

WelchAllyn

**KleenSpec[®] Vaginal Specula Illumination
System
REF 78810**

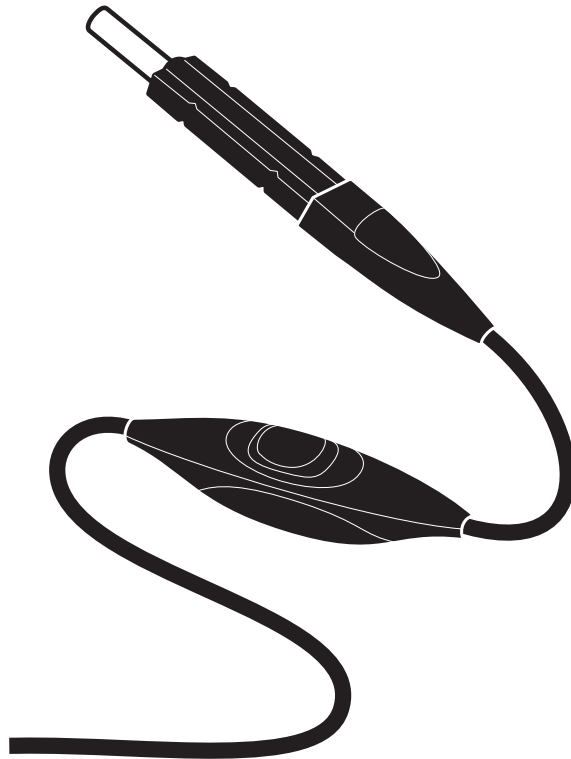


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Thank you for purchasing the Welch Allyn 78810 KleenSpec® Vaginal Specula Illumination System composing of the 78800 illuminator and the 73410 transformer. Please review this manual prior to using this system. This updated system replaces the current Welch Allyn 78010 KleenSpec Vaginal Specula Illumination System composed of the 78000 illuminator and the 73305 transformer.

Classification

Class II, Type BF Applied Part	Ordinary Equipment
Sterilize only as directed in Cleaning Section	Non-continuous Operation

Symbol Descriptions

	Warning		Consult Directions for Use
	Caution		Lamp On
	Caution, high temperatures		Lamp Off
	Caution, high intensity light		Type BF Applied Part
	Alternating Current		Direct Current
	Double Insulation		
IPX7	Illuminator is protected against the effects of temporary immersion in water (and the solutions described in this manual)	IPXØ	Transformer Plug - Not protected from the ingress of water.

Warnings and Cautions



WARNING: To avoid eye injury, do not look into the beam.



WARNING: Lamp is harmful to skin if touched. Allow lamp to cool for 5 minutes before replacing. Lamp generates heat and should remain off until just prior to and immediately after use. Do not place illuminator onto a flammable surface if lamp is illuminated.



WARNING: Disconnect transformer from outlet prior to any maintenance.



WARNING: This product is for use with the Welch Allyn KleenSpec Single-Use Vaginal Specula only. Do not use the illuminator for any other use. Lamp is hot and can cause a burn if used outside of the vaginal specula.



WARNING: KleenSpec Vaginal Specula Illumination System is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.



CAUTION: Illumination is intense.



CAUTION: Use only the cleaning methods and disinfection solutions/methods described in this manual. Clean the device prior to disinfection.



CAUTION: The Illuminator (REF 78800) is a biohazard after use. Follow good hospital practices and the instructions for cleaning and disinfection of the illuminator within this manual prior to the next usage.



CAUTION: Ensure lamp is installed and fully seated in illuminator throughout cleaning and disinfection process. The illuminator assembly is immersible (IPX7) provided the lamp is properly installed.



CAUTION: This device complies with current required standards for electromagnetic interference, and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

U.S. Federal Law restricts this device to sale by or on the order of a physician.

To remove all power from the Vaginal Illumination System, unplug the external power supply from the wall outlet.

Illuminator is capable of temporary immersion to a depth of 0.15 to 1 meter, at ambient pressure, at room and fluid temperatures of 22° C to 43° C.

There are no user-serviceable parts inside the device except the lamp. Contact the Authorized Service Center listed on page 13.

Consignes de sécurité et précautions



MISE EN GARDE : Pour éviter les blessures oculaires, ne pas regarder dans le rayon.



MISE EN GARDE : La lampe est nocive au toucher pour la peau. Laisser la lampe refroidir pendant 5 minutes avant de la remplacer. La lampe génère beaucoup de chaleur et doit rester éteinte jusque juste avant et immédiatement après utilisation. Ne pas placer l'illuminateur sur une surface inflammable si la lampe est allumée.



MISE EN GARDE : Débrancher le transformateur de la prise murale avant toute maintenance.



MISE EN GARDE : L'usage de cet instrument est strictement limité aux spéculums vaginaux Welch Allyn KleenSpec, à usage unique. Ne pas utiliser l'illuminateur à toute autre fin. La lampe est chaude et peut causer des brûlures si elle est utilisée sortie du spéculum vaginal.



MISE EN GARDE : L'illuminateur pour spéculums vaginaux KleenSpec, ne peut être utilisé en présence d'un mélange anesthésique inflammable gazeux à base d'air, d'oxygène ou d'oxyde nitreux. Une explosion pourrait se produire.



ATTENTION : Utiliser seulement les méthodes de nettoyage et les solutions et méthodes de désinfection décrites dans ce manuel. Nettoyer l'instrument avant de le désinfecter.



ATTENTION : L'éclairage est intense.



ATTENTION : L'illuminateur (REF 78800) représente un danger biologique après utilisation. Appliquer les bonnes pratiques hospitalières et respecter les consignes de nettoyage et de désinfection de l'illuminateur explicitées dans ce manuel avant l'usage suivant.



ATTENTION : S'assurer que la lampe est bien installée et montée dans l'illuminateur pendant toute la durée de la procédure de nettoyage et de désinfection. Le système illuminateur peut être immergé (IPX7) à condition que la lampe soit correctement montée.



ATTENTION : L'instrument satisfait aux normes actuelles en vigueur concernant les interférences électromagnétiques et ne devrait ni affecter ni être affecté par les autres appareils. Par mesure de précaution, éviter d'utiliser cet instrument tout près d'un autre appareil.

La loi fédérale des États-Unis limite la vente de cet instrument à un médecin ou sur ordonnance d'un médecin.

Pour éteindre complètement l'illuminateur vaginal, débrancher l'alimentation extérieure de la prise murale.

L'illuminateur peut être plongé temporairement à une profondeur variant entre 0,15 et 1 mètre à la pression atmosphérique, à une température ambiante et du liquide d'immersion comprise entre 22 °C et 43 °C.

Mis à part la lampe, cet instrument ne possède aucun composant que l'utilisateur ait à entretenir. Contacter le centre de service agréé indiqué sur la page 13.

Instructions for Use

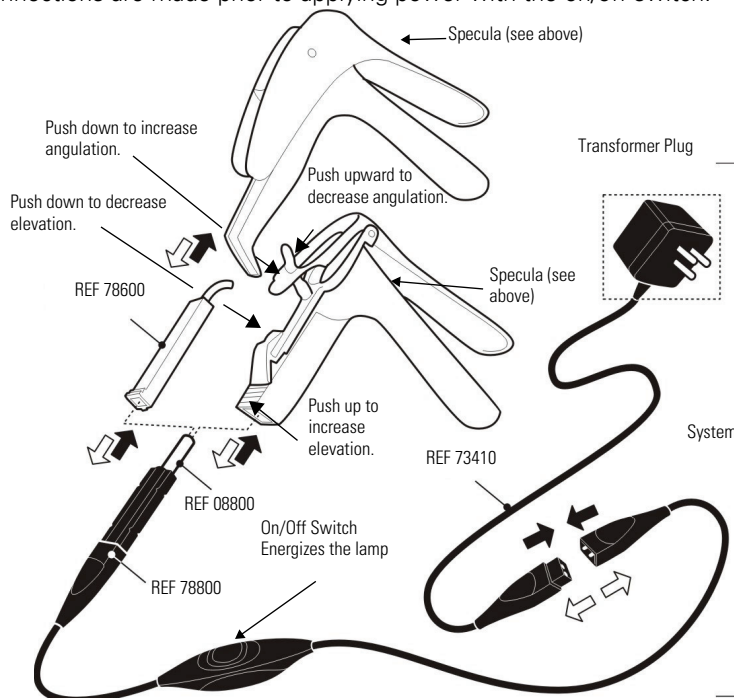
KleenSpec Vaginal Specula Illumination System

The KleenSpec Vaginal Specula Illumination System (REF 78810), consisting of the illuminator (REF 78800) and transformer (REF 73410) are designed to work with the following Welch Allyn specula: 58000S, 58001S, 58004S, 590XS, 59000, 59001, 59004, 59005, 59006, and 58600 / 58601 (with expendable illuminator 78600) for gynecological and obstetric procedures.

The transformer plug (REF 73410) provides power from the hospital-grade wall outlet to the illuminator assembly (REF 78800) which houses the lamp (REF 08800). This provides illumination to the specula and expendable illuminator (see above). This device is intended for use *only* with appropriate accessories (see above).

This product is for use with the Welch Allyn KleenSpec Single-Use Vaginal Specula only. Do not use the illuminator for any other use. Lamp is hot and can cause a burn if used outside of the vaginal specula.

Assemble the transformer to the illuminator as shown below. The illuminator then slides into the appropriate Welch Allyn accessory listed above. Verify all connections are made prior to applying power with the on/off switch.



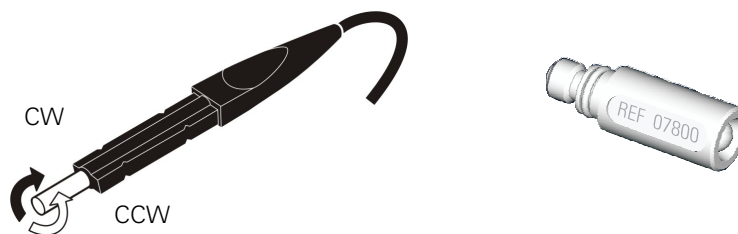
Maintenance

Preventative Maintenance

Monthly examine cords, connections, and transformer case for wear or damage.

After every use, clean the unit according to the Cleaning, Disinfection, and Sterilization section of this manual.

Lamp Replacement



The lamp is the only user-serviceable part on the Illumination System. Replace the lamp when there is insufficient illumination.

1. Disconnect the transformer from the wall outlet and then disconnect the illuminator from the transformer.
2. Allow lamp to cool for a minimum of 5 minutes and remove the lamp by unscrewing counterclockwise (CCW).
3. Inspect the lamp socket of the illuminator for damage or irregularities. Contact the authorized Service Center if any irregularities are found.
4. Replace with Welch Allyn REF 08800 lamp only.
5. Verify that the lamp o-ring is present and free from damage or debris prior to installation. If o-ring is missing or damaged, replace the lamp.
6. Install by screwing clockwise (CW).

Cleaning Disinfection, and Sterilization

		Illuminator REF 78800	Transformer REF 73405 or REF 73410	Expendable Illuminator REF 78600
Cleaning	CaviWipe (Wipe)	Yes	Yes	Yes
	Enzol (Soak)	Yes	Limited*	Yes
	Metrizyme (Soak)	Yes	Limited*	Yes
Disinfection	Caviwipe	Intermediate Level	Limited* Intermediate Level	Yes Intermediate Level
Sterilization	Autoclave	No	No	Yes**

* Do not immerse the transformer plug. Follow instructions per this manual.

** The Expendable Illuminator's ability to transmit light will degrade after repeated autoclave cycles (approximately 20) and will eventually need replacement.

Cleaning

Wipe

Transformer (REF 73405 or REF 73410), Illuminator (REF 78800), Expendable Illuminator (REF 78600)

Refer to Cleaning Table to identify the appropriate cleaning product.

1. Disconnect the transformer from the wall outlet and then disconnect the illuminator from the transformer.
2. Disconnect illuminator from expendable illuminator and remove the expendable illuminator from the speculum (58600/58601 only).



Lamp must remain installed during all cleaning and disinfection processes.

3. Follow the disinfecting wipe manufacturer's instruction and wipe cord, illuminator, or expendable illuminator completely to remove any residue.
4. This process is a rough clean only. Refer to disinfection or sterilization for further processing.

Soak

Refer to Cleaning Table to identify the appropriate cleaning product.

Illuminator (REF 78800) and/or Expendable Illuminator (REF 78600)

1. Disconnect the transformer from the wall outlet and then disconnect the illuminator from the transformer.

2. Disconnect illuminator from expendable illuminator and remove the expendable illuminator from the speculum (58600 / 58601 only).



Lamp must remain installed during all cleaning and disinfection processes.

3. Follow the cleaning solution manufacturer's instructions and soak the illuminator and/or expendable illuminator as instructed. Solution temperature is 22° C to 43° C.
4. Scrub any area of visible debris with a soft brush and thoroughly rinse the illuminator and/or expendable illuminator with 22° C to 43° C tap water to remove the cleaning solution.
5. Rough dry the illuminator and/or expendable illuminator.
6. The illuminator and/or the expendable illuminator is now ready for disinfection.

Limited Soak

Transformer (REF 73405 or REF 73410)

Refer to Cleaning Table to identify the appropriate cleaning product.

1. Disconnect the transformer from the wall outlet and then disconnect the illuminator from the transformer.
2. Follow the cleaning solution manufacturer's instructions and **soak the cord only** in the solution as instructed. Solution temperature is 22° C to 43° C.
3. Scrub any area of visible debris with a soft brush and thoroughly **rinse transformer cord only** with 22° C to 43° C tap water to remove the cleaning solution.
4. Rough dry transformer.
5. The transformer is now ready for disinfection.

Disinfection

Refer to the Cleaning Table to identify the appropriate disinfection method/product for the illuminator, expendable illuminator, and/or transformer.

Illuminator (REF 78800) and/or Expendable Illuminator (REF 78600)

1. Clean illuminator and/or expendable illuminator as instructed in "Cleaning-Soak" or "Cleaning-Wipe".
2. Follow the disinfecting wipe manufacturer's disinfection instructions.
3. Thoroughly rinse illuminator and/or expendable illuminator with 22° C to 43° C tap water to remove disinfectant.
4. Allow to dry.

Transformer (REF 73405 or REF 73410)

DO NOT IMMERSE THE TRANSFORMER PLUG.

1. Clean transformer as instructed under "Cleaning-Limited Soak" or "Cleaning-Wipe".
2. Follow the disinfecting wipe manufacturer's disinfection instructions on the cord only.

3. Thoroughly rinse the **cord only** with 22° C to 43° C tap water to remove disinfectant.
4. Allow to dry.

Sterilization

Refer to the Cleaning Table to identify the appropriate sterilization method/product for the expendable illuminator.

Wet Steam Autoclave

Expendable Illuminator (REF 78600)

1. Clean expendable illuminator as instructed in "Cleaning-Soak".
2. Place the expendable illuminator in the autoclave chamber to allow best exposure to steam. Autoclave chamber parameters are as follows:
 - Type: 132° Pre-vacuum (Hi-VAC) Steam Cycle
 - Exposure Temperature: 132°C to 135°C (270°F to 275°F)
 - Exposure Time: 3 - 5 minutes
 - Exhaust Time: Fast

Disposal

There are no harmful materials associated with the Illumination System.

Device is considered a biohazard after use. Follow good hospital practices and local ordinances in the disposal of the illuminator.


There are no risks associated with the disposal of this device after its useful life if it is cleaned and/or disinfected per the instructions in this manual.

Specifications

Classification (REF 73410)	Class II, Type BF Applied Part
Input:	120V ~ 60Hz, 100mA
Output:	4.7 VAC, 850mA
Category:	Not AP/APG Equipment
Physical Specifications:	
Illuminator:	91.4 cm (36 in)
Transformer:	183 cm (72 in)
Illumination:	
Lamp Life:	100 hours
Lamp Voltage:	4.6 V
Lamp:	Welch Allyn part no. 08800
IPX Rating:	
Illuminator:	IPX7
Transformer:	IPXØ
Environment	
Operating:	+10° C to + 35° C (50° F to 95° F), 95% RH 500 hPa to 1060 hPa
Transport/Storage:	-20° C to +49° C (-2° F to 120° F), 95% RH, 500 hPa to 1060 hPa
Intermittent Operation	
Vag Spec and Illuminator	10 minutes on max; 5 minutes off min

Approvals

CERTIFIED TO: CAN/CSA STD C22.2 NO. 601.1
CONFORMS TO: IEC 60601-1, IEC60601-1-2, UL 60601-1 STD 2601-1

 The CE Mark on this product indicates it has been tested to and conforms with the provisions noted with the 93/42/EEC Medical Device Directive.

EC	REP
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Regulatory Affairs Representative
Welch Allyn Limited
Navan Business Park
Dublin Road
Navan, County Meath, Republic of Ireland

Troubleshooting Guide

Problem	Possible Cause	Solution
Lamp does not light.	Power switch is in the off position.	Verify the power switch is in the on position. Refer to manual.
	Illuminator is not plugged into the transformer.	Verify that the illuminator is properly plugged into transformer cord.
	Transformer is not plugged in.	Verify the transformer is properly plugged into the outlet.
	Faulty Lamp	Replace with a new lamp.
	Loose Lamp	Verify that the lamp is secured into the illuminator.
	Wrong Lamp	Verify that the lamp is a REF 08800 Welch Allyn lamp.
	Damaged Lamp	Inspect the lamp and the o-ring for damage. Replace with REF 08800 lamp if damage is found.
Illuminator does not stay retained into 580 series specula or 78600 expendable illuminator.	Possible damage to the illuminator retention wings.	Inspect retention wings for damage. Replace illuminator REF 78800.
Illuminator does not stay plugged into the transformer cord.	Illuminator/transformer interconnect plug is damaged.	Inspect interconnect plug for damage. Replace either or both REF 73405, REF 73410 or REF 78800.
Light output seems low.	Faulty Lamp	Replace with a new lamp.
	Dirty lamp lens	Inspect lamp lens for debris and clean.
This guide is intended to provide assistance towards determining the fault condition of this product. Please contact the authorized Welch Allyn Service Center listed within the product owners manual for additional assistance.		

Troubleshooting Guide - Qualified Personnel Only

Problem	Possible Cause	Solution
Lamp does not light.	No power to the transformer outlet.	Verify that power is supplied to transformer outlet.
	Faulty Transformer	Test the voltage supplied through the transformer at the cord end. Verify the voltage reads approximately 4.7 volts DC (REF 73405) or 4.7 volts AC (REF 73410). Only properly trained personnel shall perform this test.
	Faulty Illuminator	Verify that the illuminator is faulty by replacing with a new illuminator or with the switch in the on position, and power supplied through the transformer (above), remove lamp and measure the voltage between the lamp socket center contact and socket threads. Verify voltage reads approximately 4.6 volts (DC with REF 73405 or AC with REF 73410). Only properly trained personnel shall perform this test.
Light output seems low.	Improper voltage supplied to the transformer.	Verify the voltage supplied to the transformer outlet meets the requirements stated in this manual.
This guide is intended to provide assistance towards determining the fault condition of this product. Please contact the authorized Welch Allyn Service Center listed within the product owners manual for additional assistance.		

Warranty and Service

Limited Warranty

Instrumentation purchased new from Welch Allyn, Inc. (Welch Allyn) is warranted to be free from original defects in material and workmanship under normal use and service for a period of one year for Welch Allyn KleenSpec Vaginal Specula Illumination System (REF 78810), comprised of the illuminator (REF 78800) and the transformer (REF 73410) from the date of first shipment from Welch Allyn. This warranty shall be fulfilled by Welch Allyn or its authorized representative repairing or replacing at Welch Allyn's discretion, any such defect, free of charge for parts and labor.

Welch Allyn must be notified via telephone of any defective product and the item must be immediately returned, with an RMA number provided by Welch Allyn, securely packaged and postage prepaid to Welch Allyn. Loss or damage in shipment shall be at the purchaser's risk.

Welch Allyn will not be responsible for loss associated with the use of any Welch Allyn product that (1) has had the date of manufacture number defaced, (2) has been repaired by anyone other than an authorized Welch Allyn Service Representative, (3) has been altered, (4) has been used in a manner other than in accordance with the instructions, or (5) has been abused or exposed to extreme environmental conditions.

THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ANY IMPLIED WARRANTY OR MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESSED OR IMPLIED. WELCH ALLYN WILL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE SALE, USE, OR IMPROPER FUNCTIONING OF THE INSTRUMENTATION REGARDLESS OF THE CAUSE. THE DAMAGES FOR WHICH WELCH ALLYN WILL BE RESPONSIBLE INCLUDE, BUT ARE NOT LIMITED TO, LOSS OF REVENUE OR PROFIT, DOWNTIME COSTS, AND LOSS OF USE OF THE INSTRUMENTATION.

Technical Assistance

If you have an equipment problem that you cannot resolve, you may call the Welch Allyn Service Center nearest you for assistance. For Technical Support or to obtain information about any Welch Allyn product, contact Welch Allyn Technical Support: (www.welchallyn.com/support) or visit www.welchallyn.com/about/company/locations.htm

Prior to contacting Welch Allyn or its service center, please refer to the following areas of the illuminator and/or transformer to identify the date of manufacture of the component(s).

- Illuminator: Four digits, month then year, stamped inverted and to the right of "REF 78800" near the lamp.
- Transformer: Four digits, month then year stamped or labeled on the prong side of the transformer plug.

If you are advised to return a product to Welch Allyn for repair or routine maintenance, schedule the repair with the service center nearest you.

Before returning a product for repair you must obtain authorization from Welch Allyn. Return Authorization number will be given to you by our service personnel. Be sure to note this number on the outside of your shipping box. Returns without a return authorization number will not be accepted for service. **Prior to shipment, please clean and disinfect the component as instructed in this manual.**



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