



Identafi[®]

Oral Mucosal Visual Enhancement System



StarDental[®] Instruments
www.identafi.net

- ⚠ Do not autoclave or sterilize.
- ⚠ This product is not for surgical use.
- ⚠ Disposable mirrors are for one-time use only; do not reuse or clean using solvents, glass mirror may detach.
- ⚠ Do not operate without disposable mirror attached; verify glass mirror is attached to disposable mirror.
- ⚠ Do not perform oral exam without using Doctor eye protection glasses.
- ⚠ Reduce ambient light to your visual requirements (best dimmer)

NOTICE Any serious incident occurring from the use of this device should be reported to StarDental immediately. If incident occurred in a EU Member State the competent authority must be notified.

Description: The StarDental Identafi® is a battery operated, hand-held multi-spectral Oral Examination Light used in conventional and specialized oral examinations.¹ Accessories include filtered eyewear and single use disposable mirrors.

The Identafi®'s white, 405 nm violet and green-amber lights each excite the oral tissues in distinct and unique ways. Specifically, biochemical changes can be observed with violet's fluorescence, while morphological changes can be seen with white and green-amber's reflectance. The direct visualization of tissue fluorescence and reflectance is using the body's natural system as an adjunctive tool for oral mucosal examination.²

Traditional Oral Examinations use only tactile and broadband white light. The Identafi®'s multi-spectral technology uses software tuned LEDs for enhanced visualization: White (**Fig 1.1**) for tissue morphology, Violet (**Fig 1.2**) for tissues' natural fluorescence, and Green-amber (**Fig 1.3**) for tissues' reflectance properties. The rose colored glasses enable the clinician to examine tissue under all three lights. Under white light, a lesion may appear raised or thickened and appear either white or red. Under violet light, normal tissue fluoresces brightly and suspicious tissue appears dark. The green-amber light enhances optical contrast between vasculature and surrounding tissue allowing the doctor to more easily observe the difference between normal and abnormal vasculature. Studies indicate abnormal tissue has a diffuse vasculature, where normal tissue's vasculature is clearly defined.³

Seeing the difference between normal and abnormal vasculature improves the doctor's ability to choose biopsy sites (**Fig 2.1**), and aids in determining the appropriate margin for surgical excision as outlined with a surgical marking pen in the violet 405 nm picture (**Fig 2.2**).

The Identafi®'s violet also causes certain microorganisms, mold and fungi to naturally fluoresce (e.g. Wood's lamp). Bacteria, mold and yeast (fungi) infected tissues may appear red, orange and/or yellow (**Fig 3.1-3.4**). The Green-amber light reflectance properties also allows the doctor to observe inflammation which also may appear red (**Fig 3.5**).

Intended Use: The Identafi® is intended to be used by qualified health care providers to enhance the identification and visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or premalignant dysplasia. The Identafi® allows for conventional oral mucosal examination and excites the tissue with Multi-Spectral lights for direct visualization of the resulting natural tissue fluorescence, reflectance and vasculature.

1. Patent 7365844 and Patents Pending 2. Cancer Research Vol. 12, 6716-6722, Nov. 15, 2006
3. Journal of Biomedical Optics 11 (1), 014018: 1-6 (2006)



Intended Use, continued: The Identafi® aids in the identification of certain microorganisms, fungi and yeast infections. This may aid in the diagnosis of disease.

The Identafi® filtered, reusable eyewear is worn by a health care professional to enhance the visual effects of violet light during an oral exam. The eyewear has been designed to block the Identafi® excitation light and allow transmission of 420-700 nm fluorescence/reflectance light.

| | |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Contraindications | No known contraindications. |
| Precautions | Store in cool, dry place. Inspect each component for damage. Do not use if damaged. |
| Warnings | DO NOT look directly at the lights, they are very bright. Do not examine patient without doctor's glasses. Do not reuse or reprocess disposable mirrors. Discard after one procedure. Exposure to high temperatures above 105°F (41°C) or cleaning solvents may damage the Identafi® and its disposable mirrors. The glass mirror may come off if dropped or reprocessed. |

Identafi® Set-Up: At the start of each day, verify that the Identafi® (**Fig 4**) is in good working order. Replace batteries with the batteries that were recharged overnight using the instructions that came with the batteries and charger.

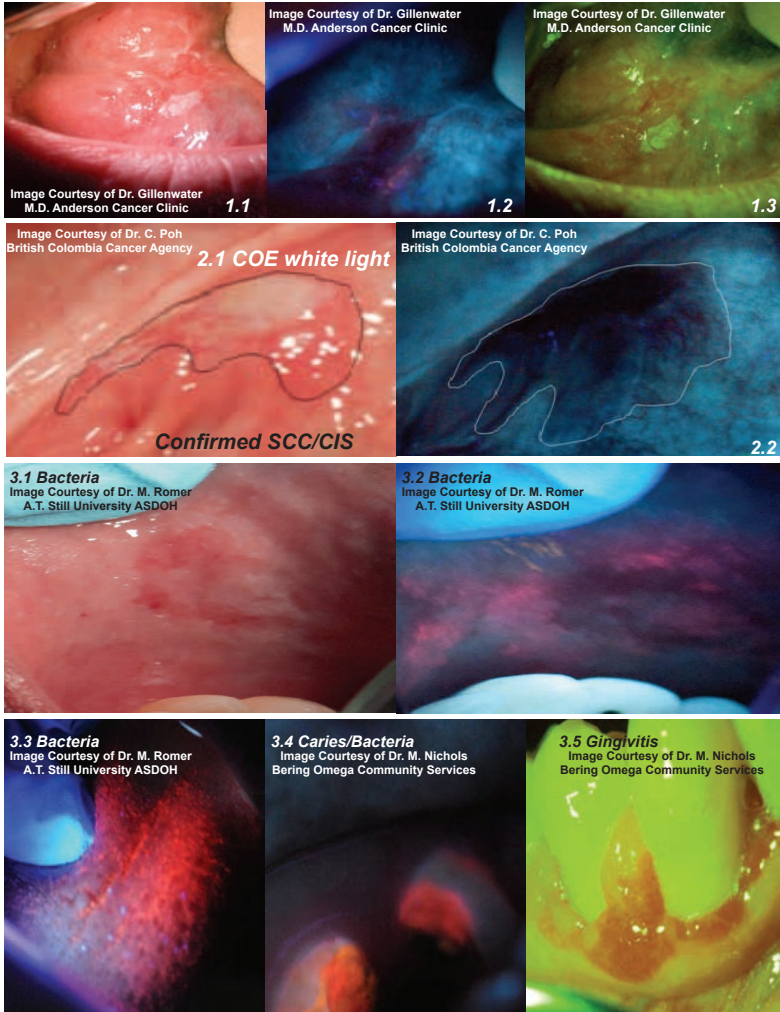
Only use compatible batteries with the Identafi wand. In order to ensure that the Identafi wand performs at its optimum capability, when the batteries need to be replaced, replace them with one of the following recommended AA battery brands: Sanyo's 'Eneloop 1500' or Tenergy's 'Centura'. If assistance is needed contact StarDental technical service at 1-866-DTE INFO (383-4636); or visit the www.identafi.net web site for battery specifications.

The separation of the body (A) from the battery cap (B) is an easy two-finger twist to unscrew. Place two fingers on taper (A), two fingers on cap (B) and twist to open at joint (C). **DO NOT** unscrew the device at the select ring (E); this will damage the device and potentially void its warranty. **Open only at point C**. Put in two AA batteries, positive contact (+) facing down. Reassemble the battery cap (**DO NOT** over tighten).

Verify that Multi-Spectral LED lenses (F) are intact. Turn the device on by rotating the select ring (E) once and pointing the LEDs (F) toward your hand or the counter top. White color light will appear. Turn the Select Ring (E) several times to the right and to the left cycling through each color and off position. The LED lights are very bright; **DO NOT** look directly at the LED lights. Verify that each light provides good illumination (white, violet and green-amber). The violet light is 7-10 times more powerful than white or green-amber, but will appear much dimmer due to the eyes' limited ability to see 405nm wavelength.

Verify the glass mirror (G) is attached to the disposable mirror and not damaged. Attach the disposable mirror with the mirror facing the LEDs (Fig 4). Inspect the doctor's glasses to ensure they are clean and in good condition.

Verify the device is in good working order by cycling through each color at least twice. Verify violet performance by putting on the rose doctor glasses, holding the light at a distance and looking directly at the light. The violet light should disappear completely except for a slight violet ring around the filter. If you see any other light, call Customer Service at 866-DTE-INFO (383-4636). If the light flashes green, the unit has been left on for over 10 minutes. Turn off to reset timer.



- A-C** To insert/remove/replace batteries place fingers at points (A) and (B) and unscrew to open at point (C).
- D** Two (2) "AA" compatible rechargeable batteries.
- E** Select Ring - rotates both directions to change between lights and on/off. - **DO NOT** unscrew the device at the select ring (E); this will damage the device and potentially void its warranty.
- F** High output 405 nm Violet and software tuned Multi-Spectral LED
- G** Disposable mirror - snaps on and off.

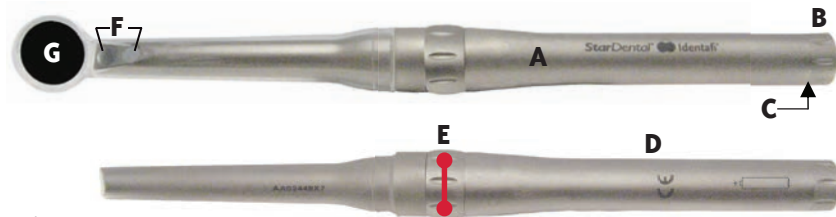


Figure 4

The Identafi® Examination:

- ⚠ Read glasses instructions before using.
- ⚠ Reduce ambient light to your visual requirements (dim to dark).
- ⚠ Clinician must wear rose colored eyewear throughout exam.
- ⚠ Do not use the Identafi® without disposable mirror attached.
- ⚠ Disposable mirrors are for one-time use only; cleaning solvents may distort optical clarity or cause the glass mirror to detach.

NOTE: Patient glasses are recommended.

1. Turn on the Identafi® at the base (D) and move the selector ring (F) to turn on the white light; additional turns of the selector ring in either direction will change the light to violet>green>amber>white>off.
2. Establish a “normal” tissue visual context for each patient with each exam light.
3. Conduct a thorough conventional oral exam (COE) with the Identafi® using white light as directed in your standard protocol. Record all relevant findings.
4. Repeat the visual examination with the Identafi® using Violet light.
 - a. Normal tissue will generally emit blue fluorescence and abnormal tissue typically appears as an irregular, dark area.
 - b. If a suspicious area is discovered, evaluate again under white and violet light again. Verify what has caused the region to appear abnormal.
 - i. Inflammation typically appears darker due to the excess blood content. With the back side of the disposable mirror, in a sweeping motion, apply a light amount of pressure to diffuse any blood from the area and observe fluorescence. If the normal blue fluorescence returns, then the lesion may have an inflammatory component.
 - ii. Hyperkeratosis may often appear bright because of strong keratin fluorescence.
 - c. Take into consideration tissue appearance under both violet and white light, its response to palpation, and salient patient history information.
 - d. Bacterial and fungi infected tissues may appear red, orange and/or yellow.
 - e. Plaque fluoresces and may appear bright reddish-orange.
5. Repeat the COE with the Identafi® using green-amber light.
 - a. Confirm suspected tissue under violet light with green-amber light.
 - i. Normal tissue reflects the green-amber color and vasculature appears more red.
 - ii. The contrast between the vasculature and surrounding tissue is due to the reflectance properties of hemoglobin which gives the doctor a second “visual context”.
 - b. Fibroids, scars, hyperkeratosis, necrotic and/or dead tissue may appear white.
 - c. Traumatized, inflamed and/or infected tissue may appear red.
6. Document all areas of concern, if you are using photography as part of your record keeping process, call StarDental® at 866-DTE-INFO (383-4636) for camera filter kit availability.

The Identafi® Examination, continued:


7. Characteristics that increase suspicion of dysplasia and/or oral cancer:
 - a. Highly darkened appearance - strong loss of fluorescence
 - b. High-risk location (e.g. lateral/ventral tongue)
 - c. Unilateral presentation
 - d. Asymmetry and/or irregular shape
 - e. Extension over more than one kind of oral structure
8. If a suspicious area can not be ruled out as benign, a follow up examination (typically in two to four weeks) is recommended to allow potential confounders to heal.
 - a. Evaluate whether the suspicious area has changed.
 - b. If the suspicious area has not cleared up, use your clinical judgment and proceed according to your standard operating procedure (e.g. biopsy, referral to a specialist, etc.).
 - c. Biopsy is the gold standard for diagnosing precancerous and cancerous lesions.
9. Inform the patient of all relevant findings and the appropriate course of action.
10. After the examination, turn off the device, remove and discard disposable mirror, clean exterior metal body with approved disinfectant and place Identafi® wand in a safe place to prevent damage.

Maintenance: The Identafi® metal body should be cleaned and disinfected between each patient by wiping with moist towelette using an approved disinfectant. Do not use disinfectant with alcohol content over 70%, hyperchlorides or phenol-based disinfectants as they may degrade the finish of the unit.

| Approved Disinfectants | |
|--------------------------|------------------------|
| Isopropyl Alcohol (<70%) | Opticide 3 Wipes |
| Sanitex Plus | Super Sani-Cloth Wipes |
| Discide | Opaciden Solution |

Clean the Identafi® Multi-Spectral LED lenses with the included glasses lens cloth.

The glasses should be cleaned with mild soap and water as needed - do not use alcohol-based cleaning agents.

- ⚠ Do not autoclave or sterilize.
- ⚠ This product is not for surgical use.
- ⚠ Do not immerse Identafi® Wand, use only approved disinfectants.
- ⚠ Disposable mirrors are for one-time use only; do not reuse  or clean using solvents, glass mirror may detach.
- ⚠ Do not use alcohol-based cleaning agents on glasses.

Visually inspect and test in the event the Identafi® is dropped or damaged. Verify that Multi-Spectral LED lenses are intact, and the select ring moves easily. If white light does not come on, or is pinkish, replace batteries with new, fully charged, batteries.

Maintenance, continued:

If white light still does not come on, call Customer Service at 866-DTE-INFO (383-4636). Verify the device is in good working order by cycling through each color at least twice. Verify violet performance by putting on the rose doctor glasses, holding the light at a distance and looking directly at the light. The violet light should disappear completely except for a slight violet ring around the filter. If you see any other light, call Customer Service at 866-DTE-INFO (383-4636). If the light flashes green, the unit has been left on for over 10 minutes. Remove battery cap completely and reinstall it to reset timer.

- ⚠ Each Identafi® is serialized for warranty and technical support.
- ⚠ Remove batteries if not in use for over one week.

| Re-order Information | Part Number |
|----------------------------------------------------------------------------------------------------|-------------|
| Complete Identafi® System, United States of America | RT3-00371 |
| Complete Identafi® System, International | RT3-00372 |
| Box of 100 Disposable Plastic Barriers | RT3-00415 |
| Box of 25 Disposable Mirrors | RT3-00105 |
| Patient Safety Glasses (yellow tint) | RT3-00113 |
| Doctor Filter Glasses (rose tint, worn over prescription glasses) | RT3-00114 |
| Doctor Script/Magnification Glasses (Rose - used with magnification insert or prescription lenses) | RT3-22000 |
| 1.0X Magnification Insert - used with Doctor Filter Glasses | RT3-22010 |
| 1.5X Magnification Insert - used with Doctor Filter Glasses | RT3-22015 |
| 2.0X Magnification Insert - used with Doctor Filter Glasses | RT3-22020 |
| 2.5X Magnification Insert - used with Doctor Filter Glasses | RT3-22025 |
| Special 35mm Camera Screw On Lens Filter (Lens Size 52mm) | RT3-23052 |
| Special 35mm Camera Screw On Lens Filter (Lens Size 55mm) | RT3-23055 |
| Special 35mm Camera Screw On Lens Filter (Lens Size 58mm) | RT3-23058 |
| Special 35mm Camera Screw On Lens Filter (Lens Size 62mm) | RT3-23062 |

Limited Warranty
O-Rings and Seals are specifically excluded from this warranty.
DentalEZ® warrants the Identafi® Oral Mucosal Visual Enhancement System to be free of defects in material and workmanship, under normal usage, under the following terms:

- | | |
|----------------------------------------------------------------------------------|----------------------------------------------------------|
| StarDental® Products: Identafi® Oral Mucosal Visual Enhancement System | Warranty Period*: 1 Year from date of purchase |
|----------------------------------------------------------------------------------|----------------------------------------------------------|
- Please note the following additional terms of our warranty and return policy:
- Warranty covers manufacturing defects only and does not cover defects resulting from abuse, accidents, misuse, improper handling, cleaning, care or maintenance or the failure to follow or observe our operating/use, maintenance and/or installation instructions. Damage resulting from the use of chemicals, cleaners, disinfectants or sterilization is not covered under this warranty nor is normal wear and tear. **Failure to use authorized parts or an authorized repair facility voids this warranty.**
 - **Liability is limited to repair or replacement of the defective part(s) or products at our sole discretion. All other liabilities, in particular liability for damages, including, without limitation, special, exemplary, consequential or incidental damages are excluded**
 - THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NO EMPLOYEE, REPRESENTATIVE OR DEALER IS AUTHORIZED TO CHANGE THIS WARRANTY IN ANY WAY OR TO GRANT ANY OTHER WARRANTY.

WARRANTY REPAIRS: Parts repaired or replaced on a product that is in warranty will be warranted for the duration of that product's original warranty.

NON-WARRANTY REPAIRS: The warranty on parts either repaired or replaced on an out-of-warranty product will cover the repaired part only and will be for the time frame of a new parts warranty period.

PRODUCT RETURN: Opened products or product returns more than a year old cannot be returned for credit. There will be a 15% (\$25.00 minimum) restocking charge on all items authorized for return.

* Provided conditions in warranty are met.

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| EC | REP |
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Product registration and additional clinical data and images are available online at www.identafi.net

