

dima Print Denture Base

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Caution: Federal law restricts this device to sale by or on the order of a dental professional.

Instructions for Use – dima Print Denture Base

1. Introduction

The following instructions for use are for dental technicians, dentists and oral surgeons who use dima Print Denture Base for final dentures and partials and is intended exclusively for professional dental work. This instruction for use also provides information about safety and environmental aspects. A safety data sheet is available on www.kulzerUS.com/downloads. In case more information is needed regarding the processing of dima Print Denture Base material, contact Kulzer Technical Service at 800-431-1785. Also see information at the end of this document. dima Print Denture Base material is a light-curable resin indicated for manufacturing and repairing of 3D printing full and partial temporary removable dentures and baseplates. dima Print Denture Base material is a Class II medical device material. dima Print Denture Base material shall be used in combination with cara Print 4.0.

2. Intended use

dima Print Denture Base is a light-curable resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-curable and auto polymerizing resins. Fabrication of dental prosthetics with dima Print Denture Base requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components: digital denture base files, based on a digital scan of an impression, digital light projection printer (cara Print 4.0) and curing light equipment (HiLite Power 3D).

3. Special manufacturing requirements

- 3.1 Digital denture file;
 - a. STL format file
 - b. Digital design
 - c. File size: less than 100mb (each file)

3.2. Digital light projection printer – cara Print 4.0

3.2.1 Hardware

- a. Polymerization technology: Digital light projection (HD DLP @ 405 nm)
- b. Building area: 103 x 58 x 130 mm
- c. Resolution (X & Y-axes): 53.6 µm
- d. Layer thickness (Z-axis resolution): 30 – 150 µm (varies by indication & speed vs. resolution needs)
- e. Average build speed: 50 mm/hour (@ 50 µm); Min./Max. build speed: 15 – 120 mm/hour
- f. Average duration of 1 print cycle: < 1 hour
- g. Connectivity: WiFi, Ethernet or USB
- h. Input format: Open STL
- i. CAD software compatibility: All CAD programs using open STL
- j. CAM software: cara Print 4.0 CAM, included with purchase
- k. Printer dimensions: 267 x 420 x 593 mm
- l. Printer weight: 21 kg

3.2.2 Features of operation software

Recommended software: cara Print 4.0 CAM performed by the cara printer manufactured by Kulzer

- a. STL file import
- b. Place and rotate file on the build plate for proper positioning
- c. Add supports via manual function or auto function

3.2.3 Printing parameters

- a. Layer thickness: 50 micron or 100 micron
- b. Optimal orientation: 90 degree tilted orientation
- c. Support point size: 0.4 – 1.0 mm
- d. Support density: 0.7 – 1.5

3.2.4 Environmental conditions

- a. Temperature: 18 – 30°C
- b. Relative humidity: 30 – 90%

3.2.5 Cleaning kit inclusive of a rinse bath, flush cutter, paper towel, squeeze bottle for isopropyl alcohol and scraper

3.2.6 Recommended printer

- a. cara Print 4.0

3.3. Recommended curing light equipment (post curing units)

3.3.1 UV curing light equipment – post processing [HiLite Power 3D]

- a. Main voltage: 100/115/230 V (via voltage selector switch)
- b. Rated frequency: 50 – 60 Hz
- c. Flash lamp power: 300 W
- d. Fuse protection: T6,3A
- e. Power consumption: 360 VA
- f. Dimensions (H x D x W): app. 225 x 330 x 220 mm
- g. Weight: app. 9.5 kg
- h. Protection rating: Class I
- i. Power-on time: 80%
- j. Curing time: 20 mins.

3.3.2 Accessories

- a. USP grade glycerin
- b. Transparent glass container and plate

4. Contraindications

dima Print Denture Base must not be used for any other purpose than dental removable or fixed dentures. Any deviation from this instruction for use may have a negative effect on the chemical and physical quality of dima Print Denture Base.

Caution: In case of an allergic reaction, please contact a physician. dima Print Denture Base contains Acrylic Oligomer and Acrylic Monomer that may cause allergic reactions in predisposed persons.

5. Hazards & precautions

Inhalation:

Avoid inhalation. High vapor concentration can cause headache and irritation of respiratory system. In case of exposure to a high concentration of vapor or mist, remove person to fresh air. Give oxygen or artificial respiration as required.

Skin contact:

dima Print Denture Base contains polymerizable monomers which may cause skin irritation (allergic contact dermatitis) or other allergic reactions in susceptible persons. If in contact with skin, wash thoroughly with soap and water. If skin sensitization occurs, discontinue use. If dermatitis or other symptoms persist, seek medical assistance.

Eye contact:

Direct contact with eyes may cause possible corneal damage. Immediately flush eyes with plenty of clean water for at least 20 minutes and consult a physician.

Ingestion:

Contact your regional poison control center immediately.

Protection:

Wear protection when handling dima Print Denture Base liquid. Protective glasses and nitrile gloves are advised. Information about the handling of the product can be found in the safety data sheet, which is available on www.kulzerUS.com/downloads.

Precautions:

When washing the printed denture bases with solvent or grinding the denture bases, it should be done in a properly ventilated environment with proper protective masks and gloves.

Adverse reactions:

Direct contact with the uncured resin may induce skin sensitization in susceptible individuals.

Proper ventilation and personal protective equipment should be used when grinding denture base resins as the particulate generated during grinding may cause respiratory, skin and eye irritation.

6. Storage conditions, expiry date, and transport

Store product in the original packaging at room temperature, in a dry and dark area, preferably not exceeding 15-25°C (60-77°F). Close the packaging after each use. The expiry date of the product is mentioned on the product label. In case of exceeding the expiry date, the product is no longer guaranteed to meet specifications and should not be used. Do not expose to UV-light and moisture.

7. Procedure to print denture base**7.1. Printing preparation**

- Select the dima Print Denture Base liquid. (It is recommended to use a different resin tank for different shades)
- Before using dima Print Denture Base, make sure to shake the product in the original packaging for approximately 5 minutes. Color deviations and print failures may occur when shaken insufficiently.
- Open the 3D printer cover and fill the resin tank of the printer with fresh dima Print Denture Base up to the middle of maximum fill line for two arches. (When filling the resin into the resin tank, use of gloves and a mask is recommended)
- Close the printer cover.

7.2. Printing (for more information review current cara Print 4.0 printer IFU)

- Load the denture model file in printer operation software, recommended by the printer manufacturer.
- Use the software tool to rotate the STL file to find the optimal position.
- Use auto-orientation or manual orientation to find its optimal position for printing. The recommended orientation is a tilted orientation such as space diagonal from a 90° angle. If auto-orientation is not satisfied, rotate to make optimal position. (For more information, please review the cara Print 4.0 application guide and CAM guide)
- Generate supports on the file.
- Slice the file.
- Send the file to the printer via Ethernet, WiFi, or manually via a USB stick.
- Make sure that the environmental conditions are as clean as possible. Dirty reservoirs or machines can cause deformation and therefore failure of the printed objects.
- Locate the file on the printer and start printer.

8. Cleaning

- Detach the printed denture base from the build platform.
- Place the platform on a cloth or paper towel with the built job facing upwards. The printed jobs can be removed from the platform using the plastic scraper or spatula included with the cara Print 4.0 accessory kit.
- Rinse the printed jobs twice with isopropanol (at least 71% alcohol) to remove any excess material. Use an ultrasonic bath and make sure to properly dry the appliance after each bath cycle. Rinse the first time for three minutes, second time for 2 minutes. The second rinse must be with clean isopropanol. Rinsing with alcohol solution should not exceed longer than 5 minutes, as this may cause defects in the printed denture.
- After cleaning make sure the printed denture is dry and free of solvent residues. Remove support structures.

9. Procedures to fabricate a denture using printed denture base

Bonding the printed teeth to the printed denture base. Attention: Use dima Teeth to fabricate a denture with dima Print Denture Base. Attention: Do not post-cure base or teeth prior to bonding step. Prepare, before post-cured, the printed teeth and printed denture base with socket shapes to receive printed teeth (tooth sockets).

Place the dima teeth into the corresponding tooth sockets on the printed denture base and check teeth fitting.

Apply the small amount of light curable adhesive into the tooth sockets and bond teeth by exposing into UV light until the teeth set in position. Recommend to use dima Denture Base for bonding. If necessary, apply small amount of dima Denture Base for bonding using an applicator to smooth the edges of the denture base and cure it.

10. Post-curing

- Cure the final denture by sinking into the glycerin container (glycerin temperature should be greater than 60°C) for at least 20 min under recommended Post-Curing Unit. For half of the post-curing time tissue side up and for another half of the time tissue side down.
- Place the printed denture into the HiLite Power 3D for final polymerization. The final properties and the final color depend on the post curing process. Post-curing is a UV-light treatment that ensures dima Print materials obtain full polymer conversion. Through this the residual monomer content is reduced to a minimum and the highest mechanical properties are achieved. This procedure is a necessary step to produce a biocompatible denture. We strongly advise use of the Kulzer HiLite Power 3D device.

Material	Total time (min.)	Post-Curing Device	Procedure
dima Print Denture Base	20 (2 x 10)	HiLite power 3D	Turn objects after 10 minutes
dima print Denture Teeth	20 (2 x 10)	HiLite power 3D	Turn objects after 10 minutes

The specifications of the dima Print Denture Base are determined on the basis of test plates, produced on our cara Print 4.0 with the corresponding settings registered in the software. The print job is post-cured with the HiLite Power 3D for 10 minutes on each side, for a total of 20 minutes. Please notice that the light sources and the printing machine need routine maintenance following the device instructions.

11. Finishing

Remove remaining support structures and finish polishing if necessary, using conventional methods. Differences in color nuance may occur due to production in batches of the raw material and product or inadequate shaking of the original packaging before use or insufficient post-curing.

12. Repair of denture and baseplates

Note: This process is only applied to temporary repair cases. It is recommended to remake the whole denture using an original design file.

Prepare a cast made of a putty using a broken denture. Prepare the fracture area by grinding to open more and roughing the outer side of fracture area.

Prime the roughened surfaces of the repair area with dima Denture Base. Place the broken denture on the cast.

Apply the dima Denture Base resin to cover the roughed and fracture areas and cure the areas by exposing light curing machine until the resin is solidified. Place the denture on the cast in the post-curing machine for 30 min. Carefully remove the denture from the cast and cure the tissue side for 30 min. Grind, polish and finish.

13. Plastic and packaging waste

The dima Print Denture Base in its polymerized form is not harmful for the environment. Residual waste material in its liquid state should be disposed of in accordance to the safety data sheet.

14. Instructions for cleaning and disinfecting

Polymerized dima Print Denture Base printing material should be cleaned with non-chemical products. If disinfecting is required before intended use, an ethanol solution can be used. Follow instructions for disinfection that accompanies the solution from the solution manufacturer. Do not use a dishwasher or thermal disinfectant.

15. Delivery units

The dima Print Denture Base is available in the following packaging size: 1000 grams.