



PALOVIA™

Skin Renewing Laser™

Instructions for Use

Read this entire booklet before using your PaloVia Skin Renewing Laser.

Read This First

To ensure proper use, and to achieve your best results, it is important that you read and understand the instructions, warnings, precautions and safety information in this booklet before using your PaloVia laser for the first time.



This symbol appears next to information about possible safety risks.

Questions? Our PaloVia Customer Care representatives are available to help. Contact us at:

PaloVia Customer Care

Phone: 1-866-PALOVIA (1-866-725-6842)

Email: info@palovia.com

Or visit palovia.com

Written Correspondence

PaloVia Customer Care

15 Network Drive

Burlington, MA 01803

Contents

Introduction	1
What's Included	2
Design Features	3
When to Use Your PaloVia Laser (Indication)	3
Safety Information	
When Not to Use (Contraindication)	4
Warnings and Precautions	4
Risks and Benefits	5
Get to Know Your PaloVia Laser	8
How Often to Use Your PaloVia Laser	11
How to Use Your PaloVia Laser	
First Time	12
Every Time	14
Steps of Use Overview	20
What to Expect	22
How to Achieve Your Best Results	23
Troubleshooting	24
Guarantee and Warranty	25
Labeling and Specifications	28
Care and Considerations	29
Contact Us	29

Introduction

Congratulations on your purchase of the PaloVia laser – the first FDA-cleared, at-home laser clinically proven to reduce fine lines and wrinkles around the eyes.

A Visible Improvement in Wrinkles ... in Just One Month

In a clinical study, a panel of doctors specializing in dermatology and plastic surgery saw a noticeable reduction in wrinkles in 92% of participants after just one month of daily treatments.*

A Proactive Way to Reverse the Signs of Aging

In the past, laser skin rejuvenation treatments were only available in a doctor's office. Now you can treat yourself in the privacy and comfort of your own home.

A Proven Technology That is FDA-Cleared

Patented fractional laser technology has been proven by dermatologists for more than a decade. For the first time, this technology has been adapted and perfected for your use at home.

*Individual results may vary.

Why It Works

How Wrinkles Form

Collagen and elastin fibers form a supportive structure in the dermal sub-layers, helping skin look smooth and youthful. With age, this supportive structure weakens, causing wrinkles to form.

Renews the Skin's Support Structure

Unlike lotions and creams, which are most effective on the skin's outer layer, the PaloVia laser also works *below* the surface where wrinkles form. Micro-fine laser light reaches deeply into the skin's sub-layers, treating the aging support structure. Then the body's natural healing process sweeps away older, damaged tissue and rebuilds it with fresh, new collagen and elastin.



What's Included



See full product details on pages 8-10.

In addition to what is provided, you will need a mirror and a standard 110V AC electrical outlet to use your PaloVia laser.



Handpiece



PaloVia Pre-Treatment Gel



Charger



Storage Case

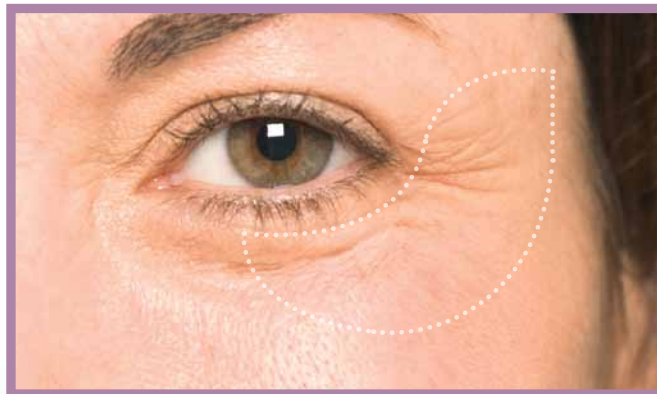
Design Features

Through years of testing, the PaloVia laser design has been perfected for home use. Its user-friendly features include:

- ▶ Intuitive, handheld design
- ▶ Easy-to-follow instructions
- ▶ Helpful audio and visual cues
- ▶ “Smart” sensors that work with the PaloVia Gel to verify skin contact
- ▶ Automatic shut-off to prevent overuse

When to Use Your PaloVia Laser (Indication)

The PaloVia Skin Renewing Laser has been FDA-cleared to treat the fine lines and wrinkles around the eyes (periorbital wrinkles).



Safety Information

Read the following important safety information before using the PaloVia laser.

WHEN NOT TO USE (CONTRAINDICATION)



DO NOT use the PaloVia laser on skin that is infected, burned or cut, as this could cause discomfort or irritation. Wait until the infection, burn or cut has healed before using the laser.

WARNINGS



You must follow these *Instructions for Use* when using the PaloVia laser. Not following these instructions may result in serious injury.



The PaloVia laser is not intended for use by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience and knowledge. Children should be supervised to ensure they do not play with the PaloVia laser.



DO NOT place or slide any part of the Treatment Window over your open eye or closed eyelid. The laser light is not visible and can cause serious and permanent eye damage.



DO NOT use the Handpiece without the PaloVia Pre-Treatment Gel and **ALWAYS** ensure the skin is dry before applying the PaloVia Gel. The Handpiece may not operate properly if used without the PaloVia Gel, or if used with another lotion or gel, or if the skin is not completely dry before applying the PaloVia Gel. Such failure to operate properly can cause serious and permanent eye damage, discomfort or skin irritation, or may damage the Handpiece or prevent it from treating your wrinkles.



DO NOT place or drop the Handpiece or Charger into water or other liquid. If the Handpiece or Charger has fallen into water or liquid, **DO NOT** touch until you first unplug it. Either of these situations could damage the Handpiece or Charger, or cause an electric shock that may lead to serious injury or death.

PRECAUTIONS



If you have a skin condition or are undergoing professional cosmetic treatments, such as injectable toxins or fillers, please check with your doctor or clinician before using the PaloVia laser.



DO NOT apply more than 5 application stamps in the exact same spot during the same treatment session. Failure to move the Handpiece between application stamps will increase redness and swelling, and may result in blisters or scabs.



Avoid getting the PaloVia Pre-Treatment Gel in your eyes, as irritation could result. If gel gets in your eye, flush your eye with water for several minutes. Call your doctor if irritation continues.



DO NOT drop the Handpiece on hard surfaces, as this could damage it.



Only use the Charger supplied with the PaloVia laser to recharge the Handpiece. Using a different Charger could damage it.



DO NOT use the PaloVia laser to treat any other wrinkles on your face, such as around the mouth, on your forehead or above your eyes. The PaloVia laser has only been clinically tested on the fine lines and wrinkles around the eyes. Using the PaloVia laser on other wrinkle areas may not improve their appearance.

Risks and Benefits

Through clinical studies, the PaloVia Skin Renewing Laser has been shown to improve the appearance of periorbital wrinkles – the fine lines and wrinkles that appear around the eyes.

Ninety women and men between the ages of 30 and 71 participated in a study that was conducted in the United States. Participants were given a PaloVia laser to take home and treat their periorbital wrinkles on a daily basis for one month (initial treatment phase), then twice a week for another three months (maintenance treatment phase) for a total of four months of treatments. Throughout the study, participants were evaluated every one to two weeks by a clinician for side effects and wrinkle improvement as a result of using the PaloVia laser.

The risks and benefits of the PaloVia laser are based on physician evaluation of the periorbital wrinkles, participant feedback and blinded evaluation (i.e., evaluator does not know when the photographs were taken) of participants' before, during and after photographs.

Risks and Benefits

Risks

Based on the results of the clinical study, only minor, expected side effects occurred.

The side effects that appeared on the treated skin most frequently after treatment included: redness (72%), dryness (22%), roughness (13%), tanned appearance to the skin (6%), swelling (5%), flaking (3%) and itching (2%). Additional side effects on the treated skin that occurred much less frequently (<1%) after treatment were crusting, pinpoint bleeding, stinging, bruising, pimple-like rash and irritated skin. Clinical results show that these side effects resolved within several minutes to five days after the participant's last daily treatment. When using the PaloVia laser daily, these side effects may diminish, but not fully resolve, before your next daily treatment.

Side effects that did not occur in this study and are not expected as a result of using this product when following all of the instructions in this booklet include: blistering, scarring, infection and skin color changes where your skin may become darker or lighter in color.

When you are treating your periorbital wrinkles with the PaloVia laser, you may feel discomfort that many participants described as stinging or pricking. There can also be a warming or slight burning sensation that can last for several minutes after the treatment. Many participants stated that these sensations lessened with continued use.

#	Cause of Adverse Event	Likelihood of Adverse Event	Adverse Effect	Likelihood of Adverse Effect
1	Overlapping 2 application stamps	Moderate likelihood	<ul style="list-style-type: none"> Slight increase in erythema (redness) Slight increase in edema (swelling) 	<p>Based on usability data:</p> <ul style="list-style-type: none"> 5 out of 10 people will have a slight increase in erythema 4 out of 10 people will have a slight increase in edema
2	Applying more than 5 application stamps in the exact same spot during the same treatment session without moving the Handpiece	Very low likelihood as it requires deliberate misuse	<ul style="list-style-type: none"> Increased erythema (redness) Increased edema (swelling) Increased bronzing (tan appearance) Blisters Scabbing Hypo/hyperpigmentation (skin color change) 	<p>Based on usability data:</p> <ul style="list-style-type: none"> 9 out of 10 people will have increased erythema 8 out of 10 people will have increased edema 2 out of 10 people will have increased bronzing 1 out of 100 people will have blisters 1 out of 100 people will have scabbing No reports of hypo/hyperpigmentation

Benefits

Participants in the clinical study were asked to respond to a series of statements about their wrinkle results. Respondents were provided with five choices: 1) strongly disagree, 2) somewhat disagree, 3) neither agree nor disagree, 4) somewhat agree and 5) strongly agree. The data showed that, after one month of daily treatments, 77% of participants strongly agreed or somewhat agreed that their wrinkles were visibly reduced, and this response increased to 82% after four months of treatments. Participants were also asked if their fine lines and wrinkles were not as deep as a result of using the PaloVia laser. After one month of treatments, 80% of participants strongly agreed or somewhat agreed that their fine lines and wrinkles were not as deep, and after four months of treatment, this number increased to 88%.

Three physicians reviewed all participant photographs taken before, during and after PaloVia laser treatments. On average, physicians graded over 90% of the study participants as having a visible improvement in their wrinkles after only two weeks of daily treatment. Throughout the Maintenance Phase, physicians found between 81-86% of the study participants had visible wrinkle improvements.

Based on clinical study data, on average, physicians found that over 59% of participants still had a visible improvement in their wrinkles three months after they completely stopped using the PaloVia laser.

In order to achieve maximum benefits from using your PaloVia laser, you must make sure that you treat ALL of your wrinkles in the eye area, including the entire length of the wrinkle.

To achieve your best results, you must carefully read and follow the instructions in this booklet.

Get to Know Your PaloVia Laser

Handpiece



Power Button: Press to turn on or off. After being turned on, “PaloVia” will appear on the LCD Screen and the Handpiece will conduct a 3-second self-testing procedure.

◀ *Startup chime and clicking sound*



Treatment Window: Laser light is delivered through the Treatment Window when it is in full contact with the skin and the Activation Button is pressed and released.



Activation Button: When the Treatment Window is in full contact with the skin, you must press and release this button to activate the laser. The Activation Button is also used to adjust the intensity level (see instructions on page 9).



Contact Light: The blue Contact Light illuminates when the Treatment Window is in full contact with the skin, signaling that the laser is ready to be activated. The blue Contact Light is not laser energy and does not treat your wrinkles.



LCD Screen: This screen displays helpful information as you use your PaloVia laser. A listing of screen messages and meanings can be found in “How to Read Your LCD Screen” on pages 9-10.

How to Read Your LCD Screen



Power is on and Handpiece is conducting a 3-second self-testing procedure.

◀ *Startup chime and clicking sound*



Intensity Level: Your PaloVia laser has 3 intensity settings: High ■■■, Medium ■■■ and Low ■■■. To change the intensity level, lift the Handpiece off the skin. Then, while looking at the LCD Screen, press and hold down the Activation Button to toggle between the 3 intensity levels. Release the Activation Button once you get to the desired level.

◀ *Short beep when level is changed*



Number: The number on the LCD Screen shows the number of applications remaining until the Handpiece automatically shuts off for 8 hours. This number resets to 25 after every 8-hour period of non-use.



Battery Symbol: The shaded area on the battery symbol indicates the level of charge remaining. You will need to charge the Handpiece before your first use and again after every 3-4 treatment sessions.



Application was interrupted and needs to be repeated (see Step 7 on page 17).

◀ *Low tone*



Blinking empty battery symbol indicates battery needs to be charged (see instructions on page 10).



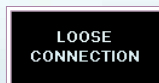
Battery is charging. Shaded area will pulse while the Handpiece is charging.

◀ *Double beep*



Battery charge is complete.

◀ *Double beep*



Charger connection is loose. Check both connections.

Get to Know Your PaloVia Laser

How to Read Your LCD Screen (Continued)

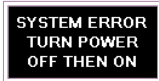


You have completed 25 application stamps within an 8-hour period. Countdown clock shows how long you need to wait before your next treatment session.



Temperature error has occurred. Store Handpiece in a cool, dry place for 2 hours before restarting.

◀ *Low tone*



System error has occurred. First try to reset the Handpiece by turning the power off, then on. If the error message remains on the screen, recharge the Handpiece for 30 minutes and try again. If the problem persists, call PaloVia Customer Care at 1-866-PALOVIA (1-866-725-6842).

◀ *Low tone*

Charger



To charge the Handpiece, plug the mini-USB end of the Charger into the base of the Handpiece and plug the other end into a standard 110V AC electrical outlet. The Handpiece will need to be charged before your first use and again after every 3-4 treatment sessions. It takes approximately 2 hours to fully charge the Handpiece.

PaloVia Pre-Treatment Gel



The PaloVia Pre-Treatment Gel **must** be applied to dry skin around the eyes prior to using the PaloVia laser to ensure proper operation of the Handpiece, proper contact with the Treatment Window and optimal light penetration during treatment. The bottle included with your PaloVia laser should last for approximately 60 treatment sessions. Additional gel is available for purchase at palovia.com or by calling PaloVia Customer Care at 1-866-PALOVIA (1-866-725-6842). See the gel bottle for a full listing of ingredients.

Storage Case



This Storage Case has been specially designed for convenient, permanent storage of your Handpiece, Charger, PaloVia Pre-Treatment Gel and this *Instructions for Use* booklet.

How Often to Use Your PaloVia Laser

There are two phases to the treatment plan – the Initial Phase and the Maintenance Phase. Follow both phases of the treatment plan for best results.

Phase	Treatment	Duration
Initial Phase	1x per day	30 days
Maintenance Phase	2x per week (every 3-4 days)	Ongoing

Helpful Tip

Conduct your treatments in the evening before bedtime, as you may experience redness and swelling after treatment that will diminish overnight.

Helpful Tip

If you stop using the PaloVia laser, your results will start to lessen. If you restart your treatments after a period of non-use, you may want to repeat the Initial Phase.

Initial Phase

Month 1

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31	1	2	3	4

Maintenance Phase

Month 2 and Beyond

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31	1	2	3	4

Intended for example only.

How to Use Your PaloVia Laser – *First Time*

When using your PaloVia laser for the first time, we recommend that you try it on your forearm, so you'll know what to expect.



DO NOT use the PaloVia laser on skin that is infected, burned or cut, as this could cause discomfort or irritation. Wait until the infection, burn or cut has healed before using the laser.



DO NOT place or drop the Handpiece or Charger into water or other liquid. If the Handpiece or Charger has fallen into water or liquid, **DO NOT** touch until you first unplug it. Either of these situations could damage the Handpiece or Charger, or cause an electric shock that may lead to serious injury or death.



If you have a skin condition or are undergoing professional cosmetic treatments, such as injectable toxins or fillers, please check with your doctor or clinician before using the PaloVia laser.



DO NOT drop the Handpiece on hard surfaces, as this could damage it.



Only use the Charger supplied with the PaloVia laser to recharge the Handpiece. Using a different Charger could damage it.

Step 1: Charge Handpiece

You will need to charge the Handpiece before using it for the first time. Plug the mini-USB end of the Charger into the bottom of the Handpiece, and plug the other end into a standard 110V AC electrical outlet. It takes approximately 2 hours to fully charge the Handpiece. Once charged, **unplug the Handpiece before use.**



Step 1: Charge Handpiece

Step 2: Turn Power On

Press the Power Button on the Handpiece. "PaloVia" will appear on the LCD Screen, and you will hear a startup chime and clicking sound as the Handpiece conducts a 3-second self-testing procedure.



Step 2: Turn Power On

Step 3: Try Your PaloVia Laser

Spread a pea-sized amount (one pump) of PaloVia Gel on dry skin on your forearm. Hold the Handpiece comfortably in your hand with your index finger positioned above the Activation Button. Then place the Treatment Window on your forearm where you've applied the gel (see picture). When you see the blue Contact Light illuminate, you will know that the Treatment Window is in full contact with your skin and that the laser is ready to be activated.

If you do not see the blue Contact Light illuminate, adjust placement of the Handpiece until the light appears.

Press and release the Activation Button. You should see the blue Contact Light flash and hear steady beeping and clicking to tell you that the laser is working. You may feel a sensation during activation that some people describe as stinging or prickling. The application lasts for about 3 seconds. When the flashing blue Contact Light turns off and the sounds stop, the application is complete.

You may feel a warming sensation following the application.

Step 4: If Desired, Adjust Intensity Level

Your PaloVia laser has 3 possible intensity levels: High ■■■, Medium ■■■ and Low ■■■. We recommend that you start at the "High" setting, but if you find the sensation too uncomfortable, you may select a lower setting.

To change the intensity level, lift the Handpiece off the skin. Then, while looking at the LCD Screen, press and hold down the Activation Button to toggle between the 3 intensity levels. Release the Activation Button once you get to the desired level.

For best results, use the highest intensity level you can comfortably tolerate.

Once you've tried the PaloVia laser on your forearm, you are ready to treat your wrinkles.



Step 3: Try Your PaloVia Laser



Step 4: If Desired, Adjust Intensity Level

How to Use Your PaloVia Laser – *Every Time*

Preparation (Steps 1 - 4)



DO NOT place or slide any part of the Treatment Window over your open eye or closed eyelid. The laser light is not visible and can cause serious and permanent eye damage.



DO NOT apply more than 5 application stamps in the exact same spot during the same treatment session. Failure to move the Handpiece between application stamps will increase redness and swelling, and may result in blisters or scabs.



DO NOT use the PaloVia laser to treat any other wrinkles on your face, such as around the mouth, on your forehead or above your eyes. The PaloVia laser has only been clinically tested on the fine lines and wrinkles around the eyes. Using the PaloVia laser on other wrinkle areas may not improve their appearance.

Step 1: Unplug Handpiece From Charger

Unplug the Handpiece from the Charger before use. The Handpiece will not activate if it is plugged in.



Step 1: Unplug Handpiece From Charger

Step 2: Check Treatment Window

Make sure that the Treatment Window is clean and free of residual PaloVia Pre-Treatment Gel. If cleaning is needed, moisten a soft cloth with water and mild soap, and wipe the window clean.

If the Treatment Window is scratched or cracked, do not use the laser. Call PaloVia Customer Care at 1-866-PALOVIA (1-866-725-6842) for further instructions.



Step 2: Check Treatment Window



DO NOT use the Handpiece without the PaloVia Pre-Treatment Gel and **ALWAYS** ensure the skin is dry before applying the PaloVia Gel. The Handpiece may not operate properly if used without the PaloVia Gel, or if used with another lotion or gel, or if the skin is not completely dry before applying the PaloVia Gel. Such failure to operate properly can cause serious and permanent eye damage, discomfort or skin irritation, or may damage the Handpiece or prevent it from treating your wrinkles.



Avoid getting the PaloVia Pre-Treatment Gel in your eyes, as irritation could result. If gel gets in your eye, flush your eye with water for several minutes. Call your doctor if irritation continues.

Helpful Tip

If you have trouble seeing your wrinkles, consider using a magnifying mirror during your treatment sessions.

Step 3: Wash and Dry Skin

Wash and gently pat your skin completely dry in the area around your eyes where you have fine lines and wrinkles.



Step 3: Wash and Dry Skin

Step 4: Apply PaloVia Pre-Treatment Gel

Make sure the skin around your eyes is completely dry. Dispense a pea-sized amount (one pump) of PaloVia Pre-Treatment Gel onto your fingertip. While looking in the mirror, apply a thin layer of the PaloVia Pre-Treatment Gel beside and underneath **both** eyes.

The PaloVia Pre-Treatment gel should lightly cover all of the wrinkles around your eyes. Do not rub the gel into the skin.



Step 4: Apply PaloVia Pre-Treatment Gel

How to Use Your PaloVia Laser – *Every Time*

Treatment (Steps 5 - 8)

Step 5: Plan Your Treatment Session

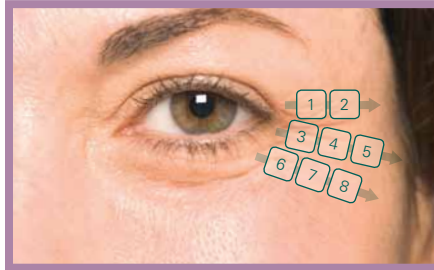
While looking in the mirror and keeping both eyes open, you will treat each wrinkle with a series of individual “application stamps.”

In general, you should plan to first treat the wrinkles beside your eye and closest to your eyebrow and work downward to treat any wrinkles under your eye.

The first application stamp should be at the start of the wrinkle nearest to the eye. Then you will use additional application stamps to follow the wrinkle out towards the hairline. On average, you will need 2-4 application stamps for each wrinkle and 6-8 application stamps around each eye.

Step 6: Turn Power On

Press the Power Button on the Handpiece. “PaloVia” will appear on the LCD Screen, and you will hear a startup chime and clicking sound as the Handpiece conducts a 3-second self-testing procedure.



Step 5: Plan Your Treatment Session

 *Outline illustrates Treatment Window placement*



Step 6: Turn Power On

Helpful Tip

The illuminated blue Contact Light is a signal that the laser is ready to be activated or, when flashing, is being activated. The blue Contact Light is not laser energy and does not treat your wrinkles.

Helpful Tip

You may need to experiment with different grips and placements before you get the steady blue Contact Light to illuminate.

Helpful Tip

Each time the Handpiece is restarted, it will default to the last intensity level selected. See page 9 for instructions on how to adjust the intensity level.

Step 7: Perform Applications Around One Eye

Hold the Handpiece so that it fits comfortably in your hand with your index finger positioned above the Activation Button (see picture 7a).

While looking in the mirror with both eyes open, place the Treatment Window directly on the first wrinkle you want to treat (see stamp #1 in picture 7b). Adjust the placement of the Handpiece until you can see in the mirror that the blue Contact Light has illuminated.

Then press and release the Activation Button. You should see the blue Contact Light flash and hear steady beeping and clicking to tell you that the laser is working. You may also feel a sensation during activation that people describe as stinging or prickling. Do not lift or slide the Handpiece during the application (about 3 seconds). When the flashing blue Contact Light turns off and the sounds stop, the application is complete, and you may feel a warming sensation.

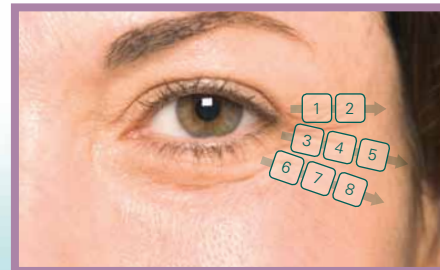
Next, lift the Handpiece off your skin and move it a distance equal to the size of the Treatment Window (less than ½ inch). When you see the blue Contact Light illuminate, press and release the Activation Button. Repeat this process, following the length of the wrinkle from the point nearest to the eye out towards your hairline.

Be sure to use enough application stamps to cover the wrinkle completely before you move on to the next wrinkle. On average, you will need 2-4 application stamps for each wrinkle and 6-8 application stamps around each eye.

If you lift the Handpiece off the skin during the 3-second application, the blue Contact Light will turn off, you will hear an error sound (a low tone) and the LCD Screen will read “Interrupted.” If this happens, simply repeat the application stamp until it is successfully completed.



Step 7a: Hold Handpiece On First Wrinkle



Step 7b: Perform Applications Around One Eye

How to Use Your PaloVia Laser – *Every Time*

Treatment (Steps 5 - 8)

Step 8: Perform Applications Around Other Eye

Switch to the other side of your face and repeat the process (Step 7) to treat the wrinkles around your other eye.



Step 8: Perform Applications Around Other Eye

Helpful Tip

Hold the Handpiece in place during each 3-second application. Sliding the Handpiece during application may diminish your results.

Helpful Tip

The application stamp is complete **only** when the beeping and clicking sounds stop and the blue Contact Light turns off.

Post-Treatment (Steps 9 - 12)

Step 9: Check Battery/ Turn Power Off

When you are done with your treatment session, check the battery symbol on the LCD Screen to determine if recharging is necessary. Then turn off the Handpiece by pressing the Power Button. The LCD Screen will turn off completely.



Step 9: Check Battery/Turn Power Off

Post-Treatment (Steps 9 - 12)

Step 10: Clean Treatment Window

Moisten a soft cloth with water and mild soap, and wipe the Treatment Window clean of any residual gel.



Step 10: Clean Treatment Window

Step 11: Recharge and Store Handpiece

Recharge the Handpiece if needed (see charging instructions on page 10). Then place the Handpiece in its Storage Case and keep in a cool, dry location, out of the reach of children.



Step 11: Store Handpiece

Step 12: Complete Skincare Regimen

Your treatment session is complete. You may continue to use your regular skincare and cosmetic products. Daily use of a sunscreen is recommended.



Step 12: Complete Skincare Regimen

Helpful Tip

The Handpiece will need to be charged after every 3-4 treatment sessions. It takes approximately 2 hours to fully charge the Handpiece.

Steps of Use Overview

Preparation (Steps 1 - 4)



Step 1:
Unplug Handpiece From Charger



Step 2:
Check Treatment Window

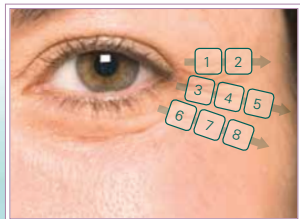


Step 3:
Wash and Dry Skin



Step 4:
Apply PaloVia Pre-Treatment Gel

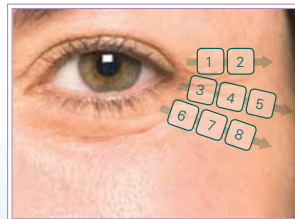
Treatment (Steps 5 - 8)



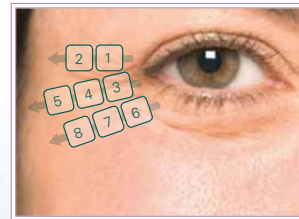
Step 5:
Plan Your Treatment Session



Step 6:
Turn Power On



Step 7:
Perform Applications Around One Eye



Step 8:
Perform Applications Around Other Eye

Post-Treatment (Steps 9 - 12)



Step 9:
Check Battery/Turn Power Off



Step 10:
Clean Treatment Window



Step 11:
Recharge and Store Handpiece



Step 12:
Complete Skincare Regimen

What to Expect

Many PaloVia users find the first month of treatment to be both exciting and challenging. If you know what to expect – and when – it can be easier.

The First Treatment Session

- ▶ Make sure to try the PaloVia laser on your forearm so you'll know the feeling to expect (see pages 12-13).
- ▶ The first treatment session is usually the longest, so it's best to start on a night when you are not tired or in a hurry. Since it's your first time, you will probably feel inexperienced. Within a few days, though, most users master the 3-4 minute treatment session.
- ▶ The “prickling” or “stinging” sensation you feel during each 3-second application stamp is normal and indicates the PaloVia laser is treating your wrinkles. If the sensation is too uncomfortable, switch to a lower intensity level (see page 9 for instructions). Many users find that these sensations lessen with continued use, so you should re-evaluate whether you can tolerate a higher setting after a few days of treatment.

For most users, the clinically proven results of laser skincare treatment are worth some minor discomfort. To give yourself the best chance of success, be patient and stick with the treatment plan. Remember, your PaloVia laser comes with a 60-Day Money-Back Guarantee, so you can try it for two months risk-free.

Initial Phase (Month 1)

- ▶ During the first month, many users experience temporary redness, which is a sign that the body's natural healing process is sweeping away older, damaged tissue. If you treat yourself at night, the redness will diminish while you sleep. If the skin around your eyes is still red in the morning, use your regular cosmetics to even out your skin color.
- ▶ Some users notice that their skin becomes rough and/or dry during the first month of use. This is another sign that your body's natural healing process is hard at work. Try applying a moisture-rich eye cream after treatment to help soothe the dryness. And, of course, you can continue to use all of your regular skincare products. Daily use of a sunscreen is also recommended.

Maintenance Phase (Month 2 and Beyond)

- ▶ After a month of daily treatments, the hard work is done. In the twice per week Maintenance Phase, most people find that the side effects are less noticeable and fully resolve between treatments.

How to Achieve Your Best Results

- ▶ Follow the full two-phase treatment plan. Use the PaloVia laser daily for one month (Initial Phase) and then switch to twice per week (Maintenance Phase).
- ▶ Treat yourself at night, before going to sleep.
- ▶ During your treatment sessions:
 - Do not move or lift the Handpiece until the 3-second application stamp is complete.
 - Treat the entire length of each wrinkle starting closest to the eye and working outward towards the hairline.
 - During each treatment session, apply at least 6-8 application stamps around each eye.
 - Use the highest intensity level you can comfortably tolerate.



Troubleshooting

Use the following information to help solve problems that may arise during use. If you still have questions, please visit palovia.com or call PaloVia Customer Care at 1-866-PALOVIA (1-866-725-6842), and we'll be happy to help.

Problem	Possible Cause	How to Resolve
Handpiece won't power on	<ul style="list-style-type: none"> ▶ Pressed wrong button ▶ Battery charge depleted ▶ Handpiece plugged into Charger ▶ Power Button released too quickly 	<ul style="list-style-type: none"> ▶ Power Button is the smaller button on the bottom of the Handpiece ▶ Recharge the Handpiece ▶ Unplug the Handpiece from the Charger before use ▶ Press and hold the Power Button until "PaloVia" appears on the LCD Screen (about 1 second)
Laser won't activate	<ul style="list-style-type: none"> ▶ Pressed wrong button ▶ Battery charge low ▶ Room temperature is too high or too low 	<ul style="list-style-type: none"> ▶ Activation Button is the larger button near the top end of the Handpiece ▶ Recharge the Handpiece ▶ Store Handpiece for 2 hours in a cool, dry place before restarting the laser
Blue Contact Light does not illuminate	<ul style="list-style-type: none"> ▶ Treatment Window is not in good contact with skin ▶ Used 25 applications within an 8-hour period ▶ Skin not prepared for treatment 	<ul style="list-style-type: none"> ▶ Adjust Handpiece placement and try again ▶ Wait 8 hours before reusing the laser ▶ Apply PaloVia Gel onto clean, dry skin prior to using the laser
Can't adjust intensity level	<ul style="list-style-type: none"> ▶ Pressed wrong button ▶ Not holding Activation Button long enough ▶ Pressed Activation Button while Treatment Window was in contact with skin 	<ul style="list-style-type: none"> ▶ Intensity level is controlled by the Activation Button near the top end of the Handpiece ▶ Hold the Activation Button for several seconds to toggle between intensity levels. Release button when desired level appears on LCD Screen. ▶ Remove Treatment Window from the skin and then, while looking at the LCD Screen, press and hold the Activation Button to toggle between intensity levels. Release button when desired level appears on LCD Screen.
Application interrupted	<ul style="list-style-type: none"> ▶ Treatment Window lost contact with the skin 	<ul style="list-style-type: none"> ▶ Adjust Handpiece placement and try again
Handpiece won't charge	<ul style="list-style-type: none"> ▶ Mini-USB and/or wall plug not fully connected 	<ul style="list-style-type: none"> ▶ Check both connections
Handpiece powers off	<ul style="list-style-type: none"> ▶ Handpiece will power off automatically after 90 seconds of inactivity 	<ul style="list-style-type: none"> ▶ Press the Power Button to restart

Guarantee and Warranty

Palomar wants you to be happy with your PaloVia Skin Renewing Laser. If you are unhappy for any reason or have any questions, we are just a phone call away. Your purchase is guaranteed. Read on for details.

The PaloVia Laser 60-Day Money-Back Guarantee

The PaloVia laser comes with a 60-day money-back guarantee. If you decide you do not want to keep the PaloVia laser for any reason within 60 days of your purchase, simply return it to the location where you purchased it for a full refund.

The PaloVia Laser One-Year Limited Warranty

Palomar tests each PaloVia laser for quality and provides a limited warranty against defects in manufacture, materials or workmanship for one year under normal use conditions.

What is Covered by This Limited Warranty?

This one-year limited warranty covers defects in materials and workmanship in the PaloVia laser. Your one-year limited warranty is valid for you alone – the original purchaser – and cannot be transferred.

What is Not Covered by This Limited Warranty?

Palomar does not make any warranty, either express or implied, with respect to the results you may achieve using the PaloVia laser. These results vary from person to person, based on a variety of factors.

This warranty is limited to the original purchaser, and offered only on PaloVia lasers purchased in the United States directly from Palomar or from an authorized PaloVia laser distributor. It does not cover PaloVia lasers where the serial number has been defaced or removed.

This limited warranty does not cover damage, defects or failure caused by abuse or misuse; improper care; impact or insertion of foreign objects; vandalism; improper storage; improper or incorrectly performed maintenance or repair; application of harmful chemicals; Acts of God, fire or water; abrasives; negligence; failure to follow manufacturer's instructions; loss of the PaloVia laser; normal wear and tear; alteration; overuse; professional use; or commercial use.

All repairs or replacements under this limited warranty must be authorized and performed by Palomar, and this limited warranty will be void if you or any other third party attempts to repair the PaloVia laser without written authorization from Palomar.

How Long Does This Limited Warranty Last?

The limited warranty begins on the date of purchase and expires one year later. The warranty period is not tolled during or extended by any period in which the PaloVia laser or any system component is being repaired or replaced.

What Should I Do if My PaloVia Laser is Defective?

In order to be eligible for service under this limited warranty, you MUST register online at palovia.com or call our Customer Care department toll-free at 1-866-PALOVIA (1-866-725-6842) within 30 days of purchasing the PaloVia laser.

If you discover a covered defect in manufacture, materials or workmanship in your PaloVia laser under normal operating conditions before the one-year warranty period expires, contact PaloVia Customer Care toll-free at 1-866-PALOVIA (1-866-725-6842) or email us at info@palovia.com for assistance. If you follow the instructions that we will provide to you for returning your PaloVia laser, Palomar will examine

Guarantee and Warranty

your PaloVia laser. If we confirm a defect covered by this limited warranty, we will, at our option, take one of the following actions: (i) replace your PaloVia laser with either a new or a refurbished PaloVia laser that is the same as or similar to the PaloVia laser you purchased; or (ii) repair your PaloVia laser using either new or refurbished parts.

If we find that your PaloVia laser is not defective, or that the problem with your PaloVia laser is not covered under this limited warranty, we will return it to you.

Warranty Limitations and Disclaimers

THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS THAT VARY FROM STATE TO STATE (OR JURISDICTION TO JURISDICTION).

PALOMAR'S RESPONSIBILITY FOR MALFUNCTIONS AND DEFECTS IN THE PALOVIA LASER, AND YOUR REMEDIES FOR THE BREACH OF THIS LIMITED WARRANTY, ARE LIMITED SOLELY TO THE REPAIR AND REPLACEMENT OF YOUR PALOVIA LASER AS SET FORTH IN THIS WARRANTY STATEMENT.

THE EXPRESS LIMITED WARRANTY SET FORTH ABOVE IS IN LIEU OF ALL OTHER EXPRESS WARRANTIES.

THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE, TO THE MAXIMUM EXTENT PERMITTED BY LAW, HEREBY EXPRESSLY LIMITED TO THE ONE-YEAR PERIOD OF THE EXPRESS LIMITED WARRANTY SET FORTH ABOVE.

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, PALOMAR DISCLAIMS ALL OTHER WARRANTIES, EXPRESS AND/OR IMPLIED. IF APPLICABLE LAW DOES NOT PERMIT THE

DISCLAIMER OF IMPLIED WARRANTIES, THEN THE DURATION OF SUCH IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY EXPRESSLY LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY SET FORTH ABOVE. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL PALOMAR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR INDIRECT DAMAGES BASED UPON BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, STRICT PRODUCT LIABILITY, TORT OR ANY OTHER LEGAL THEORY, EVEN IF PALOMAR IS ADVISED OR AWARE THAT SUCH DAMAGES MIGHT ARISE. SUCH DAMAGES INCLUDE, BUT ARE NOT LIMITED TO, LOSS OF USE OF THE PALOVIA LASER, COST OF ANY SUBSTITUTE EQUIPMENT, THE CLAIMS OF THIRD PARTIES OR DAMAGE TO PROPERTY. THIS LIMITATION DOES NOT APPLY TO CLAIMS FOR PERSONAL INJURY CAUSED BY A DEFECT IN THE PALOVIA LASER. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

THESE WARRANTY TERMS, CONDITIONS AND LIMITATIONS ALLOCATE THE RISKS OF PRODUCT FAILURE BETWEEN PALOMAR AND YOU, THE PURCHASER OF THE PALOVIA LASER. THIS ALLOCATION IS RECOGNIZED BY BOTH PARTIES AND IS REFLECTED IN THE PRICE OF THE PALOVIA LASER. BY USING THE PALOVIA LASER, YOU ACKNOWLEDGE THAT YOU HAVE READ THESE TERMS, CONDITIONS AND LIMITATIONS, UNDERSTAND THEM AND ARE BOUND BY THEM.

Product Changes

Palomar reserves the right to make changes and improvements to its products without incurring any obligation to incorporate such improvements in products previously sold.

Time for Filing Claims

Any claim for breach of this limited warranty must be commenced within twelve months following the original purchase of the PaloVia laser.

No Other Warranties

Unless modified in a writing signed by Palomar and you the purchaser of the PaloVia laser, these warranty terms, conditions and limitations are understood to be the complete and exclusive agreement between the parties, superseding all prior agreements and representations, oral or written, and all other communications between the parties relating to the subject matter of these warranty terms. No employee of Palomar or any other party (including, without limitation, distributors, dealers and retailers) is authorized to make any warranty different from or in addition to those made herein.

Miscellaneous Terms


As used in this contract, “we” and “us” refers to Palomar. “You” refers to the original purchaser of the PaloVia laser. A waiver of strict compliance with any term herein shall not be deemed a continuing waiver or waive any other terms or conditions. We shall be excused from performance to the extent of any delay or inability to perform arising due to weather events, disasters, acts of terrorism, governmental or court action or regulation, labor or materials shortages, or disputes or other circumstances not under our control. If any term herein is illegal, invalid or unenforceable then such term shall be ignored, but the remaining terms and conditions shall remain in effect.

If there is any inconsistency between this limited warranty and any warranty in packaging or materials about the PaloVia laser, the provisions of this limited warranty shall apply to the extent of such inconsistency.


Labeling and Specifications





Laser Aperture

 **INVISIBLE LASER RADIATION.
DO NOT VIEW DIRECTLY WITH
OPTICAL INSTRUMENTS.
CLASS 1M LASER PRODUCT**

This product is in conformity with performance standards for laser products under 21 CFR 1010 & 1040 except with respect to those characteristics authorized by Variance Number 2009-V0603 effective April 14, 2010 and except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

 **PALOMAR MEDICAL
TECHNOLOGIES, INC.**
15 Network Drive
Burlington, MA 01803

**MANUFACTURED
06/2010**


Intertek
3016720

AA1234567

Serial Number

Laser Specifications	
Wavelength	1410 (+/- 20) nm
Beam Divergence	0.15 (+/- .03) mrad
Pulse Duration	10ms
Maximum Output Energy	15mJ
IEC 60825-1:2007	

Care and Considerations

Storage

The PaloVia laser should be stored in a cool, dry place out of the reach of children.

Cleaning

If cleaning is needed, moisten a soft cloth with water and mild soap, and wipe the outside of the Handpiece, including the Treatment Window.

Assembly and Maintenance

The PaloVia laser does not require assembly, other than charging it before your first use. The PaloVia laser is not designed to be serviced, fixed or maintained by you. Never attempt to service it in any manner. If you have questions, please call PaloVia Customer Care at 1-866-PALOVIA (1-866-725-6842).

Travel

When traveling with the PaloVia laser outside the U.S., always check the country's voltage requirements to ensure compatibility. You may need a plug adaptor and/or a voltage converter in order to operate the device while traveling outside the U.S.

Disposal

The PaloVia laser contains a lithium-ion battery which must be removed prior to disposal of the Handpiece. For instructions on how to remove the battery, please visit palovia.com, or call PaloVia Customer Care at 1-866-PALOVIA (1-866-725-6842).

Contact Us

Questions? Our PaloVia Customer Care representatives are available to help. Contact us at:

PaloVia Customer Care

Phone: 1-866-PALOVIA (1-866-725-6842)

Email: info@palovia.com

Or visit palovia.com

Written Correspondence

PaloVia Customer Care

15 Network Drive

Burlington, MA 01803

Copyright © 2010 Palomar Medical Technologies, Inc.
PaloVia and Palomar are trademarks of Palomar Medical Technologies, Inc.
All rights reserved.

Protected by U.S. Patent No. 6,997,923. Additional patents pending.

FCC Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

PALOVIA™
Proven by dermatologists. *Perfected* for you.™

Visit palovia.com to register your PaloVia™ Skin Renewing Laser™ and to sign up for exclusive offers and updates.

palovia.com | 1-866-PALOVIA (1-866-725-6842)