1 Introduction

E-Tray is a light-curing resin for the additive manufacturing of individual dental impression trays and bite template bases. *E-Tray* has been optimized for use with Desktop Health's *Einstein*™ 3D printers and EnvisionTEC's *Perfactory® Vida, Perfactory® EnvisionOne cDLM and Perfactory® D4K Pro series* 3D printers and may only be used together with these printers and the corresponding software systems. *E-Tray* is a medical product classified as class I according to Schedule 2 of Therapeutic Goods (Medical Devices) Regulations 2002. Impression trays and bite template bases from *E-Tray* may only be manufactured by dental technicians and used on a patient by authorized users such as dentists, oral surgeons or orthodontists.
The following Instructions for Use includes safety- and environmental information, manufacturing instructions and post-processing procedures of the product, which must be strictly adhered to.

2 Indication

E-Tray is intended for the additive manufacturing of individual dental impression trays, which enable an accurate impression of the upper and/or lower jaw of a patient together with impression material. In addition, *E-Tray* is intended for the additive manufacturing of individual dental bite template bases, which form together with a wax-rim the bite template to determine the relation of the lower jaw to the upper jaw.
Individual impression trays and bite template bases from *E-Tray* are custom-made products for single use during treatment at the dentist, oral surgeon or orthodontist, under consideration of their application and intended exclusively for one patient.
The target group are patients with missing teeth, malpositioned teeth or malocclusions whereby high-risk patients are excluded.
The minimum approved wall thickness is 2mm. After several printing processes the product may show slight color changes. However, this does not reduce the quality of the application.

3 Contraindication

E-Tray may only be used for the production of individual and prefabricated dental impression trays and bite template bases. Any deviation from the Instructions for Use can negatively affect the chemical and physical properties. Consequently, the biocompatibility of the impression trays and bite template bases cannot be guaranteed.
E-Tray may not be used for the manufacturing of further products.

For patient and users:
Patients, users or third parties who come in contact with products from *E-Tray* must be informed about any side effects before use. *E-Tray* products may not be used if there are known allergies to any of the ingredients, otherwise possible side effects such as shortness of breath, gastrointestinal complaints, dizziness, anaphylactic reactions or shocks, itching and tearing (watery) eyes, headaches or reactions of the skin or mucous membrane such as irritation, rash, swelling, inflammation, redness, wheals or blisters or other allergic reactions may occur.

4 Composition

Acrylate/Methylacrylates, methacrylated Oligomers and Monomers, photo initiators, colorants/dyes and absorbers

5 Hazard and Precaution (H & P phrases) according to SDS

Inhalation:	Avoid inhaling vapor of the material.
Skin contact:	If on skin: Wash with plenty of water.
Eye contact:	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
After ingestion:	Do not induce vomiting. If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.
Interaction:	No interactions are known.
Safeguards:	Wearing of protective glasses, protective clothes and protective gloves is advised. Information about the handling of the product can be found in the safety datasheet, which is available on www.envisiontec.com.

H-Phrases	H315	Causes skin irritation.
	H317	May cause an allergic skin reaction.
	H318	Causes serious eye damage.
	H335	May cause respiratory irritation.
	H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
	H411	Toxic to aquatic life with long lasting effects.
P-Phrases	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P302 + P352	IF ON SKIN: Wash with plenty of water.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P404	Store in closed container.
	P501	Dispose of contents/container to industrial incineration plant.

6 Storage Conditions and Expiry Date

The resin needs to be stored in the original bottle between 5 – 30 °C. While removing the resin it must be protected from exposure to light, as spontaneous self-polymerization is possible. The bottle must be tightly closed after every usage and material removal. Resin inside the machine basement can be re-used for several build jobs. If the level in the basement is too low for subsequent jobs, resin from the bottle can be added as necessary. If the material is not in use, it must be poured back into the bottle. For further information on re-using and mixing material, please check the machine manual. An expiration date is given on the label of every product bottle. The use of expired material is not permitted. The impression trays and bite template bases need to be protected from exposure to light before the final use.

7 Notes on Disposal

Dispose of E-Tray and container in accordance with local regulation.
The manufactured individual impression trays and bite template bases, which are used on patients must be disposed of properly due to the risk of infection (contaminated by substances of human origin).

8 Instructions Disinfection and Sterilization

If necessary, the impression trays and bite template bases made of *E-Tray* can be disinfected before use with the following disinfectants: Cidex OPA, Chlorhexidine Digluconate 2% or a 70% Ethanol-solution. The disinfecting solutions must be used according to the manufacturer's instructions.
Products from *E-Tray* cannot be sterilized.

9 Use of Software Systems and products from other Manufacturers

The use of certified software systems for generating the STL-data and the use of additional products depends on user's assessments.

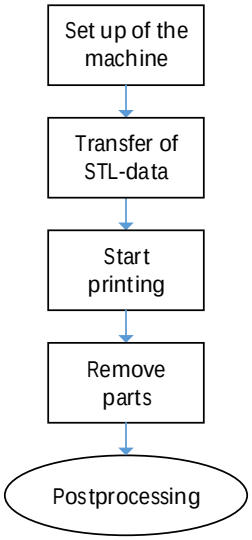
10 Delivery Unit, Symbol Explanation and Manufacturer Information

Delivery unit: *E-Tray* is available in containers of 1 kg

Symbol explanation:

CE	CE- Mark		Protect from sunlight
LOT	Batch number		Follow Instructions for Use
	Expiration date		Temperature limit
	Manufacturer		Production date
REF	Purchase order number	UDI	Unique device identification
MD	Medical device		

11 Manufacturing Process



Setup machine for the resin (Settings see machine manual) and fill the polymer tray/basement. To avoid impurities, resin mixes and contamination a separate polymer tray/basement must be used.

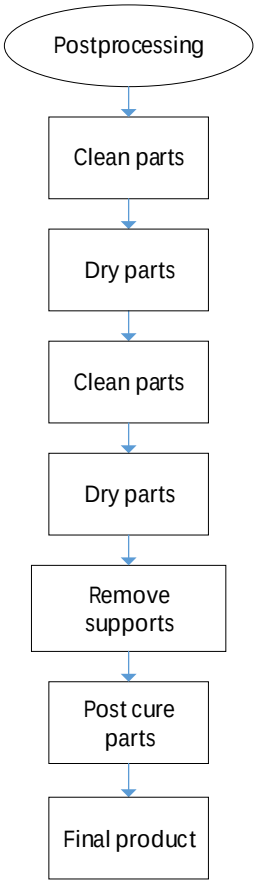
Transfer constructed STL-files for the impression trays and bite template bases to the machine (see machine/software manual) *.

Start the printing process as described in the machine manual.

When the printing is done, remove the parts carefully from the platform.

* The scanning and construction of patient's STL data is the responsibility of the customer. We recommend that only trained dental personnel perform the scanning and design. Further, a certified software such as, e.g. 3Shape is recommended. To generate the support structures, we recommend the Perfactory® RP Software (version 3.1540.1602 or later), EnvisionOne RP (version 1.0.1165 or later) or the Cambridge Software from 3Shape (version 2015 2650 or later).

12 Postprocessing



Cleaning in 2-propanol (min. >96 %) (max. 5 minutes); Cleaning under pouring conditions (no ultrasonic); Recommendation: Magnetic stirrer with bar or lab shaker. Clean and rinse gaps separately.

Dry with compressed air.

Cleaning in 2-propanol (min. >96%) (max. 2 minutes); Cleaning under pouring conditions (no ultrasonic); Recommendation: Magnetic stirrer with bar or lab shaker. Clean and rinse gaps and hard to clean areas separately.

Dry with compressed air. Place the dried part in an incubator/oven at 37 °C for 30 minutes.

Remove the supports with a scalpel or similar tool.
Use a commercially dental hand piece to clean the remaining support structures.

Light curing unit: Otoflash G171; Parameters: 2x1000 flashes (= once each side); Recommendation: under inert gas (e.g. nitrogen).
Or PCA 4000; Parameters: 15 min. at 60°C

Impression trays:
The product can now be used on the patient.

Bite template bases:
The product as a basic framework is now ready for final assembly to a bite template and can be combined with the wax-rim.

Finally, the completed impression trays can be used together with impression material on the patient just like the completed bite templates.

Maintain and calibrate equipment according to manufacturer's instructions. Using an alternative light source can affect the properties of the final product. It is not allowed to do manual correction by material removal.

13 Reporting of Undesirable Effects

In the event of adverse effects, reactions or similar occurrences arising from the use of this products, including those not listed in this Instruction for Use, these must be reported immediately to the manufacturer (by opening a support ticket via the website https://envisiontec.com/) and to the competent authority of the Member State in which the user and/or patient is established.

14 Australian Sponsor

Emergo Australia
Tower II, Level 20
Darling Park
201 Sussex Street
Sydney NSW 2000
Australia

15 Manufacturer

EnvisionTEC GmbH		
Brüsseler Str. 51	Telefon:	+49-(0)2043-98750
45968 Gladbeck	E-Mail:	info@envisiontec.com
Germany	Website:	www.envisiontec.com

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