

CONTENT

1. Laser Safety
2. What is Nail Fungus?
3. Traditional Treatments Comparison
4. Basics of Laser Treatments
5. Advantages of Laser Treatment
6. Laser units and Handpiece set
7. Methods and Parameters
8. Before and After
9. Preoperative and Postoperative

WARNING

For your own safety follow all guidelines for handling the equipment and follow the safety instructions in this manual.





Laser Safety

To avoid any injuries it is important to follow the laser safety instructions:

1. Any user of the GBOX laser system has to be trained by GIGAALASER authorized personal or by someone trained by GIGAALASER authorized personal.
2. The room / the area, where the laser system is used has to be signed with the laser warning symbols in a way that everyone can easily see that there is a laser area, which should not be entered without the adequate protection while the laser is in use.
3. Do not use the system whenever you are not sure that every component works in the dedicated way. Keep an eye on the fiber delivery: The spot shown by the aiming beam should always be round and defined, no scattering should occur. You may test this by using a light paper and holding the connector fiber end in a distance of about 5 cm (you have to put the laser on Ready mode, with laser safety goggles).
4. Whenever the laser is on Ready mode (Yellow Ready- on) every person within the area where radiation from the laser can occur (laser treatment area / laser room) has to wear laser safety goggles which is suitable to protect the eyes from laser radiation.
5. The laser has to be used only for the defined application; never irradiate any other material / tissue beside the intended use.
6. Special care should be taken to avoid irradiating reflecting materials. Reflected laser radiation can cause the same harm as direct application.
7. Switch the Ready mode to Standby mode of the laser when the laser is not in use; e. g. during operation breaks or at the end of the surgery.

What is Nail Fungus?

Onychomycosis means fungal infection of the nail. It is the most common disease of the nails and constitutes about a half of all nail abnormalities. This condition may affect toenails or fingernails. It is estimated to affect nearly 10% of the general population, with the incidence rising to nearly 30%, in patients over age 60.

The signs and symptoms of nail fungus

- Thickened nail
- Crumbly or brittle nail
- Nail distorted in shape or separated from the skin under the nail
- Nail with no lustre or shine
- Soft and powdery nail surface, which is more apparent as the infection worsens
- Build-up of bits and pieces of skin and nail fragments under the nail
- White spots or streaks on the nail surface
- Unique Odour
- Dark discoloured nail, caused by debris build-up



Fungal nail treatment is difficult because the infection is under and inside the nail, making it hard for some products to reach and destroy the infection. Fungal Nail can be tested histologically but research has proven that the results can produce false negative results, so even when the tests come back negative the Fungus is often in the nail.

Traditional Treatments Comparison

Medication may be recommended if your fungal nail infection is more severe. Antifungal medicines, such as tablets and nail paints, are the two main treatments.

Antifungal tablets

Taking antifungal medication in the form of tablets means that the treatment reaches your nail through your bloodstream.

Terbinafine and itraconazole are the two medicines most commonly prescribed for fungal nail infections and they can be very effective.

However, you may have to take the tablets for several months to ensure that the infection has completely cleared up. If you stop taking the medication too early, the infection may return.

An advantage of using antifungal tablets is that they'll also clear up any associated fungal skin infections, such as athlete's foot, at the same time.

However, side effects of antifungal tablets can include:

Headache

Itching

Loss of sense of taste

Nausea

Diarrhoea

Antifungal nail paint

Nail paint isn't considered to be as effective as tablets because it's painted onto the infected nail and has to work its way through to the infection. It can often be difficult to reach all of the infection.

A fingernail may need around six months of treatment, and a toenail may take up to 12 months.

Chemical nail removal

The abnormal infected nail plates can be removed using a paste containing 40% urea (a chemical that occurs naturally in the body which can also be manufactured). The paste is available over the counter from pharmacies.

You carefully apply the paste to the affected nails, which are covered and left overnight. You then wash the paste off in the morning and repeat the process each night after filing down the nail as instructed. It usually takes about two weeks to dissolve the nail plates.

Chemical nail removal is a painless treatment that gradually removes the abnormal nail plate and the fungus. It allows you to avoid taking tablets for several months and avoid surgery, which can be painful.

Once the nail plates have been dissolved, antifungal nail paint should be applied to the nails twice a week to prevent the nails being reinfected as the new nail forms.

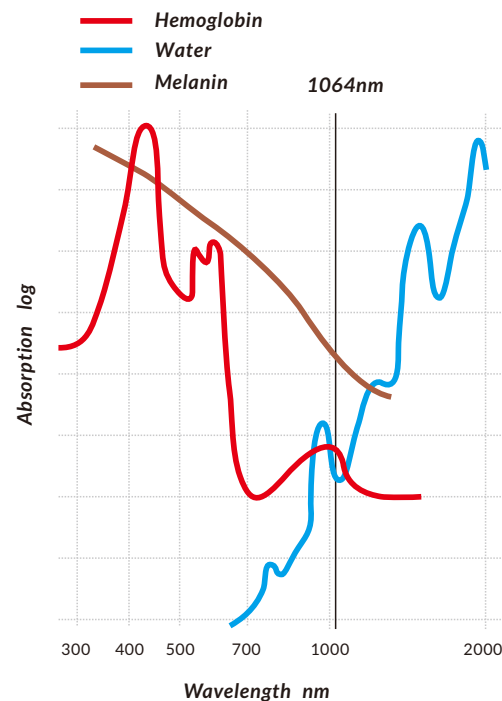


Basics of Laser Treatments

The intended effect of the laser application is based on the interaction of the radiation with the tissue components. The laser radiation is absorbed, scattered or reflected by the tissue. Air has only little influence on the GBOX radiation and therefore the interaction between air and the GBOX radiation can be neglected. Reflection plays a major role with metal, glass and other reflecting surfaces.

When we apply the GBOX radiation to tissue the reflection is not dominant. Nevertheless it is not zero! When the radiation is scattered in the tissue, it does not influence the absorption. Absorption is mainly responsible for the efficiency of the laser radiation. Absorption means that the GBOX laser radiation is converted mainly into heat, which causes the desired effects (coagulation / vaporization).

With low energy density (big laser spot or low power) the heat which is achieved in the tissue can cause heating of the tissue. The smaller the spot size is, or the higher the power is set, the warmer it gets. There is a limit, when the tissue does no longer tolerate the heating, tissue proteins denature, coagulation occurs. The next limit is achieved when tissue water (intraand extracellular water) suddenly evaporates (> 300° C). Tissue is fragmented and destroyed. Cutting / evaporation is achieved.



Advantages of Laser Treatment

With only partial efficacy and various side effects from pharmaceutical options, laser treatment is fast becoming the option of choice for nail fungus eradication.

1064nm wavelength laser has demonstrated superior results in nail fungus removal, showing safety and efficacy. It provides excellent results with deep penetration, ensuring effective treatment through the nail, without impacting other surrounding structures.

We provide many types of handpiece sets for this treatment, with different spot sizes.

During the procedure, the pathogens that cause toenail fungus are targeted, allowing the new nail to grow in healthy and clear. Unlike some medication-driven treatments for toenail fungus, the laser presents no side effects, and it is a great alternative for many patients who cannot or do not want to take oral medications. It is completely Safe with no pain.

- No medication
- No anesthesia
- Proven, effective and convenient
- Painless treatment
- No side effects and no risk

Laser units & Handpiece set

TW Handpiece

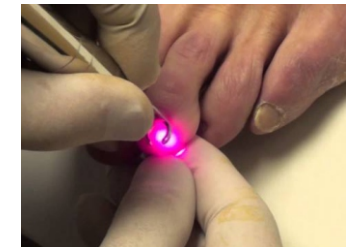


Stainless steel
Length: 160.7mm
Diameter: Φ 17mm
Spot size: 7mm
600um with
SMA905 on both sides



1064nm

Type	GBOX-10F	VELASII-30F
Wavelength	1064nm	
Maximum Power	10w	30w
Operation Mode	CW, Single Or Repeat Pulse	
Pulse Duration	25µs-10s	10ms-10s
Repetition Rate	0.05Hz-20KHz	0.05Hz-50Hz
Control Mode	Touch Screen, 8" True Color	
Warranty	12 months free warranty, 5 years technical support	
Weight	4Kg	12Kg
Packing	Carry case with carton	



All pictures from PEDITOUCH

Methods and Parameters

The treatment outcome can be reached by a single or double session, but it depends on the severity of the fungal infection. The outcome, the growth of new clear nail structures is therefore not immediately visible. Nevertheless, in about 6 - 8 weeks after the initial treatment the first new formed clear nail structures are discernible. If this is not the case, an additional treatment could be implemented. A 3rd treatment (ca. 6 - 8 weeks after the 2nd treatment) could be necessary if the fungal infection is very definitive. The ultimate result should be visible in 9 month till one year.

For this special treatment of the onychomycosis the laser has to be used with the reusable TW handpiece set with a spot size of about 7.0 mm (at a working distance of about 1 cm). For usage of this handpiece the connector fiber (600um SMA905 on both sides) is necessary. This fiber has a fiber plug on each side, which can be either inserted into the fiber coupler of the GBOX laser or into the coupler of the handpiece.

During the treatment a working distance of about 1 cm should be adhered, smaller deviants (± 0.2 cm) have no effect regarding the spot size, thus regarding the applied power density. During the treatment the handpiece has no contact to the patient, but it should be wipe disinfected after each treatment with a special alcohol-containing disinfectant solution. A transmittal between patients should be avoided.

The duration of the treatment depends on the size of the toenails, the laser settings and the speed of the movement. The laser beam should continuously guided over the nail bed, so that the complete nail (nail plate, nail wall and eponychium) is repeatedly irradiated reticular or spiral-shaped.

Due to the applied total energy there has to be a notable warming perceptible. The treatment could be temporary (about 5 - 10 seconds) paused, if the patient feels a heating pain before the necessary total energy is reached.



Laser settings for new users

Nail size	Power [W]	Pulse on [ms]	Pulse off [ms]	Total Energy [J]	Time [min : sec]
Small	8	60 - 80	90 - 110	60 - 140	0:15 - 0:50
Middle	8	60 - 80	90 - 110	120 - 280	0:30 - 1:40
Large	8	60 - 80	90 - 110	350 - 800	1:30 - 4:40

Laser settings for users with laser experience

Nail size	Power [W]	Pulse on [ms]	Pulse off [ms]	Total Energy [J]	Time [min : sec]
Small	10	10	4 - 5	60 - 140	0:09 - 0:20
Middle	10	10	4 - 5	120 - 280	0:20 - 0:40
Large	10	10	4 - 5	350 - 800	0:50 - 2:00

After the treatment, there will be a lingering sensation of heat below the nail.

This sensation will dissipate within 1 - 2 hours.

Before and After



All pictures from Dr. Tim Foran, Australia.

Preoperative and Postoperative

It is important to remove all nail polish and decorations the day before the procedure. Most people describe the procedure as being comfortable with a small hot pinch at the end that resolves quickly. Immediately following the procedure your nail may feel warm for a few minutes. The majority of patients can resume normal activities immediately. Long Term If the treatment is successful, as the nail grows you will see new, healthy nail. Nails grow slowly, so it may take up to 12 months to see an entirely clear nail.

The advantage of the laser treatment is - when correctly applied - it has no side effects. To avoid an infection of the proximate nails the patient can use an antifungal cream.

The possible side effects

Most clients experience no side effects other than a feeling of warmth during treatment and a mild warming sensation after treatment.

However, possible side effects may include a feeling of warmth and/or slight pain during treatment, redness of the treated skin around the nail lasting 24 - 72 hours, slight swelling of the treated skin around the nail lasting 24 - 72 hours, discoloration or burn marks may occur on the nail. In very rare cases, blistering of the treated skin around the nail and scarring of the treated skin around the nail may occur.

Not recommended for:

- Pregnant women
- Children under eighteen
- Anyone undergoing treatment for cancer

Methods in case of unwanted effects

The application of laser radiation can cause a burning of the tissue, which results in necrosis. Measures to treat burns have to be realized.

Second, the laser radiation causes haemostasis and the tissue gets coagulated. The amount of irreversible damaged tissue depends on the time and extends of the coagulation. Coagulated tissue is not harmful and does normally not cause any problems. In case of overheating of temperature-sensitive areas (nail wall) intensive cooling is recommended. If the surgeon applies too much energy at the edge of the treatment area (nail wall) it is comparable to burn wounds. The following clinical procedures should follow the guidelines.

Treatment related issues

Discomfort from the heating which is generated by the laser may occur. To avoid this, the user should follow the application parameter guidelines and avoid too long application times. If possible, cooling can reduce patients discomfort after the treatment. All personal, including the patient, have to wear eye protection goggles; this may lead to decreased vision regarding contrast and color by the personal and surgeon. In case of any eye injury due to disregard of the eye protection by safety goggles, an ophthalmologist has to be consulted.

Foot care tips

- There are some things you can do to help keep the infection at bay during and after treatment. These are listed below.
- Keep your feet cool and dry, and wear shoes and socks that allow your feet to breathe
- Wear clean cotton socks and avoid wearing trainers
- Treat athlete's foot with antifungal medicine as soon as possible to avoid the infection spreading to your nails
- Clip your nails to keep them short
- Use a separate pair of clippers or scissors to cut the infected nail to avoid spreading the infection to other nails
- Wear well-fitting shoes without high heels or narrow toes
- Maintain good foot hygiene
- Wear clean shower shoes when using a communal shower
- Consider seeking treatment from a podiatrist if thickened toenails cause discomfort when walking
- Consider replacing old footwear as it could be contaminated with fungal spores

