Carnation
Ambulatory Monitor

7 DAY

Instructions For Use

The Carnation Ambulatory Monitor is a single patient use, continuous recording ambulatory ECG monitor that records for up to 7 Days.

Indications for Use
The Carnation Ambulatory Monitor is designed to provide extended duration cardiac monitoring for people who are suspected of having cardiac arrhythmias.

Patient Population
The intended patient population includes both males and females not weighing less than 10 kg (22lbs) who may have cardiac arrhythmias.

Read all instructions before using this product

℞ ONLY By prescription only

For assistance in setting up, using, and maintaining the device, or to report unexpected operations or events. Contact us:

Bardy Diagnostics Inc.
316 Occidental Ave
Ste B310
Seattle, WA 98104 USA

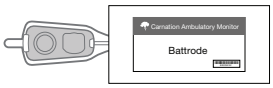
US Customer service: (844) 422-7393
EU Customer service: +31 (0) 46 7630422

EC REP MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany

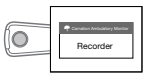
CE 0459

Table of Contents

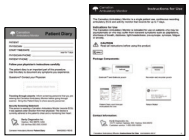
In the Box:



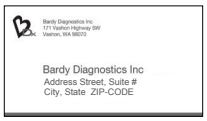
Battrode™ (packaged inside Battrode pouch)



Recorder (packaged inside Recorder pouch)



Patient Diary and Clinician Instructions for Use



Return Mailer for patient to return used device containing recording.

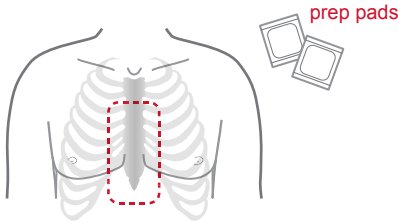
Instructions For Use

INSTRUCTIONS FOR USE

Prepare the Skin

⚠ **CAUTION: Proper skin prep required to achieve 7 Days wear.**

NOTE:
Be sure that the prepared area extends over 1 inch larger than where the patch will sit.



STEP 1
If hair is present, shave the hair as close to the skin as possible.

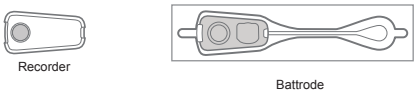
STEP 2
Use the skin prep pads provided in the mailer box to remove oils from the patient's chest.
Scrub skin with wipe or wipes until wipes remain clean after use. **IMPORTANT: Ensure skin is completely dry before monitor application.**

Instructions to Patient
Avoid activities or environments that result in severe perspiration, as this may result in the device failing to maintain adherence to the skin.

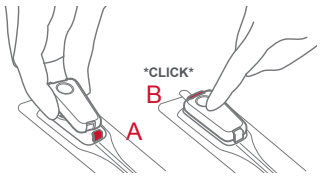
Instructions For Use

Prepare the Carnation Ambulatory Monitor

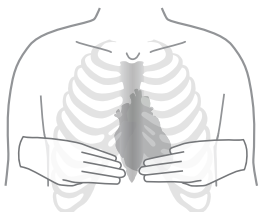
STEP 3
Remove the Recorder and Battrode from the packaging.



STEP 4
On a flat, hard surface, snap the Recorder into the Battrode by inserting the narrow end first. Within 2-3 seconds you should hear a confirmation buzz. **If there is no buzz see Operational Instructions on this page.**



STEP 5
Use both hands to find the edge of the ribcage where it meets the abdomen. Slide both hands down towards the center of the body until they meet in a little notch.



Ask the patient to inhale and exhale – after exhaling you should feel a pointed bone. This is the xiphoid process.

Instructions For Use

Apply the Carnation Ambulatory Monitor

STEP 6
Peel the liner from the back of the Carnation Ambulatory Monitor.

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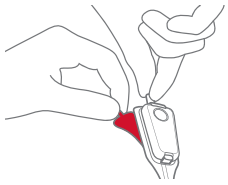

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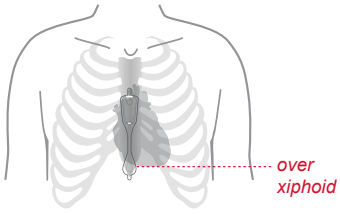
Apply the CAM to the patient's chest with the bottom of the electrode sitting over the xiphoid. Press firmly on patch adhesive for 1 minute to ensure adhesion.



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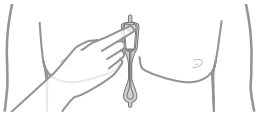
Tell patient to gently press the button when they feel symptoms, and record the time/date in the Patient Diary.



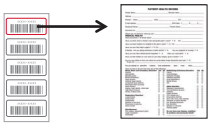
Instructions For Use

Link the Carnation Ambulatory Monitor to the patient's information

⚠ **CAUTION: Inability to diagnose if patient and physician data is missing.** The patient diary card must be kept with the Carnation Ambulatory Monitor to ensure proper diagnosis.

STEP 9
Fill in all information on the front page of the Patient Diary, including start time/date, patient initials, and physician name and phone number.

STEP 10
Barcode stickers with the device's unique serial number are found inside the mailer box and can be placed on the patient chart, or be typed into the patient's EMR.



REVIEW ALL INSTRUCTIONS IN THE PATIENT DIARY WITH THE PATIENT
Give the patient the Patient Diary and Return Mailer and explain their use. Review all Instructions and Cautions in case there is a change in performance of the Carnation Ambulatory Monitor, such as the device coming loose from the patient's chest.

Operational Instructions
If the Carnation Ambulatory Monitor becomes soiled, patients may gently wipe exterior of device, using a clean, dry cloth.

If Carnation Ambulatory Monitor becomes loose or detached from skin, patient should press the monitor back in place.

If you do not hear a confirmation buzz, place the monitor up to your ear and press the button to confirm. If no buzz, return to manufacturer.

Safety Alert Descriptions
The symbol shown below identifies a potential hazard category.

⚠ **CAUTION**
This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

General Cautions
This section lists general cautions. Those pertaining to specific functions and procedures are included in the text where appropriate.

⚠ **CAUTION: Contains ECG Electrodes which can damage skin if used improperly.**
This device should be used by or in consultation with a health care provider familiar with their proper placement and use. Apply electrodes to intact, clean skin only. Do not apply over an open wound, lesion, infected or inflamed skin.

⚠ **CAUTION: Skin irritation**
Patients with sensitive skin or with known skin conditions should use this device with caution. If irritation such as redness, severe itching or allergic symptoms (i.e. hives) develop, instruct patients to remove the device immediately and have them contact their physician.

⚠ **CAUTION: Allergic skin reaction**
Do not use this device on patients with known skin allergies or family history of skin allergies.

⚠ **CAUTION: Damage to skin**
Instruct patients to remove electrodes carefully to avoid damaging their skin.

⚠ **CAUTION: Choking hazard**
This is a prescribed medical device. Keep device and packaging away from young children.

⚠ **CAUTION: Equipment damage**
Use only as directed. Tampering with the Carnation Ambulatory Monitor may render it unusable. There are no user serviceable parts.

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Use only with approved Bardy Diagnostics down-load station.

⚠ **CAUTION: May interfere with defibrillation therapy**
To avoid ineffective defibrillation therapy, remove the Carnation Ambulatory Monitor before applying any external cardiac defibrillators.

⚠ **CAUTION: May interfere with MRI scanning**
This device is not intended for use with MRI equip-ment and could reduce effectiveness of diagnostic scanning. Remove before any MRI scan.

⚠ **CAUTION: Ineffective electronic imaging**
This device is not intended for use with imaging equipment and could reduce effectiveness of diagnostic imaging. Remove before using electronic imaging systems.

⚠ **CAUTION: Enclosure damage**
Do not use any parts that appear damaged. Check the Carnation Ambulatory Monitor for damage before using and reject any parts that have been damaged in shipping.

⚠ **CAUTION: Electrical shock**
This Carnation Ambulatory Monitor contains electrodes for monitoring ECG. Do not allow conductive parts of the electrodes on this device to come in contact with other conductive parts (including earth).

Processing Cautions
When the ECG device is returned to the processing center, these additional cautions apply.

⚠ **CAUTION: Contaminated surfaces**
When this device is returned to the reading center it will have been in contact with human skin. Follow the facility's procedures for appropriate handling.

⚠ **CAUTION: Battery may present environmental hazard**
This device contains a battery. Properly dispose of batteries in accordance with local regulations.

⚠ **CAUTION: Electronic waste may present environmental hazard**
This device is considered medical electrical equipment. Properly dispose of electronic waste in accordance with local regulations.

⚠ **CAUTION: Single use only**
The Bardy Diagnostics Carnation Ambulatory Monitor is not intended for reuse, as the monitor becomes non-functional after the first use.

EMC Guidelines
The Carnation Ambulatory Monitor needs special cautions regarding EMC, and needs to be put into service according to provided information.

⚠ **CAUTION: Electromagnetic interference (EMI)**
Portable and mobile wireless communications equip-ment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect the Carnation Ambulatory Monitor and should be kept at least a distance of 3.3 meters away from the equipment. Position the Carna-tion Ambulatory Monitor away from other electrical or electronic equipment, if possible. The presence of strong EMI fields, or electronic, surgical, or diathermy instruments in close proximity to the ECG device may cause trace noise or input overload conditions.

The ECG device is compliant with IEC 60601-1-2 EMC immunity requirements.

Symbols
Bardy Diagnostics products display one or more of these symbols and warning labels.

SYMBOL	DESCRIPTION
	Attention: Consult accompanying documents
	Warning and caution symbol
	TYPE BF APPLIED PART: F-TYPE APPLIED PART complying with the specified requirements of 60601-1 to provide a higher degree of protec-tion against electric shock than that provided by TYPE B APPLIED PARTS. Note: TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.
IP23	Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 60 from vertical. Do not immerse in bathtub or swimming.
℞ ONLY	Sold by prescription only CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Single use only
	Manufacturer
	Use-by date.
32°F (0°C) 131°F (55°C)	Do not expose to temperatures outside of these limits. For more information on environmental parameters refer to the Technical Specifications section.

SYMBOL	DESCRIPTION
500hPa 1060hPa	Atmospheric pressure must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
10% 95%	Humidity must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
	Date of manufacture
	Contains electronic equipment. Dispose of properly in accordance with local regulations.
SN	Serial number
REF	Orderable part number
LOT	Batch code
CE	CE Mark signifying conformity to EU regulations
EC REP	EU authorized representative

Technical Specifications

ITEM	SPECIFICATION
PERFORMANCE CHARACTERISTICS	
ECG channels	1 channel
Recording capacity	7 days
Recording format	Continuous
Service life	7 days
Shelf life	24 months
ELECTRICAL CHARACTERISTICS	
Frequency response	0.67 Hz to 25 Hz
Differential range	4 mV
A/D sampling rate	171 Hz
POWER REQUIREMENTS	
Battery type	Lithium primary (coin cell)
Lithium content	Lithium content < 1 g
Heavy metal content	Within weight limits of 2006/66/EC
UN compliance	Complies with UN 3090
PHYSICAL CHARACTERISTICS	
Approximate Dimensions	178mm x 38mm x 14mm
Weight	<25g
Enclosure material	Medical grade thermoplastic polymer
Flammability rating	UL- HB

ITEM	SPECIFICATION
CLASSIFICATION	
Type of protection	Internally powered
Degree of protection	Type BF applied part
Protection against objects and water ingress	IP23 (Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 60° from vertical)
ELECTRODE CHARACTERISTICS	
Number of electrodes	2
Type	Electrode incorporating electrode gel and internal lead wire
Supplied as	Disposable, non-sterile
Lead wire length	11.6 cm (no patient contact)
Materials:	Electrode gel: Medical grade conductive synthetic Adhesive: Medical grade skin adhesive

ENVIRONMENTAL SPECIFICATIONS (ECG DEVICE)	
Operating temperature	50 °F to 113°F (10 °C to 45 °C)
Operating pressure	700 to 1060 hPa
Operating humidity	10% to 95% (non-condensing)
Transport temperature	14°F to 130°F (-10 °C to 55 °C)
Storage temperature	59°F to 77°F (15 °C to 25 °C)
Transport/Storage humidity	10% to 95% (non-condensing)
Transport/Storage pressure	500 to 1060 hPa
Standards compliance	Applicable sections of IEC 60601-1, 60601-1-2, 60601-1-11, 60601-2-47

Carnation
Ambulatory Monitor

48 HOUR

Instructions For Use

The Carnation Ambulatory Monitor is a single patient use, continuous recording ambulatory ECG monitor that records for up to 48 hours.

Indications for Use
The Carnation Ambulatory Monitor is designed to provide extended duration cardiac monitoring for people who are suspected of having cardiac arrhythmias.

Patient Population
The intended patient population includes both males and females not weighing less than 10 kg (22lbs) who may have cardiac arrhythmias.

Read all instructions before using this product

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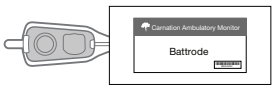

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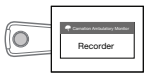
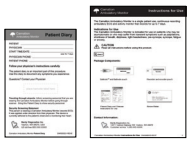
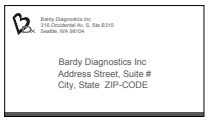


Recorder (packaged inside Recorder pouch)



Patient Diary and Clinician Instructions for Use



Return Mailer for patient to return used device containing recording.

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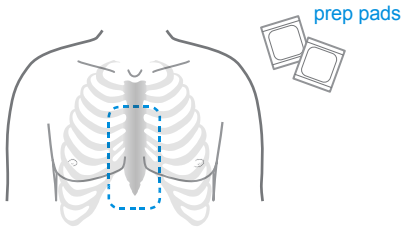
INSTRUCTIONS FOR USE

Prepare the Skin

⚠ **CAUTION: Proper skin prep required to achieve 48 hours wear.**

NOTE:
Be sure that the prepared area extends over 1 inch larger than where the patch will sit.



STEP 1
If hair is present, shave the hair as close to the skin as possible.

STEP 2
Use the skin prep pads provided in the mailer box to remove oils from the patient's chest.
Scrub skin with wipe or wipes until wipes remain clean after use. **IMPORTANT: Ensure skin is completely dry before monitor application.**

Instructions to Patient

Avoid activities or environments that result in severe perspiration, as this may result in the device failing to maintain adherence to the skin.

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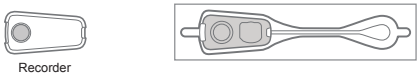
STEP 3
Remove the Recorder and Battrode from the packaging.



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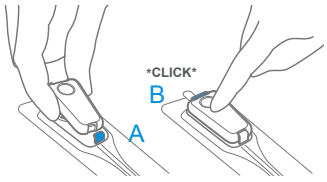
On a flat, hard surface, snap the Recorder into the Battrode by inserting the narrow end first. Within 2-3 seconds you should hear a confirmation buzz. **If there is no buzz see Operational Instructions on this page.**



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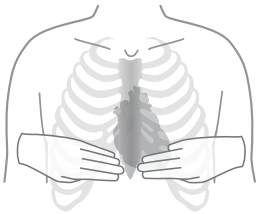
Use both hands to find the edge of the ribcage where it meets the abdomen. Slide both hands down towards the center of the body until they meet in a little notch.



Ask the patient to inhale and exhale – after exhaling you should feel a pointed bone. This is the xiphoid process.

Instructions For Use

Apply the Carnation Ambulatory Monitor

STEP 6
Peel the liner from the back of the Carnation Ambulatory Monitor.

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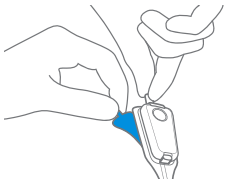

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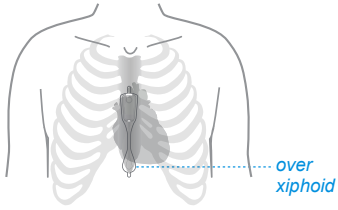

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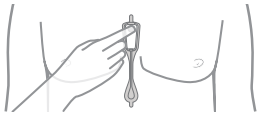

Instructions For Use

Link the Carnation Ambulatory Monitor to the patient's information

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Fill in all information on the front page of the Patient Diary, including start time/date, patient initials, and physician name and phone number.

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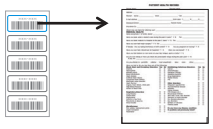
Barcode stickers with the device's unique serial number are found inside the mailer box and can be placed on the patient chart, or be typed into the patient's EMR.



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If Carnation Ambulatory Monitor becomes loose or detached from skin, patient should press the monitor back in place.

If you do not hear a confirmation buzz, place the monitor up to your ear and press the button to confirm. If no buzz, return to manufacturer.

Safety Alert Descriptions
The symbol shown below identifies a potential hazard category.

⚠ **CAUTION**
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General Cautions
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⚠ **CAUTION: Damage to skin**
Instruct patients to remove electrodes carefully to avoid damaging their skin.

⚠ **CAUTION: Choking hazard**
This is a prescribed medical device. Keep device and packaging away from young children.

⚠ **CAUTION: Equipment damage**
Use only as directed. Tampering with the Carnation Ambulatory Monitor may render it unusable. There are no user serviceable parts.

⚠ **CAUTION: Equipment damage**
Use only with approved Bardy Diagnostics down-load station.

⚠ **CAUTION: May interfere with defibrillation therapy**
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⚠ **CAUTION: May interfere with MRI scanning**
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Do not use any parts that appear damaged. Check the Carnation Ambulatory Monitor for damage before using and reject any parts that have been damaged in shipping.

⚠ **CAUTION: Electrical shock**
This Carnation Ambulatory Monitor contains electrodes for monitoring ECG. Do not allow conductive parts of the electrodes on this device to come in contact with other conductive parts (including earth).

Processing Cautions
When the ECG device is returned to the processing center, these additional cautions apply.

⚠ **CAUTION: Contaminated surfaces**
When this device is returned to the reading center it will have been in contact with human skin. Follow the facility's procedures for appropriate handling.

⚠ **CAUTION: Battery may present environmental hazard**
This device contains a battery. Properly dispose of batteries in accordance with local regulations.

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The Carnation Ambulatory Monitor needs special cautions regarding EMC, and needs to be put into service according to provided information.

⚠ **CAUTION: Electromagnetic interference (EMI)**
Portable and mobile wireless communications equip-ment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect the Carnation Ambulatory Monitor and should be kept at least a distance of 3.3 meters away from the equipment. Position the Carna-tion Ambulatory Monitor away from other electrical or electronic equipment, if possible. The presence of strong EMI fields, or electronic, surgical, or diathermy instruments in close proximity to the ECG device may cause trace noise or input overload conditions.

The ECG device is compliant with IEC 60601-1-2 EMC immunity requirements.

Symbols
Bardy Diagnostics products display one or more of these symbols and warning labels.

SYMBOL	DESCRIPTION
	Attention: Consult accompanying documents
	Warning and caution symbol
	TYPE BF APPLIED PART: F-TYPE APPLIED PART complying with the specified requirements of 60601-1 to provide a higher degree of protec-tion against electric shock than that provided by TYPE B APPLIED PARTS. Note: TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.
IP23	Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 60 from vertical. Do not immerse in bathtub or swimming.
℞ ONLY	Sold by prescription only CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Single use only
	Manufacturer
	Use-by date.
131°F (55°C) 32°F (0°C)	Do not expose to temperatures outside of these limits. For more information on environmental parameters refer to the Technical Specifications section.

SYMBOL	DESCRIPTION
1060hPa 500hPa	Atmospheric pressure must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
95% 10%	Humidity must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
	Date of manufacture
	Contains electronic equipment. Dispose of properly in accordance with local regulations.
SN	Serial number
REF	Orderable part number
LOT	Batch code
CE	CE Mark signifying conformity to EU regulations
EC REP	EU authorized representative

Technical Specifications

ITEM	SPECIFICATION
PERFORMANCE CHARACTERISTICS	
ECG channels	1 channel
Recording capacity	48 hours
Recording format	Continuous
Service life	48 hours
Shelf life	24 months
ELECTRICAL CHARACTERISTICS	
Frequency response	0.67 Hz to 25 Hz
Differential range	4 mV
A/D sampling rate	171 Hz
POWER REQUIREMENTS	
Battery type	Lithium primary (coin cell)
Lithium content	Lithium content < 1 g
Heavy metal content	Within weight limits of 2006/66/EC
UN compliance	Complies with UN 3090
PHYSICAL CHARACTERISTICS	
Approximate Dimensions	178mm x 38mm x 14mm
Weight	<25g
Enclosure material	Medical grade thermoplastic polymer
Flammability rating	UL- HB

ITEM	SPECIFICATION
CLASSIFICATION	
Type of protection	Internally powered
Degree of protection	Type BF applied part
Protection against objects and water ingress	IP23 (Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 60° from vertical)
ELECTRODE CHARACTERISTICS	
Number of electrodes	2
Type	Electrode incorporating electrode gel and internal lead wire
Supplied as	Disposable, non-sterile
Lead wire length	11.6 cm (no patient contact)
Materials:	Electrode gel: Medical grade conductive synthetic Adhesive: Medical grade skin adhesive

ENVIRONMENTAL SPECIFICATIONS (ECG DEVICE)	
Operating temperature	50 °F to 113°F (10 °C to 45 °C)
Operating pressure	700 to 1060 hPa
Operating humidity	10% to 95% (non-condensing)
Transport temperature	14°F to 130°F (-10 °C to 55 °C)
Storage temperature	59°F to 77°F (15 °C to 25 °C)
Transport/Storage humidity	10% to 95% (non-condensing)
Transport/Storage pressure	500 to 1060 hPa
Standards compliance	Applicable sections of IEC 60601-1, 60601-1-2, 60601-1-11, 60601-2-47