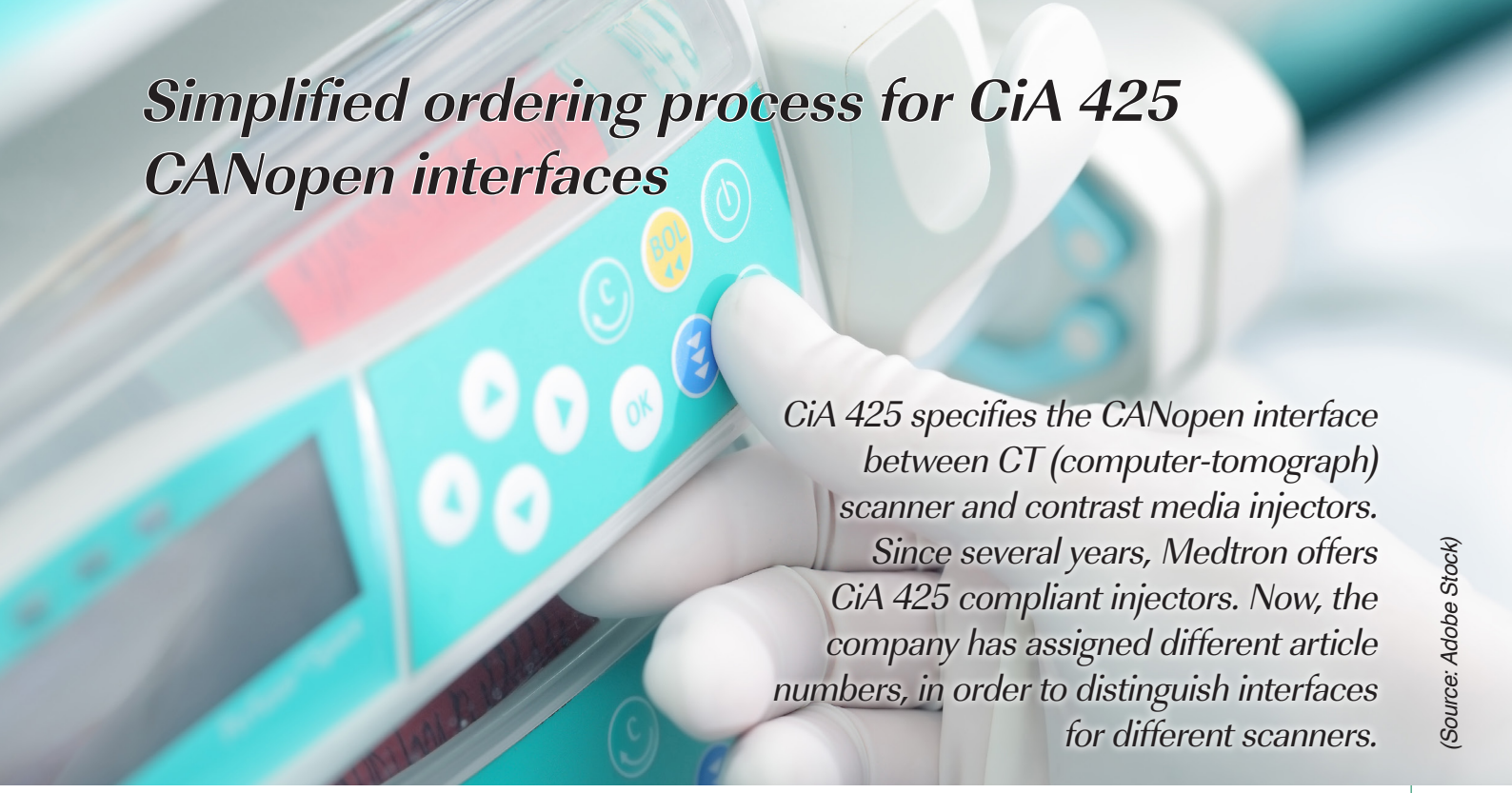
Simplified ordering process for CiA 425 CANopen interfaces



CiA 425 specifies the CANopen interface between CT (computer-tomograph) scanner and contrast media injectors. Since several years, Medtron offers CiA 425 compliant injectors. Now, the company has assigned different article numbers, in order to distinguish interfaces for different scanners.

(Source: Adobe Stock)

The CANopen application profile for medical diagnostic add-on modules is specified in the CiA 425 document series. It is developed by the special interest group (SIG) contrast media injector working under the umbrella of CAN in Automation (CiA). Part 1 provides general definitions including the connector pin-out. Part 2 specifies the injector interface. There are two versions available: Version 2.4.0 is in draft specification proposal (DSP) status available for CiA members only; version 2.2.0 is in draft specification status and therefore part of the CiA 4XX series subscription by non-members.

Usually, the CT scanner manufacturers (e.g. General Electric (GE) Healthcare, Philips, and Siemens Healthineers) implement different optional CiA 425 functions. In the past, all Medtron injector variants were combined under one article number, which often led to confusion during the ordering process. Now, each CANopen injector variant has a unique IF (interface) article number, which expresses the compatibility to different CT scanners:

- IF864 – CANopen interface class 4 (Siemens Healthineers)
- IF864B – CANopen interface class 4 (GE Healthcare)
- IF864E – CANopen interface class 1 (Siemens Healthineers)

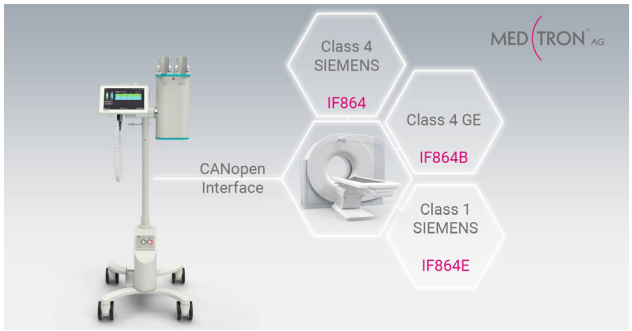


Figure 1: Introduced IF (interface) article numbers for CANopen injectors express compatibility to CT scanners from different manufacturers (Source: Medtron)

MDR certification

In order to guarantee the sale of injectors in the future, they must be equipped with the new European MDR certificates by January 2024. MDR stands for "Medical Device Regulation" and defines the requirements that manufacturers must meet in order to introduce and sell medical devices on the European market. The regulation is already in force and will successively replace the previous Medical Device Directive (MDD) by January 2024.

"What sounds so simple at first and still a long way off, represents an immense task now and in the coming months, especially for our development department," explained the company. As early as May 26, 2021, the technical documentation of Medtron Class I products (remote controls and CANopen interfaces) has been adapted to the MDR criteria. However, "adapting" is not enough here. For the most part, technical documentation must meet much higher, more detailed requirements than before and in some cases must be rewritten. Those for Class II products were to be completed by beginning of 2023. This was a sporting task that we were tackling with a high level of motivation," stated Medtron on its website.

The MDR is intended to ensure the safety of medical devices throughout Europe. Its primary purpose is to protect patients and it applies in all states of the European Union (CE area). "For our quality management, development department, product management, and sales department in particular, the implementation of the new requirements means that individual work processes have to be adapted or even completely revised," explained Medtron. "Since the intended use of the products must be described in more detail, the scope of the technical documentation for our products will also increase, which will subsequently also affect our sales partners."

In future, when preparing clinical evaluations, competitor products will have to be considered, technical equivalence will have to be demonstrated, and a clinical evaluation plan ▷

Transition period to MDR extended

On February 16, 2023, the European Parliament approved a proposal that will significantly ease the challenges of medical device manufacturers. With the latest extension of the EU 2017/745 MDR, they have the possibility to apply for an extension of the transition period for their products. The new regulation is expected to enter into force shortly through publication in the European Journal. Manufacturers will then have the prospect of the following transition periods:

- May 2026, 2026 medical devices (custom-made, class III)
- December 2031, 2027 medical devices (higher-risk, non-exempted class IIb implants and class III devices)
- December 2031, 2028 medical devices (low-risk)

will have to be drawn up. A new, extremely time-consuming process results from the requirement that the basic safety and performance requirements must be expanded and verified by the testing department.

Contrast media injection workflow optimized

The recently introduced IDS (injection data sharing) option enables the exchange of injection data with the digital radiology infrastructure. The CANopen interface synchronizes wirelessly between the injector and the CT scanner. On company's Youtube channel is a recent video on how IDS and CANopen work. The CANopen interface complies with the CiA 425 profile specification. This interface provides for the transmission of the injection parameters (volume, contrast concentration, flow rate, etc.) and the synchronized execution of the injection (start and stop).

The IDS software option, based on the DICOM standard, links the injection report with the patient data. Through IDS, users can directly access the modality worklist (patient worklist) stored in RIS using the injector. Once the examination is complete, the injection report (as a DICOM dataset) is automatically linked to the associated patient data and stored in PACS as structured report, secondary capture, or ePDF.

Additional partnerships

Since April 2023, Medtron cooperates with Röntgentekno (Imaqen) in Finland. The first conversation about the cooperation took place at the ECR European Congress of Radiology 2023 in Vienna. "With Röntgentekno (Imaqen) we are pleased to have a reliable partner at our side, which will enable us to place our product portfolio on the Finnish market in the future," stated Christoph Salzmann from Medtron. "The partnership is a perfect combination of innovative technology and medical expertise to bring radiology technology to a new level in Finland." Imaqen is owned by Röntgentekno, which was founded in 2008. The company provides products and services to healthcare professionals. The team has decades of experience in product development, manufacturing, international sales, and marketing of healthcare equipment, especially imaging equipment.

Additionallly, Medtron reported its cooperation with Guerbet in Germany and Austria. With this collaboration, both companies aim to improve the workflow between Medtron's injectors and Guerbet's contrast management solution. In addition, Medtron will distribute Guerbet's Contrast&Care solution and Guerbet will distribute the contrast media injectors, in both directions on a non-exclusive basis.

"Our goal is to be a trusted and competent partner for the radiology community, understanding their challenges and providing value-added solutions. Working with Guerbet is the logical next step in achieving this goal and offering innovative, value-added solutions in an even more complete product portfolio. Adding Guerbet's high quality contrast management solution will achieve this," said Bjørn Jochems from Medtron.

"The collaboration with Medtron is an important milestone on Guerbet's path to continuously develop our portfolio. It is our commitment to provide innovative solutions that are serving our customers to cope better with their daily challenges. Together with Medtron we are aiming to improve data- and workflow as well as to enable analytics leading to an efficiency gain in radiology departments and imaging centers," said Achim Berlis from Guerbet. ◀

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SIG contrast media injector

This CiA special interest group (SIG) has updated the CANopen profile for contrast media injectors. During the review process the group focused on the introduction of the multiple-injection protocol (MIP). The intent is to clarify and to simplify the handling of several consecutive injection protocols from the viewpoint of the medical diagnostic device (scanner). There is a probability that in the contrast media injector "unintended remainings" from the previous injection protocol could erroneously influence the processing of a new protocol. In particular historical parameter settings, adjusted with regard to a former injection protocol, could lead to an unintended and unsafe injector behavior. To avoid reprogramming and reconfiguration of the injector, the scanner has now the chance to program the multiple-injection protocol, at once. This reduces potential sources for faulty configurations.

The extension of CiA 425 is introduced backwards compatible. An already existing injector implementation processes the MIP as a "traditional" single-injection protocol. New commands are rejected and treated as any other invalid command. The new version of CiA 425-2 is currently in the CiA-internal release process. In 2024, on occasion of the annual SIG meeting, the group will start focusing on cybersecurity issues.