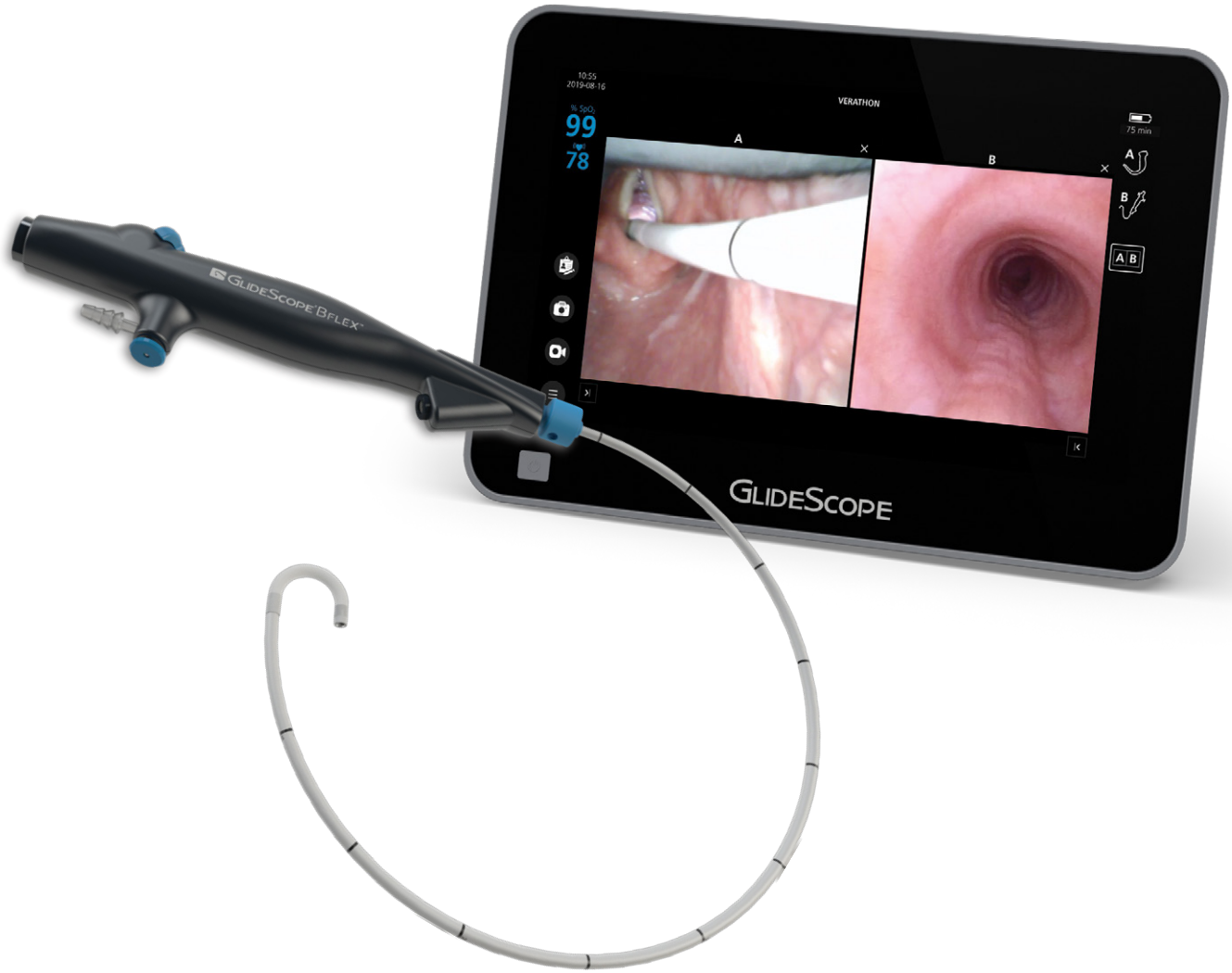

BFlex™

Single-Use Bronchoscopes for GlideScope® Core™

Operations & Maintenance Manual

BFlex
verathon

BFlex

Single-Use Bronchoscopes for GlideScope Core

Operations & Maintenance Manual

Effective: April 22, 2024

Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

Contact Information

To obtain additional information regarding your GlideScope system,
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Not all Verathon Inc. products shown or described in this manual are available for commercial sale in all countries.
Note: The BFlex 2.8 is not CE marked for sale in the following geographies: EU

Information in this manual may change at any time without notice. For the most up-to-date information, see the documentation available at verathon.com/service-and-support.

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Important Information

Product Description

The GlideScope BFlex Single-Use bronchoscope system includes the following components:

- Single-use bronchoscope
- Reusable monitor
- Reusable cable

The GlideScope BFlex device is a single-use bronchoscope which, when connected to a video monitor through a reusable cable, is intended to provide real time viewing and recording for a wide range of airway procedures.

Note: This manual covers the single-use bronchoscope and the reusable cable. For information about using a video monitor, refer to that monitor's Operations & Maintenance Manual.

Kasutusotstarve

Ühekordselt kasutatavad bronhoskoobid GlideScope BFlex on mõeldud kasutamiseks koos videomonitori, toiteta endoskoopiatarvikute ja muude lisaseadmetega, mida on vaja endoskoopia tegemiseks hingamisteedes ja trahheobronhiaalpuus.

Intended Patient Population

The GlideScope BFlex Single-Use system is for use in a hospital environment. The GlideScope BFlex bronchoscope is a single-use device designed for use in adults, with the BFlex 2.8 also designed for pediatric use (6 months to 6 years). It has been verified and validated for the following endotracheal tube (ETT) and endoscope accessory (EA) sizes:

MODEL	MINIMUM ETT INSIDE DIAMETER	EA MINIMUM WORKING CHANNEL WIDTH
BFlex 2.8	4.0 mm	—
BFlex 3.8	5.0 mm	1.2 mm
BFlex 5.0	6.0 mm	2.1 mm
BFlex 5.8	7.0 mm	3.0 mm

Note: There is no guarantee that instruments selected solely using these instrument dimensions will be compatible in combination.

Intended Use Environment and User Population

The GlideScope BFlex Single-Use Bronchoscope is intended for in-hospital use by physicians trained in the use of endoscopic equipment.

Contraindications

The GlideScope BFlex 2.8 Single-Use Bronchoscope does not have a working channel and therefore cannot be used for therapeutic purposes.

Essential Performance

The essential performance of the GlideScope BFlex Single-Use bronchoscope is visualization of the airway and tracheobronchial tree as well as certain procedures such as suction and use of endoscopic accessories sized to work with the dimensions of the bronchoscope.

Environments of Intended Use

The GlideScope BFlex Single-Use bronchoscope system is intended to be used in professional healthcare environments such as hospitals.

Ettekirjutuse avaldus

Ettevaatust: Föderaalseadused (Ameerika Ühendriigid) lubavad seda seadet müüa ainult arstil või arsti ettekirjutusel.

Notice to All Users

Verathon recommends that all users do the following:

- Read the manual before using the equipment.
- Obtain instruction from a qualified individual.
- Practice using the bronchoscope on a mannequin before clinical use.
- Acquire clinical training experience on patients without airway abnormalities.

Hoiatused ja ettevaatusabinõud

Hoiatused viitavad, et seadme kasutamine või väärkasutamine võib tekitada vigastusi, surma või muid tõsiseid kõrvaltoimeid. *Ettevaatusabinõud* viitavad, et seadme kasutamine või valesti kasutamine võib tekitada probleeme, nt talitlushäireid, rikkeid või seadme kahjustusi.

Hoiatused: Kasutamine

HOIATUS

Seadme muutmine ei ole lubatud.

HOIATUS

Enne iga kasutuskorda veenduge, et seade töötaks õigesti ja sellel ei oleks kahjustusi. Ärge kasutage seda toodet, kui seade näib kahjustatud olevat. Pöörduge hooldustööde tegemiseks kvalifitseeritud töötajate poole.

Veenduge alati, et alternatiivsed hingamisteede juhtimise meetodid ja seadmed oleksid käepärast.

Teavitage Verathoni klienditeenindust kõigist oletatavatest vigadest. Vaadake kontaktteavet veebilehelt verathon.com/service-and-support.

HOIATUS

Ärge kasutage toiteadapterit tuleohtlike anesteetikumide läheduses.

HOIATUS

Verathon ei ole analüüsinud süsteemi sobivust keskkondadega, kuhu on paigaldatud magnetresonantstomograafia seadmed. Seetõttu peab süsteemi omanik vältima seadme sattumist magnetresonantskeskkonda.

HOIATUS

Süsteemi loodud ja kasutatavad videosignaalid on mõeldud ainult seadme positsioneerimiseks. Ärge kasutage süsteemi mistahes patoloogia ainsa diagnostilise meetodina.

HOIATUS

Ärge kasutage seda süsteemi defibrillatsiooni ajal.

HOIATUS

Ärge kasutage seda süsteemi patsiendile väga tuleohtlike anesteetiliste gaaside manustamiseks. Selline kasutamine võib patsienti vigastada.

HOIATUS

Ärge kasutage ühekordselt kasutatava bronhoskoobi või tarvikute sisestamisel, paigutamisel või eemaldamisel liiga palju jõudu. Takistuse korral liigse jõu kasutamine võib põhjustada toote kahjustumist, sealhulgas distaalotsa kahjustumist või eraldumist.

HOIATUS

Bronhoskoobi otsa kahe piirkonna, mis patsiendiga kokku puutuvad, temperatuur võib tavapärase töö käigus ületada temperatuuri 41 °C (106 °F).

Esimene piirkond on otsas asuvat kaamerat ümbritsev valgust kiirgav piirkond. Näidatud viisil kasutamise korral on pidev kokkupuude selle piirkonnaga ebatõenäoline, sest kui kude selle piirkonnaga kokku puutuks, kaoks kasutamiskõlblik vaade. Seadmeid tuleb seejärel kohandada, et taastada töökaugus, mida on vaja kasutamiskõlbliku vaate jaoks.

Teine piirkond on otsa piirkond, mis ümbritseb kaamerat, ent on selle vaateväljast väljas. Pidev kokkupuude selle piirkonnaga on ebatõenäoline, sest toodet ei hoita tavaliselt pikemat aega paigal ning selle piirkonna ja sellega külgneva koe vahel on tavaliselt väike vaba liikumisruum.

Vältimaks termokahjustusi, nt limaskesta põletust, vältige pikaajalist ja pidevat kokkupuudet bronhoskoobi otsa nende piirkondadega.

HOIATUS

Imemisel ärge ületage vaakumi rõhutaset 85 kPa (638 mmHg). Vaakumi suurema rõhutaseme korral võib imemise katkestamine olla raskendatud.

HOIATUS

Ärge kasutage selle süsteemiga aktiivseid endoskoopiakomponente, nt lasersonde või elektrokirurgia seadmeid. Selline kasutamine võib patsienti vigastada või süsteemi kahjustada.

HOIATUS

Ärge sisestage tarvikuid, mille laius ületab toote tehniliste näitajate jaotises või bronhoskoobi pakendi sildil näidatud maksimaalse laiuse.

HOIATUS

Ärge lükake bronhoskoopi edasi, kui endoskoopiatarvikud ulatuvad distaalotsa avast välja. Sellest tingitud tarvikute liikumised võivad põhjustada patsiendile vigastusi. Sellest tingitud tarvikute liikumised võivad põhjustada patsiendile vigastusi.

HOIATUS

Olge patsiendist endoskoopiatarvikute eemaldamisel ettevaatlik.

HOIATUS

Enne bronhoskoobi väljatõmbamist pange distaalots neutraalsesse sirgesse asendisse. Ärge puudutage väljatõmbamise ajal juhthooba. Distaalotsa mistahes paindumine võib põhjustada patsiendile vigastusi.

HOIATUS

Kui kasutamise ajal peaks tekkima tõrge, katkestage protseduur. Asetage distaalots neutraalsesse sirgesse asendisse ja tõmmake seejärel bronhoskoop aeglaselt välja, seejuures juhthooba puudutamata.

HOIATUS

Bronhoskoopi edasi lükates või välja tõmmates, distaalotsa painutades või imedes vaadake alati tähelepanelikult videokuva. Kui te videokuva ei jälgi, võite patsienti vigastada.

HOIATUS

Enne bronhoskoobi kõrvaldamist veenduge, et kaamerast, distaalotsast või sisestustorust ei oleks ühtegi osa puudu.

Hoiatused: Töötlemine

HOIATUS

Ainult seoses kaabliga QuickConnect. Seda toodet tohib puhastada või desinfitseerida ainult GlideScope'i ja GlideRite'i toodete töötlemisjuhendis (osa number 0900-5032) esitatud heakskiidetud menetlustega. Verathon soovitab loetletud puhastus- ja desinfitseerimismeetodeid tõhususe või komponentide materjalidega sobivuse alusel.

HOIATUS

Ainult seoses kaabliga QuickConnect. Puhastustoodete saadavus on riigiti erinev ja Verathon ei suuda igal turul saadavaid tooteid katsetada. Küsige lisateavet Verathoni klienditeeninduselt. Vaadake kontaktteavet veebilehelt verathon.com/service-and-support.

HOIATUS

Ärge kasutage, töödelge ega steriliseerige ühekordselt kasutatavaid komponente korduvalt. Korduval kasutamisel, töötlemisel või steriliseerimisel võib tekkida seadme saastumise oht.

Hoiatused: Elektriseadis

HOIATUS

Elektriohutuse tagamiseks kasutage ainult kaasasolevat toiteallikat. Ühendage toitejuhe ja toiteadapter õigesti maandatud pistikupessa ning veenduge, et see oleks lahtiühendamiseks hõlpsasti ligipääsetav. Kasutage ainult Verathoni soovitatud tarvikuid ja välisseadmeid.

HOIATUS

Elektrilöögioht. Ärge püüdke süsteemi komponente avada. Avamine võib kasutajat raskelt vigastada või kahjustada seadet ja tühistada garantii. Kõikide hooldusvajaduste korral võtke ühendust Verathoni klienditeenindusega.

HOIATUS

Ainult toiteadapter: Elektrilöögioht. Ärge sukeldage toiteadapterit vette. Toiteadapteri puhastamisel kasutage korpuse välisküljel isopropüülalkoholiga niisutatud lappi.

HOIATUS

Muude kui Verathoni määratud või tarnitud tarvikute ja kaablite kasutamine võib põhjustada süsteemis elektromagnetilisi rikkeid, sh suurendada kiirgumist või vähendada häirekindlust. See võib põhjustada seadme talitlushäireid, protseduuri viivitusi või mõlemat.

HOIATUS

Kaasaskantavaid raadiosideseadmeid (sh välisseadmeid, nt antennikaableid ja välisantenne) ei tohi kasutada kuni 30 cm (12 tolli) kaugusel ühekordselt kasutatava bronhoskoobisüsteemi BFlex mistahes osast, k.a kaablitest, mille Verathon on määranud või mida Verathon pakub kasutamiseks selle süsteemiga. Kui vahekaugust ei hoita, võib süsteemi jõudlus halveneda ja kujutise kuvamine häiruda.

Ettevaatusabinõud: Kasutamine

ETTEVAATUST

Ärge kasutage bronhoskoopi sisaldava pakendi avamiseks nuga ega ühtegi muud teravat eset ning ärge kasutage bronhoskoopi, kui selle pakend on kahjustatud.

ETTEVAATUST

Enne endoskoopilise tarviku kasutamist veenduge, et see ühilduks bronhoskoobi töökanaliga.

ETTEVAATUST

Ärge hoidke BFlex-kotte otsese päikesevalguse käes.

ETTEVAATUST

Ainult Euroopa Liidu puhul: Kui selle toote kasutamise ajal juhtub tõsine vahejuhtum, peate viivitamatult teavitama ettevõtet Verathon (või selle autoriseeritud esindajat), selle liikmesriigi pädevat asutust, kus juhtum aset leidis, või mõlemat.

ETTEVAATUST

Ühekordselt kasutatavat bronhoskoopi BFlex 3.8 ei tohi kasutada 35 Fr Shiley endotrahheaaltorudega. BFlexi otsa ümbris võib kahjustuda või rebeneda.

Ettevaatusabinõud: Töötlemine

ETTEVAATUST

Ainult seoses kaabliga QuickConnect. Teavet soovitatavate töötlemislahuste käsitsemise ja kõrvaldamise kohta vaadake lahuse tootja juhistest.

ETTEVAATUST

Seadme püsiva kahjustamise oht. Toode on tundlik kuumuse suhtes, mis tekitab elektroonikale kahjustusi. Vältige süsteemi sattumist üle 45 °C (113 °F) temperatuuriga keskkonda ja ärge kasutage autoklaave ega pastöriseerimisseadmeid. Selliste meetodite kasutamine süsteemi puhastamiseks või desinfitseerimiseks tekitab seadmele püsivaid kahjustusi ja muudab garantii kehtetuks. Heakskiidetud puhastusprotseduuride ja -toodete nimekirja leiate GlideScope'i toodete töötlemisjuhendist (osa number 0900-5032).

Ettevaatusabinõud: Elektriseadis

ETTEVAATUST

Elektriliste meditsiiniseadmete kasutamisel on vaja elektromagnetilise ühilduvuse (EMC) tagamiseks rakendada erilisi ettevaatusabinõusid ning need seadmed tuleb paigaldada ja neid tuleb kasutada selles juhendis esitatud juhiste järgi. Vaadake lisateavet elektromagnetilise ühilduvuse jaotisest.

Vältige süsteemi GlideScope kasutamist teiste seadmete kõrval või nendega virnastatuna. Kui külgnev või virnastatud kasutamine on vajalik, jälgige süsteemi, et kontrollida selle normaalset talitlust konfiguratsioonis, milles seda kasutatakse.

Seade võib kiirata raadiosagedusenergiat ja väga tõenäoliselt ei tekita see kahjulikke raadiohäireid teistele läheduses asuvatele seadmetele. Ei ole tagatud, et konkreetses konfiguratsioonis häireid ei esine. Häirete esinemise ilminguks võib muu hulgas olla selle seadme või teiste seadmete talitluse halvenemine, kui seadmeid kasutatakse samal ajal. Kui see juhtub, proovige häired kõrvaldada ja taastada optimaalne pildikvaliteet, kasutades järgmisi meetmeid.

- Lülitage läheduses asuvaid seadmeid sisse ja välja, et teha kindlaks häire allikas.
- Muutke selle seadme või muude seadmete suunda või asukohta.
- Suurendage seadmete vahekaugust.
- Kui pildikvaliteet pole pärast häirete eemaldamist optimaalne, lülitage monitor välja ja uuesti sisse.
- Ühendage seade sellise vooluringi pistikupessa, millesse ei ole ühendatud teisi seadmeid.
- Kõrvaldage elektromagnethäire (EMI) või vähendage seda tehniliste lahendustega (nt varjestamisega).
- Ostke meditsiiniseadmed, mis vastavad standardi IEC 60601-1-2 EMC nõuetele.

Pidage meeles, et kaasaskantavad ja mobiilsed raadiosideseadmed (mobiiltelefonid jne) võivad mõjutada elektrilisi meditsiiniseadmeid. Rakendage töö ajal vajalikke ettevaatusabinõusid.

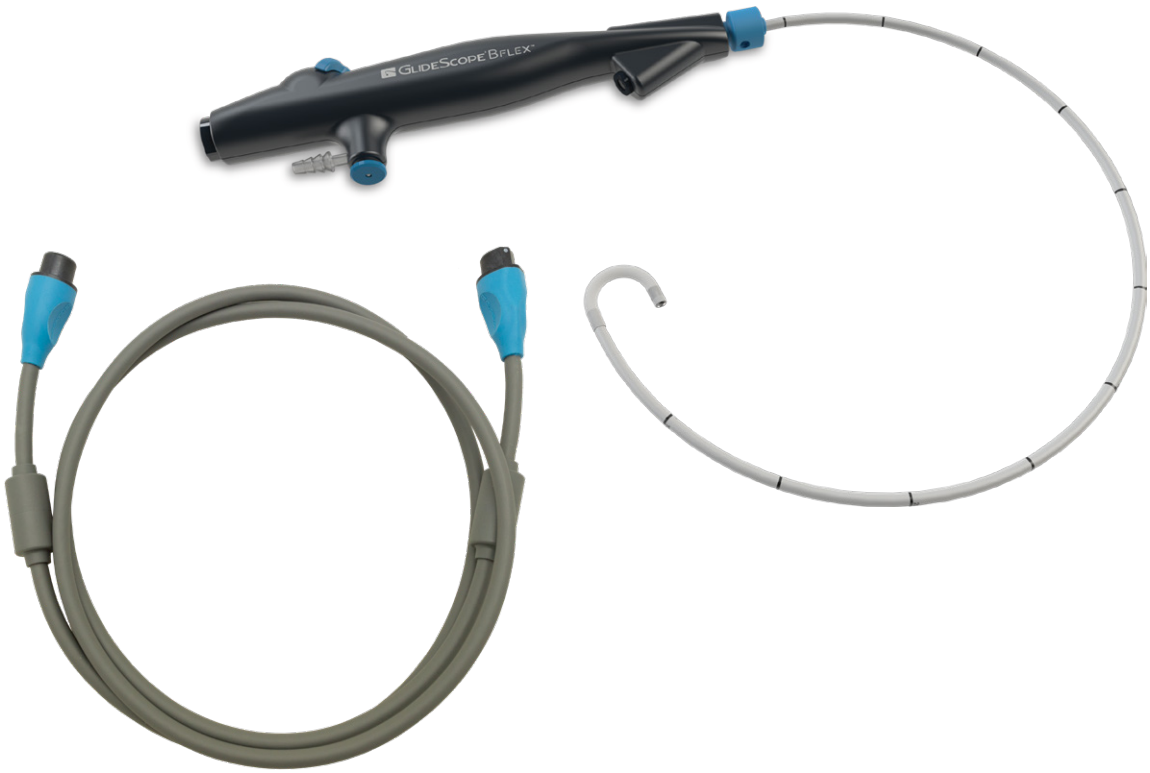
Introduction

This manual discusses the following components of the GlideScope BFlex Single-Use Bronchoscope system:

- GlideScope BFlex bronchoscope (single-use)
- GlideScope Core QuickConnect Cables (reusable)

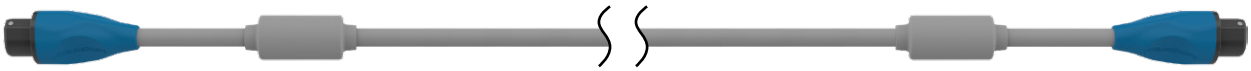
Note: This manual covers the single-use bronchoscope and the reusable cables. For information about using a video monitor, refer to that monitor's Operations & Maintenance Manual.

Figure 1. GlideScope BFlex Single-Use Bronchoscope and Cable



Parts & Accessories

Table 1. System Components

PARTS & ACCESSORIES
GlideScope BFlex 2.8 Single-Use bronchoscope 
GlideScope BFlex 3.8 Single-Use bronchoscope 
GlideScope BFlex 5.0 Single-Use bronchoscope 
GlideScope BFlex 5.8 Single-Use bronchoscope 
GlideScope Core 2m QuickConnect Cable GlideScope Core QuickConnect Cable 
Introducer 

Bronchoscope Components

The GlideScope BFlex bronchoscope is a single-use device that can be inserted either directly or through an endotracheal (ET) tube. The main components of the bronchoscope are shown in the following figure.

Figure 2. Bronchoscope Components

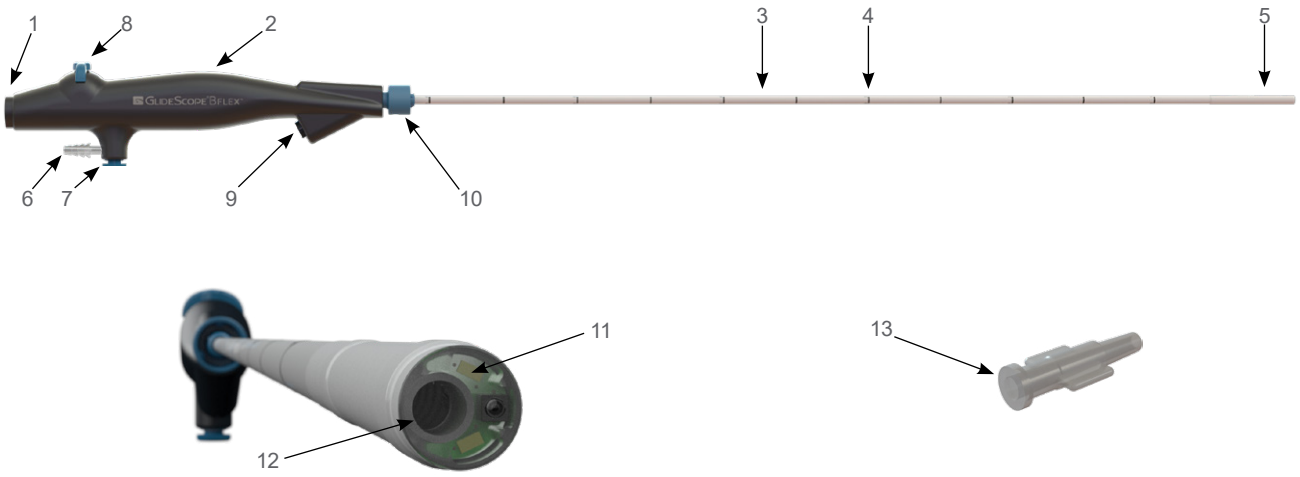


Table 2. Bronchoscope Component Descriptions

FIGURE KEY	COMPONENT	NOTES
1	Cable connector	Includes magnetic quick release
2	Handle	—
3	Insertion tube	—
4	Positioning marks	Includes marks at 50 mm intervals to assist in scope placement within the airway
5	Articulating distal tip	—
6	Suction port*	Accommodates tubing with an inside diameter between 6.0 and 7.0 mm, inclusively.
7	Suction button*	—
8	Control lever	Positions articulating distal tip
9	Accessory port*	Enables introduction of accessories or liquids.
10	Tube retainer	Enables mounting of endotracheal (ET) tubes with standard ISO connectors.
11	Camera and light	High-resolution, full-color camera with integrated LED light source and anti-fog protection
12	Working channel*	—
13	Introducer*	Connects Luer syringes securely to the accessory port

* Does not apply to BFlex 2.8.

Setting Up

Before you can use the system for the first time, you must inspect the components, set up the system, and perform a functional test as recommended by Verathon. Complete the following tasks:

1. Perform Initial Inspection—Inspect the system for any obvious physical damage that may have occurred during shipment.
2. Attach the Video Cable to the Monitor—Connect the QuickConnect cable to the monitor.
3. Attach the Bronchoscope to the Video Cable—Connect the bronchoscope to the cable.
4. Perform a Functional Check—Before you use the device for the first time, perform a functional check to ensure that the system is working properly.

Perform Initial Inspection

When you receive the system, Verathon recommends that an operator familiar with the instrument perform a full visual inspection of the system for any obvious physical damage that may have occurred during shipment.

1. Verify that you have received the appropriate components for your system by referring to the packing list included with the system.
2. Inspect the components for damage.
3. If any of the components are missing or damaged, notify the carrier and Verathon Customer Care or your local representative. For contact information, visit verathon.com/service-and-support.

Attach the Video Cable to the Monitor

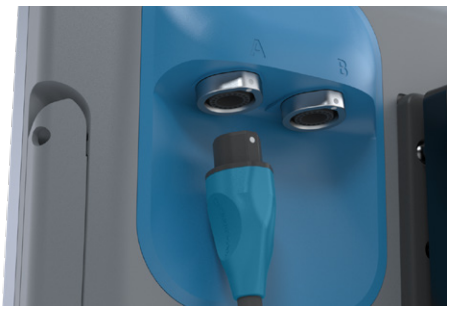
This procedure provides basic instruction on connecting video cables to a monitor. For information on a specific monitor, please refer to its Operations & Maintenance Manual, or contact Verathon Customer Care.

IMPORTANT

When using a Core 2m QuickConnect Cable, ensure the Core 15 monitor software is updated to the following versions or later:

- Version 1.8—Core 15 FHD (0570-0437)
- Version 1.10—Core 15 (0570-0404)

1. Align the dot on cable connector to the dot on one of the monitor's video connectors, and then fully insert the cable. The connector attaches to the monitor.



2. To disconnect the video cable, hold the cable connector in one hand and support the monitor with the other, and then pull. The cable disconnects from the monitor.

Attach the Bronchoscope to the Video Cable

The GlideScope QuickConnect Cable attaches the bronchoscope to the monitor, supplying power to the bronchoscope and transmitting video data from the camera to the monitor.

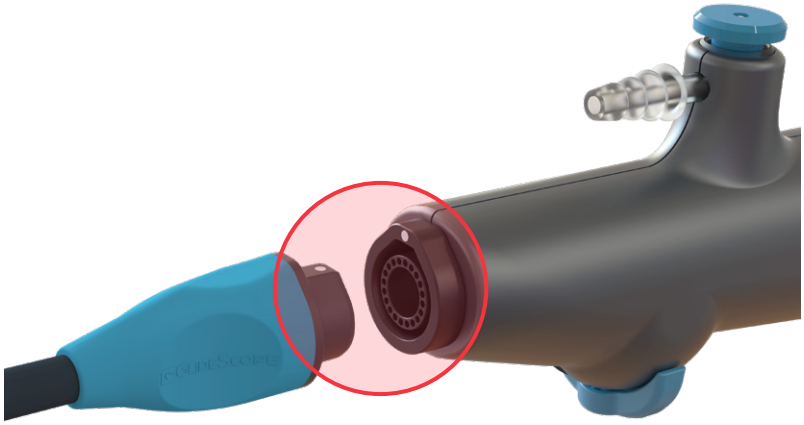
It is recommended that you leave the sterile, single-use bronchoscope in the packaging while connecting it, and that you do not remove the bronchoscope until you are ready to insert it. This helps ensure that the bronchoscope remains as clean as possible.

1. If necessary, connect the cable to the monitor according to the procedure Attach the Video Cable to the Monitor on page 13.
2. Remove the bronchoscope and the introducer from their packets.
3. Detach the protective cover from the cable connector on the bronchoscope. Discard the cover after you remove it.

4. Carefully slide the protective sleeve off the insertion tube of the bronchoscope. Discard the sleeve after you remove it.

5. Inspect the bronchoscope to ensure that it is functional..

6. Align the white dot on the opposite end of the QuickConnect Cable with the dot on the bronchoscope, and then insert the connector into the bronchoscope. Magnets in both components hold them in place during use.

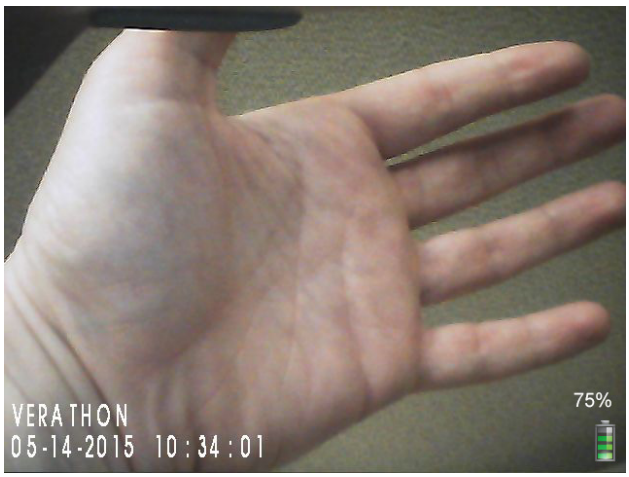


7. To disconnect a bronchoscope from the QuickConnect Cable, hold the cable connector in one hand and the handle of the bronchoscope in the other, and then pull. The bronchoscope disconnects from the cable.

Perform a Functional Check

Before you use the device for the first time, perform the following functional check to ensure that the system is working properly. Please contact your Verathon Customer Care representative if your system does not function as described below.

1. Fully charge the monitor battery (this takes approximately 6 hours).
2. Attach a QuickConnect Cable and a bronchoscope to the monitor, according to the instructions in Attach the Video Cable to the Monitor on page 13 and Attach the Bronchoscope to the Video Cable on page 14.
3. Turn the monitor on.
4. Look at the monitor screen, and verify that the image displayed is being received from the bronchoscope.



Using the Device

Before use, set up the device according to the instructions in the previous chapter, and verify the setup by completing the procedure Perform a Functional Check on page 15.

Please read the Hoiatused ja ettevaatusabinõud section before performing the following tasks.

GlideScope BFlex Single-Use bronchoscopes are equipped with an anti-fog feature that reduces camera fogging during use. To optimize the feature fully, you must allow the bronchoscope to warm up for 30–120 seconds prior to use, depending on the ambient temperature and humidity of the clinical environment. Full warmup is not necessary to use the device; if desired, you may begin the insertion procedure immediately.

Using the GlideScope BFlex components consists of the following:

- Prepare the GlideScope System
- Position the Handle and Controls
- Insert Through a Tube or Catheter (Optional)
- Insert and Flex the Bronchoscope
- Introduce Liquids or Accessories (Optional)
- Remove the Bronchoscope

Note: Follow accepted practices in order to protect the bronchoscope from contamination prior to insertion.

Procedure 1. Prepare the GlideScope System

In this procedure, you turn the system on and verify that it is functioning properly.

1. Ensure that each GlideScope component has been properly cleaned.
2. Attach the QuickConnect cable and the bronchoscope to the monitor, according to the instructions in the monitor's Operations & Maintenance Manual.
3. If you need to deliver suction through the working channel of the bronchoscope, connect a suction line to the suction port.*

   Note: The inside diameter of the suction tubing should be between 6.0 and 7.0 mm, inclusively.
4. Turn on the monitor.

   Note: If the monitor locks up, becomes unresponsive for any reason, or does not show an image from the bronchoscope, consult the monitor's Operations & Maintenance Manual for resetting instructions.
5. Ensure that the battery is sufficiently charged. If necessary, connect the monitor directly to power.
6. On the monitor screen, verify that the image displayed is from the bronchoscope camera.
7. If needed, allow the GlideScope anti-fog feature to warm up for 30–120 seconds.

   Note: The time required for the anti-fog feature to be fully optimized varies according to the ambient temperature and humidity where the equipment is being stored or used. If the bronchoscope is stored in cold conditions, additional warming time may be required for optimal performance of the anti-fog feature.

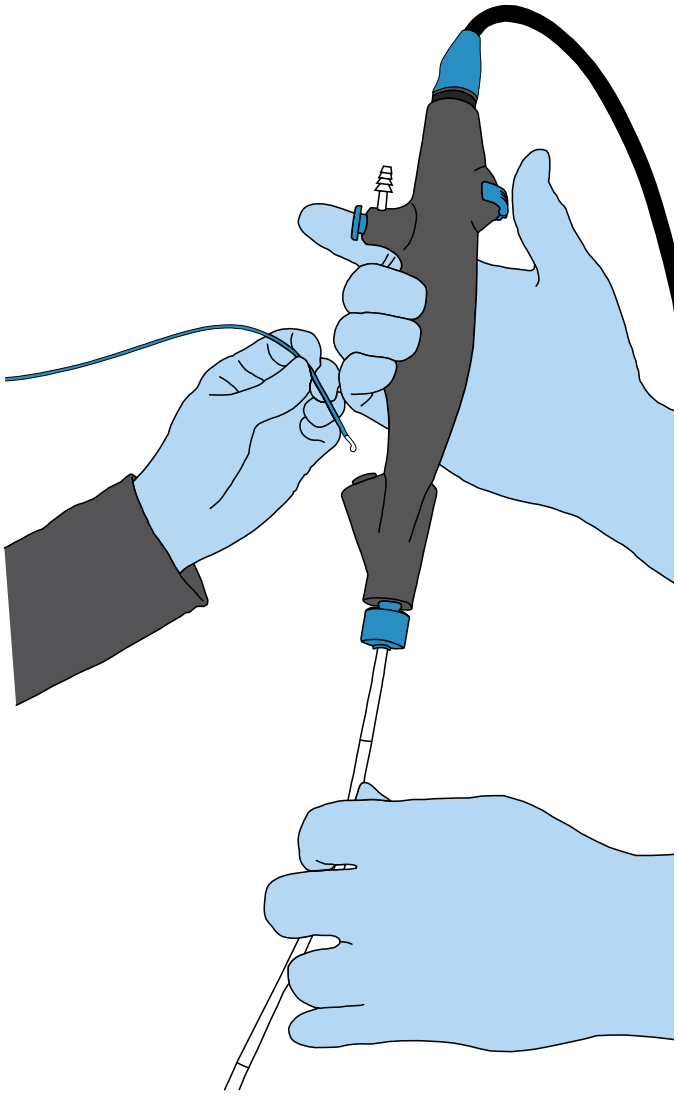
* Does not apply to BFlex 2.8.

Procedure 2. Position the Handle and Controls

With your supporting hand positioned as described in this procedure, you can regulate suction with your index finger and position the distal tip of the bronchoscope with your thumb. You can then use your other hand to introduce accessories or liquids through the working channel, to grasp and turn the insertion tube, or to provide additional support as appropriate. If you need to do several of these things at once, you may need a second person to assist.

1. Empty the hand you will use to support and operate the bronchoscope.
2. Using that hand, grasp the handle in the center.
3. Place the positioning lever under your thumb.
4. Place the suction button under your index finger. Press the button as needed to apply suction.*

   Note: To ensure full suction strength, remove any object such as a syringe or an endoscopic accessory from the working channel while applying suction.



* Does not apply to BFlex 2.8.

Procedure 3. Insert Through a Tube or Catheter (Optional)

IMPORTANT

Verathon has tested compatibility with water based, silicone based, and petroleum based lubricants.

The bronchoscope can be inserted through a tube or catheter with a compatible inside diameter, as shown in the following table.

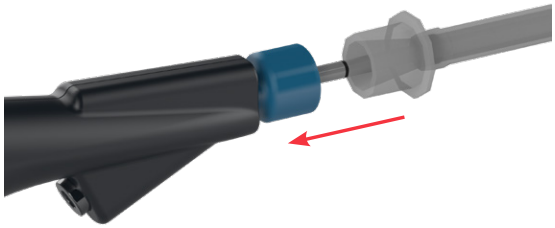
Table 3. GlideScope BFlex Bronchoscope—Endotracheal Tube Compatibility

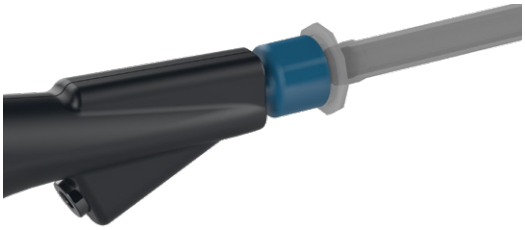
TUBES AND CATHETERS	SPECIFICATION	BFLEX 2.8	BFLEX 3.8	BFLEX 5.0	BFLEX 5.8
Endotracheal tube	Minimum Inside Diameter	4.0 mm	5.0 mm	6.0 mm	7.0 mm
Double-Lumen tube	Minimum Size	32 Fr	35 Fr	Not supported	
Airway catheter	Minimum Size	19 Fr	19 Fr		
	Minimum Inside Diameter	4.7 mm	4.7 mm		
	Maximum length	560 mm	560 mm		

Note: There is no guarantee that instruments selected solely using these instrument dimensions will be compatible in combination. Importantly, The GlideScope BFlex 3.8 Single-Use Bronchoscope should not be used with 35Fr Shiley Endobronchial Tubes. Damage or tear to BFlex tip sheath may occur.

1. Remove your thumb from the positioning lever of the bronchoscope and ensure that the distal tip is completely straight and in a neutral position.
2. Lubricate the scope, tube, or catheter, and then slowly insert the distal tip of the bronchoscope into the internal channel of the tube or catheter. If you encounter resistance while inserting the bronchoscope, pull the scope back slightly, ensure your thumb is not on the positioning lever, and then continue inserting the bronchoscope.

   If there is ongoing resistance, consider the following:
   - Apply additional lubrication to the scope, tube, or catheter.
   - Use a smaller diameter bronchoscope or a larger diameter tube or catheter.
3. As you slide the bronchoscope through the tube or catheter, keep your thumb off of the positioning lever until the monitor image and the markings on the bronchoscope indicate that the distal tip has emerged completely from the distal end of the tube or catheter.
4. After the distal tip has emerged from the tube or catheter, return your thumb to the positioning lever. Follow the positioning instructions in the following section, Insert and Flex the Bronchoscope, to maneuver the tip to its working location.
5. If you are using an endotracheal tube or double lumen tube, slide the tube's connector into the tube retainer of the bronchoscope, and then press it securely into place.





Procedure 4. Insert and Flex the Bronchoscope

The bronchoscope can be inserted using any standard oral or nasal insertion technique, with or without the use of a separate ET tube. During use, its distal tip can flex through the ranges shown in the following table.

Table 4. GlideScope BFlex Bronchoscope—Distal Tip Articulation

SIZE	RANGE OF MOVEMENT OF DISTAL TIP*
BFlex 2.8	185° up, 185° down
BFlex 3.8	175° up, 180° down
BFlex 5.0	165° up, 160° down
BFlex 5.8	140° up, 135° down

* *Values shown are averages following the sterilization stage of manufacturing.*

As you perform the insertion, use the following steps to direct the distal tip of the bronchoscope.

Note: If necessary, the bronchoscope can be wiped gently with sterile gauze.

1. Using your thumb, move the positioning lever to flex the distal tip as needed. The tip flexes with the lever as shown in the figures to the right.
2. As you carefully advance and flex the distal tip, rotate the handle around its long axis. By combining all three movements, you can direct the tip to any point in the direction of insertion.
3. Observe the black markings on the insertion tube of the bronchoscope in order to determine depth. These markings are spaced at 50 mm intervals. The first mark appears at the inward edge of the tip itself, marking the tip as 50 mm long.

Procedure 5. Introduce Liquids or Accessories (Optional)

Please read the Hoiatused ja ettevaatusabinõud section before performing the following task.

IMPORTANT

The BFlex 2.8 does not have suction capability.

In addition to supplying suction, the working channel on the bronchoscope also provides a delivery channel for the following items:

- Liquids such as sterile saline solution
- Endoscopic tools that do not require their own source of electrical power (non-powered tools) such as forceps, cutters, baskets, or brushes

The following table shows the maximum diameter of tools and accessories that can be used with each size of bronchoscope.

Table 5. GlideScope BFlex Bronchoscope—Tool and Accessory Compatibility

SIZE	MAXIMUM ACCESSORY WIDTH
BFlex 2.8	Not applicable. No working channel.
BFlex 3.8	1.0 mm
BFlex 5.0	2.0 mm
BFlex 5.8	2.6 mm

Use the following steps to introduce liquids or accessories through the working channel.

Option 1. Administering Liquids

1. Aspirate the solution into a syringe, if you have not already done so.
2. If you are using a slip-tip syringe to administer the liquid, insert the tip of the syringe into the accessory port. If you are using a luer lock syringe, use the included introducer to connect the syringe to the port.

3. Dispense the liquid into the working channel.

   Note: If suction is connected to the bronchoscope, do not apply suction while you are introducing the liquid. This causes the suction to withdraw the liquid from the bronchoscope. Conversely, to ensure full suction strength, retract the syringe or introducer while applying suction.

Option 2. Introducing Non-Powered Endoscopic Accessories

1. Move the positioning lever in order to return the distal tip as close to a straight position as possible.
2. If appropriate, position the accessory so that its distal end is collapsed as far as possible.
3. Insert the distal end of the accessory into the working channel.

4. Slide the accessory through the working channel until its end emerges from the distal tip of the bronchoscope, as shown on the monitor screen.
5. Position the distal tip of the bronchoscope and the accessory as needed to perform the procedure.

   Note: To ensure full suction strength, retract the accessory from the working channel before applying suction.

Procedure 6. Remove the Bronchoscope

If you intend to insert the bronchoscope into the same patient more than once, prepare a sterile resting area for it. Keep the bronchoscope in this area when it is not in use.

1. When possible, retract any accessories into the working channel in order to avoid interference with the distal tip during removal.
2. Return the positioning lever as close to center as possible, and then remove your thumb from the positioning lever.
3. Carefully withdraw the bronchoscope without touching the control lever.

   Note: If you encounter resistance during withdrawal, reinsert the bronchoscope slightly, and then gently rotate it, straighten the tube, or instill saline into the tube, and then attempt removal again.
4. After you have withdrawn the bronchoscope completely, examine it thoroughly. Verify that it is not damaged and none of its components are missing.
5. If necessary, detach the cable from the bronchoscope by holding the cable connector in one hand and the bronchoscope handle in the other, and then pulling them straight apart. Dispose of the bronchoscope.

Reprocessing

Some of the components in this manual may require cleaning, low-level disinfection, high-level disinfection, or sterilization between uses or under specific circumstances. For information about the cleaning, disinfection, and sterilization requirements for these components, refer to the GlideScope and GlideRite Products Reprocessing Manual, which is available at verathon.com/service-and-support/glidescope-reprocessing-products.

Hooldus ja ohutus

Korralised ülevaatused

Verathon ei nõua korralisi kontrolle, hooldust ega kalibreerimisi.

Teavitage Verathoni klienditeenindust või kohalikku esindajat kõigist oletatavatest vigadest. Vaadake kontaktteavet veebilehelt verathon.com/service-and-support.

Seadme parandamine

Kaablid ei ole kasutajate hooldatavad. Verathon ei avalda ühtegi elektriskeemi, komponentide ja osade loendit, kirjeldust ega muud teavet, mida oleks vaja seadme ja selle tarvikute parandamiseks. Kõik hooldustööd peab tegema kvalifitseeritud tehnik.

Kui teil on küsimusi, võtke ühendust Verathoni kohaliku esindaja või Verathoni klienditeenindusega.

Lugege jaotis Hoiatused ja ettevaatusabinõud.

Seadme kõrvaldamine

Süsteem ja selle tarvikud võivad sisaldada akusid ja muid keskkonnaohtlikke materjale. Kui seadme kasutusiga on lõppenud, tuleb see kõrvaldada elektri- ja elektroonikaseadmete romude käitlusnõuete kohaselt. Korraldage kõrvaldamine Verathoni hoolduskeskuse kaudu või järgige ohtlike jäätmete kõrvaldamise kohalikke eeskirju.

Warranty

ORIGINAL FIRST YEAR TOTAL CUSTOMER CARE WARRANTY

Verathon warrants the system against defects in material and workmanship. The limited warranty applies for one (1) year from the date of shipment from Verathon and applies only to the original purchaser of the system. The terms of this warranty are subject to the *Terms and Conditions of Sale* or any other contractual document between the parties.

Verathon's policy is to honor product warranties and to perform services only on products purchased from an authorized Verathon dealer. If you purchase a Verathon product or system components from an unauthorized dealer or if the original factory serial number has been removed, defaced or altered, your Verathon warranty will be void. Purchasing Verathon products from unauthorized entities could result in receipt of product that is counterfeit, stolen, used, defective, or not intended for use in your region.

If a customer's system requires service or repair, Verathon will, at its discretion, either repair or replace the customer's unit and provide a loaner unit. The customer agrees to send the defective unit to Verathon (cleaned and disinfected as appropriate) upon receipt of the loaner unit, and the customer agrees to return the loaner unit within two (2) business days of receipt of the repaired unit. All exchanged parts become property of Verathon.

Each product manufactured by Verathon is warranted to be free from defects in material and workmanship under normal use and services. Verathon's warranty does not cover defects or problems caused by the buyer's acts (or failure to act), the acts of others, or events beyond Verathon's reasonable control. The buyer shall be solely responsible, for any problem, failure, malfunction, defect, claim, damage, liability, or safety issue arising out of the following:

- Accident, theft, misuse, abuse, extraordinary wear and tear, or neglect.
- Misapplication, improper use, or other failure to follow Verathon's product instructions and safety precautions. The system shall be used in accordance with the instructions contained in this manual. This warranty does not apply if there is evidence of the equipment being exposed to temperatures in excess of 60°C (140°F).
- Use of the system in conjunction with hardware, software, components, services, accessories, attachments, interfaces, or consumables, other than those supplied or specified by Verathon.
- Products that have been repaired or maintained by anyone other than a Verathon authorized service provider. Modification, disassembly, rewiring, re-engineering, recalibration, and/or reprogramming of products other than as specifically authorized by Verathon in writing is prohibited and will void all warranties.

This warranty provides coverage if the instrument is rendered inoperable as a result of an accidental drop or mishandling after payment by the buyer of the current deductible as determined by Verathon. The deductible charge will be applied on each warranty request and may be applied an unlimited number of times per instrument.

WHAT IS COVERED?

Warranty coverage applies to the following system components:

- GlideScope Core QuickConnect Cable

Additional reusable components purchased either singularly or as a part of a system are warranted separately. Consumable items are not covered under this warranty.

PREMIUM CUSTOMER CARE WARRANTY

You may purchase a Premium Total Customer Care warranty that extends the limited warranty. For more information, contact Verathon Customer Care or your local representative.

DISCLAIMER OF ADDITIONAL WARRANTIES

There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in this chapter and the *Terms and Conditions of Sale*. The contents of this manual do not constitute a warranty.

Some states disallow certain limitations on applied warranties. The purchaser should consult state law if there is a question regarding this disclaimer. The information, descriptions, recommendations, and safety notations in this manual are based upon Verathon experience and judgment. The contents of this manual should not be considered to be all-inclusive or to cover all contingencies.

Product Specifications

Specifications, Standards, and Approvals

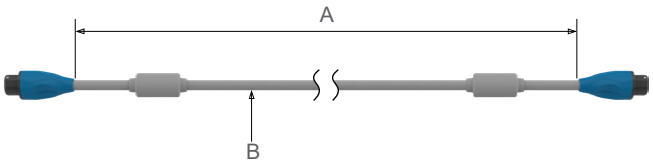
Table 6. Specifications

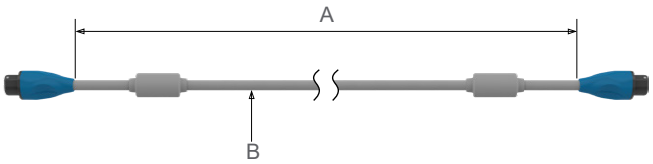
GENERAL SPECIFICATIONS			
Ingress protection against water:	Single-use bronchoscope		IPX0
	QuickConnect Cable (all)		IPX7
Expected product life:	Single-use bronchoscope	BFlex 2.8	Refer to the “use by” date indicated by the ⌛ symbol on the package label.
		BFlex 3.8	
		BFlex 5.0	
		BFlex 5.8	
OPERATING, SHIPPING, & STORAGE SPECIFICATIONS			
Operating Conditions			
Temperature:	GlideScope BFlex Single-Use Bronchoscopes		10–40°C (50–104°F)
	QuickConnect Cables		
Relative humidity:	GlideScope BFlex Single-Use Bronchoscopes		10–95%
	QuickConnect Cables		
Atmospheric pressure:	GlideScope BFlex Single-Use Bronchoscopes		700–1060 hPa
	QuickConnect Cables		
Shipping Conditions			
Temperature:	GlideScope BFlex Single-Use Bronchoscopes		-20–45°C (-4–113°F)
	QuickConnect Cables		
Relative humidity:	GlideScope BFlex Single-Use Bronchoscopes		10–95%
	QuickConnect Cables		
Atmospheric pressure:	GlideScope BFlex Single-Use Bronchoscopes		440–1060 hPa
	QuickConnect Cables		
Storage Conditions			
Temperature:	GlideScope BFlex Single-Use Bronchoscopes		18–28°C (64–82°F)
	QuickConnect Cables		-20–45°C (-4–113°F)
Relative humidity:	GlideScope BFlex Single-Use Bronchoscopes		40–60%
	QuickConnect Cables		10–95%
Atmospheric pressure:	GlideScope BFlex Single-Use Bronchoscopes		1013 hPa
	QuickConnect Cables		440–1060 hPa

Please read the Hoiatused ja ettevaatusabinõud section.

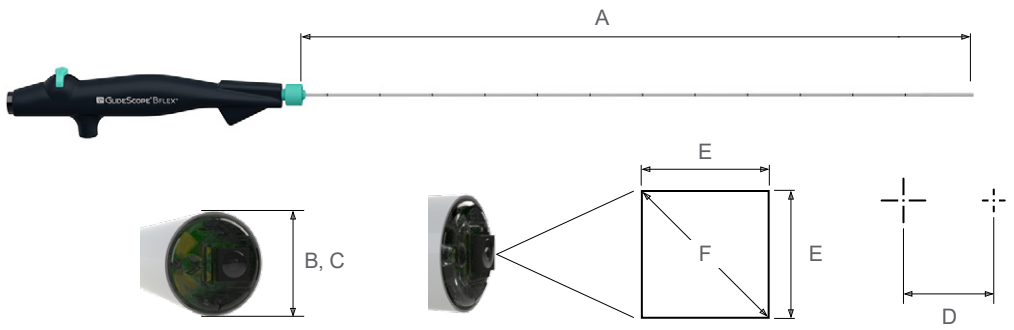
Component Specifications

Table 7. System Component Specifications

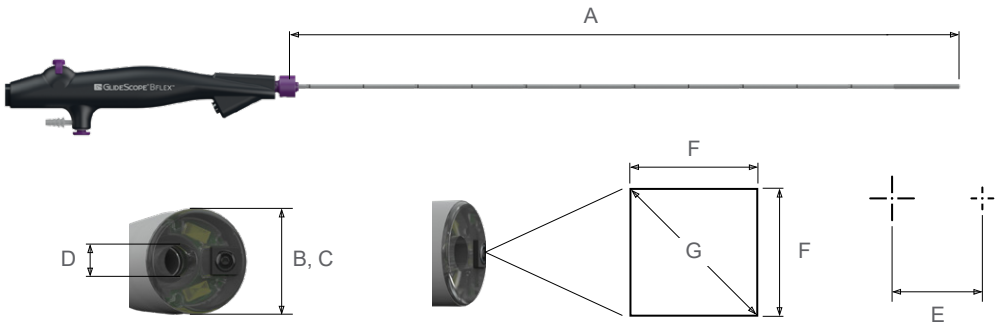
GLIDESCOPE CORE QUICKCONNECT CABLE (0600-0767)		
Specification	**Value**	
Length (A)	1524 ± 50 mm	
Diameter (B)	6.8 mm	

GLIDESCOPE CORE 2M QUICKCONNECT CABLE (0600-0843)		
Specification	**Value**	
Length (A)	1981 ± 50 mm	
Diameter (B)	6.8 mm	

BFLEX 2.8 (0570-0419)	
Specification	**Value**
Length of flexible insertion tube from distal tip (A)	610 mm
Outside diameter of flexible insertion tube (B)	2.8 mm
Maximum outside diameter of flexible insertion tube and distal tip (C)	3.3 mm
Minimum inside diameter of endotracheal tube	4.0 mm
Depth of field (D)	5–50 mm
Direction of view, relative to center line of distal tip	0°
Field of view, horizontal/vertical (E)	85°
Field of view, diagonal (F)	120°



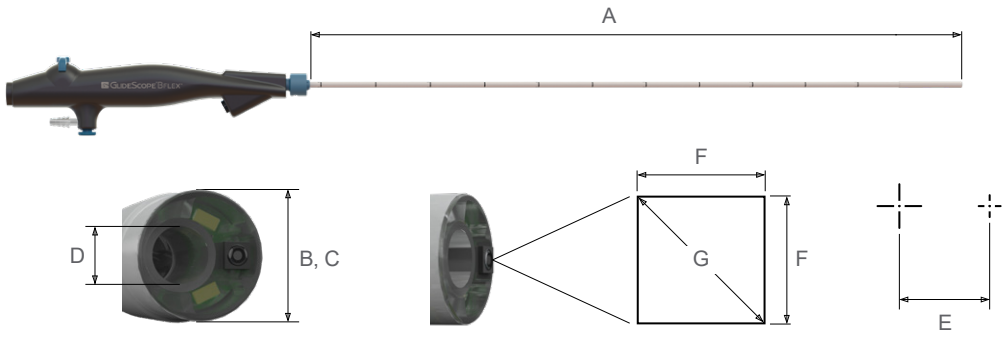
BFLEX 3.8 (0570-0380)	
Specification	**Value**
Length of flexible insertion tube from distal tip (A)	610 mm
Outside diameter of flexible insertion tube (B)	3.8 mm
Maximum outside diameter of flexible insertion tube and distal tip (C)	4.4 mm
Minimum inside diameter of endotracheal tube	5.0 mm
Average Inside diameter of working channel (D)	1.2 mm
Minimum inside diameter of working channel (D)	1.2 mm*
Maximum accessory width	1.0 mm
Length of working channel	696 mm†
Volume of working channel	0.98 cc (0.98 mL)
Depth of field (E)	5–50 mm
Direction of view, relative to center line of distal tip	0°
Field of view, horizontal/vertical (F)	85°
Field of view, diagonal (G)	120°



* *There is no guarantee that accessories selected solely using this minimum instrument channel width will be compatible in combination.*

† *There is no guarantee that accessories selected solely using maximum insertion portion width and working length will be compatible in combination.*

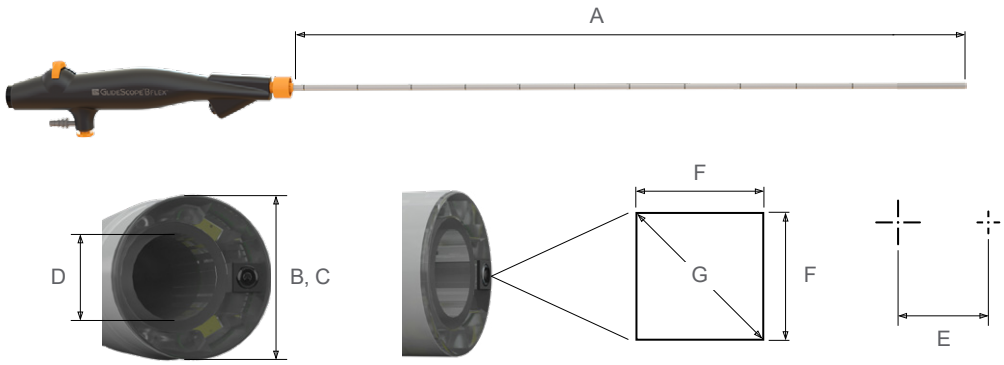
BFLEX 5.0 (0570-0374)	
Specification	**Value**
Length of flexible insertion tube from distal tip (A)	610 mm
Outside diameter of flexible insertion tube (B)	5.0 mm
Maximum outside diameter of flexible insertion tube and distal tip (C)	5.5 mm
Minimum inside diameter of endotracheal tube	6.0 mm
Average inside diameter of working channel (D)	2.2 mm
Minimum inside diameter of working channel (D)	2.1 mm*
Maximum accessory width	2.0 mm
Length of working channel	696 mm†
Volume of working channel	2.77 cc (2.77 mL)
Depth of field (E)	5–50 mm
Direction of view, relative to center line of distal tip	0°
Field of view, horizontal/vertical (F)	85°
Field of view, diagonal (G)	120°



* *There is no guarantee that accessories selected solely using this minimum instrument channel width will be compatible in combination.*

† *There is no guarantee that accessories selected solely using maximum insertion portion width and working length will be compatible in combination.*

BFLEX 5.8 (0570-0381)	
Specification	**Value**
Length of flexible insertion tube from distal tip (A)	610 mm
Outside diameter of flexible insertion tube (B)	5.8 mm
Maximum outside diameter of flexible insertion tube and distal tip (C)	6.35 mm
Minimum inside diameter of endotracheal tube	7.0 mm
Average inside diameter of working channel (D)	3.0 mm
Minimum inside diameter of working channel (D)	3.0 mm*
Maximum accessory width	2.6 mm
Length of working channel	696 mm†
Volume of working channel	5.2 cc (5.2 mL)
Depth of field (E)	5–50 mm
Direction of view, relative to center line of distal tip	0°
Field of view, horizontal/vertical (F)	85°
Field of view, diagonal (G)	120°



* *There is no guarantee that accessories selected solely using this minimum instrument channel width will be compatible in combination.*

† *There is no guarantee that accessories selected solely using maximum insertion portion width and working length will be compatible in combination.*

Electromagnetic Compatibility

The GlideScope BFlex system is designed to be in compliance with IEC 60601-1-2, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical medical installation.

The system complies with the applicable essential performance requirements specified in IEC 60601-1 and IEC 60601-2-18. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables. For more information about the essential performance of the GlideScope BFlex system, see Essential Performance on page 2.

Electromagnetic emissions

Table 8. Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	In compliance	

Electromagnetic immunity

Table 9. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	In compliance	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency	In compliance	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	In compliance	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 Cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚ 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single Phase: at 0˚	In compliance	Mains power quality should be that of a typical hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m Frequency 50/60 Hz	In compliance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz	In compliance	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance d (m)** $d=1.2\sqrt{P}$

Table 9. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	In compliance	Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: U_T is the AC mains voltage prior to application of the test level.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Accessory Conformance to Standards

To maintain electromagnetic interference (EMI) within certified limits, the system must be used with the cables, components, and accessories specified or supplied by Verathon. For additional information, see the Parts & Accessories section on page 10 and Component Specifications section on page 28. The use of accessories or cables other than those specified or supplied may result in increased emissions or decreased immunity of the system.

Table 10. EMC Standards for Accessories

ACCESSORY	MAX LENGTH
GlideScope Core QuickConnect Cable	1.57 m (5.1 ft)
GlideScope Core 2m QuickConnect Cable	2.03 m (6.7 ft)

Glossary

The following table provides definitions for specialized terms used in this manual or on the product itself. For a full list of caution, warning, and informational symbols used on this and other Verathon products, please refer to the Verathon Symbol Directory at verathon.com/symbols.

TERM	DEFINITION
A	Ampere
AC	Alternating current
AER	Automated endoscope reprocessor
C	Celsius
CFR	Code of Federal Regulations (U.S.)
CISPR	International Special Committee on Radio Interference
cm	Centimeter
CSA	Canadian Standards Association
DL	Direct laryngoscopy
DLT	Double-Lumen tube
EMI	Electromagnetic interference
ESD	Electrostatic discharge
Essential performance	The system performance necessary to achieve freedom from unacceptable risk
ET Tube	Endotracheal tube
F	Fahrenheit
g	Gram
GHz	Gigahertz
HDMI	High-definition multimedia interface
hPa	Hectopascal
Hz	Hertz
IEC	International Electrotechnical Commission
in	Inch
IPA	Isopropyl alcohol
ISM	Industrial, scientific, and medical
ISO	International Standards Organization.
ISO connector	An endotracheal tube connector designed according to ISO standards.
kHz	Kilohertz
kPa	Kilopascal
kV	Kilovolt
L	Liter
lbs	Pounds
m	Meter

TERM	DEFINITION
mAh	Milliampere-hour
MDD	Medical Device Directive
MHz	Megahertz
mL	Milliliter
mm	Millimeter
mmHg	Millimeters of mercury
MSDS	Material Safety Data Sheet
non-powered accessory	Endoscopic tool that does not require its own source of electrical power
OSHA	Occupational Safety and Health Administration (federal agency in U.S.)
powered accessory	Endoscopic tool that requires its own source of electrical power
psia	Pounds per square inch absolute
RF	Radio frequency
RH	Relative humidity
RoHS	Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment
SDS	Sodium dodecyl sulphate
V	Volt
Vrms	Voltage root mean squared
W	Watt
WEEE	Waste electrical and electronic equipment

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