

KeyModel Ultra™



Validated Printers

validated Printers
Impresoras validadas
Impresoras validadas
Imprimantes validées
Stampanti convalidate
Gevalideerde printers
Validierte Drucker
Одобренные принтеры



Validated PCUs

PCU validadas PCUs validadas PCU validées PCU convalidate Gevalideerde PCU's Validierte Bildtrommeln Одобренные камеры для отверждения

Report any serious incident occurring with this device to the manufacturer and applicable Competent Authority of the member state in which the user/patient is established.

Signalez tout incident grave survenant avec cet appareil au fabricant et à l'autorité compétente applicable de l'État membre dans lequel l'utilisateur/le patient réside.

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waar de gevonkervjanein is gevessigu. Berichten Sie jeden ernsthaften Vorfall, der bei diesem Gerät auftritt, dem Hersteller und der zuständigen Behörde des Mitgliedslandes, in dem der Benutzer/Patient ansässig ist.

Comunicare qualsiasi incidente grave dovuto a questo dispositivo, rivolgendosi al produttore e all'autorità competente del Paese in cui vive l'utente/il paziente.

Relate qualquer incidente grave que ocorra com este aparelho ao fabricante e à autoridade competente aplicável do estado-membro no qual o usuário/paciente esteja estabelecido.

Reporte cualquier incidente grave que ocurra con este dispositivo al fabricante y a la autoridad competente del Estado miembro en que esté establecido el usuario/paciente.

О любых серьезных инцидентах, произошедших с данным изделием, необходимо сообщить изготовителю и в соответствующие компетентные органы штата или страны, в которых проживает пользователь/пациент.

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Product Description: KeyPrint® KeyModel UltraTM is a liquid photopolymer resin designed for additive manufacturing in Vat Polymerization DLP printers utilizing wavelengths between 385nm–405nm. Characterized by its fast print speed, flawless surface detail, and integrated thermoforming release agent, KeyModel UltraTM is a material designed for 3D printing of dental and orthodontic models.

The user should review all applicable product labeling, including Instructions for Use, user manuals, and associated labeling for any component(s) used in conjunction with KeyModel UltraTM. Strict adherence to all labeling is critical in assuring a safe and effective printed appliance.

Contraindications: Contains acrylate monomers and oligomers, which, although rare, may cause an allergic reaction in individuals sensitive to acrylic containing products.

Warnings & Precautions

- 1. Review the product Safety Data Sheet (SDS) before use.
- 2.To ensure a safe and effective final device, Keystone Industries recommends using dedicated accessories for KeyModel UltraTM, including resin tank, build platform, and washing station.
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 3. Clean the printer build plate and vat tray before using a different batch of KeyModel UltraTM. DO NOT mix different batches of the same product.
- 4. Do not use any devices or components that are not validated in collaboration with Keystone Industries.
- 5. As per the SDS, wear proper personal protective equipment when handling KeyPrint® resins and uncured printed parts.
- 6. When pouring the resin, be careful not to splash.
- 7. Store in a cool, dry place 15°C-30°C (59°F-86°F) and away from light. Cap the bottle when not in use.
- 8. Keystone recommends against reclaiming the resin material without filtering. In the unlikely event of print failure, filter the liquid resin through a mesh screen with pore sizing <200 microns. It is a good practice to filter the resin val periodically to prevent print failures.
- Prior to use, invert and shake bottle well for 5 minutes. Color deviations and print failures may occur if the resin is insufficiently mixed.
- 10. Light sensitive resin. Shield liquid resin from exposure to ambient light. Do not leave resin in vat tray for prolonged periods.
- 11. Allow the resin to reach ambient temperature (20-25°C/68-77°F) before printing.
- 12. Limit the total wash time with Isopropanol (IPA) to no more than 5 minutes to prevent adverse effects on final physical properties.

Compatible Equipment

To ensure the printed model meets our standards for high quality, Keystone Industries collaborates with printer manufacturers to provide validated printer and post-cure settings. Visit Keystone Industries' website for a list of completed and in-process validations.

Processing Printed Parts

- 1. Pour the liquid material in the reservoir of the printer. Follow the printers' instructions for use.
- Print the part according to your printers' Instructions for use.

Keystone recommends two nesting orientations for dental models (1) Flat, with the occlusal plane parallel to the build plate or (2) Vertical, with the occlusal plane perpendicular to the build plate.

3. Remove printed parts from the build plate.

Directions for cleaning/ post-cure of printed part(s)

Keystone recommends removing support structures before Stage 1 cleaning.

1. Stage 1 Cleaning: Place printed part(s) in an Isopropanol (IPA) bath with at least

- in an isopropanol (IPA) bath with at least 97% purity. Use this bath as the first wash of any part coming from the printer. Remove excess liquid resin from the printed part(s). Run fingers over the surface, using swishing or vibrating motions with the part submerged in the IPA bath.
- Stage 2 Cleaning: Transfer the part(s) into a stage 2 IPA bath. To achieve optimal final print quality, use fresh IPA with a lower concentration of contaminants. A soft bristle brush or cotton swab dipped in IPA can help remove excess resin.
- Dry Part(s): Use compressed air to dry part(s), looking for glossy spots of residual liquid resin. If residual resin remains, repeat steps 1-3 as needed.
- 4. Post Cure: KeyModel UltraTM requires post-cure to reach optimal physical properties. After cleaning, place the part(s) in a validated post-cure box, ensuring the part is placed flat to prevent warping. Cure time will depend on the wavelength and intensity of light used. One validated method of post-curing is:

Otoflash G171: Set the post-cure box to 2000 flashes per side without nitrogen See Keystone's website for validated post-cure box settings.

Allow part to cool completely before removing from the cure-box to prevent surface defects or warping.

Disposal Considerations: KeyPrint® KeyModel Ultra™ is not an environmental hazard in its final, fully cured state. Dispose of unused and non-recyclable liquid resin materials in accordance with federal, state, and local regulations.