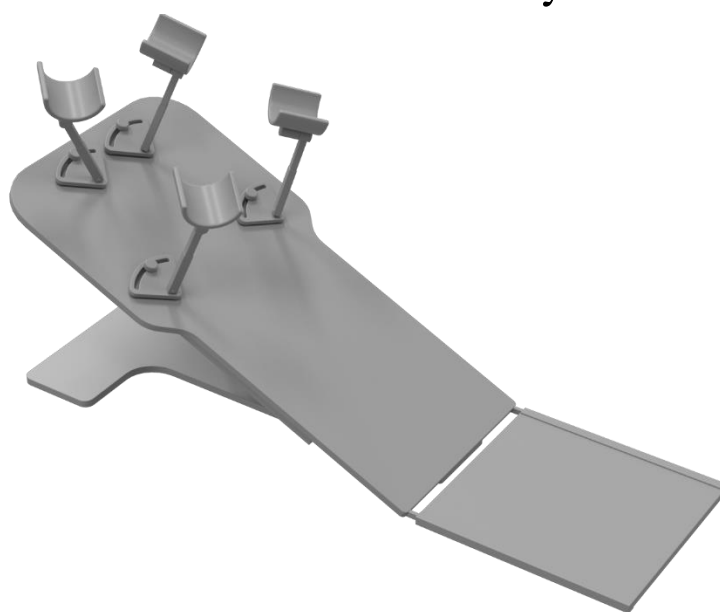


cAccessory

System Manual



Introduction

By C-RAD Positioning AB

This manual is published by C-RAD Positioning AB without any warranty. Improvements and changes to the manual due to typographical errors, insufficient information, and program and/or equipment improvements may be made by C-RAD Positioning AB at any time and without notice. Such changes will however be introduced in later editions of this manual. All rights preserved.



cAccessory is CE marked according to the Medical Device Regulation (EU) 2017/745

cAccessory System Manual

© 2020 C-RAD Positioning AB

All rights reserved.

Edited: May 2020 in Uppsala, Sweden

Publisher/Legal Manufacturer

C-RAD Positioning AB

Contact information

*Address: Sjukhusvägen 12K
753 09 Uppsala
SWEDEN*

Phone: +46 - 18 - 666930

Fax: +46 - 18 - 126930

E-mail: support@c-rad.com

Table of Contents

1	Important notice	5
1.1	Find more information	5
2	Safety instructions.....	6
2.1	Safety warnings	6
2.1.1	General.....	6
2.1.2	Electrical Hazards, EMC.....	6
2.1.3	Operating, Measurements, Maintenance.....	7
3	Intended use.....	8
4	Product description	8
4.1	Intended user and intended patient	8
4.2	Software module	8
4.3	Components	8
4.4	Configurations	10
4.5	IT network characteristics	10
5	Training.....	10
6	Patient Population.....	10
7	Environmental protection	11
8	Technical specification	11
8.1	Physical dimensions	11
8.2	Power	11
8.3	Environment.....	11
8.4	Storage and transport	11
8.5	Detection range.....	12
8.6	Reuse of RFID tags.....	12
9	Maintenance, Cleaning.....	12
10	Definitions	13
10.1	General.....	13

1 Important notice

All personnel must read this manual and be fully aware of its contents before using the system.

All personnel must be trained before starting to use the system.

If the system is used in a way not specified by C-RAD Positioning AB, the protection provided by the equipment may be reduced.

1.1 Find more information

- For instructions regarding the c4D-Catalyst system, refer to Catalyst User's Guide SP-002-110916-001 and System Manual, Catalyst SP-002-110918-001
- For instructions regarding the c4D-Catalyst⁺ system, refer to Catalyst⁺ User's Guide SP-003-190410-003 and System Manual, Catalyst⁺ SP-003-190410-002
- For instructions regarding the c4D-Sentinel system, refer to User's Guide, Sentinel CT room 001-130627-010 and System Manual, Sentinel SP-001-070625-003

2 Safety instructions

When using cAccessory with the c4D-Catalyst system or c4D-Sentinel system, make sure to observe the safety instructions given in the User's Guide for the applicable system, see chapter 1.1 Find more information. The purpose of safety instructions is to prevent accidental injuries to patients and users of the system. They should be strictly observed at all times.

2.1 Safety warnings

2.1.1 General

- Warning - Intended Use: Before installing or using cAccessory read and understand the User's Documentation. Use cAccessory only according to its intended use. If cAccessory is used in a manner not specified by C-RAD, the protection provided by the equipment may be impaired.
- Warning - Experienced User: There are severe hazards associated with ionizing radiation, radiotherapy and electrical instruments. The user must be aware of these hazards. Only those health care professionals as listed in the chapter 4.1 Intended user and intended patient are allowed to use cAccessory.
- Warning - Interference with other 3rd party devices: Prior to the use of cAccessory, review the instructions for the safe and effective use of the device in the actual clinical environment. Review and follow all instructions, among others as found in this document or in documents from other third-party devices. It is the user's responsibility to evaluate cAccessory for compatibility with other third-party devices in the intended environment.
- Warning - Modification of cAccessory: No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

2.1.2 Electrical Hazards, EMC, Radiation

- Warning - Do not open housings: Never open any housings. Service must only be performed by C-RAD or by persons authorized by C-RAD.
- Warning - Electrical shock: Do not use the system if it appears to be damaged or if it has been dropped onto the floor. Contact your nearest C-RAD dealer. Always handle your cAccessory with care.
- Warning - EMC - General: Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the chapter Technical Specifications.
- Warning - EMC RF communications equipment: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the cAccessory, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Warning - EMC - Cables: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and

result in improper operation.

- Warning - EMC - Other Equipment: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Caution - FCC - Antenna to near patient: In order to avoid the possibility of exceeding the FCC radio frequency exposure limits, human proximity to the device's antenna shall not be less than 20 cm during normal operation.
- Warning - In case of a serious error condition: Switch off cAccessory immediately. Report to C-RAD and the competent authority.
- Warning - Replacing of components: If any of the system's components have been replaced, ensure that the system is performing according to technical specification by running the installation tests.
- Warning - Make sure that the RFID tag or its placement on the accessory has no adverse effect on the performance or safety of the accessory, the treatment, treatment beam or the diagnostic process. Place the RFID tag outside the primary beam.

2.1.3 Operating, Measurements, Maintenance

- Warning - Risk for Infection: Include the cAccessory system into your surface cleaning and surface disinfection routines. Clean and disinfect the surface of the cAccessory system especially before first use and after infectious patients.
- Warning - Anti-Virus: It is under the responsibility of the user to shield the computers from internet threats (like malware, viruses, hackers, etc.).

3 Intended use

The cAccessory is intended for use in radiation therapy clinics with diagnostic or treatment equipment, to provide:

- Guidance in planning of individual accessory sets that shall be present at treatment.
- Support for accessory management.
- Validation of the planned accessories prior treatment start.

The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostics departments.

4 Product description

The cAccessory system is intended for use in radiation therapy clinics, for registration and validation of patient fixations and shielding devices (hereafter called “accessories”) to be used during treatment. The product offers a fast and secure way to prepare the treatment couch before each treatment. There are no residual risks, contra-indications or any undesirable side-effects of using the product.

The accessories are tracked using radio frequency identification (RFID). Every accessory is tagged with an RFID tag and registered in a database. An RFID reader can then detect if the accessory is present on or near the treatment couch. The software guides the user through registration and validation of the accessories for each patient.

The registration part of the cAccessory system is operated from any c4D Client in Advanced mode, and the validation part of the cAccessory is operated from c4D in Catalyst Clinical mode.

4.1 Intended user and intended patient

The intended users of the product are nurses, therapists or physicians working in radiation therapy clinics. The intended patients are patients that shall be treated with radiation therapy.







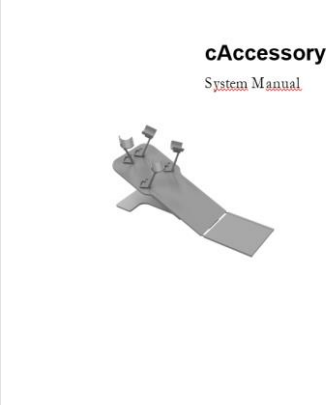
4.2 Software module



The cAccessory software module is integrated in the c4D software. The software module handles the registration of the accessories, the assigning of accessory references to patients and the validation of the accessories made before starting patient treatment.

4.3 Components

The cAccessory system consists of the following components.

Component	Product ID	Image	Description
c4D, Software	PA-003		The C-RAD software providing cAccessory functionality.

RFID Reader kit	HZ-035		<p>RFID reader for detection of RFID tags, ALR-F800 from Alien Technology</p> <p>Size: 202 x 191 x 28 mm (LxWxH) Weight: 0.85 kg</p>
			<p>RFID antenna, ALR-8698 from Alien Technology</p> <p>Size: 258 x 258 x 36 mm Weight: 0.91 kg</p>
			<p>Ceiling mount kit: Ceiling adapter Antenna mount kit</p>
			
			<p>RFID reader PoE injector kit</p>
			<p>RFID tag</p>
System Manual	SP-004		<p>System description (this document) Document Id: SP-004- 20316-003</p>

User's guide	SP-004		Instructions for use. Document Id: SP-004-200226-001
cAccessory IT Package (Only supplied for the cAccessory Standalone configuration)	IT001-0008		Computer with two sets of peripherals, interconnecting cables and KVM extender pair.

4.4 Configurations

The cAccessory system is to be installed together with the C-RAD patient positioning systems; Sentinel, Catalyst and/or Catalyst⁺. It can however also be installed in a standalone configuration, together with a dedicated computer IT package .

4.5 IT network characteristics

The RFID Reader is connected to the hospital Local Area Network (LAN).

5 Training

The training on the cAccessory system is divided into two parts: Clinical and Advanced. The clinical part is focusing on the clinical usage of the system when treating patients and the advanced part is focusing more on patient administration and detailed parts of the c4D software and system settings. The training is based on the content of the manuals.

Training is normally performed by the service engineer at the time of the installation. Contact C-RAD Positioning AB if there is any need for additional training.

6 Patient Population

The usage or not usage of the cAccessory system is not depending on which patient that is treated, therefore the system is suitable for all patients regardless of age, weight, region of body, health or condition.

7 Environmental protection

The system does not produce any waste products and its components do not contain any hazardous materials.

The manufacturer has a responsibility to take care of the system after its service life and offer the possibility to receive the systems components to be disposed. It is also possible for the customer to manage the disposal process by themselves if that is preferred and can be done in an acceptable way.

8 Technical specification

8.1 Physical dimensions

RFID Reader (ALR-F800)

Size (L x W x H)	202 mm x 191 mm x 28 mm
Weight	0.85 kg (1.88 lbs)

RFID Antenna

Size (L x W x H)	258 mm x 258 mm x 36 mm
Weight	0.91 kg (2 lbs)

RFID Tag

Size (L x W x H)	95mm x 8.15 mm x 0,3 mm
Water equivalent thickness	0.3 mm

8.2 Power

RFID Reader (ALR-F800)

Input voltage	Power over Ethernet or 12 VDC
Frequency	50/60 Hz

8.3 Environment

RFID Reader (ALR-F800)

Operating temperature	-20 °C to +50 °C (-4 °F to 122 °F)
-----------------------	------------------------------------

8.4 Storage and transport

Ambient temperature	-20 °C to +50 °C (-4 °F to 122 °F)
Humidity	15% to 95% relative humidity, non-condensing

8.5 Detection range

Detection range	Typically 1 – 4 m from the RFID antenna. The detection range is adjusted for each individual installation through an attenuation setting. <i>An unobstructed view is required in between the RFID tag and the antenna.</i>
-----------------	---

8.6 Reuse of RFID tags

A tag that has been registered cannot be registered again for another accessory.

9 Maintenance, Cleaning

No regular maintenance is need for the RFID reader or the antenna. If the reader or antenna gets dirty it is to be cleaned with a slightly damp cloth.

The RFID tags can be cleaned if needed according to hospital routines on how to clean the surface of the accessories.

10 Definitions

10.1 General

The following terms are used throughout the document:

Term	Definition
Accessory	A fixation, shielding or bolus device used to shield or hold the patient in the right position during treatment.
Registration	The process of registering an RFID-tag attached to an accessory in the software database.
Validation	The process of making sure that all required accessories are present on the treatment couch.