EXACT IMAGING

Care, Cleaning and Use Guide

for EV5C

Abdominal Transducer

Part Number 6852
Revision 1.8

CE 2797

Preface

Exact Imaging Inc.
7676 Woodbine Avenue, Unit 15
Markham, ON L3R 2N2, Canada
+1.905.415.0030
info@exactimaging.com

Emergo Europe

Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

EDAP TMS
4, rue du Dauphiné
69120 Vaulx-en-Velin
France

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

CIVCO® is a registered trademark of Civco Medical Solutions.
Verza™ and VerzaLink™ are trademarks 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 EV5C Abdominal Transducer Revision 1.8, *original instructions*

Table of Contents

Chapter 1 Introduction

Care, Cleaning and Use Guide for EV5C Abdominal Transducer provides instructions to properly care for, clean and use the Exact Imaging EV5C transducer. EV5C is an end-fire transducer with a 3.5 MHz center frequency for use in abdominal imaging and kidney biopsy.

The materials used in the construction of the EV5C transducer meet the applicable requirements of *ISO 10993-1 Biological evaluation of medical devices*.

It is important to use this *Care, Cleaning and Use Guide for EV5C Abdominal 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 EV5C Abdominal 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 urological ultrasound procedures using transducers 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 EV5C 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 26 should be performed by operators.

WARNING
EN-W77

The EV5C transducer is not intended for direct use on the heart.

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

1.2 Electrical Safety

WARNING
EN-W12

Inspect transducers often for cracks or openings in the transducer housing and connector, for scratches, 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.

1.3 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.

1.4 Bio-safety

1.4.1 General Bio-safety

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 procedure.

1.4.2 Precautions Regarding Kidney, Bladder and Pelvis Procedures

WARNING
EN-W77

The EV5C is not intended for direct use on the heart.

CAUTION
EN-C15

Use only the needle guide identified in section 2.1 in this *Care, Cleaning and Use Guide for EV5C Abdominal Transducer*. Do not use any other needle guide with the EV5C transducer.

1.4.3 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 12.

1.4.4 Precautions Regarding Consumables

WARNING
EN-W4

Do not use a single-use needle guide or any component of the *CIVCO® Verza™ Guidance System* 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 the *CIVCO® Verza™ Guidance System* if the packaging appears to be compromised.

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

2 Transducer Parts, Accessories, Consumables

Figure 1 identifies parts of the EV5C transducer (Exact Imaging Catalog Reference EV-5C).

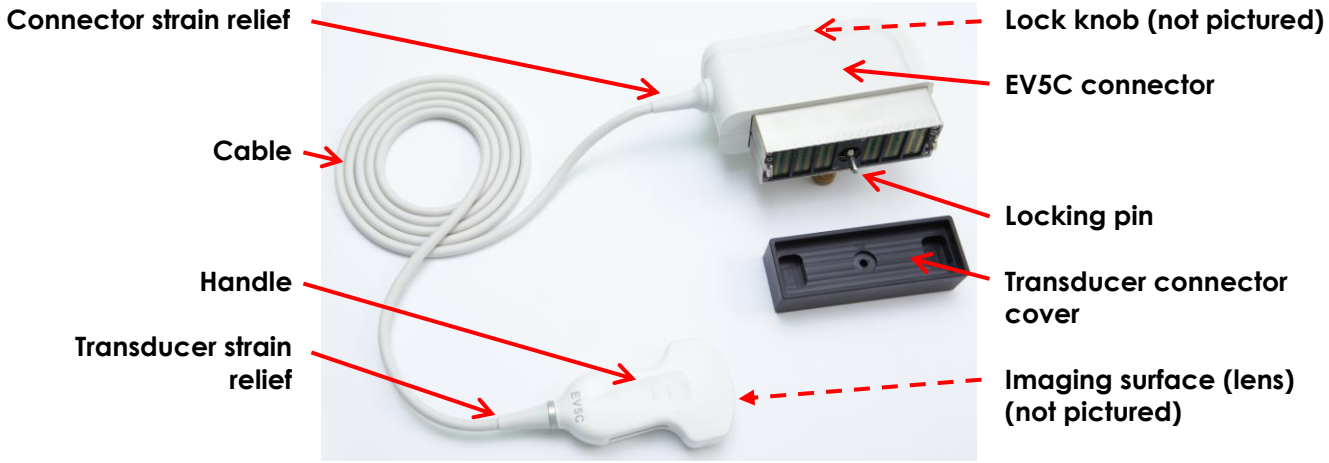

Figure 1: Exact Imaging EV5C Transducer

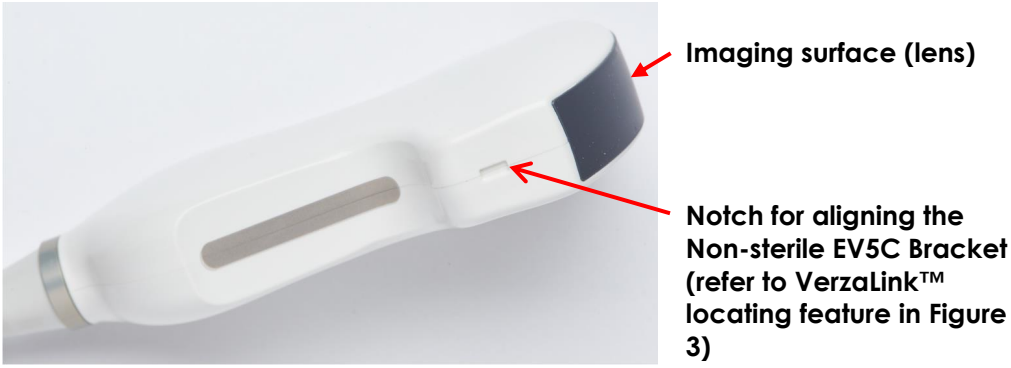

Figure 2: Exact Imaging EV5C Transducer

2.1 CIVCO® Non-sterile EV5C Bracket with CIVCO Verza™ Guidance System

For biopsy procedures using the EV5C transducer, only use the *Non-sterile EV5C bracket* with the *Verza™ Guidance System*. Both parts are manufactured by CIVCO and may be ordered from your local distributor. Refer to Appendix A for contact information.

The Non-sterile EV5C bracket consists of two parts:

- Bracket
- Latch

The *latch* secures the bracket to the EV5C transducer. The *VerzaLink™ locating feature* (refer to Figure 3) aligns with the *notch* on the EV5C transducer (refer to Figure 2).

Figure 3: CIVCO Non-sterile EV5C Bracket

Figure 4: Verza Needle Guide

The needle guide provided by the *Verza Guidance System* supports the following:

- a range of needle gauges: 25g, 22g, 21g, 20g, 18g, 17g, 16g, 15g
- five different positioning angles
- a range of depths from 2 - 15 cm

The *Verza Guidance System* is sold in a *sterile procedure kit* with the Verza needle guide, a telescopically-folded CIV-Flex™ cover, gel packet and colored elastic bands. It is available in a 24-pack configuration (CIVCO catalog reference 610-1500-24).

The *Non-sterile EV5C bracket* and the *Verza Guidance System* are available together as a kit (CIVCO catalogue reference 670-036) that consists of:

- one Non-sterile EV5C bracket
- five *Verza Guidance System* sterile procedure kits

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 5: Non-sterile EV5C bracket with Verza Needle Guide

WARNING
EN-W4

Do not use a single-use needle guide or any component of the *CIVCO® Verza™ Guidance System* 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 the *CIVCO® Verza Guidance System* if the packaging appears to be compromised.

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

WARNING
EN-W78

The Non-sterile EV5C bracket must be reprocessed before first use and after every use.

Do not attach the Non-sterile EV5C bracket to the EV5C transducer if it has not been reprocessed. Perform the reprocessing procedure referenced in section 4 on page 15 prior to attaching it to the EV5C transducer.

2.2 Latex-free Sheath

For biopsy procedures using the EV5C transducer that require the use of a latex-free sheath, Exact Imaging recommends the following sheath from Exact Imaging or one of CIVCO's distributors:

- Sterile 14 x 91.5cm (5.5" x 36") telescopically-folded CIV-Flex cover (3D) 24-pack (CIVCO catalog reference 610-542)

3 Specifications

Refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for the operating and storage environment for the EV5C 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 imaging 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.

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 EV5C transducer for Abdomen, Pelvis and Kidney studies. The following items are needed to prepare the transducer:

- CIVCO Non-sterile EV5C bracket with Verza Guidance System (Refer to section 2.1 on page 8)
- Biopsy needle (if required)
- Ultrasound gel
- Surgical (or similar) gloves
- Sterile 14 x 91.5cm (5.5" x 36") telescopically-folded CIV-Flex cover (3D) (provided in the Verza Guidance System sterile procedure kit)

1.1 Exam Type

Each transducer is associated with a specific exam type. Details for the EV5C transducer are specified in the following table:

Transducer Name	General Description	Broadband Frequency	ExactVu Exam Types
EV5C	3.5 MHz Abdominal Transducer (Curved)	5 MHz	Abdomen Kidney Pelvis (default)

Table 2: ExactVu Transducers and Exam Types

WARNING
EN-W27

Always use the correct 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 EV5C transducer for imaging-only procedures (i.e., imaging procedures without biopsy)
- Preparing the EV5C 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 EV5C transducer for use in a procedure:

- Prior to first use, follow the procedure in Chapter 5, section 2.1.2 on page 27 to perform the following task:
    - Verifying the Non-sterile EV5C Bracket / Verza Needle Guide Needle Path
- Use the instructions in the *Cleaning, Disinfecting and Sterilizing Bracket* section of the *Verza Guidance System Reference Guide* for procedures to perform the following task:
    - Reprocess the Non-sterile EV5C Bracket prior to first use
- Use the instructions in the *Using Guidance System* section of the *Verza Guidance System Reference Guide* for procedures to perform the following tasks:

- Attach the Non-sterile EV5C Bracket to the EV5C transducer
- Apply the sheath
- Prepare the Verza needle guide
- Attach the Verza needle guide to the Non-sterile EV5C Bracket

WARNING
EN-W81

Do not use the EV5C Bracket and/or Verza 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 7).
2. Line up the locking pin (see Figure 8) on the transducer connector with the lock notch on the transducer connector slot on the ExactVu system (see Figure 9) so that the transducer connector is oriented as indicated in Figure 10.
3. Push in the connector and then turn the *lock knob* to the *locked* position (see Figure 10).

   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 6: Transducer Locked Icon

Figure 7: Transducer Unlocked Icon

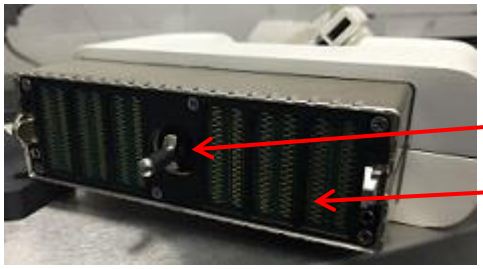

Figure 8: Locking Pin

Figure 9: Lock Notch on the Transducer Connector Slot

Figure 10: 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.

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 procedure.

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

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

4 Removing the Needle Guide and Non-sterile EV5C Bracket from the Transducer

After an imaging procedure, remove and discard the needle guide, and then remove the Non-sterile EV5C Bracket from the EV5C transducer.

To remove the needle guide from the Non-sterile EV5C Bracket:

1. Use the instructions in the *Removing Guidance System* section of the *Verza Guidance System Reference Guide* to remove the needle guide from the Non-sterile EV5C Bracket.
2. Discard the needle guide according to internal clinical procedures for safe disposal.
3. Remove the sheath from the transducer 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.

To remove the Non-sterile EV5C Bracket from the EV5C transducer:

1. Use the instructions in the *Removing Guidance System* section of the *Verza Guidance System Reference Guide* to remove the Non-sterile EV5C Bracket from the EV5C transducer.
2. Use the instructions in the *Cleaning, Disinfecting and Sterilizing* section of the *Verza Guidance System Reference Guide* to reprocess the Non-sterile EV5C Bracket.
3. Discard surgical gloves used during the procedure according to internal clinical procedures for safe disposal.

To prepare the EV5C transducer for reprocessing:

1. Wipe off any material or gel from the EV5C transducer using a damp, soft cloth.
2. Perform the reprocessing procedure for the EV5C transducer according to the instructions in Chapter 4 on page 18.

WARNING
EN-W40

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

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-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.

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.

5 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 11: Unlocked Transducer Connector Lock Knob

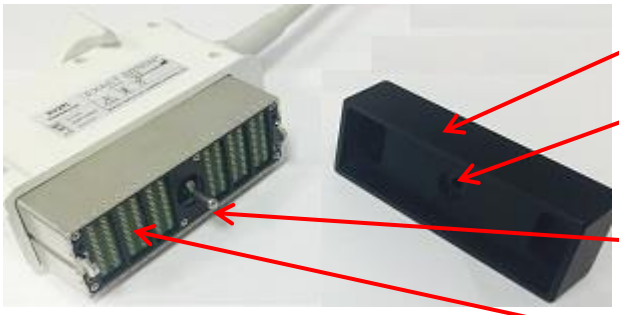

Figure 12: Transducer Connector Cover

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 biopsy procedures. (Refer to Chapter 2, section 2.2 on page 10 for information about the sheath recommended for use with the *Non-sterile EV5C Bracket* and *Verza Guidance System*.)

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.

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 reprocessing the EV5C transducer, and observe all warnings, cautions and notes.
- Reprocessing instructions for the *Non-sterile EV5C Bracket* are provided in the *Cleaning, Disinfecting and Sterilizing Bracket* section of the *Verza Guidance System Reference Guide*.

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 abdominal transducers used in biopsy procedures.

A non-critical device is defined as "a device whose surfaces contact only intact skin and do not penetrate it". This definition is applicable to abdominal transducers used in imaging-only procedures.

This reprocessing procedure dictates that thorough cleaning is required for non-critical devices and semi-critical devices, followed by disinfection for semi-critical devices.

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

CAUTION
EN-C60

The EV5C transducer is not designed and validated to withstand a reprocessing method that uses an automated reprocessor.

Further information about infection control may be found in clinical guidelines published by the *Centers for Disease Control and Prevention* as well as in internal clinical procedures specific to your health-care facility.

To obtain additional information about reprocessing or infection control procedures for the EV5C transducer, contact Technical Support using the contact information in Appendix A.

2 Preparation for Transducer Reprocessing

2.1 Required items

Prior to reprocessing the EV5C transducer, remove and discard single-use consumables (i.e., the sheath, needle guide, biopsy needle and gloves as applicable) and remove the *Non-sterile EV5C Bracket* as described in Chapter 3, section 4 on page 15.

Several items are required to perform the reprocessing procedure for the EV5C 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)
- Sterile gauze
- 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 EV5C 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 EV5C 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 14).

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

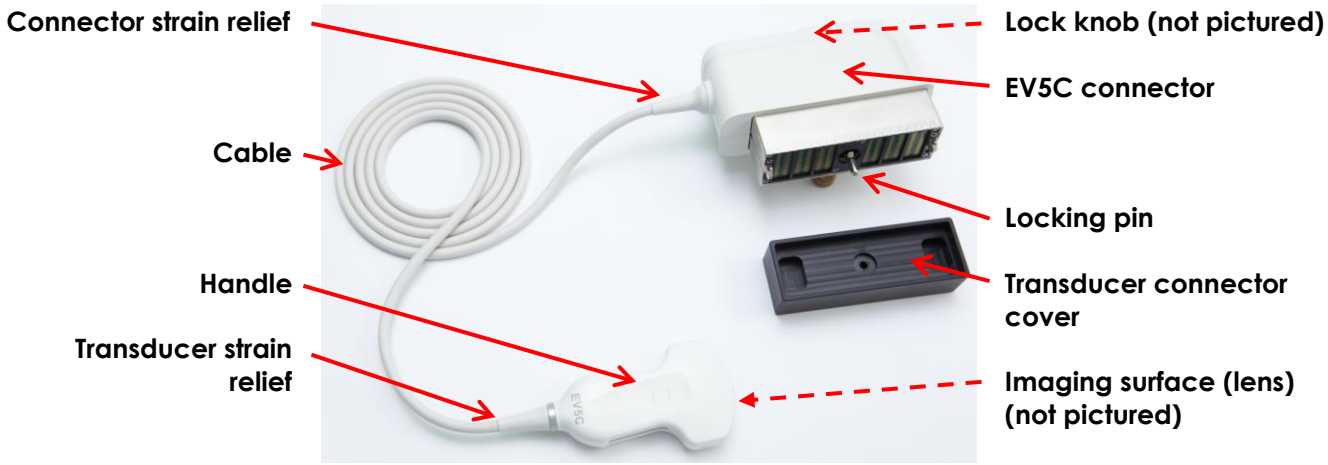

Figure 13: Exact Imaging EV5C Transducer

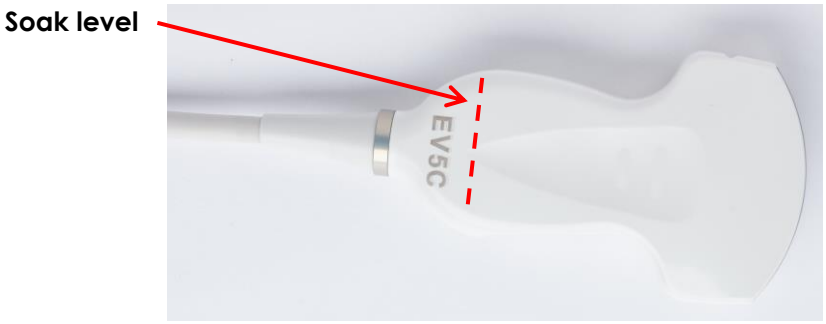

Figure 14: EV5C Soak Level

3 Surface Cleaning for the EV5C 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 the EV5C transducer, to be performed after every study

It is applicable to:

- The parts of the EV5C transducer that are above the *soak level* (refer to Figure 14).

NOTE
EN-N83

In this procedure, *above* the soak level means the direction *away* from the imaging surface (refer to Figure 14).

To surface clean parts of the EV5C transducer that are above the soak level:

1. With a low-alcohol surface disinfecting wipe, wipe the outside of the *EV5C 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 Reprocessing the EV5C Transducer

This part of the procedure consists of:

- Cleaning and high-level disinfecting applicable parts of the EV5C transducer, and is to be performed after every study and before first use

It is applicable to:

- The parts of the EV5C transducer that are on or below the *soak level* (refer to Figure 14). For parts above the *soak level* (including the cable), refer to section 3.

4.1 Cleaning the EV5C 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.
    - Thoroughly rinse any indents.

2. Use a suitable brush to brush 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. 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. Clean the EV5C transducer by using a cleaning solution and wipe as needed.
    - 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.

    - Expose the EV5C transducer to the cleaning solution to the *soak level* indicated in Figure 14 and use a wipe as needed.
    - 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. These areas should be brushed using a soft-bristled brush during cleaning of the transducer.

4. Rinse the EV5C transducer in running water, following the rinsing instructions provided by the manufacturer of the cleaner.
5. Dispose of the water used for rinsing.
6. Using a soft cloth, rough-dry the transducer.
7. Dispose of the used cleaning solution/wipe.

4.2 High-level Disinfection of the EV5C 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 EV5C transducer to be immersed to the *soak level* indicated in Figure 14.
    - Immerse the EV5C transducer in the high-level disinfectant to the *soak level* indicated in Figure 14.
    - While immersed, wipe the entire transducer with sterile gauze. While wiping:
        - Pay special attention to the lens and any channels or other areas that may be difficult for the high-level disinfectant to contact.
        - Ensure all air bubbles are removed from the surface of the transducer by flushing with a syringe.

CAUTION
EN-C25

Do not immerse the EV5C transducer beyond its *soak level*.

2. Expose the EV5C 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 EV5C transducer to be immersed to its *soak level*.
4. Rinse the EV5C 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 EV5C 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 EV5C transducer for any reason, contact Technical Support using the contact information in Appendix A.
7. Gently dry the EV5C transducer with a soft, clean cloth.

5 Inspecting the EV5C Transducer after Reprocessing

Inspect the EV5C transducer for signs of deterioration due to cleaning and disinfection after every application of the reprocessing procedure.

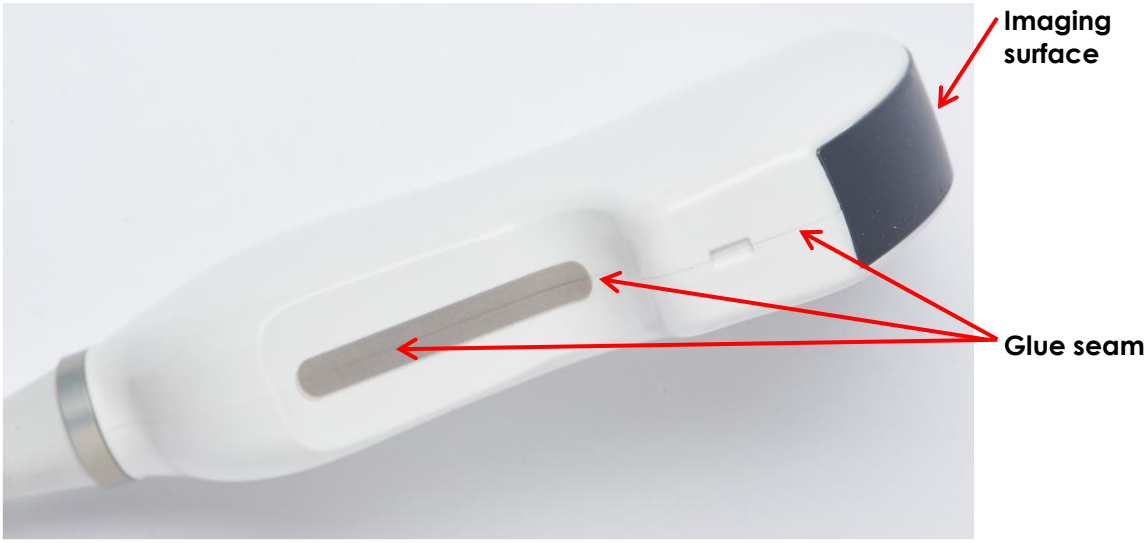

Figure 15: The EV5C Transducer

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
- No cracks in the connector

Over time, cleaning and disinfecting the EV5C transducer may cause discoloration. Discoloration does not affect the performance of the EV5C 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 EV5C transducer after Reprocessing

Store the reprocessed transducer in a transducer holder on the ExactVu system cart as described in Chapter 5, section 2.2 on page 28.

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.

Store the reprocessed *Non-sterile EV5C Bracket* in accordance with internal clinical procedures for storing sterilized devices.

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 EV5C Transducer

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

1 Careful Handling of the EV5C Transducer

In order to prevent damage, the EV5C 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 EV5C 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 EV5C 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 path

2.1.1 Visual Inspection of the EV5C Transducer

Perform a visual inspection of the EV5C transducer every three months.

What to look for	Where to look
Cracking (there should be none)	Everywhere on the transducer
Scratches (there should be none)	Everywhere on the transducer, including the imaging surface (lens)

What to look for	Where to look
Cracking or gap opening (there should be none)	• Entire length of transducer cable • Along the glue seam of transducer housing on both sides (refer to Figure 15) • Between the imaging surface (lens) and the transducer body • Transducer strain relief (at connection to cable and at connection to connector) • Connector strain relief (at connection to connector) *Note: there may be a gap between the connector strain relief and its connection to the cable.*
Gap (there should be none)	Top of the connector, near the lock knob
Scratches on the contact pads (there should be none)	EV5C connector, at the interface to the ExactVu system cart (near the locking pin)

Table 3: EV5C 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 Verifying the Non-sterile EV5C Bracket / Verza Needle Guide Needle Path

The purpose of this procedure is to verify the needle path between the Non-sterile EV5C Bracket and Verza needle guide and the center line of the EV5C transducer.

The procedure involves comparing the alignment of the biopsy needle in the Verza needle guide with the *needle guide overlay* displayed on the ExactVu system's *imaging screen*. Exact Imaging recommends verifying the needle path for the Non-sterile EV5C Bracket and Verza needle guide when improper alignment is suspected.

Required equipment:

- Tank of water
- Biopsy needle
- Needle guide for use with the EV5C transducer

To verify the needle path:

1. Fill a suitable tank with water.
2. Attach the Non-sterile EV5C Bracket and Verza needle guide set to position 3 to the EV5C transducer using the referenced procedure in Chapter 3, section 1.3 on page 12.
3. Turn on the ExactVu system and connect the EV5C transducer.
4. Immerse the EV5C transducer's *imaging surface* into the water.

CAUTION
EN-C25

Do not immerse the EV5C 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 the *needle guide overlay* for position 3.

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 biopsy needle path. The needle tip echo should be monitored at all times to identify any deviation from the desired path.

WARNING
EN-W41

After verifying the EV5C needle path, the reprocessing procedure in Chapter 4 must be performed prior to using the transducer in a procedure.

2.2 Storing the EV5C Transducer

EV5C 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.

CAUTION
EN-C36

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

To store the EV5C 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.

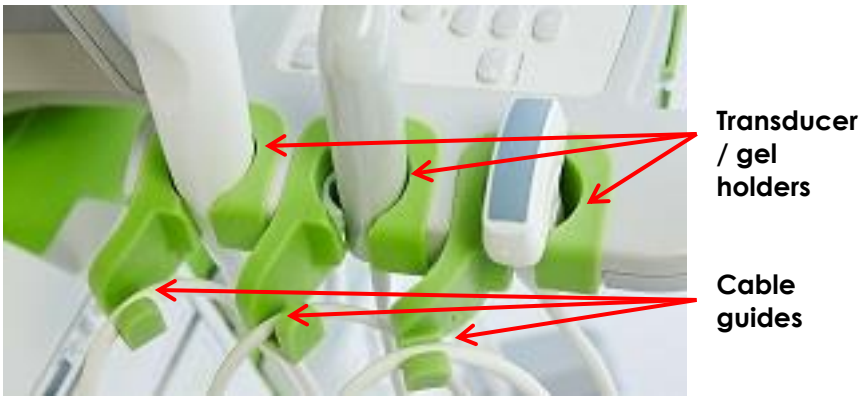

Figure 16: Transducer / Gel Holders and Cable Guides

To store the EV5C 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 EV5C transducer for returning to Exact Imaging:

1. Follow the complete procedure for reprocessing the EV5C transducer provided in provided in Chapter 4.
2. Follow the instructions provided above for storing the EV5C 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 EV5C 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 EV5C 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 EV5C transducer, when used with proper care, is designed for a working lifetime of whichever comes first of 5 years or 2500 reprocessing cycles (with a maximum of 500 disinfection 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 EV5C transducer.

2 Technical Support

If problems arise with the EV5C transducer or it does not perform as expected, contact Technical Support using the contact information in Appendix A.

Chapter 7 Disposal

When the EV5C transducer reaches the end of its working life, national rules for discarding/recycling the relevant material in each individual country must be followed.

The EV5C 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