EXACT IMAGING

Care, Cleaning and Use Guide

for EV9C

Transrectal Transducer

Part Number 6138
Revision 2.1

CE 2797

Preface

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Trademarks
Exact Imaging trademarks:
- ExactVu™
- Exact Imaging™

CIVCO® is a registered trademark of Civco Medical Solutions.

Warranty information
The ExactVu micro-ultrasound system and its accessories, when supplied and delivered new, in the original shipping container to the original purchaser, are covered under a one-year warranty that covers damage due to defective materials and workmanship, and/or failure of the equipment to operate in accordance with information in the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*.

Version information
System: ExactVu™ High Resolution Micro-Ultrasound System
Care, Cleaning and Use Guide for EV9C Transrectal Transducer Revision 2.1, *original instructions*

Table of Contents

Chapter 1 Introduction

Care, Cleaning and Use Guide for EV9C Transrectal Transducer provides instructions to properly care for, clean and use the Exact Imaging EV9C transducer. EV9C is a transrectal end-fire transducer with a 6.5 MHz center frequency.

The materials used in the construction of the EV9C transducer meet the applicable requirements of *ISO 10993-10 Biological evaluation of medical devices*.

It is important to use this *Care, Cleaning and Use Guide for EV9C Transrectal Transducer* in conjunction with other instructions for using the ExactVu system.

Document
Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System
Service Manual for ExactVu™ High Resolution Micro-Ultrasound System
Care, Cleaning and Use Guide for EV9C Transrectal Transducer (this document)
Approved Chemicals List for ExactVu Transducers

Table 1: ExactVu Labeling

Other documents that are provided with the ExactVu system include:

- Quick Reference Guide

Exact Imaging catalog references for configurations of the ExactVu micro-ultrasound system are:

- EV-SYS-220: ExactVu™ Micro-Ultrasound Imaging System (220V)
- EV-SYS-120: ExactVu™ Micro-Ultrasound Imaging System (120V)
- EV-SYS-100: ExactVu™ Micro-Ultrasound Imaging System (100V)

WARNING
EN-W1

Failure to follow safety instructions and/or using the equipment for purposes other than those described in ExactVu Labeling constitutes improper use.

WARNING
EN-W6

The use of this equipment is intended for qualified operators only.

Operators should be thoroughly familiar with the safe operation of this equipment, and should be knowledgeable in the use of urological ultrasound procedures in order to reduce discomfort and possible injury to the patient.

Read all *Labeling* provided with this equipment.

WARNING
EN-W2

Unauthorized modification of this equipment is not permitted and may compromise the safe operation of the equipment.

Chapter 2 General Information

1 Transducer Safety

The EV9C transducer meets FDA's *Track 3 Requirements*, per *Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* and the requirements of IEC 60601-2-37.

This section provides warnings and cautions that are specific to ExactVu transducers. For a complete list of warnings and cautions that apply to the ExactVu system, refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*.

1.1 General

WARNING
EN-W11

Service activities must only be performed by qualified Exact Imaging Technical Support technicians.

Opening an ExactVu transducer will void the terms of the warranty.

Only those maintenance activities specified in Chapter 5, section 2 on page 24 should be performed by operators.

1.2 Electrical Safety

WARNING
EN-W12

Inspect transducers often for cracks or openings in the transducer housing and connector, for scratches below the soak line, and for holes in and around the acoustic lens or other damage that could allow liquid entry.

If the transducer housing or connector shows any cracking or sign of damage, do not use the transducer. Contact Technical Support using the contact information in Appendix A.

Inspect the transducer cable for damage.

WARNING
EN-W88

In the event of a serious incident using ExactVu or any Exact Imaging medical device, contact Technical Support using the contract information in Appendix A as well as the authority governing medical device regulation in the locale.

A serious incident is an incident that directly or indirectly led or may have led to any of the following:

- The death of a patient, user or other person
- The temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- A serious public health threat

1.3 Interference

1.3.1 Electromagnetic (EMC)

WARNING
EN-W17

Do not activate the EV9C transducer outside the patient's body if it would not comply with electromagnetic compliance requirements. It may cause harmful interference with other nearby equipment.

1.4 Acoustic Safety

Safety information for the ExactVu micro-ultrasound system is provided in *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*. Acoustic output data and the display accuracy for these values are also provided, along with a recommendation to follow the *ALARA* (As Low as Reasonably Achievable) principle for the prudent use of ultrasound.

1.5 Bio-safety

1.5.1 Precautions Regarding TRUS (Transrectal Ultrasound) Procedures

WARNING
EN-W35

To prevent possible infection or contamination, the transducer must be reprocessed following the complete procedure in Chapter 4 prior to using it in another transrectal procedure.

Always use a sterile transducer sheath during a transrectal procedure.

CAUTION
EN-C13

It is important to prevent air bubbles from forming inside the sheath near the imaging surface of the transducer to avoid interfering with image quality.

CAUTION
EN-C15

Use only the needle guide identified in section 2.1 in this *Care, Cleaning and Use Guide for EV9C Transrectal Transducer*. Do not use any other needle guide with the EV9C transducer.

WARNING
EN-W4

Do not use a single-use needle guide or any component of a needle guide package or kit if its packaging indicates its expiry date has passed.

Operators are responsible for adhering to internal clinical procedures regarding checking for and disposing of expired consumables.

WARNING
EN-W5

Do not use a single-use needle guide or any component of a *CIVCO® Disposable Endocavity Needle Guide Kit* if the packaging appears to be compromised.

Discard the component and its packaging according to internal clinical procedures for safe disposal.

1.5.2 Precautions Regarding Biopsy Procedures

WARNING
EN-W31

The use of damaged transducers can result in injury or increased risk of infection. Inspect transducers often for sharp, pointed, or rough surface damage that could cause injury to the patient or increased risk of infection.

WARNING
EN-W29

If air bubbles or wrinkles occur near the point where the needle exits the needle guide, the sheath may be punctured by the needle during biopsy, and may increase the risk of infection.

If the sheath is punctured by the needle, discard it and re-prepare the transducer as described in Chapter 3, section 1.3 on page 11.

2 Transducer Parts, Accessories, Consumables

Figure 1 identifies parts of the EV9C transducer (Exact Imaging Catalog Reference EV-9C).

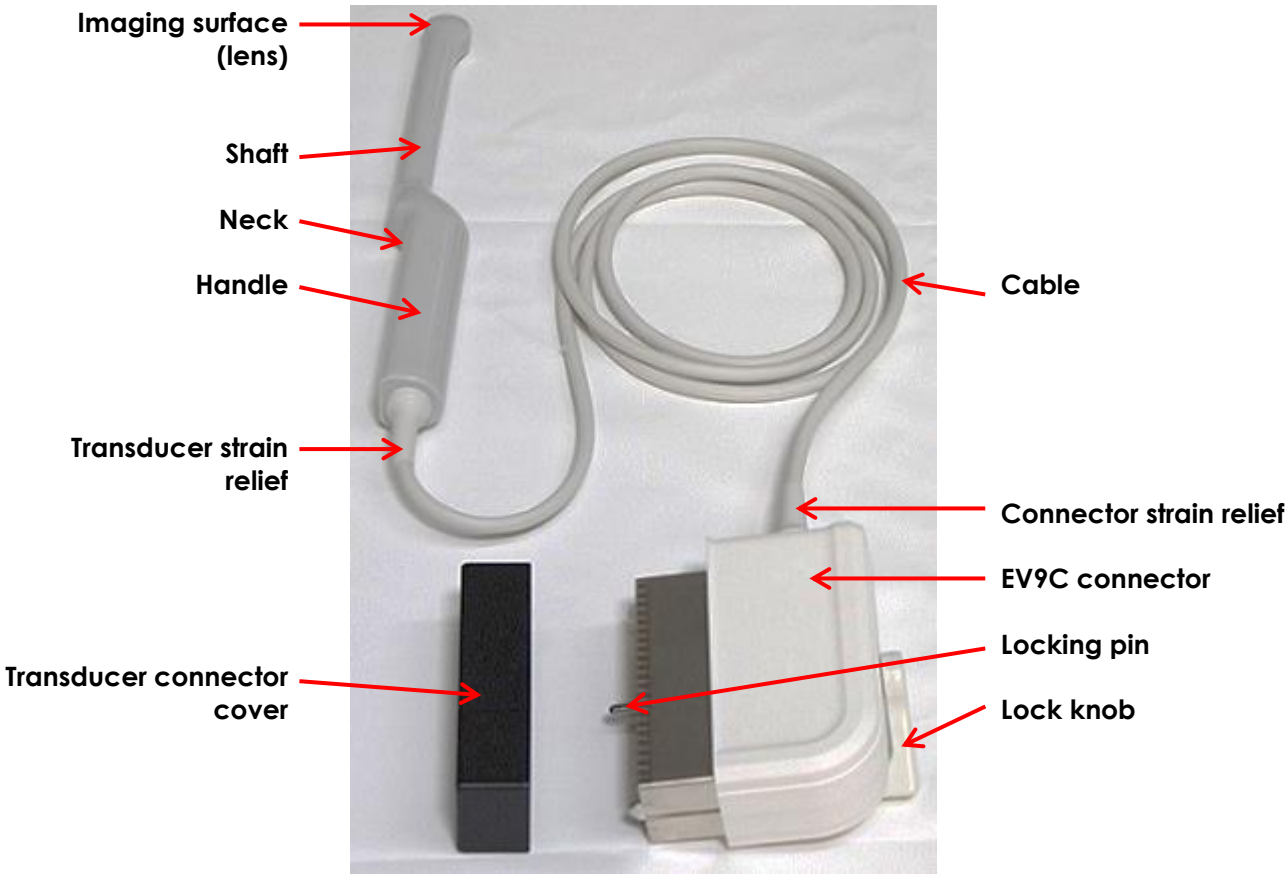

Figure 1: Exact Imaging EV9C Transducer

2.1 CIVCO® Disposable Endocavity Needle Guide

For biopsy procedures using the EV9C transducer, only use the CIVCO® *Disposable Endocavity Needle Guide*. It is manufactured by CIVCO, and may be ordered from CIVCO or one of its distributors. It is available in a 24-pack configuration (CIVCO catalog reference 610-1274-24).

Exact Imaging recommends using an 18-gauge biopsy needle.

NOTE
EN-N4

Biopsy and anesthesia needles are not available from Exact Imaging.

NOTE
EN-N5

Operators are responsible for selection of biopsy and anesthesia needles, and for adhering to internal clinical procedures regarding checking for and disposing of expired needles.

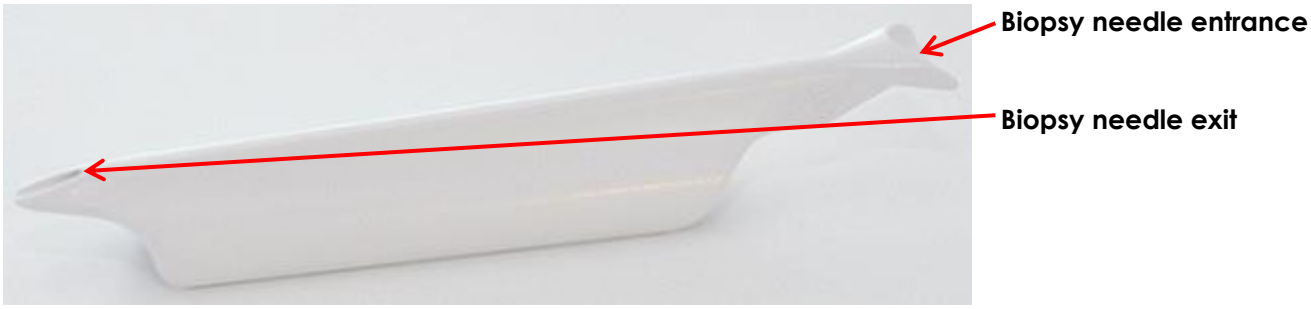

Figure 2: CIVCO Disposable Endocavity Needle Guide

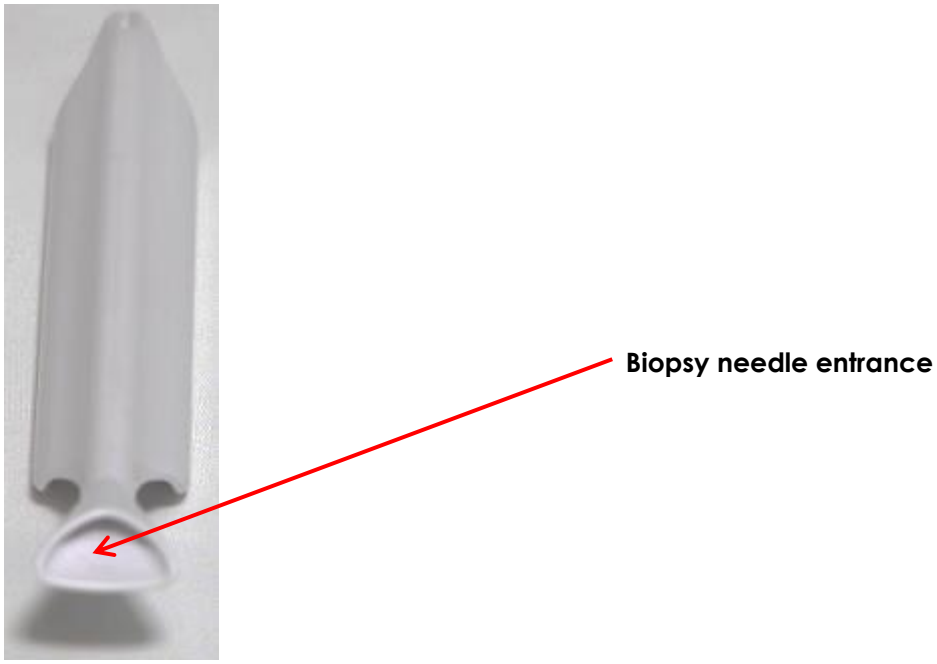

Figure 3: CIVCO Disposable Endocavity Needle Guide

WARNING EN-W4	Do not use a single-use needle guide or any component of a needle guide package or kit if its packaging indicates its expiry date has passed. Operators are responsible for adhering to internal clinical procedures regarding checking for and disposing of expired consumables.
WARNING EN-W5	Do not use a single-use needle guide or any component of a *CIVCO® Disposable Endocavity Needle Guide Kit* if the packaging appears to be compromised. Discard the component and its packaging according to internal clinical procedures for safe disposal.

2.2 Latex-free Sheath

For biopsy procedures using the EV9C transducer that require the use of a latex-free sheath, use one of the following options from CIVCO or one of its distributors.

- Sterile 2.6 x 30 cm (1" x 11.8") NeoGuard cover 50-pack (CIVCO catalog reference 610-1038)
- Sterile 2.6 x 30 cm (1" x 11.8") NeoGuard cover 24-pack (CIVCO catalog reference 610-843)
- Sterile 2.0 x 30 cm (0.8" x 11.8") NeoGuard cover 24-pack (CIVCO catalog reference 610-1126)

3 Specifications

Refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for the operating and storage environment for the EV9C transducer.

Chapter 3 Preparing for Imaging

1 Prepare the Transducer for a Procedure

The ExactVu system is designed to optimize the workflow of a standard TRUS procedure. It is designed based on the assumption that its operators will wish to begin imaging as quickly as possible. Once the ExactVu system is turned on, it initializes, the software launches, and it may be used for imaging immediately.

WARNING
EN-W28

Always wear gloves when handling sterile items.

NOTE
EN-N68

Always use an adequate amount of sterile gel on the transducer imaging surface.

NOTE
EN-N12

Connect the transducer to the ExactVu system according to internal clinical protocols for biopsy.

This procedure assumes the transducer will be connected to the ExactVu system after it has been prepared for the procedure in which it will be used.

The following section describes how to prepare the EV9C transducer for *Prostate Biopsy* studies. The following items are needed to prepare the transducer:

- CIVCO Disposable Endocavity Needle Guide for use with Exact Imaging EV9C transducer (Refer to 2.1 on page 8)
- Biopsy needle
- Anesthesia needle
- Ultrasound gel
- Surgical (or similar) gloves
- Sterile transducer sheaths (Exact Imaging recommends using the sheaths provided with the CIVCO Disposable Endocavity Needle Guide, or latex-free sheaths for patients identified as latex-sensitive or talc-sensitive. Refer to Chapter 2, section 2.2 on page 9 for information about recommended latex-free sheaths.

1.1 Exam Type

Each transducer is associated with a specific exam type. Details for the EV9C transducer are specified in the following table:

Transducer Name	General Description	Broadband Frequency	ExactVu Exam Types
EV9C	9 MHz Prostate Transrectal Transducer (Curved)	8.5 MHz	Prostate TRUS Biopsy

Table 2: ExactVu Transducers and Exam Types

WARNING
EN-W27

Always use the specific transducer for the intended exam type.

1.2 Presets

The *image preset* settings for each transducer/exam type combination have been optimized on the ExactVu system to give the best compromise between producing low acoustic output and sufficient power to view features on the structure being imaged as quickly as possible. The default imaging settings for all transducers are intended to ensure the lowest acoustic output during imaging. The default imaging settings for all transducers are displayed on the imaging screen when a transducer, exam type and image preset are selected.

1.3 Preparing the Transducer

These instructions are applicable to:

- Preparing the EV9C transducer for imaging-only procedures (i.e., imaging procedures without biopsy)
- Preparing the EV9C transducer for biopsy procedures

WARNING
EN-W28

Always wear gloves when handling sterile items.

WARNING
EN-W31

The use of damaged transducers can result in injury or increased risk of infection. Inspect transducers often for sharp, pointed, or rough surface damage that could cause injury to the patient or increased risk of infection.

WARNING
EN-W47

Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some patients.

Exact Imaging recommends using a latex-free sheath for patients identified as latex-sensitive or talc-sensitive.

Be prepared to treat allergic reactions promptly.

CAUTION
EN-C13

It is important to prevent air bubbles from forming inside the sheath near the imaging surface of the transducer to avoid interfering with image quality.

To prepare the EV9C transducer for imaging-only procedures:

- Use the instructions in the *Reference Guide* provided in the CIVCO *Disposable Endocavity Needle Guide* package, specifically referencing the section:
    - Covering the Transducer

To prepare the EV9C transducer for biopsy procedures:

- Use the instructions in the *Reference Guide* provided in the CIVCO *Disposable Endocavity Needle Guide* package, specifically referencing the sections:
    - Covering the Transducer
    - Attaching Needle Guide to Transducer
    - Covering the Transducer and Needle Guide

If a recommended latex-free transducer sheath is used instead of those provided in the CIVCO *Disposable Endocavity Needle Guide* package, use the instructions provided with the latex-free transducer sheath.

WARNING
EN-W81

Do not use a CIVCO *Disposable Endocavity Needle Guide* if it does not attach securely and correctly to the transducer.

WARNING
EN-W29

If air bubbles or wrinkles occur near the point where the needle exits the needle guide, the sheath may be punctured by the needle during biopsy, and may increase the risk of infection.

If the sheath is punctured by the needle, discard it and re-prepare the transducer as described in this section.

2 Connecting the Transducer to the ExactVu System

NOTE
EN-N12

Connect the transducer to the ExactVu system according to internal clinical protocols for biopsy.

This procedure assumes the transducer will be connected to the ExactVu system after it has been prepared for the procedure in which it will be used.

WARNING
EN-W8

Do not unfreeze imaging and hold the transducer in mid-air without there being ultrasound gel applied to the transducer's imaging surface. Doing so may cause the temperature on the imaging surface to heat, and possibly cause injury to the patient.

To connect the transducer to the ExactVu system:

1. On the transducer connector, turn the *lock knob* to its *unlocked* position (refer to the *unlocked icon* in Figure 5).
2. Line up the locking pin (see Figure 6) on the transducer connector with the lock notch on the transducer connector slot on the ExactVu system (see Figure 7) so that the transducer connector is oriented as indicated in Figure 8.
3. Push in the connector and then turn the *lock knob* to the *locked* position (see Figure 8).

   When the ExactVu system is powered on, the *Transducer Element Check* is automatically executed when a transducer is connected. Refer to Refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for information about the *Transducer Element Check*.

Figure 4: Transducer Locked Icon

Figure 5: Transducer Unlocked Icon

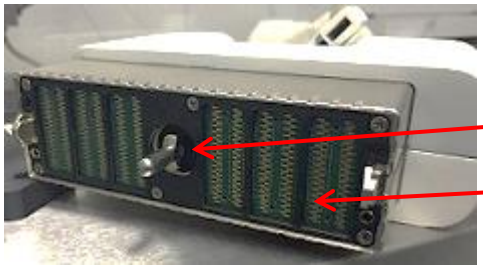

Figure 6: Locking Pin

Figure 7: Lock Notch on the Transducer Connector Slot

Figure 8: Transducer Connector Orientation

3 Performing a Biopsy Procedure

NOTE
EN-N82

Refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for information about set-up operation for the ExactVu system.

Perform the biopsy procedure according to internal clinical protocols for prostate biopsy. Observe all cautions and warnings related to performing prostate biopsy using the ExactVu system.

3.1 Removing the Needle Guide from the Transducer

After a TRUS (transrectal ultrasound) procedure, remove and discard the needle guide.

To remove the needle guide from the EV9C transducer:

- Unclip the needle guide and discard it according to internal clinical procedures for safe disposal.

WARNING
EN-W36

Never reuse a single-use needle guide.

After use, discard the needle guide according to internal clinical procedures for safe disposal.

3.2 Removing and Discarding Other Consumables

To remove and discard other consumables:

1. Remove the sheath from the transducer and discard it according to internal clinical procedures for safe disposal.
2. Discard surgical gloves used during the procedure according to internal clinical procedures for safe disposal.
3. Wipe off any material or gel from the EV9C transducer using a damp, soft cloth.

CAUTION
EN-C24

Use caution to prevent damaging the transducer during cleaning and to avoid scratching the transducer's *imaging surface* (i.e., the lens). This will damage the transducer.

WARNING
EN-W20

To avoid cross-contamination, follow all internal clinical procedures for infection control for personnel and equipment.

WARNING
EN-W49

To ensure optimal performance of the ExactVu™ High Resolution Micro-Ultrasound system, use only the accessories and consumables listed in this document and other ExactVu instructions for use listed in Table 1 on page 4.

Verify that the supply of consumables for upcoming procedures is adequate. Replacement needle guides and sheaths may be ordered from your local distributor. Refer to Appendix A for contact information.

4 Disconnecting the Transducer

To disconnect the transducer from the ExactVu system:

1. On the connected transducer connector, turn the lock knob to its *unlocked* position.
2. Grip the connector firmly and pull it out of the transducer connector slot.
3. Line up the locking pin on the transducer connector with the notch on the *transducer connector cover*.
4. Attach the *transducer connector cover* to the connector (to protect the contact pads).

Figure 9: Unlocked Transducer Connector Lock Knob

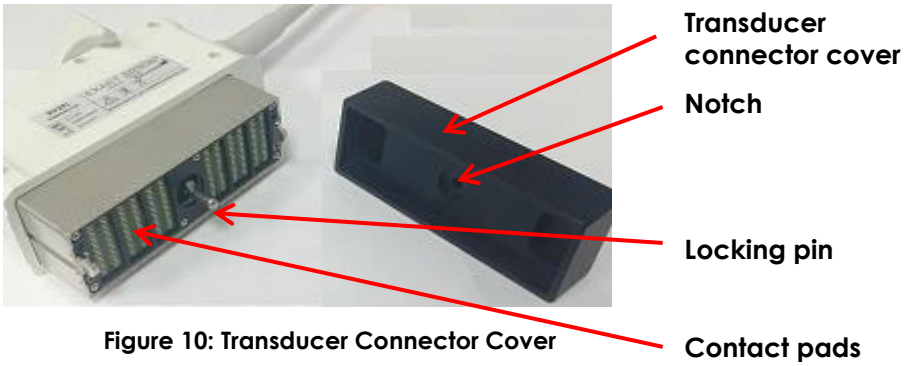

Figure 10: Transducer Connector Cover

CAUTION
EN-C23

Do not transport or clean the transducer without attaching the *transducer connector cover*. Do not allow debris or moisture to come in contact with the contact pads on the connector. Failure to use the *transducer connector cover* can cause damage to the transducer.

Chapter 4 Transducer Reprocessing

ExactVu operators have an obligation and responsibility to provide the highest possible degree of infection control to patients, co-workers and themselves. It is the responsibility of the operator to verify and maintain the effectiveness of the infection control procedures in use. Adequate reprocessing is necessary to prevent disease transmission.

Always use sterile, legally marketed transducer sheaths for transrectal procedures.

These reprocessing procedures do not apply to single-use devices. Single-use devices (including the needle guide and biopsy needle) and sheaths should be discarded according to internal clinical procedures.

NOTE
EN-N71

For the parts of the transducer that are not in contact with the sheath, cleaning with a low-alcohol surface disinfecting wipe is sufficient. Refer to *Approved Chemicals List for ExactVu Transducers*.

Equipment must be cleaned as appropriate for the procedure prior to each use.

- After every use, follow proper procedures for cleaning and waste disposal.
- Follow the procedure in this section for cleaning and disinfecting the EV9C transducer, and observe all warnings, cautions and notes.

WARNING
EN-W80

The use of damaged transducers may cause the reprocessing procedure in this chapter to be ineffective.

If the transducer shows any sign of damage, do not use the transducer. Contact Technical Support using the contact information in Appendix A.

1 General

High-level disinfection is required for semi-critical devices, defined by the *Centers for Disease Control and Prevention* as "a reusable medical device that comes in contact with mucus membranes or non-intact skin". This definition is applicable to ultrasound transducers used in transrectal ultrasound (TRUS) procedures, as well as applicable accessories.

In typical TRUS procedures, the use of a sterile gel and a transducer sheath are recommended. This procedure dictates that the parts of the transducer that are in contact with the sheath are to be cleaned following guidelines for semi-critical devices, i.e., using high-level disinfection.

WARNING
EN-W21

Failure to properly clean transducers and applicable accessories carries a risk of infection to patients, due to residual microbial contamination.

WARNING
EN-W40

Reprocess transrectal transducers as soon as possible after use to prevent biological materials from drying on them.

CAUTION
EN-C60

The EV9C transducer is not designed and validated to withstand a reprocessing method that uses an automated reprocessor.

2 Preparation for Transducer Reprocessing

2.1 Required items

Several items are required to perform the reprocessing procedure for the EV9C transducer:

- Cleaner and disinfectant (For a list of cleaning agents and disinfectants approved by Exact Imaging for use in this procedure, refer to *Approved Chemicals List for ExactVu Transducers*)
- Soft cloths and a soft-bristled brush (such as a nail brush)
- A cleaning station, including a cleaner container, a high-level disinfection container, and a rinse container for using cleaning and disinfection solutions
- Transducer connector cover (to protect the contact pads on the EV9C connector from moisture)
- Personal protective equipment (sterile gloves, surgical mask) as recommended by the manufacturer of the cleaning agent or disinfectant

NOTE
EN-N81

Cleaning and disinfecting chemicals are not available from Exact Imaging.

2.2 EV9C Transducer Parts Requiring Reprocessing

This procedure calls for washing, soaking and rinsing the transducer in various solutions. In all cases, the transducer should be exposed to solution levels that are approximately half-way up the handle (refer to *soak level* in Figure 11).

Contact should not be made between the solution and the electrical components of the transducer.

CAUTION
EN-C22

At no time should the transducer connector, the cable, or transducer strain relief be washed, rinsed or soaked in any solution.

Exposure of these parts to excessive moisture can cause damage to the transducer.

CAUTION
EN-C50

Proper handling conditions during reprocessing means:

- the transducer lens is protected
- the transducer cable is not twisted
- the transducer connector cover is attached to the transducer connector

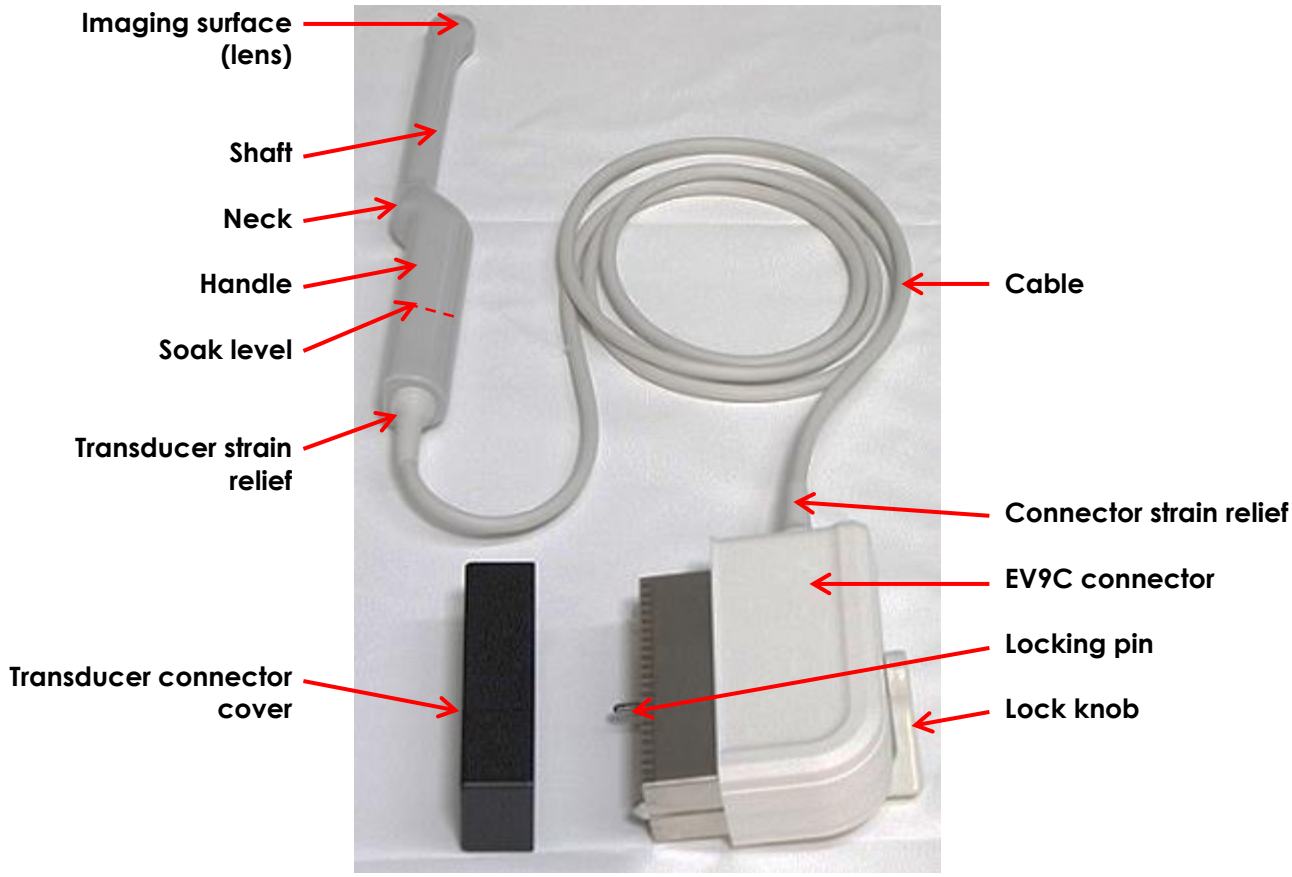

Figure 11: Exact Imaging EV9C Transducer

3 Surface Cleaning for the EV9C Transducer

Surface cleaning is required for non-critical devices, defined by *Centers for Disease Control and Prevention* as "a reusable medical device that comes in contact with unbroken skin and does not penetrate it".

This part of the procedure consists of:

- Cleaning non-critical parts of the EV9C transducer using a cleaner disinfectant, and is to be performed after every study and before first use

It is applicable to:

- The parts of the EV9C transducer that do not come into contact with the sheath during a TRUS procedure, or in other words, the part of the transducer that is above the *soak level* (refer to Figure 11).

NOTE
EN-N83

In this procedure, *above* the soak level means the direction *away* from the imaging surface (refer to Figure 11).

To surface clean parts of the EV9C transducer that are above the soak level:

1. With a low-alcohol surface disinfecting wipe, wipe the outside of the *EV9C connector*.

2. With a low-alcohol surface disinfecting wipe, wipe the *cable* in a direction towards the transducer handle.
3. With a low-alcohol surface disinfecting wipe, thoroughly wipe the area from the *transducer strain relief* to the *soak level.*

NOTE
EN-N148

Over time, minor scratches may develop on the transducer handle. These areas should be wiped using a low-alcohol wipe.

4. Dispose of used cleaning materials as per internal clinical procedures for safe disposal.

4 Cleaning and Disinfecting the EV9C Transducer

This part of the procedure consists of:

- Cleaning and high-level disinfecting applicable parts of the EV9C transducer, and is to be performed after every study

It is applicable to:

- The parts of the EV9C transducer that come into contact with the sheath during a TRUS procedure, or in other words, the part of the transducer that is on or below the *soak level* (refer to Figure 11). For parts above the *soak level* (including the cable), refer to section 3.

4.1 Cleaning the EV9C Transducer

NOTE
EN-N73

Ensure that the cleaner has not passed its expiry date.

CAUTION
EN-C23

Do not transport or clean the transducer without attaching the *transducer connector cover*. Do not allow debris or moisture to come in contact with the contact pads on the connector. Failure to use the *transducer connector cover* can cause damage to the transducer.

1. Rinse the transducer in warm running water to remove excess debris.
2. Use a soft cloth to wipe the transducer in water or the cleaner to remove all visible residue before soaking.
    - If any residue has dried on the transducer, gently rub it with moist gauze, sponge or a soft-bristled brush (such as a nail brush) to completely remove the residue.

NOTE
EN-N148

Over time, minor scratches may develop on the transducer handle, neck and shaft. These areas should be brushed using a soft-bristled brush during cleaning of the transducer.

CAUTION
EN-C24

Use caution to prevent damaging the transducer during cleaning and to avoid scratching the transducer's *imaging surface* (i.e., the lens). This will damage the transducer.

3. When using a cleaning solution:
    - Prepare the cleaning solution according to the manufacturer's instructions for the selected cleaner using the dilution ratio specified. Refer to *Approved Chemicals List for ExactVu Transducers*.

NOTE
EN-N76

The cleaning solution may be prepared in advance of cleaning the transducer.

    - Fill the *cleaner container* with a sufficient volume of cleaning solution for the EV9C transducer to be immersed to the *soak level* indicated in Figure 11.
    - Immerse the EV9C transducer in the cleaning solution to the *soak level* indicated in Figure 11.

CAUTION
EN-C25

Do not immerse the EV9C transducer beyond its soak level.

4. Expose the EV9C transducer according to the instructions for use provided by the manufacturer of the cleaner listed in the *Approved Chemicals List for ExactVu Transducers*.
    - If any residue remains, gently rub the transducer with moist gauze, sponge or a soft-bristled brush (such as a nail brush) to completely remove the residue.

NOTE
EN-N148

Over time, minor scratches may develop on the transducer handle, neck and shaft. These areas should be brushed using a soft-bristled brush during cleaning of the transducer.

5. Rinse the EV9C transducer in running water, following the rinsing instructions provided by the manufacturer of the cleaner.
6. Dispose of the water used for rinsing.
7. Using a soft cloth, rough-dry the transducer.
8. Dispose of the used cleaning solution/wipe.

4.2 High-level Disinfection of the EV9C Transducer

NOTE
EN-N74

Ensure the high-level disinfectant to be used has not passed any of its expiry dates. Check (as applicable):

- The manufacturer's expiry date marked on the container
- The maximum allowable time after opening the container
- The maximum allowable reuse time

NOTE
EN-N75

Follow any manufacturer's instructions regarding verification of minimum effective concentrations.

1. When using a solution:
    - Prepare the high-level disinfectant according to the concentrations recommended by the manufacturer.
    - Fill the high-level disinfection container with a sufficient volume of high-level disinfectant for the EV9C transducer to be immersed to the *soak level* indicated in Figure 11.
    - Immerse the EV9C transducer in the high-level disinfectant to the *soak level* indicated in Figure 11.

CAUTION
EN-C25

Do not immerse the EV9C transducer beyond its *soak level*.

2. Expose the EV9C transducer according to the instructions for use provided by the manufacturer of the high-level disinfectant listed in the *Approved Chemicals List for ExactVu Transducers*.

CAUTION
EN-C46

Do not exceed the duration of exposure recommended in the instructions for use provided by the manufacturer of the high-level disinfectant.

3. Fill the *rinse container* with a sufficient volume of sterile water or tap water for the EV9C transducer to be immersed to its *soak level*.
4. Rinse the EV9C transducer with sterile water or tap water, unless otherwise indicated by the manufacturer's instructions.
5. Rinse the transducer in large volumes of fresh water, following the manufacturer's rinsing instructions for the high-level disinfectant that was used.

WARNING
EN-W39

Ensure no residual disinfectant remains on the transducer after disinfection. This could cause serious side effects for the patient.

Three separate large volume rinses are required.

6. Check the entire EV9C transducer for any residual organic material.
    - If any is present below the *soak line*, repeat all steps for cleaning and disinfecting the transducer.
    - If any is present above the *soak line*, repeat all steps for surface cleaning the transducer.
    - If it is not possible to reprocess the EV9C transducer for any reason, contact Technical Support using the contact information in Appendix A.
7. Gently dry the EV9C transducer with a soft, clean cloth.

5 Inspecting the EV9C Transducer after Reprocessing

Inspect the EV9C transducer for signs of deterioration due to cleaning and disinfection after every application of the cleaning and disinfecting procedure.

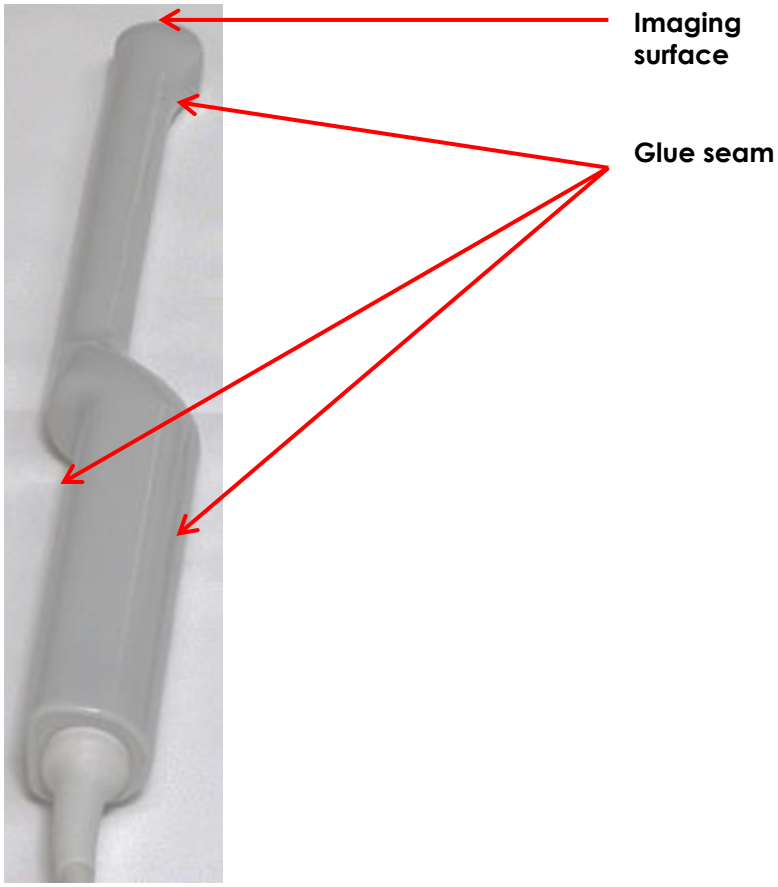

Figure 12: The EV9C Transducer

There should be:

- No scratches on the *imaging surface*
- No scratches on the transducer
- No gap in any *glue seam*

- No cracks in the handle or shaft
- No cracks in the connector

Over time, cleaning and disinfecting the EV9C transducer may cause discoloration. Discoloration does not affect the performance of the EV9C transducer; however, if considerable discoloration is observed over a period of approximately six months, contact Technical Support using the contact information in Appendix A.

NOTE
EN-N69

If you notice any deterioration in the performance of any ExactVu transducer, contact Technical Support using the contact information in Appendix A.

6 Storing the EV9C transducer after Reprocessing

Store the transducer in a transducer holder on the ExactVu system cart as described in Chapter 5, section 2.2 on page 26.

WARNING
EN-W22

Before putting a reprocessed transducer into the transducer holder on the ExactVu system cart, ensure the holder is clean to avoid the risk of cross-contamination.

WARNING
EN-W79

To avoid the risk of cross-contamination, never store a transducer in the transducer holder on the ExactVu system cart unless the transducer has been reprocessed as described in Chapter 4.

7 Disposing of Consumed Cleaning and Disinfection Materials

Dispose of used cleaning materials as per internal clinical procedures for safe disposal.

Do not exceed the maximum reuse period or expiry dates for any cleaning or disinfecting chemicals.

Dispose of cleaning and disinfecting chemicals after the reuse period indicated by the manufacturer.

Chapter 5 Caring for the EV9C Transducer

Caring for ExactVu transducers includes careful handling, maintenance, reprocessing (as described in Chapter 4).

1 Careful Handling of the EV9C Transducer

In order to prevent damage, the EV9C transducer must be handled carefully at all times. This includes:

- During use
- While performing the reprocessing procedure
- While performing maintenance activities
- During storage

Follow these guidelines when handling the EV9C transducer:

- Keep the transducer cable away from the system's *castors* when the ExactVu system is being moved
- Do not kink or acutely bend the cable
- Handle the transducer connector with care and always use the *transducer connector cover* when it is not connected to the ExactVu system
- Do not let any part of the transducer impact or drop onto a hard surface

2 Maintenance of ExactVu Transducers

2.1 Inspecting the Transducer

The EV9C transducer must be checked regularly to maintain a high level of safety and performance. Exact Imaging recommends an inspection procedure that consists of two parts:

- Visual inspection
- Check the needle guide alignment

2.1.1 Visual Inspection of the EV9C Transducer

Perform a visual inspection of the EV9C transducer every three months.

What to look for	Where to look
Cracking (there should be none)	Transducer shaft
Scratches (there should be none)	• Imaging surface (lens) • Transducer shaft • Transducer neck • Transducer handle

What to look for	Where to look
Cracking or gap opening (there should be none)	• Transducer strain relief • Connector strain relief (at connection to cable) • Connector strain relief (at connection to connector) • Entire length of transducer cable
Gap (there should be none)	Top of the connector, near the lock knob
Scratches on the contact pads (there should be none)	EV9C connector, at the interface to the ExactVu system cart (near the locking pin)

Table 3: EV9C Transducer Inspection

If you observe mechanical damage during the visual inspection, contact Technical Support using the contact information in Appendix A.

WARNING
EN-W80

The use of damaged transducers may cause the reprocessing procedure in Chapter 4 to be ineffective.

If the transducer shows any sign of damage, do not use the transducer. Contact Technical Support using the contact information in Appendix A.

2.1.2 Checking the EV9C Needle Guide Alignment

The procedure to check the alignment of the EV9C needle guide consists of comparing the alignment of the biopsy needle in the *needle guide* with the *needle guide overlay* displayed on the ExactVu system's *imaging screen*. Exact Imaging recommends checking the EV9C needle guide alignment when improper alignment is suspected.

Required equipment:

- Tank of water
- Biopsy needle
- Needle guide for use with the EV9C transducer

To check the needle guide alignment:

1. Fill a suitable tank with water.
2. Attach the needle guide to the EV9C transducer using the procedure in Chapter 3, section 1.3 on page 11.
3. Turn on the ExactVu system and connect the EV9C transducer.
4. Immerse the EV9C transducer's *imaging surface* into the water.

CAUTION
EN-C25

Do not immerse the EV9C transducer beyond its soak level.

5. Start imaging to produce an image on the monitor.
    - Use the *Gain* knob to adjust the gain as required.

6. Using the ExactVu system's *Workflow* touch screen, enable *Biopsy sub-mode*.

NOTE
EN-N82

Refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for information about set-up operation for the ExactVu system.

7. Insert the biopsy needle into the needle guide. Align the markings on the needle to the needle guide entrance, and observe the needle guide overlay on the image.

   The needle tip on the image should align with the corresponding marking on the needle guide overlay.

If the alignment is not acceptable, contact Technical Support using the contact information in Appendix A.

WARNING
EN-W48

The *needle guide overlay* provides an indication of the expected needle path. The needle tip echo should be monitored at all times to identify any deviation from the desired path.

WARNING
EN-W41

After checking the EV9C needle guide alignment, the reprocessing procedure in Chapter 4 must be performed prior to using the transducer in a procedure.

2.2 Storing the EV9C Transducer

EV9C transducers may be stored in the transducer holders on the front of the ExactVu system cart.

WARNING
EN-W22

Before putting a reprocessed transducer into the transducer holder on the ExactVu system cart, ensure the holder is clean to avoid the risk of cross-contamination.

WARNING
EN-W79

To avoid the risk of cross-contamination, never store a transducer in the transducer holder on the ExactVu system cart unless the transducer has been reprocessed as described in Chapter 4.

CAUTION
EN-C36

When storing a transducer in the transducer holder, ensure the cable does not get twisted.

To store the EV9C transducer on the ExactVu system cart:

1. Place the clean and dry transducer in one of the transducer holders.
2. Guide the slack part of the cable through the cable guide.

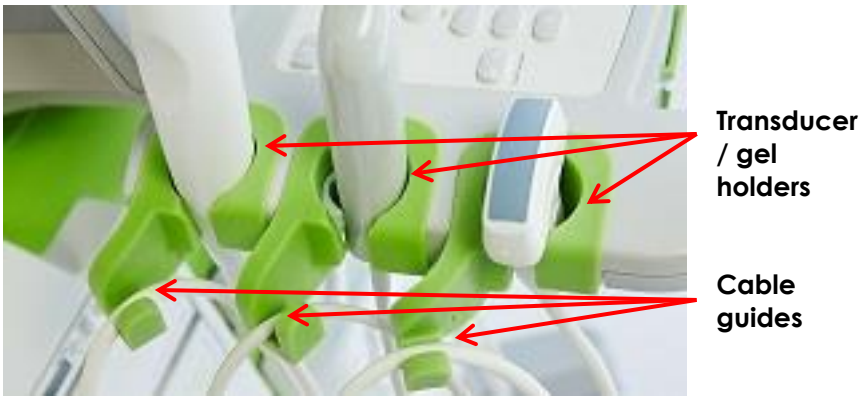

Figure 13: Transducer / Gel Holders and Cable Guides

To store the EV9C transducer in its shipping package:

1. Connect the *transducer connector cover* to the *transducer connector*.
2. Place the *transducer connector* inside the shipping package.
3. Straighten the transducer cable, and then place the transducer in the shipping package.
4. Place the transducer cable inside the shipping package, ensuring that no part of the cable is twisted.

To package the EV9C transducer for returning to Exact Imaging:

1. Follow the complete procedure for cleaning and disinfecting the EV9C transducer provided in provided in Chapter 4.
2. Follow the instructions provided above for storing the EV9C transducer in its shipping package.
3. Seal the shipping package with packing tape.
4. Contact Technical Support using the contact information in Appendix A to obtain an RMA (Return Material Authorization) number. The RMA number must appear on the shipping label.

Follow these guidelines when storing the EV9C transducer:

- Make sure that the transducer is clean and dry before storing it
- Refer to *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for environmental conditions for storage
- Store the transducer separately from other instruments so it won't get damaged accidentally

CAUTION
EN-C38

To prevent damage during storage and transportation, keep the transducer within the temperature range specified in the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*.

Follow these guidelines when transporting the EV9C transducer:

- Do not transport the transducer without the *transducer connector cover* attached
- Do not allow debris or moisture come in contact with the contact pads on the *transducer connector*

CAUTION
EN-C37

To prevent damage, Exact Imaging recommends securely packaging transducers during transportation.

Chapter 6 Service and Repair

1 Working Life of ExactVu Transducers

The EV9C transducer, when used with proper care, is designed for a working lifetime of whichever comes first of 5 years or 2500 reprocessing cycles. The working lifetime for Exact Imaging transducers is based on their ability to withstand the effects of cycles of the reprocessing procedure without degrading functionality or compromising safety. Therefore, the lifetime is determined beginning when the transducer is first reprocessed.

Where internal clinical procedures are not already in place for tracking the number of reprocessing cycles performed on a device, Exact Imaging recommends the use of a tally marking system for the EV9C transducer.

2 Technical Support

If problems arise with the EV9C transducer or it does not perform as expected, contact Technical Support using the contact information in Appendix A.

Chapter 7 Disposal

When the EV9C transducer reaches the end of its working life, national rules for discarding/recycling the relevant material in each individual country must be followed.

The EV9C transducer is designed for a working lifetime of 5 years, when used with proper care. The ExactVu system is designed for a working lifetime of 5 years.

For consumables such as needle guides, sheaths, gloves and needles, follow internal clinical procedures for safe disposal.

If further information is required regarding disposal of the ExactVu system and its accessories, contact Technical Support using the contact information in Appendix A.

Appendix A Contact Information

For Technical Support

Region	Phone number	Email address
All regions except North America – contact EDAP TMS	+33(0)472 153 150	ccc@edap-tms.com
North America (US, CA, MX) – contact EDAP USA	+1 (512) 852-9685	service@edap-usa.com

For ordering consumables and other accessories and parts

Region	Phone number	Email address
France (FR), Belgium (BE) - contact EDAP TMS	+33(0)472 153 150	order@edap-tms.com
Germany (DE), Austria (AT), Switzerland (CH) - contact EDAP TMS GmbH	+49 461 80 72 590	order@edap-tms.de
North America (US, CA, MX) - contact EDAP USA	+1 (512) 832-7956	order@edap-usa.com
All other regions - contact EDAP TMS	+33(0)472 153 150	order@edap-tms.com