

Why

- Compliance with Standards is Required for Market Access
 - Many countries require IEC 60335 compliance (or equivalent national versions) for certification and legal sale.
- Ongoing Quality Control & Documentation
 - Technical documentation, risk assessments, and safety reports must be kept up to date.
- National Adaptations
 - Some countries have localized versions

Technical Documentation

- Technical Documentation for IEC 60335 Compliance
- You must maintain **comprehensive technical documentation** that proves your product meets safety requirements. This documentation is essential for **certification, audits, and regulatory approvals.**

Example: A fridge, IEC 60335 compliance, the docs

- General Product Information
 - Product Name & Model Number
 - Intended Use (e.g., domestic or commercial refrigeration)
- Electrical & Mechanical Design Documents
 - Electrical wiring layout
- Risk Assessment & Safety Analysis
 - Identifying risks related to electric shock, overheating, fire, mechanical failure, entrapment, and refrigerant leakage
 - Protective Measures

Why

- Standards compliance
 - IEC 60335-1:2020 (International Electrotechnical Commission)
 - Household and similar electrical appliances - Safety - Part 1: General requirements
 - Swedish standard · SS-EN 60335-1
- Guidance for Industry
 - FDA (Food and Drug Administration) Guidance
 - Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products
 - Enforcement Policy for Clinical Electronic Thermometers
 - <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>

FDA Guidance - Instructions for Use

Content that FDA recommends be placed under the preparation instructions section includes, but is not limited to, the following:

- Information about supplies and materials for administering the dose (for example, a bowl and spoon for mixing a drug product with food; alcohol wipes to prepare an injection; an adhesive bandage to cover an injection site)
- Information about the time needed to allow a refrigerated product to warm to room temperature or the maximum amount of time the product may remain unrefrigerated before use
- Instructions to check the drug product for particles or discoloration and to check the expiration date on the product's label

4. *Visual of Drug Product*

Following the purpose statement, FDA generally recommends that the IFU display a visual of the drug product and, if the drug is a constituent part of a drug-led, drug-device combination product, a visual of the device or devices used to administer the drug. Choose the best type of visual that clearly depicts the drug product, such as a photograph, simple illustration, or line drawing. If a product consists of multiple parts, FDA recommends visually identifying and clearly labeling each part of the product, including the device constituent part(s) if applicable. In some cases, it can also be useful to include further explanation of the purpose or function of the parts of the product, including the device constituent part(s) if applicable.

FDA Guidance - Instructions for Use

APPENDIX: INSTRUCTIONS FOR USE — RECOMMENDED ORDER OF INFORMATION

Numbers in parentheses correspond to items 1 through 10 in Section III.B, Specific Content Recommendations, of the guidance. The main body of this guidance contains detailed information about each item. This example is for a drug that is not a biological product.

- (1) **INSTRUCTIONS FOR USE**
- (2) **[Insert Product Title]**

(3) This Instructions for Use contains information on how to [insert applicable action verb^a] [Insert Drug Name^b]

(4) [Insert visual of drug product]

(5) **Important Information You Need to Know Before [Insert Applicable Action Verb^c] [Insert Drug Name]**

(6) **Preparing to [Insert Applicable Action Verb^d] [Insert Drug Name]**

(7) **[Insert Applicable Action Verb^e] [Insert Drug Name]**

(8) **Storing [Insert Drug Name]**

(9) **Disposing of [Insert Drug Name]**

(10) [At the bottom of the last page of the IFU, insert resources for additional information on how to use the drug product (for example, a telephone number that patients can call to speak with a customer service representative)]

FDA Guidance - Instructions for Use

INSULINPRO

- **Preparing to Inject INSULINPRO** † Make sure you have the following supplies: an insulin syringe and alcohol wipes. If the insulin was refrigerated, take it out before use.
- **Injecting INSULINPRO** † Use the drug as instructed. Clean the injection site, draw the insulin, and inject it into a suitable area.
- **Storing INSULINPRO** † Keep the insulin in a safe place. Avoid extreme temperatures.
- **Disposing of INSULINPRO** † After use, throw the syringe in the trash.

FDA Guidance - Instructions for Use

- ▼ file:/D:/Git-workspace/oxygen-ai-dita-ot-plugins/samples/ai-checks/mymedicine/bad.dita:
 - ▼ errors:
 - issue: The preparation instructions do not specify time requirements for temperature adjustments.
 - fix: Add instructions on how long to leave the insulin out of refrigeration before use.
 - line: 6
 - column: 12
 - url: file:/D:/Git-workspace/oxygen-ai-dita-ot-plugins/samples/ai-checks/mymedicine/bad.dita
 - ▼ errors:
 - issue: The assembly instructions for injections are incomplete.
 - fix: Include detailed instructions for assembling the syringe and checking insulin for particles and discoloration.
 - line: 6
 - column: 12
 - url: file:/D:/Git-workspace/oxygen-ai-dita-ot-plugins/samples/ai-checks/mymedicine/bad.dita
 - ▼ errors:
 - issue: The administration instructions lack specific guidance on injection sites.
 - fix: Provide details on recommended injection sites and instructions for rotating injection sites.
 - line: 9
 - column: 12
 - url: file:/D:/Git-workspace/oxygen-ai-dita-ot-plugins/samples/ai-checks/mymedicine/bad.dita
 - ▼ errors:
 - issue: The storage instructions are vague and lack necessary details.
 - fix: Specify refrigeration requirements and include the required safety statement: 'Keep out of reach of children.'
 - line: 11
 - column: 12
 - url: file:/D:/Git-workspace/oxygen-ai-dita-ot-plugins/samples/ai-checks/mymedicine/bad.dita
 - ▼ errors:
 - issue: The disposal section lacks specific disposal instructions for syringes.
 - fix: Include guidance on using a sharps container for used syringes to prevent injury or infection.

Standards: IEC 60335-1

7.12.4 The instructions for **built-in appliances** shall include information with regard to the following:

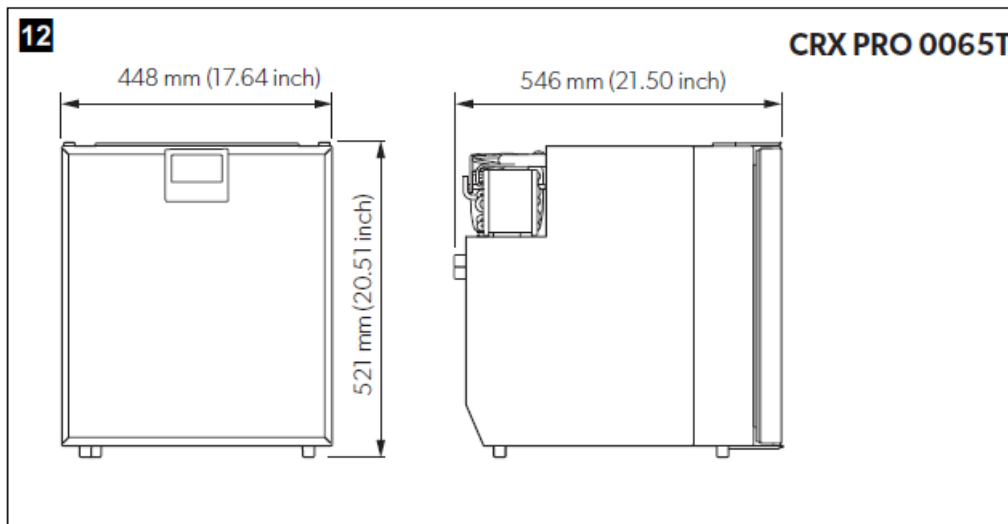
- dimensions of the space to be provided for the appliance;
- dimensions and position of the means for supporting and fixing the appliance within this space;
- minimum distances between the various parts of the appliance and the surrounding structure;
- minimum dimensions of ventilating openings and their correct arrangement;
- connection of the appliance to the supply mains and the interconnection of any separate components;
- necessity to allow disconnection of the appliance from the supply after installation, unless the appliance incorporates a switch complying with 24.3. The disconnection may be achieved by having the plug accessible or by incorporating a switch in the fixed wiring in accordance with the wiring rules.

7.12.8 The instructions for appliances connected to the water mains shall state

- the maximum inlet water pressure, in pascals;
- the minimum inlet water pressure, in pascals, if this is necessary for the correct operation of the appliance.

Standards: IEC 60335-1

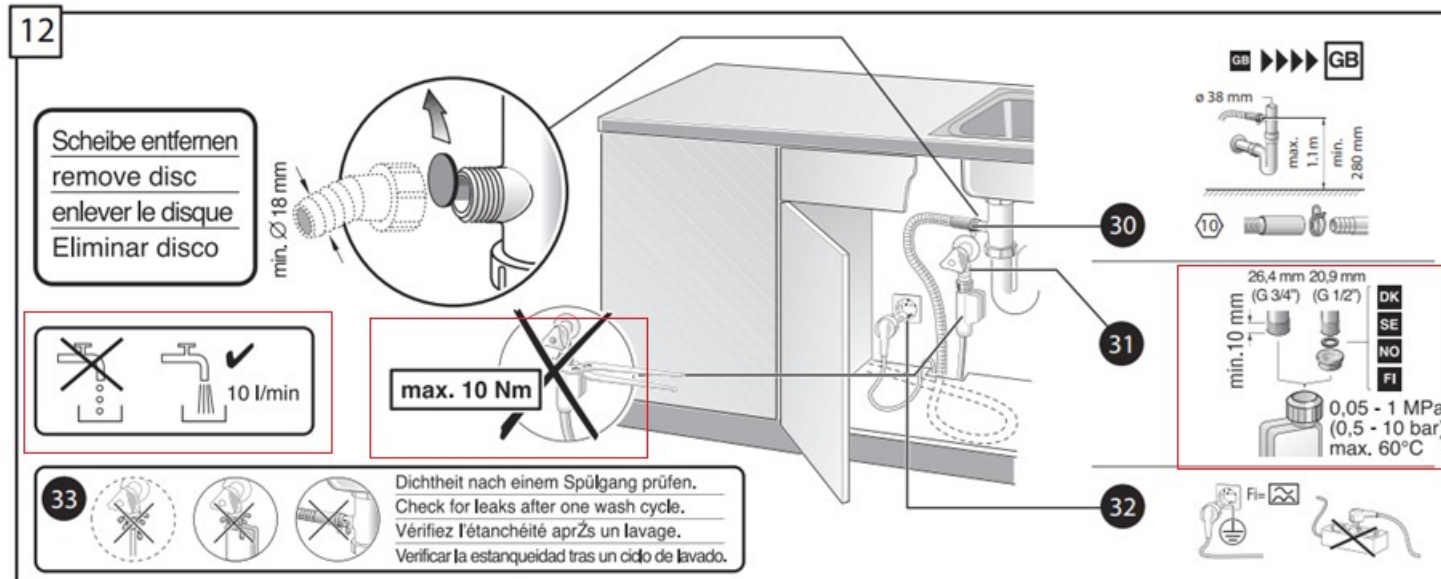
CRX PRO 0050T, CRX PRO 0065T



The image provides the dimensions of the **CRX PRO 0065T** appliance. The space occupied by this appliance is:

- **Width:** 448 mm (17.64 inches)
- **Height:** 521 mm (20.5 inches)
- **Depth:** 546 mm (21.50 inches)

Standards: IEC 60335-1



From the image, I can see that the water flow requirement for proper functioning of the dishwasher is **10 liters per minute (10 l/min)**, as indicated in the bottom left section.

Regarding the water pressure, the required range is **0.05 - 1 MPa (0.5 - 10 bar)**, with a maximum temperature of **60°C**, as shown in the bottom right section of the image.

The required torque when fixing the water supply is a **maximum of 10 Nm**, as indicated in the image near the pipe connection.

THANK YOU!

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