# Instruction For Use

## TempoTouch

**In Vitro Diagnostic Medical Device**

**For use in performance evaluation studies only**

**DYAMEO**

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**WARNING:**

The TempoTouch device is an in vitro diagnostic medical device used for near patient testing. It must not be used in direct contact with the patient.

# 1. Device presentation

## 1.1. Intended use

"TempoTouch is an optical spectrum analyzer collecting fluorescence signal emitted by diagnostic devices used in combination and displaying their results"

## 1.2. Characteristics

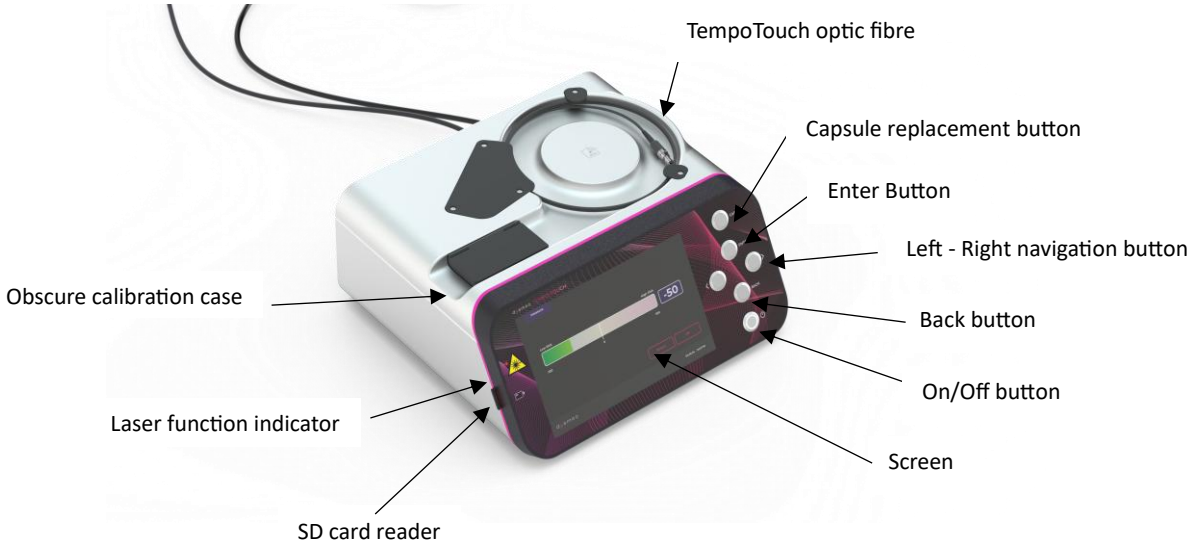
TempoTouch is designed to be used in combination with TempoCaps for In Vitro analysis. The device is used by hospital staff.
Each measurement takes around five seconds, enabling the user to perform many tissue analyses.
TempoTouch is an automated device that displays qualitative results.
The use of this device does not in any way replace the need for a histological analysis.

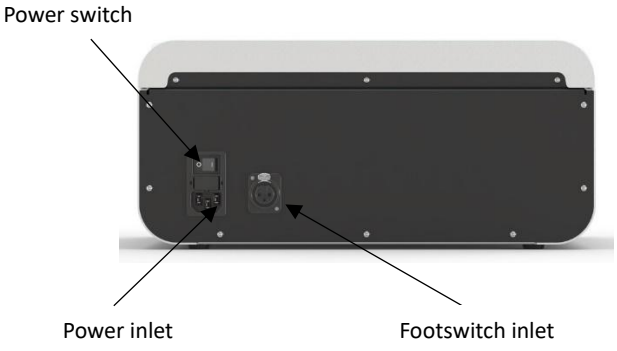
## 1.3. Counter indications

- None identified to date

## 1.4. Device Description

### 1.4.1. TempoTouch




Footswitch

Power cable

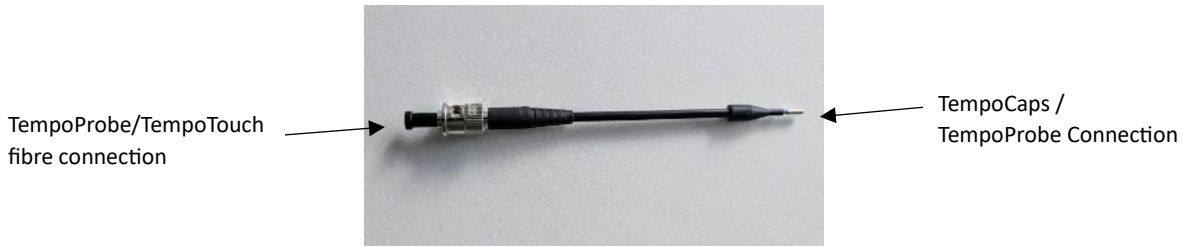
| Quantity | Designation |
|---|---|
| 1 | Optoelectronic device TempoTouch |
| 1 | Optic fibre TempoProbe – length 1.5 m |
| 1 | Footswitch – lg 0.8 m |
| 1 | Power cable – lg 2 m |
| 1 | SD card |

*Technical characteristics of the device*

| | |
|---|---|
| **Device dimensions** | 35 x 35 x 20 cm |
| **Weigth** | 10 kg |
| **Power supply** | 100-240 VAC – 50/60Hz (single-phase, grounded, ISO 60601 certified) |
| **Nominal voltage variation** | ± 10% |
| **IP class** | 20 |
| **Operating conditions** | Temperature +5°C à +40°C<br>Humidity ≤ 80%<br>Atmospheric pressure: 70 to 106 kPa<br>Overvoltage category : OVC II |
| **Laser** | Laser output power: <1 mW<br>Laser class : 1<br>Laser impulsion: continuous emission with shutter opening 3x250ms for each measurement.<br>Wavelength : 488 nm<br>Power consumption : 50 VA max |
| **Security** | Fuse : 1 A / 250VAC |
| **External output type** | SDCard |
| **Battery** | CR 1225 3V lithium battery on motherboard |
| **Software version** | v0.12 |
| **Software Safety class** | Safety class A |
| **IVD-DM** | Classe A (selon le règlement UE 2017/745) |
| **Storage and transport conditions** | Temperature -10°C à +70°C<br>10% <Humidity≤ 90%<br>Atmospheric pressure : 59,5 to 101,3 kPa |
| **Operating environment** | Hospital use (operating room) – Indoor use |
| **Operating altitude** | < 2000 meters |
| **Pollution degree** | Degree 2 |

### 1.4.2. TempoProbe

The TempoProbe is a dedicated single-use optical fibre which is installed on the TempoTouch optical fibre.



#### 1.4.3. TempoCaps

TempoCaps are in vitro diagnostic medical devices used in combination with the TempoTouch device. Dyameo is currently developing a single type of capsule.

| Designation | Instruction for use |
|---|---|
| TempoCaps EGFR Marker | REG-REC-022-C-V0-Instruction For Use TempoCaps EN. |

# 2. Target population

## 2.1. Patient profile:

Men and women aged over 18 years.

## 2.2. User profile:

- Surgeon: Preparation, checking, reference, measurement, acquisition, capsule change

## 2.3. Operating environment:

- Hospital environment

# 3. Precautions for use

---------- **WARNING** ----------

- **Laser emitting device**. Do not point the optical fibre in the direction of the eyes, a reflective surface or any optical device (telescope, microscope, etc.) when emitting the laser beam.
- The device must be operated by a qualified operator (hospital staff, doctor, etc.).
- The device must not come into contact with the patient.
- Install the appliance on a flat, stable surface
- No modifications to the device are authorised.
- Only use accessories supplied by Dyameo. If the footswitch or power cord fails, contact Dyameo.
- The device must be positioned so as to ensure access to the power cable in the event of an emergency.
- It is strictly forbidden to open the casing of the device
- The device must only be used with accessories listed by Dyameo as compatible.
- The appliance must be plugged into a compatible socket fitted with an earthing terminal.

- The device complies with the applicable electromagnetic compatibility standards. If you notice any malfunction due to interference or other factors in the presence of another device, please contact Dyameo.

- Do not spill any liquid on the device and do not place anything on top of the device other than the TempoProbe / TempoCaps.

- The device is not intended for use in the sterile field of the operating room.

- Check the integrity of the device case, power cable, optical fibre, footswitch and cable before each use.

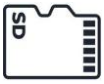
- Check that all component are securely in place (screws, removable parts). If the integrity of any of these elements is not compliant, do not use the device and contact Dyameo.

- Do not place the appliance near a source of heat.

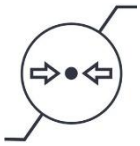
## 4. Remaining risks

*No remaining risk identified*

## 5. Logos and pictograms

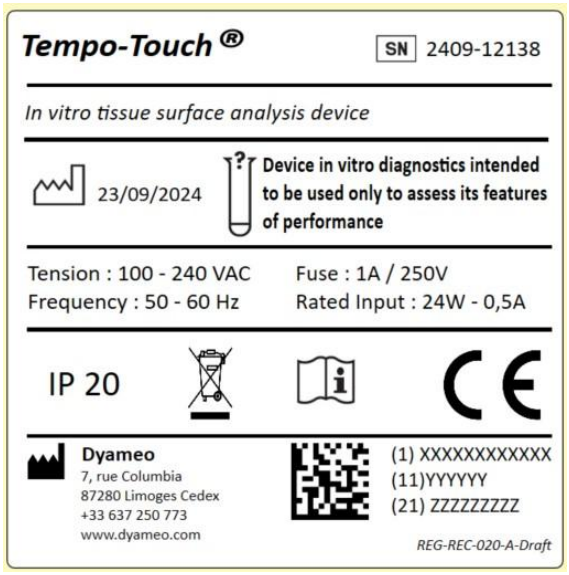
| **Front panel** | |
|---|---|
|  | Switching on the ON/OFF device |
|  | **Warning:** Presence of a laser source |
|   | SD card slot |

| **Rear panel** | |
|---|---|
|  | Indicates an in vitro diagnostic device which is intended to be used only to evaluate its performance characteristics before being placed on the market for use in medical diagnosis. |
| SN | Serial number |
| IP | Protection class |
|  | **Recycling:** This device must be eliminated in a structure adapted to reprocessing and recycling. Consult the manufacturer. |
|  | Consult the instructions for use |

| | |
|---|---|
|  | Humidity limit |
|  | Temperature limit |
|  | Atmospheric pressure limit |
|  | Do not use if the packaging is damaged |
|  | Fragile; handle with care |
|  | Read the instructions for use |
|  | Susceptible to Humidity |
|  | Packaging  orientation indicator |
|  | Manufacturing date |
|  | Manufacturer |
|  | UDI Number |
|  | CE Marking |
|  | Laser source emission |

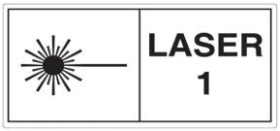
## 6. Labelling

- Device main label

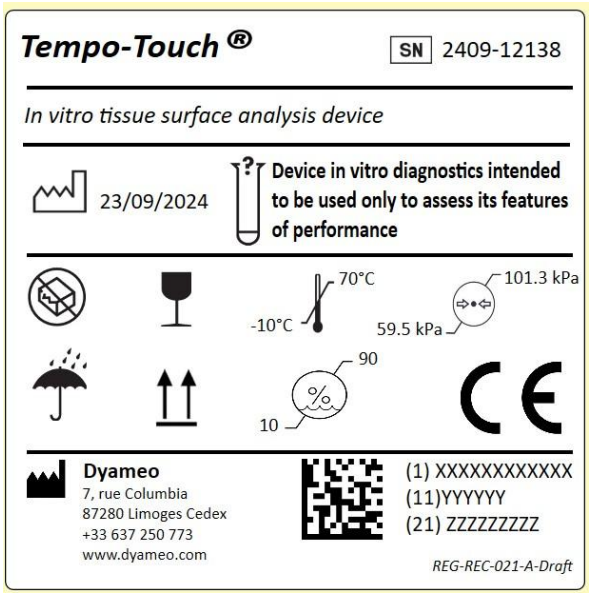



- ISED compliance labelling (requirements ICES-001)


- Laser class identification label




- Packaging label



# 7. TempoTouch operation

## 7.1. Capsule lifetime

The capsules can be used for a maximum of 6 analyses (or 'touches', i.e. contact with a tissue). In normal use, the first analysis is made during the reference phase (see §7.5). The user will therefore be able to perform 5 touches on a tissue for analysis purposes if only one reference measurement is made.Afin de garantir des performances optimales :

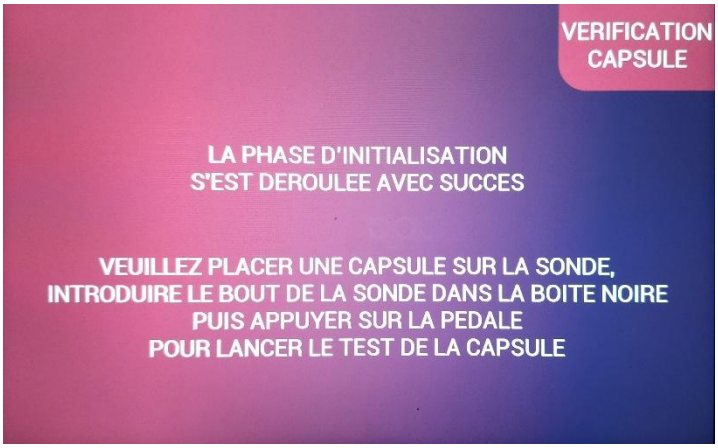
- A counter for the number of touches is triggered at the reference phase. This counter is incremented during the analyses, authorising a maximum of 5 touches. Beyond this, a message appears requesting the user to change the capsule (see §7.8).
- A timer is triggered as soon as the capsule is installed (§ 7.4.3.):
  - After 5 minutes without measurement (reference or analysis), the device asks you to place the TempoCaps in a saline solution.
  - After 15 minutes without measurement, the device asks you to change the capsule.la capsule (§ 7.4.3.)

## 7.2. Setting up the device

- Place the device on a flat surface such as a table or stand. To ensure stability, the device must stand on its 4 feet.
- Install the device on a table within 2m of a power socket
- Connect the footswitch.
- Plug the device into a conventional 220V earthed socket.
- Switch on the power button at the back of the unit.

## 7.3. Powering up and initialisation

- Press the « ⏻ » button on the front of the device. After switching on the device :
  - Initialization is performed to check that all the internal components are working properly.
  - The laser temperature is controlled to reach the optimum temperature for analysis (this may take a few minutes).



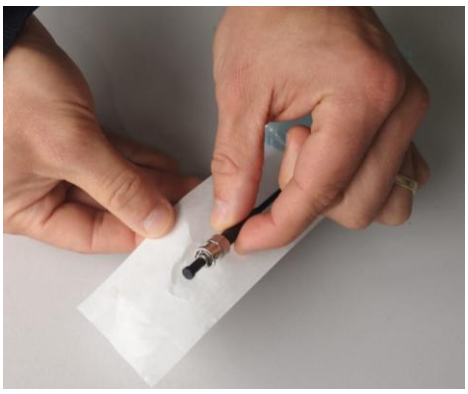

- The device displays the message above, confirming that the initialization phase has been successful.
- Follow the instructions for connecting the TempoProbe and attaching a TempoCaps capsule as specified below.

## 7.4. Connecting the probe and capsule

### 7.4.1. Connecting the TempoProbe

➢ The TempoProbe is packaged in a flexible, non-sterile sachet:

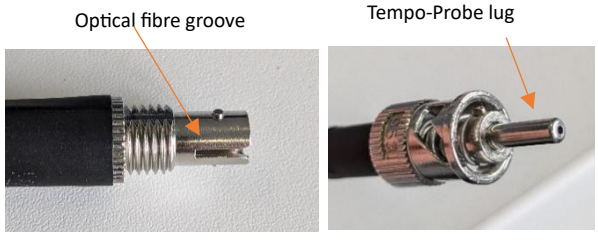
- Open the bag on the connector side to remove the TempoProbe probe by grabbing it by the plastic sheath :



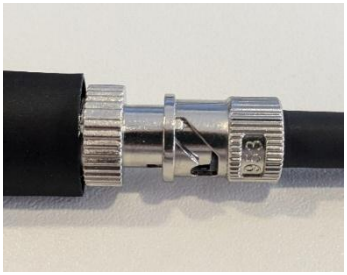
➢ The probe must be clean, with the plugs still connected to the ends.

- Remove the protective cap from the side of the connector, which must be clean and free of any marks.

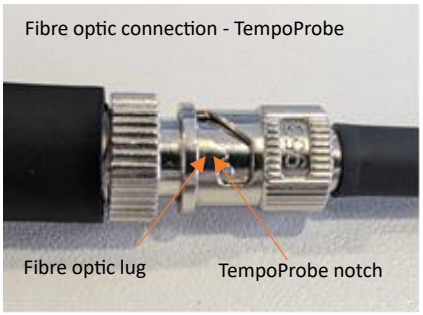
- Connect the TempoProbe to the device's fibre optic cable: align the groove on the fibre optic cable connection with the lugs on the TempoProbe connection.




- Push until the lug on the fibre optic connector fits into the groove on the TempoProbe connector.



- Rotate the TempoProbe connector to insert the fibre optic lug into the notch designed for this purpose.



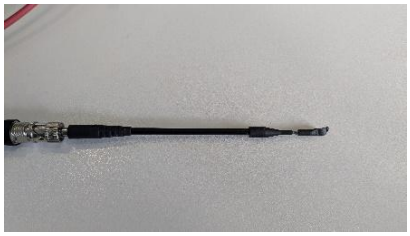

- Visually check that the TempoProbe is correctly connected to the fibre optic cable and press 'ENTER'.

➢ If any anomaly is noticeable when removing the TempoProbe from its packaging (cap missing, bend or impact on the probe, etc.), please dispose of the TempoProbe (see §8) and take a new one.

### 7.4.2. Positioning the capsule

➢ The capsules are packaged in a non-sterile pouch, like the TempoProbe. They are to be opened in the same way. Capsule storage tubes must contain a single capsule upside down in a transparent liquid. If this is not the case, do not use the capsules and contact Dyameo.

- Remove the cap from the TempoProbe. Be careful not to touch the end of the TempoProbe.
- Check that the stainless steel ferrule is clean and free of marks.



- Pierce the lid containing the capsule with the probe. Insert the end of the fibre into the capsule until it clips into place.

- Remove the fibre with the plug.

- During this step, you can also remove the probe without the blue plug. In this case, make sure that the capsule is still correctly attached to the end of the TempoProbe after passing through the blue plug.

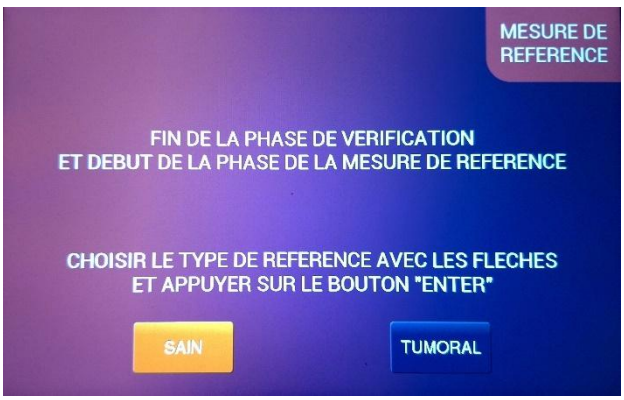
- The probe is ready to use.

### 7.4.3. Capsule verification phase

- This stage checks the conformity of the capsule. It must be performed away from ambient light to ensure accurate collection of the emitted light signal. Place the end of the probe and the capsule in the black compartment of the unit.

- Close the trapdoor and press the TempoTouch footswitch to initiate the verification.

- When the verification phase has been successfully completed, the screen below appears.




➢ If the capsule is deemed non-compliant by the device:

- Check that the capsule is properly clipped to the TempoProbe
- Check the connection of the TempoProbe to the device.

➢ If an anomaly is found, correct it and repeat the verification measurement.
- If the error persists, change the capsule, press 'Back' and repeat the operation.
- If the error persists a second time, Turn off the TempoTouch, change both the TempoProbe and the capsule, restart the TempoTouch and repeat the initialization process.

➢ If the error persists, do not use the device for the operation and contact Dyameo.

## 7.5. Reference measurement

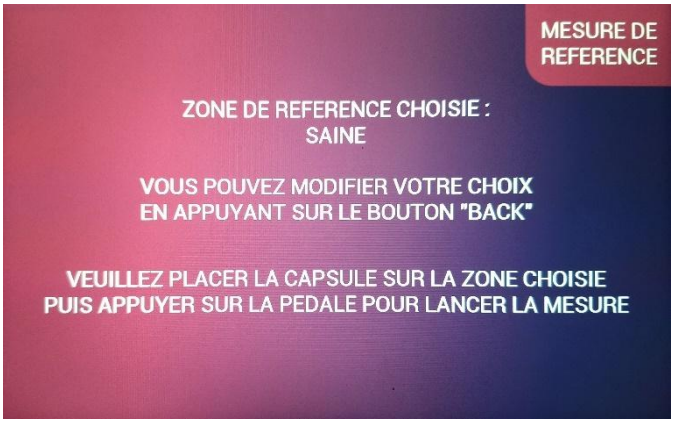
To make a comparison between healthy and tumour tissue, the device needs a reference measurement. According to the surgeon's choice and the surgical specimen, this reference measurement must be taken either:

- on tissue that has been visually identified as clearly healthy. This tissue must be similar to that in which the tumour developed. This is referred to as a 'Healthy' reference.
- on tissue that has been visually identified as clearly tumoral, budding and non-necrotic. This is referred to as 'TUMORAL' reference.

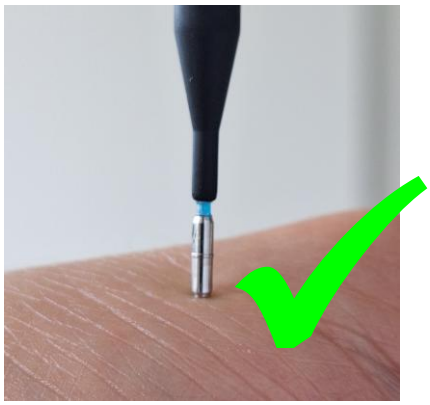
➢ The device must not be used if it is impossible to identify with a reasonable degree of certainty an area of healthy or tumoral tissue that can be used as a reference.

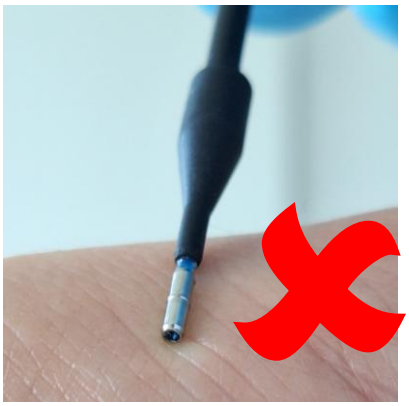
➢ The device cannot be used on areas that have been burnt, for example by an electric scalpel or laser. This applies both to the reference measurement and to subsequent measurements.

- Use the left and right navigation keys to select the type of tissue you want to use as reference - 'HEALTHY' or 'TUMORAL' - and press 'ENTER'.
- The device displays a screen so you can double-check the choice you have previously made



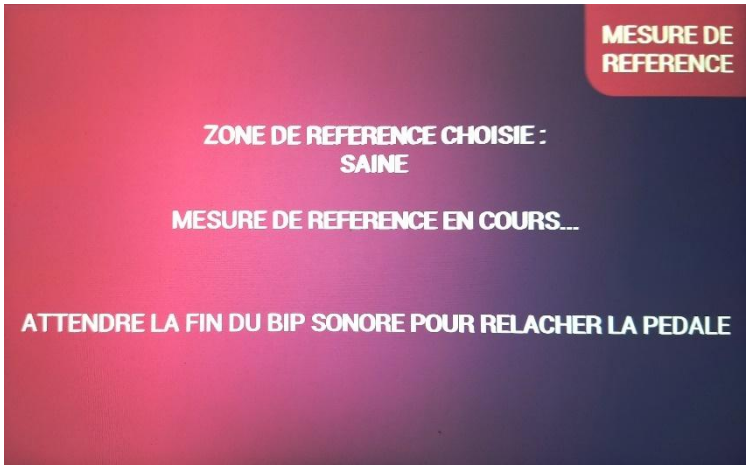

- Position the probe on the tissue to be analysed, keeping it as perpendicular as possible to the plane of the tissue.
- Hold the probe in place for about 5 seconds.





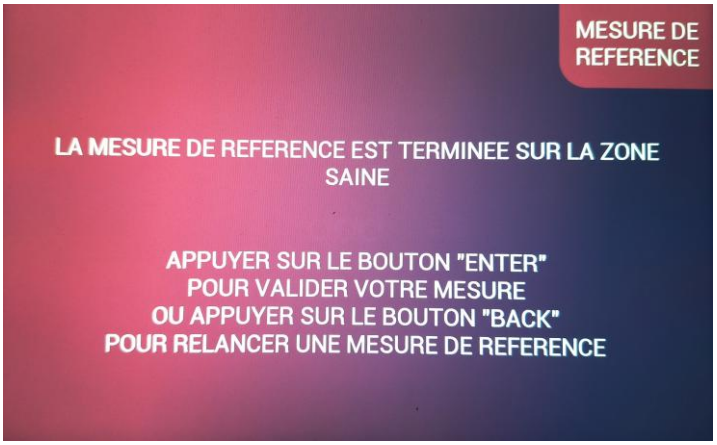
- Press the footswitch to start a measurement.

➢ While the measurement is being captured :
  - The red light under the 'laser' logo is illuminated.
  - An audible signal is also emitted.
  - The display indicates a measurement in progress.




- Hold the probe still on the tissue and keep the footswitch pressed until the sound of the buzzer stops.

- Once the measurement is complete, press the 'ENTER' button to save the reference measurement.



- If the measurement is invalid (if the probe has been moved during the measurement, or if the surgeon identify afterward a more representative area of healthy or tumour tissue usable as reference), press 'BACK' and repeat the reference measurement as described above.

- Each reference performed decreases the number of possible future measurements with the same capsule.

## 7.6. Carrying out analysis

### 7.6.1. Carrying out the measurement

- Once the capsule has been checked and the reference measurement taken, the surgeon can proceed with the analysis of the explanted tissue.


- Place the probe in contact with the tissue you intend to analyse, in the same way as for the reference sample.

- Start the measurement by pressing the footswitch until the end of the acoustic signal.

### 7.6.2. Display of results

- 3 levels of results are possible :
  - $EGFR_{low}$ : The tissue is considered healthy
  - $EGFR_{intermediate}$ : The tissue cannot be analysed with precision. The surgeon follows the usual operating procedure (frozen section analysis, etc.).
  - $EGFR_{high}$ The tissue is considered to have a high level of EGFR.

- For each analysis, the results are reported in the history in order of analysis. The last measurement is displayed on the main part of the screen.


- To start a new measurement, reposition the probe on the tissue to be analysed and press the footswitch.

➢ When the capsules have reached their maximum number of analysis, a message appears prompting you to change capsules.

## 7.7. Replacing the capsule

➢ After 5 analyses (or less if several reference measurements have been carried out), the capsule must be changed..

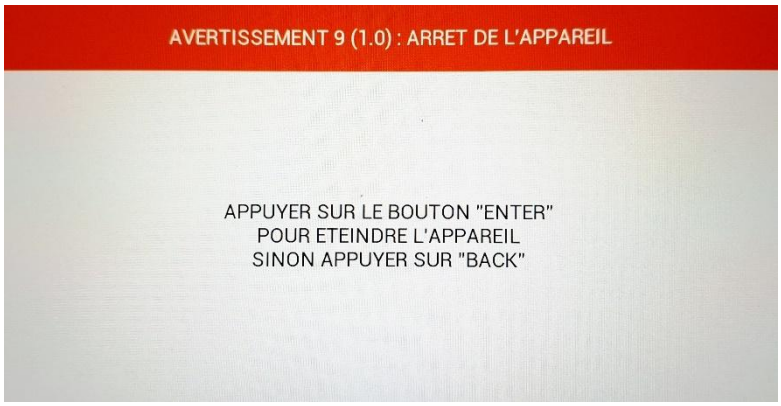
- Remove the capsule from the TempoProbe using a pair of pliers or tweezer. Be sure to position it on the top of the capsule (towards the porthole) when removing it to avoid damaging the optical fiber.
- Press the 'CAPSULE' button to start the replacement procedure. Follow the procedure described in §7.4.2.

## 7.8. Switching off the device at the end of the procedure

➢ Once you have finished using the device for a patient, it has to be powered off :

- Press the « ⏻ » button. A message prompting you to confirm the shutdown is displayed

- Press ‘ENTER’ to confirm that you want to switch off the device.
- If the “⏻“ button has been pressed inadvertently, press ”BACK’ to go back and cancel switching off the device.




➢ If use is interrupted for more than one hour, It is recommended to switch off the device by turning the power switch on the rear panel to position ‘0’.

- Disconnect the TempoProbe from the optical fibre. Dispose of the TempoProbe and the capsules as infectious risk waste (IRW) waste in accordance with your institution's guidelines.
- Make sure that the end of the device's optical fibre is still intact. If this is the case, replace the protective cap and wind it, without forcing it, into the recess provided for this purpose.
- Unplug the power cord and footswitch
- Store the device in accordance with §10.

## 8. Disposal

➢ The capsules and probe are single-use and must be disposed of after the operation as infectious risk waste (IRW) in accordance with operating theatre practices..

➢ The TempoTouch must never be disposed of. In the event of a fault or problem, it must be returned to Dyameo.

➢ The lifetime of the device is estimated at 5 years if annual maintenance is carried out in accordance with Dyameo's recommendations.

➢ For any enquiries, please contact Dyameo:

- To the following address : contact@dyameo.com
- At : +33 555 782 795

## 9. Cleaning and disinfection

➢ The Dyameo device should be cleaned with a soft cloth moistened with cleaning product. We recommend cleaning the device before and after use.

➢ Do not use harsh products.

## 10. Transport and storage

- The TempoTouch must be transported and stored in accordance with the recommendations below and in a dry, ventilated place

| | |
|---|---|
| **Transportation and storage** | Temperature -10°C à +70°C<br>10% < Humidity ≤ 90%<br>Atmosphéric pressure : 59,5 kPa à 101,3 kPa |

## 11. Maintenance and servicing

- Preventive maintenance of the device is carried out annually by Dyameo, at the following intervals:

| Maintenance | Periodicity |
|---|---|
| Change of optical fibre | Annual |
| Laser recalibration | Annual |
| Replacement of the CR1225 internal battery | Quadrennial |

## 12. Device lifetime

The TempoTouch has a lifetime of 5 years.

## 13. Error messages and alerts

### 13.1. List of errors

- When a major error is detected, the device's main functions are deactivated (laser, TECS, shutter closed). The device must be restarted.

| Code erreur | Désignation | Conduite à tenir |
|---|---|---|
| E127 | Laser power too high | If the message appears, contact Dyameo with the error code |
| E129 | Power supply | |
| E130 | Internal temperature | |
| E131 | Laser temperature | |
| E132 | Laser ON Offset | |
| E133 | Laser OFF Offset | |

## 13.2. Alert lists

- When a minor error is detected, the system is blocked until the error is corrected.
- When a warning has ended, the pop-up window disappears.

| Alert code | Designation | What to do |
|---|---|---|
| W001 | SD cards | Check that the SD card is correctly inserted |
| W002 | RTC communication | Switch the device off and on again. If the problem persists, contact Dyameo. |
| W003 | Wrong date | Switch the device off and on again. If the problem persists, contact Dyameo. |
| W004 | Screen communication | Contact Dyameo |
| W005 | Ambient light too bright | Repeat the measurement under the conditions specified |
| W006 | Footswitch connection | Check the connection with the footswitch. Switch the device off, disconnect and reconnect the pedal, then switch the device back on. If the problem persists, contact Dyameo. |
| W007 | Footswitch must be released | Release the pedal. If the problem persists, disconnect the pedal, check that nothing is obstructing its movement and reconnect it. If the problem persists, contact Dyameo. |
| W008 | Spectrometer communication | Switch the device off and on again. If the problem persists, contact Dyameo. |
| W009 | Power button pressed | Press 'ENTER' to switch off the device or 'BACK' to cancel. If the problem persists, call Dyameo. |
| W010 | Measure instability | Take another measurement on the tissue without moving the capsule during the analysis. If the problem persists and is systematic, contact Dyameo. |
| W011 | Incorrect configuration | Switch the device off and on again. If the problem persists, contact Dyameo |
| W012 | Laser temperature control | Wait for the Peltier module to cool the laser. If the laser does not reach its nominal temperature within 5 minutes, switch the device off and on again. If the problem persists, contact Dyameo. |
| W013 | Control footswitch released during acquisition | Repeat the measurement without releasing the pedal before the end of the audible signal and the result display. |
| W014 | Verification measurement outside the limits | Repeat the analysis. If the message reappears, check the connection between the optical fibre and the TempoProbe, then between the TempoProbe and the TempoCaps. Take another measurement. If the problem persists, change the capsule. If the problem persists, change the TempoProbe and the capsule (new kit). |
| W015 | Maximum measurement with the capsule | Repeat the measurement in the dark case if this was a TempoCaps verification, or repeat the analysis, holding the TempoProbe orthogonally to the tissue and pressing lightly. If the problem persists, change the capsule and repeat the measurement. |
| W016 | Reference measurement outside the limits | If the message reappears, check the connection between the optical fibre and the TempoProbe, then between the TempoProbe and the TempoCaps. Take another measurement. If the problem persists, change the capsule. If the problem persists, change the TempoProbe and the capsule (new kit). |

| | | |
|---|---|---|
| W017 | Analysis measurement outside the limits | If the message reappears, check the connection between the optical fibre and the TempoProbe, then between the TempoProbe and the TempoCaps. Take another measurement. If the problem persists, change the capsule. If the problem persists, change the TempoProbe and the capsule (new kit). |
| W018 | The capsule must be placed in saline solution before use. | If the capsule has not been used within 5 minutes after the verification phase, the user should immerse the capsule in saline solution. |
| W019 | The capsule must be changed | If the capsule has not been used within 15 minutes after the verification phase, the user must change the capsule by pressing the 'Capsule' button. |
| W020 | Score too low | Beware of the high risk of uncertainty in the reference measurement. It is possible that the tissue used is not really healthy. Press 'ENTER' to continue if you are sure of your initial choice, or change the capsule and take a new reference by pressing 'CAPSULE'. |
| W021 | Score too high | Beware of the high risk of uncertainty in the reference measurement. It is possible that the tissue used is not really representative of the tumour tissue. Press 'ENTER' to continue if you are sure of your initial choice, or change the capsule and take a new reference by pressing 'CAPSULE'. |
| W022 | Spectrometer saturation reference | The signal measured is too strong for the detector. Repeat the measurement, paying particular attention to the ambient light. If the problem persists, change the capsule. |
| W023 | Spectrometer saturation analysis | The signal measured is too strong for the detector. Repeat the measurement, taking into account the ambient light. If the problem persists, change the capsule. |

## 14. Electromagnetic immunity

| Category | Standard | Test values |
|---|---|---|
| Electrostatic discharges | IEC 61000-4-2 | ± 4 kV contact discharge<br>± 2 kV, ± 4 kV, ± 8 kV Air discharge |
| Electromagnetic field | IEC 61000-4-3 | 3 V/m (80 MHz à 6 GHz) |
| Rapid electrical transients in bursts | IEC 61000-4-4 | ± 1 kV (5 kHz ou 100 kHz) - Continuous power supply |
| Shock waves | IEC 61000-4-5 | ± 0,5 kV line to line - AC<br>± 1 kV shore line - AC |
| RF line disturbances | IEC 61000-4-6 | 3 V (150 kHz à 80 MHz) |
| Magnetic field at mains power | IEC 61000-4-8 | 3 A/m (50 Hz, 60 Hz) |

## 15. Electromagnetic compatibility

| Emission test | Conformity |
|---|---|
| RF Emission CISPR 11 | Group 1, Class A |

# Annex 1 – Device final control declaration

Dyameo undertakes to perform the routine release tests F.2 to F.4 on its TempoTouch device described in Annex F 'Individual series tests' of ISO 61010-1 'Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 1: General requirements'.

These tests are carried out on every TempoTouch device manufactured.