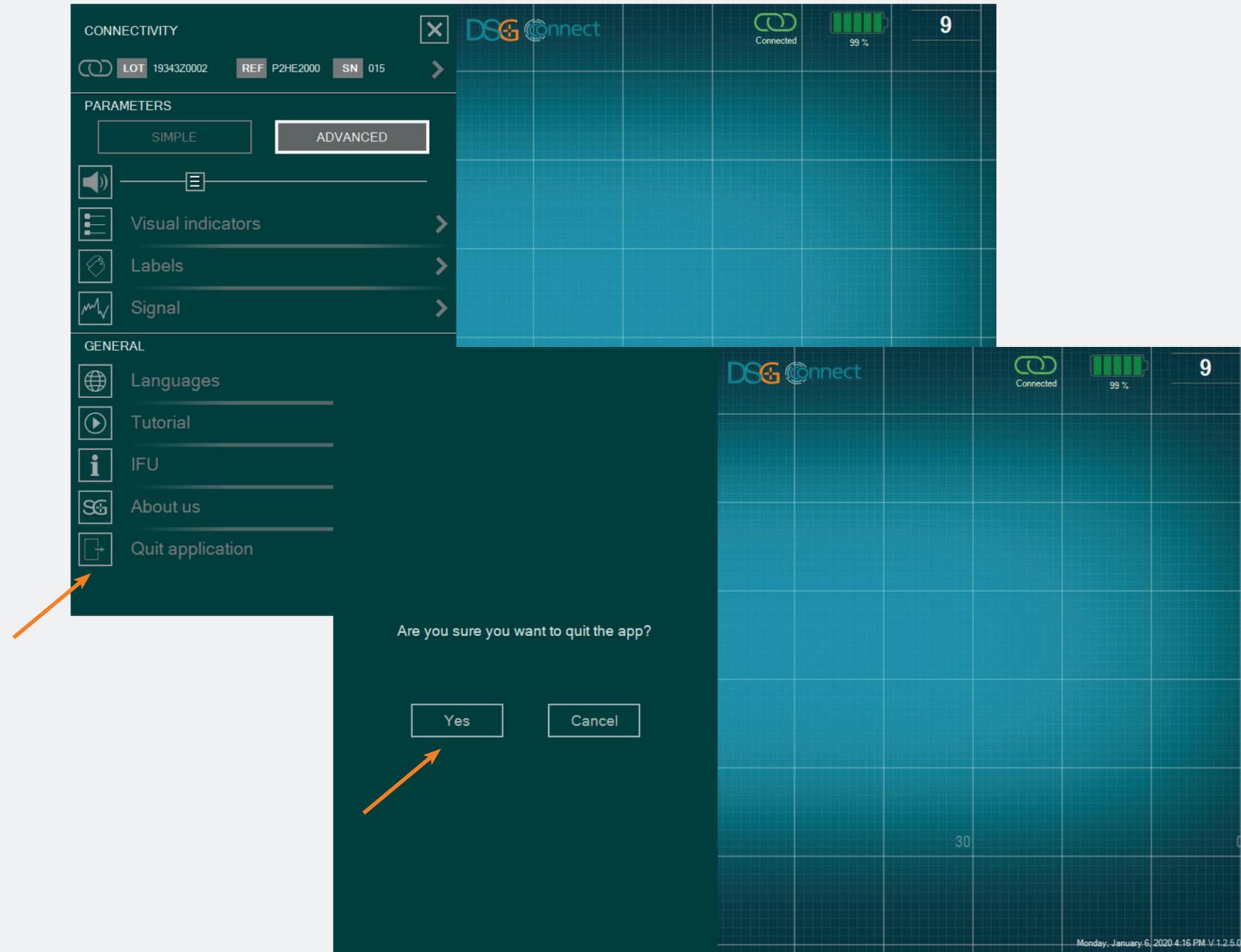
- The IFU of the DSG Connect App is available in the parameters.

Version Summary & About Us



- “About Us” refers to the general company information and the Version Summary.
- The Version Summary refers to the version of the DSG Connect App and current version.

App Quit



- To quit the App, click on the button Quit application:  .

Battery



- From 20%, the “Low Battery” notification will pop up.
- At this stage, we advise you to plug the power cord to the tablet to recharge the battery.

Connection



- If the wireless communication is lost, go on the settings menu and select an active DSG Connect device.

Memory Capacity



- This notification will pop up if you have low memory on your tablet.
- It is recommended to clean the tablet memory regularly to prevent the tablet to run out of memory.
- This could result in the software slowing down, or cause it to freeze, or resulting in the inability to review live data or record additional data.

For any question, please contact SpineGuard
at contact@spineguard.com