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Chairside Software

Instructions for Use

Issued on: 2026-11

CE 3022

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1. Device Description **2**
1.1. Device details 2
1.2. Intended Purpose 2
1.3. Intended Patient population 2
1.4. Contraindications 2
1.5. Intended User 2
1.6. Intended Use Environment 2
1.7. How Chairside works 3
1.7.1. General description 3
1.7.2. Clinical Benefits 3
1.8. AI/ML–functions 3
1.8.1. General description 3
1.8.2. AI/ML models 4
1.8.3. How it is used 4
1.8.4. AI/ML-input requirements 4
1.8.5. Clinical Benefits 4
1.8.6. AI/ML performance 5
1.8.7. Quantitative performance results 5
1.8.8. Interoperability 5
2. Warnings & Precautions **6**
2.1. Explanation 6
2.2. List of Warnings and cautions 6
3. Residual Risks **7**
4. Data Privacy & Cybersecurity **7**
4.1. Data privacy 7
4.2. Cybersecurity 8
4.2.1. Security Patches & Updates 9
5. System & Network Requirements **9**
5.1. System Requirements 9
5.2. Network Requirements 9
6. Installation & Operation **9**
6.1. Installation 9
6.2. Operation Workflow 9
6.3. AI Scan Review Instructions: 9
6.4. Software decommissioning 10
7. Accessing the Electronic IFU (eIFU): **10**
8. Troubleshooting & Support **10**
8.1. Troubleshooting 10
8.2. Support 10
9. Adverse Event Reporting **10**
10. Manufacturer & Australian Sponsor **11**
10.1. Legal Manufacturer 11
10.2. Australian Sponsor 11
11. Product Label **11**
12. Symbols Glossary 11

Downloaded by Prasen Modi on Nov-20-2026 13:35:17 GMT-05:00 valid until Jan-04-2027 13:35:17 GMT-05:00

1. Device Description

1.1. Device details

The current software version and build number can be found within the application by navigating to the 'About' screen.

#	Version 1.125.1
UDI	081020609CHAIRSIDENZ (Basic UDI-DI)

1.2. Intended Purpose

Dandy Chairside supports trained dental professionals in determining whether a digital impression acquired for a restorative or prosthetic case is technically complete and of sufficient quality to support fabrication of a custom-made dental restoration. Operating on scan data received from a compatible intra oral scanner, the software analyses the scan for defined technical quality characteristics and presents the resulting findings to the user. The user reviews those findings together with the scan and decides whether to proceed with the scan or to acquire a new one. The software supports, and does not replace, the dental professional's judgment on scan acceptability. It is intended for use by trained dental professionals in dental clinics and dental laboratories. It does not diagnose oral conditions, determine treatment, or design the restoration.

Chairside is not intended for the diagnosis of oral conditions or identification of the required treatment.

Indications: The device is not intended to diagnose, treat, or monitor medical conditions or diseases, and it does not analyze patient health status. Instead, it supports the technical assessment and workflow management of intra oral scan data generated by external scanning systems.

1.3. Intended Patient population

The intended patient population consists of patients undergoing intraoral digital scanning as part of restorative or prosthetic dental procedures.

This includes patients receiving dental restorations such as crowns, bridges, implants, inlays, onlays, or other prosthetic devices that require a digital impression or intra oral scan as part of the clinical workflow.

The Chairside device does not directly interact with the patient and does not analyze the patient's health status or disease.

1.4. Contraindications

There are no device-specific contraindications.

1.5. Intended User

Licensed dentists, Dental hygienists, Dental assistants, Dental laboratory staff.

Users are expected to have appropriate training in dental workflows and the use of intra oral scanning systems. Chairside is not intended for use by untrained personnel.

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1.6. Intended Use Environment

Chairside is intended for use in Dental clinics and Dental laboratories.

1.7. How Chairside works

1.7.1. General description

Dandy Chairside is a software medical device intended to support digital dental workflows by enabling the creation, management, and submission of dental cases based on intraoral scan data acquired from compatible third-party scanning systems. The software is designed for use in dental clinics and laboratories to facilitate coordination between clinicians and dental laboratories during restorative and prosthetic procedures.

Chairside operates as a desktop application deployed on managed Windows-based systems. It interfaces with external intraoral scanners through a standardized integration layer, allowing users to initiate and guide scanning workflows, visualize and manipulate three-dimensional (3D) scan data, and prepare digital impressions for submission.

Chairside includes an optional software feature, AI Scan Review, which provides automated, algorithm-based analysis of intraoral scan data to assess technical quality and completeness. This feature identifies potential scan issues, such as incomplete data capture, gaps, or unclear margin regions, and presents advisory indicators and optional recommendations for rescan or refinement. AI Scan Review may also generate a preliminary margin line as a visual aid; however, this output is intended solely as a starting point for user review and refinement.

The device operates within a distributed system architecture consisting of a local application (Chairside), a version management component (Chairside Launcher), and cloud-based backend services (Orthly Web). The backend services provide centralized data management, case processing, and execution of machine learning algorithms associated with AI Scan Review. Secure data transmission is used to communicate between the local application and backend services.

1.7.2. Clinical Benefits

Dandy Chairside does not provide diagnostic or therapeutic benefit directly; the software improves patient management by enabling a digital workflow that allows clinicians to review and modify the scan in real-time.

Description of the Clinical Benefits for the AI/ML functions is provided under 1.8.5.

Note: Dandy Chairside is a workflow optimization tool. It does not provide direct diagnostic or therapeutic benefits.

1.8. AI/ML–functions

1.8.1. General description

AI Scan Review is an optional, advisory feature of Dandy Chairside that automatically analyses intraoral scan data to help the clinician assess the technical quality and completeness of a scan before a case is submitted. It runs on Dandy's managed backend using a fixed ("locked") set of models and algorithms that do not learn or change during use; any change is delivered only as a new, validated software version. AI Scan Review is non-diagnostic: it does not interpret clinical images, diagnose disease, detect caries or pathology, or influence the care pathway. Its outputs are non-binding aids, colour-coded overlays, highlighted regions and a findings list, and the licensed clinician remains the sole decision-maker, reviewing every scan and remaining free to accept, edit or reject the software's findings.

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1.8.2. AI/ML models

AI Scan Review combines machine-learning models with deterministic geometric algorithms across the following functions:

- **Jaw segmentation (supporting model).** A 3D convolutional neural network classifies the scan surface into tooth, gingiva and preparation regions. It is the shared upstream input on which the clearance, undercut and margin-line functions depend.
- **Unclear margins / margin-line prediction.** A machine-learning model predicts the preparation margin and fits an editable margin-line spline, presented as a visual aid the clinician can accept or redraw.
- **Occlusal clearance detection.** A geometric algorithm compares the prepared surface against the opposing jaw relative to the minimum material thickness and flags teeth with insufficient clearance via a colour-coded overlay.
- **Path-of-insertion (POI) undercut detection.** A geometric algorithm computes candidate insertion axes and alerts the user when no valid path clears the margin.
- **Gaps analysis (denture scans).** A geometric algorithm aligns the scan to a template and highlights critical versus non-critical regions of missing data.

1.8.3. How it is used

Within the normal workflow the clinician loads the completed scan, runs AI Scan Review, inspects the highlighted low-quality or incomplete regions and the findings list, re-scans the areas indicated where needed, and then approves or rejects the scan for submission. The margin-line prediction can be reviewed and edited directly on the 3D model.

⚠	WARNING	Because its detection thresholds are deliberately tuned to limit false positives, the function does not flag every genuine scan-quality issue; an absence of a flag must not be interpreted as confirmation that a scan is adequate, and the clinician must still verify scan quality independently
⚠	WARNING	The predicted margin line is an advisory aid and may require correction. AI Scan Review is non-diagnostic and does not detect caries or pathology, it must not be used for any diagnostic purpose.

1.8.4. AI/ML-input requirements

To obtain results which are representative for clinical use, the following AI/ML data input requirements are specified:

- Intra-oral scans obtained with a supported intra-oral scanner specified in section 1.8.8
- Intra-oral scans which fulfil the respective quality criteria:
  - Data should be complete
  - Free from clinical artifacts and noise
  - Sufficient coverage and accurate occlusal registration
  - A standard CAD format (e.g. OBJ, STL or PLY)

1.8.5. Clinical Benefits

The following clinical benefits are defined when using the Dandy AI/ML-functions:

The AI/ML functions benefit users by providing the clinician with accurate information related to the quality of the scan.

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⚠	Caution	AI Scan Review is intended to support the clinician in assessing scan quality prior to submission. It does not provide direct diagnostic or therapeutic benefits.

1.8.6. AI/ML performance

The below table visualizes the performance of the several AI/ML-models and heuristics models embedded within the Dandy Chairside software. Performance characteristics may change over time as specified in section 1.8.6, performance will exceed the metrics displayed below.

Metric	Performance specification
Accuracy	≥ 90%
Sensitivity / Recall (TPR)	≥ 50%
Specificity (TNR)	≥ 90%
Precision (PPV)	≥ 85%

Note: Separate performance specifications apply to ML models: Jaw segmentation MeanIoU ≥ 80% (0.80); Margin-line prediction F1 ≥ 70%.

1.8.7. Quantitative performance results

For each model embedded within the Dandy Chairside software, performance has been tested on an independent test dataset. For each of the models the test dataset has different sizes and characteristics. The performance results are shown in the table below. Each of the results exceeds the intended performance specification set out in section 1.8.5.

Function (config)	Metric	Result	95% CI (Wilson)
Occlusal Clearance (0.4 mm leeway; n=152 pos / n=100 neg)	Accuracy	94.0%	[90.3%, 96.3%] (n=252)
	Precision (PPV)	97.3%	[92.2%, 99.1%] (n=96)
	Sensitivity (TPR)	61.0%	[53.1%, 68.4%] (n=152)
	Specificity (TNR)	97.5%	[92.3%, 99.2%] (n=100)
POI Undercut (0.05 threshold; n=~100 pos / n=~100 neg)	Accuracy	94.6%	[88.7%, 97.5%] (n=110)
	Precision (PPV)	91.5%	[81.7%, 96.3%] (n=59)
	Sensitivity (TPR)	54.0%	[44.3%, 63.4%] (n=100)
	Specificity (TNR)	95.0%	[88.8%, 97.8%] (n=100)
Jaw segmentation (supporting ML, n= > 1,000)	Tooth-only MeanIoU	0.92	n/a
	Prep-only MeanIoU	0.83	n/a
Margin-line prediction (ML; n=1,196)	F1 score @ 70 µm	0.71	Tolerance used for the claim

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Function (config)	Metric	Result	95% CI (Wilson)
Gaps Analysis (supporting ML)	Accuracy	**98.2%**	[97.2%, 98.8%] (n=1099)
	Precision (PPV)	**87.5%**	[71.9%, 95.0%] (n=32)
	Sensitivity (TPR)	**63.6%**	[48.9%, 76.2%] (n=44)
	Specificity (TNR)	**99.6%**	[99.0%, 99.9%] (n=1055)

1.8.8. Interoperability

Dandy Chairside Software integrates with intraoral scanners to support digital workflows. The software bundle delivered to customers is an Electron-based application provided by Dandy.

Chairside supports two scanner-specific application variants:

- Trios Chairside (integrating with 3Shape Unite Scanner)
  - 3Shape Trios 3 Scanner
  - 3Shape Trios 5 Scanner
- Vision Chairside (integrating with AlliedStar ScanPro)
  - Dandy Vision Scanner

When there is no scanner connected, or a scanner is connected that Chairside does not support, the application clearly communicates that there is no scanner connected.

⚠	WARNING	Dandy Chairside should not be used with unsupported scanner manufacturer types and variants.

2. Warnings & Precautions

Before using this software, you must have read and understood all instructions to ensure safe and correct use. Be aware of the following warnings and cautions when using the software.

2.1. Explanation

⚠	WARNING	A warning informs the user of potential risks and details the expected behaviour to avoid injury, user harm or device damage.
⚠	Caution	A caution indicates a situation in which an operator requires action or awareness in order to avoid undesirable consequences.

2.2. List of Warnings and cautions

⚠	WARNING	The AI Scan results are provided for information purposes only, results generated are not intended for direct diagnosis or for direct therapeutic decision making. The results require review and correction (as needed) by qualified dental professionals.
⚠	WARNING	The system does not detect caries or pathology.
⚠	WARNING	Because its detection thresholds are deliberately tuned to limit false positives, the function does not flag every genuine scan-quality issue; an absence of a flag must not be interpreted as confirmation that a scan is adequate, and the clinician must still

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		verify scan quality independently.
⚠	WARNING	The predicted margin line is an advisory aid and may require correction. AI Scan Review is non-diagnostic and does not detect caries or pathology, it must not be used for any diagnostic purpose.
⚠	WARNING	Dandy Chairside should not be used with unsupported scanner manufacturer types and variants.
⚠	WARNING	The software is solely intended to inform qualified dental professionals; the software is not intended as a replacement for clinical diagnosis or therapeutic decision making.
⚠	Caution	Network interruptions may delay case submission.
⚠	Caution	Verify patient identity and case information.
⚠	Caution	AI Scan Review is intended to support the clinician in assessing scan quality prior to submission. It does not provide direct diagnostic or therapeutic benefits.
⚠	Caution	Provision of the software on the preinstalled computerised system by Dandy should only be used for the intended purpose as described within this Instructions for Use.
⚠	Caution	It is strictly prohibited to adjust any of the system's security settings; adjustment of such settings places patient safety and data confidentiality, integrity and availability at risk.
⚠	Caution	It is your responsibility to ensure that you connect the system to the internet over secure connections only; using insecure connections places patient safety and data confidentiality, integrity and availability at risk.
⚠	Caution	In the event of any suspected loss of confidentiality, availability or integrity caused by the use of the Dandy software, you are responsible for immediately informing the Dandy organization through the contact information provided under the section 'support'.
⚠	Caution	In the event of any suspicious or unexpected software behaviour you are responsible for immediately informing the Dandy organization through the contact information provided under the section 'support'.
Important note		Re-scan if data corruption or upload failure occurs.

3. Residual Risks

It is the responsibility of the user to take note of the warnings and cautions available within these instructions for use.

⚠	Warning	The software is solely intended to inform qualified dental professionals, the software is not intended as a replacement for clinical diagnosis or therapeutic decision making.

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There are no known undesirable side-effects.

4. Data Privacy & Cybersecurity

4.1. Data privacy

The software is operated remotely by the Dandy organisation. As data processing will include processing personal health information (PHI) to achieve its intended purpose, Dandy processes Personal Data on behalf of the clinic or laboratory under applicable privacy legislation. Data processing is executed under assignment by the Data Controller through a Data Processing Agreement.

⚠	Caution	In the event of any suspected loss of confidentiality, availability or integrity caused by the use of the Dandy software, you are responsible for immediately informing the Dandy organization through the contact information provided under the section 'support'.

As the use of the software you bear the responsibility to secure the systems that you use to avoid breach of confidentiality. You can take the following actions to further strengthen secure use of the Dandy software:

- Never document your access credentials and make use of a password management system
- Do not share your access credentials with any other person, instead create or request the creation of additional user accounts
- Always terminate active user sessions when leaving a mobile device with access to the software unattended

Where individual patient data is deleted from the Dandy Chairside software, the data is deleted within a month from any remaining back-ups within Dandy. Once permanently deleted data can no longer be restored or reconstructed otherwise.

4.2. Cybersecurity

In addition to the measures described above, the Dandy organization is committed to securing the software to the latest standards, the following security measures have been implemented:

- PHI when stored locally is encrypted at rest via OS disk encryption (e.g., BitLocker)
- The computer system runs a anti-virus and malware software (e.g., Microsoft Defender)
- Data transmitted to cloud services uses TLS 1.2+ encryption
- Cloud databases and storage are encrypted at rest
- Users authenticate with individual accounts; backend services use JWT tokens
- Role-Based Access Control (RBAC) limits access to authorized functions
- PHI is not shared across clinics; each practice can only access its own data
- AI Scan Review workflow transmits anonymized scan data (no PHI)
- Cloud infrastructure hosted on Google Cloud Platform (GCP) with IAM, audit logging, and Cloud Armor protections

⚠	Caution	Provision of the software on the preinstalled computerised system by Dandy should only be used for the intended purpose as described within this Instructions for Use.
⚠	Caution	It is strictly prohibited to adjust any of the system's security settings, adjustment of such settings places patient safety and data confidentiality, integrity and availability at risk.

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⚠	Caution	In the event of any suspicious or unexpected software behaviour you are responsible for immediately informing the Dandy organization through the contact information provided under the section 'support'.
⚠	Caution	It is your responsibility to ensure that you connect the system to the internet over secure connections only, using insecure connections places patient safety and data confidentiality, integrity and availability at risk.

4.2.1. Security Patches & Updates

The organization will, from time to time implement security and non-security related updates to ensure on-going performance and security of the software system. Users will be notified by Dandy upon pending updates which may affect availability of the Dandy Chairside software.

4.2.2. Reporting vulnerabilities

If there are suspected vulnerabilities identified within the Dandy Chairside software, we urge you to report such vulnerabilities to bugbounty@meetdandy.com or vulnerabilities@meetdandy.com.

5. System & Network Requirements

5.1. System Requirements

Chairside runs on a managed workstation distributed and controlled via Microsoft Intune MDM. Minimum workstation requirements:

- Windows 11pro (64-bit)
- Intel i7 CPU or better
- 32 GB RAM
- 477GB Storage HDD
- Administrative privileges for installation (required for MDM enrollment)

5.2. Network Requirements

- Chairside communicates with Dandy backend services over secure outbound connections
- Stable internet connection
- Recommended minimum bandwidth: 20 Mbps download / 5 Mbps upload (scan uploads)
- Network access to TCP port 443 outbound (HTTPS)
- TLS 1.2+ is required for all connections to the Dandy cloud infrastructure
- Chairside does not require inbound firewall exceptions.

6. Installation & Operation

6.1. Installation

The full installation of the Dandy Chairside software is performed by Dandy. There are no actions required on the end of the user to start using the software. Once the user starts the use of the software, the user is provided with the relevant user credentials and required to change their password in order to start using the software.

6.2. Operation Workflow

- Launch the application and select the patient.
- Acquire an intraoral scan.
- Review scan quality.
- Submit the case to the lab.

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6.3. AI Scan Review Instructions:

- Load completed scan.
- Run AI Scan Review.
- Inspect highlighted low-quality regions.
- Re-scan as needed.
- Approve or reject scan.

6.4. Software decommissioning

The software is provided pre-installed on a Dandy owned computer system. Upon replacement or termination of the cooperation with Dandy, the computer system is to be returned to Dandy.

Dandy is responsible for the full in-house decommissioning of the software from the computer system and will ensure the full and irreversible deletion of any customer and or PHI data remaining on the computer system, within the period specified by the Data Controller within the Data Processing Agreement.

7. Accessing the Electronic IFU (eIFU):

- A copy of this IFU is available on this website: http://dandy.dental/chairside-product-ifu
- A printed copy of this IFU can be requested and will be provided free of charge within 7 calendar days.
- This version of the IFU is identified on the website as the version approved for Australia.

8. Troubleshooting & Support

8.1. Troubleshooting

Event	Resolution
Failure to submit case	• Check internet connection
Unable to log in	• Verify credentials • Request new password
Missing scan data	• Confirm scanner import completed

8.2. Support

In the event of any detected software failures or bugs, or in the event of any suspected security incident, data breach, or potential patient harm, the user is responsible for immediately contacting Dandy to request for further support. Within the software a direct link to the support channels of Dandy is available (phone, email and support form) to reach out to the Dandy team.

Alternatively, you can contact Dandy directly via the details provided in Section 10 of this instructions for use.

9. Adverse Event Reporting

The user is responsible for reporting any potential concerns with regards to the performance, security or privacy of the software. Such concerns must be reported to Dandy and the Australian sponsor at the contact details provided in section 10 (specifically section 10.1 & 10.2).

In Australia, adverse events (including events that might have led to death or serious injury) involving the software must be reported to Dandy and the Australian sponsor; the Australian sponsor reports adverse events

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to the Therapeutic Goods Administration (TGA) as required. Healthcare providers and healthcare facilities may also report an adverse event directly to the TGA through the Incident Reporting and Investigation Scheme (IRIS) on the TGA website (www.tga.gov.au).

10. Manufacturer & Australian Sponsor

10.1. Legal Manufacturer

	Zima International, Inc. d/b/a Dandy 22 Cortlandt Street, 30th Floor, New York, NY 10007 United States **Direct contact details:** Phone +1-866-310-8665 Email Doctors@meetdandy.com

10.2. Australian Sponsor

	Dandy Labs AUS Pty Ltd Tower One International, Towers Level 46 100 Barangaroo Avenue Sydney NSW 2000 Australia

11. Product Label

An example of the Australian product label which can be located within the software is presented below.

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Dandy Chairside MD

CE 3022

Software version: 1.125.1

Zima International, Inc. d/b/a Dandy
22 Cortlandt Street, 30th Floor
New York, NY 10007, United States

Australian Sponsor:
Dandy Labs AUS Pty Ltd
Tower One International Towers, Level 46
100 Barangaroo Avenue
Sydney NSW 2000, Australia

Date of manufacture:
2026-11

Build number: 1.125.1

UDI **UDI-DI:** (01) 00810206091326
UDI-PI: (8012) 1.125.1

(EN) Dandy Chairside — Class IIa medical device software

Dandy Chairside supports trained dental professionals in determining whether an digital impression acquired for a restorative or prosthetic case is technically complete and of sufficient quality to support fabrication of a custom-made dental restoration. Operating on scan data received from a compatible intra oral scanner, the software analyses the scan for defined technical quality characteristics and presents the resulting findings to the user. The user reviews those findings together with the scan and decides whether to proceed with the scan or to acquire a new one. The software supports, and does not replace, the dental professional's judgment on scan acceptability. It is intended for use by trained dental professionals in dental clinics and dental laboratories. It does not diagnose oral conditions, determine treatment, or design the restoration. Chairside is not intended for the diagnosis of oral conditions or identification of the required treatment.

Consult instructions for use (eIFU):
https://dandy.dental/chairside-product-ifu

Caution
Consult the IFU for warnings & precautions.

12. Symbols Glossary

Symbol	Title	Description
CE	Conformité Européenne	The software complies with the European legislation with regards to medical devices (MDR 2017/745). The Notified Body number is displayed adjacent to the CE marking (3022).
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	Legal manufacturer	Indicates the medical device manufacturer
MD	Medical Device	Indicates the item is a medical device

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	Date of manufacture	Indicates the date when the medical device was manufactured. For Dandy this refers to the software release date.
	Model number	Indicates the model number or type number of a product. For Dandy this refers to the software version number.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Unique device identifier	Indicates a carrier that contains unique device identifier information

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Garvin Tran	Manager, Operations - QMS	19-Nov-2026 17:02
Review	Garvin Tran	Manager, Operations - QMS	19-Nov-2026 17:03
Approve	Samrat Allabadi	Sr Manager, Operations - Quality	20-Nov-2026 13:34

* Datetime fields are displayed according to the system time zone: (GMT-05:00) Eastern Standard Time (America/New_York)