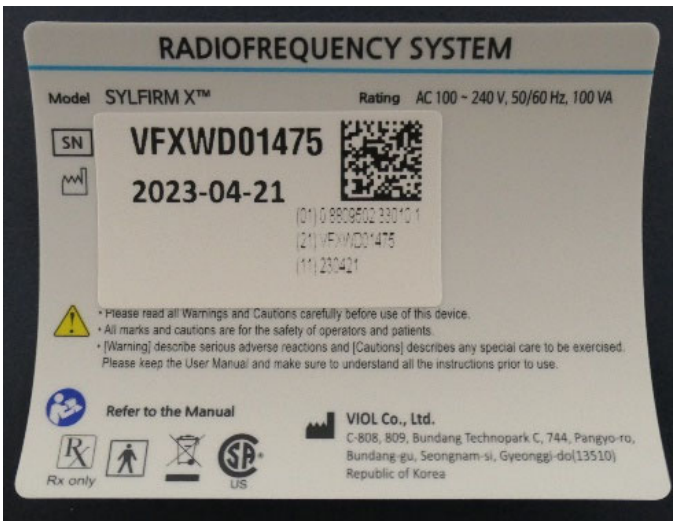
APPENDIX 17

Product Inspection Report – Sylfirm X

This is a Product Inspection Report responsive to ITC Inv. No. 337-TA-1356, for infringement of US 9,320,536 (“’536”), US 9,775,774 (“’774”), US 10,869,812 (“’812”).

The product Inspected is the Sylfirm X Manufactured by VIOL Co. Ltd. The nameplate is shown below.



The inspection was conducted on June 26th 2023 at the law offices of Latham & Watkins LLP, 650 Town Center Drive, 20th Floor, Costa Mesa, CA.

Also supplied was a 45 page User Manual labelled “SYLFIRM X User Manual (VO-UM-SFX-03), Rev 06 Rev. date 2022-04-20. Additional details and illustrations are provided in the User Manual.

General Arrangement

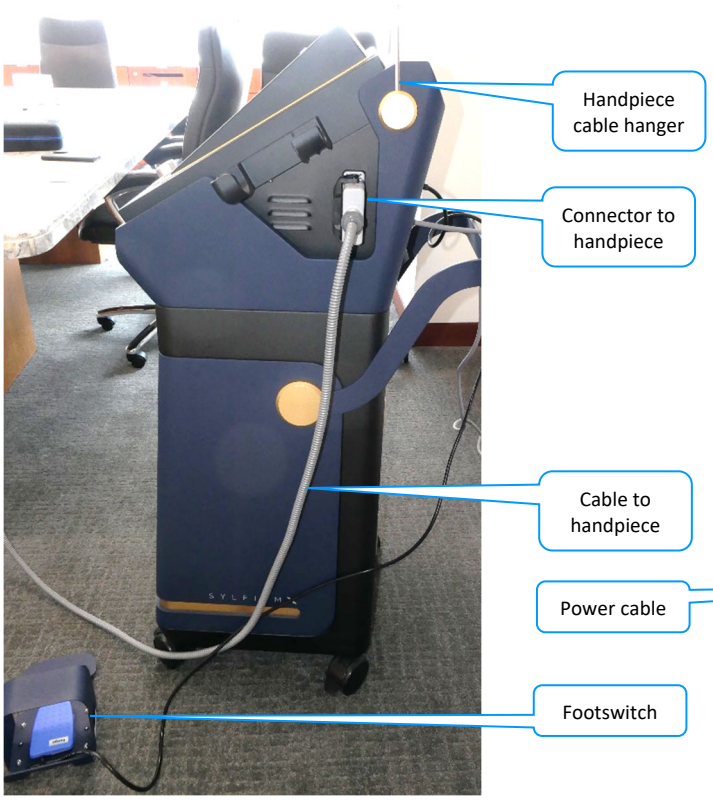
The product consists of a console containing electronics, a display, and various cable connectors. One of the connectors (including a securing latch) is for the cable to the handpiece, another is for the footswitch, and one is for power.

A general overview of the console is shown in the pictures below.

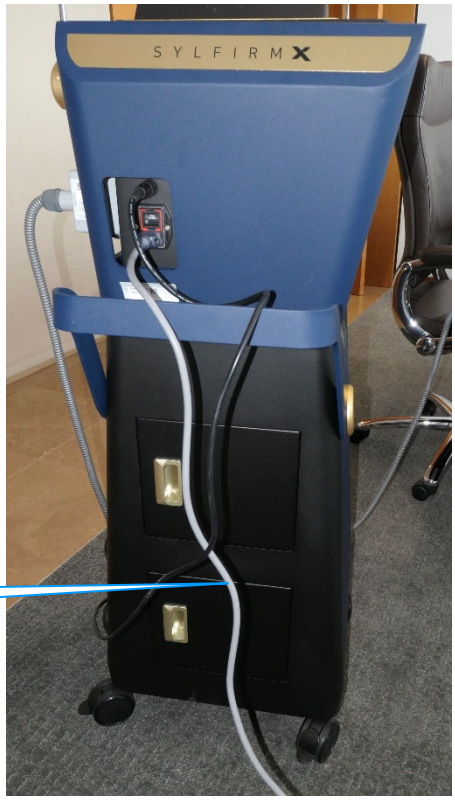
Product Inspection Report – Sylfirm X

Front

Left hand side



Right hand side



Rear

The console also contains a handpiece holder, storage drawers, and a handpiece cable hanger.

Control Panel

The console carries two color LCD screens – a parameter display and a touchscreen panel for setting predetermined parameters, Parameters are adjusted in Standby mode, and are used in delivering therapy in Ready mode. Controls available are:

- Auto shot interval
- Depth (0.3 mm to 4 mm)
- Power (Level 0 to 12)
- Interval time between motor movements in auto shot mode (0.1 to 1.0 sec)
- Waveform (Several options – refer to user manual for descriptions)
- Mode Select – Single Shot delivers one shot each time the foot switch is depressed, whereas Auto continuously delivers shots while the footswitch is depressed.
- Standby – Ready toggle
- Shot count reset
- A gear icon for access to various other parameters.

Control of all parameters was verified. Photos of different power levels are shown below as examples.

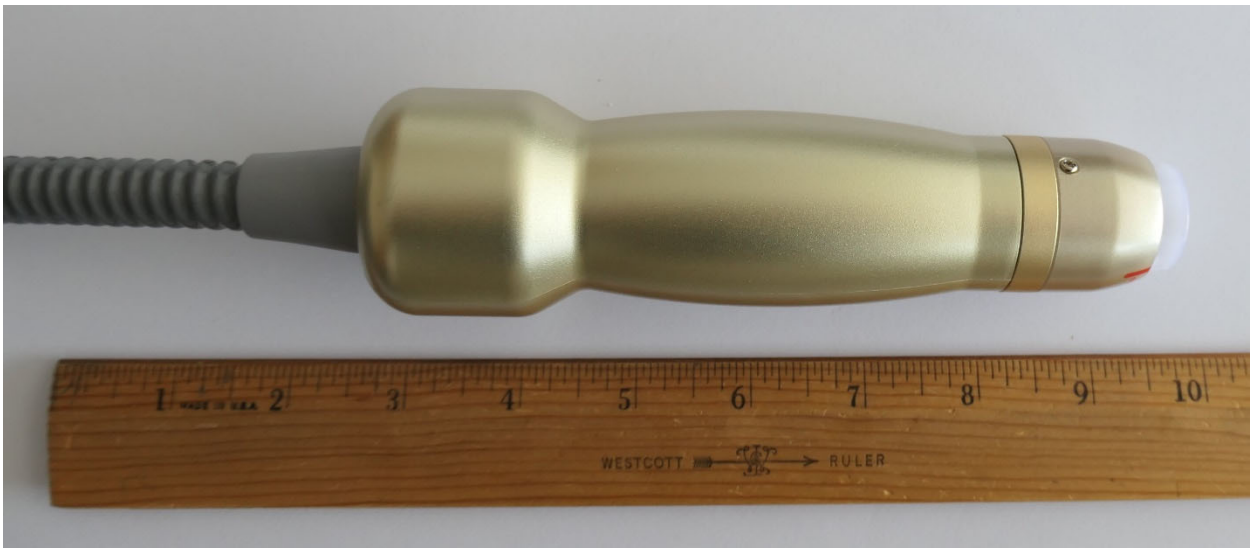
Handpiece cable and connector

The handpiece is connected to the main console via a cable and multipin connector on the console, which includes a latching mechanism to prevent accidental removal, as shown in the photo below.

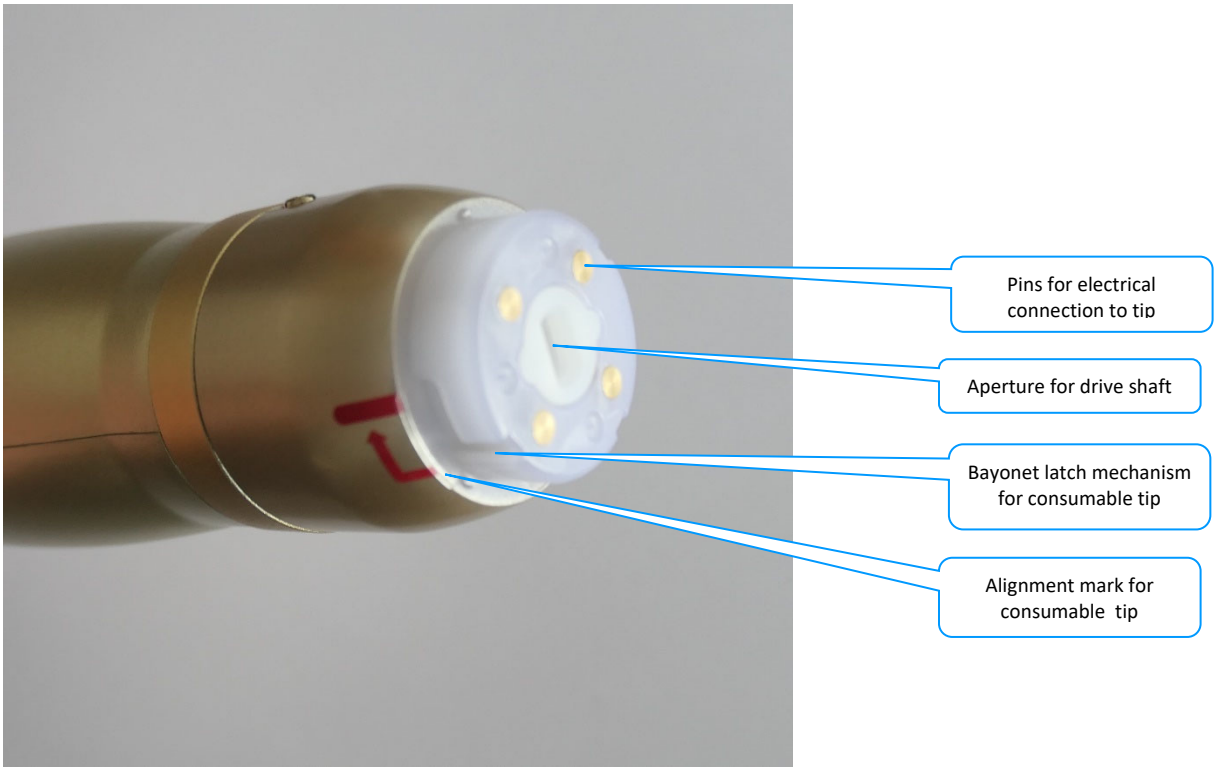
The information about the handpiece is on a label affixed to the handpiece connector, as shown below. This particular handpiece is model PRB-SFX, Serial number P/B-1555 or 0108809502330170.

Handpiece

A photo of the handpiece without a consumable tip attached is below.

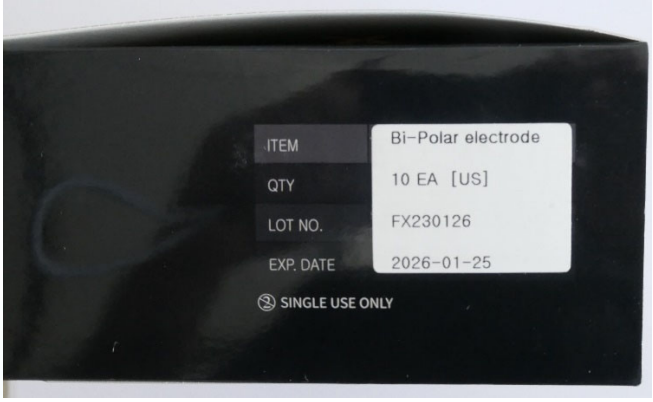


The end of the handpiece has four electrical contacts, an aperture for the drive shaft, and a bayonet latching mechanism to allow connection and removal of the consumable tip, as shown below.

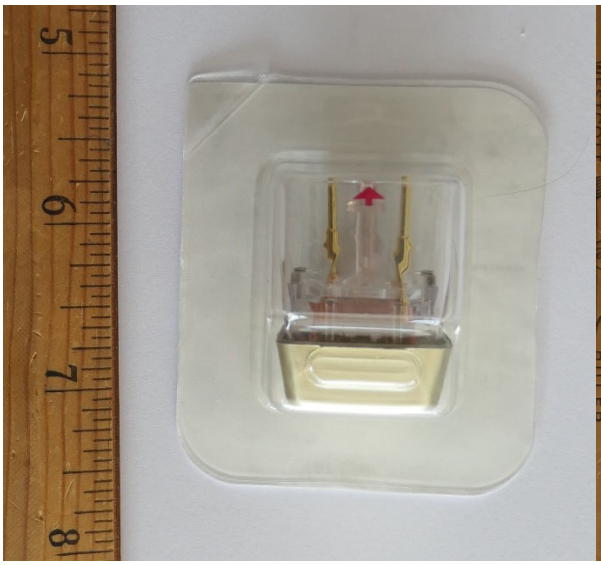


Consumable Tip

The consumable tip comes in a box of ten, and each consumable tip is individually packaged. Photos of the box of consumable tips and the label on the underside are shown below.

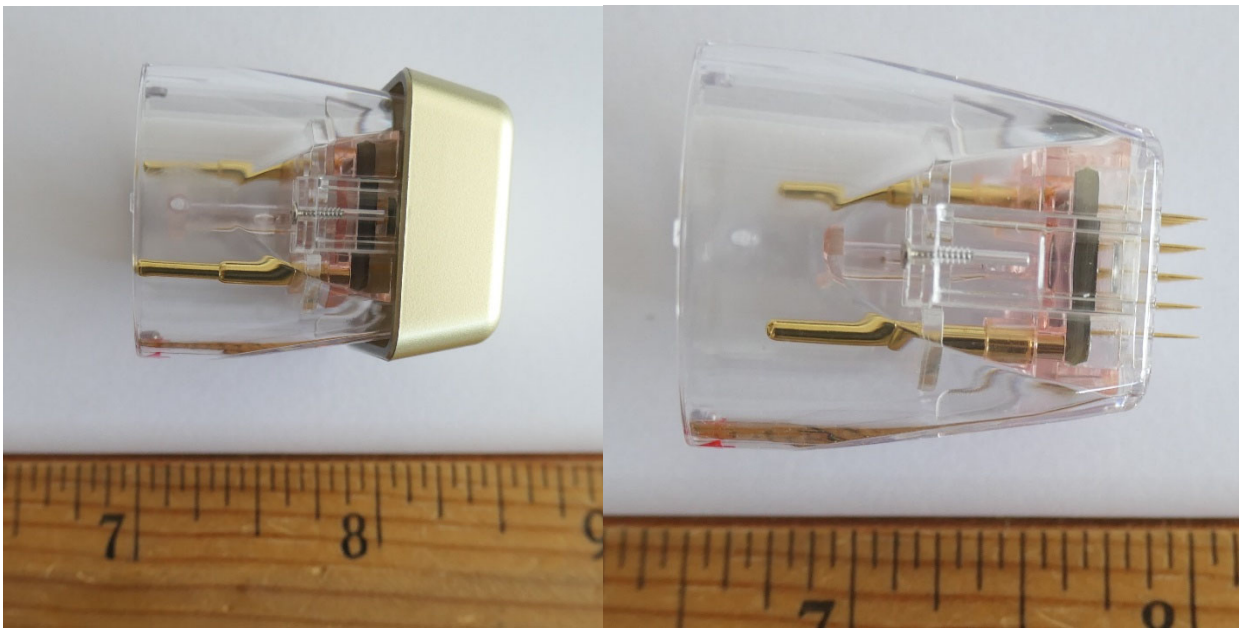


Each consumable tip is individually packaged in a plastic blister pack, with label on one side, as shown below.

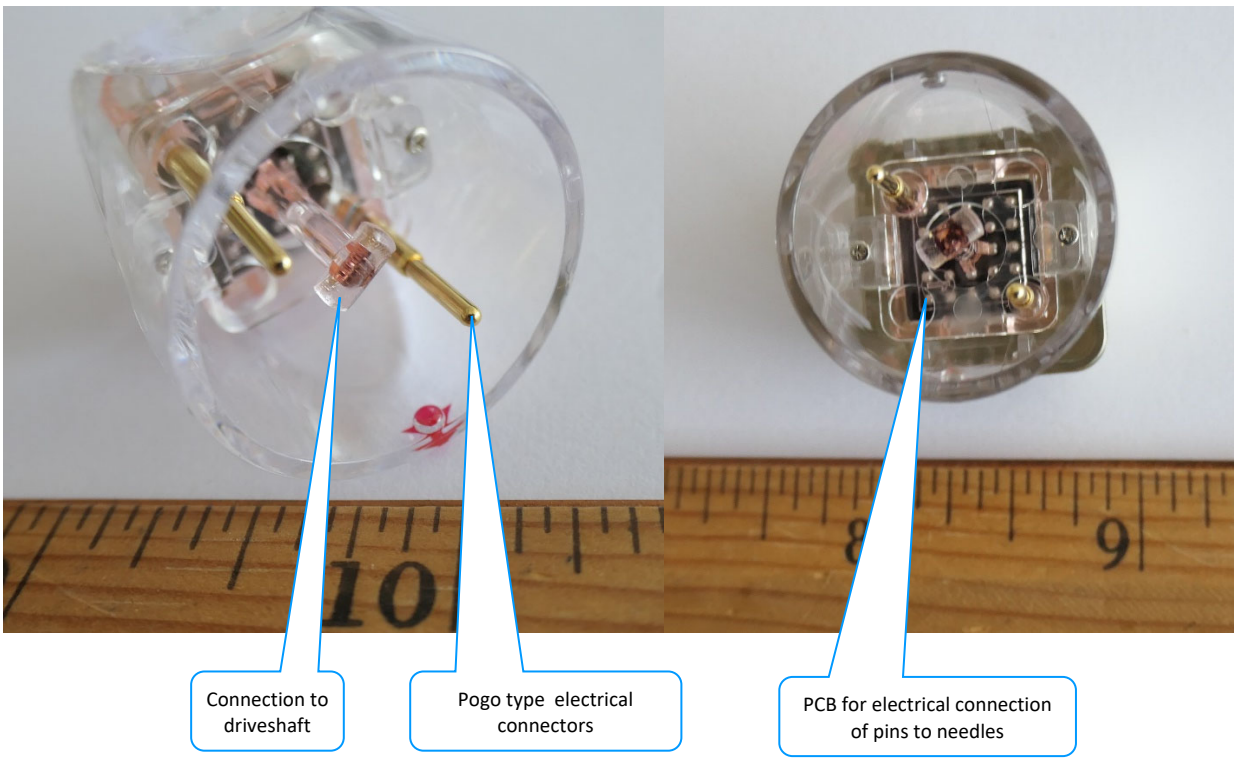


Each consumable tip has a protective cap to prevent exposure of the extendable needles, as shown in the left hand picture below.

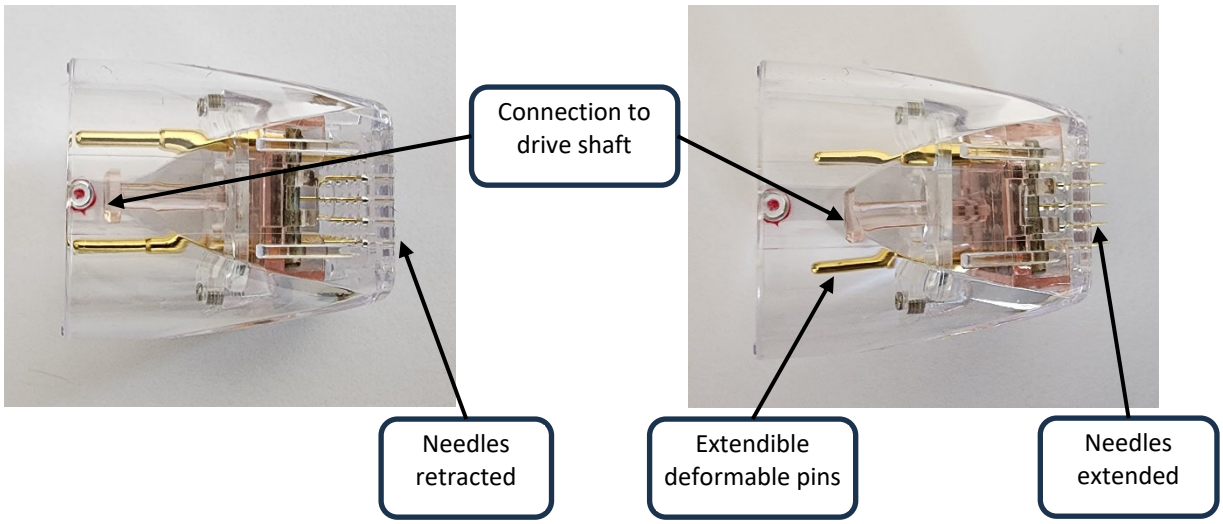
When the protective cap is removed, it is possible to extend the needles by placing a finger inside the needle tip assembly and gently pushing, as shown in the right hand picture below. This particular tip has 25 needles.



Inside views of the tip are shown below, both direct and oblique. This view shows the spring loaded electrical connectors and the connection to the driveshaft in the handle.



The two spring loaded pins (pogo type connectors) in the tip make electrical contact with the handpiece contacts.



Attaching the Consumable Tip to the Handpiece

The consumable tip is attached to the handpiece with a latching bayonet mechanism. The operator lines up the arrow on the tip with the end of the bent arrow on the handpiece, and then pushes down on the tip, and rotates clockwise relative to the handpiece to engage the latching mechanism. (Note, this is shown without the protective cap, which should always stay in place when attaching the needle tip assembly to the handpiece.)

The tip can be released from the handpiece by reversing the order – gently rotating the top anti-clockwise relative to the handpiece.

Engagement of the disposable needle tip with the handpiece is confirmed when the arrow on the disposable tip lines up with the solid line on the handpiece, as shown below.

Operation

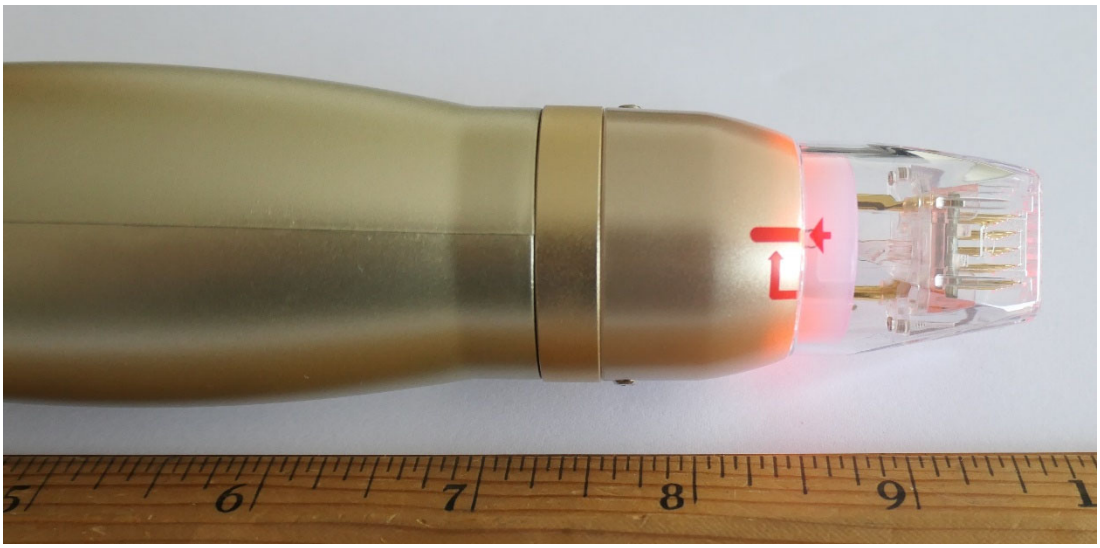
Each “shot” of therapy includes the following elements:

- Light is delivered,
- Needles are extended to a predetermined depth,
- RF energy is applied at a predetermined intensity, and
- Needles are retracted.

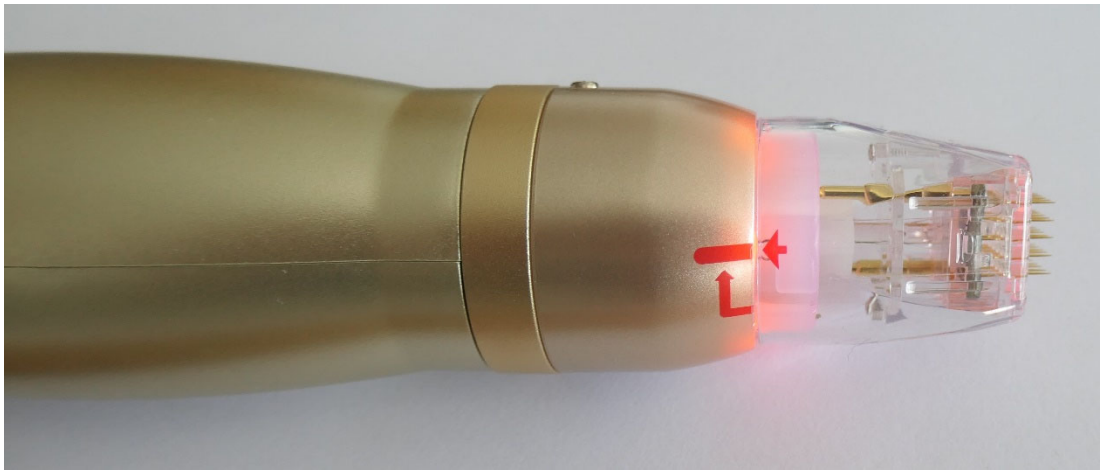
After each shot the system is ready to deliver another shot, either one at a time (Single Shot Mode), or automatically with a predetermined time between shots.

In operation, the tip is placed against the patient’s skin, the footswitch is actuated, and one or more shots are delivered. The parameters of each shot are predetermined from the selections in the Standby mode. Each shot results in energizing the motor in the handpiece to extend the needles to the predetermined depth, illuminating the needles through the translucent plastic of the tip, and applying RF energy.

The picture below shows the handpiece energized but with the needles retracted.



The picture below shows the handpiece energized and the needles extended.



As can be seen in both the photographs above, there is a light source inside the handpiece which is energized when the footswitch is actuated. Also as seen in the photographs above, illumination of the LEDs in the handpiece also illuminates the needles.

RF Signal

It was possible to confirm the presence of a strong pulsed RF signal by placing an oscilloscope probe adjacent to the needle tips and then activating the footswitch.

The intensity and duty cycle of the RF energy is predetermined from the parameters entered by the user.