



Loupe Systems

USER GUIDE

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DESIGNS FOR VISION, INC. LOUPE SYSTEMS

Designs for Vision, Inc. Loupe systems are precise instruments customized to the user's specifications and working preferences. They are designed to have superior ergonomics and visualization.

INDICATIONS FOR USE

The Designs for Vision, Inc. Loupe systems are magnification devices meant to be worn as a visual aid during standard and fluorescent guided procedures(if equipped) by qualified clinical professionals. They are intended to magnify surgical fields oral cavities or other clinical sites.

CONTRAINDICATIONS

None known

WARNINGS



Save these instructions. This manual contains important safety and operating instructions



Always examine the unit and accessories for damage before commencing use. Damaged accessories must not be used and must be replaced. Use original Designs for Vision, Inc. parts

and accessories only. The use of unapproved parts may void the warranty.



Before any use, make sure all parts and side shields, if applicable are secure to the glasses



If the equipment is used in a manner not specified by Designs for Vision, Inc., the protection provided by the equipment may be impaired



Your Loupe System is to be used exclusively for the indicated purpose described.



No modification of this equipment is allowed. Performing unauthorized modification on the equipment, accessories or the product labelling may void the warranty



Loupes must be stored in provided instrument box after every use



Do not remove or tamper with marking and/or ID numbers on your device. Will void the warranty.

For indoor use only



Do not force the protective case closed. Re-position loupes if necessary. May cause damage if placed in case improperly. Do not remove rubber protective insert from case



Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SPECIFICATIONS

GUIDELINES	
Your Loupe System is manufactured according to the Food & Drug Administration's Statement Policy, updated April 1, 2018, regarding impact-resistant lenses, Regulation 801.410(c)(1) Subpart H- Special Requirements for Specific Devices	
ENVIRONMENTAL CONDITIONS	
TEMPERATURE:	10°C to 40°C
RELATIVE HUMIDITY:	30% to 75%
ATMOSPHERIC PRESSURE:	700 to 1060 hPa
TRANSPORT & STORAGE	
TEMPERATURE:	-40°C to 70°C
RELATIVE HUMIDITY:	10% to 75%
ATMOSPHERIC PRESSURE:	500 to 1060 hPa

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DEVICE DESCRIPTION

Designs for Vision, Inc's loupe systems come in multiple frame styles and magnification choices ranging from 1.7x to 6.0x. Your unique loupe system has been fabricated to your working position and eyeglass prescription from your eyecare professional, (if applicable).

Your Loupe System includes these main components:

- Frame with Rx if applicable
- Loupes
- Nose Pads
- Carrying Case with Personalized Nameplate
- Side Shields

Accessories include:

- Operation Manual
- Registration Card
- Chum straps
- Lens Cleaning Cloth
- Product Evaluation Survey

Thank you for purchasing your Designs for Vision, Inc. Loupe System! If this is your first time using magnification, you may encounter a learning curve called over accommodation. Since our loupes are custom made to your unique measurements, you should see a single field of view when looking through your loupes. Practicing where your instruments come in and out of the magnified field helps overcome the learning curve.

Welcome to the Designs for Vision family. We have been helping clinicians see The Visible Difference® since 1961.

*-Richard E Feinbloom
President & CEO*

DIRECTIONS FOR USE

Before using your loupes check to see if your frame is level. First place your loupes on a flat surface, make sure the ends of both temples sit flat on the surface, if one or both temples do not touch the surface (blue arrow Fig 1b) your frame needs to be adjusted, see Figure 1a and 1b for a

representation of a level and non-level frame. For adjusting your temples see page 11



FIG. 1A



FIG. 1B

HOW THE LOUPES ALIGN WITH THE EYE

Your frames have a built in pantoscopic tilt (Fig 2 in red) which means that the front of your frame is tilted towards your face. This allows for greater declination angle.

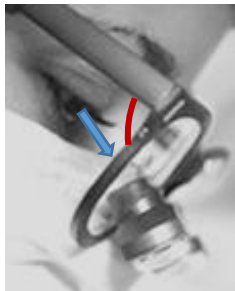
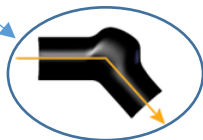
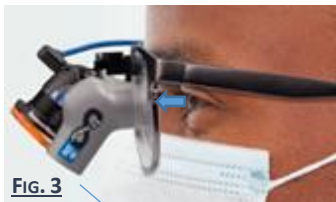


FIG. 2

Infinity VUE™

USING THE INFINITY VUE™ LOUPES

The Infinity Vue™ Loupe system is ergonomically designed to allow the user to look straight ahead while as shown in Figure 3 viewing the oral/surgical cavity. The Infinity Vue re-directs straight line of sight downwards placing the user in a more natural position to work.



When you put your Infinity Vue™ loupes on for the first time you may want to instinctively look down especially if you've been wearing our standard loupes. Just remember to look forward with your neck straight (*Vision Up Ergonomics*).

Note: The Headlight shown in Figure 3 sold separately

ADJUSTING NOSE PADS

To further improve alignment, the nose pads will need to be adjusted properly to your face. Please follow the steps below to make these adjustments. *All adjustments should allow the surface of the nose pads to sit flat to your nose.*

FIG. 4

Figure 4: If the loupes are resting above your line of sight bend the nose pads outwards or upwards, which will decrease their height.

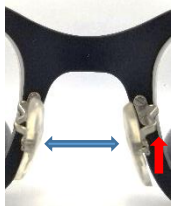


Figure 5: If the loupes are resting below your line of sight push the nose pads inwards or downwards, which increases height.

FIG. 5



Figure 6: To adjust the nose pads for a low bridge, bend the wires down and away from the frame, re-adjust the width of the nose pads if necessary.

FIG. 6

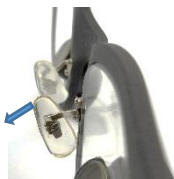


Figure 7: If the saddle nosepad is installed on the frame as seen in Figure 6, the nose pads can be adjusted by moving the lower half of the nosepad in or out. These do not have vertical adjustment.

FIG.7

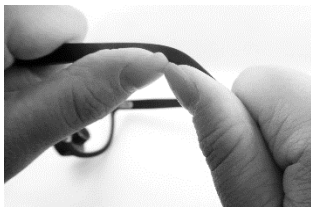


ADJUSTING TEMPLES

The temple tips on most frames are adjustable. To secure your loupes to your head, you can bend the temple tips around your ear.

Place both thumbs together on the temple tip and slowly bend the tip until you get the temple to form the correct fit, which may take a few tries to get right.

FIG.8



ADJUSTING THE CHUM STRAP

Your loupe system is supplied with a set of chum straps. These are used to secure your loupe system to your head. To install these onto your frame, slide each end of the chum strap onto the temple tips. To tighten the chum strap, slide the grommet, towards your head until it secures the frame as seen in Figure 9.

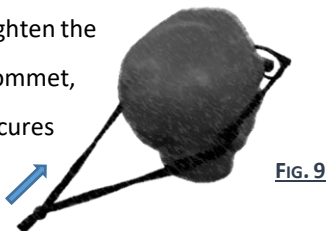


FIG. 9

Nylon Ball Style Strap

The two ends of the chum strap have adjustable loops that are used to secure the chum to the temple of the glasses. Slide the loop up the temple as shown in Figure 10, then push the ring up towards the temple to tighten the



FIG. 10

loop. The final position of the strap should look similar to Figure 11. Repeat for other side



FIG. 11

INSTALLING SIDE SHIELDS

For Yeoman Frames:

On the inside of your side shields there are 6 teeth, rotate the side shield so the bottom three teeth wrap around the bottom of the temple as seen in Figure 12.

Once in position, rotate the side shield around the temple. Once the side shield is on the temple, open up the temple and slide the side shield

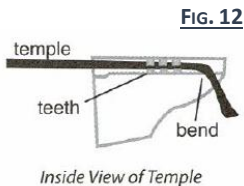


FIG. 12

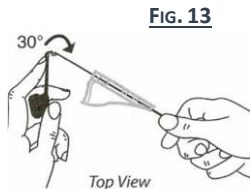
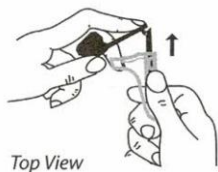


FIG. 13

FIG. 14



is in its final position as shown in Figure 15

towards the front of the frame seen in Figures 13 and 14 , the side shield should go over the front of the frame when the side shield



FIG. 15

For Retro or Steam Frames or Icon:

To install the side shields on the Nike® Retro or Steam frames, first close the temple until the front separates from the front of the frame as seen in Figure 16.

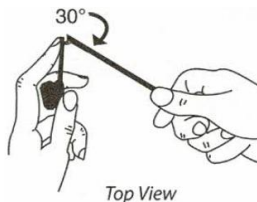


FIG. 16

Slide the end of the side shield with the slides facing in, onto the front of

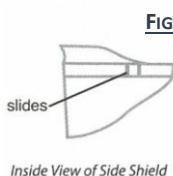


FIG. 17

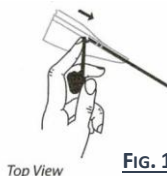


FIG. 18

the temple. Continue to slide the side shield down the temple until it rests on the front of the frame shown in Figures 17 and 18. The final position is shown in Figure 19. The front of the side shield should be about a $\frac{1}{4}$ " away from the front of the frame.



FIG. 19

For SkyView/Designer Frames:

To install the side shields on a SkyView/Designer frame, insert the temple tip into the side shield making sure it goes in between the inner slides and the wall of the side shield as shown in Figure 20

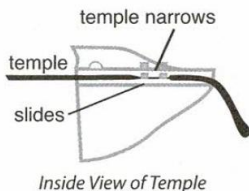


FIG. 20

Once the temple is in position, slide the side shield up the temple until it goes past the front of the frame as shown in Figure 21.

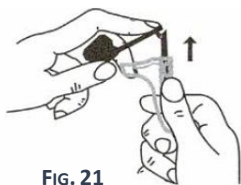


FIG. 21

The side shield should be about a ¼" away from the front of the frame. The final position of the side shield can be seen in Figures 22 and 23



FIG. 22



FIG. 23

Front View

INSPECTION AND PREVENTATIVE MAINTENANCE

Your new loupe system is a custom-made precision optical instrument incorporating your eyeglass prescription throughout the design. Please adhere to the following instructions for proper cleaning and disinfecting, or damage can result.

- Recommended disinfectant: Clorox HC Verasure Wipes (Ammonia-based)
- Recommended cleaner: Windex
- Intended Cleaning/Disinfection:
 - First, perform disinfection on all exposed sections with a Clorox Verasure HC wipe (alcohol-free) or other ammonia-based disinfectant. Wipe the sections and then allow to air dry for two minutes.
 - Clean all disinfected sections with Windex or a standard glass cleaner and a soft, lint-free cloth, making sure not to scratch the surfaces.
- Prohibited Use:
 - This device is not intended to be sterilized
 - Do not autoclave this device
 - Devices should not be submerged or soaked in cleaners or disinfectants.
 - Do not use Alcohol, Amino, Phenol, Peroxide or Iodine complex-based solutions on this device.

- Using solutions/liquids other than recommended on this device may void warranty.
- Protect your loupes, always store in the instrument box provided with the rubber insert in place.

MAINTENANCE REQUIREMENTS ---

- If your eyeglass prescription changes and you want it updated into your loupes, contact Designs for Vision Customer Service Department and request a quote.
- Contact our Customer Service Department *before* you send your glasses in for repair.

DESCRIPTION OF VARIOUS SYMBOLS

	<i>ATTENTION / CAUTION</i>
	<i>READ ACCOMPANYING DOCUMENTS</i>
	<i>MANUFACTURER</i>
	<i>EUROPEAN DISTRUBUTOR</i>
	<i>INDICATES CONFORMITY OF THE PRODUCT WITH EU MDR 2017/745</i>

WARRANTY

Designs for Vision, Inc (the “Company” warrants its Surgical Loupes as to material, manufacturing and workmanship, to the original purchaser for the life of his or her practice.

This warranty is limited to the repair (by the Company) or replacement of the surgical Loupes, at the sole option of the Company. This warranty does not cover any consequential,

special or incidental damages and it does not cover any damages caused by modification, alteration, repair or service by or damage caused by misuse or improper maintenance. This warranty does not extend to frames made by manufacturers other than the Company even if provided by the Company.

We trust that our product meets with your satisfaction. If you have any questions or problems or claims under this warranty with this product, please call our Customer Service Department at the listed toll-free number 1-800-345-4009. One of our Customer Service Representatives will inform you of the necessary procedures for the adjustment or return of the instrument.

1. If these telescopes must be returned for any reason, *before* you ship them, please Contact Customer Service at: DesignsforVision.com/Service.htm
2. Pack in a box with packing list and copy of invoice
3. Ship to: Designs for Vision, Inc.

4000 Veterans Memorial Hwy.
Bohemia, NY 11716-1024
Attn: Repairs



Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste. It must be collected separately, and must be disposed as per local regulations - RoHS 3 (EU 2015/863)

NOTES

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland



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1.800.345.4009

Outside the US-Call Local Distributor



Manufactured by Designs for Vision, Inc
4000 Veterans Memorial Hwy Bohemia, NY 11716
United States

Toll Free 800/345-4009 • Fax 631/585-3404 •

Web Site: www.DesignsForVision.com

E-mail: info@dvimail.com •



Emergo Europe B.V.
Prinsessegracht 20 2514 AP,
The Hague NETHERLANDS

P/N: 0075-8511-0079