

# Stryker

User Guide





# **Table of Contents**

Warnings and Cautions	3
Product Description/Intended Use	5
Indications/Contraindications	5
System Configuration	5
Location and Function of Parts and Controls	5
Front	5
Rear	6
Carrying the printer	7
Connections	7
USB Port Connection	7
Before Printing	9
Notes on Handling the Ink Ribbon and Paper	9
Loading the Ink Ribbon and Paper	
Replacing the Ink Ribbon and Paper	13
Printing	14
Precautions	16
Safety	16
Installation	
Transportation	
Cleaning	
Cleaning the Internals of the Printer	
Ink Ribbon and Paper	
Iecnnical Specifications	
About the Sell-Laminating Color Printing Pack (SEPC-100/SEPC-110)	20
Troubleshooting	21
Explanation of Indicators	22
If a Paper Jam Occurs	23
Adverse Event Reporting	30
Warranty and Return Policy	30
License	

# Warnings and Cautions

### WARNING

- 1. Federal law (United States of America) restricts this device to use by, or on order of, a physician.
- 2. Users of this Digital Color Printer must possess knowledge of proper surgical techniques, including preoperative and operative procedures to ensure successful use of these devices. For more information, contact your local Stryker representative.
- 3. Carefully unpack the device and check if any damage occurred during shipment. If damage is detected, refer to the standard warranty.
- 4. Read this manual thoroughly and be familiar with its contents prior to using this equipment.

#### To reduce the risk of fire or electric shock, do not expose this apparatus to rain or moisture.

To avoid electrical shock, do not open the cabinet. Refer servicing to qualified personnel only.

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

#### No modification of this equipment is allowed.

#### Symbols on the products



#### Consult the instructions for use Follow the directions in the instructions for

use for parts of the unit on which this symbol appears.





This symbol indicates the date of manufacture.



This symbol indicates the serial number.



This symbol indicates the version of the accompanying document. This symbol indicates the European

EC REP Community representative, and appears next to the European Community representative's name and address.

Medical Device: This symbol indicates the MD medical device in the European Community.



This symbol indicates the equipotential terminal which brings the various parts of a system to the same potential.

#### Storage and transport temperature

This symbol indicates the acceptable temperature range for storage and transport environments.



#### Storage and transport humidity

This symbol indicates the acceptable humidity range for storage and transport environments.



#### Storage and transport pressure

This symbol indicates the acceptable atmospheric pressure range for storage and transport environments.

#### For accessories



LOT

This symbol indicates the do not reuse.

This symbol indicates the batch code.

This unit has no power switch.

To disconnect the main power, unplug the power plug. When installing the unit, incorporate a readily accessible disconnect device in the fixed wiring, or connect the power plug to an easily accessible socket-outlet near the unit. Do not position the ME equipment where it is difficult to unplug the power plug.

If a fault should occur during operation of the unit, operate the disconnect device to switch the power supply off, or unplug the power plug.

The Stryker Standard Warranty and Return Policy is void if any of these warnings are disregarded.

#### For the customers in the U.S.A.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

You are cautioned that any changes or modifications not expressly approved in this manual could void your authority to operate this equipment.

All interface cables used to connect peripherals must be shielded in order to comply with the limits for a digital device pursuant to Subpart B of part 15 of FCC Rules.

#### For the customers in Canada

This unit has been certified according to Standard CAN/ CSA-C22.2 No.60601-1.

#### For the customers in the U.S.A and Canada

When you use this product connected to 240 V single phase, be sure to connect this product to a center tapped circuit.

# Important safeguards/notices for use in the medical environments

- All the equipments connected to this unit shall be certified according to Standard IEC 60601-1, IEC 60950-1, IEC 60065 or other IEC/ISO Standards applicable to the equipments.
- 2. Furthermore all configurations shall comply with the system standard IEC 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult your local Stryker service technician.
- 3. The leakage current could increase when connected to other equipment.
- 4. For this particular equipment, all accessory equipment connected as noted above, must be connected to mains via an additional isolation transformer conforming with the construction requirements of IEC 60601-1 and providing at least Basic Insulation.
- 5. This equipment generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the instruction manual, it may cause interference to other equipment. If this unit causes interference (which can be determined by unplugging the power cord from the unit), try these measures: Relocate the unit with respect to the susceptible equipment. Plug this unit and the susceptible equipment into different branch circuit.

#### Warning

The printer must be properly connected to the isolation transformer prior to use. Failure to do so may result in a higher leakage current for the printer.

#### **Li** Caution

When you dispose of the unit or accessories, you must obey the laws in the relative area or country and the regulations in the relative hospital regarding environmental pollution.



This product contains waste electrical or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately.

#### Warning on power connection

Use a proper power cord for your local power supply.

- 1. Use the approved Power Cord (3-core mains lead) / Appliance Connector / Plug with earthing-contacts that conforms to the safety regulations of each country if applicable.
- 2. Use the Power Cord (3-core mains lead) / Appliance Connector / Plug conforming to the proper ratings (Voltage, Ampere).

If you have questions on the use of the above Power Cord / Appliance Connector / Plug, please consult a Stryker service technician.

# **Warning on power connection for medical use**

Please use the following power supply cord. With connectors (plug or female) and cord types other than those indicated in this table, use the power supply cord that is approved for use in your area.

	United States and Canada
Plug Type	HOSPITAL GRADE*
Cord Type	Min.Type SJT Min.18 AWG
Minimum Rating for Plug and Appliance Couplers	10A/125V
Safety Approval	UL Listed and CSA

\*Note: Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked 'Hospital Only' or 'Hospital Grade'.

#### **1** Caution

Do not use the device in a MR (Magnetic Resonance) environment.

It may cause a malfunction, fire, and unwanted movement.

# Product Description/ Intended Use

The SDP1000 Stryker Digital Color Printer, REF 0240080230, is a dye sublimation thermal transfer printer providing high quality and high resolution printing of Stryker Digital Capture Device image data on A4 or letter size paper in full color (256 gradations process and 16.7 million colors).

It prints images by pressing a thermal head, heated according to the input image data, against a dedicated ink ribbon coated with sublimation ink, transferring the ink onto special thermal printing paper.

This device is intended for use in medical environments, such as clinics, examination rooms, and operating rooms.

#### Indications/Contraindications

The Stryker Printer is a medical accessory, that when used with the SDC systems, is intended to be used to record operative procedures.

There are no known contraindications.

#### **System Configuration**



# Location and Function of Parts and Controls

Introduction

#### Front



#### **1 On/standby switch/indicator**

When this switch is pressed, the indicator lights, and the printer enters the ready state. When it is pressed again, the indicator flashes and then goes out, and the printer enters the standby state.

- **2 Paper cover** Printouts stack here.
- **3 Paper outlet** Printouts are ejected here.
- **4** Vent openings
- 5 Media tray (page 10) The ink ribbon and paper are loaded here.
- 6 Stopper (page 14) Flip this stopper up in order to prevent the ejected printouts from falling.

#### 7 Indicators

The indicators are as shown below:



#### **(A)** TRAY LOCK indicator

Lights when the media tray cannot be pulled out.

#### **B RIBBON/PAPER** indicator

Lights when an error involving the ink ribbon or paper occurs.

Also, flashes while cleaning is in progress.

#### © ALARM indicator

Lights when an error such as a paper jam occurs.

#### **D PRINT** indicator

Lights while printing is in progress.

Do not pull out the media tray while the TRAY LOCK indicator is lit. It may cause damage. The location and cause of an error can be determined

according to which of the indicators (PRINT, ALARM, RIBBON/PAPER and TRAY LOCK) are on or flashing. For details, refer to "Explanation of Indicators" on page 22.

#### **8** STOP button (page 14)

Press this button to stop a continuous printing operation.

When this button is pressed, the printer returns to ready state after the current page is printed and ejected.

#### Rear



#### **1** $\forall$ USB connector

Connects to a computer equipped with a USB interface (which conforms to USB 2.0), etc., using a USB cable (supplied).

- 2 ★ Equipotential ground terminal connector Used to connect to a ground (equipotential) plug to bring the various parts of the system to the same potential.
- **3** Vent openings
- 4 ~AC IN connector (page 7) Use the hospital grade power cord provided.
- **5** Security slot Used to attach a security cable.
- 6 USB cable stopper (page 8) Fixes the USB cable to prevent it from being disconnected.

#### Preparation

# Carrying the printer

Hold both sides of the printer as shown below when carrying the printer.



#### Note

NEVER handle or lift the printer as shown.



#### Note

Retain the original carton and packing materials in case you have to transport this unit in the future.

# Connections

After connecting a USB connecting cable to the printer and the Stryker Digital Capture Device, connect the power cord.

#### **USB Port Connection**



#### WARNING

#### Using this unit for medical purposes

This equipment's connectors are not isolated. Do not connect any device other than one which conforms to IEC 60601-1.

When an information technology device or AV device that uses an alternating current is connected, current leakage may result in an electric shock to the patient or operator. If use of such a device is unavoidable, isolate its power supply by connecting an isolation transformer, or by connecting an isolator between the connecting cables. After implementing these measures, confirm that the reduced risk now conforms to IEC 60601-1. Preparation

#### Securing the USB cable

After you connect the USB cable to the printer, it is recommended that you use the cable stopper to secure the USB cable to prevent it from being accidentally disconnected.



# Preparation

#### Notes

- Make sure that the USB cable is connected securely at both ends.
- Operation of the printer is not guaranteed for connection to a USB hub.

#### Operation

# **Before Printing**

Once the printer is connected to the Stryker Digital Capture Device (page 7) and before initiating printing, the paper and ink ribbon need to be loaded as described below.

# Notes on Handling the Ink Ribbon and Paper

#### Do not re-use

Doing so may result in malfunction and negatively affect printing results.

#### Compatible ink ribbon and paper

- Be sure to use only ink ribbon and paper that is intended specifically for use with this printer.
- Always use the ink ribbon and paper provided in the same package together. Each printing pack contains two ink ribbons rolls and two paper rolls.
- For details on the ink ribbon and paper that can be used in this printer, see "Ink Ribbon and Paper" on page 19.

#### Handling the ink ribbon

- Do not separate the two spools of the ink ribbon before loading it in the printer.
- An IC board is built into one of the spools. Do not touch the terminals of the IC board, and do not allow them to come into contact with metal objects, etc. Furthermore, do not strike, bend or drop the ink ribbon; doing so could make the ink ribbon unusable.



- Do not attempt to re-use a used ink ribbon.
- Do not rewind the ink ribbon.
- Do not touch the surface of the ink ribbon, and do not leave it exposed in a dusty location. Fingerprints and dust on the surface of the ink ribbon can cause smudges in printed output, and can damage the thermal head.

• Since, like other color dyes, the dyes used in this ink ribbon may discolor over time, the product will neither be replaced nor be warranted against any color change.

#### Handling paper rolls

- Place the paper roll vertically on the stable place, when opening the wrapping. If you open the wrapping holding it with hands or placing it horizontally, you may drop it. Dropping may result in an injury.
- Be sure not to open the wrapping with a knife such as a cutter. This may damage a paper roll and ink ribbon and you may not be able to use them for printing.
- Whenever you set down a paper roll, place it standing on its end as show in the figure below. If you place it on its side, it could roll of the surface and fall, possibly causing personal injury.



• Always hold a paper roll securely with two hands. Dropping a paper roll could cause personal injury. Any dust on the printing surface will result in poor printout quality.



Hold securely with two hands

#### Notes on storing ink ribbons and paper

- Do not store ink ribbons and paper in locations exposed to high temperatures, high humidity, dust, or direct sunlight.
- Do not open the ink ribbon and paper packages until you are ready to use them.
- If it is necessary to store a partially used ink ribbon or paper roll for an extended period of time, it is recommended that they be stored in their original bags.

#### Loading the Ink Ribbon and Paper

When using the printer for the first time, it is necessary to first load the paper and ink ribbon.

#### CAUTION

Do not touch any unit circuitry and the patient at the same time.

If the unit malfunctions, it may generate voltage that could be harmful to the patient.

Make sure that the printer is not performing an operation, and then pull out the media tray. As shown in the figure below, hook your fingers under the bottom edge of the media tray and pull the tray out, using your other hand to support the media tray from the bottom.



The media tray is normally locked in place when it is in the printer. The lever that releases the media tray is located behind the bottom edge of the tray. To unlock the tray, simply pull the lever with your fingers.

#### **I** Notes

- Do not pull out the media tray while the TRAY LOCK indicator is lit. It may cause damage.
- Be careful not to drop the media tray when pulling it out. Dropping the media tray may result in an injury. When pulling out and inserting the media tray, hold the handle part with one hand and support the media tray from the bottom with the other hand, while making sure both of your hands are securely holding the media tray.
- Do not leave the media tray partially opened. When performing work on the media tray, pull it out of the printer completely.
- Perform the work while the removed tray is placed on a stable surface.
- Do not set the media tray down in a dusty location. Dust can cause smudges in printed output, and can damage the thermal head.

**2** Separate the two spools of the ink ribbon.



**3** Load the ink ribbon in the media tray. Place the ink ribbon in the media tray so that the IC board of the ink ribbon is positioned as shown in the figure below.



#### Note

If there is any slack in the cleaning ribbon after it is placed in the tray, take up the slack by turning the spool in the direction indicated by the arrow in the following figure.



4 Set the selector for the paper holder (blue). Turn the knob on the paper holder (blue) selector to match the size of the paper roll.



1

Operatior

The selector settings and paper rolls correspond as follows.

- LT (letter size): SEPC-110
- A4 (A4 size): SEPC-100

#### Note

Do not turn the selector beyond the range of the paper size marks when setting it. Doing so may result in damage.

**5** Insert the paper holders into the paper roll. A pink paper holder and a blue paper holder are provided with the printer. Insert these paper holders into the ends of the paper roll as shown in the figure below, with the pink paper holder in the end closer to the pink adhesive label and the blue paper holder in the end closer to the blue label.



#### Notes

• If the edges of the paper on the ends of the paper roll are not even, it is necessary to make the edges even (being careful not to crumple the edges while doing so) before placing the paper roll in the media tray. Using a paper roll with uneven edges can cause a malfunction.



- Do not strike or squeeze the paper roll. Doing so could break or bend the paper roll, and could result in poor printing quality.
- If inserting the paper holder into the paper roll is difficult when loading the paper roll, squeeze the roll from both sides to restore its shape.



• Correctly insert the paper holders all the way.

#### If the paper holder selector comes off

The selector could come off if you drop the blue paper holder. Follow the procedure described below to reattach the selector to the paper holder.

 As shown in the figure below, put the selector in the bobbin, line up the ▼ mark on the selector with the arrow on the bobbin, and then push the selector into place.

The hook on the selector snaps into the notch on the bobbin marked by the arrow.



#### Note

There are two hooks on the selector: one indicated by the  $\bigvee$  mark and the other on the opposite side of the selector. Do not install the selector so that the hook on the side opposite of the  $\bigvee$  mark is in the notch on the bobbin marked by the arrow, as doing so could result in damage to the paper holder.

2 Turn the selector in the direction indicated by the arrow in the figure below until it clicks into place.



- **6** Load the paper roll in the media tray.
  - ① Open the media tray cover.



Place the paper roll in the media tray so that the arrow on the label points toward the ink ribbon side. You can load the paper roll in the correct direction by matching the colors of the paper holders inserted into the paper roll with the colors on the media tray.



3 Close the media tray cover so that it clicks into place.



#### Note

Once the paper roll has been loaded, do not touch the printing surface (the inner surface of the paper roll). Fingerprints or sweat on the surface of the paper, or even creases in the paper, could result in poor printing quality.

7 Carefully peel off the adhesive labels from the paper roll in the direction indicated by the arrow.



#### Note

Be certain to remove the labels completely. If the labels are not peeled off carefully, they can leave adhesive on the paper. Leaving any of the label in the printer can cause a malfunction.

8 Insert the media tray into the printer. Push the media tray in until it clicks into place.



#### I Notes

• Dropping the media tray while it is loaded with paper and ink ribbon could cause personal injury. Always use two hands when carrying the media tray, supporting the media tray from the bottom.



- Removing the adhesive labels before closing the cover can cause a malfunction.
- Wind the paper roll if the leading edge of the paper is touching the ink ribbon. If the leading edge of the paper is left resting on the ink ribbon, malfunctions may occur.



Leading edge of paper

#### If the ink ribbon becomes torn while still in use

Cellophane tape, etc., can be used to repair a torn ink ribbon so that the remainder of the ribbon can be used.

#### **Replacing the Ink Ribbon and Paper**

Once the ink ribbon or paper have been used to print the specified number of sheets, follow the procedure described below to replace the ink ribbon and paper.

#### Notes

- Be sure to replace the ink ribbon and the paper roll at the same time.
- The ink ribbon and paper roll both contain excess material. Even if there appears to be some excess ink ribbon or paper remaining, replace both with a new ink ribbon and paper roll. Attempting to use the remaining excess ink ribbon or paper can cause a malfunction.
- **1** Make sure that the TRAY LOCK indicator is extinguished then pull out the media tray.

#### i Notes

- If the media tray does not pull out, do not force it out. Press the () On/standby switch to enter the standby state, and then press the switch again to turn the printer ON. Try pulling the media tray again after the printer finishes initializing.
- After a printing operation is completed, the thermal head is very hot. When pulling out the media tray, be careful not to touch the thermal head. Touching

the thermal head could result in a burn. Also, be careful not to scratch the thermal head.

**2** Open the cover of the media tray and remove the paper roll.



**3** Remove the paper holders from the paper roll.



#### Note

Be sure to retain the paper holders for use with the next paper roll. Do not discard the paper holders.

**4** Remove the ink ribbon.



Roll together the two spools of the ink ribbon that you just removed.



Load the new ink ribbon and paper.For details on how to load ink ribbon and paper, refer to step 2 onward for "Loading the Ink Ribbon and Paper" on page 10.

# Printing

#### **Before printing**

- Is the printer connected to a Stryker Digital Capture Device? (page 7)
- Has the media tray been properly loaded? (page 10)



**1** Press the printer  $\bigcirc$  On/standby switch to turn on the power of the printer.

The  $\bigcirc$  On/standby indicator lights and initialization of the printer begins.

The PRINT, ALARM, RIBBON/PAPER, and TRAY LOCK indicators light simultaneously during initialization of the printer, and go out when initialization is complete.

- **2** Turn the Stryker Digital Capture Device on.
- **3** Using the Stryker Digital Capture Device, initiate a printing operation.

The PRINT indicator flashes while the image data is being received, and then remains steadily lit while printing is in progress.

#### Notes

- Do not place objects on the paper cover that will obstruct printing. Doing so may result in damage.
- Although the paper being printed may come into view in the paper outlet while printing is in progress, do not touch the paper until printing is completed. Doing so could result in misoperation.
- Do not allow more than 10 printouts to accumulate on the paper cover. Leaving too many printouts on the paper cover could cause a paper jam.
- Do not press the <sup>(1)</sup> On/standby switch to enter the standby state while printing is in progress. Doing so may cause a paper jam or the ink ribbon to break.

• Do not open the media tray while printing is in progress.

If the media tray is opened, printing stops and the PRINT, ALARM, RIBBON/PAPER, and TRAY LOCK indicators all light simultaneously. In such an event, press the <sup>(1)</sup> On/standby switch once to enter the standby state and then press the switch again to turn the printer ON, and check that there is no paper jam or the ink ribbon is not broken. Also, if printing was partway through, cut off the used part of the paper roll with a pair of scissors or the like before using the printer.

#### Notes

#### Storing printed images

- Avoid storing printouts in a location subject to high temperatures, high humidity, excessive dust or direct sunlight. Such conditions could result in fading.
- Do not stick tape on a printout. Also, do not let printouts come into contact with materials which contain plasticizers, such as erasers or desk mats.
- Do not allow volatile organic solvents, such as alcohol, to come into contact with printouts.

#### **Cancelling continuous printing**

Press the STOP button. Printing of the current item finishes, and then the printer enters the ready state once the printout is ejected.

#### When printing is disabled

The printer will not operate if the ALARM, RIBBON/ PAPER or TRAY LOCK indicator is on. For details, see "Explanation of Indicators" on page 22.

# If the ink ribbon runs out while continuous printing

The printer terminates the printing operation. Once the new ink ribbon is loaded, the printing operation automatically resumes and the remaining images are printed.

#### Using the stopper

To prevent ejected printouts from falling off of the paper cover, insert your finger in the depression on the edge of the stopper and then flip the stopper up in the direction indicated by the arrow in the diagram below.



# When removing and then reloading a partially used paper roll

If the paper roll is not tightly rolled, roll it up more tightly before reloading it.



#### **i** Note

When removing a partially used paper roll, be sure to place the media tray on a stable surface before beginning. If you drop the media tray while it contains a paper roll, it could cause personal injury.

When removing and inserting the media tray, be sure to use both hands, with one hand holding the handle and the other hand supporting the media tray from the bottom.



#### Miscellaneous

# **Derecautions**

#### Safety

- Operate the printer using the power source specified in "Technical Specifications" (page 20).
- Be careful not to damage the power cable by placing or dropping heavy objects on it; it is dangerous to use the unit with a damaged power cable.
- If you do not intend to use the printer for a long time, press the () On/standby switch on the printer to enter the standby state and then remove the power plug.
- Unplug the power cable by grasping the plug, not the cable itself.
- Do not disassemble the unit. There is a danger of electric shock from the internal parts.
- Be careful not to spill water or other liquids on the unit, or to allow combustible or metallic material to enter the cabinet. If used with foreign matter in the cabinet, the unit is liable to fail, or present a risk of fire or electric shock.
- If the unit malfunctions or if a foreign body falls into the cabinet, disconnect the power immediately and consult your local Stryker representative.

#### Installation

- Avoid placing the unit in a location subject to:
- mechanical vibration
- high humidity
- excessive dust
- direct or excessive sunlight
- extremely high or low temperatures
- Ventilation holes are provided on the back of the unit to prevent the unit from overheating. Be careful not to obstruct them with other objects or by covering the unit with a cloth etc.
- To prevent internal heat built-up, leave enough room around the printer for air to circulate through the ventilation holes (intake) on the left and right hand side and the ventilation holes (exhaust) on the rear of the cabinet (at least more than 10 cm).

#### On condensation

• If the printer is subjected to wide and sudden changes in temperature, such as when it is moved from a cold room to a warm room or when it is left in a room with a heater that tends to produce quantities of moisture, condensation may form inside the printer. In such cases the printer will probably not work properly, and may even develop a fault if you persist in using it. If moisture condensation forms, turn off the power and leave the printer standing for at least one hour.

- If the printing pack is subjected to wide and sudden changes in temperature, condensation may form on the ink ribbon or paper inside. This will cause the printer to malfunction. Also, if the printing pack is used in this state, spots are likely to appear on the printout.
- To store a half-used printing pack, replace it in its original packing and reseal the package. If possible, keep the sealed printing pack in a cool, dark location. To subsequently use the printing pack, place it, in its sealed package, in a warm room for several hours. Doing so prevents condensation from forming when the printing pack is removed from its package.

#### Transportation

#### When transporting the printer, be certain to first remove all accessories, including the ink ribbon and paper. Carrying the printer with accessories installed can later cause the printer to malfunction. It is recommended that the ink ribbon and paper roll be stored in their original bags.

#### Warning

To avoid electric shock and potentially fatal injury, unplug the console from the electrical outlet before cleaning.

Do not sterilize the printer or immerse it in any liquid. Doing so will damage the unit.

#### Cleaning

#### Note

Before you clean the printer, be sure to press the <sup>(1)</sup> On/ standby switch to enter the standby state and then remove the power plug.

#### When the cabinet becomes dirty

When solvents such as benzene or thinner, or acid, alkaline or abrasive detergent, or chemical cleaning cloths are used on the printer surface, the surface finish may be damaged. Take care with respect to the following:

- Clean the printer surface with a 50 to 70 v/v% concentration of isopropyl alcohol or a 76.9 to 81.4 v/v% concentration of ethanol.
- Stubborn stains may be removed with a soft cloth such as a cleaning cloth lightly dampened with mild detergent solution and then cleaned using the above chemical.
- Do not use unnecessary force to rub the printer surface with a stained cloth. The printer surface may be scratched.
- Do not keep the printer surface in contact with a rubber or vinyl resin product for a long period of time. The surface finish may deteriorate or the coating may come off.

#### **Cleaning the Internals of the Printer**

Perform thermal head cleaning if lines and marks appear on printouts, and perform roller cleaning if scratches appear at regular intervals.

#### Thermal head cleaning

To maintain print quality, we recommend that you perform regular thermal head cleaning once a month or once after every 10 printing packs used.

- 1 Make sure that the printer is not performing an operation, and then pull out the media tray.
- **2** Confirm whether there is paper inside.
- Remove the ink ribbon.For details on how to remove the ink ribbon, see step 4 of "Replacing the Ink Ribbon and Paper" on page 13.
- **4** Load the cleaning ribbon. For details on how to load the cleaning ribbon, see steps 2 and 3 of "Loading the Ink Ribbon and Paper" on page 10.



#### Note

If there is any slack in the cleaning ribbon after it is placed in the tray, take up the slack by turning the spool in the direction indicated by the arrow in the following figure.



**5** Insert the media tray into the printer. When the TRAY LOCK indicator is lit and the printer finishes initializing, the RIBBON/PAPER indicator flashes and cleaning starts automatically. When cleaning is completed, the paper that was used for cleaning is ejected and the TRAY LOCK indicator is extinguished.

If you want to clean the rollers, proceed to "Roller cleaning" on page 17. If you are not cleaning the rollers, continue with the steps below.

- 6 Make sure that the TRAY LOCK indicator is extinguished then pull out the media tray.
- **7** Remove the cleaning ribbon.
- **8** Load the ink ribbon.
- **9** Insert the media tray into the printer.

#### Notes

- Store the cleaning ribbon in a location without dust (such as in a bag).
- Place the removed media tray on a stable surface when loading and removing the cleaning ribbon.
- Dropping the media tray while paper is loaded may result in an injury. When pulling out and inserting the media tray, hold the handle part with one hand and support the media tray from the bottom with the other hand, while making sure both of your hands are securely holding the media tray.

#### **Roller cleaning**

On rare occasion, scratches may appear at regular intervals on printouts as shown in the following. These scratches appear when the rollers inside the printer are dirty and indicate that cleaning is necessary.



You can remove dust and other particles attached to the rollers by using a cleaning sheet, which may be purchased separately.

The following describes the cleaning procedure.

#### Notes

- Perform roller cleaning while the cleaning ribbon is still inside the printer after thermal head cleaning.
- Keep a scratched printout and remember the direction it was facing when ejected. You will need it later to confirm the position of the scratches.

- Be sure to use only one cleaning sheet per cleaning procedure. Using more than one sheet for a single roller cleaning procedure may result in malfunction.
- **1** If thermal head cleaning has not been performed, perform steps 1 to 5 of "Thermal head cleaning" on page 17.

#### **i** Note

When performing roller cleaning, do not pull out the media tray after thermal head cleaning is performed.

**2** Remove the paper that is ejected after thermal head cleaning is performed.



Keep the STOP button pressed and take your finger off the button when the TRAY LOCK indicator is lit. About 20 cm of paper is fed out of the printer from the paper outlet.



4 Remove the backing paper ① from the cleaning sheet and attach the cleaning sheet to the partially ejected paper, then remove the backing paper ②.



#### Notes

- Orient the scratched printout that you kept in the direction it was facing when ejected, and use it to align the position of the cleaning sheet with the position of the scratches.
- Press the cleaning sheet with your finger to make sure that it is firmly affixed.



- Make sure there is no air trapped under the cleaning sheet and the corners of the sheet are not curling up. Such cases will result in paper jams.
- If air is trapped under the cleaning sheet, be sure to press it out.

**5** Press the STOP button.

Roller cleaning with the cleaning sheet starts.



Miscellaneous

3

Miscellaneous

When cleaning is completed, the paper is ejected and the TRAY LOCK indicator is extinguished.

#### Notes

- The cleaning sheet is ejected with the paper. Discard the paper and do not reuse it.
- To perform roller cleaning again, repeat the procedure from step 3.
- If an error occurs, restart the procedure from step 1.
- 6 Make sure that the TRAY LOCK indicator is extinguished then pull out the media tray.
- **7** Remove the cleaning ribbon.
- **8** Load the ink ribbon.
- **9** Insert the media tray into the printer. This completes the cleaning procedure.

#### Notes

- As paper is used during cleaning procedures, the specified number of prints possible with a paper roll may be reduced if the same roll is used for multiple cleaning procedures.
- If there is not enough paper, the paper on which the cleaning sheet is attached may remain on the paper holder after cleaning is performed. In such cases, be sure to replace the paper roll.
- If the cleaning sheet is not ejected despite sufficient paper, cut off the paper on which the cleaning sheet is attached from the paper holder, and repeat the procedure from step 2.



#### **Expected Service Life**

The SDP1000 Digital Color Printer has an expected service life of 5 years. End of life is normally determined by wear and damage due to use. When the device has reached the end of its service life, dispose of it according to local laws and hospital practices.

# Ink Ribbon and Paper

#### Self-Laminate Color Printing Pack SEPC-100

Contains two color ink ribbons and two rolls of paper (A4-size width).

#### Self-Laminate Color Printing Pack SEPC-110

Contains two color ink ribbons and two rolls of paper (Letter size width).

#### Printable quantity

The number of printouts that can be made with a single set of ink ribbon and paper is shown below.

Printing pack	SEPC-100	SEPC-110
Number of sheets	50 sheets	50 sheets
Print size	A4	Letter

For symbols on the accessories, see page 3.

#### Notes

- Do not change the ink ribbon and paper roll when they are only partially used. Doing so can cause problems. The number of printouts indicated above is not quarantined.
- When the ink ribbon is used up, replace both the ink ribbon and the paper roll.
- Destroy and discard ink ribbon per NIST Media Sanitization Standards. (For customers in the U.S.A.)

# **Technical Specifications**

Power requirements 100 - 240 V AC, 50/60 Hz 3.4 — 1.4 A Input current Operating temperatures 5 °C — 35 °C (41 °F — 95 °F) Operating humidity 20% - 80% (no condensation) **Operating** pressure 700 hPa — 1,060 hPa Storage and transport temperature -20 °C -- +60 °C (-4 °F -- +140 °F) Storage and transport humidity 20% - 80% (no condensation) Storage and transport pressure 700 hPa — 1,060 hPa Dimensions Approx.  $317 \times 425 \times 207 \text{ mm} (w \times d \times h)$ Weight Approx. 11.5 kg Printing system Dye transfer sublimation thermal printing Thermal head 11.83 dot/mm, 2,560 dots (301 dpi) Gradations 8-bit (256-level) processing each for yellow, magenta, and cyan Maximum print size A4 size: 202 × 287 mm Letter size:  $208 \times 269$  mm Picture elements A4 size:  $2,392 \text{ dots} \times 3,400 \text{ dots}$ Letter size: 2,464 dots  $\times$  3,192 dots Printing time Approximately 76 seconds (A4 size) Approximately 72 seconds (Letter size) Interface Hi-Speed USB (USB 2.0) Component supplied Paper holder: ① Paper holder (pink) (1): P12811 2 Paper holder (Blue) (1): P12812 Cleaning Ribbon (1) P12814 Media Tray (1) P12813 Hospital Grade Power Cord (118 in) (1) (For US/CANADA use only) PN 12760 CD-ROM(1) P12744 Optional accessories Ink ribbon/paper roll (2 rolls of paper; 2 rolls of ribbon) Self-Laminating Color Printing Pack Letter size (SEPC-110) 0240080231 Self-Laminating Color Printing Pack A4 size (SEPC-100) 0240080232 **Cleaning Sheet Pack** 0240080233

Design and specifications are subject to change without notice.

Medical Specifications

Protection against electric shock:

Class I

Protection against harmful ingress of water:

Ordinary

Degree of safety in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide Mode of operation:

Continuous

#### About the Self-Laminating Color Printing Pack (SEPC-100/SEPC-110)

#### Caution

When you dispose of the unit or accessories, you must obey the laws in the relative area or country and the regulations in the relative hospital regarding environmental pollution.

#### Precautions

- Store unopened paper rolls in a cool dark place.
- Open paper rolls only when ready to use.
- Please refer to the printer's instruction manual about how to load the paper roll.
- Promptly load the paper roll into the tray and place into the printer.
- This paper roll is specifically designed for the SDP1000 Stryker Digital Color Printer. Do not use with printers from other manufacturers.

# Troubleshooting

If a problem appears, check the following troubleshooting guide first and perform whatever action is necessary to solve the problem. If the problem persists, turn off the printer and consult with your local Stryker representative.

Symptom	Possible causes and remedies
The printer does not print even though images are being sent from the computer.	<ul> <li>The printer is in the standby state (the <sup>(1)</sup>On/standby indicator is not lit).         → Press the <sup>(1)</sup>On/standby switch.     </li> <li>The printer is not connected properly.         → Check the connections (page 7).     </li> </ul>
The printer does not print.	<ul> <li>An indicator on the printer is displaying an error status.</li> <li>→ Refer to "Explanation of Indicators" on page 22 and take the appropriate action.</li> </ul>
The paper roll cannot be loaded in the media tray.	<ul> <li>The paper roll is being loaded with the colors of the paper holders and the colors on the media tray incorrectly matched.</li> <li>→ Load the paper roll so that the colors of the paper holders and the colors on the media tray match (page 12).</li> </ul>
The paper does not feed.	<ul> <li>The paper roll is loaded with the colors of the paper holders and the colors of the labels affixed to the paper roll incorrectly matched.</li> <li>→ Load the paper roll so that the colors of the paper roll so that the colors of the paper holders and colors of the labels affixed to the paper roll match (page 11).</li> <li>The paper roll is loaded with the left and right reversed (when the paper roll has been reloaded).</li> <li>→ Load the paper roll in the proper direction (page 12).</li> <li>The paper holder selector does not match the size of the paper roll.</li> <li>→ Set the selector properly (page 10).</li> <li>The label affixed to the paper roll has not been peeled off.</li> <li>→ Peel the label off properly (page 12).</li> <li>The paper roll is wound to loosely.</li> <li>→ Rewind the paper roll and then load it (page 15).</li> <li>The leading edge of the paper roll is folded.</li> <li>→ Cut off the folded part so that the paper becomes straight (page 24).</li> </ul>
The print area is printed offset.	<ul> <li>The paper holder selector does not match the size of the paper roll.</li> <li>→Set the selector properly (page 10).</li> </ul>
There are marks and stripes on the print side.	<ul> <li>The thermal head is dirty.</li> <li>→ Perform thermal head cleaning (page 17).</li> </ul>
Scratches appear at regular intervals.	<ul> <li>The rollers inside the printer are dirty.</li> <li>→ Perform roller cleaning (page 17).</li> </ul>

Symptom	Possible causes and remedies
The media tray cannot be opened.	<ul> <li>The power may have been turned off during the printing operation.         <ul> <li>→Press the <sup>(1)</sup> On/standby switch to turn on the power of the printer and initialize the printer.</li> </ul> </li> <li>The printer may not have been able to recover from an error.         <ul> <li>→Press the <sup>(1)</sup> On/standby switch to enter the standby state and then press the <sup>(1)</sup> On/standby switch again to turn on the power. If the media tray still cannot be opened, press the <sup>(1)</sup> On/standby switch to enter the standby state and then disconnect the power cord and contact your dealer.</li> </ul> </li> </ul>
The fan turns when the printer is in the ready state.	• The printer is performing temperature control. This is not a malfunction.

# **Explanation of Indicators**

The meanings of the indicators on the printer when they are on or flashing are described below.

Indicator	Status	Possible causes and remedies		
() On/	On	The printer is turned on.		
standby (green)	Flashing	The printer is entering the standby state.		
TRAY LOCK (orange)	On	The media tray cannot be pulled out because the mechanical action is going, eg. printer initializing, tray recently closed, printer cleaning cycle in process. It lights up with other LED.		
RIBBON/ PAPER <sup>1)</sup> (orange)	On	<ul> <li>One of the following causes.</li> <li>A paper roll has not been loaded. <ul> <li>→ Load a paper roll (page 11).</li> </ul> </li> <li>An ink ribbon has not been loaded. <ul> <li>→ Load an ink ribbon (page 10).</li> </ul> </li> <li>The ink ribbon has been used up. <ul> <li>→ Load a new ink ribbon and paper roll (page 13).</li> </ul> </li> <li>A ribbon error has occurred. <ul> <li>→ Check that an ink ribbon has been loaded properly.</li> </ul> </li> </ul>		
	Flashing	<ul> <li>LED will flash slowly when there are 6 to 15 sheets of media remaining.</li> <li>LED will flash rapidly when there are 5 or fewer sheets of media remaining.</li> <li>LED will flash three consecutive times at once when: <ul> <li>Thermal head or roller cleaning is in progress.</li> <li>The printer is waiting to begin roller cleaning.</li> <li>→Press the STOP button to begin.</li> <li>The cleaning ribbon is loaded.</li> <li>→Remove the cleaning ribbon.</li> </ul> </li> </ul>		
ALARM <sup>1)</sup> (orange)	On	<ul> <li>One of the following causes.</li> <li>The media tray is not closed. <ul> <li>→Close the media tray properly.</li> </ul> </li> <li>A paper jam has occurred in the printer. <ul> <li>→Remove the jammed paper (page 23).</li> </ul> </li> <li>The paper outlet is full of printouts. <ul> <li>→Remove the printouts that are blocking the paper outlet.</li> </ul> </li> </ul>		

Indicator	Status	Possible causes and remedies		
RIBBON/ PAPER, ALARM <sup>1)</sup>	On	<ul> <li>One of the following causes.</li> <li>The paper roll has run out. <ul> <li>→Load a new ink ribbon and paper roll (page 13).</li> </ul> </li> <li>A paper feed error has occurred. <ul> <li>→Check the ink ribbon and paper roll.</li> </ul> </li> <li>A paper eject error has occurred. <ul> <li>→Check the ink ribbon and paper roll.</li> </ul> </li> </ul>		
	Flashing <sup>2)</sup>	<ul> <li>One of the following causes.</li> <li>A ribbon error occurred while cleaning was in progress. <ul> <li>→ Check that the cleaning ribbon has been loaded properly.</li> </ul> </li> <li>A paper jam occurred inside the printer while cleaning was in progress. <ul> <li>→ Remove the jammed paper (page 23).</li> </ul> </li> <li>The paper roll ran out while cleaning was in progress. <ul> <li>→ Load a new paper roll.</li> </ul> </li> <li>A feed error occurred while cleaning was in progress. <ul> <li>→ Check the cleaning ribbon and paper roll.</li> </ul> </li> <li>An eject error occurred while cleaning was in progress. <ul> <li>→ Check the cleaning ribbon and paper roll.</li> </ul> </li> </ul>		
PRINT	On	Printing is in progress.		
(green)	Flashing	Image data is being received.		
	Flashing slowly	The printer is waiting until the thermal head reaches a temperature at which printing is possible. Once that temperature is reached, the PRINT indicator will light.		
All of TRAY LOCK, RIBBON/ PAPER, ALARM, and PRINT	On	<ul> <li>The printer is initializing.         → After pressing the <sup>(1)</sup> On/standby switch to turn on the printer, this indicator remains lit while the printer is initializing. Wait until initialization is complete.</li> <li>The media tray was opened during printing.         → Press the <sup>(1)</sup> On/standby switch to enter the standby state, press the <sup>(1)</sup> On/standby switch again to turn on the power, and then check the ink ribbon and paper roll.</li> <li>A serious failure has occurred.         → Press the <sup>(1)</sup> On/standby switch to enter the standby state, and then press the <sup>(1)</sup> On/standby switch to enter the standby state, and then press the <sup>(1)</sup> On/standby switch again to turn on the power. If the printer is still unable to recover from the failure, press the <sup>(1)</sup> On/standby switch to enter the standby state and then disconnect the power cord and contact your dealer.</li> </ul>		

Footnotes for the previous chart:

- <sup>1)</sup> During continuous printing, the PRINT indicator lights at the same time if there are still images remaining.
- <sup>2)</sup> Only the RIBBON/PAPER indicator flashes. The ALARM indicator is lit.

# If a Paper Jam Occurs

While the printer is printing, if the ALARM indicator lights and any of the following messages appears on the computer monitor, it is possible that a paper jam has occurred in the printer:

"A paper jam has occurred. Remove the jammed paper." "A paper jam has occurred. Printing has stopped. Remove the jammed paper and then resume printing."

"There is a problem with a motor or a sensor. Printing has stopped. Turn the printer off and then back on again, and then resume printing."

If a paper jam has occurred, follow the procedure described below to check the status of the paper roll.

1 Make sure that the printer is not performing an operation, and then pull out the media tray.



#### Note

If the media tray does not pull out, do not force it out. Press the <sup>(1)</sup> On/standby switch to enter the standby state, and then press the switch again to turn the printer ON. Try pulling the media tray again after the printer finishes initializing.

**2** Open the media tray cover, check whether there is printing on the paper, and cut the paper. Cut the paper as follows.

#### If there is printing on the paper

Cut off the printed portion with a pair of scissors.



#### If there is no printing on the paper

Make sure that the leading edge of the paper is not creased or wrinkled.

If the leading edge is creased or the paper is wrinkled, cut off the leading edge or wrinkled portion with a pair of scissors or the like.



Tighten any looseness in the paper roll (page 15), and close the media tray cover until it snaps into place.

#### **4** Insert the media tray into the printer.



#### Notes

- When removing the paper roll, be sure to place the media tray on a stable surface before beginning.
- If you drop the media tray while it contains a paper roll, it could cause personal injury. When removing and inserting the media tray, be sure to use both hands, with one hand holding the handle and the other hand supporting the media tray from the bottom.
- When cutting the paper roll, be sure to cut so that the leading edge of the paper is straight. Loading the paper into the printer with the leading edge cut as follows may result in damage to the printer.



3

#### Important EMC notices for use in the medical environments

- The SDP1000 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the instructions for use.
- The SDP1000 is intended for use in a professional healthcare facility environment.
- The portable and mobile RF communications equipment such as cellular phones can affect the SDP1000.

#### <u>i</u> Warning

- Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the SDP1000. Otherwise, degradation of the performance of this equipment could result.
- If the SDP1000 will be used adjacent to or stacked with other equipment, normal operation of the SDP1000 under such configurations should be verified via observation.
- The use of accessories and cables other than those specified, with the exception of replacement parts sold by Stryker, may result in increased emissions or decreased immunity of the SDP1000.

Gui	Guidance and manufacturer's declaration - electromagnetic emissions				
The SDP1000 is inte The customer or the	The SDP1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the SDP1000 should assure that it is used in such an environment.				
Emission test	Compliance	Electromagnetic environment - guidance			
RF emissions		The SDP1000 uses RF energy only for its internal			
CISPR 11	Group 1	function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.			
RF emissions	21 2	The SDP1000 is suitable for use in all			
CISPR 11	Class B	and those directly connected to the public low-			
Harmonic		voltage power supply network that supplies buildings used for domestic purposes.			
emissions	Class A				
IEC 61000-3-2					
Voltage fluctuations/flicker emissions	Complies				
IEC 61000-3-3					

#### Guidance and manufacturer's declaration - electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, a relative humidity of at least 30% is recommended.
IEC 61000-4-2	±15 kV air	±15 kV air	
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	±1 kV for input/ output lines	±1 kV for input/ output lines	
Surge	±1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	±2 kV line(s) to earth	±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% $U_{\rm T}$ (100% dip in $U_{\rm T}$ ) for 0.5/1 cycles <sup>a</sup> 40% $U_{\rm T}$ (60% dip in $U_{\rm T}$ ) for 5 cycles 70% $U_{\rm T}$ (30% dip in $U_{\rm T}$ ) for 25/30 cycles <sup>a</sup> (for 0.5 sec) 0% $U_{\rm T}$ (100% dip in $U_{\rm T}$ ) for 250/300 cycles <sup>a</sup> (for 5 sec)	0% $U_{\rm T}$ (100% dip in $U_{\rm T}$ ) for 0.5/1 cycles <sup>a</sup> 40% $U_{\rm T}$ (60% dip in $U_{\rm T}$ ) for 5 cycles 70% $U_{\rm T}$ (30% dip in $U_{\rm T}$ ) for 25/30 cycles <sup>a</sup> (for 0.5 sec) 0% $U_{\rm T}$ (100% dip in $U_{\rm T}$ ) for 250/300 cycles <sup>a</sup> (for 5 sec)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SDP1000 requires continued operation during power mains interruptions, it is recommended that the SDP1000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: <i>U</i> + is the a	a.c. mains voltage	prior to application	l of the test level.
a For example, 10/12 means 10 cycles at 50 Hz or 12 cycles at 60 Hz.			

The SDP1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the SDP1000 should assure that it is used in such an environment.

(	Guidance and manufacturer's declaration - electromagnetic immunity				
The SDP1000 is i	The SDP1000 is intended for use in the electromagnetic environment specified below. The customer or the				
user of the SDP I	000 should assure	that it is used in si	uch an environment.		
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance		
			Portable and mobile RF communications equipment should be used no closer to any part of the SDP1000, including cables, than the recommended separation distance calculated from the equation appliance to the frequency of the transmitter. <b>Recommended separation distance</b>		
Conducted RF	3 Vrms	3 Vrms	$d = 1.2 \sqrt{P}$		
IEC 61000-4-6	150 kHz to 80 MHz outside ISM bands ∘				
	6 Vrms 150 kHz to 80 MHz in ISM bands ∘	6 Vrms			
Radiated RF	3 V/m	3 V/m	IEC 60601-1-2 : 2007		
			$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz		
IEC 61000-4-3	80 MHz to				
	2.7 GHz		IEC 60601-1-2 : 2014 $d = 2.0 \sqrt{P}$ 80 MHz to 2.7 GHz		
			Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).		
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>		
			Interference may occur in the vicinity of equipment marked with following symbol:		

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SDP1000 is used exceeds the applicable RF compliance level above, the SDP1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SDP1000.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Miscellaneous

#### Recommended separation distances between portable and mobile RF communications equipment and the SDP1000

The SDP1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the SDP1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SDP1000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter m					
output power	IE	EC 60601-1-2 : 200	IEC 60601-1-2 : 2014			
of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	150 kHz to 80 MHz	80 MHz to 2.7 GHz	
vv	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.0 \sqrt{P}$	
0.01	0.12	0.12	0.23	0.12	0.20	
0.1	0.38	0.38	0.73	0.38	0.63	
1	1.2	1.2	2.3	1.2	2.0	
10	3.8	3.8	7.3	3.8	6.3	
100	12	12	23	12	20	

For transmitters rated a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

#### Guidance and manufacturer's declaration - electromagnetic immunity

The SDP1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the SDP1000.

Otherwise, degradation of the performance of this equipment could result.

Immunity test	Band <sup>a</sup>	Service <sup>a</sup>	Modulation	IEC 60601 test level	Compliance level	
Proximity fields from RF	380 MHz - 390 MHz	TETRA 400	Pulse modulation 18 Hz	27 V/m	27 V/m	
wireless communications equipment	430 MHz - 470 MHz	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	28 V/m	28 V/m	
IEC 61000-4-3	704 MHz - 787 MHz	LTE Band 13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m	
	800 MHz - 960 MHz	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	28 V/m	28 V/m	
	1700 MHz - 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation 217 Hz	28 V/m	28 V/m	
	2400 MHz - 2570 MHz	Bluetooth WLAN 802. 11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28 V/m	28 V/m	
	5100 MHz - 5800 MHz	WLAN 802. 11 a/n	Pulse modulation 217 Hz	9 V/m	9 V/m	
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.						
a For some services, only the uplink frequencies are included.						

# **Adverse Event Reporting**

Any serious incident that has occurred in relation to this device should be reported to Stryker and, in the European Union, to the competent authority of the Member State in which the affected person resides.

# Warranty and Return Policy

#### **Product Warranty**

Stryker Endoscopy warrants all products, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker Endoscopy with the products for a period of one year from the date of purchase (the "Warranty Period"). This warranty shall apply only to the original end-user purchaser of products directly from Stryker Endoscopy or a Stryker Endoscopy authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker Endoscopy.

If a valid warranty claim is received within the Warranty Period, Stryker will, in its sole discretion: (1) repair the product at no charge, (2) replace the product at no charge with a product that is at least functionally equivalent to the original product, or (3) refund the purchase price of the product. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker Endoscopy personnel without the prior written consent of Stryker Endoscopy; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker Endoscopy representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components, including replacement lamps.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial Warranty Period or, if the initial Warranty Period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The inspection, testing, acceptance or use of the products and services furnished hereunder shall not affect Stryker's obligation under this warranty, and such warranty shall survive inspection, test, acceptance and use.

Notwithstanding the above, (i) the following products are warranted for a period of ninety (90) days from the date of purchase: Scopes, Associated Scope Hardware, Fiber Optic Cables, Laparoscopic Instruments, VCRs, Monitors, and Ink Jet Printers; (ii) SDP1000 Stryker Digital Color Printers are warranted for three (3) years from the date of purchase; and (iii) replacement light bulbs are warranted for a period of sixty (60) days from the date of purchase.

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. STRYKER SHALL NOT HAVE ANY TORT LIABILITY TO CUSTOMER WITH RESPECT TO THE PRODUCTS AND SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

#### **Return Policy**

Stryker Endoscopy values customer relationships and strives for satisfaction in purchases made by our customers. Therefore, we offer a return policy for most products. Under this policy, customers may return purchased products to Stryker Endoscopy, within 90 days of customer's receipt of the product, for a credit or a refund of the purchase price paid, less shipping and handling and applicable restocking fees. Products that fail after the first 90 days may be covered by and are subject to the terms of applicable product warranty. Sterile products may not be returned for credit or refund unless they are in their original, unopened packaging or if they are in breach of the applicable warranty.

Restocking Fees: Unless the product is defective or the return is the direct result of a Stryker Endoscopy error, a restocking fee of 10% may be charged on all returned products.

A Returned Merchandise Authorization (RMA) number must be obtained from Stryker Endoscopy before returning product. To obtain an RMA number, please contact Stryker Endoscopy Customer Service at 1.800.624.4422.

Please send any returned products to:

Stryker Endoscopy Attn: Returns 5900 Optical Court San Jose, CA 95138, USA

With the return, please include the following:

- 1. RMA number
- 2. Purchase order number
- 3. Original invoice number
- 4. Name, address, and account number (of the organization returning the product)
- 5. Itemized list of the items being returned 6. Reason for the return
- 7. Product Experience Report/Complaint number, if applicable

Please carefully package the product being returned. Credit will not be given for items that are damaged in return shipment due to inadequate packaging.

Stryker Endoscopy does not accept any COD returns. Return shipping costs are borne by the customer unless Stryker Endoscopy specifically agrees otherwise.

Please clean and sterilize all potentially contaminated products prior to returning them to Stryker Endoscopy. It is unlawful to transport bio-contaminated products through interstate commerce, unless they are properly packaged and labeled as such. Stryker Endoscopy reserves the right to destroy contaminated product at the customer's expense and charge the customer for a replacement unit.

Please remove any "Protected Health Information" as defined in the Health Insurance Portability and Accountability Act of 1996 from products prior to returning them to Stryker Endoscopy.

If a return does not comply with these terms, Stryker Endoscopy reserves the right to destroy the product at the customer's expense. Any replacement would be at the customer's expense.

# License

"The FreeType Project LICENSE" and "The Catharon Open Source LICENSE" software are provided in this unit. We provide this software based on license agreements with their owners of copyright. Based on requests by the owners of copyright of these software applications, we have an obligation to inform you of the following.

#### The FreeType Project LICENSE

Copyright 1996-2002 by David Turner, Robert Wilhelm, and Werner Lemberg Source code provided by the FreeType Project is used for TrueType font rasterizing.

#### The Catharon Open Source LICENSE

Copyright(c) 2000 by Catharon Productions, Inc. Source code provided by Catharon Productions Inc is used for TrueType font hinting.







Produced for: Stryker Endoscopy 5900 Optical Court San Jose, CA 95138 USA 1-800-624-4422

U.S. Patents: www.stryker.com/patents

P12706 H 2020/08

