

# HandyRay-Pro FAQ

1. Does HandyRay-Pro control the volume of blood collection for oneself?
: If a user wants to get more volume of the samples, it is recommended that the user increases the laser level to emit the higher energy.
2. Do we have to buy a new product or replace used parts including the battery to new parts after we use more than 30,000 times, the HandyRay-Pro?
: Lameditech can give a warranty to a customer by 30,000 times of HandyRay-Pro within a year. But a customer actually can use the device about 60,000 times. When the usage exceeds 60,000 times, the energy output gradually weakens and the number of failed blood collection increases. You need to buy a new product at this time.
3. How long does HandyRay-Pro take to recharge and use?
with one recharge, the user can use the device up to around 300 shots depending on the level of laser (at low level, a bit more than 300 shots and at high level, a bit less than 200 shots). In addition, it takes 1 and half hour to fully charge the device and 70% of battery capacity is charged in the first 40min and after that, the battery is slowly charged to full capacity for the safety reason.
4. What is the minimum volume of capillary blood obtain by the device in Adults?
: The user can get 30µl~50µl of the capillary blood sample easily and get more blood sample by gently squeezing the finger from the lower part to up (around up to 80µl)
5. What is the minimum volume of capillary blood obtain by the device in children?
There is no difference between the adults and children. Only difference is the laser level applied (We recommend level 1 for the children)
6. What is the minimum volume of capillary blood obtain by the device in Neonates?
We have neonate clinical data. We have checked to get maximum 150µl blood collection by HandyRay-Pro.
7. Is the HandyRay-Pro suitable to perform capillary blood drawn on Foot of Neonates for neonatal testing on blood spot filter
Yes, HandyRay-Pro is suitable to get the capillary blood from foot of Neonate. There were no side effects during the clinical test and confirmed the size of blood collection injury appears much smaller than needle lancet.
8. The use of the plastic CAP on the tip of the device its only as a preventive Contamination barrier in between patient skin and HandyRay-Pro?
CAP has two functionalities. One is the prevention of the direct contact between the device and the skin to eliminate the secondary infection risk and the other is the protect the lens of the device from the contamination as the laser device is the optical device.
9. Up to how many shots can be perform during a Blood sampling procedure with the HandyRay-Pro?
Total estimated life of HandyRay-Pro is 30,000 times and the user use it around 300 times with one full recharge. It takes one and half hour to fully recharge the device and 70% of the battery can be recharged for the first 40 minutes.

10. Based Lameditech experience with HandyRay-Pro can you please let us know average tissue repair in days after Er: YAG beam used on the HandyRay-Pro? in Adults, Children and Neonates? If any publication available will be helpful

The tissue is fully recovered within 1~2days based on our test

11. If it is any condition that restricts the use of HandyRay-Pro?

The following patients are restricted from use

1. Hemophilia
2. Blood coagulation disorders including thrombocytopenia

12. If can be send via email any scientific publication/ technical evaluation at reference center for HandyRay-Pro will be of great value since I personally will do some presentations to clinicians and Laboratory staff.

: I have attached the clinical trial report which we performed to validate the efficacy and safety and submitted for Korea FDA and US FDA, CE and ANVISA approval. In addition, currently we are in progress of the additional marketing clinical trial to show various benefits and application of HandyRay series including the superiority in terms of pain. We expect to complete the marketing clinical trial by June and will share the report with our business partners

13. HandyRay-Pro have different levels of laser from 1 to 5, Selection of each level its proportional to:

- 13-1) Laser duration in milliseconds and thus more capillary vessel permeability?
- 13-2) Penetration to different extracts of the dermal tissue?
- 13-3) Size of the lesion on skin (more diameter on lesion by laser beam)
- 13-4) Level of pain (1 less pain -> 5 more pain) caused by the laser beam once touch the tissue?

The user can select the laser level based on the thickness of the skin to be punctured. The energy strength by laser level are as below. As the higher level has the higher energy, the laser beam can penetrate deeper at the higher level.

Level 1 : 150mJ  $\pm$ 20%

Level 2 : 180mJ  $\pm$ 20%

Level 3 : 210mJ  $\pm$ 20%

Level 4 : 230mJ  $\pm$ 20%

Level 5 : 270mJ  $\pm$ 20%