



VITAWARE

Vitaware Ortho Software (OrthoLab) Instructions for Software Use

Last amended: February 2025 (revision number 1.3)

This document is an electronic copy of the basic 'Instructions for Use' of Vitaware Ortho Software. Detailed instructions can be found in the 'User Manual'

Description of Vitaware Ortho Software

Vitaware™ Ortho Software is a solution for dental treatment planning whereby digital models for clear aligner manufacture are generated via processing, analysis, and CAD-based manipulations of dental scans (intra-oral and scanned impressions/casts). The medical device incorporates the entire software for use by dental clinicians.

Indications for Use

Vitaware Ortho Software is intended for use as a decision-support system for the processing of dental scan input files into output files containing digital treatment plans for patients with mild to moderate orthodontic malocclusions and/or aesthetic misalignments treatable with custom-made orthodontic appliances including clear aligner devices. The software performs no direct diagnosis and makes no treatment decisions on behalf of the user. The output of the treatment plan may be downloaded as files in STL format, a standard stereolithographic file format, or OBJ format, a standard 3D image format, for fabrication of dental casts, which may be used to fabricate sequential aligner trays or retainers.

Warnings and Recommendations

This product is for use by GDC-registered dental clinicians in the UK only and should be used only by those with a professional level of English.

English is the language used in the Vitaware Ortho Software interface and documentation.

All outputs must be verified by the responsible UK clinician overseeing any subsequent orthodontic treatment.

Vitaware Ortho Software is available to users via a desktop app interface. Any patient data imported to the system is transferred to and stored on Vitaware managed servers and databases, in an encrypted form, to support effective processing and case management. It is the responsibility of the end-users to follow the local laws related to appropriate handling and transfer of personal data – for example GDPR (EU) – and to discard or anonymise patient information when required. Please refer to the relevant section in the User Manual regarding how personal data is stored, to ensure your usage is compliant.

It is recommended to use Vitaware Ortho Software within a hardware and/or network environment in which cyber security controls have been implemented including anti-virus and use of firewall.

Accuracy

Vitaware Ortho Software dental scan processing is designed to preserve the accuracy of surfaces present in the imported dental scan. The processed digital models have a maximal error of 150 microns from the imported scan.

Note: The accuracy of a model vs the true patient dentition is dependent on the accuracy and quality of the imported dental scans. Dentists should ensure intra-oral scans and/or impressions accurately capture all accessible regions of tooth crowns and at least 3 millimeters of gingiva.

The software uses various mechanisms to interpolate and or predict dental surfaces which are not typically captured by input scans, including interproximal surfaces, roots, bone, and additional gingiva. These surfaces should not be relied on to support treatment decision making.

Other Ways of Viewing this Information and Emergencies

End-users of Vitaware Ortho Software can request a free paper copy of this document. To do so, please contact info@vitaware-ortholab.com

If information is needed in an emergency, please call +441392971966

In the event that this document is temporarily unavailable, we recommend suspending use of the software until access is restored, unless you have a paper copy of this document.

There are no foreseeable medical emergencies related to this device. If you believe that the device may have directly or indirectly contributed to a patient's injury or death, then please immediately contact info@vitaware-ortholab.com.

Dialog Symbols

Vitaware Ortho Software uses a set of standard symbols (icons) when displaying information dialogs. The table below provides information about each symbol's meaning and the associated risk level.

Symbol	Meaning
	• Hint or Information • Risk level: Low • The information provided may be useful, but ignoring it has no suspected impact on the patient
	• Warning or potential usage error • Risk level: Medium • The information provided is related to an operation that has succeeded or a state of the data that has been entered, but the user must be aware of some details that may describe an unexpected result or side effects from the operation, which could have an impact on the patient
	• Error/failure in operation • Risk level: Low • An operation has failed. Despite a negative outcome, no change will take place and so no undesirable side effects will occur

Instructions for Use

Accessing Vitaware Ortho Software

Access is gained via a web browser by visiting <https://app.vitaware-ortholab.com> where users with a registered account can sign in and access the software features and data. The User Manual can be accessed at any time from the settings cog in the top-right corner of the app, containing detailed usage instructions.

A dentist account is required for use which can be requested at <https://vitaware-ortholab.com/register-your-interest/> which requires completion of an enrollment form and subsequent approval period. Updates on account creation will be provided by email. Access is free for approved dentists however fees may apply when processing cases.

Recommended System Requirements

Vitaware Ortho Software is distributed via a web link to enable software access from a multitude of web browsers over an internet connection. The application uses a combination of cloud-based and local computing on the users device.

A desktop computer or laptop is recommended for using the software although some tablets may also support the app.

A minimum of 2GB of available RAM (recommended 8GB) and 1GB GPU memory is required for reasonable performance.

A keyboard and mouse are recommended for efficient usage, but not required (a touchpad or touchscreen would be required alternatively).

Devices must be internet-enabled and connected with access unrestricted by Local Area Networks, Domain Name Systems, Virtual Private Networks, or Firewalls.

A robust internet connection with minimum upload and download connection speeds of 5Mbps and ping less than 50ms is suggested as a minimum to avoid connection related issues, although upload and download connections speeds of 20Mbps+ are recommended to avoid delays due to data transfer.

Manufacturer Details



Vitaware Ortho Software

Manufactured in 2025 by Vitaware Ltd.

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Vitaware Ortho Software is a UKCA marked product

GMDN: 5484 (CAD/CAM Software)

Current Availability as a Certified Medical Device

For more information on the current availability and plans for Vitaware Ortho Software as a CE-marked product in your country, please contact info@vitaware-ortholab.com