

SYSTEMS AND METHODS FOR CONTROLLING LASER TREATMENTS USING REFLECTED INTENSITY SIGNALS**RELATED APPLICATIONS**

The present application claims priority to U.S. Provisional Application Serial No. 63/615,994, titled "SYSTEMS AND METHODS FOR CONTROLLING LASER TREATMENTS USING REFLECTED INTENSITY SIGNALS," filed on December 29, 2023, the content of which is hereby incorporated by reference in its entirety.

BACKGROUND

Directed energy (e.g., electromagnetic including optical, mechanical, acoustic including ultrasound, etc.) is increasingly a method of choice for treating various pathological conditions of the human body. One type of pathological condition that uses directed energy for treatment is urinary stone disease, including kidney and bladder stone, which is estimated to affect 12% of the world population. While most patients with kidney stone disease can pass stones naturally, severe cases of kidney stone disease (e.g., in which the patient cannot pass the kidney stone) require medical intervention including use of directed energy. If severe cases of kidney stone disease are left untreated, extreme pain, nausea, vomiting, infection, blockage of urine flow, and loss of kidney function can soon follow.

Laser lithotripsy is one method of using directed energy to treat urinary stones, which uses directed laser energy, delivered via a fiber, to target the stone. Laser lithotripsy can be advantageous to other forms of directed energy (e.g., ultrasound) because laser light, during laser lithotripsy, can be delivered by a fiber, which is flexible enough to curve and traverse different hard-to-reach structures. In addition, the small outer diameter of the fiber allows its insertion into the working channels of most surgical instruments, including practically all scopes (rigid, semi-rigid, and flexible) used in urology. During laser lithotripsy, directed light energy from the laser is delivered to the stone, which breaks the stone into either finer particles that can be passed naturally, or bigger fragments that can be removed using auxiliary tools (e.g., baskets). Alternatively, the bigger fragments can be aspirated through a working channel of a scope (e.g., an endoscope).

Typically, during a laser lithotripsy procedure a practitioner (e.g., a doctor or surgeon) identifies a stone target by using a built-in-endoscope camera to receive images of the internal area of the patient. However, because the camera is the only device providing feedback to the practitioner, issues with the camera or during the image acquisition process (e.g., temporary obstruction of the camera's surgical field of view, camera's electronics malfunction, and the like) and variations in surgeons' reaction time can lead to inaccuracies, inefficiencies, errors, treatment time protraction/prolongation etc., in the lithotripsy procedure. Thus, it would be desirable to have improved systems and methods for controlling medical treatment processes.

SUMMARY OF THE DISCLOSURE

Aspects and non-limiting examples are directed to methods and systems for performing and controlling surgical laser treatments.

In accordance with one embodiment, there is provided a method for controlling a surgical laser system that includes providing a surgical fiber configured to receive light reflected from a target in a surgical treatment area and deliver laser radiation from a treatment laser source to a treatment target, and providing a computing device configured to couple with at least two photodetectors, each photodetector configured to detect an intensity of reflected light from the target in a different selected wavelength band, the computing device further configured to: receive the reflected light intensity in at least two selected wavelength bands, generate optical data corresponding to the reflected light intensity, and identify the target as the treatment target or a non-treatment target based at least in part on the optical data and a predetermined calibration based on at least one known target.

In one example, the method further includes performing the predetermined calibration.

In a further example, performing the predetermined calibration includes positioning a distal end of the surgical fiber in quasi-contact with at least one known target. In a further example, the at least one known target is stone, tissue, a surgical component, or a surgical treatment area medium.

In a further example, at least one of generating the optical data and performing the predetermined calibration includes determining at least one ratio of a reflected light intensity

of one selected wavelength band to a reflected light intensity of a different selected wavelength band.

In a further example, performing the predetermined calibration further comprises: obtaining multiple reflected light intensity values from each known target of the at least one known target, and establishing a threshold ratio value based at least in part on the multiple reflected light intensity values from each known target. In a further example, the method further includes determining a ratio value associated with a predetermined percentile for each known target using the multiple reflected light intensity values, and establishing the threshold ratio value based on the ratio value associated with the predetermined percentile and a predetermined scaling factor. In a further example, the predetermined scaling factor is based at least in part on historic reflected light intensity values. In a further example, the predetermined percentile is based at least in part on historic reflected light intensity values from at least two known targets. In a further example, the predetermined percentile is in a range selected from 50th to 97th. In a further example, the predetermined percentile is the 80th percentile.

In one example, the method further includes generating at least one frequency distribution of values for each ratio of the at least one ratio, and determining the ratio value associated with the predetermined percentile for each known target based on the frequency distribution.

In one example, generating the optical data includes determining the at least one ratio for the target in the surgical treatment area, and identifying the target comprises: comparing a ratio value of the at least one ratio for the target in the surgical treatment area to the threshold ratio value, and determining whether the target in the surgical treatment area is a treatment target based on the comparison. In a further example, in response to a determination that the target in the surgical treatment area is a treatment target, identifying the target as a treatment target, or in response to a determination that the target in the surgical treatment area is not a treatment target, identifying the target as a non-treatment target.

In one example, determining whether the target in the surgical treatment area is a treatment target is performed in between every N laser pulses emitted by the treatment laser source, wherein N is an integer between 1 and 1000.

In one example, determining whether the target in the surgical treatment area is a treatment target is performed after modifying a laser operating parameter of the treatment laser source.

In one example, establishing the threshold ratio value further comprises defining a multidimensional decision space having n decision options based on M ratios, where M is an integer between 1 and 100. In a further example, the method further includes defining multidimensional threshold separation lines between the n decision options in the multidimensional decision space for discrimination between each of the M ratios.

In one example, the method further includes determining a difference value between a first ratio value associated with the predetermined percentile for a first known target and a second ratio value associated with the predetermined percentile for a second known target, comparing the difference value to a threshold difference value, and in response to a determination that the difference value meets or exceeds the threshold difference value, establishing the threshold ratio value based on the first ratio value and the second ratio value. In a further example, generating at least one frequency distribution of values for each ratio of the at least one ratio, and determining the ratio value associated with the predetermined percentile for each known target based on the frequency distribution. In a further example, the method further includes determining the threshold difference value, wherein determining the threshold difference value comprises: comparing a first difference value associated with a frequency distribution generated using a first ratio of the at least one ratio to a second difference value associated with a frequency distribution generated using a second ratio of the at least one ratio, and determining whether the first difference value or the second difference value is larger, and in response to a determination that the first difference value is larger than the second difference value, selecting the first difference value as the threshold difference value, or in response to a determination that the second difference value is larger than the first difference value, selecting the second difference value as the threshold difference value. In another example, the method further includes assigning a weighting factor to the ratio associated with the largest difference value. In another example, the threshold ratio value is based on an average of the first and second ratio values.

In one example, the computing device is further configured to generate a control signal for controlling operation of a treatment laser based on the identification of the target.

In a further example, the control signal includes activation, de-activation or an operating parameter setting for the treatment laser.

In one example, the computing device is further configured to generate an audio, visual, or tactile signal to an operator based on the identification of the target.

In one example, the treatment target is a stone and the non-treatment target is tissue or a surgical component or a surgical treatment area medium. In a further example, the method further includes positioning the distal end of the surgical fiber in quasi-contact with the stone, activating the treatment laser source so as to deliver laser radiation through the surgical fiber, and ablating at least a portion of the stone using the laser radiation.

In one example, the computing device is configured to couple with three photodetectors and the three different selected wavelength bands are selected from a group consisting of: about 400-410 nm, about 440-480 nm, about 460-480 nm, about 510-530 nm, about 540-560 nm, about 550-570 nm, about 570-580 nm, about 580-600 nm, about 600-620 nm, about 690-710 nm, about 740-760 nm, about 790-810 nm, about 920-940 nm, about 970-990 nm, and about 1150-1350 nm.

In one example, the computing device is further configured to identify the target as a treatment target or a non-treatment target based at least in part on a comparison against stored data from previously recorded reflected intensity values.

In one example, the computing device is further configured to identify the target as a treatment target or a non-treatment target based at least in part on a machine learning model.

In one example, the computing device is further configured to identify the target as a treatment target or a non-treatment target based at least in part on a mathematical algorithm derived at least in part from at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band.

In accordance with another exemplary embodiment, there is provided a surgical laser system that includes a surgical fiber configured to receive light reflected by a target in a surgical treatment area and deliver laser radiation from a treatment laser source to a treatment target, and a computing device configured to couple with at least two photodetectors, each photodetector configured to detect an intensity of reflected light from the target in a different selected wavelength band, and configured to: receive the reflected light intensity in at least

two selected wavelength bands, generate optical data corresponding to the reflected light intensity, and identify the target as the treatment target or a non-treatment target based at least in part on the optical data and a predetermined calibration based on at least one known target.

In one example, the surgical fiber is configured to deliver light from a source of light to the surgical treatment area.

In one example, the at least one known target is stone, tissue, a surgical components, or a surgical treatment area medium.

In one example, the computing device is further configured to perform at least a portion of the predetermined calibration. In a further example, at least one of generating the optical data and performing the predetermined calibration includes determining at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band. In a further example, performing the predetermined calibration further comprises: receiving multiple reflected light intensity values from each known target of the at least one known target, and establishing a threshold ratio value based at least in part on the multiple reflected light intensity values from each known target. In a further example, the computing device is further configured to: determine a ratio value associated with a predetermined percentile for each known target using the multiple reflected light intensity values, and establish a threshold ratio value based on the ratio value associated with the predetermined percentile and a predetermined scaling factor. In one example, the predetermined percentile is based at least in part on historic reflected light intensity values from at least two known targets.

In one example, the computing device is further configured to: generate at least one frequency distribution of values for each ratio of the at least one ratio, and determine the ratio value associated with the predetermined percentile for each known target based on the frequency distribution.

In one example, generating the optical data includes determining the at least one ratio for the target in the surgical treatment area, and identifying the target comprises: comparing a ratio value of the at least one ratio for the target in the surgical treatment area to the threshold ratio value, and determining whether the target in the surgical treatment area is a treatment target based on the comparison. In a further example, the computing device is configured

such that: in response to a determination that the target in the surgical treatment area is a treatment target, identifying the target as a treatment target, or in response to a determination that the target in the surgical treatment area is not a treatment target, identifying the target as a non-treatment target. In a further example, the computing device is configured to determine whether the target in the surgical treatment area is a treatment target is performed in between every N pulses emitted by the treatment laser source, wherein N is an integer between 1 and 1000.

In one example, the computing device is further configured to: determine a difference value between a first ratio value associated with the predetermined percentile for a first known target and a second ratio value associated with the predetermined percentile for a second known target, compare the difference value to a threshold difference value, and in response to a determination that the difference value meets or exceeds the threshold difference value, establish the threshold ratio value based on the first ratio value and the second ratio value. In a further example, the computing device is further configured to: generate at least one frequency distribution of values for each ratio of the at least one ratio, and determine the ratio value associated with the predetermined percentile for each known target based on the frequency distribution. In a further example, the computing device is further configured to determine the threshold difference value, and determining the threshold difference value comprises: comparing a first difference value associated with a frequency distribution generated using a first ratio of the at least one ratio to a second difference value associated with a frequency distribution generated using a second ratio of the at least one ratio, and determining whether the first difference value or the second difference value is larger, and in response to a determination that the first difference value is larger than the second difference value, selecting the first difference value as the threshold difference value, or in response to a determination that the second difference value is larger than the first difference value, selecting the second difference value as the threshold difference value.

In one example, the light reflected from the target is broadband light and the different selected wavelength bands include wavelength bands selected from the list consisting of: about 400-410 nm, about 440-480 nm, about 460-480 nm, about 510-530 nm, about 540-560 nm, about 550-570 nm, about 570-580 nm, about 580-600 nm, about 600-620 nm, about 690-

710 nm, about 740-760 nm, about 790-810 nm, about 920-940 nm, about 970-990 nm, and about 1150-1350 nm.

In one example, the surgical system further includes a treatment laser, and the computing device is further configured to generate a control signal for controlling operation of the treatment laser based on the identification of the target.

In one example, the treatment target is a stone and the non-treatment target is tissue or a surgical component or a surgical treatment area medium.

In one example, the computing device is further configured to generate an audio, visual, or tactile signal to an operator based on the identification of the target.

In one example, the computing device is further configured to identify the target as a treatment target or a non-treatment target based at least in part on a mathematical algorithm derived at least in part from at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band.

In accordance with another exemplary embodiment, there is provided a method for controlling a surgical laser system that includes providing a surgical fiber configured to receive light reflected from a target in a surgical treatment area, and providing a computing device configured to couple with at least two photodetectors, each photodetector configured to detect an intensity of reflected light from the target in a different selected wavelength band, the computing device further configured to: receive the reflected light intensity in at least two selected wavelength bands, generate optical data corresponding to the reflected light intensity, and identify the target as a treatment target or a non-treatment target based at least in part on the optical data and a predetermined calibration based on at least two known targets.

In one example, the method further includes performing the predetermined calibration. In a further example, at least one of generating the optical data and performing the calibration includes determining at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band. In a further example, performing the predetermined calibration further comprises: obtaining multiple reflected light intensity values from each known target of the at least two known targets, and establishing a threshold ratio value based at least in part on the multiple reflected light intensity values from each known target. In a further example, the method

further includes determining a ratio value associated with a predetermined percentile for each known target based on the multiple reflected light intensity values from each known target, determining a difference value between a first ratio value associated with the predetermined percentile for a first known target and a second ratio value associated with the predetermined percentile for a second known target, comparing the difference value to a threshold difference value, and in response to a determination that the difference value meets or exceeds the threshold difference value, establishing the threshold ratio value based on the first ratio value and the second ratio value. In a further example, the method further includes generating at least one frequency distribution of values for each ratio of the at least one ratio, and determining the ratio value associated with the predetermined percentile for each known target based on the frequency distribution. In a further example, the method further includes determining the threshold difference value, wherein determining the threshold difference value comprises: comparing a first difference value associated with a frequency distribution generated using a first ratio of the at least one ratio to a second difference value associated with a frequency distribution generated using a second ratio of the at least one ratio, and determining whether the first difference value or the second difference value is larger, and in response to a determination that the first difference value is larger than the second difference value, selecting the first difference value as the threshold difference value, or in response to a determination that the second difference value is larger than the first difference value, selecting the second difference value as the threshold difference value. In one example, the method further includes comprising assigning a weighting factor to the ratio associated with the largest difference value. In another example, the threshold ratio value is based on an average of the first and second ratio values.

In one example, generating the optical data includes determining the at least one ratio for the target in the surgical treatment area, and identifying the target comprises: comparing a ratio value of the at least one ratio value for the target in the surgical treatment area to the threshold ratio value, and associating the target in the surgical treatment area with a known target of the at least two known targets based on the comparison. In one example, the method further includes determining whether the known target is a treatment target, and in response to a determination that the known target is a treatment target, identifying the target

as a treatment target, or in response to a determination that the known target is not a treatment target, identifying the target as a non-treatment target.

In accordance with another exemplary embodiment, a surgical laser system is provided that includes a surgical fiber configured to receive light reflected by a target in a surgical treatment area, and a computing device configured to couple with at least two photodetectors, each photodetector configured to detect an intensity of reflected light from the target in a difference selected wavelength band, and configured to: receive the reflected light intensity in at least two selected wavelength bands, generate optical data corresponding to the reflected light intensity, and identify the target as a treatment target or a non-treatment target based at least in part on the optical data and a predetermined calibration based on at least two known targets.

In one example, the computing device is further configured to perform at least a portion of the calibration. In a further example, the computing device is configured such that at least one of generating the optical data and performing the calibration includes determining at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band. In a further example, the computing device is configured such that performing the predetermined calibration further comprises: obtaining multiple reflected light intensity values from each known target of the at least two known targets, and establishing a threshold ratio value based at least in part on the multiple reflected light intensity values from each known target. In a further example the computing device is further configured to determine a ratio value associated with a predetermined percentile for each known target based on the multiple reflected light intensity values from each known target, determine a difference value between a first ratio value associated with the predetermined percentile for a first known target and a second ratio value associated with the predetermined percentile for a second known target, compare the difference value to a threshold difference value, and in response to a determination that the difference value meets or exceeds the threshold difference value, establish the threshold ratio value based on the first ratio value and the second ratio value. In a further example, the computing device is further configured to generate at least one frequency distribution of values for each ratio of the at least one ratio, and determine the ratio value associated with

the predetermined percentile for each known target based on the frequency distribution. In a further example, the computing device is further configured to determine the threshold difference value, and determining the threshold difference value comprises: comparing a first difference value associated with a frequency distribution generated using a first ratio of the at least one ratio to a second difference value associated with a frequency distribution generated using a second ratio of the at least one ratio, and determining whether the first difference value or the second difference value is larger, and in response to a determination that the first difference value is larger than the second difference value, selecting the first difference value as the threshold difference value, or in response to a determination that the second difference value is larger than the first difference value, selecting the second difference value as the threshold difference value.

In one example, generating the optical data includes determining the at least one ratio for the target in the surgical treatment area, and identifying the target comprises: comparing a ratio value of the at least one ratio for the target in the surgical treatment area to the threshold ratio value, and associating the target in the surgical treatment area with a known target of the at least two known targets based on the comparison.

In one example, the computing device is further configured to determine whether the known target is a treatment target, and in response to a determination that the known target is a treatment target, identifying the target as a treatment target, or in response to a determination that the known target is not a treatment target, identifying the target as a non-treatment target.

Still other aspects, non-limiting examples, and advantages of these example aspects and non-limiting examples, are discussed in detail below. Moreover, it is to be understood that both the foregoing information and the following detailed description are merely illustrative examples of various aspects and non-limiting examples, and are intended to provide an overview or framework for understanding the nature and character of the claimed aspects and non-limiting examples. Non-limiting examples disclosed herein may be combined with other non-limiting examples, and references to “an non-limiting example,” “an example,” “some non-limiting examples,” “some examples,” “an alternate non-limiting example,” “various non-limiting examples,” “one non-limiting example,” “at least one non-limiting example,” “this and other non-limiting examples,” “certain non-limiting examples,”

or the like are not necessarily mutually exclusive and are intended to indicate that a particular feature, structure, or characteristic described may be included in at least one non-limiting example. The appearances of such terms herein are not necessarily all referring to the same non-limiting example.

The foregoing and other aspects and advantages of the present disclosure will appear from the following description. In the description, reference is made to the accompanying drawings that form a part hereof, and in which there is shown by way of illustration one or more exemplary versions. These versions do not necessarily represent the full scope of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are provided to help illustrate various features of non-limiting examples of the disclosure, and are not intended to limit the scope of the disclosure or exclude alternative implementations.

FIG. 1 is a schematic illustration of a non-limiting example of a smart laser system in accordance with aspects of the present disclosure.

FIG. 2 is a schematic illustration of an integrated laser-surgical system with the smart laser system of FIG. 1 being implemented in a surgical environment.

FIG. 3 is a schematic illustration of the optical adapter of FIG. 2.

FIG. 4 is a schematic illustration of the non-limiting example of the smart laser system of FIG. 1, further illustrating additional or optional components of the system.

FIG. 5 is a schematic illustration of another laser system. FIG. 5 also shows schematic representation of an optical adapter in accordance with aspects of the disclosure.

FIG. 6 is a cross-sectional view of the multicore fiber, and light(s) sources, light detector(s), that interact therewith.

FIG. 7 is a schematic of another example of a laser system.

FIG. 8A is a flowchart of a process for determining that treatment target is a target material or is tissue.

FIG. 8B is a graph showing one example of an optical data profile for use in a laser treatment in accordance with the present disclosure.

FIG. 9 is a graph showing examples of reflection spectrum of LED for different treatment targets normalized to maximal level in accordance with aspects of the disclosure.

FIG. 10 is a graph showing examples of spectrums LED light reflected spectrum of LED non-normalized to spectra of LED for different targets in accordance with aspects of the disclosure.

FIG. 11 is a table of total (integrated) value of reflected light of LED in specific spectral ranges in signal for different targets in accordance with aspects of the disclosure.

FIG. 12 is a graph showing examples of spectrum of ratio of stone/tissue for different treatment targets in accordance with aspects of the disclosure.

FIG. 13 is a flowchart of a process for determining a distance between a distal end of a fiber and a treatment target.

FIG. 14 is a further flowchart to FIG. 13 of a process for determining a distance between a distal end of a fiber and a treatment target.

FIG. 15 is a schematic of a calibration routine in accordance with aspects of the disclosure.

The upper portion of FIG. 15 is a schematic of a calibration routine with pulsed probing or pilot beam source in accordance with aspects of the disclosure. The lower portion of FIG. 15 is a schematic of a calibration routine with continuous wave probing source or pilot beam in accordance with aspects of the disclosure.

FIG. 16 is a graph showing a relationship between a contact coefficient value and a contact distance between the tip of the fiber and a target in accordance with aspects of the disclosure.

FIG. 17 is a graph showing a relationship between the derivative of a contact coefficient and a contact distance between the tip of the fiber and a target in accordance with aspects of the disclosure.

FIG. 18 is a graph showing the relationship between a contact coefficient and different types of stone and soft tissue material in accordance with aspects of the disclosure.

FIG. 19 is another example of a functional schematic of another laser system.

FIG. 20 is a schematic illustration of a non-limiting example of a smart laser system in accordance with aspects of the present disclosure.

FIG. 21a is a flowchart of one example for a process of an in-patient calibration sequence in accordance with aspects of the disclosure.

FIG. 21b is a flowchart of one example of a lithotripsy procedure in accordance with aspects of the disclosure.

FIGS. 22a and 22b are histograms of two different examples of stone and soft tissue distinction in accordance with aspects of the disclosure.

FIG. 23 is a schematic of a time diagram of the sensor operation in accordance with aspects of the disclosure.

FIG. 24 is a schematic of one example of a two-dimensional decision space using two pairs of selected wavelengths in accordance with aspects of the disclosure.

FIG. 25 is a schematic of two histograms collected during calibration for two ratios in accordance with aspects of the disclosure.

FIG. 26 is a schematic explaining calculations used to determine variables using two ratios in accordance with aspects of the disclosure.

FIG. 27 is a table showing six example clinical cases performed on patients in accordance with aspects of the disclosure.

FIGS. 28a and 28b are graphs showing a relationship between two different ratios within the context of a mathematical algorithm, which in this example is a linear curve, in accordance with aspects of the disclosure.

FIGS. 29a and 29b are graphs showing two more examples of plotted ratios and their linear relationship in accordance with aspects of the disclosure.

DETAILED DESCRIPTION OF THE PRESENT DISCLOSURE

As described above, there are a variety of medical procedures or treatments that utilize lasers or photomedicine. One non-limiting example of a medical treatment is the optical or laser treatment of a target material using an optical fiber that is a surgical optical fiber. A target material may, in one non-limiting example, include a stone or calculus, or other material. The stone or calculus may be located in a bladder (e.g., often referred to as a bladder stone), located in the kidney (e.g., often be referred to as a kidney stone), located elsewhere in the renal or urinary system (e.g., referred to a urinary stone, a renal stone, or other stone), or may be located elsewhere. Additionally or alternatively, the target material may not be a stone or calculus or may not be associated with the renal or urinary system, but may be a material located elsewhere in the body or in other systems in the body. Examples

of other relevant laser procedures include treatments of various urinary system pathologies such as benign prostate hyperplasia (BPH), bladder/prostate cancers, ureter strictures etc. In these procedures, laser energy is used for tissue ablation/vaporization, incision, coagulation and hemostasis. Furthermore, essentially equivalent procedures are used in other areas of surgery, such as, e.g., gastroenterology and laryngology.

Regardless of the particular clinical application or target material, it can be difficult for a medical practitioner to perform a medical procedure on a target material within a patient. For example, the field of view (“FOV”) of the camera may only be clear right before laser pulses are used on the target material, and thus the laser pulses may obscure the FOV of the camera (e.g., the laser pulses undesirably interact with the imaging sensor of the camera, thereby obstructing the clear representation of features in the image including the laser beam relative to the target material). Thus, only utilizing imaging data from the camera of the scope may result in non-ideal images of the surgical field, which can have spatial and temporal resolution limitations. In addition, even assuming that the imaging data is completely clear, extensive practitioner skill, capability, and experience is required for conducting a safe and efficient treatment (e.g., the practitioner reacting to changing conditions during the treatment).

As another example, the interaction between the light from the laser and the target material can make it difficult to ensure that the laser light is actually being directed at the target material (and not healthy tissue) during all processes of the procedure. An ablation procedure via laser lithotripsy can be characterized by multiple processes including (1) the formation of water vapor bubbles (and a vapor channel) in front of the distal end of the fiber, (2) the overheating of water in the operational area due to absorption of laser energy, (3) the formation of craters on the target material (along with retropulsion impact) with eventual fragmentation and dusting of the target material (e.g., the stone).

During each of these processes stone fragments and bubbles (including water vapor) can track in all directions, which scatters the illumination and obstructs or otherwise obscures the view of the treatment area. In fact, as the procedure naturally progresses, the camera’s FOV can become more and more clogged (e.g., polluted) and eventually it becomes very difficult to discern the target within the images from the camera. In these moments, some practitioners see two options. First, the practitioner can take a more liberal approach to

treatment and direct the laser at targets believed to be the target material (or a particle of the target material). However, because the practitioner's "view" is obscured (e.g., the FOV of the camera is significantly obscured), the risk of collateral damage to soft tissue (e.g., inadvertently directing laser light at non-treatment targets including healthy tissue) can increase significantly, and the risk of breaking the fiber can also increase significantly (e.g., due to mechanical pressure to a stone). Second, the practitioner can take a more conservative approach to treatment, which can involve the practitioner stopping firing, decreasing the laser power, temporarily increasing the irrigation fluid flow (e.g., for purposes of clearing the camera's FOV), and the like. However, unwanted results of this conservative approach can include prolonging the treatment time, prolonging the anesthesia time (which can be crucial in some cases), and limiting the practitioner's ability to finish treatment in one session thereby significantly increasing the cost of treatment (e.g., requiring multiple treatment sessions). Regardless of the treatment approach, major complications with soft tissue damage (even though this is quite rare and arises in just less than 1% of the interventions) still occurs and can be quite serious. In fact, the most severe cases can lead to perforation of the kidney or ureter wall, eventually requiring unwanted urgent kidney or ureter surgery.

In some non-limiting examples, a laser system (e.g., a computing device of the laser system) can determine a distance between a treatment target or target material (e.g., a kidney stone), and act accordingly based on the determined distance (e.g., changing the treatment laser parameters such as CW power, pulse peak power, pulse shape and pulsewidth, interval between pulses, pulse frequency and average power, stopping the laser light altogether, informing the operator about condition detected and the like). In this way, the targeting of the laser light to the target material can be made more efficient. For example, when the surgical optical fiber is not quite in contact with the target material and while the laser fires pulses, the ablation efficiency is lowered because more laser energy is spent on heating the water and this decreases the laser fluency (power density) on the treatment target. In other words, the laser light is less focused on a specific location on the target material already having the liquid water vaporized off, and is more distributed around areas surrounding the specific location, which includes liquid water thereby using the laser light to heat the water (rather than being directed at and fracturing the target material).

As another example, the formation of bubbles during the treatment process can push the stone further away from the fiber tip (e.g., termed retropulsion), which can inadvertently (and undesirably) increase the distance between the distal end of the fiber and the target material thereby causing inefficiencies in treatment. Regardless of the cause of undesirable changes in distances (or non-ideal distances), determining a distance (including ensuring a predetermined distance) between tissue and the distal end of the fiber can increase treatment efficiencies (and allow the laser system or the practitioner to act accordingly).

In some non-limiting examples, a laser system can distinguish between different types of stone, and can distinguish between stone and tissue (e.g., soft tissue). In this way, the laser system can determine if the treatment target is actually being targeted by the laser light, and can determine particular laser operation parameters that are tailored to the treatment target (e.g., different treatment targets can necessitate different laser operation parameters). For example, if the treatment target is stone, and the laser system determines that reflected light indicates tissue rather than stone, then the laser system (or a practitioner controlling the laser system) can act accordingly (e.g., turn off the laser, decrease the power of the laser, etc.). Alternatively, if the treatment target is stone, and the laser system determines that the laser light is targeting stone (rather than tissue), then the laser system (or a practitioner) can increase the power (frequency, pulse width, etc.) of the laser light with proper confidence that the laser light is being directed at the stone. As another example, the laser system can determine that the treatment target is target material or tissue, and if the treatment target is target material, the system can determine a type of target material. In this way, the laser system (or a practitioner) can adjust the laser operation parameters (e.g., CW power, pulse peak power, pulse shape and pulsewidth, interval between pulses, pulse frequency and average power of the laser light), based on the determination of the target material (or tissue) and type thereof. For example, different types of stone have different material properties (e.g., having a different hardness), which can benefit from different laser operation parameters. In particular, harder stones can require a higher energy laser pulse, while softer stones can require a lower energy laser pulse. Regardless of the treatment target, the ability to discern between stone (and types thereof) and tissue can shorten the procedure time and increase the success of the treatment outcome.

In some non-limiting examples, the laser system can provide information about whether or not the fiber position is in contact with tissue and can optimize the laser light and tissue interaction mechanism for the desired effect (e.g., using the mechanical energy of the bubble (for example, for separation of prostate capsule and adenoma tissue) using thermo-mechanical energy released by the absorption of the laser light, using thermal energy released by absorption of laser energy, etc.). For example, the laser system can be used to discern different tissue types (e.g., a prostate capsule, an adenomas tissue, etc.), each of which can have different desired predetermined distances from the distal tip of the fiber to the treatment target (in this case tissue), and can have different desired predetermined distances than calculi. For example, tissue can have a predetermined distance between the distal tip of the fiber that is within a range between 1 millimeter and 10 millimeters (e.g., which can facilitate a mechanical effect in the tissue). As another example, calculi (or tissues that are desired to be ablated or coagulated) can have a predetermined distance between the distal tip of the fiber is within a range between 0 millimeter and 5 millimeters (e.g., which can facilitate thermal ablation, thermal-mechanical ablation, etc., which can be used for tissue vaporization, incision, coagulation, etc.).

As noted, the scope may be any of a variety of surgical or other medical scopes, including specialized or special-purpose scopes. The scope may include an imaging system and/or camera to receive images of the internal area of the patient. Image data from the scope may be used by the integrated systems described herein for analysis, control, and/or user feedback.

In some non-limiting examples, including when contact with tissue is desired, the laser system can create a bubble in a controlled manner. For example, the laser system can generate laser light that is a pre-pulse (that is not treatment laser light) to form a controlled bubble (and a vapor channel, or in other words a “Moses” channel). Correspondingly, the laser system can determine if (and when) a stone or tissue material is reached within this bubble (e.g., the vapor channel contacting the stone or other target). In this way, the use of treatment laser light can be avoided until after the vapor channel contacts the stone, thereby better controlling laser light delivery and reducing stone retropulsion displacement (e.g., improving visibility, improving targeting of the treatment target, improving treatment efficiency etc.). In some cases, this controlled bubble can also be made continuously at the

distal end of the fiber (e.g., the bubble being present continually while treatment laser light is delivered), which can avoid uncontrolled vaporizing of other water within the treatment region and increase tissue ablation efficiency. In some configurations, such as with the controlled bubble made continuously at the distal end of the fiber, the laser system can control the laser such that treatment laser light is allowed only at times when the target tissue is detected (e.g., using the processes described herein), for example in a non-contact (popcorn) mode of stone fragment ablation.

In some non-limiting examples, utilizing light from sources other than the treatment laser can be advantageous in that the light from the other sources does not undesirably interact with tissues, stones, etc. For example, the light can advantageously have a lower power than the power of the laser treatment light from the treatment laser.

FIG. 1 is a schematic representation of a non-limiting example of a smart laser system 100 in accordance with aspects of the invention. As used herein, the term “smart” refers to the ability of one or more components of the laser system 100 to engage in two-way communication (i.e., transmit and/or receive a signal) with one or more other components of the system, such as a controller or control system of the laser system 150. For example, a control system (described in more detail below) can control other components of the system such as the laser driver 101 or laser source 110 (e.g., modify the laser operating parameters) in response to signals corresponding to the patient and/or treatment area that are transmitted to the control system via one or more sensors.

The system 100 comprises a multi-functional optical adapter 105, a laser source 110 to generate treatment radiation, a laser driver 101, a control system 150 that includes a processor for performing smart functionality, and surgical optical fiber 145 which can be part of the laser system or as a separate device. Laser driver 101 is a source of laser pumping current and voltage. For example, it can be the driver of a diode laser or a flash lamp. Diode lasers can be used for direct tissue treatment or for pumping solid-state or fiber lasers. Flash lamps can be used for pumping a solid state laser. The laser source 110 generates laser radiation, which is delivered to the optical adapter 105 via optical fiber or free beam 140. The laser radiation is partially reflected in the optical adapter 105 for laser power monitoring and then is coupled into the surgical optical fiber 145. The laser radiation from a distal end of the surgical optical fiber 145 interacts with a treatment target (i.e., treats tissue or stone) in

the surgical treatment environment 102. The optical adapter 105 is also connected to sources of probe signals 130, e.g., a probe light source (also can be an excitation light source), and one or more sensors 120 of electromagnetic radiation. Probe signals from the source of probe signals 130 are also coupled into the surgical optical fiber 145 (via the optical adapter 105) and the returning probe signal (also referred to herein as probe signal data) as well as other electromagnetic radiation generated in the surgical treatment environment that may be partially deflected into the sensors 120 (via the optical adapter 105) for further reference and analysis.

During interaction of the surgical laser radiation with liquid in the treatment zone, biological tissue, stone, and/or surgical components, like a basket, certain electromagnetic signals are reflected or generated in response to excitation and can propagate through the surgical optical fiber 145 into the optical adapter 105, where they are further directed to particular sensors 120. These electromagnetic signals can include probe signal data based off the source of probe signals, which can be directed into the sensors 120 (via the optical adapter 105). A control system 150 receives the signals from the sensors 120 and performs an analysis which is then used by the control system 150 to control other components of the system, such as the laser driver 101 and laser source 110. Laser sources 110 can be any laser with parameter(s) optimized for desired therapeutic effect and transmittive through surgical fiber 145. For example, for a urological procedure such as lithotripsy and using silica fiber, the laser sources may have a wavelength in the range of 1.85 – 2.2 μm , a pulse energy 0.001 to 10 J, a peak power 0.1 to 100 kW, and an average power 2 – 200 W. The laser source can be Ho:YAG, Tm:YAG, Tm:YLF and other solid state lasers having such parameters and flash lamp or diode pumped. Another example is a Tm fiber laser configured with a diode pump in free-running or Q-switch modes of operation. This laser can also be used for soft tissue procedures. In addition, lasers with wavelengths of 400-600 nm can be used. A diode laser, for example, with a wavelength of 400-460 nm, or 780-1100 nm, or 1300-2100 nm, or second harmonic of Nd:YAG laser with a wavelength of 530 nm can be used. Such a laser can operate in continuous wave (CW) mode with a power of 10 – 300 W. A diode or diode-pumped laser, such as a fiber laser source, can also be preferable for some configurations.

In another aspect of the invention, the smart laser may be a part of an integrated treatment system (FIG. 2), which, in addition to the laser system 100 and surgical fiber 145,

may include a scope (flexible, semi-flexible, or rigid) 167, an aspiration, irrigation or aspiration/irrigation sub-system 170, and an Artificial Intelligence (AI) - run control center 151. The AI control center performs the initial processing of signals from imaging system 166 of the scope 167, the aspiration/irrigation sub-system 170, and implements synchronization with the laser system 110 and the laser driver 101. Scope 167 includes a handle, a rigid, semi-rigid, or flexible shaft 168 with imaging/video sensor 171 and illumination light sources like LED or lamp 169 (lamp with fiber delivery) with illumination emission from the distal end of the shaft. AI-run control center 151 can be integrated with laser system controller 150, or may be a separate unit or integrated with scope imaging system 166 with initial processing and control of video sensor 171.

In accordance with one embodiment, the smart laser may receive and process visual information received by the video camera of the scope 169. This information can be used stand-alone or in combination with other informational channels available to the system from sensors 120 (elastic scattering, fluorescence etc.) and information about laser parameters from controller 150. This information can be used for detection and recognition of various treatment conditions such as: 1) detecting/distinguishing between soft tissue and stone, 2) recognition of stone type and stone substructure, 3) recognition of soft tissue type (e.g., capsule/adenomas tissue boundary, detecting/distinguishing a tumor and normal tissue), 4) the distance between tissue or stone and the fiber distal end, 5) tissue bleeding, 6) surgical field visualization quality which can be compromised by scattering of light on products of ablation, 7) stone retropulsion displacement, 8) popcorning performance, 9) distal tip damage or contamination, 10) flashing in treatment area, 11) treatment organ recognition.

The camera image can be further processed by the image processor 166 or the AI-run control center. The image processing algorithm is developed, optimized and validated for each clinical embodiment using an analysis of the clinical endoscopic video imaging and machine-learning methodology.

Use of information from the imaging system of endoscope 166 will further increase the accuracy of measuring a distance to the target, differentiating between stones and soft tissues, and identifying a stone or tissue type. When the LED of the scope is used for target illumination, the LED spectrum will become available to the control center in real time.

Real time information from the imaging system 166 and from the sensor 120 can be combined and processed in the laser control system or AI-run control system in real time to increase accuracy and for redundancy purposes. For example, the distance between a stone or tissue and the distal end of the fiber can be measured by the back reflection signal of the endoscopic LED, or by processing the image of the endoscopic video system. A command for enabling or disabling laser emission or changing one or more laser parameters in predefined ranges can be issued if both signals are in acceptable ranges.

Smart laser system (FIG. 1) or smart laser system integrated with endoscope and other devices (FIG. 2) in accordance with various aspects is designed to operate using the following steps. The 1st step is to obtain a signal from the surgical treatment environment 102 using surgical fiber 145 and sensors 120 or/and signals from endoscopic imaging system 166 and other devices such as irrigation/aspiration system 170. The 2nd step is to process this signal to provide information about the surgical treatment environment or surgical fiber and instruments in the surgical treatment environment. The 3rd step is to send a signal from the laser system control unit to the laser driver to automatically change a pumping current and/or voltage to adjust the laser's pulse power, temporal profile and peak power, laser energy, interval between laser pulses and repetition rate, and average laser power to achieve a desired clinical outcome. The 3rd step can include, in some instances, a full interruption of laser energy delivery. In some embodiments, the 3rd step can result in generating an audio or visual signal to an operator. This can include optional coding of a visual signal color and/or intensity of the audio signal with a different tone and/or intensity to request a change in the laser parameter by the operator. The 4th step is to evaluate the clinical outcome and includes the assessment of the achieved clinical outcome and a decision as to whether to stop or to continue treatment.

Table 1 below is a list of non-limiting examples of the types of features and functions provided by certain embodiments of the systems and methods.

System Feature	Function	Benefit
Detection of contact with stone, and hard or soft tissue	Allows laser emission only when the fiber tip is close to a predefined distance stone or tissue	Prevents water overheating and unintended firing on soft tissue, reduces retropulsion and more efficient popcorning, and distinguishes between contact with stone or soft tissue to protect soft tissue from unwanted damage (perforation, ablation, or coagulation)
Detection of stone type	Recognize stone type	Automatic control of laser setting to increase the speed of ablation
Detection of soft tissue type	Recognize tissue type and status (including prostate capsule, and benign and malignant lesions)	Improves safety and precision of BPH, bladder cancer, and other soft tissue treatments

Table 1 – Examples of Functionality

FIG. 3 shows a schematic illustration of an optical adapter 105, which is one example of the optical components of the optical adapter 105 that can facilitate directing light to and from different ports. For example, the optical adapter 105 can include beamsplitters 214, 216, 218, 220, and lenses 222, 224. Each of the beamsplitters 214, 216, 218, 220 can be positioned within the optical adapter 105 (e.g., the housing of the optical adapter 105) and each can be oriented in the same way (e.g., angled as illustrated in FIG. 3). The angle between the axis of the laser beam and normal to the beamsplitter surface can be in the range 10 to 70 degrees, preferably for some applications, 30 to 50 degrees. However, while there are four beamsplitters illustrated, other numbers of beamsplitters can be used, especially, for example, when there are a different number of pairs of ports. Thus, in some cases, the number of beamsplitters can match the number of aligned ports of the optical adapter 105 (e.g., with the exception of the ports 162, 164). In addition, while all the beamsplitters 214, 216, 218, 220 are illustrated as being oriented in the same way, it should be appreciated that the beamsplitters 214, 216, 218, 220 can be oriented in different ways, with the directing of light between ports being changed by the orientation of the beamsplitter. Each beamsplitter can have dielectric coatings with maximal transmission of the laser beam and optimal reflection in spectral ranges of the probing beam and back reflection signals associated with ports connected to that beamsplitter. In addition, some ports can include a lens or sets of lenses to re-image the proximal end of the surgical fiber 159 onto the detector.

As shown in FIG. 3, a beamsplitter 214 can be positioned between (and aligned with) ports 166, 174, another beamsplitter 216 can be positioned between (and aligned with) ports 168, 176, another beamsplitter 218 can be positioned between (and aligned with) ports 170, 178, further beamsplitter 220 can be positioned between (and aligned with) ports 172, 180, and each of the beamsplitters 214, 216, 218, 220 can be positioned between (and aligned with) the ports 162, 164. Each of the beamsplitters 214, 216, 218, 220 can direct light into (and out of) respective ports 174, 176, 178, 180, and each is able to transmit laser light therethrough to the optical port 164 (and to the surgical fiber 145). For example, light can be emitted into the port 174, directed by the beamsplitter 214 through the optical port 164 and into the proximal end of the fiber 145, which can follow in the direction 226 (e.g., which can extend from the proximal end to the distal end of the fiber 145). As another example, light that is directed into the distal end of the fiber 145 along the direction 228 (e.g., which can extend from the distal end to the proximal end of the surgical fiber 145) can be emitted through the port 164, can pass through the lens 224, and can be directed by the beamsplitter 220 through the port 180.

In some non-limiting examples, the lens 222 can be in optical communication with the treatment laser, and can be positioned in front of the port 162 within the optical adapter 105 behind each of the beamsplitters 214, 216, 218, 220. In some cases, the lens 222 can be a collimating lens. In this way, laser light can be collimated after passing through the lens 222. In some non-limiting examples, the lens 224 can be a focusing lens, which can focus light that passes through the focusing lens in the direction 226, and can diverge light that passes through the focusing lens in the direction 228. In some cases, the lens 224 can be positioned behind the port 164 and in front of each of the beamsplitters 214, 216, 218, 220 within the optical adapter 105.

FIG. 4 shows the schematic illustration of FIG. 1, but further includes an input device 262 and an output device 260. That is, the system described above with respect to FIG. 1 may be adapted to include a variety of user interfaces, such as a display that may form the output device 260 and a variety of user controls or input devices that can form the user input 262.

FIG. 5 shows a schematic illustration of a laser system 300, which can be a specific implementation of the laser system described above, or others described herein. The laser

system 300 can include an optical adapter 305 (which can also be referred to as an optical coupler, an optical module, etc.) as shown in FIG. 3. A non-limiting list of components or features shown in FIG. 3 that can be included in the optical adapter 305 include at least one port, an inverse fiber combiner 381 (also, illustrated in FIG. 6), a laser power monitor 382, a quartz block 383, a collimating lens 384, beamsplitters 385a, 385b, an aiming beam source 386, a focusing lens 387, a protective window 388, a coupling lens 389, a filter 390, and a fiber connector 391.

The optical adapter 305 can be a multi-functional component, where the optical adapter 305 can direct light along different optical paths. For example, the optical adapter 305 can direct the laser radiation from the laser source into the surgical fiber 345 using lenses 384 and 387. In addition, the optical adapter 305 can direct light to one or more detectors to monitor light back reflected from the target or non-target light, other light, etc. In some cases, a light source can emit a visible laser beam (e.g., green light as in FIG. 5) as an aiming beam into the surgical fiber 345 using the beamsplitter 385a. For example, the visible laser beam can be emitted toward the beamsplitter 385a, which can be directed by the beamsplitter 385a so that the visible laser beam is directed into the proximal end of the surgical fiber 345.

In some non-limiting examples, probe light from the source of probe light 330 can be directed into the proximal end of the surgical fiber 345 using a reflective prism or mirror. Light that is transmitted back through the surgical fiber 345 from the distal end and to (and out) the proximal end can be separated using a beamsplitter and additional beamsplitters (not shown), can be directed into a single or multicore fiber (e.g., using a coupling lens to direct the light into the fiber), and can deliver this light to one or more light detectors. In addition, in some non-limiting examples every light detector can be configured with a spectral filter to select a desired wavelength or wavelengths.

FIG. 6 shows a cross-sectional view of the multicore fiber 381. As shown in FIG. 6, the multicore fiber 381 includes multiple optical channels (e.g., seven as illustrated), with each optical channel being associated with a light detector, or a light source.

For example, in one configuration, each of the first, second, third, fourth, and sixth optical channels can be in optical communication with a respective light detector (or a respective light source). In some cases, the seventh optical channel can be in optical communication with a light source. In another configuration, the first and second optical

channels can be in optical communication with a first light detector, the third and fourth optical channels can be in optical communication with a second light detector, and the fifth and sixth optical channels can be in optical communication with a third light detector.

In some configurations, each optical channel of the multicore fiber 381 can be in optical communication with a respective light source, and a respective light detector. For example, each respective light source can emit light into the respective optical channel of the multicore fiber 318, while each light detector can receive light from the respective optical channel. In some configurations, each optical channel of the multicore fiber 318 can include a beamsplitter, each of which can facilitate directing light from a respective light source to a respective optical channel and receiving light from the respective optical channel and to the respective light detector. In some cases, this configuration of having a light source and a light detector for each optical channel can reduce the number of ports needed for the optical adapter 305. In some cases, while the multicore fiber 381 is illustrated, the multicore fiber 381 can be substituted with multiple fibers. In this case, each of the multiple fibers corresponds to an optical channel of the multicore fiber 381.

FIG. 7 shows a schematic of another example of a laser system 500 with a surgical fiber 545 and an endoscope 560. Laser system 500 can combine three types of light sources – a treatment laser, a pilot laser, and a probing light source. Light is distributed or otherwise guided from the proximal end to the distal end of the surgical fiber 545. The surgical fiber 545 can be inserted into the endoscope 560 and may include a flexible component with the distal fiber tip. The end of the endoscope 560 can be directed into the patient's organ 552 (e.g., a urethra, a bladder, a ureter, a kidney, etc.). An illumination light source 564 (e.g., an LED light source) can be provided at the distal end of the shaft of the endoscope 560, as shown in FIG. 7. This light source 564 can illuminate the operation/manipulation field inside the organ (or other location inside the patient). The endoscope 560 can include a video camera (imaging sensor) 562 that can translate the real-time image of the operation/manipulation field onto an outside monitor/screen and optionally to an image processor. Using a camera and one or more analyzed signals from the disclosed system, the doctor can guide the surgical fiber along the urethra, bladder, ureter, kidney channel to approach and find the target 530, such as a stone that needs to be fragmented, or soft tissue (e.g., tumor) that needs to be treated (vaporized, coagulated or excised).

The probing light source can be any one of a number of different light sources, including LED light sources with narrow or broad spectrums, and these light sources can have any number of different wavelength ranges, including wavelength ranges in the UV, visible, near IR range, etc. In some non-limiting examples, the probing light source can be a laser light source having any one of a number of different wavelengths, including those that match the peak absorption of a target chromophore, non-limiting examples of which include 400-450 nm, 500-600 nm, 940 – 1100 nm, 1150-1350 nm, 1400-1600 nm, and 1850-2200 nm. In some instances, these wavelength(s) may correspond to specific physiological features. For instance, 400-450 nm and 500-600 nm relate to hemoglobin absorption, which can be used to distinguish between tissue and stone materials because soft tissue contains hemoglobin and stone does not (e.g., tissues absorb these wavelengths more than calculi). In another example, 520-540 nm is related to a range of commonly used aiming beam wavelengths (for example, see aiming beam in optical adapter of FIG. 5) and the aiming beam can be used as a probing beam. In another example, 940-1000 nm, 1400-1600 nm and 1850-2200 nm relate to peaks of water absorption (tissue contains more water than stones), and 400-940 nm or 1150-1350 nm are related to the opposite case of water transmission. Therefore, these wavelengths can show different probing responses from stone vs. soft tissue, which can be used to distinguish between these two types of physiological materials.

FIG. 8A shows a flowchart of a process 600 for determining that a treatment target is a target material or is tissue. As described above, a target material may be a stone or calculus, or other material. The stone or calculus may be located in a target area such as the bladder, ureter or the kidney, or located elsewhere in the renal or urinary system. Additionally or alternatively, the target material may not be a stone or calculus or may not be associated with the renal or urinary system, but may be a material located elsewhere in the body or in other systems in the body.

The process 600 can be implemented using any of the laser systems described herein (e.g., the laser system 100), and the process 600 can be implemented using one or more computing devices as appropriate (e.g., the computing device 150). Furthermore, as will be described below, the process may utilize a robotic surgical system or may utilize clinician control instead of robotic control.

At 602, the process 600 can include moving a fiber to a treatment region that includes a treatment target (e.g., a target material). In one embodiment, the distal end of the fiber may be positioned in contact or quasi-contact with at least one known target. In one non-limiting example, the fiber can be moved manually. As another non-limiting example, a computing device can cause a robotic surgical system to move the fiber to the treatment region, and can cause the fiber to be at a desired position relative to the treatment target. In some cases, this can include a computing device inserting the fiber into a tube of a medical scope, and inserting the medical scope (e.g., with the fiber positioned therein), into a patient. In one example, the insertion, whether manual or robotic, may be via a urethra of the patient. In other cases, a clinician or a computing device can cause the shaft of the medical scope to be inserted into the patient within the treatment region, and subsequently, can cause the fiber to be inserted into a working channel of the shaft of the medical scope until a distal end of the fiber is inserted through the shaft of the medical scope. While this discussion has been described with reference to a computing device, such is just one non-limiting example. The process 600 can include a practitioner or clinician controlling the system and the medical scope, including positioning the scope and/or fiber in the patient and moving the fiber until the distal end of the fiber reaches the treatment region (e.g., at the predetermined distance from the treatment target).

At 604, the process 600 can include a computing device (or the practitioner) causing a light source to emit a first light (also referred to herein as simply “light”) toward the treatment region. For example, the light source can emit first light into a proximal end of the fiber, which can propagate through the fiber and can be emitted out the distal end of the fiber into the treatment region. In some cases, the light source can be positioned within or proximate to the treatment region (e.g., being coupled to the medical scope). In some cases, the first light can be a broad continuous spectrum of light, or the first light can include one or more wavelengths within a range between substantially 400 nm to substantially 750 nm. In some cases, the first light can be pulsed (e.g., having multiple pulses, each of which has a pulse width). In some cases, the first light can be white light (e.g., the first light source being configured to emit the white light, such as a white LED). In some configurations, the first light can be coherent light (e.g., with the light source being a laser source). In some cases, the first light can be non-treatment light (e.g., the first light not being configured to elicit a

therapeutic response when the first light is directed at a target, which can include ablation, coagulation, etc.). In some cases, the first light can have an average power of less than 100 mW. In this way, the first light does not undesirably interact with the treatment target, which can disrupt receiving a portion of the first light, thereby disrupting the identification of the treatment target.

At 606, the process 600 can include directing a portion of the reflected (back reflected) first light to a light detector. In some cases, the portion of the first light can be transmitted back into the distal end of the fiber, can propagate through the fiber, and can be emitted out of the proximal end of the fiber and directed to a detector (e.g., via an optical adapter). In some cases, the portion of the reflected first light can be passed through an optical filter before reaching a detector. Thus, for example, the process 600 can include filtering the portion of the reflected first light by passing the portion of the reflected first light through an optical filter that restricts the portion of the reflected first light to wavelengths within a range (e.g., the visible light range). One example of such a system is described below in reference to FIG. 20.

At 608, the process 600 can include a computing device receiving data from the light detector. For example, the data can correspond to a portion of the reflected first light (e.g., having been filtered) interacting with the light detector. In some cases, the data can include an intensity for one or more wavelengths of the portion of the reflected first light. For example, the one or more wavelengths can be within a range between substantially 350 nm to substantially 750 nm, a range between substantially 400 nm to substantially 700 nm, etc. In some cases, the data can include an optical back reflected spectrum. In some cases, a computing device can normalize the data, based on the light emission spectrum of the light source (e.g., because the amplitudes of the first light are not entirely uniform across all wavelengths of the first light). In some cases, a computing device can filter the data (e.g., using a low pass filter, a high pass filter, a band pass filter, a band stop filter), which can remove one or more intensity values (for one or more wavelengths within a wavelength range), can amplify intensity values, or the like.

At 610, the process 600 can include a computing device determining that the treatment target is a tissue or a stone material, based on the optical data. Optical data can comprise signals from optical detectors (photosensors). Examples of optical detectors

include photodiodes, 1D or 2D matrix of photo sensors (charge-coupled device (CCD) as an example). For instance, 1D matrix optical data may be produced by spectrometers, and 2D matrix optical data may be produced by imaging sensors. Optical data may represent electrical current or voltage from optical detectors in analog or digital form that can be subsequently transmitted to a computing device.

A data profile or optical data profile or optical data temporal profile can refer to data or optical data as a function of time. The data profile can be a single optical data profile from a single detector or a matrix of optical data profiles from a 1D or 2D matrix of photosensors. As will also be described, a characteristic optical data profile or characteristic optical data temporal profile can refer to a stored/known data as a function of time, whereby the underlying material or material properties that produced the profile are known, such as a predefined calibrated or preset profile. To this end, a characteristic data profile can be used to identify a data profile in a target environment during a clinical procedure. That is, the data profile can be compared with the characteristic data profile during treatment to control the treatment laser, as will be described.

For example, a computing device can analyze an intensity of the light at a selected wavelength or wavelengths using the data, for example, by comparing an optical data profile to a characteristic data profile, or other criteria, and can determine that the treatment target is a tissue or a target material based on the comparison. As a more specific example, a computing device can analyze an intensity profile of the optical signal acquired by the detector and compare this detected optical profile to a characteristic optical data profile that serves as a criteria against which to determine that the treatment target is a target material.

Furthermore, such can be used as characteristic criteria. For purposes of the present application, “characteristic criteria” can mean a previously-generated optical data profile associated with a specific analytical conclusion based upon pre-clinical or clinical collection studies stored in the computing device. Such characteristic criteria may be temporal in nature, such as will be described with respect to FIG. 8B which provides a signal profile for reflecting light indicating stone or tissue being targeted, or may be based upon absolute or relative units, such as the spectral profiles found in FIGS. 9, 10, 11, and 12 identifying tissue and types of stones.

Referring to FIG. 8B, a graph is provided showing one example of an optical data profile for use in laser treatment, such as described above. Data or optical data collected or otherwise received by the detector, which is back reflected light (sourced from the light source (illumination sources) of the surgical scope or probing light) from the target area/surgical environment. The back reflection light intensity or power is continuously changing during treatment and has a different level and time behavior depending on the position of the distal end of the fiber and scope relevant to the target and non-target materials and laser operation. When the distal end of the fiber is far from the target, which can be 1 to several millimeters (time interval 1701 and 1702) the intensity level of back reflected light 1717 is low and shows some scattering from the overall environment, including from the liquid and wall of the treatment organ. If a surgeon activates a laser on this fiber and scope position, the back reflection signal will be oscillating due to the bubbles that form and collapse (induced by the treatment laser) on the distal end of the surgical fiber and the corresponding back reflection scattered on these bubbles in interval 1702. When the fiber has been moved closer to a stone surface at 1703 (about 1-2 mm), the back reflected light intensity will increase toward a maximal level achieved when in contact with the stone at 1704. Notably, the oscillation amplitude and irregularity can also increase at the same time, due to additional back reflected light caused by the product of stone ablation. During 1705, the distal end of the fiber has lost contact with the stone. When losing contact with the stone, the back reflection signal decreases, as illustrated at 1705, toward a level similar to pre-contact with stone at interval 1706. If the surgeon moves the fiber toward soft tissue, such as the ureter wall, the back reflection signal will increase at interval 1707 to a maximal level reached when in contact with the soft tissue, while the amplitude of oscillation will increase at 1708. As will be described, upon determining such a data profile, the laser sources may be disabled, the laser power may be decreased, the energy or interval between pulses may be adjusted, or the like, either by the surgeon or the system. This continues as the back reflection signal drops to a level typical for back reflection from tissue.

During all this time, the control system may perform real-time comparisons of this optical data profile with a characteristic optical data profile. Several criteria can be used for the comparison. For example, the signal level 1717 and 1718 can be compared with known, non-contact and contact levels for contact with a target or without contact with a target, with

or without treatment laser operation. Furthermore, average levels 1711, 1714, maximum levels 1712, 1715, minimum levels 1713, 1716, an interval between oscillations 1718, length of oscillation, and a statistic related to time intervals and amplitude of oscillation or the like may be evaluated. Thus, the characteristic or known optical data profile or key attributes thereof are processed against or compared to the optical data profiles collected in pre-clinical or clinical studies for different surgical treatment environments. The computing device (control system) performs a comparison in real-time of the optical data profile with the characteristic optical data profile using one or multiple criteria.

Additionally or alternatively, the computing device may determine an integrated intensity by determining the area under the optical backreflection spectrum within a wavelength range (e.g., from 540 nm to 590 nm), or by summing together each intensity value for each wavelength of the data within a wavelength range. Then, a computing device can determine that the treatment target is a target material based on the integrated intensity value being greater than a criteria value, or a computing device can determine that the treatment target is a tissue based on the integrated intensity value being less than the criteria value.

At 612, the process 600 can include a computing device determining a type of target material (e.g. a uric stone, a calcium oxalate monohydrate stone, a cysteine stone, or the like.) for the treatment target based on the data, after for example, a computing device determined that the treatment target is a target material. In some cases, a computing device can follow a similar process at block 610 to determine the type of target material from a plurality of possible types of target material. For example, a computing device can compare a profile or an intensity value for a wavelength to a criteria value and can determine the type of target material based on the comparison to a characteristic profile or intensity. As another example, a computing device can compare an integrated intensity value to a criteria and can determine the type of target material based on the comparison. In some cases, a computing device can determine a type of target material, based on comparing an intensity profile from the data to a characteristic profile. Additionally or alternatively, the computing device can compare an amplitude of a wavelength(s) to one or more criteria values. For example, a computing device can determine that the target material is a uric stone, based on an amplitude of a selected wavelength of the data (or an integrated intensity value) being greater

than a first criteria and a second criteria, with the second criteria being larger than the first criteria. As another example, a computing device can determine that the target material is a calcium oxalate monohydrate stone, based on the amplitude of the wavelength of the data (or the integrated intensity value) being between the first criteria and the second criteria. As yet another example, a computing device can determine that the target material is a cysteine stone, based on the amplitude of the wavelength of the data (or the integrated intensity value) being less than the first criteria and the second criteria.

At 614, the process 600 can include a computing device for determining a distance between the distal end of the fiber and the treatment target, based on the determined treatment target. For example, different treatment target types or features (e.g., size) can have a corresponding predetermined desired distance associated therewith (e.g., stored in a database). As a more specific example, a computing device can receive a predetermined distance that is associated with the determined treatment target or target feature, such as size, (e.g., in a database). For example, a computing device can receive a predetermined distance for the treatment target corresponding to a target material (and/or size of the target material), based on a computing device determining that the treatment target is a target material (and the type of the target material). Correspondingly, a computing device can receive a predetermined distance for the treatment target corresponding to a tissue, based on the computing device determining that the treatment target is a tissue. In some cases, this can be advantageous, in that predetermined distances can be optimized for specific treatment targets. For example, treatment targets that are tissue are desired to have a greater distance than calculi. In addition, harder stone types can benefit from a smaller distance (e.g., more focused laser light being directed at a harder stone) as opposed to softer stone. Thus, for example, when the treatment target has been determined to be stone target material, the distance can be smaller than a predetermined distance for a tissue, and when the treatment target has been determined to be tissue, the distance can be greater than a predetermined distance for stone. Correspondingly, when the treatment target has been determined to be a target material having hard material property, the distance can be less than a predetermined distance for a target material having a softer material property than the hard material property.

At 616, the process 600 can include a computing device determining laser operation parameters for a treatment laser, based on the above analysis. In some cases, the laser operation parameters for the treatment laser can include one or more of a pulse peak power, a pulse shape, a pulse width, an interval between pulses, a frequency of the laser light, a power of the laser light (e.g., an average power), a total duration of the laser light, and the like. In some cases, a computing device can receive one or more predetermined laser operation parameters for the treatment target corresponding to a target material (and in some instances a type of the target material), based on a computing device determining that the treatment target is a target material (and the type of the target material). In other cases, a computing device can receive one or more predetermined laser operation parameters for the treatment target corresponding to a tissue, based on the computing device determining that the treatment target is a tissue. In some non-limiting examples, having predetermined laser operation parameters can be advantageous in that the predetermined laser operation parameters can be tailored to a specific treatment target and type thereof. For example, tissues benefit from CW power operation and calculi benefits from pulse operation with high peak power (e.g., because higher amounts of laser light directed to calculi can be advantages to fracture the target material). Thus, one or more predetermined laser operation parameters for tissue can be lower than one or more predetermined laser operation parameters for calculi (and vice versa). Similarly, one or more predetermined laser operation parameters for a first type of calculi can be higher than one or more predetermined laser operation parameters for a second type of calculi (e.g., with the first type of calculi being harder than the second type of calculi).

In some non-limiting examples, block 616 can include a computing device notifying a practitioner based on the results from one or more determinations. For example, a computing device can present on a display of a laser system or endoscopic image the results of the determination from the block 610, which can include presenting on a display that the treatment target is a treatment target material or a non-treatment target material. In addition, a computing device can present on a display the determined distance (e.g., a predetermined distance) associated with the treatment target and/or can present on the display the determined laser operation parameters associated with the treatment target, etc.

In some non-limiting examples, the treatment target has already been predetermined to be tissue, or target material (and a type thereof). In this case, for example, the process 600 can be used to determine that the current treatment target (e.g., in front of the distal end of the fiber) matches with the predetermined treatment target. In this case, a computing device can determine that the current treatment target (e.g., determined at the block 610, 612) corresponds or does not correspond with the predetermined treatment target. If a computing device determines that the current treatment target matches with the predetermined treatment target, then a computing device can control operation of the treatment laser (e.g., including enabling firing of the treatment laser, causing the treatment laser to emit laser light, increasing one or more laser operation parameters for the treatment laser such as average power, peak power, etc.). However, if a computing device determines that the current treatment target does not match with the predetermined treatment target (e.g., that the predetermined treatment target is stone and the current treatment target is tissue), then the computing device can control operation of the treatment laser (e.g., including disabling firing of the treatment laser, stopping the treatment laser from emitting laser light, changing one or more laser operation parameters such as decreasing laser power). In addition, if the computing device determines that the current treatment target does not match with the predetermined treatment target, then the computing device can alert a practitioner by, for example, presenting an alert on the display, flashing or sound. In this way, during a laser procedure, a computing device can, in real time, adjust operation of the treatment laser if the current treatment target is not the actual predetermined treatment target, which can prevent undesirable firing of the laser, increase treatment efficiency and safety, etc.

In some non-limiting examples, the treatment target can be identified to be a stone target material versus tissue, because stone can reflect, scatter, etc., a greater amount of light than does tissue - especially within particular wavelength ranges (e.g., a wavelength ranges of 410 nm to 460 nm and 550 nm to 590 nm) in which the tissue absorbs light within the wavelength range (e.g., due to hemoglobin absorbing the light). For example, FIG. 9 is a graph showing examples of the optical back reflected spectrums of back reflected light (reflected and scattered from a surface of stone or tissue, back scattered from bulk stone or tissue, etc.) of a scope LED illumination from different types of stone and kidney tissue. In this instance, back reflected light that propagated through the surgical fiber was directed into

another fiber which was connected to a spectrometer (Thorlabs Inc., CCS100/M 350 - 700 nm). The surgical fiber had a core diameter of 0.2 mm and extended from the ureteroscope tip by 3 mm. The distance between the surgical fiber tip and the surface of the stone or tissue was about 1 mm. By analyzing the spectra shown in FIG. 9, it is shown that there are substantial differences between the spectra of different stone types (e.g., COM, uric acid, cysteine) and between the spectra of stone and soft tissues. Different stone types have different levels of reflection in all wavelength ranges. Soft tissue has a specific local minimum in the range 540 - 590 nm, which can be used for soft tissue identification.

FIG. 10 is a graph showing examples of the same spectra of back reflected/scattered LED light from stones and from soft tissue but normalized to the original LED spectrum. These spectra can be used for identification of different types of stones and soft tissues. Various stone types and their differentiation against soft tissue can be identified by spectrum analysis (e.g., through differentiating or integrating the spectral curves in all regions or in the most sensitive spectral ranges). This information can be used for identification of stone or stone type and soft tissue before applying laser energy.

FIG. 11, which is a table, shows an integral of back reflected/scattered spectra of endoscopic LED signals from stones and soft tissue in different spectral ranges. The table shows examples of the integral back reflected LED signals from stones and soft tissue in different wavelength ranges: whole range of 410-700 nm, blue ranges of 410-460 nm, green-yellow range 510-620 nm, and narrow ranges of 410-430 nm, 550-590 nm. Tissue type (hard tissue or soft tissue) and stone type (e.g., an exact stone type) can be identified by integral signals in the wavelength ranges mentioned above. For example, during laser treatment of a kidney stone in a ureter, a surgeon should keep the distal end of the surgical fiber in contact with stone. However, if a surgeon accidentally loses contact with the stone and touches the ureteral wall and continues firing, the wall can be perforated with undesirable side effects. These experiments showed a surprisingly high difference in back reflected signals from stone and soft tissue (2x to 4x, depending on stone type). In some instances, when the back reflected signal decreases by more than 1.2x - 1.7x during treatment, the laser system can send an audible and/or visual warning signal to a surgeon to stop firing or the laser system can stop lasing automatically.

FIG. 12 is a graph showing examples of the spectra of back reflected/scattered LED light from stone that has been normalized by the spectra of the back reflected LED light from soft tissue. Variations in this ratio can be used for identifying stone vs soft tissue.

FIGS. 13 and 14 collectively show a flowchart of a process 700 for determining a distance between a distal end of a fiber and a treatment target. The process 700 can be implemented using any of the laser systems described herein (e.g., the laser system 100), and the process 700 can be implemented using one or more computing devices as appropriate (e.g., the computing device 150).

At 702, the process 700 can include a computing device (or operator) moving a fiber to a treatment region that includes a treatment target, which can be similar to block 602 of process 600. At 704, process 700 can include a computing device causing a light source to emit a first light toward the treatment region, according to a calibration procedure, which can be similar to block 604 of process 600. At 706, the process 700 can include a computing device causing a treatment laser to emit laser light toward the treatment region. In some cases, the laser light can have a laser pulse, and the first light can have one or more pulses (e.g., three pulses). In some cases, a first pulse of the first light can be emitted before the laser pulse (e.g., the first light being emitted before the leading edge of the laser pulse), a second pulse of the first light can be emitted during emission of the laser pulse (e.g., the second pulse being situated between a rising edge of the laser pulse and a falling edge of the laser pulse), and a third pulse of the first light can be emitted after emission of the laser light (e.g., after the trailing edge of the laser pulse). An example of this configuration is shown in the upper region of FIG. 15, in which the first light is the probing source (light), and the first, second, and third pulses of the first light correspond to the pulse A, the pulse B, and the pulse C, respectively.

In some non-limiting examples, the first light can be emitted continuously before, during, and after the emission of the laser pulse. For example, the first light can include a first pulse which can be emitted before, during, and after the emission of the laser pulse. An example of this configuration is shown in the lower region of FIG. 15, in which the first light is the probing source (light) that is emitted before, during, and after the laser pulse.

Referring back to FIG. 13, at the block 708, the process 700 can include directing a portion of the first light to a light detector, which can be similar to block 606 of process 600.

At block 710, process 700 can include a computing device receiving first data from the light detector, which can correspond to the portion of the reflected first light (e.g., having been filtered) interacting with the light detector. Block 710 can be similar to block 608 of process 600. In some configurations, the portion of the reflected first light, which is directed to the light detector to generate the first data, can be directed back into the distal end of the fiber and emitted out the proximal end of the fiber to the light detector. The portion of the reflected first light can correspond to one or more sections of the first light, with a first section being emitted before the laser pulse, with a second section being emitted during the laser pulse, and with a third section being emitted after the laser pulse.

At 712, process 700 can include a computing device determining one or more calibration values, based on the first data (e.g., which can be filtered). In some cases, the data can include one or more first intensity values corresponding to the first light being emitted before the laser pulse (e.g., the first section of the portion of the first light), one or more second intensity values corresponding to the first light being emitted during the emission of the laser pulse (e.g., the second section of the portion of the first light), and one or more third intensity values corresponding to the first light being emitted after the emission of the laser pulse (e.g., the third section of the portion of the first light). In some non-limiting examples, a computing device can determine a first calibration value from the one or more first intensity values (e.g., by averaging them together), can determine a second calibration value from the one or more second intensity values (e.g., by averaging them together), and can determine a third calibration value from the one or more third intensity values (e.g., by averaging them). Each of the calibration values can be utilized to more accurately determine the distance. For example, the one or more first, second, and third intensity values each correspond to different conditions of the treatment region. Namely, the one or more first intensity values can correspond to the treatment region being free of a bubble (e.g., at the distal end of the fiber), the one or more second intensity values can correspond to the treatment region including a bubble (e.g., at the distal end of the fiber), and the one or more third intensity values can correspond to the treatment region including a vapor channel through the bubble. In this way, depending on the relationship between the emission of subsequent light relative in time to the emission of subsequent laser light, the distance determination can be more accurate.

At 714, process 700 can include a computing device (or operator) moving the fiber to the treatment region. In some cases, this can include a computing device moving a distal end of the fiber to a predetermined distance (e.g., using process 600) relative to the treatment target. Block 714 can be similar to block 702.

At 716, process 700 can include a computing device causing the treatment laser to emit second laser light towards the treatment region. In some cases, block 716 can be omitted if, for example, the treatment laser is to only emit laser light after determining the distance.

At 718, process 700 can include a computing device causing the light source (or a different light source) to emit a second light toward the treatment region, which can be similar to block 704. In some cases, using the same light source can be advantageous in that the calibration procedure can be tailored to the particular light source.

At 720, process 700 can include directing a portion of the reflected second light (e.g., which can be filtered) to the light detector (or a different light detector), which can be similar to block 708. At 722, process 700 can include a computing device receiving (and filtering) second data from the light detector (or the different light detector), which can be similar to block 710.

At 724, process 700 can include a computing device determining a distance between a distal end of the fiber and the treatment target based on the second data (and based on one or more of the calibration values). In some cases, a computing device can compare an intensity value from the second data to a curve that relates intensity values and distances (of the distal end of the fiber to the treatment target). In some cases, the curve can be associated with the type of treatment target (e.g., target material (and corresponding type) or tissue). In some cases, a computing device can calibrate the second data by applying one or more (e.g., a combination) of the first, second, or third calibration values to each intensity value of the second data, depending on when the second data was acquired relative to the second laser light (if applicable). For example, if the second laser light was not emitted at all, or if the second laser light was emitted after, before, not during, etc., the second light, then the first calibration value can be applied to the second data (e.g., to each intensity value of the second data). In some cases, calibrating the second data can include subtracting each intensity value of the second data from the first calibration value, and dividing by the first calibration value.

In other words, calibrating the second data can include determining a relative change between each intensity value of the second data and the first calibration value.

In some configurations, determining the distance between the distal end of the fiber and the treatment target at block 726 can include repeating blocks 718-722 to cause the light source (or another light source) to emit third light, which can be directed to the light detector (or a different light detector), to generate third data that can be received by a computing device. In this case, a computing device can determine a change between an intensity value (e.g., calibrated according to one or more of the calibration values) of the third data and an intensity value (e.g., calibrated according to one or more of the calibration values) of the second data (e.g., by subtracting the data). Then, a computing device can compare the change in intensity values to a curve that relates the derivative of the intensity values and the distances (of the distal end of the fiber to the treatment target). In some cases, using the change in intensity values can be a more robust way to determine the distance.

At 726, the process can include a computing device notifying a practitioner, based on the results from the one or more determinations, and displaying the results. Block 726 can be similar to block 616 of process 600. In some cases, this can include a computing device presenting on a display the distance.

In some non-limiting examples, when a predetermined distance has already been determined or received by a computing device, the distance determined at block 724 can be a current distance. In this case, a computing device can determine the difference between the current distance and the predetermined distance, and present on a display the difference (or otherwise notify a practitioner of the difference). In some cases, if a computing device determines that the current distance exceeds a predetermined distance, then a computing device can control operation of the treatment laser (e.g., including enabling firing of the treatment laser, causing the treatment laser to emit laser light, increasing one or more laser operation parameters for the treatment laser to operate according to, etc.). However, if a computing device determines that the current distance does not exceed the predetermined distance, then the computing device can control operation of the treatment laser (e.g., including disabling firing of the treatment laser, stopping the treatment laser from emitting laser light, decreasing one or more laser operation parameters, etc.). In addition, if the computing device determines that the current distance exceeds the predetermined distance,

then the computing device can alert a practitioner by, for example, presenting an alert on the display. In this way, during a laser procedure, a computing device can, in real time, adjust operation of the treatment laser if the current distance deviates from the predetermined distance, which can prevent undesirable firing of the laser, can increase treatment efficiency, etc. For example, sometimes during laser treatment the target material moves (e.g., known as retropulsion) and in this case because the distance between the distal end of the fiber and the treatment target can be determined, tissue is not undesirably treated with laser light (e.g., the computing device can cause the treatment laser to stop firing). As another example, during “popcorning” after the target material fractures into pieces and is suspended or floats in urine, the treatment laser is not always in the line of site with each of these particles. So, when a particle is close enough to the distal end of the fiber, the computing device can cause the treatment laser to fire, thereby creating an automatic firing procedure as particles are brought close enough to the distal end of the fiber - even when images from a medical scope are obscured.

In some non-limiting examples, process 700 can be described with reference to a specific implementation of the laser system. For example, at the beginning of a lithotripsy procedure, an endoscope can be manipulated such that the distal end of the fiber enters or is otherwise inserted into the channel of the kidney (or ureter). The distal end of the fiber is still virgin and the response signal of the probing light source as detected by the sensors (e.g., photodiode) is original and initially related only to Fresnel reflection on the distal end. A calibration procedure can be commenced at this time since there is no risk of tissue damage and there is no stone present. As such, the doctor can initiate the calibration procedure, e.g., by pressing a calibration pedal (button). Once initiated, a laser emits radiation one or several times with certain predetermined parameters (pulse power, pulse width, and frequency). These laser parameters cause water in the surgical environment to overheat, which leads to bubble formation on the fiber tip side. Simultaneously, the computing device synchronizes the calibration pulse with the three (or more) original baseline (reference) pulsed probe source signals into memory: at the moment right before the pulse (moment A), during the pulse (moment B) and right after the pulse (moment C), as shown in FIG. 15. Basically,

(around 3-4 % depending on the source wavelength) with some impact of Fresnel reflection on the air-to-water boundary inside the formed bubble – the part of back reflection that approaches the surgical fiber, and C – the boundary condition between the A and B cases when the initial bubble is smaller or has even already collapsed. The probe source can also be a continuous wave source, as shown in FIG. 15. With this calibration procedure complete, the doctor can proceed to the treatment.

During the doctor's manipulation and guiding of the fiber (e.g., a surgical fiber) inside the kidney/ureter channel, the computing device registers or otherwise detects incoming response signals initiated by the probing source that are reflected back from the distal end of the fiber. The computing device can compare this response signal(s) with signal A of the calibration procedure. At this point, a "contact coefficient" parameter can be implemented that is more precise than absolute values that may differ from time to time depending on multiple circumstances. According to one example, the contact coefficient parameter can be calculated as: $K1 = (A1 - A)/A$, where A is a reference signal in "water" being measured during the calibration procedure, and A1 is the current incoming signal in the absence of laser pulses. When there is no stone/tissue around the fiber tip, $A1 = A$ and $K1 = 0$. When the fiber tip approaches the target, backreflection from the target increases the A1 parameter and K1 increases. FIG. 16 is a graph showing the relationship between the contact coefficient for stone and soft tissue and the gap between the fiber tip and the target using a probing source wavelength of 1550 nm. As a soft tissue sample, kidney tissue was used.

The graph in FIG. 16 indicates that by approaching soft tissue up to the point of full contact, K1 increases from 0 up to 0.33, and for stone material K1 increases from 0 to 1.39. It is to be appreciated however, that the specific K1 values will depend on several application-specific factors, including the laser, the optical system, the overall system design that is being implemented, the fiber diameter, and other parameters. The K1 values should therefore be evaluated in advance for each laser system design.

In this example, if the computing device can determine that K1 increases to 0.33, then it is likely that the tip is in contact with tissue. If tissue is not the intended target, then the system disables power to the treatment laser so as not to cause tissue injury. The doctor can thus continue to find the stone and correct the position of the fiber tip. However, if the target is indeed tissue, the system allows the laser to turn on when $K1 > 0.2$ (but not more than 0.4)

and the gap is about 200 microns or less. Only when K1 is over 0.4 and up to 1.4 or even more, should the computing device, in some cases, determine that it is indeed stone material situated in front of the fiber tip and turn on the laser when the gap is 0.5 to 0 mm. With K1 with the target and the laser can be turned on. In some instances, during calibration mode the laser can fire with a lower energy and power if the stone is not detected and automatically switch to a higher energy and power if a stone is detected. This minimizes the retropulsion effect and overheating of the liquid in the treatment area to prevent soft tissue damage.

In some non-limiting examples, other characteristics of the measured signal can be advantageously used for more precise identification of the target and the distance to the target. As an example, FIG. 17 is a graph showing the relationship between the derivative of the contact coefficient and the gap between the fiber tip and the target, which can serve as a more sensitive measure of the target type and distance to its surface.

Once it is determined that the treatment laser can be enabled, the doctor can proceed with stone treatment. In some instances, a pedal may be used by the doctor for activating the treatment laser. Laser pulses with certain parameters (power, width, frequency etc.) start firing, which initiates several processes. First, if some kind of gap exists between the fiber tip and the target, then the laser pulses will cause local overheating and vaporize the water (existing in the gap) first. A bubble forms and starts to grow. The front side of the bubble reaches the stone surface to create a vapor channel and the “Moses effect” occurs. From this moment on, laser pulses impact not only the water but also the stone and thus become more “effective.” Further stone surface ablation leads to surface fragmentation and local crater formation and subsequent crater growth. Small stone particles created as a product of the laser ablation separate from the stone surface and track in all directions, including the fiber tip direction, and stone dusting occurs. Retropulsion can also occur, which leads to the stone moving and distancing itself from the fiber tip. If the pulse frequency is low enough, then after one pulse and before the next subsequent pulse, the bubble begins to collapse and a gap between the end of the fiber and the stone fills with water. After the bubble collapses, there is a stone with a crater in it at a distance from the front of the fiber tip. When the next pulse begins, this set of processes starts over again. During the time that the laser is turned on and during stone treatment, the response (probing signals detected by sensors) of the probing

source changes dramatically due to backscattering from the product of ablation. This is due to several things, one being the changing nature of the amount of backscattering. Another is the change in the Fresnel reflection from the fiber tip according to the changing environment around the tip (e.g., “air” or “water” environment, smooth stone surface or stone surface with craters, distance to the stone, small particle tracking, lack of small particle tracking, absorption of laser light by a product of ablation, contaminated fiber distal end, and heated area of fiber distal tip, etc.). Prior to the pulse, the level of the probing source response signal should be minimal (Fresnel reflection in water is less than on the air). During the laser pulse, the level of the probing source response signal can be at its maximum (Fresnel reflection on air is maximum and backscattering of a porous crater and of tracking microparticles is maximum). In the time period right after the pulse, the probing source response signal should be something in between these minimum and maximum levels.

A computing device can receive the response signals related to the probing source and can analyze these signals and control the laser system based on this analysis, e.g., determine whether the stone is still in the ablation area and not distanced to another area. If the stone is not in the treatment area, the control system automatically stops operation of the laser. To do this, the control system may need to implement additional “contact coefficient” parameters K2 and K3 that are similar to K1. In some instances, K2 is a parameter related to the moment B - during or right before the end of the pulse, where $K2 = (B1 - B)/B$, and K3 is related to the moment C - right after the pulse, where $K3 = (C1 - C)/C$. For example, B is a reference signal in “air” (bubble) that is measured during the calibration procedure and B1 is the current incoming signal during or right before the end of the pulse. Further, C is a reference signal and boundary condition between the A and B cases when the initial bubble is smaller or has even already collapsed and is measured during the calibration procedure, and C1 is the current incoming signal right after the pulse. These additional contact coefficient parameters can be determined during calibration, and like K1, K2 and K3 should also be evaluated in advance for each laser system design. The calculation of K1, K2, and K3 parameters during the calibration process and the use of these parameters in combination with real time results can provide the best probability of stone contact detection during laser pulses.

Different kidney and ureter stones (calculi) such as calcium oxylate monohydrate (COM stone), uric acid, cysteine, and others have different microstructures, different chemical compositions, (feasibly) different typical shapes and sizes, consist of different amounts of water inside, amongst other distinctions. Therefore, these different types of calculi most likely have different backscattered and/or back-reflected probing source signals and thus have different contact coefficient parameters (K1, K2 and K3) when the distal end of the fiber is in front of the stone of some kind.

FIG. 18 is a graph showing the relationship between the contact coefficient K1 for different types of stone and soft tissue where the fiber tip is in contact with the target (the gap between the fiber tip and the target is 100 microns or less) using a probing source wavelength of 1550 nm at 15 different points of stone or tissue. According to one example, soft tissues (chicken breast, pork kidney and beef heart) 5-0.8, uric acid stone $K1 = 0.6-1.8$. However, it is to be appreciated that K1 can depend on various other parameters such as the probing source wavelength, the fiber diameter, the fiber distal end angle to stone surface, the condition of the fiber distal end, the distance between the fiber distal end to the stone surface (as described above), the current laser system design, and many other factors. Still, if these parameters are considered equal, the determined K1 coefficients will relate to different types of stone as is shown in FIG. 18. This can be used in real time to distinguish between different types of stone with a high probability. If the doctor is able to have such assistance during surgery with the described stone type detector, he or she (and/or the control system) will be able to select (choose) the best laser parameters (such as pulse power, width, frequency and other) in order to fragment the determined type of calculi with the highest possible efficiency. In some instances, this parameter can be predetermined and pre-set into the smart laser system (e.g., the control system) for purposes of proposing (suggesting) or otherwise conveying to the doctor the currently determined stone type that is in front of the fiber tip during surgery. This stone type detector is configured to work when the laser is working. Furthermore, the stone type detector also works even when the stone is not homogeneous but chemically consists of two or more types of calculi, and/or has a changing fragmentation regime (mode) according to the current state (part) of stone in real time. This ability leads to preventing water overheating and shortens the time it takes to perform the surgery procedure. Changing or otherwise modifying a laser

treatment parameter (e.g., laser operating parameter) according to the stone composition (based on feedback) can also be done automatically by the control system.

A computing device controlled laser system can therefore be used to receive and analyze response signals corresponding to the probing source in real time before, during, and after laser pulses for purposes of distinguishing between contact with stone vs. soft tissue. In addition, image data from the imaging sensor of the scope can provide information regarding contact detection with stone and with soft tissue, and the results from image processing can be used to determine the stone and soft tissue type and condition. The system can also assist in controlling the laser for purposes of helping the doctor make more informed decisions, increase the efficiency of the stone treatment, shorten the procedure time, and to avoid injuries caused by improper positioning of the fiber tip during laser pulses where the camera's view is limited by stone dust.

In accordance with at least one non-limiting example, FIG. 19 is one example of a functional schematic of the laser system. The synchronizing signal (CLOCK) originates in a clock generator. A laser source such as a laser diode emits a probe pulse on each arrival of the clock forefront. The period of pulses is greater than the longest time of flight of a pulse that goes from the beginning to the end of an instrument and then backward. The forefront duration can be less than 0.1 ns, and the pulse duration can be several nanoseconds. Low average power is ensured by a short pulse duration and a large period of pulses. If the power is insufficient for stable detection of a reflected signal, then the pulses are additionally amplified.

The laser emission is then coupled into the fiber instrument and partly reflected from the distal end of the fiber or a crack in the fiber. In instances where the cleave angle is too large at the distal end of the fiber, the reflected power can be too small to be detected. This situation is discussed in further detail below.

The reflected pulse is received by a sensor such as a photodiode. The signal is then digitized by a comparator, and the reference level of the comparator is then adjusted. In some instances, the target level of the comparator is half the amplitude of the pulse. Once it leaves the comparator, the reflected signal goes to the data input of a D flip-flop. A synchronizing signal is delayed in a phase-locked loop by a variable magnitude with a step less than 0.1 ns and goes to a clock input of the D flip-flop. The result of a comparison

between these two inputs is latched at different moments of time, which makes it possible to fix the moment of transition of the result of the comparison from zero to one, and consequently to fix the forefront of the reflected pulse.

Two regimes of operation are possible. In the first regime, the delay of a latching clock is scanned step-by-step over all delay ranges that correspond to a length of a fiber instrument. Thus, the moment of pulse return is fixed and the fiber length is measured. In the second regime, the range of delays that correspond to a small zone around the tip of the fiber instrument is employed. In this instance, the reflection of a pulse from a tip is fixed. If the reflected pulse disappears, two variants are possible: a crack inside a fiber, or a very large cleave angle at the tip of the fiber instrument. Both situations demand immediate termination of laser emission. Operation of a device in the first regime gives detailed information about the fiber instrument, but the second regime takes less time.

As mentioned previously, calculi (e.g., kidney stones, ureter stones, etc.) and soft tissues have different structures (and material properties) that create specific responses by a probing light (e.g., light from one of the light source(s)). For example, different stones can have different chemical compositions, with stones in general mostly containing minerals with water present in the inter-crystalline and microcrystalline spaces (e.g., about 10% of the total volume of the stone). In addition, stones can contain small organic molecule additions, and each stone can have different micro structures, macro structures, shapes, surface structures, and conditions. Each of these can define the stone's optical properties, which can include a spectrum of the absorption, a spectrum of the scattering coefficients, the angle distribution of scattered light, etc. In some cases, the stones backscatter the probing light, which results in different types of scattering (e.g., Rayleigh, Mie, etc.). In contrast to stones, tissues (e.g., kidney, ureter, soft tissues, etc.) can include an organic extracellular matrix, vascular systems, and cells. Aside from the substantial difference in water content between tissues and stones (e.g., tissues containing substantially 70-80% water, while stones can contain substantially 10% water), tissues can have a non-porous structure and smoother surface (as compared to stones). As a result, tissues have different optical properties than stones. For example, tissues can scatter light less than stone material (e.g., in most conditions), especially in the ranges of wavelengths where there is significant water or blood absorption (e.g., the light being absorbed by the tissues and thus not scattering). Thus, the light directed back into

the distal end of the fiber can be used to determine (e.g., by a computing device) if the treatment target (or other structure near the fiber) is stone, or is tissue. In addition, the light directed back into the distal end of the fiber can even discern the type of stone, if, for example, the treatment target has been determined to be a stone.

In some non-limiting examples, when the probing light approaches the treatment target (or other structure near the fiber), the amount of the light directed back into the distal end of the fiber increases (e.g., the probing light reflecting off the target and being directed into the distal end of the fiber). For example, when the distal end of the fiber 108 is in contact with the treatment target (in some instances the gap is about 100 microns or less), the amount of the light directed back into the distal end of the fiber (e.g., derived from a light source that emits the probing light) is maximized at least because more of the light is directed back into the fiber rather than being dissipated within the treatment region. This response, however, can be different for stones than for soft tissue because the backscattered amount of light from the stones and from soft tissue differs, especially in the wavelength ranges where blood and/or water absorption occurs (e.g., because the tissue absorbs more of this light than stone, and thus a larger amount of back-reflected light in these wavelengths occurs for stones). The probing light (e.g., which can be a laser beam) can have several wavelengths where a contrast between the back-reflected signal of the stone and the tissue (e.g., soft tissue) is maximized. In some non-limiting examples, the probing light can be a broad continuous spectrum source (e.g., the probing light having one or more wavelengths within a range of substantially 400 nm to substantially 750 nm), such as an LED or a lamp for purposes of obtaining a broad spectrum back-reflected signal from the tissue or stone.

In some non-limiting examples, by establishing or otherwise determining certain thresholds, desired ranges or above or below limits of the reflected light directed back into the distal end of the fiber (e.g., the intensity of the reflected light directed back into the distal end of the fiber light, from, for example, the probing light emitted) that correspond to contact (or quasi-contact) with the treatment target (e.g., stone verses tissue), a computing device can detect when the fiber is in contact with the treatment target. As used herein, the term “contact” refers to a fiber-target distance of less than 0.5 mm, whereas the term “quasi-contact” refers to fiber-target distances that are between 0.5 mm and 1.5 mm. For example, a computing device can receive data from a detector (e.g., one of the light detector(s)) that

detects the backscattered light (e.g., the reflected light directed back into the distal end of the fiber) and can determine a distance between a distal end of the fiber and the treatment target based on the data (e.g., an analysis of the data), which can include determining whether or not the fiber is in contact with the treatment target. This process can be implemented in real time (e.g., relative to a practitioner) so as to provide (and present on a display) a current distance between the distal end of the fiber and the treatment target so that the laser system (or practitioner) can adjust control of the treatment laser accordingly. In some non-limiting examples, the process of detecting the backscattered light (if any) from the distal end of the fiber and its comparison to a limit or range (e.g., one or more reference value(s) based on data from urine, water, air, or the like, without the presence of the treatment target, or based on data from a surgical component such as a catheter, a basket, a stent, a sheath, etc.) can allow the laser system to determine the approach to the target, to detect contact with the target, and the ability to distinguish whether the target is a stone (of some kind), a tissue, or a surgical component.

In some non-limiting examples, when the fiber is in contact with or not farther than a predetermined distance (e.g., 1 mm) from the treatment target or surgical component(s), the practitioner (or a computing device) can turn on the treatment laser or increase the laser power/energy of the laser treatment light to treat the treatment target. In some cases, when the fiber is in contact or close to a surgical component, the practitioner (or a computing device) can turn off the treatment laser or decrease the power of the laser treatment light to prevent laser damage of surgical components. In some configurations, when the distance is farther than a desired range or limit, or when the treatment target is target material but the portion of the subject is determined to be tissue and the treatment is not intended to ablate or coagulate soft tissue, the laser system (e.g., the computing device) can notify the practitioner to prevent emission of the laser treatment light. In some cases, then, the laser system (e.g., a computing device) can turn on the treatment laser, turn off the treatment laser, change the power of the laser treatment light, change the energy of the laser treatment light, etc., based on the data from the reflected light directed back into the distal end of the fiber (e.g., the backscattering light).

In some non-limiting examples, the laser system (and others described herein) can be calibrated to certain desired ranges or levels of the analyzed data, or data combinations (e.g.,

data from more than one detector). This can lead to the ability to either interrupt operation of the treatment laser, or give a warning to the practitioner (e.g., audio through via a speaker, a visual signal presented on a display, etc.) and propose a further action. In some non-limiting examples, either scenario can require the user's input as to whether to continue treatment (e.g., continuing delivering the laser treatment light), adjust operating conditions (e.g., adjust the treatment laser operation parameters, move the fiber 108, pause the delivery of the laser treatment light for a period of time, etc.), or to ignore the system recommendations.

In some non-limiting examples, the laser system can be calibrated within a particular clinical environment prior to treatment, or can even be configured to self-calibrate during a clinical procedure. The laser system can also be configured to accumulate feedback signals (e.g., data from the light directed back into the distal end of the fiber) and analyze patterns and classify them based on particular characteristics and reactions of the user to increase the potential for "smarter" responses and recommendations. In some cases, then, the laser system can function semi- autonomously, autonomously, etc.

In some non-limiting examples, the laser treatment light from the treatment laser, the light from each light source(s), and the light received by each light detector can be implemented in different ways. For example, the laser system can include one or more fiber optical couplers to facilitate light from each light source reaching the fiber, laser treatment light from the treatment laser reaching the fiber, and light from the fiber 108 reaching each light detector. For example, the laser system can include a $N \times 1$ tree coupler (i.e., a first tree coupler) with N inputs and 1 output, in which each of the N inputs can be in optical communication with a respective light source(s), and the 1 output can be in optical communication with the fiber (e.g., coupled to the proximal end of the fiber). Correspondingly, the laser system can include a $1 \times N$ tree coupler (i.e., a second tree coupler) in which the 1 input can be in optical communication with the fiber (e.g., coupled to the proximal end of the fiber) and each of the N outputs can be in optical communication with a respective light detector. In some cases, the laser system can include a 3×1 tree coupler (i.e., a third tree coupler) in which a first input of the three can be coupled to the output of the first tree coupler, a second input of the three is coupled to the input of the second tree coupler, and a third input of the three is coupled to the laser fiber (e.g., that directs the laser treatment light). Then, the output of the third tree coupler can be coupled to the proximal end of the

fiber. In this way, each light source, each light detector, and the treatment laser can be in optical communication with a respective fiber, each of which can be coupled to the fiber. Thus, each respective fiber can define a different optical path for light emitted by each light source, the treatment laser, and for light received by each light detector. While this is only one example, others are contemplated for routing the different optical channels to (and from) the fiber. For example, a multicore optical cable can be in optical communication with the fiber, with each channel of the multicore optical cable being in optical communication with a respective light detector. Similarly, a multicore optical cable can be in optical communication with the fiber, with each channel of the multicore optical cable being in optical communication with a respective light source.

Additional System Features to Facilitate Treatment of Tissues and Calculi with Directed Energy

The use of directed energy is increasingly a method of choice to treat various pathological conditions of the human body. Different kinds of directed energy are known in the art: electromagnetic (ranging from X-ray to RF), mechanical (including directed particles – e.g., electrons or protons), acoustic (including ultrasound), and others. Critical to the success of the treatment is the ability of the operator to correctly target the desired pathology while minimizing collateral damage to surrounding intact tissue and ensuring overall patient safety.

In accordance with various aspects, one objective is to provide advanced techniques to assist the operator in achieving these goals based on registration and interpretation of various diagnostic information obtained from the prospective treatment sites and surrounding areas. Most of the embodiments disclosed herein deal with laser lithotripsy of urinary calculi; however, applications directed to other conditions, body areas, and forms of directed energy can be readily made by those skilled in the art and are included within the scope of this disclosure.

Laser lithotripsy is a well-known and effective way of treating urinary stones. Laser energy is delivered from a laser to the distal end of the optical fiber inserted into an endoscope (including, but not limited to, flexible, semi-rigid, and rigid scopes). The distal tip of the fiber is placed in front of the target, the laser is fired, and absorption of the laser

energy by the stone target leads to destruction of the stone. Various techniques (e.g., fragmentation, popcorning, and dusting) for delivering the laser energy are known in the field. Once the target stone is split into sufficiently small fragments, these fragments can be passed naturally. Alternatively, they can be removed using auxiliary tools (e.g., baskets) or aspirated through the working channel of the scope.

Conventionally, the operator (e.g., surgeon or physician) identified the target as a stone by using a monitor that displays a real-time picture received from a built-in endoscope camera with the target area illuminated by the endoscope LED or other source. However, this technique poses potential problems concerning the field of view of the camera. For example, the doctor still can experience difficulties viewing the target while the laser is firing or right after the laser stops firing since there are multiple processes that take place: bubble and microbubble formation at the distal tip of the fiber, and blocking of the image of the stone or tissue due to scattering of the illumination light off the product of stone ablation. During such processes stone dust tracks in all directions, which leads to scattering of the illumination provided by the LED or other light source and to other energy source scattering. The camera's field of view becomes more and more obscured (polluted) after the laser is turned on, and eventually in many cases, it becomes impossible for the doctor to determine the target by using only the image from the camera. In these moments the doctor is basically blind and presents a possible collateral risk of soft tissue damage during this timeline of the treatment. To avoid this, the doctor usually stops firing and temporarily increases fluid flow for purposes of clearing the field of the view of the camera. Another problem is that the stone can be in close contact with soft tissue, such as, for example, a stone in the ureter. When a surgeon is treating such a stone in a scanning mode (dancing mode) and moves to the edge of the stone, the edge of the stone is in contact with a mucosal surface and it is very difficult to prevent the laser from firing on the mucosal tissue. This can result in thermal damage to the ureter wall, which can result in scar tissue formation and ureteral stricture, i.e., a narrowing of the ureteral channel (stenosis). When a narrowing in the ureter occurs, the kidney cannot function normally and will be damaged over time. Treatment for ureteral stricture may include surgical implantation of a stent to open the narrowed section of the ureter or surgery to reconstruct the urinary tract.

The unwanted result in these instances is that the treatment and anesthesia time are prolonged, which can be crucial in some cases. The most severe cases can lead to perforation of the kidney or ureter wall and eventually to unwanted urgent kidney or ureter surgery being required. The procedure should prevent mucosal tissue perforation and collateral damage of the wall of the bladder, kidney, or ureter. Furthermore, if there is a gap between the distal tip of the fiber laser and the stone (i.e., the fiber tip and the stone are not in direct contact with one another), e.g., more than about 0.5 to 1.5 mm, then the ablation efficiency will be less than the theoretical maximum or be less than what is otherwise potentially attainable (when compared to a desirable fiber position scenario) due to laser beam attenuation, which increases the treatment time as well.

Ensuring contact of the laser fiber with the stone prevents water overheating and the active use of the popcorning mode leads to better stone fractioning and prevents unintended firing on soft tissue. The possibility of adding additional assistance to the doctor (beyond the view from the camera) for purposes of detecting contact with stone or soft tissue and distinguishing between these surfaces (to be confident of the correct position of the distal tip of the fiber) as a part of a smart (intelligent) laser system would result in a substantial increase in such a system's value and importance. In alternative embodiments that include treatment configurations where contact with soft tissue is desired (e.g., tumor treatment) and when a clear image from the field of view of the camera is difficult or complicated to obtain, providing information about whether or not the fiber position is in contact with soft tissue can lead to shortening and optimization of the procedure as well.

In accordance with at least one embodiment, means for identifying the target are provided and, in embodiments where a fully automatic mode is employed, the controlled emission of the directed energy is implemented. This allows for the laser lithotripsy treatment to be more efficacious, safe, and convenient for the doctor and minimizes procedure time and the time needed for learning the laser lithotripsy technique.

According to certain embodiments, an operational principle is based on the differences between the light reflection intensity values or reflection coefficients (or other energy reflection properties) of stones, soft tissues, ambient medium (water), and, potentially, other objects (e.g., surgical components) present in the treatment field (e.g., surgical instruments, stents, etc.) for selected wavelength bands. The reflection intensity and/or

reflection coefficient is defined within the context of the directed energy used. In some embodiments, the wavelength(s) of the optical energy (and its reflected wavelength) is in a range of 200 to 11,000 nm, preferably in a range of 300 to 2,700 nm, and most preferably in a range of 400 to 1,200 nm, and in some embodiments is in a range of 410-700 nm. The absolute values of the reflected intensity signals may vary widely depending on the illumination conditions (typically, an LED in the scope), as well as the signal acquisition conditions. Hence, in accordance with various embodiments a ratiometric approach is used to classify the target. Furthermore, in some instances *a priori* knowledge about the reflective properties of the materials involved may not be sufficient for reliable system calibration, in which case individual in-patient calibration is required.

Per one or more aspects of the ratiometric approach, the ratios of the reflected signal intensities at multiple wavelength bands may be combined in different ways to yield optimal separation (i.e., distinction) between the classes of targets of interests (primarily, stones and soft tissues). For example, optical data can be generated that corresponds to the reflected light intensity and this can involve determining at least one ratio of a reflected light intensity of one selected wavelength band to reflected light intensity of a different selected wavelength band. The ratiometric technique can also be used in a calibration routine, as discussed further below. The thresholds of the firing decision (enable/disable or adjust the directed energy emission) can also be set in several ways. Finally, the system may provide informational feedback to the operator regarding the class of the target through various sensory means.

One example of an intelligent/smart system 600 is shown in FIG. 20 in accordance with at least one embodiment. System 600 comprises a laser system with a surgical fiber 645, an endoscope (in at least one instance the surgical fiber is at least partially incorporated into the endoscope), and a reflected signal analyzer module or feedback analyzer (i.e., controller or computing device). This system does not use a spectrometer.

The treatment laser or laser source 610 is a fiber laser, solid-state laser, or other type of treatment laser. One non-limiting example of a fiber laser includes a thulium fiber laser (TFL) as shown in FIG. 20. Lasers sources emitting energy at other wavelengths are also within the scope of this disclosure. The laser radiation emitted from the laser source 610 is directed through the endoscope and directed at the target 630. In essence, the treatment laser

is configured to treat the treatment target with laser radiation. The laser radiation emitted from the laser source 610 is also delivered to the optical adapter 605, as previously described.

A (broadband or selected band) source of light 615 is built or otherwise integrated into the endoscope (typically, LED source; however, low power lasers, laser-pumped fluorescent lamps, LED-pumped fluorescent lamps, thermal sources, such as xenon, halogen, etc. lamps are also possible) and is configured to illuminate the field of operation/manipulation (surgical treatment area) inside the patient. According to at least one embodiment, the light source 615 is a laser light source configured to emit light in a wavelength range of 350-2700 nm, and in some embodiments the light source 615 is a broad spectrum illumination light source configured to emit light in a wavelength range of 300-2700 nm. It is to be appreciated that in accordance with some embodiments, the source of light 615 may comprise separate lasers (e.g., two or more lasers, each with their own wavelength).

The detection arm of system 600 implements the use of optical fiber 645 (also referred to herein as surgical fiber), the optical adapter 605, an interconnecting fiber 695, a beam divider 685, a feedback analyzer 650 (also referred to herein as a computing device), optical filters (e.g., 690a-690i) and corresponding photodetectors (e.g., 646a-646i).

As discussed in further detail below, the surgical fiber 645 is configured to receive light (e.g., light from light source 615) that is reflected from the target 630 in a surgical treatment area. In certain embodiments, the surgical fiber 645 is also configured to deliver light from light source 615 to the surgical treatment area, as previously described. In some embodiments, the surgical fiber 645 is also configured to deliver laser radiation from the treatment laser source 610 to the treatment target, as previously described. The surgical fiber 645 may be configured as a multicore fiber, as previously mentioned. The computing device 650 is configured to couple with at least two of the photodetectors 646a-646i. Each photodetector 646 is configured to detect an intensity of reflected light from the target 630 in a different selected wavelength band. In some embodiments, phase-sensitive detection is implemented, which involves modulation of the illumination light. A photodetector configured to be phase sensitive may also be used in such an embodiment. As also discussed in further detail below, the computing device 650 is configured to receive the reflected light intensity in at least two (different) selected wavelength bands, generate optical data

corresponding to the reflected light intensity, and identify the target as a treatment target or a non-treatment target based at least in part on the optical data and a predetermined calibration based on at least one known target.

In accordance with various embodiments, the detection arm is capable of implementing several (e.g., up to 5) wavelength-specific channels yielding reflected signal intensities. For example, reflected signals from the treatment area are directed through the surgical fiber 645, interconnecting fiber 695, and into the optical adapter 605, which directs them to the beam divider 685, which splits the reflected signal into respective channels that each include an optical filter 690 and a photodiode or other type of photodetector 646. The filter 690 transmits reflected signal wavelengths of interest (i.e., predetermined wavelengths) to the photodiode 646, which is used in the analysis performed by the feedback analyzer or computing device 650 (which can be a computer processor as known in the art). In addition, system 600 may also comprise an endoscope camera (not shown in FIG. 20) that translates the real-time picture of the surgical treatment area field of view through to an outside monitor/screen that can be viewed by the operator. In some embodiments, the camera can be used in combination with an analyzed signal from the disclosed system (i.e., analyzed data obtained from the detection arm(s)), to help the operator guide the surgical fiber 645 in the treatment field. It is to be appreciated that according to some embodiments, a portion or portions of the optical train between the interconnecting fiber 695 and the detectors 646 can be implemented as free-space optics.

Since the light source 615 is typically broadband, the wavelength selection is performed in the detection arm via the optical filters 690a-690i. According to one embodiment, the spectral bands may be selected from the following list (although it is to be appreciated that this list is exemplary and that other wavelengths may be used as well): about 400-410 nm, about 440-480 nm, about 460-480 nm, about 510-530 nm, about 540-560 nm, about 550-570 nm, about 570-580 nm, about 580-600 nm, about 600-620 nm, about 690-710 nm, about 740-760 nm, about 790-810 nm, about 920-940 nm, about 970-990 nm, and about 1150-1350 nm.

In accordance with various aspects, the wavelengths up to 620 nm are related to or are otherwise associated with hemoglobin absorption (soft tissues contains hemoglobin but stones do not), whereas wavelengths longer than 620 nm are sensitive to differences in

scattering properties as well as to absorption by other chromophores. While the center wavelengths of the detection bands lie within the above ranges, the spectral widths of the detection bands (FWHM) may vary between 1 and 50 nm (preferably, 10 to 30 nm, and in some embodiments is 25 nm).

One or more varieties of the signal detectors or photodetectors (e.g., photodiode 690) may be used, e.g., multi-pixel photon counters (MPCCs), photomultiplying tubes (PMT's), or photodiodes (PDs, with a broad inclusion of these types of devices, including avalanche and PIN PDs, preferable).

There are several techniques that are suitable for separating the reflected signal into individual wavelength channels. In one embodiment, the total signal is split into N channels using a fiber splitter, with subsequent spectral filtration of each individual channel (e.g., the use of a beam divider, such as beam divider 685 as shown in FIG. 20). In other embodiments, the wavelength separation can be performed by using a set of beamsplitters (and configured with wavelength-selective coatings), prisms, cubes, or other similar wavelength-selective elements with subsequent detection of the respective wavelength bands at individual channels (by the detector, such as the photodiode 646 (PD)).

Calibration

While some embodiments may implement the use of pre-programmed calibration tables or use a pre-procedure device calibration on phantom materials, at least one embodiment utilizes an in-patient calibration performed immediately prior to the actual procedure. The calibration (also referred to herein as a predetermined calibration) may be performed at the start of each procedure (e.g., for each patient). An exemplary overall process flow of the in-patient (predetermined) calibration is shown in FIG. 21a. Applicant discovered that clinical studies performed using the pre-treatment in-patient calibration (described in further detail below) provided significant improvement in the clinical performance and safety of the treatment.

FIG. 21a shows a flowchart of a process 1000 for an in-patient calibration procedure according to one embodiment. The process 1000 can be implemented using system 600. At 1002 the process 1000 can include delivering the fiber to a surgical treatment area. This may include inserting the fiber into a scope and delivering the scope to the treatment area. Step

1002 may be performed by a surgeon or a device configured to perform this step. At 1004 the calibration procedure initiates. Using the image from the FOV of the camera positioned on the distal end of the scope, the doctor positions the tip in front of one or more various known target materials and obtains reflected intensity values from the photodetectors 646 that are coupled to the computing device 650. In some embodiments, the distal end of the surgical fiber is positioned to be in quasi-contact with at least one known target.

According to at least one embodiment, multiple reflected light intensity values are obtained from each known target of at least one known target. In some embodiments, the at least one known target is stone, tissue, a surgical component, or a surgical treatment area medium, which may also be referred to herein as a liquid medium (e.g., aqueous environment inside kidney). In one embodiment, the at least one known target is tissue. In another embodiment, at least two known targets are used. In certain embodiments, the two known targets may be stone and tissue.

When collecting multiple reflected light intensity values, the doctor or operator may position the distal end of the fiber tip in front of tissue (e.g., using the image from the camera to identify the tissue) and obtain multiple reflected light intensity values (from each photodetector 646) of the light from light source 615 as it is emitted from the distal tip of the scope and reflects off the tissue material and reflected light is captured by surgical fiber 645 and directed back to the computing device 650. The same process may be repeated for one or more other known targets, such as stone, and optionally other known targets such as surgical components and/or surgical treatment area medium (e.g., liquid).

If tissue is the known target material, then at 1006 the distal end of the scope is moved over the known target tissue and data (reflected intensity signal data) is collected (e.g., by having the surgeon depress a foot pedal or an assistant presses a button on the screen) for a predetermined period of time (e.g., 20 seconds) while the treatment laser 610 is off. This entails light from light source 615 being directed to the target tissue and the reflected light from this source off the target area being directed to detection channels as described herein.

During calibration, the treatment laser power can be disabled or lowered to a safe level for soft tissue, and for stone material, the treatment laser can be configured to emit power above the ablation threshold for the stone to guarantee contact or quasi-contact

between the fiber tip and stone (typically 0-1.5 mm). For instance, if stone is the known target material, then at 1008 the distal end of the scope is moved over the target stone for a predetermined period of time (e.g., 1-20 seconds) and data is collected (e.g., by having the surgeon depress a foot pedal) while the treatment laser 610 is on, but at a low pulse energy setting. For instance, the pulse energy may be less than 0.5 J, with some examples having a pulse energy of 0.025 to 0.1 J, with a 10-100 Hz repetition rate and an average power of 1 to 10 watts (W). In one embodiment, the pulse energy is sufficient to create some dusting as the operator moves the fiber across the stone surface. According to another example, the pulse energy is about 0.1 J with a peak power at about 500 W, with a 60 Hz repetition rate. In this example the settings ensure that the calibration signal is obtained from the bulk of the stone, and not only from a thin superficial layer that may not be representative of the actual stone. Reflected light from light source 615 during this action is detected by the detection channels.

At 1010 the process 100 can include a computing device (feedback analyzer 650) analyzing data received from the detection channels. This includes utilizing one or more “baseline” raw reflected intensity signals and calculated ratios of reflected light intensity within selected bands of wavelengths from each type of material that is stored in a database of the computing device.

As mentioned previously, a ratiometric technique can be applied to the reflected intensity data obtained from the known targets (and targets that may be unknown or otherwise not verified) during the procedure, as explained in further detail below. At least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band is generated or otherwise calculated by computing device 650 at step 1012. As an example, in some embodiments three different photodetectors are used (i.e., three channels) which yield a reflected intensity values for each wavelength band: wavelength band 1 (I_1), wavelength band 2 (I_2), and wavelength band 3 (I_3). At least three different ratios can then be calculated: $R_1 = I_1/I_2$, $R_2 = I_2/I_3$, and $R_3 = I_1/I_3$. In one embodiment, the different selected wavelength bands are selected from a group consisting of: about 400-410 nm, about 440-480 nm, about 460-480 nm, about 510-530 nm, about 540-560 nm, about 550-570 nm, about 570-580 nm, about 580-600 nm, about 600-620 nm, about 690-710 nm, about 740-760 nm, about 790-810 nm, about 920-940 nm, about 970-

990 nm, and about 1150-1350 nm. According to one embodiment, the wavelength bands are centered on at least one of 475 nm, 550 nm, and/or 575 nm. In accordance with various aspects, the wavelength values may be chosen based on their ability to provide the greatest difference in reflected intensity values between stone and tissue targets. For instance, at 475 nm, there is a decrease in reflected intensity for tissue, whereas the reflected intensity value for stone at this wavelength remains relatively high. In this example, two materials are of interest, stone and tissue (with stone being the eventual desired target for the treatment laser). Many samples can be taken for each of the “known” tissue and stone materials. In some embodiments, up to five different photodetectors are used (i.e., five channels).

At step 1014 at least one frequency distribution of values from each ratio (of at least one ratio) is then generated or otherwise determined by computing device 650 (for each (known) target). In some embodiments, the frequency distribution may take the form of a histogram. Two examples of histograms or plot of the distribution of ratio values for an embodiment where two known targets are used are shown in FIGS. 22a and 22b, where a value of the number of samples (y-axis) is plotted against one ratio value (e.g., R_1 , R_2 , or R_3) (x-axis) for each of the stone and tissue materials.

FIGS. 22a and 22b are frequency distributions in the form of histograms (for a distribution of ratios of reflected signal intensity collected during calibration) of two different examples of stone and soft tissue distinction, where FIG. 22a shows an example of a “good” separation (where the reflected intensity ratios indicate the target is the desired target e.g., a stone and not tissue), and FIG. 22b shows an example of a “bad” separation (where the reflected intensity ratios indicate that either the target is not the desired target (tissue, when the desired target is stone) or it is not clear that the desired target is one or the other). The reflected intensity ratio values can also be used to detect if the object in front of the distal end of the tip of the scope is an instrument (e.g., a surgical component such as a catheter, a basket, a stent, a sheath, etc.). In this instance, a calibration routine would involve having the physician obtain reflected intensity signal values from a “known” catheter, basket, stent, or sheath via the same procedure as outlined above via the FOV from the camera.

In at least one embodiment, and in continuation of the example using three different ratios as discussed above, three different histograms may be generated, one for ratio R_1 , one for ratio R_2 , and one for ratio R_3 . FIG. 22a may represent a non-limiting example of the

histogram results from R_1 , and FIG. 22b may represent a non-limiting example of the histogram results from R_3 . Clear (i.e., “good”) separation between the tissue and stone materials is shown in FIG. 22a and “bad” separation between the tissue and stone materials is shown in FIG. 22b. The analysis discussed below would result in the ability for the data (and ratio) associated with FIG. 22a to provide a framework for the actual stone ablation procedure that is performed after the calibration.

In accordance with certain aspects, the in-patient calibration establishes differentiation between soft tissue and calculi (e.g., see FIGS. 22a and 22b). During the calibration process, the reflected signals are collected in all N wavelength channels. Then $N(N-1)/2$ unique pairs of the signals are formed, the respective signal ratios are computed, and each pair is analyzed in terms of quality of stone-tissue separation. As previously outlined, FIG. 22a may be the result from R_1 (using the example from above), and FIG. 22b may be the result from R_3 .

Various specific techniques can be used to analyze the signal ratio(s) to optimize stone and tissue separation (distinction). In one embodiment, the concept of a ratio value associated with a predetermined percentile for each known target (based on the respective histograms) is used. This is shown as step 1016 in FIG. 21a. In this example, the computing device 650 determines a ratio value associated with a predetermined percentile for each known target based on the histogram. For example, two ratio values corresponding or otherwise associated with an 80th percentile (the predetermined percentile in this example) of all tissue and stone samples, S_{T80} and S_{S80} respectively, are computed. For example, the line marked “Min” in FIG. 22a may mark S_{S80} (the R_1 ratio value associated with the 80th percentile for stone) where 80% of the stone histogram data falls to the left of S_{S80} and 20% of the stone histogram data falls to the right of S_{S80} . The line marked “Max” in FIG. 22a may mark S_{T80} (the R_1 ratio value associated with the 80th percentile for tissue) where 80% of the tissue histogram data falls to the right of S_{T80} and 20% of the tissue histogram data falls to the left of S_{T80} . In a similar manner, the line marked “Min” in FIG. 22b may mark S_{S80} (the R_3 ratio value associated with the 80th percentile for stone) and the line marked “Max” in FIG. 22b may mark S_{T80} (the R_3 ratio value associated with the 80th percentile for tissue).

According to at least one embodiment, the predetermined percentile is based at least in part on historic reflected light intensity values from at least two known targets. For

example, reflected intensity values from known targets (and their calculated ratios) from previous (historic) procedures (e.g., in vitro and/or clinical testing) can be stored and analyzed by a practitioner and/or the computing device. Over time, frequency distributions such as that shown in FIG. 22a (with two known targets) can be analyzed to determine where an ideal percentile is positioned in the distribution and that value can be selected as the predetermined percentile. In some embodiments, the predetermined percentile is in a range selected from 50th to 97th, and in further embodiments, the predetermined percentile is in a range selected from 75th to 95th, and in yet further embodiments, the predetermined percentile is the 80th percentile, and in some embodiments the predetermined percentile is the 95th percentile.

In one embodiment, a difference value between the ratio values associated with the predetermined percentiles for each known target is accepted as an indicator for the quality of separation. This is shown as step 1018 in FIG. 21a. This step may include determining a difference value between a first ratio value associated with the predetermined percentile for a first known target (of at least two known targets) and a second ratio value associated with the predetermined percentile for a second known target. The wavelength pair with the best separation (e.g., the ratio value R associated with the largest difference value R_1 , as explained in further detail below) is then selected for subsequent use during the procedure. For example, the difference value between S_{S80} and T_{T80} for R_1 of FIG. 22a is designated as R_1 in FIG. 22a and the difference value between S_{S80} and T_{T80} for R_3 of FIG. 22b is R_3 in FIG. 22b.

It should be noted that in the flowchart of FIG. 21a, the analysis output of step 1012 may employ a form other than a frequency distribution in the form of a histogram (step 1014) as the output. For instance, the analysis may produce graphical or other types of data representations and models (e.g., pie charts, bar charts, data matrix), or any other output capable of functioning as a basis for the determining the ratio value associated with the predetermined percentile for each known target.

In at least one embodiment, the difference value (associated with each ratio value) is compared to a threshold difference value. In one embodiment, the threshold difference value R_1 (a first difference value) is R_3 (a second difference value) and computing

device 650 determines whether the first difference value or the second difference value is larger. In response to a determination that the first difference value is larger than the second difference value, then the first difference value is selected as the threshold difference value, and in response to a determination that the second difference value is larger than the first difference value, selecting the second difference value as the threshold difference value. In

R_1 is larger than R_3 , signifying a greater degree of separation

R_1 may be chosen or otherwise be used

as the threshold difference value. In other embodiments, a threshold difference value may be established by an operator, or may be established by the computing device 650 (e.g., on the basis of stored data, other stored information, mathematical algorithm(s), etc.).

Once the reflected intensity wavelength pair is defined (i.e., which ratio R value yields the best separation criteria), the actual separation criterion S_{SP} may also be defined in various ways. In one embodiment, S_{SP} can be computed as an average of S_{T80} and S_{S80} , which is explained in further detail below.

In accordance with one embodiment, and using the framework set out in the example from above, in response to a determination that the difference value meets or exceeds the threshold difference value, a threshold ratio value (or range of values) can be established that is based at least in part on the first ratio value and the second ratio value (e.g., establishing a threshold ratio value based at least in part on the multiple reflected light intensity values from each known target). In accordance with various aspects, the threshold ratio value can be considered to be based at least in part on the multiple reflected light intensity values from each known target. This can be performed by the computing device 650 and is shown as step 1022 in FIG. 21a. For instance, using the example from above, FIG. 22a (associated with R_1)

R_1 that meets or exceeds the threshold difference value. The first ratio value associated with the predetermined percentile for the first known target (stone) is approximately 0.57 in FIG. 22a. The second ratio value associated with the predetermined percentile for the second known target (tissue) is approximately 0.66. A threshold ratio value may be established or otherwise determined based on the first ratio value and the second ratio value. For example, an average ratio value based on the first and second ratios may be established as the threshold ratio value. Referring to FIG. 22a, the line marked "Medium" line as shown in FIG. 22a marks an average (i.e., 50%) between the 0.57 value of the first

ratio and the 0.66 value of the second ratio. This line can be established as the threshold ratio value (having a value of approximately 0.61 for this example in FIG. 22a). During an actual procedure, and in accordance with at least one embodiment, a comparison of a ratio obtained during a “live” surgical treatment procedure can be compared against the threshold ratio value. A target (in the “live” surgical treatment area during the course of an actual procedure) can be associated with a known target based on this comparison. For example, using FIG. 22a, R_1 values associated with a target in an actual surgical treatment area during a procedure can be compared to the threshold ratio value of 0.61. Ratio values greater than 0.61 (to the right of the 50% line) will associate the target in the actual surgical treatment area with tissue material and ratio values less than 0.61 (to the left of the 50% line) will associate the target in the actual surgical treatment area with stone material.

In a different embodiment, the computing device 650 is configured to establish each ratio associated with the predetermined percentile as a threshold ratio value for the respective known material. The threshold ratio value can be used during an actual procedure to verify that the object in front of the camera is the actual desired target. For instance, using the

R_1 meets or exceeds the threshold difference

value, and the ratio values associated with the 80th percentiles for each of tissue and stone can be used during an actual procedure. For stone, the threshold ratio value for R_1 is approximately 0.57 and for tissue the threshold ratio value for R_1 is approximately 0.66 in the example shown in FIG. 21a. During an actual procedure, if the ratio value for R_1 obtained from “live” measured reflected intensity data (from a target in the surgical treatment area) meets or exceeds the predetermined percentile associated with the corresponding threshold ratio value, then the target can be associated with the known target. For example, if the R_1 value from the “live” procedure is calculated as 0.55, then this value meets or exceeds the 80th percentile (predetermined percentile) associated with the corresponding threshold ratio value of 0.57 for R_1 of the known stone material and the target material can be associated with a known target (in this case stone). If the R_1 value from the “live” procedure is calculated as 0.67, then this value meets or exceeds the 80th percentile associated with the corresponding threshold ratio value of 0.66 for R_1 of the known tissue material and the target material can be associated with a known target (in this case tissue). Note that in this example the R_1 value of 0.66 would not meet or exceed the predetermined percentile value associated

with the corresponding threshold ratio value for R_1 of the stone material and therefore the target in this second instance cannot be identified as stone.

It is to be appreciated that other selection criterion may perform the functionality of the threshold ratio value. For example, other math formulas or algorithms may be used to establish a source of comparison or setting a reference. Furthermore, in some embodiments the selection criteria may be automatically and dynamically adjusted during the procedure, based on the log (store data) of recorded stone/non-stone signals and operator's actions.

It is noted that during calibration if no pair (of ratio values) provides sufficient separation between the targets, then automatic control of laser emission may be disabled or, alternatively calibration may be attempted again with different laser settings (e.g., laser power).

It is to be appreciated that one or more components of the calibration may be implemented using a computing device, such as a computer processor. For instance, software may be provided on the computing device that performs one or more steps of the calibration procedure and can include prompts for the operator (e.g., position the fiber to obtain reflected intensity values from a known target such as tissue or stone). It is to be appreciated that software may also be provided on the computing device that performs one or more steps of the procedure (after calibration), which is discussed in further detail below.

During Procedure

In accordance with one embodiment, the analysis performed in the calibration forms the basis for the actual treatment procedure. A flowchart for one example of a lithotripsy procedure or process 1055 is shown in FIG. 21b in accordance with one embodiment. Broadly speaking, the analysis performed in the calibration (step 1000 in FIG. 21b, an example of which is shown in FIG. 21a) forms the basis for the actual lithotripsy procedure, including the basis for whether an automatic mode 1071 is initiated (or recommended to a surgeon), or the system recommends remaining in manual mode at 1073 during the actual procedure.

According to at least one embodiment, the computing device 650 is configured to generate a control signal for controlling operation of the treatment laser 610 based on the identification of the target 630. In some embodiments, the target is a stone, and the non-

treatment target is tissue or a surgical component or a surgical treatment area medium (e.g., liquid). In some embodiments, the control signal includes activation, de-activation, or an operating parameter setting for the treatment laser. Non-limiting examples of operating parameter settings for the treatment laser include pulse peak power, pulse shape, pulse width, pulse energy, interval between pulses, repetition rate, average power, and continuous wave (CW) power.

The reflected signal intensities may also be used during the course of a procedure. As mentioned previously, at least one ratio for a target in the surgical treatment area can be determined by computing device 650 from the reflected intensity value (s) using the photodetectors 646a-646i. This is shown as step 1065 in FIG. 21b. For example, if the calibration routine produced results that indicated that R_1 provided the best difference value (and hence the best separation), then R_1 would be determined for an actual target in the surgical treatment area. The ratio value R_1 of an actual target would then be compared (e.g., by the computing device 650) with the threshold ratio value that was determined in the calibration routine (as indicated at step 1067 in FIG. 21b). The computing device 650 then associates the target in the surgical treatment area with a known target based on the comparison. In some embodiments, the computing device 650 determines whether the target in the surgical treatment area is a treatment target based on the comparison. At step 1069 the target in the surgical treatment area is identified. For example, in response to a determination that the known target is a treatment target (e.g., stone), the target is identified as a treatment target, and in response to a determination that the known target is not a treatment target, the target is identified as a non-treatment target (e.g., tissue, surgical component, treatment medium). The type of treatment target is input to the computing device 650 by an operator.

Once the target in the surgical treatment area is identified, then either an automatic mode (step 1071) or a manual mode (1073) is recommended to the surgeon (or operator). For example, if the target in the surgical treatment area is identified as stone material, then an automatic mode may be recommended by the computing device 650. This recommendation can be relayed to the surgeon any one of a number of different ways, e.g., through a visual representation (on a screen), and/or audible notification, and/or tactile notification, as described in more detail below.

If automatic mode is recommended, then at 1075 the surgeon makes a decision as to whether or not the treatment proceeds (yes) in automatic mode (at 1079) or (no) proceeds in manual mode (at 1077). Automatic mode enables the computing device 650 to control the firing of the laser (laser emission) without the aid of the surgeon. Manual mode allows for the surgeon to remain in control of actuating the laser device 610 to fire. No matter which mode, the process commences by positioning the distal end of the surgical fiber in quasi-contact with the stone (if stone is the treatment target), activating the treatment laser source so as to deliver laser radiation through the surgical fiber, and ablating at least a portion of the stone using the laser radiation. One or more additional steps may include inserting an endoscopic surgical instrument (that includes the surgical fiber) into the internal organ (e.g., kidney) of the patient.

In accordance with at least one embodiment, the procedure terminates once all stones above a certain size have been removed (e.g., by ablation) from the surgical treatment area (e.g., ureter, urethra, kidney, bladder, etc.). In some embodiments, this entails stone particles that are less than 250 microns in diameter, since these can be passed naturally by the human body. In some embodiments, the procedure removes stones with an efficacy such that no stones are detectable in the patient at a 7-day post-surgery follow-up appointment.

It is to be appreciated that alternative methods to what is described in FIG. 21b are also within the scope of this disclosure. For instance, the surgical fiber may be positioned into the internal organ of the patient and the distal end may then be positioned in quasi-contact with at least one known target. The calibration process may then commence, which includes collecting the reflected light that characterizes the known target (e.g., tissue). Once calibration is complete, the distal end of the fiber may be positioned in quasi-contact with a target (e.g., stone) and if the target is identified as a treatment target (based at least in part on the calibration), then the treatment laser is activated and the stone may be ablated using laser radiation emitted by the treatment laser.

As will be recognized by those of skill in the art, conventional lithotripsy procedures make use of a foot switch or foot pedal that is activated by the surgeon or user that in turn functions to activate the treatment laser and hence stone fragmentation. Conventionally, the foot switch is activated under direct visual control by the user. This action can be performed many times during the procedure because the user will switch off the laser when he or she

sees that the fiber tip is in proximity to the mucosal wall and determines that damage to the mucosal wall may occur if the laser fires. Repeated on/off cycling of the footswitch leads to a longer procedure time, and fatigue in the user creates the potential to direct laser energy at an unintentional target, such as tissue. In accordance with an additional aspect of this disclosure, the user may continuously depress the foot pedal and the computing device 650 (when in an automatic mode of operation) actually activates the laser and modulates the output based on the identified target. For example, if the treatment laser is positioned in front of identified stone material (when the treatment target is stone), the computing device 650 will control the treatment laser to fire the laser, and if a few seconds later the treatment laser is positioned in front of tissue, (a non-treatment target) the computing device 650 will control the treatment laser to de-activate, all while the foot pedal is still depressed by the user. This reduces procedure time, eliminates fatigue by the user, and allows for a safer procedure.

According to another embodiment, the operator can have an opportunity to use and/or adjust the separation criterion during the actual procedure to optimize the efficacy/safety balance. In accordance with at least one embodiment, determining whether the target is a treatment target or a non-treatment target is performed in between every N laser pulses emitted by a treatment laser, where N is an integer between 1 and 1000. In one embodiment, feedback signals (reflected light intensities of light 615 reflected off target) are analyzed during the procedure between the laser pulses, e.g., after every Nth pulse, and in some embodiments, N equals 1 so the analysis occurs after every pulse. In some embodiments, determining whether the known target is a treatment target or a non-treatment target is performed after modifying a laser operating parameter of a treatment laser. For instance, target analysis may be performed if the treatment laser power, frequency, or other operating parameter is modified or otherwise changed. An example of this process is shown in the time schematic at the bottom of FIG. 23. In this example, in between each pulse, the reflected signal ratios are analyzed to determine if the distal end of the scope (which includes the laser fiber) is positioned in front of a stone, tissue, or instrument (surgical component). The desired target in this instance is stone material and laser emission is disabled when stone material is not detected (to prevent tissue damage) or enabled or otherwise resumed when stone material is detected.

In accordance with various aspects, the system is configured to operate in either a “passive” or “active” mode. In the passive mode, the system will notify the operator when the fiber is not positioned in front of or on the stone (based on the selected separation criterion). The notification to the operator can be achieved through a variety of methods, including (but not limited to), audio (e.g., a specific tone or voice message), visual (e.g., through light indicators), tactile (e.g., through vibrating mechanical feedback, such as in the scope handle), or picture-in-picture video (e.g., when information from the feedback sensor is added to the scope video to create an augmented picture). In the active mode, the system (i.e., computer controller/computing device) will have control over the laser emission.

Emergency Room application - In accordance with certain embodiments, a laser system configured in a similar manner as described herein in reference to system 600 can be implemented in an emergency room environment. For example, the identification of the target as a treatment target or a non-treatment target based at least in part on the optical data and the predetermined calibration based on at least two known targets may be performed during an emergency room visit by a patient. In such a setting, a patient arrives at the emergency room with a stone positioned in the urethra. The endoscope can be positioned by emergency room personnel in the urethra with the fiber tip positioned in front of the stone. This can be performed by the user using the imaging camera incorporated into the endoscope and coupled with a video screen. The calibration routine (as outlined in FIG. 21a) can be performed by the computing device 650 in combination with the user directing the distal tip of the endoscope to one or more known targets including tissue (e.g., wall of urethra) and/or stone material. An aspect of this method and implementation is that the user (e.g., emergency room surgeon) can perform the procedure without comprehensive urological training and thus substantially increase the quality of care for the patient and simultaneously reduce the cost of the procedure.

Other Calibration Options

Returning now to aspects related to the calibration procedure outlined in FIG. 21a, according to some embodiments the in-patient calibration procedure can be configured with additional capabilities or functionalities. For example, in one embodiment an additional

calibration can be performed in the ambient medium (liquid), i.e., when all the targets are sufficiently (e.g., more than 3 to 7 mm) far away from the distal tip of the fiber. Such information can help improve recognition of the situation when the fiber is too far from the target to deliver the energy in an efficient manner. On the other hand, in this situation the system can allow laser emission if the “popcorn” mode of operation is selected by the operator. In addition, an extra calibration procedure may be performed with the tools/instruments placed in or near the procedure fields (e.g., stent, ureteral access sheath etc.), as mentioned previously (i.e., the stent, ureteral access sheath, and other surgical components would be “known” targets in the calibration routine).

In accordance with an additional embodiment, the use of a decision space can be implemented for purposes of evaluating reflected intensity signals. This approach can function to enhance the quality of the stone/tissue separation evaluation. In particular, rather than selecting one single pair of the wavelengths to proceed, two or more pairs demonstrating the best results can be used. A multidimensional decision space having M decision options based on at least two ratios may be defined, where M is the total number of ratios. In some embodiments, M is an integer between 1 and 100. FIG. 24 is a schematic of one example of a two-dimensional decision space using two pairs of selected wavelengths (i.e., two ratios of reflected intensity values, e.g., R_1 (I_1/I_2) and R_2 (I_2/I_3)). In this example, $n=3$ (n denotes the number of possible outcomes, e.g., stone, tissue, etc.), and the decision space becomes two-dimensional (2D). In some embodiments, multidimensional threshold separation lines between the n decision options (separation surfaces) can be defined in the multidimensional decision space for discrimination between each of the M ratios. This approach is also shown in FIG. 24, where a single separation criterion becomes a separation line, as indicated. When the number of the wavelength pairs used further increases, the dimensionality of the decision space increases as well. For example, three wavelength pairs would result in a 3D space. The number of separation surfaces will increase with the number of possible outcomes but will not necessarily be equal to the number of possible outcomes.

As previously discussed, the robustness of stone/tissue separation can be further enhanced by using two or more pairs (of wavelengths) (i.e., ratios). In the situation where three wavelengths are selected, at least three ratios (of pairs) are available. In most cases, two pairs provide good separation between the stones and soft tissue while the third pair

shows minimal separation. Use of the two “best separation” pairs can provide a more accurate distinction or discrimination between the targets than use of just one pair.

According to at least one embodiment, a weighting factor may be assigned to a ratio associated with the largest difference value. For instance, if two ratios R_1 and R_2 are calculated, then the ratio R that provides better separation R) is assigned a greater weightage. For weight, a quantity called “effect size” commonly used in statistical methods is used. The effect size takes into account both the difference in means as well as variability with the multiple measurements for the two different targets.

Method 1: According to one embodiment, a linear combination of the two ratios with the weighting factors is used. An example of this approach is shown in FIG. 25, which shows histograms collected during calibration for two ratios, with ratio 1, r_1 on the left side, and ratio 2, r_2 shown on the right side of FIG. 25. The weighted ratio is calculated as: $(\alpha_1 * r_1 + \alpha_2 * r_2) / (\alpha_1 + \alpha_2)$ where α_1 , α_2 are the weighting factors and calculated from

$\alpha_1 = \text{effect_size_1} = (r1_m_soft - r1_m_stone) / (\text{geometric mean of } s1_stone \text{ and } s1_soft),$

$\alpha_2 = \text{effect_size_2} = (r2_m_soft - r2_m_stone) / (\text{geometric mean of } s2_stone \text{ and } s2_soft)$

where

r_1 = ratio 1

r_2 = ratio 2

$r1_m_stone$ = mean of r_1 for stone

$r1_m_soft$ = mean of r_1 for tissue

$r2_m_stone$ = mean of r_2 for stone

$r3_m_soft$ = mean of r_2 for tissue

$s1_stone$ = standard deviation for ratio 1 of stone

$s1_soft$ = standard deviation for ratio 1 of tissue

$s2_stone$ = standard deviation for ratio 2 of stone

$s2_soft$ = standard deviation for ratio 2 of tissue

FIG. 26 is a schematic explaining the variables used, the calculation of the effect size, the weighting factors, and the build of histogram post calibration measurements. In another

embodiment, in computation of the effect size, instead of the mean, other measures of the center of the data are used rather than the mean, such as the median.

Method 2: According to another embodiments, optimization by varying the weighting factors may be used. For example, weighting factors can be defined as beta1 and beta2 so the expression for weighted r is

$$\text{Weighted } r = (\text{beta1} * r1 + \text{beta2} * r2) / (\text{beta1} + \text{beta2})$$

For beta1: lower-limit: upper-limit: increment

For beta2: lower-limit: upper-limit: increment

Calculate weighted r.

End loop for beta2

End loop for beta1

In accordance with at least one aspect the (beta1, beta2) combination that maximizes the distinction is determined. As an example, distinction = ratio of effect-sizes (where effect-size is the ratio of mean/size distribution (s.d.) for stone, soft tissue).

In some embodiments, information/data from prior procedures may be used as part of the analysis. In accordance with an additional embodiment, the target may be identified as a treatment target or a non-treatment target based at least in part on a comparison against historic and/or stored data from previously recorded reflected intensity values. In addition, the calibration procedure performed at the start of a given procedure may make use of historic and/or stored data. It is noted that stored data refers to data that is not indicative of the current target site and can refer to reflected intensity values previously measured and recorded or otherwise collected from prior procedures or experiments and stored in a database (prior to the procedure being performed).

As mentioned, the calibration procedure may make use of historic and/or stored data. In accordance with certain embodiments, the methods and systems disclosed herein may determine a ratio value associated with a predetermined percentile for each known target using multiple reflected intensity values, and then establish the threshold ratio value based on this ratio value and a predetermined scaling factor. For instance, the threshold ratio value T may be expressed as:

$$T = A * X$$

where A is a predetermined scaling factor and X is the ratio value associated with a predetermined percentile. In accordance with certain embodiments, the predetermined scaling factor is based at least in part on historic reflected light intensity values. In essence, this implies that the threshold ratio value for a particular target material can be determined ahead of a procedure and stored and then used during a future procedure. In addition, the calibration routine may implement the use of a single known target, such as tissue, and the threshold ratio value can be used as a source of comparison against the calculated ratio values obtained from the reflected intensities of the “current” known target (e.g., tissue).

In some embodiments, the stored data may correspond to a multivariate dataset according to some embodiments. The computing device 650 may be configured to make this comparison. In some embodiments, information about already performed clinical cases can be organized and stored into a database. The database can be structured in terms of anatomical locations (bladder, ureter, kidney), the instrument used (rigid, flexible), fiber size, etc. Once these parameters are defined for a planned procedure, the data points from the database can be added (and in some instances with a certain weight) to the in-patient calibration data points.

In accordance with other embodiments, the target may be identified as a treatment target or a non-treatment target based at least in part on a mathematical model and/or algorithm that is utilized by the computing device 650.

According to some embodiments, the target is identified as a treatment target or a non-treatment target based at least in part on a machine learning model. The computing device 650 may be configured to utilize the machine learning model (and/or execute a machine learning model) for making this assessment. For example, an artificial intelligence system can analyze the success rate of the previously performed procedures and adjust the separation criteria (lines, surfaces etc.) using machine-learning techniques. The machine learning algorithm may be implemented via machine learning software installed on the computing device 650 and typically comprises a neural network and is configured to undergo at least one training phase as understood by those skilled in the art.

Use of the methods and system described herein (e.g., in system 600) can measurably improve clinical outcomes of the lithotripsy procedure. The list of parameters (not all-inclusive) that can be improved include:

Number of mucosal thermal damage zones
 Total surface area of mucosa thermal damage
 Total procedure time
 Total laser procedure time (i.e., the time duration from the time the laser is first turned on until the laser is last turned off)
 Total footswitch (foot pedal) ON time
 Total laser emission time (i.e., the total time the laser is firing)
 Actual duty cycle = total emission time / total laser ON time
 Number of footswitch press/release cycles
 Stone treatment time (ablation rate)
 Stone-free rate
 Fragment size distribution
 Complications grading

FIG. 27 is a table listing six (6) examples of lithotripsy procedures performed on actual patients. Cases 1, 3, 5, and 6 show results from procedures performed using a system as described above in reference to system 600 of FIG. 20 and demonstrate the beneficial effects of using the disclosed system. For example, in all cases with active stone identification, the total laser procedure as well as the total procedure time were reduced in comparison to respective comparison cases 2 and 4, which were performed without the use of the disclosed configuration. In addition, laser emission time, the actual duty cycle, and the number of off/on foot pedal cycles were reduced in the cases using the disclosed system when compared to their control cases. The amount of time the foot pedal was on was also reduced for the cases using the disclosed system.

In accordance with an additional aspect, the system can be used to recognize bleeding and suggest to the doctor the use of hemostatic parameters. In the active mode, a switch to the hemostatic parameters can be automated.

Additional Concepts and/or Improvements

In accordance with at least one embodiment, the signal strength of reflected intensity signals received by the computing device 650 is improved by incorporating custom beam splitters in beam divider 685 (also see beam splitters 214, 216, 218, 220 of FIG. 3) that are

configured to increase the signal level and as a result, increase the signal-to-noise (SN) ratio for a particular channel. For example, a custom beam splitter may be implemented that is configured with a high level of transmission in the desired wavelength band and high reflection in the wavelength bands outside of the desired wavelength band. In some instances, the use of a custom beam splitter may increase the SN ratio by a factor of 2, and in some instances is improved by a factor of at least 3 in comparison with off-the-shelf 50/50 beam splitters. This increase in the SN ratio in turn can also enhance (in some instances by a factor of 2) the separation between the stone and tissue ratios (e.g., the frequency distribution will more directly reflect a “good” separation such as that shown in FIG. 22a).

In accordance with another embodiment, spectral detection and/or analysis may be performed on light coming from light source 615 before it reaches the target 630 (e.g., incoming LED signal). For example, in some embodiments, the spectrum (reflected light intensity across the entire light source wavelength band) from at least one known target (e.g., stone and/or tissue) is normalized to the spectrum of the light source 615. This is done in certain instances because different light sources (e.g., broadband light sources) have widely varying intensity (illumination) profiles from one another. One manufacturer may have an intensity peak at around 460 nm, whereas another manufacturer may have an intensity peak at 625 nm, whereas another may have a peak at 590 nm.

In accordance with another embodiment, a mathematical algorithm or model between different ratio values may be determined and used as part of the process/algorithm for determining a treatment target from a non-treatment target. This can be performed by the computing device. In other words, the computing device is configured to identify the target as a treatment target or a non-treatment target based at least in part on a mathematical algorithm derived at least in part from at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band. In accordance with at least one embodiment, a curve fitting algorithm may be applied to different ratio values. In some instances, a curve may be established for different ratio values based on reflected intensity values (I_1 at 475 nm, I_2 at 550 nm, and I_3 at 575 nm) taken as part of a calibration routine and/or during a procedure. For example, each of FIGS. 28a and 29a show a plot where one ratio I_1/I_3 (y axis) is plotted against a second ratio I_1/I_2 (x axis) based on reflected intensity values from two known target materials (stone and tissue).

In this case, two linear curves (one for tissue, one for stone) could be determined or otherwise established as the mathematical algorithm between the two ratio values, as indicated in the figure. The equation defining this linear curve can serve as an additional parameter that can be used for distinguishing tissue from stone during a procedure. A similar plot is shown in FIGS. 28b and 29b for I_2/I_3 plotted against I_1/I_2 for stone and tissue targets. All of these plots are constructed from data taken from two known targets (stone and tissue) over the course of one or more procedures, which was analyzed and stored, similar to the type of data discussed above in reference to historic and/or stored data.

As can be seen in both sets of figures, the linear fitting curves (and/or aspects of the curves, such as the slope) based on the ratios from the reflected intensity values for each of the stone and tissue are different from one another. According to some embodiments, the curve fitting algorithms based on different ratios and known targets can be measured, calculated and stored and used in further calibrations and/or actual procedures. For example, during a procedure, ratio values are calculated for a target that is currently in front of the distal tip of the fiber and the computing device can compare these measured intensity values and calculated ratio values to the curve fitting algorithms to determine what target material is in front of the distal tip of the fiber. In other words, the computing device can determine if the ratio values calculated during the procedure correspond with the stored curve fitting algorithms. It is to be appreciated that the stored and calculated ratio values may be obtained in some instances from in vitro and/or clinical testing. Taking FIG. 28a as an example, if measured ratio values during a live procedure gives coordinates of 0.85, 0.63 (x,y) and these coordinates "fit" or otherwise correspond to the stored linear equation for tissue (marked as the linear curve for tissue) within a predetermined statistical confidence level, then this can serve as an additional parameter to calculate and compare against and adds additional confidence that the target in front of the distal tip of the fiber is tissue. In a similar way, if the measured ratio values during a live procedure gives coordinates of 0.60, 0.38 and these coordinates fit to the stored linear equation for stone, then this raises the confidence level that the target at the distal tip of the fiber is stone.

According to another embodiment, the ellipses shown in FIGS. 28a,b, 29a,b may also be determined and used during a calibration and/or procedure. This ellipse may also be referred to as a confidence ellipse. The ellipses shown in these figures correspond to tissue

and are generated during a tissue calibration procedure where multiple reflected intensity values and the corresponding ratios are calculated and plotted (and the known target is tissue). According to some embodiments, the ellipse can be determined based on this measured calibration data, and in some embodiments stored ratio values may also be used (or used instead). During the procedure, measured ratio values that yield coordinates outside of the ellipse may be considered non-tissue material (e.g., stone). As an example, if a kidney stone ablation procedure is underway, and during a procedure a coordinate value is calculated as 0.90, 0.70 (using FIG. 28a), then this falls into the interior of the tissue ellipse and the laser can be shut off (since tissue is not the target). If the coordinate value comes back as 0.65, 0.38, then this falls outside the tissue ellipse and the target can be considered stone and treatment may continue. However, as can be seen in FIG. 28a, if a measured procedure ratio value gives coordinates of 0.70, 0.45, this coordinate is “within” the ellipse but appears to fall into the black data for stone (i.e., there is some overlap). At this point, this coordinate could be compared to the stored linear equations for tissue and stone and in this instance, they fit the linear equation for stone, so it is more likely that the target in front of the distal tip of the fiber is stone.

Although a linear curve fitting algorithm is discussed in these particular examples, it is to be appreciated that other types of mathematical relationships are within the scope of this disclosure, including non-linear, logarithmic, exponential, or polynomial curve fitting algorithm. IN addition, it is to be appreciated that although a 2D graph is shown, the same could be repeated with a three-dimensional space (using a 3rd ratio) where an ellipsoid could be generated.

The present disclosure has described one or more preferred non-limiting examples, and it should be appreciated that many equivalents, alternatives, variations, and modifications, aside from those expressly stated, are possible and within the scope of the disclosure.

It is to be understood that the disclosure is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The disclosure is capable of other non-limiting examples and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description

and should not be regarded as limiting. The use of “including,” “comprising,” or “having” and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items. Unless specified or limited otherwise, the terms “mounted,” “connected,” “supported,” and “coupled” and variations thereof are used broadly and encompass both direct and indirect mountings, connections, supports, and couplings. Further, “connected” and “coupled” are not restricted to physical or mechanical connections or couplings.

As used herein, unless otherwise limited or defined, discussion of particular directions is provided by example only, with regard to particular non-limiting examples or relevant illustrations. For example, discussion of “top,” “front,” or “back” features is generally intended as a description only of the orientation of such features relative to a reference frame of a particular example or illustration. Correspondingly, for example, a “top” feature may sometimes be disposed below a “bottom” feature (and so on), in some arrangements or non-limiting examples. Further, references to particular rotational or other movements (e.g., counterclockwise rotation) is generally intended as a description only of movement relative a reference frame of a particular example of illustration.

In some non-limiting examples, aspects of the disclosure, including computerized implementations of methods according to the disclosure, can be implemented as a system, method, apparatus, or article of manufacture using standard programming or engineering techniques to produce software, firmware, hardware, or any combination thereof to control a processor device (e.g., a serial or parallel general purpose or specialized processor chip, a single- or multi-core chip, a microprocessor, a field programmable gate array, any variety of combinations of a control unit, arithmetic logic unit, and processor register, and so on), a computer (e.g., a processor device operatively coupled to a memory), or another electronically operated controller to implement aspects detailed herein. Accordingly, for example, non-limiting examples of the disclosure can be implemented as a set of instructions, tangibly embodied on a non-transitory computer-readable media, such that a processor device can implement the instructions based upon reading the instructions from the computer-readable media. Some non-limiting examples of the disclosure can include (or utilize) a control device such as an automation device, a special purpose or general-purpose computer including various computer hardware, software, firmware, and so on, consistent with the

discussion below. As specific examples, a control device can include a processor, a microcontroller, a field-programmable gate array, a programmable logic controller, logic gates etc., and other typical components that are known in the art for implementation of appropriate functionality (e.g., memory, communication systems, power sources, user interfaces and other inputs, etc.).

The term “article of manufacture” as used herein is intended to encompass a computer program accessible from any computer-readable device, carrier (e.g., non-transitory signals), or media (e.g., non-transitory media). For example, computer-readable media can include but are not limited to magnetic storage devices (e.g., hard disk, floppy disk, magnetic strips, and so on), optical disks (e.g., compact disk (CD), digital versatile disk (DVD), and so on), smart cards, and flash memory devices (e.g., card, stick, and so on). Additionally it should be appreciated that a carrier wave can be employed to carry computer-readable electronic data such as those used in transmitting and receiving electronic mail or in accessing a network such as the Internet or a local area network (LAN). Those skilled in the art will recognize that many modifications may be made to these configurations without departing from the scope or spirit of the claimed subject matter.

Certain operations of methods according to the disclosure, or of systems executing those methods, may be represented schematically in the FIGS. or otherwise discussed herein. Unless otherwise specified or limited, representation in the FIGS. of particular operations in particular spatial order may not necessarily require those operations to be executed in a particular sequence corresponding to the particular spatial order. Correspondingly, certain operations represented in the FIGS., or otherwise disclosed herein, can be executed in different orders than are expressly illustrated or described, as appropriate for particular non-limiting examples of the disclosure. Further, in some non-limiting examples, certain operations can be executed in parallel, including by dedicated parallel processing devices, or separate computing devices configured to interoperate as part of a large system.

As used herein in the context of computer implementation, unless otherwise specified or limited, the terms “component,” “system,” “module,” and the like are intended to encompass part or all of computer-related systems that include hardware, software, a combination of hardware and software, or software in execution. For example, a component may be, but is not limited to being, a processor device, a process being executed (or

executable) by a processor device, an object, an executable, a thread of execution, a computer program, or a computer. By way of illustration, both an application running on a computer and the computer can be a component. One or more components (or system, module, and so on) may reside within a process or thread of execution, may be localized on one computer, may be distributed between two or more computers or other processor devices, or may be included within another component (or system, module, and so on).

In some implementations, devices or systems disclosed herein can be utilized or installed using methods embodying aspects of the disclosure. Correspondingly, description herein of particular features, capabilities, or intended purposes of a device or system is generally intended to inherently include disclosure of a method of using such features for the intended purposes, a method of implementing such capabilities, and a method of installing disclosed (or otherwise known) components to support these purposes or capabilities. Similarly, unless otherwise indicated or limited, discussion herein of any method of manufacturing or using a particular device or system, including installing the device or system, is intended to inherently include disclosure, as non-limiting examples of the disclosure, of the utilized features and implemented capabilities of such device or system.

As used herein, unless otherwise defined or limited, ordinal numbers are used herein for convenience of reference based generally on the order in which particular components are presented for the relevant part of the disclosure. In this regard, for example, designations such as “first,” “second,” etc., generally indicate only the order in which the relevant component is introduced for discussion and generally do not indicate or require a particular spatial arrangement, functional or structural primacy or order.

As used herein, unless otherwise defined or limited, directional terms are used for convenience of reference for discussion of particular figures or examples. For example, references to downward (or other) directions or top (or other) positions may be used to discuss aspects of a particular example or figure, but do not necessarily require similar orientation or geometry in all installations or configurations.

This discussion is presented to enable a person skilled in the art to make and use non-limiting examples of the disclosure. Various modifications to the illustrated examples will be readily apparent to those skilled in the art, and the generic principles herein can be applied to other examples and applications without departing from the principles disclosed herein.

Thus, non-limiting examples of the disclosure are not intended to be limited to non-limiting examples shown, but are to be accorded the widest scope consistent with the principles and features disclosed herein and the claims below. The following detailed description is to be read with reference to the figures, in which like elements in different figures have like reference numerals. The figures, which are not necessarily to scale, depict selected examples and are not intended to limit the scope of the disclosure. Skilled artisans will recognize the examples provided herein have many useful alternatives and fall within the scope of the disclosure.

The aspects disclosed herein in accordance with the present disclosure, are not limited in their application to the details of construction and the arrangement of components set forth in the following description or illustrated in the accompanying drawings. These aspects are capable of assuming other non-limiting examples and of being practiced or of being carried out in various ways. Examples of specific implementations are provided herein for illustrative purposes only and are not intended to be limiting. In particular, acts, components, elements, and features discussed in connection with any one or more non-limiting examples are not intended to be excluded from a similar role in any other non-limiting examples.

Also, the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. Any references to examples, non-limiting examples, components, elements or acts of the systems and methods herein referred to in the singular may also embrace non-limiting examples including a plurality, and any references in plural to any non-limiting example, component, element or act herein may also embrace non-limiting examples including only a singularity. References in the singular or plural form are not intended to limit the presently disclosed systems or methods, their components, acts, or elements. The use herein of “including,” “comprising,” “having,” “containing,” “involving,” and variations thereof is meant to encompass the items listed thereafter and equivalents thereof as well as additional items. References to “or” may be construed as inclusive so that any terms described using “or” may indicate any of a single, more than one, and all of the described terms. In addition, in the event of inconsistent usages of terms between this document and documents incorporated herein by reference, the term usage in the incorporated reference is supplementary to that of this document; for irreconcilable inconsistencies, the term usage in this document controls. Moreover, titles or subtitles may

be used in the specification for the convenience of a reader, which shall have no influence on the scope of the present disclosure.

Having thus described several aspects of at least one example, it is to be appreciated that various alterations, modifications, and improvements will readily occur to those skilled in the art. For instance, examples disclosed herein may also be used in other contexts. Such alterations, modifications, and improvements are intended to be part of this disclosure, and are intended to be within the scope of the examples discussed herein. Accordingly, the foregoing description and drawings are by way of example only.

As used herein, “relevant quantity” – scalar or vector quantity obtained from the collected data through application of at least one of the following operations: weighted integration, weighted differentiation, averaging, normalization to reference data, addition, subtraction, multiplication, division. The particular set and order of operations is selected by the final analysis objective (e.g., discrimination of target vs. non-target tissue). So obtained quantity is then compared to a set of generally multi-dimensional thresholds to achieve desired analysis goal.

As used herein, “data” or “optical data” – any sequence or combination of signals obtained from the optical detectors in the system, including, but not limited to, raw signal values, temporal profiles of the signals, spectral signatures of the signals, max/min values of the signals, correlation functions of the signals, mean values of the signals over a time period, standard variations of the signals.

As used herein, target material and stone can be used interchangeably. For example, a target material can be a stone, and a stone can be a target material.

It is to be appreciated that although most of the non-limiting examples disclosed herein deal with laser lithotripsy of urinary calculi, other applications that address other conditions, such as bladder and other body stones, tissue incision, vaporization, and coagulation, other body areas and forms of directed energy are also within the scope of this disclosure.

Various features and advantages of the disclosure are set forth in the following claims.

CLAIMS

What is claimed is:

1. A method for controlling a surgical laser system comprising:
providing a surgical fiber configured to receive light reflected from a target in a surgical treatment area and deliver laser radiation from a treatment laser source to a treatment target; and
providing a computing device configured to couple with at least two photodetectors, each photodetector configured to detect an intensity of reflected light from the target in a different selected wavelength band, the computing device further configured to:
receive the reflected light intensity in at least two selected wavelength bands;
generate optical data corresponding to the reflected light intensity; and
identify the target as the treatment target or a non-treatment target based at least in part on the optical data and a predetermined calibration based on at least one known target.
2. The method of claim 1, further comprising performing the predetermined calibration.
3. The method of claim 2, wherein performing the predetermined calibration includes positioning a distal end of the surgical fiber in quasi-contact with at least one known target.
4. The method of claim 3, wherein the at least one known target is stone, tissue, a surgical component, or a surgical treatment area medium.
5. The method of claim 2, wherein at least one of generating the optical data and performing the predetermined calibration includes determining at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band.
6. The method of claim 5, wherein performing the predetermined calibration further comprises:

obtaining multiple reflected light intensity values from each known target of the at least one known target; and
establishing a threshold ratio value based at least in part on the multiple reflected light intensity values from each known target.

7. The method of claim 6, further comprising:
determining a ratio value associated with a predetermined percentile for each known target using the multiple reflected light intensity values; and
establishing the threshold ratio value based on the ratio value associated with the predetermined percentile and a predetermined scaling factor.
8. The method of claim 7, wherein the predetermined scaling factor is based at least in part on historic reflected light intensity values.
9. The method of claim 7, wherein the predetermined percentile is based at least in part on historic reflected light intensity values from at least two known targets.
10. The method of claim 9, wherein the predetermined percentile is in a range selected from 50th to 97th.
11. The method of claim 10, wherein the predetermined percentile is the 80th percentile.
12. The method of claim 7, further comprising:
generating at least one frequency distribution of values for each ratio of the at least one ratio, and
determining the ratio value associated with the predetermined percentile for each known target based on the frequency distribution.
13. The method of claim 6, wherein generating the optical data includes determining the at least one ratio for the target in the surgical treatment area, and identifying the target comprises:

comparing a ratio value of the at least one ratio for the target in the surgical treatment area to the threshold ratio value; and

determining whether the target in the surgical treatment area is a treatment target based on the comparison.

14. The method of claim 13, further comprising:

in response to a determination that the target in the surgical treatment area is a treatment target, identifying the target as a treatment target, or

in response to a determination that the target in the surgical treatment area is not a treatment target, identifying the target as a non-treatment target.

15. The method of claim 14, wherein determining whether the target in the surgical treatment area is a treatment target is performed in between every N laser pulses emitted by the treatment laser source, wherein N is an integer between 1 and 1000.

16. The method of claim 14, wherein determining whether the target in the surgical treatment area is a treatment target is performed after modifying a laser operating parameter of the treatment laser source.

17. The method of claim 6, wherein establishing the threshold ratio value further comprises defining a multidimensional decision space having n decision options based on M ratios, where M is an integer between 1 and 100.

18. The method of claim 17, further comprising defining multidimensional threshold separation lines between the n decision options in the multidimensional decision space for discrimination between each of the M ratios.

19. The method of claim 7, further comprising:

determining a difference value between a first ratio value associated with the predetermined percentile for a first known target and a second ratio value associated with the predetermined percentile for a second known target;

comparing the difference value to a threshold difference value; and
in response to a determination that the difference value meets or exceeds the threshold difference value, establishing the threshold ratio value based on the first ratio value and the second ratio value.

20. The method of claim 19, further comprising:
generating at least one frequency distribution of values for each ratio of the at least one ratio, and
determining the ratio value associated with the predetermined percentile for each known target based on the frequency distribution.
21. The method of claim 19, further comprising determining the threshold difference value, wherein determining the threshold difference value comprises:
comparing a first difference value associated with a frequency distribution generated using a first ratio of the at least one ratio to a second difference value associated with a frequency distribution generated using a second ratio of the at least one ratio; and
determining whether the first difference value or the second difference value is larger;
and
in response to a determination that the first difference value is larger than the second difference value, selecting the first difference value as the threshold difference value, or
in response to a determination that the second difference value is larger than the first difference value, selecting the second difference value as the threshold difference value.
22. The method of claim 21, further comprising assigning a weighting factor to the ratio associated with the largest difference value.
23. The method of claim 19, wherein the threshold ratio value is based on an average of the first and second ratio values.

24. The method of claim 1, wherein the computing device is further configured to generate a control signal for controlling operation of a treatment laser based on the identification of the target.
25. The method of claim 24, wherein the control signal includes activation, de-activation or an operating parameter setting for the treatment laser.
26. The method of claim 1, wherein the computing device is further configured to generate an audio, visual, or tactile signal to an operator based on the identification of the target.
27. The method of claim 1, wherein the treatment target is a stone and the non-treatment target is tissue or a surgical component or a surgical treatment area medium.
28. The method of claim 27, further comprising:
positioning the distal end of the surgical fiber in quasi-contact with the stone;
activating the treatment laser source so as to deliver laser radiation through the surgical fiber; and
ablating at least a portion of the stone using the laser radiation.
29. The method of claim 1, wherein the computing device is configured to couple with three photodetectors and the three different selected wavelength bands are selected from a group consisting of: about 400-410 nm, about 440-480 nm, about 460-480 nm, about 510-530 nm, about 540-560 nm, about 550-570 nm, about 570-580 nm, about 580-600 nm, about 600-620 nm, about 690-710 nm, about 740-760 nm, about 790-810 nm, about 920-940 nm, about 970-990 nm, and about 1150-1350 nm.
30. The method of claim 1, wherein the computing device is further configured to identify the target as a treatment target or a non-treatment target based at least in part on a comparison against stored data from previously recorded reflected intensity values.

31. The method of claim 1, wherein the computing device is further configured to identify the target as a treatment target or a non-treatment target based at least in part on a machine learning model.
32. The method of claim 1, wherein the computing device is further configured to identify the target as a treatment target or a non-treatment target based at least in part on a mathematical algorithm derived at least in part from at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band.
33. A surgical laser system comprising:
a surgical fiber configured to receive light reflected by a target in a surgical treatment area and deliver laser radiation from a treatment laser source to a treatment target; and
a computing device configured to couple with at least two photodetectors, each photodetector configured to detect an intensity of reflected light from the target in a different selected wavelength band, and configured to:
receive the reflected light intensity in at least two selected wavelength bands;
generate optical data corresponding to the reflected light intensity; and
identify the target as the treatment target or a non-treatment target based at least in part on the optical data and a predetermined calibration based on at least one known target.
34. The surgical laser system of claim 33, wherein the surgical fiber is configured to deliver light from a source of light to the surgical treatment area.
35. The surgical laser system of claim 33, wherein the at least one known target is stone, tissue, a surgical components, or a surgical treatment area medium.
36. The surgical laser system of claim 33, wherein the computing device is further configured to perform at least a portion of the predetermined calibration.

37. The surgical laser system of claim 36, wherein at least one of generating the optical data and performing the predetermined calibration includes determining at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band.

38. The surgical laser system of claim 37, wherein performing the predetermined calibration further comprises:

receiving multiple reflected light intensity values from each known target of the at least one known target; and

establishing a threshold ratio value based at least in part on the multiple reflected light intensity values from each known target.

39. The surgical laser system of claim 38, wherein the computing device is further configured to:

determine a ratio value associated with a predetermined percentile for each known target using the multiple reflected light intensity values; and

establish a threshold ratio value based on the ratio value associated with the predetermined percentile and a predetermined scaling factor.

40. The surgical laser system of claim 39, wherein the predetermined percentile is based at least in part on historic reflected light intensity values from at least two known targets.

41. The surgical laser system of claim 39, wherein the computing device is further configured to:

generate at least one frequency distribution of values for each ratio of the at least one ratio, and

determine the ratio value associated with the predetermined percentile for each known target based on the frequency distribution.

42. The surgical laser system of claim 38, wherein generating the optical data includes determining the at least one ratio for the target in the surgical treatment area, and identifying the target comprises:

comparing a ratio value of the at least one ratio for the target in the surgical treatment area to the threshold ratio value; and

determining whether the target in the surgical treatment area is a treatment target based on the comparison.

43. The surgical laser system of claim 42, wherein the computing device is configured such that:

in response to a determination that the target in the surgical treatment area is a treatment target, identifying the target as a treatment target, or

in response to a determination that the target in the surgical treatment area is not a treatment target, identifying the target as a non-treatment target.

44. The surgical laser system of claim 43, wherein the computing device is configured to determine whether the target in the surgical treatment area is a treatment target is performed in between every N pulses emitted by the treatment laser source, wherein N is an integer between 1 and 1000.

45. The surgical laser system of claim 39, wherein the computing device is further configured to:

determine a difference value between a first ratio value associated with the predetermined percentile for a first known target and a second ratio value associated with the predetermined percentile for a second known target;

compare the difference value to a threshold difference value; and

in response to a determination that the difference value meets or exceeds the threshold difference value, establish the threshold ratio value based on the first ratio value and the second ratio value.

46. The surgical laser system of claim 45, wherein the computing device is further configured to:

generate at least one frequency distribution of values for each ratio of the at least one ratio, and

determine the ratio value associated with the predetermined percentile for each known target based on the frequency distribution.

47. The surgical laser system of claim 46, wherein the computing device is further configured to determine the threshold difference value, and determining the threshold difference value comprises:

comparing a first difference value associated with a frequency distribution generated using a first ratio of the at least one ratio to a second difference value associated with a frequency distribution generated using a second ratio of the at least one ratio; and

determining whether the first difference value or the second difference value is larger; and

in response to a determination that the first difference value is larger than the second difference value, selecting the first difference value as the threshold difference value, or

in response to a determination that the second difference value is larger than the first difference value, selecting the second difference value as the threshold difference value.

48. The surgical system of claim 33, wherein the light reflected from the target is broadband light and the different selected wavelength bands include wavelength bands selected from the list consisting of: about 400-410 nm, about 440-480 nm, about 460-480 nm, about 510-530 nm, about 540-560 nm, about 550-570 nm, about 570-580 nm, about 580-600 nm, about 600-620 nm, about 690-710 nm, about 740-760 nm, about 790-810 nm, about 920-940 nm, about 970-990 nm, and about 1150-1350 nm.

49. The surgical system of claim 33, further comprising a treatment laser, and the computing device is further configured to generate a control signal for controlling operation of the treatment laser based on the identification of the target.
50. The surgical system of claim 33, wherein the treatment target is a stone and the non-treatment target is tissue or a surgical component or a surgical treatment area medium.
51. The surgical system of claim 33, wherein the computing device is further configured to generate an audio, visual, or tactile signal to an operator based on the identification of the target.
52. The surgical system of claim 33, wherein the computing device is further configured to identify the target as a treatment target or a non-treatment target based at least in part on a mathematical algorithm derived at least in part from at least one ratio of a reflected light intensity of one selected wavelength band to a reflected light intensity of a different selected wavelength band.