euspen's 26th International Conference & Exhibition, Krakow, PL, June 2026
www.euspen.eu

Automated Multi-Balloon Drug-Coating System with Configurable Process Parameters

Yixue Wang[1], Michal Szczepanski[1], Nicolas Kayser[1], Gregor Dürre[2], Robby Simon[3], Frank Wasmuth[3], André Hutsky[3], Annika Brehmer[1], Julian Polte[1,4]

[1] *Fraunhofer Institute for Production Systems and Design Technology IPK, Germany*
[2] *InnoRa GmbH, Germany*
[3] *Organical CAD/CAM GmbH, Germany*
[4] *Institute for Machine Tools and Factory Management IWF, Technische Universität Berlin, Germany*

yixue.wang@ipk.fraunhofer.de

Abstract
Drug-coated balloon catheters are widely used in minimally invasive cardiovascular interventions, where coating quality and process consistency are critical for clinical performance. Despite their importance, drug-coating processes for balloon catheters are still largely performed manually, leading to limited throughput, variability in coating quality, and potential safety risks due to operator exposure to hazardous chemicals.
This paper presents the Coater Mk2, an automated drug-coating platform for balloon catheters. The nine-axis system processes up to five balloons per cycle, with overlapping coating and drying phases to increase throughput. Each balloon position has individually configurable process parameters, enabling accurate, repeatable coating across heterogeneous balloon designs. A confocal displacement sensor is integrated for automatic detection of balloon geometry and for future spatially resolved coating-thickness measurement. In addition, the use of an open-source control platform allows the delivery of fully accessible source code alongside the machine, enabling end users to adapt and customize the process control software to specific production requirements.
Experimental results demonstrate stable and repeatable automated coating for a representative range of commonly used balloon catheter types, while certain less common balloon geometries remain challenging and are subject to ongoing development.

balloon catheter, drug-coating, automation, multi-workpiece processing, configurable process

1. Introduction

Percutaneous coronary intervention (PCI) is the most widely used treatment for coronary artery diseases (CAD) [1]. Two of the most common long-term complications of PCI are in-stent restenosis (ISR) and stent thrombosis (ST). Although the rates of ST have been nearly abolished and ISR rates have declined with the current gold-standard second-generation drug-eluting stents (DES), late ISR of DES remains a valid concern in the field of interventional cardiology [2]. Drug-coated balloons (DCBs) provide a stent-free alternative to DES, reducing risks like ST and ISR and the need for prolonged dual antiplatelet therapy [3].

Coating balloons with an active substance such as paclitaxel or sirolimus is commonly carried out by spraying, dipping, or micro-pipetting onto the balloon surface [4]. Spraying is straightforward to automate and can provide good coverage, but only part of the sprayed drug solution necessarily reaches and adheres to the balloon, which limits control over the effective drug load. Dipping is simple and robust to perform manually, yet the amount of drug actually taken up by the surface depends on fluid properties, withdrawal conditions, and geometry, and therefore remains difficult to quantify precisely. Micro-pipetting, in contrast, enables accurate volumetric dosing of the drug solution onto the balloon, but achieving a continuous, homogeneous coating layer along the entire balloon length is challenging [5]. These method-specific limitations underline the need for an automated coating system that combines precise dosing, controlled motion, and integrated sensing to ensure reproducible drug loading and coating uniformity across different balloon designs.

Based on an existing prototype [6], the Coater Mk2 project addresses these limitations by developing an automated coating platform suitable for industrial application. The mechanical system was designed and built by Organical CAD/CAM GmbH, Berlin, Germany while Fraunhofer IPK, Berlin, Germany was responsible for the control system, sensor integration, and process development. InnoRa GmbH, Berlin, Germany contributed application-specific expertise, supported process definition, and participated in the experimental validation of the coating results. This paper presents the resulting multi-balloon coating system, with a focus on the integration of the hardware platform with real-time control, sensing, and configurable process parameters to enable reliable and scalable drug-coating processes.

In the coating approach adopted here, originally explored in [6], a droplet of drug solution is formed on the balloon surface near one end, dragged along the surface to generate a continuous coating layer, and continuously replenished by the coating needle to maintain an approximately constant droplet volume.

2. Mechanical system

The Coater Mk2 was designed to enable parallel processing of up to five balloon catheters while providing fast, precise, and responsive motion behaviour for accurate process control, ease of use for operators, and compatibility with cleanroom operation.

As shown in Figure 1, the machine comprises nine CNC-controlled axes. Three linear axes position the needle and confocal sensor relative to the balloons. Five rotational axes drive the catheter positions: for each balloon, both catheter ends are driven synchronously by two coupled motors, avoiding torsion within the balloon during rotation. An additional axis agitates the coating fluid during long coating cycles to maintain a homogeneous drug solution. Typical coating cycles per balloon are in the range of several minutes and are primarily limited by solvent evaporation rather than axis motion.

Catheters are clamped on one side using a chuck and on the other side via a luer lock interface, which also serves for balloon inflation and deflation. Magnetic locking elements between the two ends stabilize the catheter during rotation. The integrated air-pressure system can be connected to a centralized compressed-air supply, with adjustable pressure control to accommodate different balloon types and inflation requirements.

All connectors and fluid paths that contact the coating solution or the catheter use standardized medical interfaces and materials compatible with medical applications. The machine structure is predominantly stainless steel and is designed for installation inside a clean bench within a cleanroom, providing additional containment of solvents and enhanced operator safety, while ensuring that possible spills do not compromise the mechanical integrity of the system.

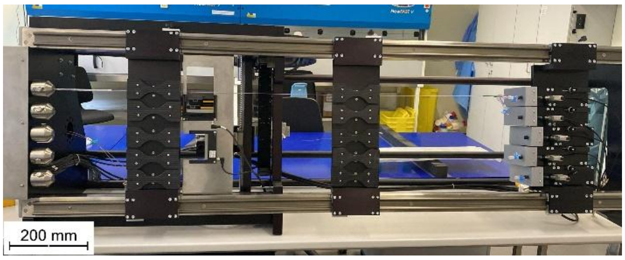

Figure 1. Overall view of the 9-axis Coater Mk2, with one balloon catheter mounted

Organical CAD/CAM GmbH designed and built the mechanical hardware and implemented the foundational integration of the EtherCAT-based drive system with the LinuxCNC control environment [7], providing the real-time motion platform on which the control and process logic described in the following sections are implemented.

3. Component integration

Several key components were integrated to support automated operation and to prepare the system for future, metrology-based quality assurance.

3.1. Syringe pump

The syringe pump SPM P100-O from the company Advanced Microfluidics, Ecublens, Switzerland controls the delivery of the drug solution during coating and is mounted on the side of the machine, attached to the agitation axis. The pump is driven by its own microcontroller and firmware and exposes a serial communication interface. Integration into the control system was implemented in Rust instead of relying on the manufacturer's closed-source Python library, improving long-term maintainability and portability across different Linux environments. The pump interface supports deterministic triggering and logging of dosing events, enabling synchronization with axis motion and traceable documentation of the applied coating volume.

3.2. Confocal sensor

A high-precision confocal displacement sensor IFD2411-3 from the company Micro-Epsilon Messtechnik GmbH & Co. KG, Ortenburg, Germany is used for automatic and precise detection of the balloon geometry. Unlike camera- or standard laser-based approaches, confocal sensing is well suited for the highly transparent balloon material, which is difficult to detect optically with conventional methods. The sensor's limited measurement range requires careful positioning to accommodate balloon curvature, but in return it offers repeatable measurements with a typical repeatability $R \leq 10$ µm.

Three main measurement modes are implemented:

- **Radius detection:** The sensor is gradually moved towards the balloon until valid measurement data is obtained. This allows the actual radius r under coating pressure p to be determined, which is typically lower than the nominal operating radius r_n specified by the manufacturer.
- **Roundness measurement:** The balloon is rotated by $\alpha = 360°$ while the sensor measures the radius r, generating a cross-sectional profile with mean radius $\bar{r}$ and standard deviation σ. This enables the user to detect out-of-round balloons or insufficient inflation before coating and to reject unsuitable workpieces.
- **Position detection:** The sensor is moved along the balloon's rotational axis, and an edge-detection algorithm is applied to the measured profile to automatically identify the start and end positions of the balloon. The detected edges can be visually confirmed by the operator.

The roundness measurement mode and position detection mode can be combined to measure the balloon before and after coating, enabling estimation of coating thickness and surface smoothness along the balloon in the future.

3.3. Optical sensors

The light barriers AO903 from the company autosen GmbH, Essen, Germany are used to reference the needle position. During referencing, the needle is moved through the beam in a staircase pattern to pinpoint the exact position of the needle tip. The measured position is compared to stored reference data to compute an offset, improving repeatability and reducing setup variability.

Together, the integrated pump and sensors provide the necessary feedback and actuation for reliable process execution and establish the basis for future metrology-driven process qualification and automated workpiece screening.

4. Control software

The Coater Mk2 control software is built on top of LinuxCNC and uses the real-time motion and I/O infrastructure described in the previous sections. The software is structured in modular components responsible for axis control, pump control, sensor handling, process sequencing, and the graphical user interface (GUI) (see Figure 2). This modularity facilitates extension and long-term maintainability.

The coating process is implemented as an automated sequence with clearly defined states, including system referencing, balloon detection, coating, and drying. A typical cycle comprises:

1. Referencing of all axes and sensors,
2. Loading of the syringe pump with the drug solution,
3. Automatic detection of balloon position and geometry using the confocal sensor,
4. Configuration or selection of process parameters,
5. Execution of the automated coating and drying cycle.

Coating is executed balloon by balloon, while drying phases overlap with the coating of subsequent balloons. This coordinated sequencing increases throughput compared to single-balloon processing without compromising coating quality.

All process-relevant parameters, including axis speeds, drying time, coating paths and coating volume, are configurable through the GUI. Each of the up to five balloon positions can store an individual parameter set, enabling heterogeneous balloons to be processed within the same batch. This reduces setup effort and allows recipes for frequently used balloon types to be reused.

The GUI provides access to parameter configuration, live status information (axis positions, sensor states, pump status), and basic diagnostics. It is implemented as a thin layer on top of the control logic, with LinuxCNC ensuring deterministic execution of motion and I/O commands in the background. The use of an open-source control platform allows delivery of fully accessible source code with the machine, enabling end users to adapt and customize both process logic and operator interface to specific production requirements.

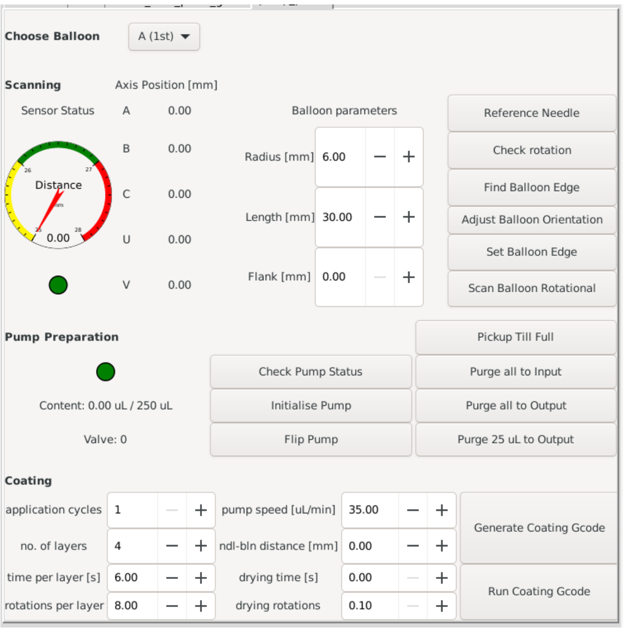

Figure 2. GUI of the Coater Mk2 with configurable process parameters and status monitoring

5. Results

The automated process was validated using three representative balloon catheter types covering a range of geometries and use cases. The automated coating results were evaluated using three acceptance criteria:

- visual control, requiring that the drug coating is distributed over the entire balloon surface including the flank areas;
- average active pharmaceutical ingredient (API) load per surface area, in this case caffeine, determined via wash-off testing followed by high-performance liquid chromatography (HPLC), with a target of $m_{API} = 3\ \mu g/mm^2 \pm 0.1\ \mu g/mm^2$;
- coating thickness, measured with a Keyence 065T sensor, requiring a local coating thickness $50\ \mu m \leq \Delta r \leq 200\ \mu m$ at all measured positions.

5.1. Configuration A

This balloon type had a diameter $10\ mm \leq d \leq 12\ mm$ and a length $l = 30$ mm, designed for use with a $d_g = 0.035"$ guidewire. A balloon of configuration A in the drying process is depicted in Figure 3.

For these balloons, an acceptance rate of $\eta_{acc} = 95\ \%$ was achieved. The system demonstrated stable and repeatable coating performance, including controlled coating of the balloon flanks. Automated alignment using the confocal sensor, combined with the torsion-free dual-end drive, ensured reliable positioning and rotation. No visible defects such as runs or dripping were observed under the tested conditions. Overlapping of coating and drying phases between different balloon positions was successfully executed, confirming that the multi-balloon architecture can increase throughput for this balloon class without compromising coating quality.

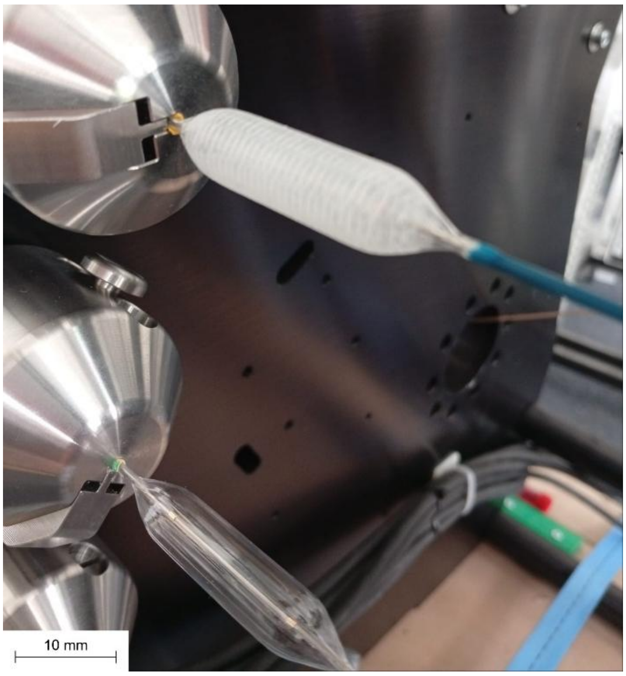

Figure 3. Balloon of configuration A, before coating (bottom) and after coating (top)

5.2. Configuration B

This balloon type had a diameter $d = 3$ mm and a length $l = 40$ mm, designed for use with a $d_g = 0.035"$ guidewire.

For this configuration, an acceptance rate of $\eta_{acc} = 85\ \%$ was achieved. While geometrically regular balloons were selected, the system was able to perform the full automated sequence including referencing, balloon detection, coating, and drying. However, the small diameter d resulted in a higher sensitivity to geometric tolerances and alignment errors. Minor deviations in clamping or needle positioning had a stronger impact on detection success rate and coating uniformity than for larger balloons. Some balloons had to be rejected before coating while some required repeated manual alignment, indicating a need for better fixtures and alignment strategies optimized for small-diameter balloons.

5.3. Configuration C

This balloon type had a balloon diameter $d \geq 4$ mm and a balloon length $l = 80$ mm on a catheter of length $l_c = 165$ mm, designed for use with a $d_g = 0.018"$ guidewire.

For this geometry, the available mechanical tensioning range and current fixation concept proved to be limiting. The longer balloon and catheter length led to residual sagging and reduced stiffness, which decreased positional stability during rotation and made the coating process more sensitive to disturbances. As a result, process stability did not yet reach the level achieved for the balloons of Configuration A, at a low acceptance rate of $\eta_{acc} = 60$ %. These results point to the need for improvements in the clamping and tensioning mechanism as well as potential adaptations of the process parameters for long balloons.

Overall, the experiments confirm that the Coater Mk2 can reliably automate coating for balloon types within a certain geometric and stiffness envelope, while also revealing the current mechanical limitations for more challenging geometries. The integrated sensing and configurable process parameters proved effective for systematic parameter adjustment and for identifying the key design aspects that require refinement in future iterations.

6. Conclusion

6.1. Summary

This paper presented the development and initial validation of the Coater Mk2, an automated drug-coating platform for balloon catheters. The system is based on a nine-axis mechanical architecture capable of processing up to five balloons in a single process cycle, with overlapping coating and drying phases to increase throughput. It combines LinuxCNC and EtherCAT for deterministic multi-axis motion control, a syringe pump integrated via a dedicated Rust-based interface, a confocal displacement sensor for balloon geometry and position measurement, and optical sensors for needle referencing.

The control software implements an automated sequence comprising axis referencing, balloon detection, parameter configuration, coating, and drying. Three balloon configurations were tested, covering diameters 3 mm $\leq d \leq$ 12 mm and balloon lengths 30 mm $\leq l \leq$ 80 mm. For the balloons with 10 mm $\leq d \leq$ 12 mm and $l = 30$ mm, stable and repeatable coating was achieved, including controlled coating of the balloon flanks. For small-diameter balloons and longer, more flexible balloons, the tests revealed increased sensitivity to clamping, alignment and tensioning, indicating the current boundaries of the mechanical design.

6.2. Conclusions

The results demonstrate that the Coater Mk2 provides a viable platform for automating the coating of balloon catheters within a defined geometric and stiffness envelope. Compared to established manual coating processes such as in [4], the system reduces operator-dependent variability and operator exposure to hazardous solvents, while still supporting operation in a cleanroom environment. In comparison to potentially automated spray-coating (similar to [8]) or dip-coating workflows, the Coater Mk2 achieves superior dosing control, while also creating more evenly coated surfaces than automated micropipette system described in [5]. Compared to the earlier prototype in [6], the Coater Mk2 also advances the state of the art by combining multi-axis motion, integrated syringe pump control, and configurable process parameters, enabling reproducible execution of complex coating sequences and supporting processing of up to five workpieces.

6.3. Future work

Future work will focus on extending the mechanically stable range of balloon geometries, with particular emphasis on longer balloons with lengths up to $l = 200$ mm on $d_g = 0.018"$ guidewires. Achieving this will require revised clamping and tensioning concepts and improved guidance to maintain sufficient stiffness and positional stability over the full balloon during rotation.

On the metrology side, the confocal sensor functionality will be extended from geometric alignment towards quantitative evaluation of coating thickness Δr and surface quality by comparing pre- and post-coating measurements. Additional work will include expanded testing with further balloon variants, refinement of process recipes, and enhanced software functions for recipe management, diagnostics, and data logging. Finally, user documentation covering setup, operation, maintenance and fault diagnosis will be completed to support transfer of the system into routine use and further industrialization.

References

[1] Lee H-I, et al. 2021 A multilayer functionalized drug-eluting balloon for treatment of coronary artery disease *Pharmaceutics* **13** 614.

[2] Bhogal S, Hill A P, Merdler I, Wermers J P, Ben-Dor I and Waksman R 2024 Drug-coated balloons for coronary artery disease: An updated review with future perspectives *Cardiovasc. Revasc. Med.* **69** 79-89.

[3] Her A, Ahmad W, Bang L, et al. 2025 Drug-coated balloons-based intervention for coronary artery disease: The second report of Asia-Pacific Consensus Group *JACC: Asia* **5** 701-17.

[4] Petersen S, Kaule S, Stein F, et al. 2013 Novel paclitaxel-coated angioplasty balloon catheter based on cetylpyridinium salicylate: Preparation, characterization and simulated use in an in vitro vessel model *Materials Science and Engineering C* **33** 10 4244-50.

[5] Fuglsby K, Anderson J A, Engebretson D and Lamichhane S 2020 Development of an automated micropipette coating method for drug-coated balloons *J. Biomed. Mater. Res. B Appl. Biomater.* **108** 2258-75.

[6] Uhlmann E, Hein C, Schlüter M, Wang Y and Dürre G 2023 Automated manufacturing of drug-coated balloons for coronary artery disease *Proc. 23rd Int. Conf. of the European Society for Precision Engineering and Nanotechnology* ICE23244.

[7] LinuxCNC Project 2025 *LinuxCNC* available at https://linuxcnc.org

[8] Jelonek K, et al. 2025 Evaluation of Ultrasonic Spray Method for Application of Sirolimus-Eluting Coating on Bioresorbable Vascular Scaffolds *Int. J. Mol. Sci.* 26(15).