US006002482A

United States Patent [19]

Rothfritz et al.

[11] **Patent Number: 6,002,482**

[45] **Date of Patent: Dec. 14, 1999**

[54] **DISPOSABLE CALIBRATION DEVICE**

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[73] Assignee: **Spectrx, Inc.**, Norcross, Ga.

[21] Appl. No.: **09/124,090**

[22] Filed: **Jul. 29, 1998**

Related U.S. Application Data

[63] Continuation-in-part of application No. 09/054,490, Apr. 3, 1998, Pat. No. 5,924,981, which is a continuation-in-part of application No. 08/904,766, Aug. 1, 1997, which is a continuation-in-part of application No. 08/621,182, Mar. 21, 1996, abandoned, which is a continuation-in-part of application No. 08/587,949, Jan. 17, 1996, Pat. No. 5,860,421.

[51] **Int. Cl.**[6] **G01B 9/02**

[52] **U.S. Cl.** **356/351**; 600/306

[58] **Field of Search** 378/44, 48, 98; 356/351, 357, 346; 346/10, 19; 600/306, 315

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,677,652	7/1972	Little	356/183
4,029,085	6/1977	Dewitt et al.	128/2
4,177,798	12/1979	Leveque et al. .	
4,241,738	12/1980	Lubbers et al. .	
4,267,844	5/1981	Yamanishi	128/633
4,322,164	3/1982	Shaw et al.	356/243
4,344,438	8/1982	Schultz .	
4,360,270	11/1982	Jeck	356/243
4,362,935	12/1982	Clark, III	378/48
4,423,736	1/1984	DeWitt et al. .	
4,495,413	1/1985	Lerche et al.	250/252.1
4,499,375	2/1985	Jaszczak	250/252.1
4,500,782	2/1985	Allemann et al.	250/291
4,642,422	2/1987	Garwin et al.	178/18
4,700,708	10/1987	New et al.	128/633

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

747 002 A1 11/1996 European Pat. Off. A61B 5/00

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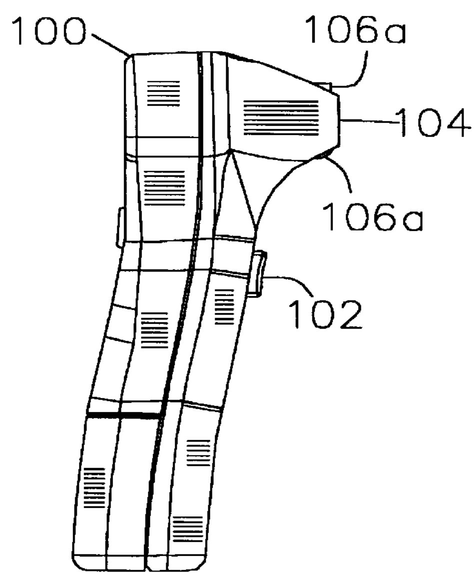
Attorney, Agent, or Firm—Fleshner & Kim

[57] **ABSTRACT**

A combined infection shield and calibration or reference target for use with a measuring instrument includes a removable calibration/reference layer. The removable calibration/reference layer has predetermined optical characteristics that can be utilized to calibrate or reference the instrument. The calibration/reference layer may have predetermined reflectance or scattering properties, a predetermined transmissivity to light, or it may have predetermined fluorescence properties. When the calibration/reference layer is removed from the remaining portions of the device, the portion of the calibration/reference layer having the predetermined optical characteristics is irrevocably altered such that the calibration/reference layer cannot be reused. The combined infection shield and target may be attached to a shield holder, which in turn is attached to an instrument. Alternatively, the infection shield and target may be attached directly to an instrument.

61 Claims, 8 Drawing Sheets



U.S. PATENT DOCUMENTS

4,744,656 5/1988 Moran et al. 356/243
4,768,516 9/1988 Stoddart et al. .
4,770,179 9/1988 New et al. 128/633
4,790,324 12/1988 O'Hara et al. .
4,796,633 1/1989 Zwirkoski 128/634
4,847,493 7/1989 Sodal et al. 250/252.1
4,867,557 9/1989 Takatani et al. .
4,868,126 9/1989 Schwartz 436/10
4,894,547 1/1990 Lefell et al. .
4,911,559 3/1990 Meyst et al. .
4,914,720 4/1990 Knodle et al. 250/343
4,975,581 12/1990 Robinson et al. 250/339
4,981,355 1/1991 Higgins 356/243
5,030,986 7/1991 Dwyer et al. 355/20
5,088,834 2/1992 Howe et al. .
5,119,819 6/1992 Thomas et al. .
5,146,091 9/1992 Knudson .
5,169,235 12/1992 Tominaga et al. .
5,311,273 5/1994 Tank et al. 356/43
5,337,289 8/1994 Fashing et al. 367/140
5,349,961 9/1994 Stoddart et al. .
5,353,790 10/1994 Jacques et al. 128/633
5,355,880 10/1994 Thomas et al. .
5,360,004 11/1994 Purdy et al. .
5,365,925 11/1994 Lee 128/634
5,371,358 12/1994 Chang et al. 250/226
5,383,452 1/1995 Buchert .
5,411,032 5/1995 Esseff et al. .
5,416,816 5/1995 Wenstrup et al. 378/18
5,435,309 7/1995 Thomas et al. .
5,458,140 10/1995 Eppstein et al. .
5,487,607 1/1996 Makita et al. .
5,557,399 9/1996 De Groot 356/357
5,792,049 8/1998 Eppstein et al. 600/306

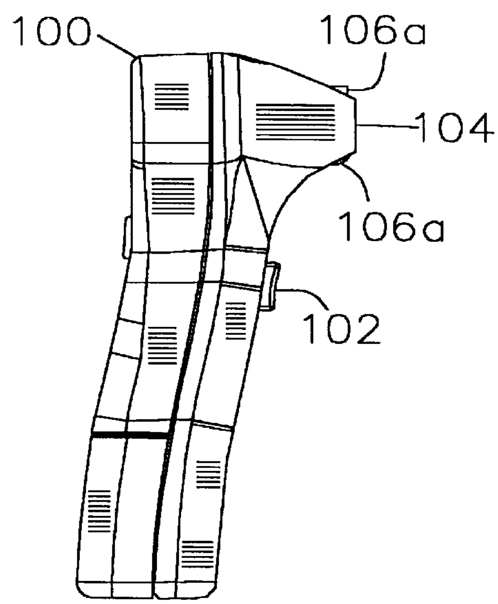


FIG. 1

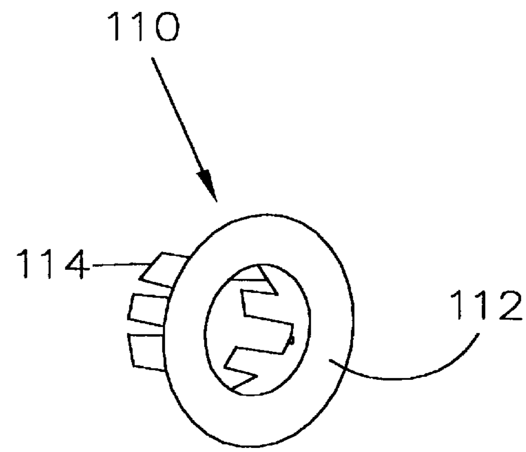


FIG. 2

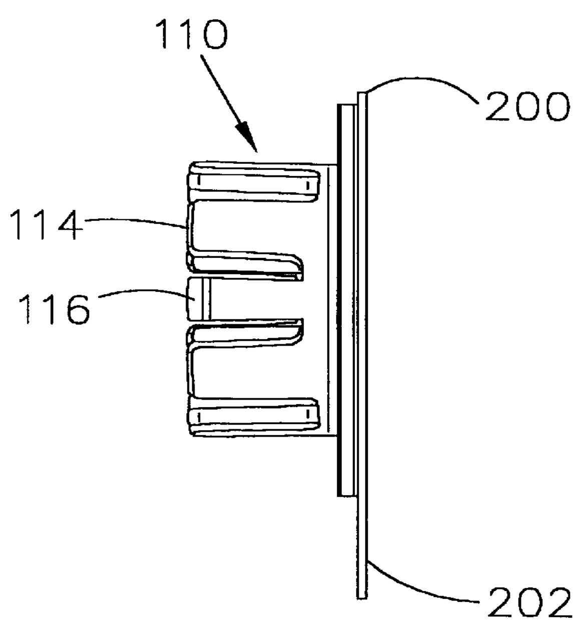


FIG. 3

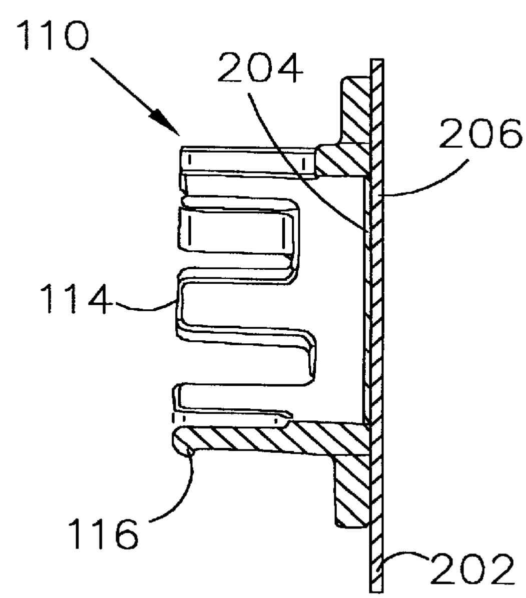


FIG. 4

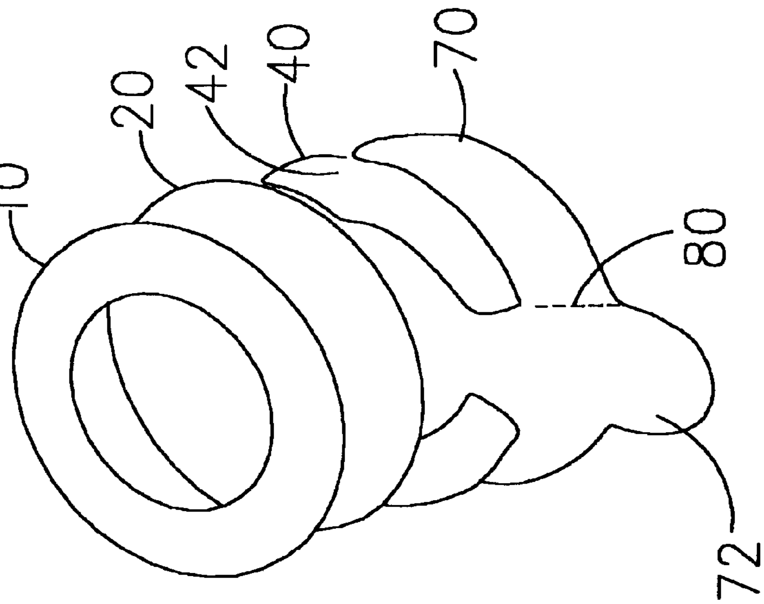


FIG. 6

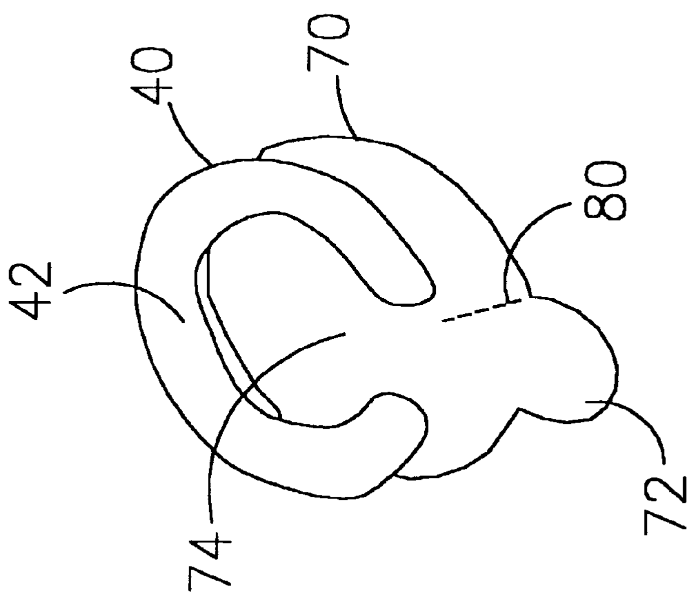


FIG. 5

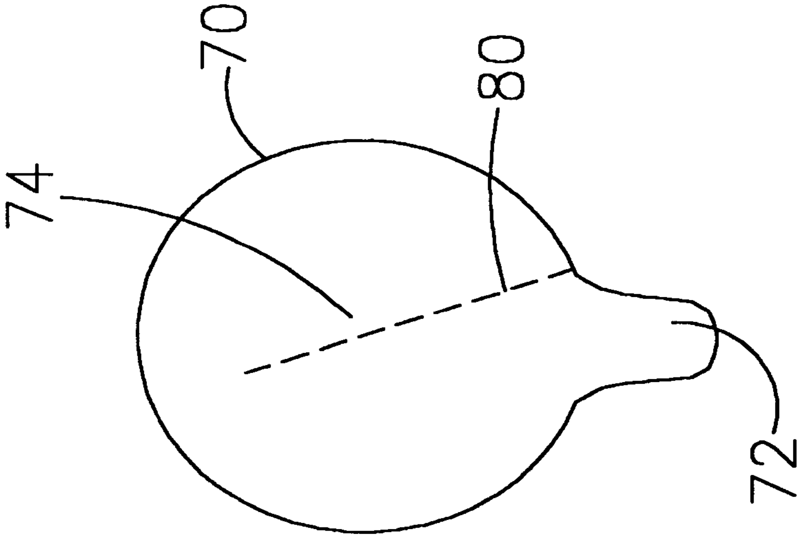


FIG. 8

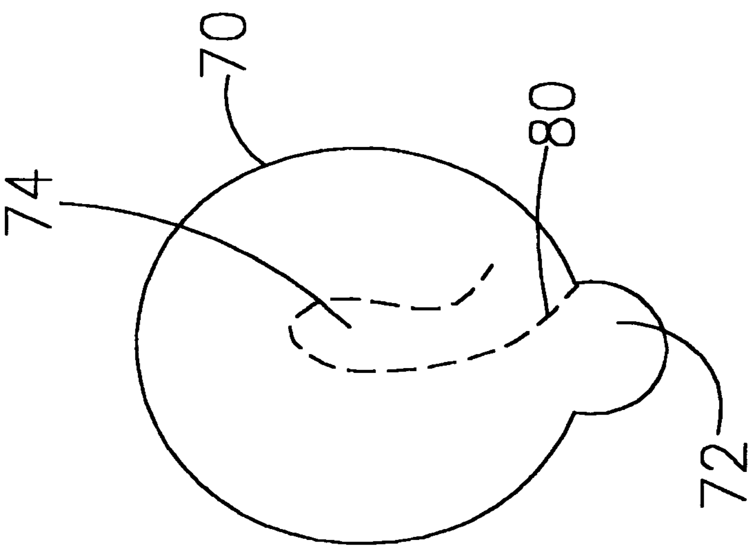


FIG. 7

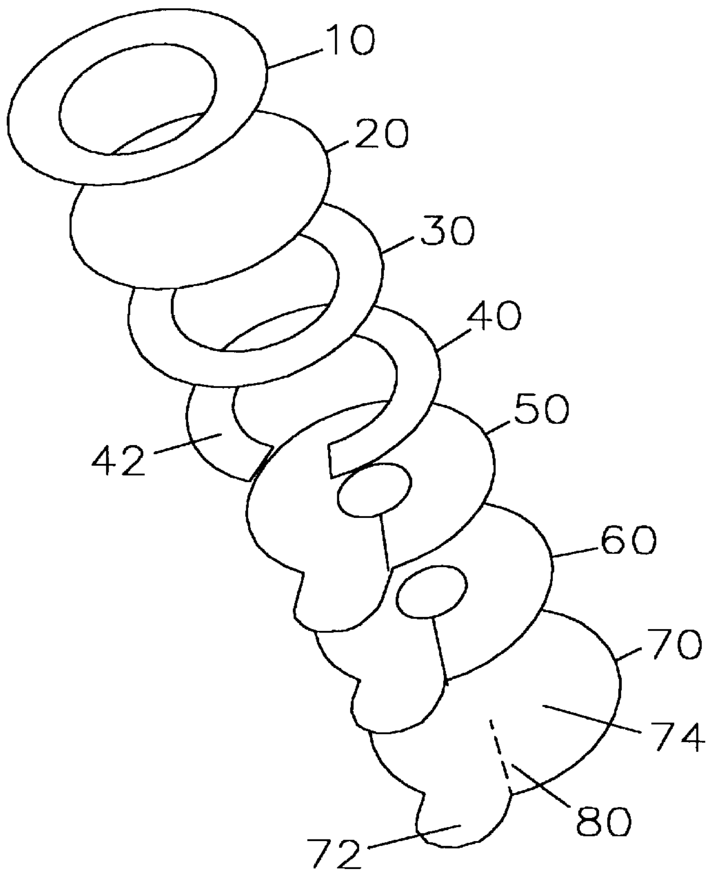


FIG. 9

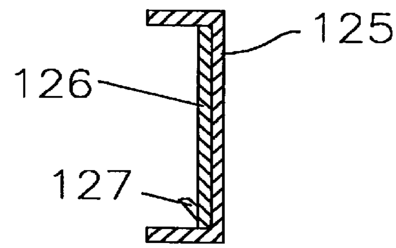


FIG. 11A

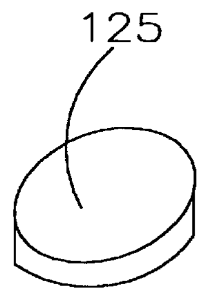


FIG. 11B

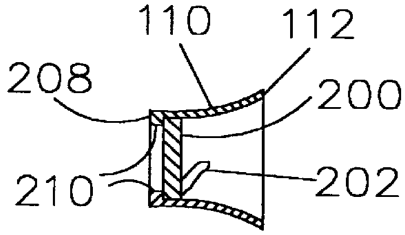


FIG. 10

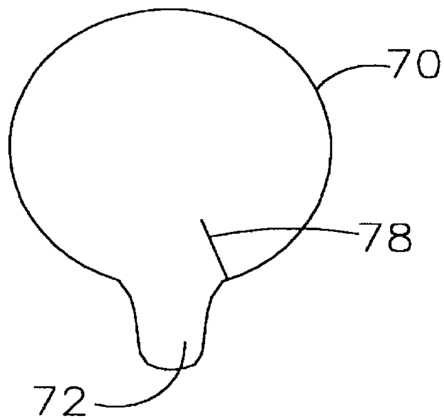


FIG. 12

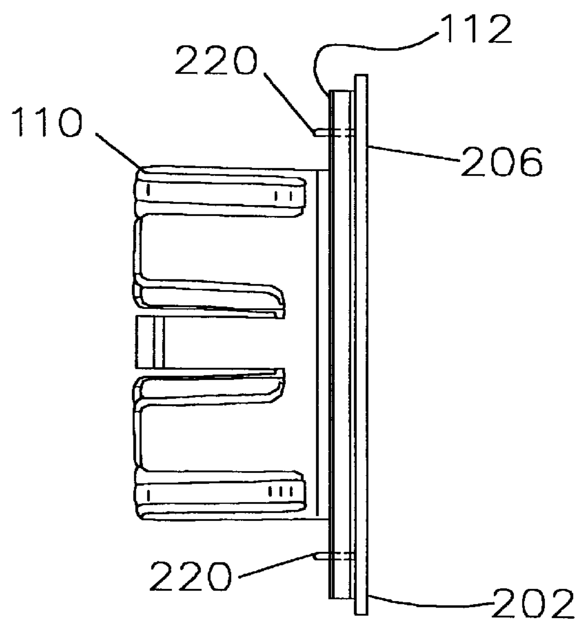


FIG. 13

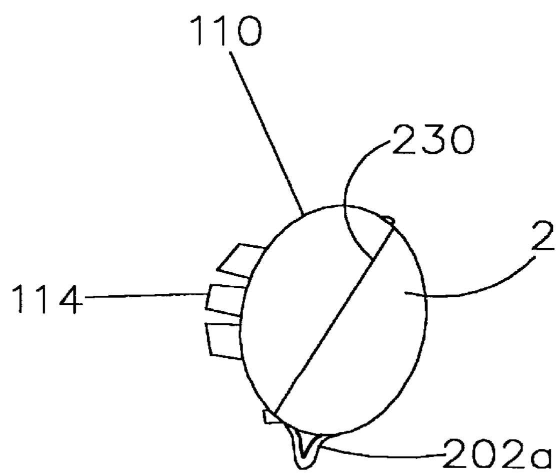


FIG. 14

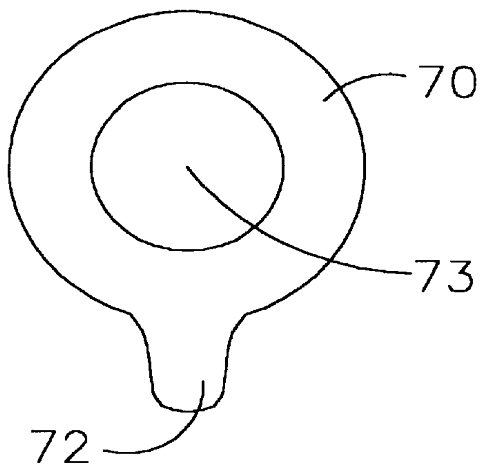


FIG. 15

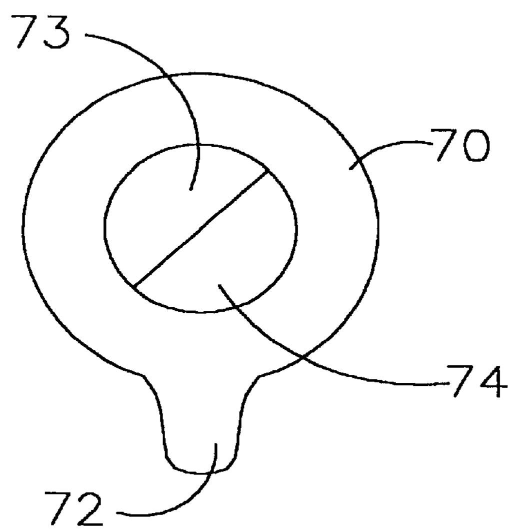


FIG. 16

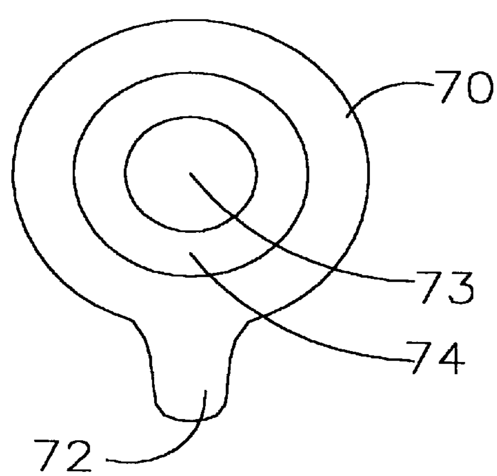


FIG. 17

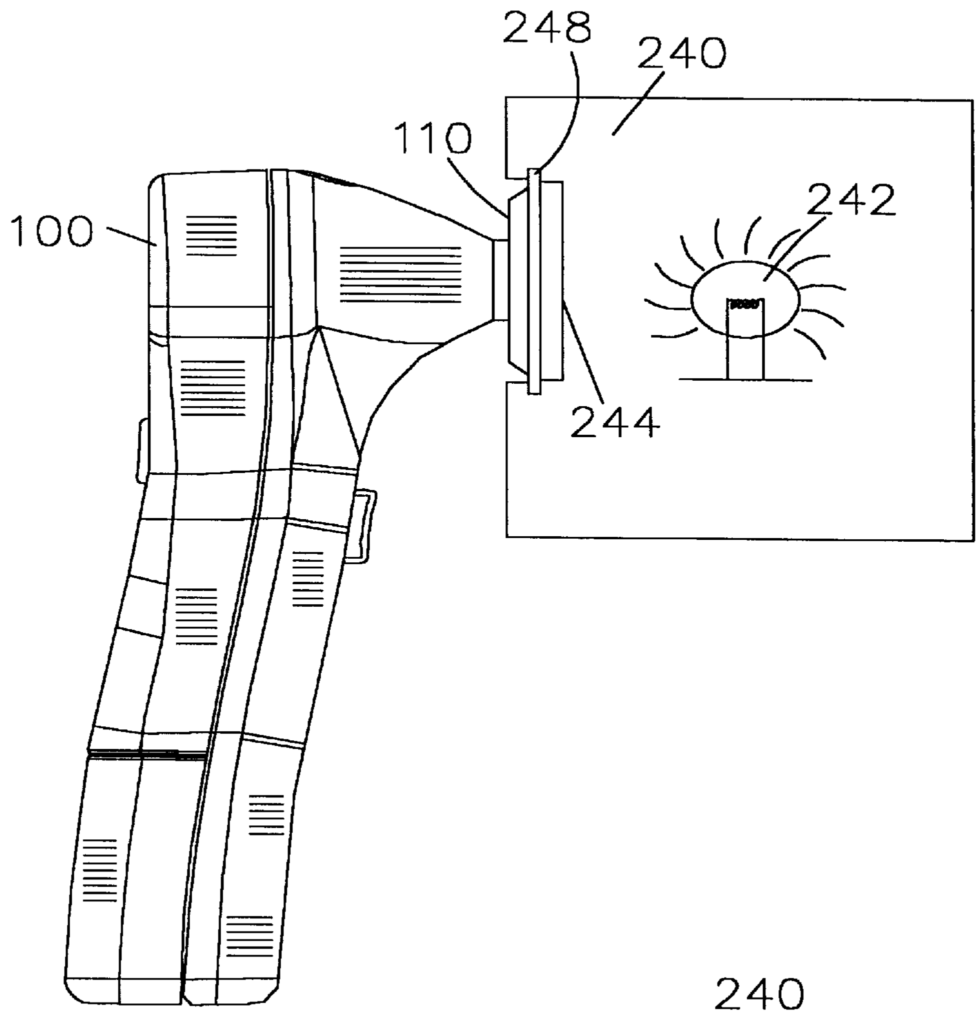


FIG. 19

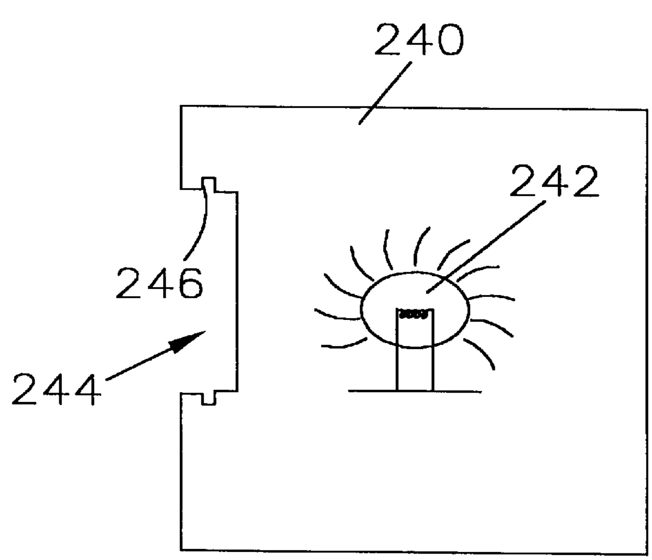


FIG. 18

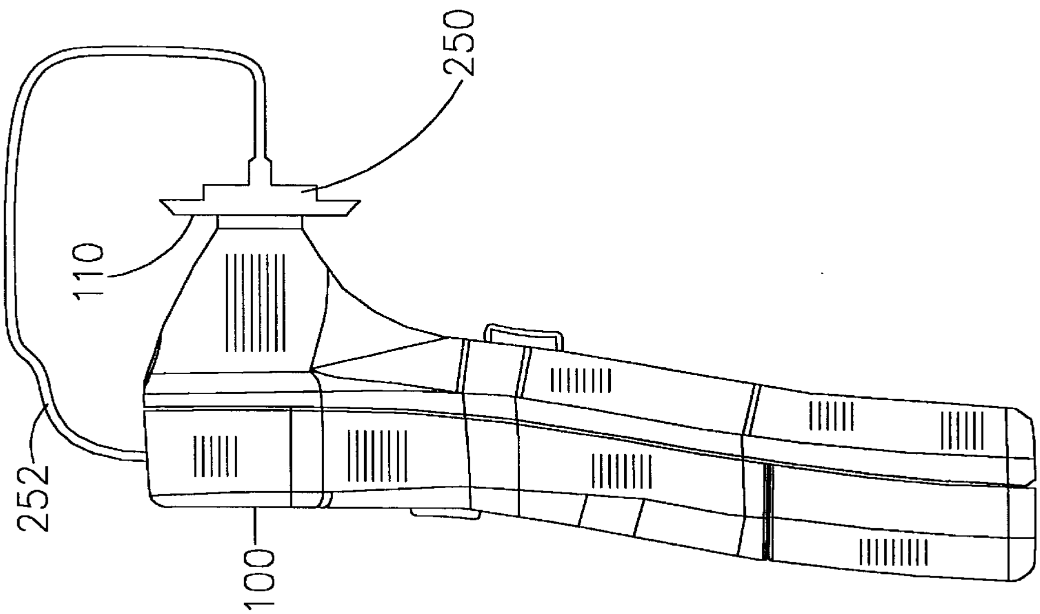


FIG. 20B

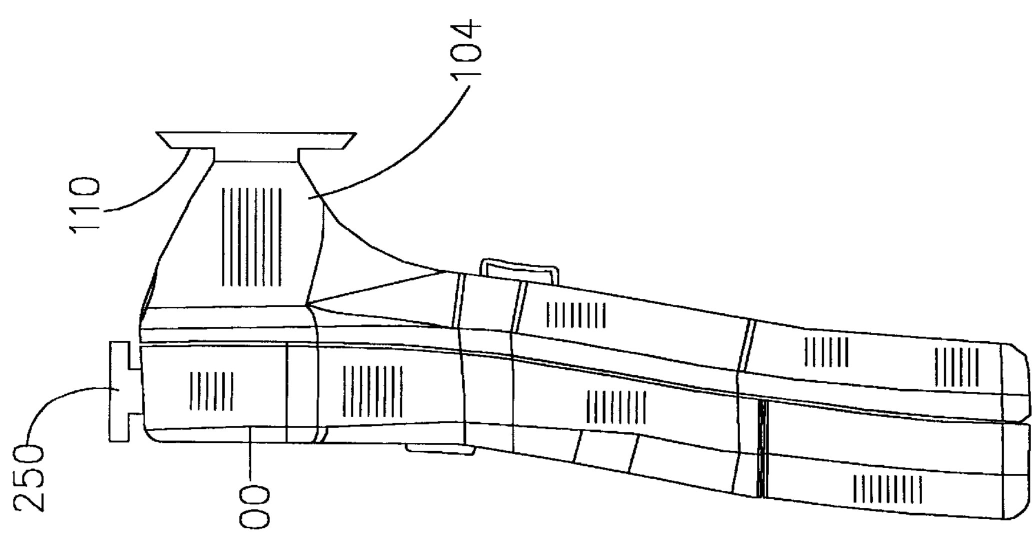


FIG. 20A

DISPOSABLE CALIBRATION DEVICE

This application is a continuation-in-part of U.S. patent application Ser. No. 09/054,490, filed Apr. 3, 1998 now U.S. Pat. No. 5,924,984; which in turn is a continuation-in-part of U.S. patent application Ser. No. 08/904,766, filed Aug. 1, 1997; which in turn is a continuation-in-part of U.S. patent application Ser. No. 08/621,182, filed Mar. 21, 1996 now abandoned; which in turn is a continuation-in-part of U.S. patent application Ser. No. 08/587,949, filed Jan. 17, 1996. The contents of all four parent applications are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a device for calibrating a measuring instrument or serving as a reference target.

2. Background of the Related Art

There are a variety of measuring instruments that utilize electromagnetic radiation to detect physical characteristics or conditions of a material. Such instruments may be used to detect colors or spectroscopic characteristics of objects, or to determine a characteristic of an object. Such an instrument may also be used by medical personnel to diagnose a condition of a patient.

Typically, the instrument will emit radiation at one or more wavelengths, and the emitted radiation is directed toward a target object, or target tissue on a patient. Reflected, transmitted, scattered or emitted radiation that interacts with the target object or tissue, or possibly fluorescent radiation generated by the target object or tissue in response to the emitted radiation, is then detected by the instrument and analyzed to determine characteristics of the target object or tissue, or to determine a condition of the patient.

An example of such an instrument is shown in FIG. **1**. The instrument **100** includes a trigger **102** for activating the device. When activated, the device emits radiation at one or more wavelengths from a nose portion **104**. Radiation that is reflected, transmitted, scattered or emitted from the target object or patient is then collected by the nose portion **104** and analyzed by a detector of the instrument to determine a characteristic of the target object, or a condition of the patient. The instrument could also be configured such that it receives and analyzes radiation that is naturally emitted from the tissue or object.

Instruments like the one shown in FIG. **1** may require periodic calibration to maintain their accuracy. Over time, various characteristics of the instrument, including the amplitude of the output radiation and the spectral distribution of the output radiation, as well as the total radiation power output, can vary due to environmental conditions, or simple aging of the radiation emitting elements and other elements in the instrument. In addition, a detector of the instrument can have differing sensitivities depending upon environmental conditions or the age of the detector. For instance, a change in temperature of only a few degrees can significantly affect the sensitivity of a radiation detector. For these reasons, the measuring instrument may require a calibration or reference reading prior to taking an actual measurement.

In a calibration operation, the instrument is aimed at a calibration target having known optical properties and radiation is directed toward the target. Radiation is then reflected, transmitted, scattered or emitted by the calibration target and detected by a detector of the instrument. Because the calibration target has known optical properties, the amount and distribution of radiation reflected, transmitted, scattered or emitted by the calibration target and received back in the instrument provides an indication of the radiation directed toward the target. A calibration operation allows a baseline measurement to be taken in order to determine the qualitative end quantitative performance of the light source, detector and other instrument components in order to ensure that the instrument will deliver accurate results.

In a reference operation, the instrument is aimed at a target having known optical properties and radiation is directed toward the target. A predetermined amount of radiation generated by the instrument is reflected, transmitted or scattered by the target, or the radiation causes the target to emit radiation. This reflected, transmitted, scattered or emitted radiation is detected by the detector of the instrument. The results of detection operation can then be used as a standard or reference against which a target object or patient measurement is judged. A reference operation is typically conducted at the point of use. A target object or patient reading could then be derived by determining a difference or ratio between a target object or patient detection operation, and a detection operation conducted on a reference target. Because the optical properties of the reference target are known, variations in light output or detector sensitivity can be accounted for by use of the reference target. This ensures that the instrument continues to deliver accurate results.

SUMMARY OF THE INVENTION

The invention is a device and method that can be used to calibrate or reference a measuring instrument for purposes of taking a measurement.

A calibration or reference device embodying the invention may include a fluorescent portion that produces fluorescent radiation in response to an excitation radiation. The excitation radiation may come from the instrument itself or from an external source.

A calibration or reference device embodying the invention may also be at least partially transmissive to radiation, so that radiation transmitted through the device can be used to conduct a calibration or reference operation. The optical properties of the transmissive calibration/reference device are controlled so that a predetermined amount of radiation is allowed to pass through the target. This type of device could be used with a radiation source in the instrument itself, or with an external source of radiation.

A calibration or reference device embodying the invention may include a shield to prevent contamination or infection of the measured article. In some embodiments, the device may comprise both an infection/contamination shield and a calibration or reference target with known optical properties integrated into a single unitary element.

A device embodying the invention is configured to be attached to the operative end of a measuring instrument. Once attached, the instrument may perform one or more measurement cycles using a calibration or reference target of the device having known optical properties. After a calibration/reference operation has been successfully performed, the portion of the target relevant to the calibration/reference is removed and the instrument is used to perform an object or patient measurement. If the target device incorporates a contamination/infection shield, the shield may remain attached to the instrument to prevent contamination or infection of the measured object/patient.

In a preferred embodiment, the device is configured such that removal of the target irrevocably destroys the portion of the target relevant to the calibration/reference operation, thus precluding another use of the target. As explained more fully below, when such a device embodying the invention is used with a medical instrument which is configured to perform only a single patient reading after each calibration/reference operation, such use can help to ensure that patients are not contaminated or infected, and that no cross-contamination between patients is possible.

Methods embodying the invention could make use of reflective, transmissive or fluorescent calibration/reference devices described above.

In a method embodying the invention that makes use of a fluorescent calibration target, excitation radiation would be applied to the fluorescent portion of the target, and fluorescent radiation generated by the target would be used to perform a calibration or reference operation. In such a method, the step of detecting the fluorescent radiation generated by the target could comprise determining time characteristics of the fluorescent emissions through a burst and monitor method, a phase shift method, or a fluorescence depolarization method.

In methods embodying the invention that make use of a transmissive calibration/reference device, radiation could be generated by the measuring instrument, or an external light source, and the excitation radiation would be applied to the transmissive portion of the calibration/reference device. Radiation passing through the transmissive portion is then detected by the measuring instrument and used to conduct a calibration/reference operation.

Additional advantages, objects, and features of the invention will be set forth in part in the description which follows, and in part will become apparent to those having ordinary skill in the art upon examination of the following, or may be learned from practice of the invention. The objects and advantages of the invention may be realized and attained as particularly pointed out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will be described in conjunction with the following drawing figures, wherein like reference numerals refer to like elements, and wherein:

FIG. **1** is a side view of a measuring instrument embodying the invention that can be used with a calibration/reference device embodying the invention;

FIG. **2** is a perspective view of a portion of a calibration/reference device embodying the invention;

FIG. **3** is a side view of a calibration/reference device embodying the invention; FIG. **4** is a sectional view of a second calibration/reference device embodying the invention;

FIG. **5** is an exploded perspective view of a calibration target embodying the invention;

FIG. **6** is an exploded perspective view of a calibration/reference target and an infection shield embodying the invention;

FIG. **7** is a plan view of a calibration/reference target embodying the invention;

FIG. **8** is a plan view of another calibration/reference target embodying the invention;

FIG. **9** is an exploded perspective view of a calibration/reference target and infection shield embodying the invention;

FIG. **10** is a sectional view of another calibration/reference device embodying the invention;

FIG. **11**A is a sectional view of a calibration/reference device embodying the invention;

FIG. **11**B is a perspective view of an exterior of the calibration/reference device shown in FIG. **11**A;

FIG. **12** is a plan view of another calibration/reference target embodying the invention;

FIG. **13** is a side view of another calibration/reference device embodying the invention;

FIG. **14** is a perspective view of another calibration/reference device embodying the invention;

FIG. **15** is a plan view of another calibration/reference target embodying the invention;

FIG. **16** is a plan view of another calibration/reference target embodying the invention;

FIG. **17** is yet another embodiment of a calibration/reference target embodying the invention;

FIG. **18** is a diagram of an external light source that can be used with a measuring instrument and transmissive calibration/reference device embodying the invention;

FIG. **19** is a diagram showing a measuring instrument embodying the invention performing a calibration operation or a measurement operation utilizing an external light source;

FIG. **20**A is a diagram of a measuring instrument embodying the invention, and

FIG. **20**B is a diagram showing a measuring instrument embodying the invention conduction a calibration/reference operation with a transmissive calibration target.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The terms "calibration target" and "reference target" are used interchangeably in the following text to refer to a target having known optical properties. The invention is applicable to both calibration targets and reference targets, and use of either term should not be construed as limiting. Also, measuring instruments that utilize the methods and calibration/reference targets embodying the invention make use of electromagnetic radiation. The terms electromagnetic radiation, radiation and light are intended to be equivalent terms, all of which refer to electromagnetic radiation.

A calibration/reference device embodying the invention may be comprised of several parts. The first part is simply a device for anchoring a contamination/infection shield and a calibration/reference target to a measuring instrument. If the instrument is like the one shown in FIG. **1**, a shield holder **110**, as shown in FIG. **2**, can be used to attach an infection/contamination shield and a calibration/reference target to the nose portion **104** of the instrument **100**.

As seen in FIGS. **2–4**, the shield holder **110** has a plurality of finger-like projections **114** arranged in a cylindrical shape. Some or all of the projections **114** may include a lip **116** which is engageable with the nose portion **104** of the instrument **100** to attach the device to the instrument. If the shield holder **110** is made from a flexible material, such as a molded plastic, the shield holder **110** can be snapped onto the nose **104** of the instrument **100** so that the lips **116** engage the nose **104**.

A multilayer combined contamination shield and calibration target **200** can then be affixed to a front annular surface **112** of the shield holder **110**. In a preferred embodiment of the invention, the combined contamination shield and calibration target **200** is attached to the shield holder **110** with a layer of adhesive. The combined contamination shield and calibration target **200** may include a user graspable tab **202** for removing the calibration target after a calibration or reference operation has been performed.

Of course a calibration target **200** could also be mechanically attached to the shield holder **110** by any type of mechanical attachment mechanism such as staples, clips, pins, etc. FIG. **13** shows an embodiment where a calibration target **206** is attached to a shield holder **110** with a plurality of pins **220** arranged around the periphery of the shield holder **110**.

In an alternate embodiment, as shown in FIG. **4**, an infection shield **204** may be separately mounted to the shield holder **110**. The infection shield **204** could simply be a clear plastic portion of the shield holder **110**, which is integrally molded with the shield holder **110**. The infection shield **204** could also be a substantially transparent film that is attached to the shield holder **110**. A calibration target **206** could then be attached to the front annular surface **112** of the shield holder **110** via an adhesive layer or some type of mechanical attachment device. The calibration target **206** would include a user graspable tab **202** for aiding removal of the calibration target after a calibration or reference operation has been performed.

A calibration/reference target embodying the invention is shown in FIG. **5**. The target includes a calibration layer **70** having a central portion **74** with known optical properties. A user graspable tab **72** is formed as a part of the calibration layer **70**. Also, a double-sided adhesive layer **40** is used to attach the calibration layer **70** to a shield holder **110**, as shown in FIG. **4**. In alternate embodiments, the adhesive layer **40** can be used to attach the calibration layer **70** to an infection/contamination shield layer which is then attached to the shield holder **110**, as shown in FIG. **3**. In still other embodiments, the double-sided adhesive layer **40** could be replaced with an adhesive that is applied to the calibration layer **70** or a shield holder **110** in a liquid, gel or paste form.

The calibration layer **70** and the double-sided adhesive layer **40** are carefully constructed so that when the calibration target is removed from a shield holder, the target portion **74** in the center of the calibration layer **70** will tear in a predetermined manner. To that end, the calibration layer **70** may include a reduced strength portion **80**, which could be a slit, a perforation or a crease. The reduced strength portion **80** in the embodiment shown in FIG. **5** is a perforation that extends from a peripheral edge of the calibration layer **70**, towards the central area **74**. When a user grasps the tab **72** and pulls on the tab to remove the calibration layer **70** from a shield holder, the calibration layer **70** will tend to tear along the reduced strength portion **80**.

In the embodiment shown in FIG. **5**, the adhesive layer **40** has a horseshoe shape such that a portion of the calibration layer **70** having the reduced strength portion **80** is aligned with the gap in the adhesive layer **40**. Also, in a preferred embodiment, a first side **42** of the adhesive layer **40** will have a relatively low adhesive strength, and the opposite side of the adhesive layer **40** will have a greater adhesive strength. In this configuration, the lower adhesive strength side **42** of the adhesive layer **40** is used to attach the calibration layer **70** to a shield holder. When a user pulls on the tab **72** to remove the calibration layer **70**, the lower adhesive strength side **42** will separate from the shield holder before the higher adhesive strength side separates from the calibration layer **70**. Thus, the adhesive layer **40** is fully removed along with the calibration layer **70**. Also, because of the gap in the adhesive layer **40**, the portion of the calibration layer immediately to the right of the reduced strength portion **80** will tend to remain attached to the shield holder while the portion of the calibration layer **70** adjacent the tab and located beneath the gap in the adhesive layer **40** will pull upward and away from the shield holder. This will cause the calibration layer **70** to begin to tear along the reduced strength portion **80**. As the user continues to pull on the tab **72**, the tearing of the calibration layer **70** will tend to continue across the center portion **74** having the optical properties used to perform a calibration operation.

If a liquid, gel or paste adhesive is used to attach the calibration layer **70** to a shield holder **110**, there will not be varying adhesive strengths. However, in such an embodiment it would be advantageous if the adhesive had a greater affinity for the calibration layer **70** than for the shield holder **110**. In this case, most, if not all, of the adhesive would remain attached to the calibration layer **70** as it is removed from the shield holder **110**. Thus, no adhesive remaining on the shield holder **110** would contact the skin of a patient or a surface to be measured when the instrument and attached shield holder **110** are used to take a measurement.

Similarly, if some type of mechanical attachment mechanism is used to attach the calibration layer **70** to a shield holder **110**, it may be advantageous if the mechanical attachment mechanism is more firmly attached to the calibration layer **70** than to the shield holder **110**. This would result in the attachment mechanism being removed from the shield holder along with the calibration layer, leaving the shield holder **110** free of any protrusions when used to take a measurement. For instance, in the embodiment shown in FIG. **13**, the pins **220** attaching the calibration target **206** to the shield holder **110** could be more firmly attached to the calibration target than the shield holder **110**. The cylindrical shafts of the pins **220** would extend through the annular portion **112** of the shield holder **110**. Ends of the pins **220** that protrude out the back side of the annular portion **112** could have a slightly enlarged diameter, thus holding the pins **220** and the attached calibration target **206** firmly to the shield holder **110**. When the user pulls the calibration target **206** away from the shield holder **110**, the pins **220** will pull out of the holes in the annular portion **112**. Also, by arranging the pins in a particular orientation with respect to the user graspable tab **202** of the calibration target **206**, the calibration target can be caused to tear or separate in a predetermined manner.

Once a calibration layer **70** has been completely removed from a shield holder, the central portion **74** of the calibration layer **70** should be irrevocably damaged so that the calibration layer **70** cannot be re-used for a new calibration operation. In the embodiment shown in FIG. **4**, because the side of the adhesive layer **40** in contact with the calibration layer **70** has a greater adhesive strength than the side **42** which was attached to the shield holder, all of the adhesive layer should remain attached to the calibration target and be removed from the shield holder along with the calibration layer **70**.

As mentioned above, the calibration target shown in FIG. **5** is intended to be used with a shield holder **110** as shown in FIG. **4**. This type of shield holder **110** includes its own integral infection/contamination shield **204**.

In an alternate embodiment, as shown in FIG. **6**, both a calibration target and an infection/contamination shield are attached to the exterior of a shield holder. In this embodiment, a first double-sided adhesive layer **10** is attached to a front edge **112** of a shield holder **110**, like the one shown in FIG. **3**. The opposite side of the adhesive layer **10** is then attached to an infection/contamination shield **20**.

In a preferred embodiment, the infection/contamination shield **20** is substantially transparent. An adhesive layer **40** and a calibration layer **70** are then attached to the infection shield **20**. The adhesive layer **40** and the calibration layer **70** have generally the same properties as those described for the embodiment shown in FIG. **5**. That is, a first side **42** of the adhesive layer **40** has a relatively low adhesive strength, and the opposite side of the adhesive layer, which is attached to the calibration layer **70**, has a greater adhesive strength. Thus, when a user pulls the tab **72** of the calibration layer **70** and removes the calibration layer, both the calibration layer **70** and the adhesive layer **40** are removed. This leaves just the infection/contamination shield **20** attached to the shield holder **110** and the instrument **100**. Of course the double-sided adhesive layers **10** and **40** could also be replaced with a liquid, gel or paste adhesive, or with a mechanical attachment device, as described above.

Once a calibration/reference operation has been conducted, and the calibration target is removed, the instrument can be used to conduct a measurement on a patient or an object. Light generated by the instrument passes through the infection shield **20**, strikes the patient or object, and is reflected back through the infection shield **20** to a detector of the device. After a patient or object measurement has been completed, the shield holder **110** and the attached infection shield **20** are removed from the instrument **100** and disposed of.

The calibration layer **70** can have a reduced strength portion **80** configured in many different ways. In the embodiments shown in FIGS. **5** and **6**, the reduced strength portions extend from a peripheral edge towards a center **74** of the calibration layer **70**. This encourages the calibration layer to tear across the center **74** of the calibration layer **70**, which is the portion having optical properties used to calibrate a measuring instrument. In preferred embodiments, the reduced strength portion **80** does not extend beyond the annular radial width of the adhesive layer **80** so that light cannot penetrate through the calibration layer **70** and affect a calibration or reference operation.

In alternate embodiments, as shown in FIGS. **7** and **8**, the reduced strength portion can have different configurations. In the embodiment shown in FIG. **7**, the reduced strength portion **80** traverses a path across the central region **74** of the calibration layer **70**. In the embodiment shown in FIG. **8**, the reduced strength portion **80** proceeds in a direct line across the center **74** of the calibration layer **70**. Each of these embodiments is intended to ensure that as the calibration layer **70** is removed, the central portion **74** used to calibrate the instrument is altered in a destructive manner so that the calibration layer cannot be reused.

In still other embodiments, a cutting device could be incorporated into the calibration layer **70**, or into the shield holder **110** or the instrument itself. One such embodiment is shown in FIG. **12**, where a wire or monofilament **78** is attached to or embedded in the calibration layer **70**. The wire or monofilament **78** will cause the calibration layer **70** to tear in a predetermined manner when a user pulls on the tab **72**. Although FIG. **12** shows the wire or monofilament extending only partway across the calibration layer **70**, the wire or monofilament could extend further or completely across the calibration target **70**. The wire or monofilament could also be arranged in a pattern, like the reduced strength portion **80** shown in FIG. **7**.

In alternate embodiments, a wire or monofilament could also be attached to the shield holder. In the embodiment shown in FIG. **14**, a wire or monofilament **230** is stretched across the back of the calibration layer **200**, with ends of the wire or monofilament being attached to the shield holder **110**. Also, the wire or monofilament **230** could be replaced with any other type of cutting device that will cause the calibration layer **70** to tear or separate in a predetermined manner when being removed from a measuring instrument.

If the measuring instrument **100** which is used in conjunction with a device embodying the invention is configured so that only a single patient or object measurement may be conducted after each calibration operation, a calibration device embodying the invention can help to prevent patient infection or patient or object cross-contamination.

When a user attempts to use the measuring instrument, a shield holder with an infection/contamination shield and a calibration target will first be attached to the instrument **100**. Next, a calibration/reference operation will be performed. Once the calibration/reference operation is complete, the user will grasp a tab **72** on the calibration target and pull on the tab to remove the calibration target. This will cause the calibration target and any attached adhesive layer to be removed from the shield holder. The act of removing the calibration target will destroy at least the portion of the calibration target having the optical properties used to calibrate/reference the instrument **100**. Thus, it will be impossible to reuse the calibration target. The user would then proceed to conduct a patient or object measurement with the shield holder and infection shield still attached to the instrument **100**. The results of the measurement can then be noted or recorded.

Because the instrument will not perform a second patient or object measurement without first performing another calibration/reference operation, the user will be forced to remove both the shield holder and the infection shield and replace it with a new device that includes a new infection shield and a new calibration target. The user will be forced to perform another calibration operation before the device can be used to perform another patient or object measurement. For this reason, it should be impossible for the device to be used to take two measurements on two different patients or objects using the same shield holder and infection/contamination shield. This prevents cross-contamination between different patients or objects.

Also, an interlock mechanism in the nose of the measuring instrument may interact with a shield holder of a device embodying the invention to inform the instrument when a shield holder is removed. The instrument can then be configured so that no patient measurements can be performed once a shield holder has been removed from the instrument. This should discourage users from attempting to conduct a measurement without an infection/contamination shield in place, thereby reducing the opportunity for patient or object cross-contamination. Similarly, the interlock mechanism could be configured to prevent more than one patient or object measurement cycle from being performed before a shield holder is removed and another one is inserted.

In a preferred embodiment of the invention, the shield holder is configured as shown in FIG. **3**, and a combined infection/contamination shield and calibration target **200** will be constructed as shown in FIG. **9**. In this embodiment, a first double-sided adhesive layer **10** is used to attach the combined infection/contamination shield and calibration target to the shield holder **110**. The opposite side of the double-sided adhesive layer **10** is adhered to a shield layer **20**. Next, a clear release liner **30** is attached to the infection/contamination shield **20**. The release liner **30** will remain permanently attached to the infection shield **20**, but will provide a controlled release of the remaining portions of the combined infection shield and calibration target.

Next, a second double-sided adhesive layer **40** is attached to the release liner **30**. As in the previous embodiments, a gap is formed in the adhesive layer **40**. Next, a spacer layer **50** is attached to the opposite side of the second adhesive layer **40**. The spacer layer **50** serves to space a calibration layer a precise distance from an emitting end of an instrument to which the device is attached. A third double-sided adhesive layer **60** then attaches a calibration layer **70** to the spacer layer **50**. Of course, the double sided adhesive layers **10**, **40** and **60** could all be replaced with a liquid, gel or paste adhesive, or by a mechanical attachment device, as explained above.

The central portion **74** of the calibration layer **70** will be exposed to light emitted by an emission end of an instrument to which the device is attached. Also, reduced strength portions are formed in the spacer layer **50**, the third double-sided adhesive layer **60** and the calibration layer **70**. As explained above, the reduced strength portions cause the calibration layer **70** to tear in a predetermined manner when the calibration layer **70** is removed from the remaining portions of the device. Also, the reduced strength portions are oriented in a predetermined manner with respect to the gap in the second double-sided adhesive layer **40**. Preferably, the reduced strength portions are positioned adjacent one side of the gap. When the device is oriented in this manner, pulling on the tab **72** of the calibration layer **70** causes the calibration layer to tear along the reduced strength portion **80** and to irrevocably damage the central portion **74** of the calibration layer **70**.

Of course, the reduced strength portions could also be replaced by a cutting device, as explained above, to cause the calibration layer to tear or separate in a predetermined manner.

In an alternate embodiment of the invention, the shield holder could be configured as shown in FIG. **10**. In this embodiment, the narrower portion of the shield holder is to be attached to a measuring instrument, and the larger diameter flared portion **112** extends away from the device. A flexible annular ring of material **210** on the rear of the shield holder may engage projections **106***a* on the nose portion **104** of a measuring instrument **100**, as shown in FIG. **1**. In this embodiment, a combined infection/contamination shield and calibration target **200** is located adjacent the back side **208** of the shield holder **110**, instead of being located on the front end **112**. The combined infection/contamination shield and calibration target **200** still includes a user graspable tab **202** which can be pulled to remove the calibration target. This embodiment, like the embodiment shown in FIG. **4**, could have an infection shield mounted on the shield holder and a separate calibration target which is adhered to the shield holder or the infection/contamination shield.

Another alternate embodiment of a calibration/reference device is shown in FIGS. **11**A and **11**B. In this embodiment, a reference target holder **125** has a cup-like shape. A calibration target **126** may be mounted on the inside of the holder **125**, as shown in FIG. **11**A. Alternatively, if the holder **125** is transparent, the calibration target **126** could be mounted on the outside of the holder **125**. The holder **125** could be formed of any rigid or semi-rigid material. In a preferred embodiment, the holder **125** would be made of molded plastic. The calibration target **126** could be pre-mounted on the holder **125**, such that the entire assembly can be used for a period of time, then discarded. Alternatively, the calibration target **126** could be removably mounted on the holder **125**, such that the holder **125** can be re-used multiple times with different calibration targets **126**. In this instance, the calibration target **126** could include a user graspable tab **127** that aids removal of the calibration target **126** from the holder **125**.

To use this type of calibration device, the user would place the calibration device over the detector of a measuring instrument. For instance, the calibration device could be placed over the nose **104** of the measuring instrument **100** shown in FIG. **1**. The measuring instrument would then conduct a calibration operation using a portion of the calibration target **126** having known optical properties. The user would then remove the calibration device from the measuring instrument and conduct a measurement on a target object or tissue.

An embodiment like the one shown in FIGS. **11**A and **11**B could be used with a measuring device that does not require a calibration operation to be performed prior to each measurement. This embodiment could be used for periodic calibration of a measuring device. The holder would ensure that the calibration target is correctly positioned relative to the light source and detector of the measuring instrument. Also, the sidewalls of the holder **125** would serve to block outside light from reaching a detector of the device, thereby ensuring the calibration operation is accurate.

In a preferred embodiment of the device, the calibration target **126** would be removably mounted on the holder **125**. The user would obtain a calibration target **126** and first place the calibration target **126** on the inside of the holder **125**. The user would then conduct a calibration operation as described above. After the calibration operation has been performed, the user could remove the calibration target **126** from the holder **125** using the user graspable tab **127**, so that the holder can be reused with another calibration target **126**.

Either of the calibration targets shown in FIGS. **5** and **6** could be used with the holder **125** shown in FIGS. **11**A and **11**B. If the calibration target shown in FIG. **5** is used, and the calibration target is attached to the inner side of the holder **125** (as shown in FIG. **11**A) the double sided adhesive layer **40** could be used to attach the calibration layer **70** to the inside of the holder **125**. In this instance, the calibration layer **70** would have known optical properties on the side of the calibration layer **70** opposite the adhesive layer **40**, which is the side that would face the detector of a measuring instrument. If the calibration target is attached to the outside of the holder **125** (not shown), the calibration layer **70** of the calibration target would have known optical properties on the side facing the adhesive layer **40**, and the holder **125** would be at least partially transparent.

If the calibration target shown in FIG. **6** is used, an additional adhesive layer on the side of the calibration layer **70** opposite the adhesive layer **40** could be used to attach the calibration device to the inside of the holder **125**. In this instance, when the holder is placed over the output end of the measuring instrument, the double sided adhesive layer **10** would be pressed against and adhere to the measuring instrument. Then, after a calibration operation has been performed, when the holder **125** is removed from the measuring instrument, it will leave the entire calibration target attached to the measuring instrument. The user would then remove the calibration layer **70**, and its attached adhesive layer **40**, so that the shield layer **20** and the double sided adhesive layer **10** remain attached to the measuring instrument. The instrument could then be used to conduct measurements, and the shield layer **20** would act as a contamination or infection shield Also, in alternative embodiments, the adhesive strength of the adhesive layers could be designed such that removal of the cover **125** from the measuring instrument, after a calibration operation, will cause the calibration layer **70** and adhesive layer **40** to also be removed from the measuring instrument. This would leave the measuring instrument, with the shield layer **20** and adhesive layer **10**, ready to perform a measurement operation. The user could then remove the calibration layer **70** from the holder **125** so that the holder **125** can be re-used. Alternatively, the holder **125** and the attached calibration layer **70** and adhesive layer **40** could simply be discarded.

Also, in some embodiments of the calibration devices described above, the portion of a calibration/reference target having known optical properties need not be simply reflective/scattering. In an alternate embodiment, a target layer of a calibration device embodying the invention could include a fluorescent portion which emits fluorescent electromagnetic radiation in response to an excitation light. An embodiment of a fluorescent calibration layer is shown in FIG. **15**. In this embodiment, a fluorescent portion **73** is centered on the calibration layer **70**.

When a calibration device that includes a fluorescent calibration layer is attached to a measuring instrument, light from a light source of the measuring instrument can be used to excite the fluorescent portion **73**. The fluorescent portion **73** would then emit fluorescent light, which can be detected by a detector of the measuring instrument. The fluorescent light emitted by the fluorescent portion **73** may be at a different wavelength than the light used to excite the emissions. Thus, a fluorescent calibration device can be used to calibrate an instrument for light emissions in a different portion of the spectrum than would be possible with simply a reflective calibration device.

Also, even when a calibration target having a fluorescent portion is used, by selectively receiving only the same wavelengths that were emitted by the measuring instrument, one can conduct a calibration based on scattered light. By selectively receiving only the wavelengths corresponding to fluorescent light generated by a target, one can conduct a calibration operation based only on the fluorescent light, thereby preventing reflectance/scattering properties of the target from affecting the calibration operation.

Also, a calibration/reference operation performed with a fluorescent calibration/reference target could be designed to determine time characteristics of the fluorescent target. For instance, the fluorescent target could be illuminated with a relatively short duration burst of excitation light, then the fluorescent emissions from the fluorescent target could be monitored to determine how long it takes for an amplitude of the fluorescent emissions to decay below a threshold value. The details of such a method are provided in U.S. Pat. No. 5,348,018 to Alfano et al, the contents of which are hereby incorporated by reference.

In an alternate method of conducting a calibration/reference operation with a fluorescent target, the fluorescent target could be illuminated with an amplitude modulated beam of excitation light. Because an amplitude of the excitation light modulates with time, an amplitude of the fluorescent light would also modulate with time, but at the same frequency. A detector of a measuring instrument could monitor the fluorescent light generated by the fluorescent target and compare the amplitude modulations of the fluorescent light with the amplitude modulations of the excitation light. A phase shift between the excitation light modulation and the fluorescent light modulation provides an indication of the time characteristics of the fluorescent target. Also, a demodulation factor which represents a ratio of the amplitudes of the excitation light to the amplitudes of the fluorescent light could be used, in conjunction with the phase shift, to determine properties of the fluorescent calibration device. Details of such a method are provided in U.S. Pat. No. 5,628,310 to Rao et al., the contents of which are hereby incorporated by reference.

In still other methods of using a fluorescent calibration/reference target, rotation of polarization of fluorescent light generated by the target, with respect to a polarization plane of the excitation light, can be used to determine time characteristics of the fluorescent target. In this method, a polarized excitation light would illuminate the fluorescent target. The detector mechanism of the measuring instrument would be configured to determine a polarization orientation of fluorescent light output by the fluorescent target in response to the excitation light. The amount of polarization rotation of the fluorescent light, with respect to the polarization plane of the excitation light could also be used to determine time characteristics of the fluorescent target. Details of such a method are provided in U.S. Pat. No. 5,515,864 to Zuckerman, the contents of which are hereby incorporated by reference.

In yet another embodiment of the invention, as shown in FIG. **16**, a calibration layer **70** includes a central region having a fluorescent portion **73** and a portion **74** having known scattering/reflection properties. When a calibration device including a calibration layer as shown in FIG. **16** is mounted on a measuring instrument, light emitted from a light source of the instrument can both scatter/reflect off the portion **74** having known properties, and the light can excite fluorescent emissions from the fluorescent portion **73**. The scattered or reflected light, and fluorescent emissions from the fluorescent portion **73** can be detected by a detector of the measuring instrument and used to calibrate or reference the instrument.

In still another embodiment, as shown in FIG. **17**, a fluorescent portion **73** may be centered within a region **74** having known scattering/reflective properties. Alternatively, the portion having known scattering/reflective properties could be centered in a larger fluorescent portion. When a target layer **70**, as shown in FIG. **17**, is incorporated in a calibration device embodying the invention, both light scattered by the portion **74** and fluorescent light emitted by the fluorescent region **73** can be used in a calibration or reference operation.

The two portion calibration layers **70** shown in FIGS. **16** and **17** allow for a calibration operation to rely on light having different wavelengths. The light reflected from the portion **74** having known optical properties will be at the same wavelength as the light emitted by the measuring instrument. Fluorescent light generated by the fluorescent portion **73** will be at a different wavelength. This type of calibration/reference operation could be particularly useful for measuring instruments that utilize light at more than one wavelength to conduct a measurement operation. This type of calibration/reference operation could also be useful for a device that utilizes both fluorescent light generated by a target object, and light that is scattered or reflected from the target object to conduct a measurement operation.

In still other embodiments of the invention, the target layer **70** may be partially transmissive so that light transmitted through the target layer can be used to perform a calibration or reference operation. For instance, in the embodiment shown in FIG. **5**, the central region could have known transmissive properties so that light transmitted through the central region **74** may be used to perform a calibration or reference operation. The amplitude of the transmitted light at one or more wavelengths could be detected, or the polarization characteristics of the transmitted light could be detected, as described above. Two methods for performing a calibration or reference operation using a transmissive calibration target will now be described with reference to FIGS. **18**, **19**, **20**A and **20**B.

FIG. **18** shows an external light source that can be used to perform a transmissive calibration or reference operation, and to conduct a transmissive measuring operation. The external light source **240** includes a light source **242**, which can be in the form of an incandescent or fluorescent bulb, a light emitting diode, a laser, or any other device capable of generating electromagnetic radiation. An aperture **244** allows light from the light source **242** to escape the device. A slot **246**, or any other type of mechanical attachment mechanism, can be used to mount a sample to be measured in the aperture **244** of the light source **240**.

FIG. **19** shows a measuring instrument **100** being used to conduct a calibration or measurement operation using the external light source **240**. If a calibration operation is to be performed, the light source **242** is turned on, and a calibration or reference device is mounted on the measuring instrument **100**. The calibration device would include a calibration/reference target mounted on a shield holder **110**. The calibration device is then pressed against the aperture **244** of the external light source **240**. Light from the light source **242** passes through the aperture, and a portion of the light also passes through the calibration device. The light transmitted through the calibration device is received by a detector within the measuring instrument **100** and used to conduct a calibration or reference operation. In some embodiments of the device, a clear window **248** may be mounted in the aperture **244**, and the calibration target may be pressed directly against the window **248**.

Once a calibration or reference operation has been successfully performed, the calibration layer of the calibration device would be removed so that the device is ready to conduct a patient or object measurement. Removal of the calibration device could leave a shield holder **110** and an associated infection shield attached to the measuring instrument **100**. An object to be measured may then be mounted on a slide **248** that is inserted into the aperture **244** of the external light source **240**. The shield holder **110**, without the calibration target, would then be pressed against the slide **248**, and the measurement device would be activated to conduct a measurement. Light from the light source **242** would pass through the slide **248**, the sample mounted thereon, and the infection shield and shield holder **110**, and the transmitted light would be detected by a detector of the measuring instrument **100**. The transmitted light would then be used to conduct a measurement operation.

This type of an embodiment could be useful for measuring optical properties or colors of objects capable of being mounted on slides **248** that are inserted into an external light source **240**. In alternate embodiments, the measurement operation could be performed directly on an object without the use of the external light source **240**. In this embodiment, the external light source **240** would be used only to perform a calibration or reference operation with a transmissive calibration target.

In the embodiment shown in FIGS. **20**A and **20**B, a light source of the measuring instrument would be used to conduct a transmissive calibration and/or measuring operation. The measuring instrument **100** would include a means for applying light to a calibration/reference target mounted on the instrument **100**. The means could include a light source inside the instrument **100** which transmits light through an optical fiber to a light head **250**. In alternate embodiments, the light head **250** could include an integral light source. In either event, the light head **250** may be attached to a retractable tether **252** for holding the light head **250** in place on top of the instrument **100** when it is not in use. If an optical fiber is used to conduct light from a source inside the instrument to the light head **250**, the optical fiber could be inside the tether **252**.

With an embodiment like the one shown in FIGS. **20**A and **20**B, a shield holder **110** and an attached transmissive calibration target would be mounted on a nose portion **104** of the measuring instrument **100**. Next, the retractable light head **250** would be pulled out of the device and placed over the transmissive calibration target attached to the shield holder **110**. The device would then be activated so that light is emitted from the light head **250**, is transmitted through the transmissive target, and is detected by a detector of the instrument **100** so that a calibration/reference operation may be performed.

Once a calibration/reference operation has been performed, the light head **250** could then be retracted back into the measuring instrument, and the calibration target would be removed from the shield holder **110**. This would place the instrument in a condition ready for a patient or object measurement. The measurement operation could be conducted such that light emitted from the nose portion **104** of the instrument is reflected/scattered from the target object and is detected by the instrument. Alternatively, the light head **250** could be used to provide light for a measurement operation.

In some of the embodiments described above, a calibration operation has relied on light that is reflected or scattered from, or transmitted through, a portion of a calibration target having known optical properties. This could involve determining an amplitude of the reflected/scattered/transmitted light at one or more wavelengths. In other devices and methods embodying the invention, the radiation output to the calibration target could have a particular polarization orientation. The measuring instrument could then be configured to determine a polarization orientation of the reflected/scattered/transmitted light. Such a method could rely on the relative attenuation of a polarized or depolarized component of reflected/scattered/transmitted light, or an extent of depolarization.

In yet another embodiment of the invention, a plurality of emitter and detector pairs could be arranged in an array on a measuring instrument. During a calibration operation using any of the calibration devices described above, the light output from the emitters could reflect/scatter/transmit through portions of the calibration device and impinge on the respective detectors. If a fluorescent calibration target is used, fluorescent light from the target could impinge on the detectors. After the calibration operation is conducted, the same emitter/detector pairs could be used to interrogate multiple points on a target material or tissue. Such a configuration would allow the measuring instrument to develop an image of the target material or tissue, or an image of reflective/transmissive/fluorescent properties of the target.

In still other embodiments, one or more light sources could illuminate/excite a target material or tissue, and reflected/scattered/transmitted light, or fluorescent light, passing from the target material or tissue could impinge on a detector array configured generate an image of the material or tissue, or an image of the reflective/transmissive/fluorescent properties of the target material or tissue. For instance, a charged coupled device (CCD) could be used as the detector array. The calibration devices described above could be used to calibrate or reference a measuring instrument that utilizes such a detector array.

Many variations could be made to the embodiments described above without departing from the spirit or scope of the present invention. For instance, although each of the embodiments shown in FIGS. **2**–**20**A and **20**B have a shield holder and a calibration/reference target that is generally circular or annular in shape, any other shape could be used without departing from the invention. For instance, the shield holder, infection shield and calibration target could be rectangular, square, or any other shape necessary to conform to the shape of the instrument to which the device is attached.

Also, the calibration layers **70** of the embodiments described above could have any type of optical, transmissive or fluorescent properties used to conduct a calibration or reference operation. As mentioned above, use of the term “calibration target” in the specification and claims is intended to encompass both calibration targets and reference targets. Likewise, use of the term “calibration operation” is intended to encompass both calibration and reference operations.

In any one embodiment of the invention, the calibration layer would have very specific reflective, transmissive and/or fluorescent properties. However, calibration/reference targets embodying the invention might include different types of calibration layers having different reflective/transmissive/fluorescent properties. For instance, colored calibration targets could be provided in a variety of different skin tones. A calibration device embodying the invention could then be selected by a user based on a patient’s skin tone or age, and the selected calibration target could be used to calibrate an instrument.

Also, the reflective/transmissive/fluorescent properties of the target may be selected such that the instrument can be calibrated/referenced at the mean or the median of the expected measurement range. Such a strategy will provide maximum measurement accuracy since any error is at a minimum for measurements closest to the calibration value. Using the example of the patient skin tone described above, the reflectance of the calibration target can be formulated such that its reflectance matches the median reflectance of the patients expected to be measured with the instrument. As an additional example, the fluorescence lifetime and/or quantum yield of a fluorescent target may be selected such that it equals the median lifetime and/or quantum yield of the fluorescing analyte being measured.

Also, although each of the embodiments described above have a user graspable tab attached to the calibration layer, other types of user graspable tab configurations are possible. For instance, instead of being a tab, a cord, a string or a ring of material could be attached to the calibration layer. For instance, in the embodiment shown in FIG. **14**, the user graspable tab **202***a* is a loop of material whose ends are attached to the calibration layer **200**. Each of these items is easy for the finger of a user to grasp and to pull. The invention is intended to include any type of user graspable tab, cord, string, ring, or other device that can be used to remove the calibration layer from the remaining portions of the device.

Furthermore, in the embodiments described above, an infection shield and a calibration target are attached to a shield holder, which in turn is attached to the instrument. Some embodiments of the device may not utilize a shield holder. In these embodiments, the infection shield and/or the calibration target may be directly attached to a measuring instrument. These embodiments may use an adhesive layer or a mechanical attachment device to attach the infection shield and the calibration target to the instrument.

Still further, if the instrument which the device is used with is not used for medical purposes, and infection or cross-contamination is not an issue, a device embodying the invention may simply comprise a calibration layer. The calibration target in FIG. **5** provides an example of such an embodiment. This calibration target could be directly attached to the measuring instrument.

The foregoing embodiments are merely exemplary and are not to be construed as limiting the present invention. The present teaching can be readily applied to other types of apparatus. Many alternatives, modifications, and variations will be apparent to those skilled in the art. In the claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. For example, although a pin and an adhesive layer may not be structural equivalents, in that a pin employs a cylindrical penetrating structure to secure two parts together, whereas an adhesive layer does not penetrate the parts and extends over a greater surface area, in the environment of fastening two parts together, a pin and an adhesive layer may be equivalent structures.

What is claimed is:

1. A method of calibrating a measuring instrument, comprising the steps of:

arranging a fluorescent calibration device on a measuring instrument, wherein the fluorescent calibration device includes a structure that is attachable to the measuring instrument and a fluorescent calibration target that is removably attached to the structure;

conducting a calibration measurement using the fluorescent calibration device; and

removing at least a portion of the fluorescent calibration device from the measuring instrument.

2. The method of claim **1**, wherein the removing step comprises removing the fluorescent calibration target from the structure, and leaving the structure of the fluorescent calibration device attached to the measuring instrument such that radiation can pass through the structure during a subsequent measuring operation.

3. The method of claim **1**, wherein the step of conducting a calibration measurement comprises the steps of:

illuminating the fluorescent calibration target of the calibration device with electromagnetic radiation; and

measuring electromagnetic radiation passing from the fluorescent calibration target to the measuring instrument.

4. The method of claim **3**, wherein the illuminating step comprises illuminating the fluorescent calibration target with electromagnetic radiation having a first wavelength range, wherein the measuring step comprises measuring electromagnetic radiation having a second wavelength range, and wherein the first and second wavelength ranges are not co-extensive.

5. The method of claim **3**, wherein the measuring step comprises measuring fluorescent electromagnetic radiation generated by the fluorescent calibration target.

6. The method of claim **5**, wherein the measuring step further comprises measuring radiation that is scattered or reflected from the fluorescent calibration target.

7. The method of claim 5, wherein the measuring step comprises measuring a time characteristic of the fluorescent electromagnetic radiation.

8. The method of claim 5, wherein the measuring step comprises measuring a polarization characteristic of the fluorescent electromagnetic radiation.

9. The method of claim 3, wherein the measuring step comprises the steps of:

measuring electromagnetic radiation scattered from the fluorescent calibration device; and

measuring fluorescent electromagnetic radiation generated by the fluorescent calibration target.

10. The method of claim 3, wherein the illuminating step comprises illuminating the fluorescent calibration target with a burst of electromagnetic radiation, and wherein the measuring step comprises measuring an amount of time required for fluorescent electromagnetic radiation produced by the fluorescent calibration target in response to the burst of illuminating electromagnetic radiation to decay below a threshold value.

11. The method of claim 1, wherein the step of conducting a calibration measurement comprises the steps of:

illuminating the fluorescent calibration device with amplitude modulated electromagnetic radiation;

measuring electromagnetic radiation passing from the fluorescent calibration device to the measuring instrument; and

determining a phase shift between the illuminating amplitude modulated electromagnetic radiation and the electromagnetic radiation passing from the fluorescent calibration device to the measuring instrument.

12. The method of claim 11, wherein the measuring step comprises measuring fluorescent electromagnetic radiation generated by a fluorescent calibration target of the fluorescent calibration device.

13. The method of claim 11, further comprises a step of determining a demodulation factor, wherein the demodulation factor represents a ratio of amplitudes of the illuminating electromagnetic radiation and the electromagnetic radiation passing from the fluorescent calibration device to the measuring instrument.

14. The method of claim 1, wherein the step of conducting a calibration measurement comprises the steps of:

illuminating the fluorescent calibration device with polarized electromagnetic radiation;

measuring electromagnetic radiation passing from the fluorescent calibration device to the measuring instrument; and

determining a polarization difference between the illuminating electromagnetic radiation and the electromagnetic radiation passing from the fluorescent calibration device to the measuring instrument.

15. A method of calibrating a measuring instrument, comprising the steps of:

placing a transmissive calibration device over an output end of a measuring instrument;

conducting a calibration operation using the transmissive calibration device wherein the measuring instrument measures transmissive properties of the transmissive calibration device during the calibration operation; and

removing at least a portion of the transmissive calibration device from the measuring instrument.

16. The method of claim 15, wherein the removing step comprises leaving a structure of the transmissive calibration device attached to the measuring instrument such that radiation can pass through the structure during a subsequent measuring operation.

17. The method of claim 15, wherein the step of conducting a calibration operation comprises the steps of:

illuminating a portion of the transmissive calibration device with electromagnetic radiation; and

measuring electromagnetic radiation passing through the transmissive calibration device.

18. The method of claim 17, wherein the illuminating step comprises illuminating a portion of the transmissive calibration device with electromagnetic radiation generated by the measuring instrument.

19. The method of claim 17, wherein the illuminating step comprises illuminating a portion of the transmissive calibration device with electromagnetic radiation generated by a source external to the measuring instrument.

20. A method of calibrating a measuring instrument having a detector, comprising the steps of:

arranging a fluorescent calibration device on the measuring instrument;

conducting a calibration operation, wherein polarized fluorescent radiation passes from the fluorescent calibration device to the detector of the measuring instrument; and

removing at least a portion of the calibration device from the measuring instrument.

21. The method of claim 20, wherein the removing step comprises leaving a structure of the calibration device attached to the measuring instrument such that radiation can pass through the structure during a subsequent measuring operation.

22. The method of claim 20, wherein the step of conducting a calibration operation comprises measuring a polarization characteristic of the polarized fluorescent radiation passing from the fluorescent calibration device to the detector.

23. The method of claim 20, wherein the step of conducting a calibration operation comprises illuminating the fluorescent calibration device with polarized excitation radiation.

24. The method of claim 23, wherein the step of conducting a calibration operation comprises determining a polarization difference between the polarized excitation radiation and the polarized fluorescent radiation passing from the fluorescent calibration device to the detector.

25. A method of conducting a calibrated measurement on a target object with a measuring instrument having an imaging detector array, comprising the steps of:

arranging a calibration device on the measuring instrument;

conducting a calibration operation, wherein radiation passes from the calibration device to the detector array of the measuring instrument;

removing a portion of the calibration device from the measuring instrument while leaving a structure of the calibration device attached to the measuring instrument; and

conducting a measurement operation by obtaining an image of the target object based on radiation that passes from the target object, through the structure and to the detector array.

26. The method of claim 25, wherein the measurement operation comprises obtaining an image of at least one of scattering characteristics, fluorescent characteristics and transmissive characteristics of the target object.

27. A calibration device, comprising:

a structure having an opening through which radiation can pass; and

a removable calibration target arranged on said opening, wherein the removable calibration target includes a fluorescent portion.

28. The calibration device of claim 27, wherein the structure comprises an adhesive portion configured to adhere the removable calibration target to a measuring instrument.

29. The calibration device of claim 27, wherein the removable calibration target includes at least one reduced strength portion configured such that the removable calibration target will tear or separate along the at least one reduced strength portion when the removable calibration target is removed from other portions of the calibration device.

30. The calibration device of claim 29, wherein the at least one reduced strength portion comprises at least one of a perforation, a crease and a slit.

31. The calibration device of claim 27, further comprising a cutter for causing the calibration target to tear or separate in a predetermined manner when the calibration target is removed from other portions of the calibration device.

32. The calibration device of claim 27, wherein the calibration target includes a user graspable tab that aids a user in removing the calibration target from the structure.

33. The calibration target of claim 27, further comprising a shield layer attached to the structure.

34. The calibration target of claim 33, wherein the shield layer is arranged on the structure such that when the calibration target is removed from the structure, the shield layer remains attached to the structure.

35. A calibration device, comprising:

a structure having an opening through which radiation can pass; and

a removable calibration target arranged on said opening, wherein the removable calibration target includes a transmissive portion configured to allow a measurement instrument conduct a calibration operation based on radiation transmitted through the transmissive portion.

36. The calibration device of claim 35, wherein the structure comprises an adhesive portion configured to adhere the removable calibration target to a measuring instrument.

37. The calibration device of claim 35, wherein the removable calibration target includes at least one reduced strength portion configured such that the removable calibration target will tear or separate along the at least one reduced strength portion when the removable calibration target is removed from other portions of the calibration device.

38. The calibration device of claim 37, wherein the at least one reduced strength portion comprises at least one of a perforation, a crease and a slit.

39. The calibration device of claim 35, further comprising a cutter for causing the calibration target to tear or separate in a predetermined manner when the calibration target is removed from other portions of the calibration device.

40. The calibration device of claim 35, wherein the calibration target includes a user graspable tab that aids a user in removing the calibration target from the structure.

41. The calibration target of claim 35, further comprising a shield layer attached to the structure.

42. The calibration target of claim 41, wherein the shield layer is arranged on the structure such that when the calibration target is removed from the structure, the shield layer remains attached to the structure.

43. A calibration device, comprising:

a calibration target holder configured to be arranged on a measuring instrument and to block external light from reaching a detector of a measuring instrument when the holder is arranged on the measuring instrument; and

a calibration target having known optical properties that is mountable on the holder.

44. The calibration device of claim 43, wherein the calibration target is removably mountable on the calibration holder.

45. The calibration device of claim 43, wherein the calibration target includes:

a shield layer; and

a target layer having known optical properties.

46. The calibration device of claim 45, wherein the calibration device is configured such that when the calibration device is arranged on a measuring instrument, and the target layer is removed, the shield layer remains attached to the measuring instrument.

47. A measuring system for measuring characteristics of a target object, comprising:

a housing;

a calibration device that includes a structure and a removable calibration target arranged on the structure, wherein the calibration device is removably attachable to the housing, and wherein the calibration device is configured such that the calibration target can be removed from the structure while the structure remains attached to the housing; and

a detector array mounted on the housing and configured to detect an image of a target object.

48. The measuring system of claim 47, wherein the system is configured such that during a measurement operation, radiation passes from a target object, through the structure of the calibration device, and to the detector array.

49. The measuring system of claim 47, wherein the system is configured to obtain an image of at least one of scattering characteristics, transmissive characteristics and fluorescent characteristics of a target object.

50. The measuring system of claim 47, wherein the system is configured to conduct a calibration operation using radiation passing from the calibration target to the detector array.

51. A method of calibrating a measuring instrument, comprising the steps of:

arranging a calibration device on a measuring instrument;

illuminating the calibration device with polarized radiation;

detecting a polarization characteristic of light that is scattered or reflected from the calibration device.

52. The method of claim 51, wherein the arranging step comprises arranging a calibration device including a structure and a calibration target on the measuring instrument, and wherein the method further comprises the step of removing the calibration target from the structure while the structure remains attached to the measuring instrument such that radiation can pass through the structure during a subsequent measurement operation.

53. A method of calibrating a measuring instrument, comprising the steps of:

arranging a calibration device on a measuring instrument, the calibration device including a structure and a calibration target that is removably attached to the structure;

illuminating the calibration device with polarized radiation;

detecting a polarization characteristic of light that is scattered from or transmitted through the calibration device; and removing the calibration target from the structure of the calibration device while the structure remains attached to the measuring instrument such that radiation can pass through the structure during a subsequent measurement operation.

54. A method of calibrating a measuring instrument, comprising the steps of:

arranging a fluorescent calibration target on a measuring instrument;

illuminating the fluorescent calibration target with a burst of electromagnetic radiation; and

detecting an amount of time required for fluorescent electromagnetic radiation produced by the fluorescent calibration target in response to the burst of electromagnetic radiation to decay below a threshold value.

55. A method of calibrating a measuring instrument, comprising the steps of:

arranging a fluorescent calibration target on a measuring instrument;

illuminating the fluorescent calibration target with amplitude modulated electromagnetic radiation;

measuring electromagnetic radiation passing from the fluorescent calibration target to the measuring instrument; and

determining a phase shift between the illuminating amplitude modulated electromagnetic radiation and the electromagnetic radiation passing from the fluorescent calibration target to the measuring instrument.

56. The method of claim **55**, further comprising a step of determining a demodulation factor, wherein the demodulation factor represents a ratio of amplitudes of the illuminating electromagnetic radiation and the electromagnetic radiation passing from the fluorescent calibration target to the measuring instrument.

57. A method of calibrating a measuring instrument, comprising the steps of:

placing a removable calibration target in a light blocking device;

placing the light blocking device, with the removable calibration target, over an output end of a measuring instrument;

conducting a calibration operation wherein electromagnetic radiation output from the measuring instrument is scattered from the removable calibration target back to a detector of the measuring instrument;

removing the light blocking device from the measuring instrument; and

removing the removable calibration target from the light blocking device.

58. The method of claim **57**, further comprising the steps of:

placing the light blocking device, without the removable calibration target, over the output end of the measuring instrument; and

conducting a calibration operation wherein electromagnetic radiation output from the measuring instrument is scattered from the light blocking device back to a detector of the measuring instrument.

59. The method of claim **58**, further comprising the steps of:

placing a shield layer into the light blocking device after all calibration steps have been performed;

placing the light blocking device over the output end of the measuring instrument; and

removing the light blocking device from the measuring instrument while leaving the shield layer attached to the output end of the measuring instrument.

60. The method of claim **59**, further comprising a step of removing a release layer from the shield layer after the shield layer has been placed into the light blocking device to expose an adhesive on the shield layer, and wherein the step of placing the light blocking device over the output end of the measuring instrument causes the shield layer to adhere to the output end of the measuring instrument.

61. The method of claim **57**, wherein the step of removing the light blocking device from the measuring instrument leaves a shield layer of the removable calibration target attached to the output end of the measuring instrument.

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