

CordAlign™ Precision Wand: Major System Blocks

Integrating Imaging, Alignment, and Automated Delivery for Safer Dupuytren Treatment

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The CordAlign™ Precision Wand (CPW) is architected as a modular, integrated system composed of multiple coordinated subsystems, each responsible for a specific aspect of imaging, guidance, alignment, safety, or controlled drug delivery. Together, these system blocks create a unified platform capable of detecting Dupuytren cords with ultra-high-frequency ultrasound, analyzing tissue characteristics in real time, determining precise needle alignment, and executing controlled micro-dose injections under clinician supervision. The block-level structure below outlines the core functional units of the CPW system, their principal components, and the basic performance specifications that define their roles within the overall device architecture.

AI-Guided Delivery (Overview)

In Dupuytren treatment, clinicians often perform **multiple injections spaced 5–10 mm apart** along the length of the cord to ensure uniform enzymatic weakening before manipulation. Freehand ultrasound makes this sequence difficult to perform reliably because each injection must be delivered into the narrow geometric center of a small, variably shaped fascial structure. CPW's architecture supports this multi-injection strategy by combining ultra-high-frequency imaging, real-time cord boundary detection, centerline tracking, and actuator control. As the wand moves along the cord, the AI system identifies recommended sequential injection sites, validates spacing and alignment, and enables the micro-dose actuator only when safety and geometric criteria are satisfied. This transforms multi-injection delivery into a **standardized, reproducible workflow** integrated across the system blocks described below.

1. UHF Ultrasound Imaging Block (UCP Detector)

Key Components

- Ultra-high-frequency (UHF) linear transducer array
- Front-end analog signal conditioning
- Beamforming electronics (ASIC or digital)
- Acoustic coupling interface (miniature nosecone)

Basic Specifications

- **Frequency:** 20–30+ MHz
- **Axial Resolution:** 75–150 μm
- **Lateral Resolution:** 150–300 μm
- **Depth Range:** 3–15 mm (optimized for palm)
- **Frame Rate:** ≥ 30 fps
- **Aperture Width:** 10–20 mm
- **Function:** Real-time imaging of superficial structures for cord detection and measurement

2. AI-Based Guidance & Alignment Block

(Details are in Section 11)

Key Components

- Embedded processor (CPW-S) OR
- Wireless-linked mobile processor (CPW-C)
- AI/ML segmentation algorithms

- Depth and centerline detection subroutines
- Angulation deviation detection
- Motion compensation algorithms

Basic Specifications

- Real-time classification of:
 - cord boundaries
 - tendon vs. cord differentiation
 - cord diameter
 - centerline trajectory
- Safety checks:
 - depth validation
 - alignment lock-out
- Output to:
 - Onboard display (CPW-S)
 - External app (CPW-C)
- Sequential injection planning: Identifies 5–10 mm spacing intervals, tracks previous injections, and guides the wand to the next validated point along the cord

3. Needle Alignment Channel Block

Key Components

- Rigid mechanical channel aligned with UHF beam
- Needle guide exit port
- Sterile disposable needle path insert

Basic Specifications

- Fixed geometric coupling between imaging plane and needle path
- Positional tolerance ≤ 0.25 mm
- Enables sub-millimeter targeting of the cord centerline
- Integrates with micro-dose delivery actuator

The fixed geometric coupling between the imaging plane and needle trajectory is essential for multi-injection workflows, enabling the AI module to repeatedly align the needle path to the cord's centerline across several closely spaced injection points.

4. Micro-Dose Auto-Syringe Delivery Block

Key Components

- Precision actuation mechanism (stepper/piezo)
- Replaceable sterile medication cartridges
- Pressure and volume control sensors
- Electronic actuation driver

Basic Specifications

- Controlled micro-dose delivery
- Electronic rate and pressure control
- Injection only after alignment + clinician approval
- Cartridge-based sterile medication loading
- Designed to prevent enzyme extravasation and tissue damage

To support sequential dosing along the cord, the actuator works in coordination with the AI guidance system. The auto-syringe will only arm when the wand reaches the next validated injection site and spacing from prior injections is confirmed. Each micro-dose is logged with its spatial location to maintain a consistent multi-injection sequence.

5. Control & User Interface Block

Key Components

For CPW-S (Standalone):

- Integrated micro-display (1–2")
- Physical or touch controls
- Local CPU/GPU for image rendering

For CPW-C (Connected):

- External mobile/tablet/PC app
- Wireless interface for visualization and control
- UI/UX for:
 - alignment cues
 - real-time ultrasound image
 - injection readiness confirmation
 - sequential injection guidance prompts and spacing validation indicators

Basic Specifications

- Real-time display of:
 - cord geometry
 - depth
 - alignment cues
- Explicit clinician confirmation prior to injection
- Optional LED indicators for minimalistic wand design

6. Communications & Connectivity Block

Key Components

- Wireless chipset (BLE 5.0 or WiFi-Direct)
- Optional wired USB-C interface
- Encrypted data transfer protocols
- Firmware update mechanism

Basic Specifications

- Secure transmission of ultrasound frames + metadata
- Cybersecurity compliant
- High-reliability connectivity (meets IEC 60601-1-2 EMC/EMI requirements for medical devices)

7. Power & Battery Management Block

Key Components

- Rechargeable lithium battery
- Power management IC
- USB-C or inductive charging system
- Battery-level monitoring

Basic Specifications

- ≥ 3 hours operating time
- Low-thermal operation for handheld comfort

- Automatic power-down safety modes

8. Mechanical & Ergonomic Block

Key Components

- Medical-grade polymer housing
- Ergonomic grip for single-hand use
- Structural frame holding:
 - transducer array
 - needle guide
 - actuator
 - electronics

Basic Specifications

- Wand mass: < **150 g**
- Length: **12–15 cm**
- Balanced weight distribution for fine motor control
- Non-immersive sterilizable design

9. Sterility & Biocompatibility Block

Key Components

- Disposable sterile injection cartridge
- Biocompatible plastics and elastomers (ISO 10993)
- Splash-resistant wand body

Basic Specifications

- Patient-contacting parts meet ISO 10993
- Cartridges single-use only
- Wand disinfectable between uses

10. Safety & Risk Mitigation Block

Key Components

- Alignment lock-out logic
- Depth monitoring algorithms
- Tissue misclassification alarms
- Injection interlocks
- System self-checks (hardware & software)

Basic Specifications

- Prevents injection when:
 - alignment is inadequate
 - cord is not identified reliably
 - tendon/nerve proximity too close
- Monitors actuator performance
- Ensures clinician confirmation prior to administration
- Injection-spacing lock-out: Prevents dose administration if the wand is positioned too close to a previous injection (<5 mm), reducing risk of enzyme overlap or tissue overload.

11. AI Neural Network–Based Control System (App + Embedded Logic)

(Major CPW System Block)

The AI Neural Network–Based Control System provides real-time interpretation of UHF ultrasound data, alignment verification, tissue classification, and injection authorization logic. This subsystem is central to CPW’s ability to deliver precise, consistent, and safe injections.

11.1 Key Components

A. AI/ML Inference Engine

- Convolutional neural networks (CNNs) optimized for UHF ultrasound images
- Lightweight inference models suitable for real-time performance
- Tensor kernels for feature extraction (cord edges, tendon texture, boundaries)

B. Image Preprocessing & Feature Extraction Module

- UHF noise filtering
- Texture-based discrimination features
- Dynamic range compression
- Motion stabilization algorithms for hand/wand movement

C. Alignment & Safety Logic

- Real-time centerline computation
- Needle-to-cord deviation vector analysis
- Depth monitoring + tissue proximity alerts
- Injection lock-out conditions
- S
- sequential-site generation logic for planning and validating 5–10 mm injection spacing

D. Control System App (Mobile / Tablet / PC)

For CPW-C configuration:

- High-resolution ultrasound display
- Visual and acoustic alignment prompts
- Injection readiness indicator
- Secure clinician confirmation interface
- Recording, reporting, procedure-log generation

E. Embedded AI Module (Standalone CPW-S only)

- On-device processor for:
 - ultrasound rendering
 - AI inference
 - alignment logic
- Optimized thermal/power profile for handheld operation

11.2 Core Specifications

Performance Requirements

- **Latency:** < 50 ms end-to-end (image → decision → feedback)
- **Frame Rate Support:** ≥ 30 fps continuous
- **Inference Accuracy:**
 - Cord boundary detection > 95% reliability
 - Cord vs tendon differentiation ≥ 98% after training
 - Centerline tolerance: ±0.25 mm
- **Robustness:** Works across variations in:
 - palm thickness
 - skin tone
 - local edema
 - cord composition (hypoechoic / mixed / fibrotic)

- Spatial sequencing accuracy sufficient to identify and differentiate adjacent injection sites separated by 5–10 mm

Neural Network Architecture

- **Backbone:** Lightweight CNN / MobileNet derivative or custom UHF-tuned CNN
- **Segmentation Head:** UNet-like structure for boundary extraction
- **Regression Head:** Centerline and depth computation
- **Classifier Branch:** Tissue classification: cord vs tendon vs noise

Hardware Requirements

For CPW-S (Standalone):

- Embedded processor: ARM Cortex-A series or equivalent
- Minimum RAM: 1–2 GB
- AI accelerator optional

For CPW-C (Connected):

- iPhone/iPad/PC CPU/GPU executes neural network
- CPW hardware transmits UHF data stream

11.3 Functional Responsibilities

1. UHF Image Interpretation

- Identifies Dupuytren cord
- Distinguishes cord from flexor tendons and other tissues
- Computes cord depth, diameter, boundaries

2. Real-Time Centerline Extraction

- Identifies the exact geometric middle of the cord
- Maps centerline across the injection path
- Tracks centerline continuously as the wand moves

3. Needle Alignment Verification

- Compares expected needle trajectory with cord centerline
- Provides “alignment achieved” or “adjust required” cues
- Detects over-rotation, tilt, or drift of the wand

4. Injection Safety Logic

- Prohibits injection unless:
 - alignment is within tolerance
 - cord classification is confident
 - depth is safe
 - no tendon/vascular structure is in risk zone

5. Clinician Interaction & Confirmation

- Displays real-time ultrasound (CPW-C: via app; CPW-S via micro-display)
- Visual indicators:
 - **Green** = safe alignment
 - **Yellow** = borderline alignment
 - **Red** = locked out
- Requires explicit clinician approval before injection

6. Data Logging and Reporting

- Records each injection:
 - alignment quality
 - position
 - dose
 - timestamp

- Optional integration with EMRs

11.4 Safety and Regulatory Functions

AI Safety Features

- Fail-safe defaults (no injection if uncertain)
- Multi-layer classification (boundary + texture + depth + motion)
- Continuous self-check of input signal quality
- Safeguards against incorrect spacing by blocking injection when the wand is placed at a site too close to a previous dose

Cybersecurity

- Encrypted Bluetooth/WiFi data
- Secure firmware updates
- Optional cloud-based analytics disabled by default

Regulatory Alignment

- Supports FDA expectations for:
 - AI/ML transparency
 - Real-time decision support
 - Human-in-the-loop requirement
- Logs sufficient metadata for post-procedure review

11.5 Differences Between CPW-S and CPW-C

Feature	CPW-S (Standalone)	CPW-C (Connected)
AI Processing	On-device	Mobile/tablet/PC
Display	Micro-display	Full-screen app
Heat & Power	Higher	Lower
Size	Slightly larger	Minimalistic wand
Upgrades	Firmware updates	App updates
AI Complexity	Mid-level	High (GPU available)
Regulatory Burden	Higher	Shared with host device

Summary Table of Major CPW Blocks

Block	Key Capability / Purpose	Core Components	Basic Specifications
1. UHF Ultrasound Imaging Block (UCP Detector)	High-resolution imaging of superficial hand structures and Dupuytren cords	20–30+ MHz UHF linear array, analog front-end, beamforming electronics	75–150 μm axial resolution; 150–300 μm lateral resolution; 3–15 mm depth; ≥ 30 fps
2. AI Neural Network–Based Control System	Real-time tissue differentiation, cord boundary detection, centerline extraction, alignment verification, injection lock-out logic	CNN/UNet-based segmentation model, alignment algorithms, motion compensation, mobile/embedded inference engine	< 50 ms processing latency; ≥ 30 fps; ± 0.25 mm centerline accuracy; cord vs tendon classification $\geq 98\%$
3. Needle Alignment Channel Block	Ensures geometric coupling between imaging	Rigid mechanical channel, needle guide, sterile needle path insert	Alignment tolerance ≤ 0.25 mm; precise centerline targeting

Block	Key Capability / Purpose	Core Components	Basic Specifications
	plane and needle trajectory		
4. Micro-Dose Auto-Syringe Delivery Block	Controlled, safe delivery of enzymatic agent into cord centerline	Precision actuator, sterile disposable cartridges, pressure/volume sensors	Electronically controlled micro-dosing; clinician-confirmation lockout; consistent delivery pressure
5. Control & User Interface Block	Provides clinician feedback, visualization, and injection approval interface	Micro-display (CPW-S) OR mobile/tablet/PC app (CPW-C); LED indicators; buttons or touch interface	Real-time ultrasound display (CPW-C or CPW-S); alignment cues; explicit injection confirmation; app logging
6. Communications & Connectivity Block	Connects CPW hardware to external control system (CPW-C) and supports data transfer	Bluetooth 5.0 / WiFi-Direct module, USB-C interface, encryption firmware	Secure data transmission; high-reliability connection; OTA firmware/app updates
7. Power & Battery Management Block	Provides energy for imaging, AI processing, and injection control	Rechargeable lithium battery, PMIC, USB-C or inductive charging	≥3 hours continuous operation; temperature-controlled operation; low-noise power supply
8. Mechanical & Ergonomic Block	Provides structural integrity, device balance, and clinician comfort	Medical-grade polymer housing, ergonomic grip, internal frame	Wand mass <150 g; length 12–15 cm; suitable for single-hand operation
9. Sterility & Biocompatibility Block	Ensures safe patient contact and sterile injection pathway	ISO 10993-compliant materials, disposable sterile cartridges, disinfectable surfaces	Sterile injection pathway; wand suitable for non-immersive disinfection
10. Safety & Risk Mitigation Block	Prevents harmful injections and ensures system reliability	Alignment lock-out, depth monitoring, tissue misclassification alarms, actuator safety checks	Multi-layer fail-safe logic; injection blocked unless all validation criteria met
11. Human Factors & Usability Block	Ensures clinician usability across patient variations and settings	Ergonomic design, intuitive controls, clear alignment cues, minimal workflow complexity	Single-hand use; support for sequential injections; validated across diverse users and conditions