Intelli-Case---
Improving Compliance for the "Gold Standard" Lens Care System

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FINALLY, a hydrogen peroxide disinfection/cleaning system that can be as safe and easy to use as multipurpose solutions!

There are numerous reports suggesting that 16-31% of contact lens wearers discontinue wearing contact lens and return to glasses.[1-7] One of the most frequent problems with those who continue to wear contact lens is the low levels of compliance to the approved regimens.[5] Consumers who use multipurpose disinfection solutions (MPS) have the worst compliance with the available lens care systems.[8] Additionally, biocompatibility issues with MPS solutions and certain silicone hydrogel lens materials persist, adding another layer of problems for MPS disinfection systems.[9]

Patients are often discontinued from use of MPS disinfection systems because of sensitivities to the chemicals in these products. For such patients, hydrogen peroxide system is the only remaining option for disinfecting their lens. Using a hydrogen peroxide disinfection system alleviates using any of the bioactive chemicals in multi-purpose solutions. The chemicals used in MPS systems are often uptaken into lenses, reducing the antimicrobial efficacy of the solution, and yet are subsequently released onto the surface of the eye during wear.[10] Many patients may simply stop wearing contact lens rather than switching to a hydrogen peroxide system with all of its issues of use.

All hydrogen peroxide disinfection systems use a specially designed platinum disk that neutralizes the hydrogen peroxide. The cases supplied by various manufacturers vary in the time required and the chemistry used to neutralize the peroxide. However, the peroxide cases used today do not "control" any aspect of the disinfection/neutralization process. There are several variables that have significant impact on the sufficiency of the disinfection cycle: a) initial concentration of peroxide used; b) rate of neutralization of the peroxide; c) residual peroxide concentration at the end of the neutralization process. Current systems rely exclusively on compliance by patients, and the user is reminded of non-compliance only by the burning and stinging upon insertion of the lens into the eyes.

Today there is a new "intelligent" lens case (intelli-Case) for use with the hydrogen peroxide disinfection/cleaning solutions for use with both RGP and soft contact lenses that can help patients overcome many of the issues associated with use of hydrogen peroxide systems. This new technology provides guidance each step of the process of lens disinfection as well as providing the assurance to patients that their lenses are safe and comfortable to wear at the end of the cycle. Providing assurance of compliance makes hydrogen peroxide with the intelli-Case a practical

option for all patients, who no longer fear of irritation when inserting the lens into the eye and who are assured of adequate disinfection of their lens.

The new intelligent lens case from NovaBay, based on 21st century technology, allows patients to know they are using the system properly. Their lenses will be fully disinfected by the end of the disinfection cycle and free of irritation when inserted into the eyes. The intelli-Case is designed to assure that full strength ophthalmic peroxide solution is being used. It prevents the user from adding fresh peroxide or "topping off" to the solution remaining in the case to begin the next cycle. It lets one know when the cycle is done and provides assurance of very low residual peroxide, thus preventing burning and stinging on insertion. It lets one know when it's time to replace the case.

How does Intelli-Case work?

The intelli-Case (Figure 1) is furnished with 3 indicator lights that monitor a number of aspects of the disinfection/cleaning regimen. A red light to let patients know the lenses are not safe to be used and/or the cycle must be started over, a yellow light to let you know that the system is busy working and a green light to let you know that disinfection is complete and lenses are ready for use.

Figure 1

All controlled by the 21st century by semiconductor technology shown in Figure 2; Sophisticated in design but easy for the patient to use

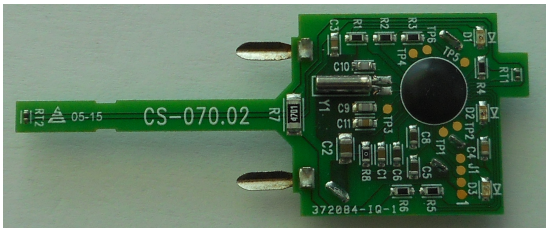

Figure 2

What does the case really do to make sure that patients have a safe, non-irritating contact lens, both soft and RGP lenses, after hydrogen peroxide disinfection? From the beginning of the cycle, the sensors in the case measure the process of neutralization of hydrogen peroxide by the platinum catalyst, while blinking the yellow light. The neutralization process produces heat by an exothermic reaction. The system measures the rise in temperature (rate of neutralization), and assures it is in the range designed for the solution supplied with the case. The rates of this reaction are very predictable within a wide range of ambient temperatures where peroxide care system may be used from 40^0F to 104^0F (10^0C to 40^0C). If a patient uses the wrong solution, for example a bottle of saline or "drug store" peroxide, in the system, or tops off the residual solution in the case, the red blinking light will let the user know that adequate disinfection is not possible and that user needs to start over. If the peroxide solution used for disinfection is old or below the proper strength of peroxide, then adequate disinfection is not possible. This will cause the intelli-Case to blink the red light. While the process is ongoing (busy), the yellow light continues to blink. When the neutralization is complete, the green light blinks to let the user know that lenses are disinfected and safe to wear.

It is well known that over time the platinum catalyst becomes "fouled" by tear components and needs to be replaced. This is true for all peroxide systems. If the catalyst becomes "fouled" during normal use of the intelli-Case, such that it cannot provide adequate neutralization of the peroxide, the red light will blink to warn of an unsafe condition. With current peroxide cases, there is no way to know that the catalyst has become "fouled" and cannot adequately neutralize the peroxide. Such a condition results in burning and stinging when lenses are inserted.

All peroxide cases should be replaced periodically at times specified in the "Instructions for Use". However, users rarely replace the case at the specified time. Failure to do so may ultimately result in conditions leading to build up of tear film components and biofilm on the catalyst surface. This, in turn, may increase the risk of irritation or the transfer of harmful microbes to the lens prior to insertion. To prevent this scenario, the intelli-Case is deactivated after 65 cycles of use (continuous blinking of the red light), thus preventing the further use of the case. After 60 cycles of disinfection, the intelli-Case signals the user that the case needs to be replaced soon by blinking all three of the light, red, yellow, and green when the cap is removed after the completion of a cycle.

The intelli-Case is designed using the latest computer chip and sensing technology available in the 21st century. With the development of this technology, a new level of safety and effectiveness will be available to contact lens wearers who chose to use hydrogen peroxide to disinfect their contact lens. Importantly, the intelli-Case is very easy for anyone to use – as simple as 1,2,3. In Figure 3, these simple steps are summarized.

Since the FDA cleared the intelli-Case earlier this year, Initial reactions of contact lens wearers have been very positive, both from existing peroxide users and those switching from multi-purpose solutions. Marketing support studies have begun. NovaBay is planning to introduce the intelli-Case into selective markets by the end of the year.

Using the Intelli-Case

1. Fill the case vial with ophthalmic hydrogen peroxide solution. Place the contract lens in the appropriate basket and place the cap into the solution, screwing the cap onto the vial. – YELLOW LED begins blinking.
2. If there is anything fatally wrong with the neutralization process, the RED LED will begin blinking indicating that the cycle cannot be completed successfully and the cycle must be restarted.
3. After the disinfection cycle has been successfully completed, the blinking YELLOW LED will turn to the a blinking GREEN LED at which time contact lens can be removed and safely inserted into the eyes.

The peroxide neutralization cycle is in progress

The peroxide neutralization cycle is not proceeding as expected and must be restarted

The disinfection and neutralization cycle has successfully completed and contact lens are disinfected and safe to inserted into the eyes

Figure 3

References

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