

DescriptionMethod and Apparatus for Detecting and Measuring
Conditions Affecting ColorSPECIFICATION

This is a continuation-in-part of U.S. patent application Serial No. 08/239,733, which is a continuation-in-part of U.S. patent application Serial No. 08/021,657, now patent No. 5,313,267. Serial No. 08/021,657 is a continuation of Serial No. 204,938, filed June 6, 1988, a continuation of Serial No., 904,369, filed September 8, 1986 a continuation-in-part of U.S. patent application Serial No. 833,661, filed February 21, 1986, which is a continuation of U.S. patent application Serial No. 514,618, filed July 18, 1983.

BACKGROUND OF THE INVENTION

This invention relates to a method and apparatus for the detection and/or measurement of a condition that affects the color of a test subject, and more particularly to a process and instrument for measuring at least one color characteristic or factor of a biological test subject indicative of the condition of interest.

Visual observation of a subject for changes in coloration indicative of a particular condition has often occurred. The subject may be a person or animal being observed to determine the presence or absence of a medical condition. The color characteristics or a single color characteristic of other test subjects such as biopsy specimens or excretions have diagnostic value.

REPLACED SHEETS SG

- | | | |
|-------------------------------------|-------------|--------------------------------------|
| ☒ | Description | : paged ...3... to paged
33 |
| ☒ | Claim(s) | : paged to paged
43 |
| ☐ | Drawing(s) | : paged to paged
43 |
| ☐ | Abstract | : paged to paged
43 |

An individual person's skin color is often assessed by her or his doctor. Hypertension, tuberculosis, sclerosis of the liver, to name just a few, are examples of ailments with symptomatic skin color changes among at least a sizeable population segment. Hair color evaluation and dental coloration evaluation are valuable. These may bear on the health of the individual, or on the health of the individual's hair and teeth, or these may permit accurate cosmetic activities, for example, to counteract graying or to accurately match new dental work to existing teeth.

Likewise, the condition of plants and agricultural products is visually inspected for color as an indication of condition. Contamination of soil is likewise apparent from visual inspection. Such visual inspections are subjective. Measuring by instrument the color characteristics that are key to the visual inspection has the benefit of objectivity and consistency.

In the past, hyperbilirubinemia in newborns has been detected by visually observing an individual for jaundice or by routinely taking and testing a blood sample. Upon detection, hyperbilirubinemia has been treated by phototherapy. During the course of phototherapy, blood samples have been taken and tested at regular intervals until it was determined that the level of serum bilirubin had decreased to an acceptable level.

In infants, there is little blood available for use in the blood testing for hyperbilirubinemia. So much blood is drawn that transfusions are often necessary to replace the drawn blood. The newborn is thereby exposed to all of the risks that transfusions bring. Blood sampling and transfusions are, of course, painful to the newborn, and as with any invasive procedure, both present medical risks, such as for

example, risk of infection. There is a need, therefore, for a reliable, noninvasive technique for detecting and measuring a skin color affecting medical condition such as hyperbilirubinemia.

This is one example of a wider need for procedures and instruments to objectively and consistently determine a color characteristic or factor indicative of the condition of a test subject or indicative of a particular ailment or condition. The methods and apparatus of this invention can be employed where previously visual inspection, of which examples are given above, has been carried out at least in part on the basis of observable color characteristics.

BRIEF SUMMARY OF THE INVENTION

According to this invention there is provided a method and apparatus for detecting and quantitatively measuring a condition affecting the color of a test subject. The method includes measuring at least one color characteristic of the subject.

In one exemplary procedure according to this invention at least one skin color characteristic is measured at least at first and second points in time. To test for hyperbilirubinemia, the two measurements are then compared for change. In the preferred procedure a second skin color characteristic is also measured. On the basis of this measurement the subject can be assigned to one of plural categories among which varying amounts of change in the first-mentioned skin color characteristic are indicative of the presence of a medical condition. The first characteristic is then observed for a change of measured value sufficient to indicate the medical condition for a subject in that category. Preferably, a base reading of at least the first color characteristic is first made at a time the subject is without characteristic skin coloration



indicative of the medical condition for which he or she is to be tested.

In the case of hyperbilirubinemia detection, the first skin color characteristic is Hunter b, which is a color factor dependent on the relative content, in a color, of two opponent colors, yellow and blue. Hunter b is a factor comprising a first function (Y) weighted in a first portion of the spectrum, the yellower portion, a second function (Z) weighted in a second portion of the spectrum, the bluer portion, and a weighting term ($1/Y^{1/2}$) that is a function of the lightness of a color and that decreases the value of the color factor as lightness increases. Y and Z are part of the three tristimulus values X, Y and Z known to the color scientist for the purpose of defining a color. They are measurable by commercially available instruments such as colorimeters.

In the case of testing newborns for hyperbilirubinemia, readings of Hunter b and the Hunter lightness measure L are made shortly after birth. These can provide the base reading since hyperbilirubinemia does not manifest itself immediately after birth. The first reading is preferably made within five hours, but as soon as possible after birth. Subsequent readings are then made during the next few days. The subsequent readings of Hunter b are compared with the first, baseline reading of Hunter b to determine whether Hunter b has increased to an extent that indicates a degree of jaundice characteristic of hyperbilirubinemia for a person having the range of the subject's particular skin lightness L. L is measured during each subsequent test to be sure that it remains close to the original reading. This gives a degree of confidence that the test procedures are being conducted appropriately.

In the event that the medical condition affecting skin color is detected in a procedure like that described above for hyperbilirubinemia, then the measuring of skin color characteristics continues at regular intervals until the symptomatic color characteristic abates sufficiently to indicate the individual's recovery from the medical condition. In the case of hyperbilirubinemia, phototherapy is administered once a sufficient change in Hunter b is observed to indicate the jaundice of hyperbilirubinemia. Throughout the course of phototherapy, then, the Hunter b and L characteristics are continually monitored until the jaundice has been eliminated. This has the value of permitting early removal of the newborn from under the phototherapy lamps, since there is the danger of damage to the newborn's eyes in the event eye protection is prematurely removed or accidentally dislodged.

The apparatus used in accordance with this invention includes a color measuring device such as a colorimeter and computational means for storing and comparing the characteristic or characteristics that are measured when testing for the condition. Where Hunter b is measured for the purpose of detecting hyperbilirubinemia, a colorimeter capable of calculating Hunter b and L can be used. This can be a commercially available colorimeter with this capability. The computational means preferably has sufficient memory to store one or more previous readings and should be programmed to compare previous and current readings to detect changes in Hunter b and L. Preferably the colorimeter and the computational means are integrated in a single instrument, but the commercial colorimeter can be utilized in cooperation with, for example, a personal computer, which stores and can compare Hunter b and L values from measurements taken at timed intervals. Likewise, the computational means, whether an

integrated part of the instrument or a separate computer, can be used to store ranges of lightness L and the increases in Hunter b that, for the various lightness ranges, indicate an unacceptable increase in serum bilirubin.

In one method according to the invention Hunter L and b are used to detect hyperbilirubinemia. Hunter L is monitored for consistency each time measurements are made. The change in Hunter b is monitored for a warning of hyperbilirubinemia. In another method according to the invention Hunter L, a and b are used. Hunter L is monitored for consistency, Hunter b is monitored for a warning of hyperbilirubinemia, and Hunter a is observed for additional information as to the infant's condition. The ordinary ranges of Hunter a for individuals is known. If Hunter a lies outside the ordinary range the reason for this should be determined. If it is because the infant is flushed from crying or has just been washed and rubbed dry, the Hunter a variation from the norm is not an indication of a medical problem. If Hunter a is above the ordinary range, but the infant has not been crying, has not been recently washed, phototherapy is not in progress, or some other non-medical reason is not apparent, a circulatory problem could be the reason. The situation bears watching to observe if a medical condition is present. Also, Hunter a sometimes increases just before the jaundice due to hyperbilirubinemia increases Hunter b. Hunter a, then, may be a warning, calling for closer observation to observe if a medical condition is present. A decrease in Hunter a along with an increase in both Hunter L and Hunter b such that the ratio of Hunter L to Hunter b remains essentially constant can mean that the infant is anemic and therefore pale, in which case the increase in Hunter b (with a simultaneous increase in Hunter L) would not be

indicative of hyperbilirubinemia. The observation of Hunter a then may suggest various medical conditions and it allows one to understand the Hunter L and b readings better and to be more certain whether they are or are not indicative of hyperbilirubinemia.

Preferably, each skin color characteristic measurement used to assess the presence or absence of the condition for which testing is carried out is actually an average of multiple tests. For example, when newborns are tested for the jaundice that signals hyperbilirubinemia, multiple readings are made at multiple sites. Five or six Hunter value readings are made at, for example, each of several locations which may include some or all of a forehead location, at least one chest location, a cheek location and two back locations. Out of range Hunter L, a and b values are discarded. At each site, the Hunter readings that have the highest and lowest values of L, a and b are discarded, then all of the readings of each Hunter characteristic are averaged for each site. Subsequent readings are made in the same manner at exactly the same sites and compared. As used herein, the terms "Hunter a," "Hunter b," and "Hunter L" include such average values, but are not limited to just the values arrived at by the averaging technique unless expressly so-limited. The discarding and averaging is readily accomplished by the computational provisions of the test equipment. The averaging technique may improve the testing of other than skin color where the testing steps of this invention are used, for example in the evaluation of hair by color measurement.

In skin color testing, it is important to cleanse the site utilizing a cleansing agent that does not contribute any coloration. Likewise, when testing is carried out on test subjects other than an individual's skin, the test subject should be free of any color

altering contaminant. In skin color testing, the site on the test subject should be dry, and in all cases the instrument should have the capability of being applied to the site in such a manner that ambient light does not enter the instrument.

Determination of the first and second skin color characteristics, Hunter L and b, at just one point in time can indicate or strongly suggest a medical condition affecting skin color if the first characteristic measurement is observed to lie outside a range of values for that characteristic known by experience to be normal for a subject having the particular measured value of the second characteristic. Again the value of Hunter a should be observed and if abnormal the reason should be sought. For example, in many individuals hyperbilirubinemia is strongly suggested if Hunter b and L are measured and it is determined that, based on skin color categories previously observed, Hunter b is above any ordinary value for a subject with skin having the L value measured. Also, even if baseline readings of Hunter b and L (and preferably a) are not made to establish values when no jaundice is present in the individual, changes in the value of Hunter b can nevertheless signal the presence of hyperbilirubinemia if measurements of the Hunter values are made at timed intervals in the foregoing fashion. Out of the ordinary increases in Hunter b, of for example two or more points, can be an indication of hyperbilirubinemia when the measured L value remains in a constant range from one measurement to the next. Similarly, large decreases in Hunter b, of for example two or more points, can be an indication of hyperbilirubinemia from which the infant is recovering, again if L remains relatively constant. If Hunter a changes due to a medical condition such as anemia and the ratio of Hunter L and Hunter b changes, then it is likely necessary to take

the anemia into account, for example by using a different change in Hunter b to indicate hyperbilirubinemia or by multiplying Hunter b by a compensatory factor.

Significant testing has established the value of the foregoing techniques in detecting hyperbilirubinemia. The same techniques will indicate other jaundice-producing medical conditions in human and animal subjects. Hepatitis or liver disorders are examples of such medical conditions susceptible to diagnosis with the methods and apparatus of this invention.

Tuberculosis has been observed to affect skin color in dark skinned individuals such as many persons of African descent. Appropriate color measurement in accordance with this invention may provide a valuable diagnostic tool.

Biopsy specimens, body fluids, excretions, etc. are visually inspected for color. The techniques and instrumentation according to this invention can provide objectivity and consistency to such inspections.

The above and further advantages of this invention will be better understood with reference to the following detailed description of the preferred embodiment taken in combination with the attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1a is a block diagram illustration of an instrument for determining Hunter L, a and b values and for comparing changes in Hunter b to Hunter b changes predetermined to be indicative of hyperbilirubinemia.

Figure 1b is a diagrammatic illustration of exemplary memory content in an instrument like that of Fig. 1a.

Figure 2 is a schematic illustration in block diagram form illustrating the steps in the process of monitoring an infant for hyperbilirubinemia based upon

changes in Hunter b in skin color and including measuring and reviewing Hunter b and L.

Figure 3 is a schematic illustration in block diagram form illustrating the steps in the process of monitoring an infant for hyperbilirubinemia based on Hunter b including measuring and reviewing Hunter a as well as Hunter b and L.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Any modern version of two general types of color-measuring instruments, colorimeters and spectrophotometers, is an example of instruments suitable for the skin color measurement according to a preferred embodiment of this invention. The basic components of either type of instrument are a light source, a sample illumination and viewing arrangement, a means of selecting certain wavelengths of light for the measurement, a detector of the light reflected from the sample, and some relatively simple computing capacity. In commercially available instruments the main purposes of the computing capacity are to store and apply calibration information and to calculate various color coordinates for later use. In Fig. 1a, a color measuring instrument 10 is illustrated. An individual person's skin 11 is illuminated by the instrument as generally indicated by the broken line arrow 12, and the instrument receives illumination reflected from the skin 11 as generally indicated by the broken line arrow 13. Based on the illumination received by reflection from the skin, the instrument 10 develops the coordinates Y, x and y. In Fig. 1a the instrument 10 is a colorimeter, commercially available and suitable for development of the values Y, x and y.

Another type of instrument that can be used in the skin color categorization method according to this invention is the spectrophotometer that measures the

skin reflectance at discrete wavelengths and from these data derives tristimulus values, from which can be computed the Hunter color values used to measure skin color for diagnostic purposes as discussed below.

Important to the use of a commercial colorimeter of the kind employed for the color measurement instrument 10 of Fig. 1a is the calibration of the instrument using a standard. In the early use of an instrument of this kind by the inventors, the "Light Skin" sample from the Macbeth Color Checker, described in the publication of C.S. McCamy, H. Marcus, and J.G. Davidson, "A Color-Rendition Chart," J. Appl. Photogr. Eng. 2, 95-99 (1976) was used. A tile of this approximate color was selected for its greater durability as an instrument standard. It was found, however, that the use of the "Light Skin" painted paper as the primary standard did not adequately avoid the phenomenon known as metamerism, by which objects that look alike (have the same perceived color) under some kinds of light sources, or to some observers, do not match under other types of light sources, or to other observers. By this phenomenon colorimeters may not read their colors the same as the average human observer would under the daylight type light source usually employed for visual observation. This could lead to an error in colorimeter calibration.

As an improved primary standard, the skin was selected of a subject whose skin color measurements were highly reproducible, and in the approximate center of the range of skin colors of the human population. The spectral reflectance factors of the skin of this subject were carefully measured on a Macbeth 1500 Plus spectrophotometer (Macbeth, New Windsor, New York); these data are given in column 2 (second from left) of Table I at the wavelengths listed in column 1 (the leftmost column). By using well-established techniques

of computer color matching, carried out on an ACS 1800 system equipped with an ACS SpectroSensor II color measuring instrument (Datacolor International, Lawrenceville, New Jersey), a colorant formulation matching this skin color was developed. The spectral reflectance factors for this match are given in column 3 of Table I. It may be seen that the data closely match those of column 2, indicating the absence of metamerism. Calculations according to the CIE 1976 CIELAB system showed that the two data sets match to within 0.27-0.36 units, less than can be perceived by human color vision, for daylight, incandescent light, and cool white fluorescent light, the three most commonly used light sources for the proposed applications.

The above-mentioned formulation was made up in a stable, durable material, and tiles were prepared as instrument standards. The spectral reflectance factors of one of these tiles are given in column 4 of Table I. It was found, however, that the improvement in calibration resulted in color coordinates that were significantly different from those obtained in the many studies made with the earlier system. A decision was made to adjust the calibration values of the new tiles in order to achieve consistent results between the new and old methods of calibration. Column 5 of Table I gives the adjusted set of spectral reflectance factors for the tile of column 4. The CIE and Hunter color coordinates, for measurement with the specular component excluded and calculated for CIE standard illuminant C and the 1931 2° CIE standard observer, are also tabulated for each of the samples in the table.

TABLE I

Wave-lengths, nm.	Skin Standard	Formulation	Tile, correct	Tile, adjusted
400	19.03	20.70	21.51	16.67
420	18.96	20.69	21.10	16.93
440	21.53	21.68	20.99	17.65
460	25.36	24.43	23.27	20.56
480	28.06	28.30	27.82	25.67
500	30.13	30.77	29.03	27.94
520	31.19	31.31	29.38	28.24
540	30.01	30.84	28.48	27.59
560	31.41	30.76	28.22	27.33
580	32.85	34.01	31.49	30.12
600	44.37	43.54	42.58	40.52
620	51.24	51.57	51.27	47.93
640	54.56	55.09	55.56	51.10
660	57.09	57.60	59.22	53.82
680	58.67	60.41	61.82	56.55
700	59.95	62.69	63.93	58.87
X	37.14	37.28	36.14	33.76
Y	34.66	34.89	33.07	31.53
Z	28.50	28.54	27.63	24.20
x	0.3703	0.3702	0.3732	0.3732
y	0.3456	0.3464	0.3415	0.3523
L	58.87	59.07	57.51	56.15
a	9.31	9.02	11.54	9.05
b	12.51	12.70	11.77	13.75

With a suitable standard, basically, calibration is carried out by forcing the colorimeter 10 to give the desired color coordinates Y, x and y mentioned above, while utilizing the colorimeter with the standard tile chosen. The method of calibration is known

for particular instruments and follows a series of steps prescribed by the manufacturer that need not be detailed here.

In skin color testing, prior to each test of a subject, each test site is cleansed. A cleansing agent, such as isopropyl alcohol, which leaves behind no coloration, is suitable. The site is well dried to avoid any wetness which may interfere with the reflection of light from the skin 11 to the instrument 10. In all cases of testing, with the instrument correctly calibrated, the measuring head or instrument orifice is placed against the test site to be measured. Care is taken to avoid the admission of ambient light to the instrument. Pressing the head firmly against the test site prevents the entry of ambient light. Additionally, it was determined that best results are obtained if one removes the instrument from the test site briefly, between illuminations. This can be provided for in software by a conventional delaying routine and, if desired, with an appropriate display instructing the user to remove the instrument briefly well away from the skin.

In a colorimeter of the type shown in Fig. 1a, at block 10 the instrument has an internal microprocessor or other computing capability so that it is able to develop the color coordinates Y , x and y from the measured values X , Y and Z (Y being the same in each case). Certain colorimeters develop the Hunter color coordinates L , a , and b . Since the degree of computation that the color measuring device 10 (i.e. colorimeter or spectrophotometer) internally performs varies, the manner of calculating the Hunter values from the tristimulus coordinates is useful to an understanding and practice of the invention and will enable correct use of a CPU by appropriate calculation to perform the invention with any commercially available colorimeter

or spectrophotometer. Most modern color measuring instruments begin with measurement of the tristimulus values X, Y, and Z. From these can be derived the CIE chromaticity coordinates x and y:

$$x = X / (X + Y + Z) \quad (1)$$

$$y = Y / (X + Y + Z) \quad (2)$$

The instrument 10 of Fig. 1a outputs the triplet of values x, y and Y as the starting point for further calculations by a central processing unit which can be dedicated microprocessor circuitry or personal computer 15. The remaining two tristimulus values X and Z are available by computation as follows:

$$X = xY/y, \text{ and} \quad (3)$$

$$Z = (1-x-y)Y/y \quad (4)$$

In the preferred embodiment, in any event, the CPU according to Fig. 1a develops the Hunter value b discovered in accordance with this invention to be capable of use to detect and monitor hyperbilirubinaemia. The Hunter b value is one of three values derived by Richard S. Hunter in 1958. Richard S. Hunter, "Photoelectric Color Difference Meter," J. Opt. Soc. Am. 48, 985-995 (1958). The equations for these are:

$$L = 10 (Y)^{1/2} \quad (5)$$

$$a = 17.5 (1.02 X - Y) / Y^{1/2} \quad (6)$$

$$b = 7.0 (Y - 0.847 Z) / Y^{1/2} \quad (7)$$

where L is a lightness coordinate whose values correlate better with the visual perceptions of the lightness of object colors than do values of Y; a is a coordinate denoting redness or greenness, for which positive values denote that the color is red rather than its opponent color green, and negative values of a denote the opposite; and b is a yellowness-blueness coordinate, for which positive values denote that the color is yellow rather than the opponent color blue, and negative values of b denote the opposite. For yellow colors, starting with a = b = 0 and an appropri-

ate high value of L, which would be a light grey, increasing positive values of b result in a series of colors that may be described as light yellowish grey, pale yellow, light yellow, brilliant yellow and vivid yellow, in turn. Thus b is a measure of the "intensity" of the yellow color.

Historically, all three Hunter values, a, b and L, have been utilized to describe a color. The inventors have determined that one can use the Hunter skin lightness measure L and comparative determinations of the Hunter value b developed at time intervals to measure the jaundice that is symptomatic of hyperbilirubinemia and by that measurement of jaundice detect the presence or absence of the ailment. The coordinate b provides a reliable measure of the yellow undertone of the color of human skin. This does not mean that Hunter a and Hunter L should be ignored, but they are not used in the usual way to define a color. In the particular arrangement of Fig. 1a, wherein the colorimeter 10 produces the values Y, x, y, the computer 15 derives the Hunter values L and b. The Hunter lightness skin color characteristic L affects the amount of increase in the yellow measure Hunter b that indicates hyperbilirubinemia. Following the procedure represented in Fig. 2, steps 1 to 4 and preferably using an averaging technique described below, a newborn is measured, preferably within 2-5 or 2-6 hours of birth, to establish the initial, baseline values of Hunter L and b, L_0 and b_0 . A baseline Hunter a, a_0 , may be calculated at this time, too, for the purposes explained below. At step 3, out of range values are discarded, i.e. values outside the range $20 > L > 80$, $2 > a > 50$ and $2 > b > 40$. At step 4, highest and lowest values of Hunter a and b from each site are discarded. The values are recorded, at step 5, for example by placement in machine memory 17. Thereafter, again

preferably using the averaging technique described below, throughout the next several days, Hunter L and b (and a, if used) are measured at intervals as represented by step 6 of Fig. 2. L is compared to the value originally measured as indicated at step 7. It should not vary more than 3 to 5 points (depending on the range of L being measured) or the test is discontinued as at step 8. This is so unless there is another explanation. Unless discontinued as explained above, Hunter b is compared at step 9 to the baseline value established shortly after birth. As determined at step 10, if Hunter L remains consistent, if at any time Hunter b increases two points or more for skins with L values at or below approximately 51 or three points or more for skins with L values above approximately 51, then hyperbilirubinemia is indicated, a confirming blood test should be conducted, and phototherapy, the usual treatment for this condition, may be prescribed. Hunter b increases of one to two points for L values at or below approximately 51 and Hunter b increases of two to three points for L values above approximately 51 can be used as red flags or warning signs requiring closer monitoring.

When the measured value of Hunter L at any time is found to have varied more than 3-5 points the test procedure is suspect and the test may be discontinued. Hunter L variations of this magnitude do not ordinarily occur in skin color measurement. Unless this change can be explained by a change in the condition of the subject (such as anemia or phototherapy treatment, which would lighten the subjects entire skin color measurement and range, but in direct ratio of L and b) the test would be suspect. But if the change in Hunter L can be explained as above, then an adjustment factor would be used to calculate L and b.

During phototherapy, then, the testing procedure according to this invention can be used with an adjustment factor for the lightening of the skin color while under the phototherapy lights.

As indicated, it has been the inventors' practice to require the additional measurement of Hunter a at each testing. The best procedure in which Hunter a is utilized is illustrated in Fig. 3. Again the averaging technique is preferably used as described below. Based upon the testing of the skin color of several million individuals, the inventors have identified some 210 broad categories of skin coloration. That is to say, 210 broad ranges of Hunter L, a and b have been identified. Hunter L and b values for each of these categories are shown in Table II, Appendix A hereto. Table III, below, provides the ranges of Hunter a reasonably to be expected. For certain values of L, Hunter a above a particular value has not typically been observed. Should the test indicate a Hunter a outside any previously observed range for a particular L and b, this would be taken as at least a further indication of some disorder in a condition of the subject if the Hunter a value cannot otherwise be accounted for, e.g. from crying or drying after bathing. This occurrence is represented at step 7 of Fig. 3.

The measurement of Hunter a can have the further value of a warning that the jaundice associated with hyperbilirubinemia may shortly occur since, at times Hunter a will increase in value just before Hunter b increases.

If, then, an infant has not been crying (which boosts Hunter a), and an increase in Hunter a is observed, Hunter b bears watching for signs of hyperbilirubinemia.

TABLE III

If Hunter L values are:	Then Hunter a values are:
24 (or less) to 44	4 to 16
45 to 54	4 to 18
55 to 59	5 to 25
60 to 71 (or more)	6 to 30

As mentioned, for greater accuracy an averaging technique is employed. Multiple Y, x and y readings are made with the colorimeter 10 at several different sites. For example, measurements are made at one or more locations on some or all of the subject's forehead, cheek, chest and back, as suggested in the steps of the method outlined in Fig. 2. In a preferred embodiment, 5 or 6 readings at each of 5 different sites are made. Hunter a, b and L values are calculated for each reading. The high and low values of a, b and L from each site are discarded by the computer or computational provisions of the Fig. 1a instrumentation, for example. The instrument or the computer 15 then averages all of the remaining values of Hunter a, b and L for each site. The average a, b and L thus calculated for each site are then used as the Hunter a, b and L values in the previously described testing for hyperbilirubinemia.

Some variation of b value occurs in dependence on the body location where readings are taken. Consistently averaging the values of Hunter a, b and L calculated from measurements taken at the same several locations on each individual can be used to eliminate any uncertainty resulting from such variations. The consistent measurement of consistent sites is essential throughout the entire procedure.

A hospital's measure of serum bilirubin typically uses a scale different from the measure of Hunter b detected by the above procedure. In extensive tests at one hospital, a linear relation was observed between serum bilirubin measured using the hospital's scale and the Hunter b measurement according to the invention. In that hospital, 12 was the serum bilirubin value that signalled monitoring or treatment of hyperbilirubinaemia. Steps 12-15 of Fig. 2 and 13-16 of Fig. 3 calculate the serum bilirubin level from the above procedures and compare it to the determination made by blood test.

Correlation between Hunter b and the hospital bilirubin count (BRC) was determined to be in accordance with the following equation:

$$BRC = 2.5 ([\{ 47/L \}^{1/2} b] - 6.8) \quad (8)$$

where BRC equals the hospital bilirubin count, the number 47 is the average L for the entire database gathered over the course of research, and L and b are the average Hunter values determined as described above.

The term in braces modifies b according to the value L relative to its average, in this case 47, according to a square root (superscript 1/2) function. It may be easier to understand the above equation if it is written another way. If the modified b (in square brackets) is called MODB:

$$MODB = 6.8 + 0.4 BRC \quad (9)$$

The numbers 6.8 and 0.4 (= 1/2.5) are, respectively, the intercept and slope of the straight line relation between modified b and BRC. The 6.8 is the value of MODB when BRC = 0 and is related to the average baseline skin color. The 0.4 shows how rapidly MODB changes as BRC increases, an increase of 2.5 in BRC raises MODB by one point.

The equation is exemplary only and may vary in detail when applied to a larger database or to bilirubin count values from another hospital since hospitals do not have a standard scale used consistently from one hospital to the next. However, the linear relationship between MODB and BRC indicates relatively straightforward conversion of measured L and b to arrive at a particular hospital's bilirubin count value so that the medical practitioner can employ the optical measurement of jaundice in accordance with this invention in the same way she or he employed bilirubin count previously.

In the system of Fig. 1a, following the routine of Fig. 2, from the initial measurement preferably within 2-5 or 2-6 hours of birth, the CPU calculates the initial Hunter values L_0 , a_0 and b_0 and stores these in the Baseline Values addresses of the data portion or RAM of memory 17. The data RAM (or nonprogram) portion 18 of the memory 17 is indicated in Fig. 1b. A relatively permanent section 18a of RAM 18 stores the data of Table II (and Table III if Hunter a is to be checked) and data such as the ranges of L that establish categories of skin coloration for which varying Hunter b value changes are significant. A more often revised memory segment stores the results of the measurements performed with the instrument. Based on a relatively straightforward program retained in the permanent ROM memory, from the measurements taken at intervals, the CPU calculates the new values of L , a , and b (or L and b to follow the procedure of Fig. 2), retrieves L_0 , a_0 and b_0 , and subtracts those from the new values of L , a , and b . The change in Hunter L , a and b , ΔL , Δa and Δb , can be displayed, or preferably, the CPU determines if the change in L indicates an error by comparing the change in L to that value, stored in the RAM 18 of the memory 17, that raises the suspicion of test error. If there is no suspicion of error, then

the CPU determines whether an increase in b is above the value, again stored in memory, that indicates monitoring or treatment of hyperbilirubinemia for the particular value of L that has been measured. Similarly, for an infant that has previously been diagnosed with hyperbilirubinemia and is undergoing phototherapy, the same order of decrease to within 2 or 3 points of baseline, depending on L, can indicate recovery and phototherapy may be ended. The CPU memory 17 can be provided with Table II, or another compilation of the categories of skin coloration, which the CPU then can use as a look-up table to determine if Hunter a has a value outside of previously observed ranges for the particular Hunter L and b. Also, if desired, the CPU can calculate and display the hospital's measure of serum bilirubin based upon changes in Hunter b, for example by applying equation 8 above.

Even in the absence of an initial reading, based on observed ranges of skin coloration, measurement of either Hunter L and b or L, a and b can warn of the likelihood of hyperbilirubinemia if a Hunter b value is measured that is in excess of Hunter b ordinarily observed for subjects with that value of L. Hunter b values exceeding those ordinarily observed for individuals in a particular range of Hunter L values can be determined by reference to Table II. For example, it will be apparent that no individual whose skin has a Hunter L value between 24 and 26 has measured above 13 in Hunter b. Such a measurement may be used to determine that a blood test is advisable. In all instances, however, even where there has not been a Hunter b baseline established, an increase over time of 2, 3 or more Hunter b points indicates the likelihood of hyperbilirubinemia, and if the change is a decrease, this is indicative of a recovering newborn.

Table IV is an actual set of measurements made on a three day old infant. Using the averaging technique described above, Hunter L of 48.0 and Hunter b of 11.1 is calculated. Converting to the hospital bilirubin count in the equation (9) above, a bilirubin count of 10.5 was calculated.

TABLE IV

	L	a	b	Y	x	y
Forehead	47.8	21.6	11.6	22.9	0.411	0.333
	48.6	19.5	11.5	23.6	0.404	0.335
	48.8	21.2	11.6	23.8	0.407	0.333
	46.7	21.6	11.6	21.8	0.413	0.333
	48.6	21.6	11.8	23.6	0.410	0.333
	48.0	22.1	11.7	23.1	0.412	0.332
Forehead	46.4	20.5	11.2	21.5	0.409	0.333
	46.0	20.3	11.1	21.1	0.409	0.333
	47.4	21.4	11.6	22.4	0.411	0.333
	46.1	21.4	10.7	21.2	0.409	0.330
	46.3	20.4	11.2	21.5	0.409	0.333
	46.9	20.7	11.3	22.0	0.409	0.333
Chest	50.5	16.5	11.2	25.5	0.391	0.336
	50.9	15.3	11.2	25.9	0.388	0.338
	50.1	17.5	11.2	25.1	0.395	0.336
	50.7	16.9	11.2	25.7	0.392	0.336
	50.4	16.4	11.1	25.4	0.391	0.336
	50.1	17.3	11.1	25.1	0.394	0.335
Back	49.0	17.1	11.1	24.0	0.395	0.336
	48.7	16.3	11.0	23.7	0.394	0.337
	48.3	16.6	10.6	23.3	0.393	0.335
	49.2	16.6	10.9	24.2	0.393	0.336
	49.1	18.3	11.3	24.1	0.399	0.335
	50.0	18.0	11.4	25.0	0.397	0.336

	L	a	b	Y	x	y
Back	46.2	15.8	10.5	21.4	0.395	0.337
	45.3	16.5	10.2	20.5	0.397	0.335
	45.9	16.0	10.4	21.1	0.395	0.336
	45.5	14.4	10.3	20.7	0.392	0.338
	46.3	16.1	11.0	21.4	0.398	0.339
	47.3	16.9	10.9	22.3	0.397	0.336

The invention can afford good evidence of jaundice resulting from medical conditions other than hyperbilirubinemia. Liver disorders in adults and children produce jaundice, for example. These and other skin color characteristics can be factors in diagnosing additional diseases that affect skin color. It has been observed, for example, that at least among dark skinned individuals, such as African Americans or others of African descent, skin color is affected by tuberculosis.

The application of the method and apparatus is not limited to the jaundice-related testing described above. Experiments with rhesus monkeys have shown a correlation between hormone levels and the coloration of the female monkey's very visible reddened hind end. An instrument like that described above was able to distinguish varying levels of reddening in an individual test subject's posterior using Hunter a and Hunter L in a similar fashion to that described above. The hormone level of the subject was thus indicated by the methods and apparatus of this invention.

Successful experimentation has begun on the evaluation of the condition of laboratory mice based upon the use of Hunter a and Hunter L in a similar fashion to that described above.

Table V, Appendix B, is a broad categorization of human hair coloration. In addition to diagnostic use, test procedures and instruments according to this inven-

tion can be used to determine how to restore the hair to its natural color, or with reference to the categories of Table V, hair that has changed in color by greying or by bleaching or dying can be restored to a more natural appearance, whether the test subject's original coloring or a chosen color consistent with the limitation of the categories identified in Table V.

In much the same way, tooth coloration can be assessed by this invention and the techniques described can be used to arrive at a natural coloring of replacement dental work consistent with existing or replacement teeth.

Plant and crop specimens are good candidates for the application of the procedures and apparatus of the invention. For example, conditions leading to the degradation of grain stored in silos are observable based upon color change. Determination of these conditions by instrument is made possible by the techniques of the present invention, and this opens the way to automated monitoring for this purpose. Soil samples from oil spills when measured by these procedures and apparatus indicate the degree of soil contamination by oil or gasoline. Testing of such soil contamination has been successfully conducted. Biological test subjects of a great variety can be tested by means of the present invention.

From the foregoing it should be apparent that the methods and apparatus described are exemplary and not intended to limit the scope of protection of the invention as set forth in the appended claims.

APPENDIX A

TABLE II

No.	Hunter L	Hunter b
1.	<27	-5*
2.	<27	6
3.	<27	7
4.	<27	8
5.	<27	9
6.	<27	10
7.	<27	11
8.	<27	12+**
9.	27 to <30	-5
10.	27 to <30	6
11.	27 to <30	7
12.	27 to <30	8
13.	27 to <30	9
14.	27 to <30	10
15.	27 to <30	11
16.	27 to <30	12+
17.	30 to <33	-5
18.	30 to <33	6
19.	30 to <33	7
20.	30 to <33	8
21.	30 to <33	9
22.	30 to <33	10
23.	30 to <33	11
24.	30 to <33	12+
25.	33 to <36	-5
26.	33 to <36	6
27.	33 to <36	7
28.	33 to <36	8
29.	33 to <36	9
30.	33 to <36	10
31.	33 to <36	11
32.	33 to <36	12+

No.	Hunter L	Hunter b
33.	36 to <39	-5
34.	36 to <39	6
35.	36 to <39	7
36.	36 to <39	8
37.	36 to <39	9
38.	36 to <39	10
39.	36 to <39	11
40.	36 to <39	12
41.	36 to <39	13
42.	36 to <39	14
43.	36 to <39	15+
44.	39 to <42	-5
45.	39 to <42	6
46.	39 to <42	7
47.	39 to <42	8
48.	39 to <42	9
49.	39 to <42	10
50.	39 to <42	11
51.	39 to <42	12
52.	39 to <42	13
53.	39 to <42	14
54.	39 to <42	15+
55.	42 to <45	-5
56.	42 to <45	6
57.	42 to <45	7
58.	42 to <45	8
59.	42 to <45	9
60.	42 to <45	10
61.	42 to <45	11
62.	42 to <45	12
63.	42 to <45	13
64.	42 to <45	14

* The designation -5 means less than 5 but more than 4.

** The designation 12+ means more than 12 but less than 13.

No.	Hunter L	Hunter b
65.	42 to <45	15
66.	42 to <45	16
67.	42 to <45	17
68.	42 to <45	18+
69.	45 to <48	-5
70.	45 to <48	6
71.	45 to <48	7
72.	45 to <48	8
73.	45 to <48	9
74.	45 to <48	10
75.	45 to <48	11
76.	45 to <48	12
77.	45 to <48	13
78.	45 to <48	14
79.	45 to <48	15
80.	45 to <48	16
81.	45 to <48	17
82.	45 to <48	18+
83.	48 to <51	-5
84.	48 to <51	6
85.	48 to <51	7
86.	48 to <51	8
87.	48 to <51	9
88.	48 to <51	10
89.	48 to <51	11
90.	48 to <51	12
91.	48 to <51	13
92.	48 to <51	14
93.	48 to <51	15
94.	48 to <51	16
95.	48 to <51	17
96.	48 to <51	18
97.	48 to <51	19
98.	48 to <51	20+
99.	51 to <54	-5
100.	51 to <54	6
101.	51 to <54	7

No.	Hunter L	Hunter b
102.	51 to <54	8
103.	51 to <54	9
104.	51 to <54	10
105.	51 to <54	11
106.	51 to <54	12
107.	51 to <54	13
108.	51 to <54	14
109.	51 to <54	15
110.	51 to <54	16
111.	51 to <54	17
112.	51 to <54	18
113.	51 to <54	19
114.	51 to <54	20+
115.	54 to <57	-5
116.	54 to <57	6
117.	54 to <57	7
118.	54 to <57	8
119.	54 to <57	9
120.	54 to <57	10
121.	54 to <57	11
122.	54 to <57	12
123.	54 to <57	13
124.	54 to <57	14
125.	54 to <57	15
126.	54 to <57	16
127.	54 to <57	17
128.	54 to <57	18
129.	54 to <57	19
130.	54 to <57	20+
131.	57 to <60	-5
132.	57 to <60	6
133.	57 to <60	7
134.	57 to <60	8
135.	57 to <60	9
136.	57 to <60	10
137.	57 to <60	11
138.	57 to <60	12

No.	Hunter L	Hunter b
139.	57 to <60	13
140.	57 to <60	14
141.	57 to <60	15
142.	57 to <60	16
143.	57 to <60	17
144.	57 to <60	18
145.	57 to <60	19
146.	57 to <60	20+
147.	60 to <63	-5
148.	60 to <63	6
149.	60 to <63	7
150.	60 to <63	8
151.	60 to <63	9
152.	60 to <63	10
153.	60 to <63	11
154.	60 to <63	12
155.	60 to <63	13
156.	60 to <63	14
157.	60 to <63	15
158.	60 to <63	16
159.	60 to <63	17
160.	60 to <63	18
161.	60 to <63	19
162.	60 to <63	20+
163.	63 to <66	-5
164.	63 to <66	6
165.	63 to <66	7
166.	63 to <66	8
167.	63 to <66	9
168.	63 to <66	10
169.	63 to <66	11
170.	63 to <66	12
171.	63 to <66	13
172.	63 to <66	14
173.	63 to <66	15
174.	63 to <66	16

No.	Hunter L	Hunter b
175.	63 to <66	17
176.	63 to <66	18
177.	63 to <66	19
178.	63 to <66	20+
179.	66 to <69	-5
180.	66 to <69	6
181.	66 to <69	7
182.	66 to <69	8
183.	66 to <69	9
184.	66 to <69	10
185.	66 to <69	11
186.	66 to <69	12
187.	66 to <69	13
188.	66 to <69	14
189.	66 to <69	15
190.	66 to <69	16
191.	66 to <69	17
192.	66 to <69	18
193.	66 to <69	19
194.	66 to <69	20+
195.	≥69	-5
196.	≥69	6
197.	≥69	7
198.	≥69	8
199.	≥69	9
200.	≥69	10
201.	≥69	11
202.	≥69	12
203.	≥69	13
204.	≥69	14
205.	≥69	15
206.	≥69	16
207.	≥69	17
208.	≥69	18
209.	≥69	19
210.	≥69	20+

APPENDIX B

TABLE V

CATEGORY NAME	L		a		b	
	Min	Max	Min	Max	Min	Max
Black	0.00	14.00	-10.00	3.00	-10.00	5.00
Darkest Dark Brown	14.00	16.00	-10.00	3.00	-10.00	1.00
Darkest Dark Brown	14.00	16.00	-10.00	3.00	1.00	1.15
Darkest Dark Brown	14.00	16.00	-10.00	3.00	1.15	1.25
Darkest Dark Brown	14.00	16.00	-10.00	3.00	1.25	3.00
Darker Dark Brown	16.00	19.00	-10.00	3.00	-10.00	2.70
Darker Dark Brown	16.00	19.00	-10.00	3.00	2.70	2.95
Darker Dark Brown	16.00	19.00	-10.00	3.00	2.95	3.20
Darker Dark Brown	16.00	19.00	-10.00	3.00	3.20	10.00
Darker Dark Brown (Cool Auburn Tones)	16.00	19.00	2.00	3.00	-10.00	2.70
Darker Dark Brown (Warm Auburn Tones)	16.00	19.00	2.00	3.00	3.20	10.00
Brown	19.00	22.00	0.00	6.00	-10.00	2.95
Brown	19.00	22.00	0.00	6.00	2.95	3.20
Brown	19.00	22.00	0.00	6.00	3.20	3.45
Brown	19.00	22.00	0.00	6.00	3.45	10.00
Brown (Warm Auburn Tones)	19.00	22.00	3.50	6.00	3.45	10.00
Brown (Cool Auburn Tones)	19.00	22.00	3.50	6.00	-10.00	3.45
Medium Brown	22.00	27.00	1.00	6.00	-10.00	3.75
Medium Brown	22.00	27.00	1.00	6.00	3.75	4.00
Golden Med. Brown	22.00	27.00	1.00	6.00	4.00	4.25
Golden Med. Brown	22.00	27.00	1.00	6.00	4.25	10.00
Medium Brown (Warm Auburn Tones)	22.00	27.00	3.50	6.00	4.25	10.00
Medium Brown (Cool Auburn Tones)	22.00	27.00	3.50	6.00	-10.00	4.25
Darkest Med. Blonde	27.00	28.00	1.80	6.00	-5.00	6.00
Darkest Med. Blonde	27.00	28.00	1.80	5.00	6.00	6.50
Darkest Med. Blonde	27.00	28.00	5.00	6.00	6.00	6.50
Darkest Med. Blonde	27.00	28.00	1.80	6.00	6.50	15.00
Medium Blonde	28.00	31.00	1.80	6.00	-5.00	6.00
Medium Blonde	28.00	31.00	1.80	5.00	6.00	6.50
Med. Golden Blonde	28.00	31.00	5.00	6.00	6.00	6.50
Med. Golden Blonde	28.00	31.00	1.80	6.00	6.50	15.00

* Negative values are used in this table in their ordinary sense, to denote values less than zero.

CATEGORY NAME	L		a		b	
	Min	Max	Min	Max	Min	Max
Lightest Med. Blonde	31.00	33.00	1.80	6.00	-5.00	6.00
Lightest Med. Blonde	31.00	33.00	1.80	5.00	6.00	6.50
Lightest Med. Blonde	31.00	33.00	5.00	6.00	6.00	6.50
Lightest Med. Blonde	31.00	33.00	1.80	6.00	6.50	15.00
Light Blonde	33.00	36.00	1.80	6.00	-5.00	7.00
Light Blonde	33.00	36.00	1.80	5.00	7.00	7.50
Light Blonde	33.00	36.00	5.00	6.00	7.00	7.50
Light Blonde	33.00	36.00	1.80	6.00	7.50	20.00
Lighter Blonde	36.00	40.00	1.80	6.00	-5.00	8.00
Lighter Blonde	36.00	40.00	1.80	5.00	8.00	8.50
Lighter Blonde	36.00	40.00	5.00	6.00	8.00	8.50
Lighter Blonde	36.00	40.00	1.80	6.00	8.50	20.00
Lightest Blonde	40.00	80.00	1.80	7.00	-5.00	9.00
Lightest Blonde	40.00	80.00	1.80	5.00	9.00	10.00
Lightest Blonde	40.00	80.00	5.00	7.00	9.00	10.00
Lightest Blonde	40.00	80.00	1.80	7.00	10.00	30.00
Light Red	22.00	28.00	6.00	30.00	-5.00	3.50
Light Red	22.00	28.00	6.00	30.00	3.50	3.75
Light Red	22.00	28.00	6.00	30.00	3.75	4.00
Light Red	22.00	28.00	6.00	30.00	4.00	30.00
Medium Red	19.00	22.00	6.00	30.00	-10.00	3.50
Medium Red	19.00	22.00	6.00	30.00	3.50	3.75
Med. Golden Red	19.00	22.00	6.00	30.00	3.75	4.00
Med. Golden Red	19.00	22.00	6.00	30.00	4.00	30.00
Dark Red	14.00	19.00	3.00	30.00	-10.00	2.50
Dark Red	14.00	19.00	3.00	30.00	2.50	2.75
Dark Red	14.00	19.00	3.00	30.00	2.75	3.00
Dark Red	14.00	19.00	3.00	30.00	3.00	30.00
Red Blonde	27.00	40.00	6.00	30.00	6.00	30.00
Red Blonde	40.00	80.00	7.00	30.00	6.00	30.00

-31-

CATEGORY NAME	L		a		b	
	Min	Max	Min	Max	Min	Max
Black/Dk Brown/Med Brown/Brown w/ 70% - 90% Grey	27.00	50.00	-10.00	1.80	-10.00	3.75
Black/Dk Brown/Med Brown/Brown w/ 70% - 90% Grey	27.00	50.00	-10.00	1.80	3.75	4.00
Black/Dk Brown/Med Brown/Brown w/ 70% - 90% Grey	27.00	50.00	-10.00	1.80	4.00	4.25
Black/Dk Brown/Med Brown/Brown w/ 70% - 90% Grey	27.00	50.00	-10.00	1.80	4.25	10.00
Black/Dk Brown/Med Brown/Brown w/ 40% - 60% Grey	23.00	27.00	-10.00	1.00	-10.00	3.75
Black/Dk Brown/Med Brown/Brown w/ 40% - 60% Grey	23.00	27.00	-10.00	1.00	3.75	4.00
Black/Dk Brown/Med Brown/Brown w/ 40% - 60% Grey	23.00	27.00	-10.00	1.00	4.00	4.25
Black/Dk Brown/Med Brown/Brown w/ 40% - 60% Grey	23.00	27.00	-10.00	1.00	4.25	10.00
Grey Hair Program						
Light Brown/Darkest Blonde						
40% - 60% Grey	4.00	10.00	-10.00	-0.08		
70% - 90% Grey	10.00	999.00	-10.00	-0.08		
Dark Red, Medium Red or Medium Light Red						
40% - 60% Grey	6.00	10.00	-10.00	-0.80		
70% - 90% Grey	10.00	999.00	-10.00	-0.80		
Light Red or Red Blonde						
40% - 60% Grey	5.00	7.00	-10.00	-0.80		
70% - 90% Grey	7.00	999.00	-10.00	-0.80		
Medium to Medium Dark Blonde						
40% - 60% Grey	1.70	4.00	0.00	0.00		
70% - 90% Grey	4.00	999.00	0.00	0.00		
Light Blonde Hair						
40% - 60% Grey	-99.99	-0.25	-1.75	-1.25		
70% - 90% Grey	-99.99	-0.25	-99.99	-1.75		

Claims

1. A process of detecting a condition in a subject, which condition includes a symptomatic, detectable change in coloration of the subject; the process comprising the steps of:
 - (a) at a first point in time, measuring with a color measuring instrument the value of a color factor in the color of the subject, said color factor being dependent on the content of said coloration in the subject's color,
 - (b) measuring with the color measuring instrument, at least at one further point in time, the value of said color factor in the color of the subject, and
 - (c) comparing the values of the factor determined at said first and further points in time to determine whether there has been exhibited a change therein of a predetermined magnitude evidencing said medical condition.
2. The process according to claim 1 wherein steps (a) and (b) comprise measuring a color factor that varies with relative content of opponent colors.
3. The process according to claim 2 wherein steps (a) and (b) further comprise measuring a color factor that is dependent on lightness of the coloration of the subject.
4. The process according to claim 1 wherein steps (a) and (b) comprise measuring a color factor that comprises a first function weighted in a first portion of the spectrum, a second function weighted in a second portion of the spectrum, and a weighting term that is a function of the lightness of the





color and that modifies the value of the color factor.

5. The process according to claim 4 wherein the first portion of the spectrum is a yellower portion of the spectrum and the second portion of the spectrum is a bluer portion of the spectrum.
6. The process according to claim 1 wherein steps (a) and (b) comprise measuring Hunter b.
7. The process according to claim 5 wherein the condition is hyperbilirubinemia, the subject is an infant and step (a) comprises measuring at a first point in time that is within a predetermined period after birth.
8. The process according to claim 5 wherein the condition causes jaundice in a human child or adult test subject, thereby effecting change in the measured color factor.
9. The process according to claim 1 wherein steps (a) and (b) comprise measuring with a color measuring instrument that has memory and computational means, and wherein the process further comprises the step of storing in the memory the color factor value determined by measuring coloration of the subject at a first point in time, and the step of comparing the values of the factor comprising comparing by the computational means the stored color factor value and the value of said color factor measured at the at least one further point in time to arrive at the difference in the color factor values.





10. The process according to claim 1 wherein the steps (a) and (b) comprise making multiple color measurements and determining the average of the multiple measurements.
11. The process according to claim 10 wherein steps (a) and (b) comprise making at least a plurality of the multiple measurements at varying locations on the subject.
12. The process according to claim 1 further comprising the step of:
 - (d) establishing a plurality of coloration classes in which a differing change in value of said color factor is indicative of the condition.
13. The process according to claim 12 wherein step (d) comprises establishing a plurality of coloration classes that are colors within varying ranges of lightness.
14. The process according to claim 13 wherein steps (a) and (b) comprise measuring Hunter b and step (d) comprises establishing coloration classes that are colors within varying ranges of Hunter L, the process further comprising the step of measuring by instrument the Hunter L of the subject.
15. The process according to claim 14 wherein the coloration is skin coloration the step (d) comprises establishing coloration classes that include a first class of skin coloration having a Hunter L at or below a value of substantially 51 and a second class of skin coloration having a Hunter L above the value of substantially 51, increases in Hunter b values of substantially two or more points for skin coloration





of the first class being indicative of hyperbilirubinemia, and increases in Hunter b values of substantially three or more points for skin coloration of the second class being indicative of hyperbilirubinemia.

16. A process of detecting a condition in a subject, which condition includes a symptomatic coloration; the process comprising the steps of:
 - (a) measuring with a color measuring instrument the value of a color factor in the color of the subject, said color factor being dependent on the content of said coloration in said color,
 - (b) establishing a range of factor-dependent values characteristic of subjects without said medical condition, and
 - (c) comparing with said range of values the value of the color factor determined in said step of measuring.
17. The process according to claim 16 wherein the coloration is skin coloration, and step (a) comprises measuring Hunter b and the process comprises detecting hyperbilirubinemia.
18. The process according to claim 16 wherein step (a) comprises measuring the color factor Hunter a.
19. The process according to claim 17 wherein step (c) comprises recording values of Hunter b associated with at least one other color factor in individuals without hyperbilirubinemia, step (c) comprises comparing the Hunter b of the skin color of the subject with the Hunter b values previously recorded for individuals comparable with the subject in the at least one other color factor of their skin color.





20. Apparatus for measuring a coloration indicative of a condition, the apparatus including a means for receiving reflected light from a subject, means for deriving from the reflected light a color factor dependent on the content of said coloration in the color of the subject, means for storing the color factor, and means for calculating the change in value of the color factor from the values of the color factor derived at first and second points in time.
21. The apparatus according to claim 20 further comprising means for determining whether the change in value of the color factor is indicative of the condition.
22. The apparatus according to claim 21 wherein the apparatus comprises means for determining a first function weighted in a first portion of the spectrum, means for determining a second function weighted in a second portion of the spectrum, and means for determining a weighting term that is a function of the lightness of the color of the subject and that decreases the value of the color factor as the lightness increases, said means for deriving the color factor comprising means for calculating the color factor from the first and second functions and the weighting term.
23. The apparatus according to claim 22 wherein the first portion of the spectrum is a yellower portion of the spectrum and the second portion of the spectrum is a bluer portion of the spectrum.





24. The apparatus according to claim 23 wherein the first function is Y, the second function is Z, and the weighting term is $1/Y^{1/2}$.
25. The apparatus according to claim 21 wherein the color factor is Hunter b.
26. The apparatus according to claim 21 wherein the color factor is Hunter a.
27. The apparatus according to claim 21 wherein the color factor is a measure of yellowness.
28. The apparatus according to claim 25 further comprising means defining ranges of the Hunter lightness value L, means for determining into which range of L a measured coloration falls, means establishing a value of change of Hunter b indicative of the condition for each range of L, and means for comparing the calculated change in the value of Hunter b to the value of change indicative of the condition for the appropriate range of L.
29. The apparatus according to claim 28 further comprising means establishing a warning value of change of Hunter b for each range of L that is less than the values of change of Hunter b indicative of the condition, and means for detecting when the value of change of Hunter b exceeds the warning value for the relevant range of L, whereby further testing is indicated.
30. The apparatus according to claim 20 further comprising means for deriving from the reflected light a further color factor, and means for calculating the





change in value of the further factor as an indicator of reliability of the test procedure.

31. The apparatus according to claim 30 further comprising means for comparing the change in value of the further factor with a value predetermined as an indicator of possible error in the measuring procedure.
32. The apparatus according to claim 30 wherein the further factor is Hunter L.
33. The apparatus according to claim 20 wherein the coloration is skin coloration, the medical condition is hyperbilirubinemia, and the color factor is Hunter b.
34. The apparatus according to claim 33 further comprising means for converting the value of Hunter b to a value representing serum bilirubin count.
35. Apparatus for measuring a skin coloration indicative of a medical condition, the apparatus including a means for receiving reflected light from a subject, means for deriving from the reflected light at least first and second color factors, means for establishing multiple ranges of coloration based on at least the first and second color factors and means for detecting when the value of the first color factor lies outside a range for coloration having a measured value of the second color factor, whereby the medical condition is indicated as a possible cause of the out-of-range value of the first color factor.

This Sheet Has Been Replaced



36. The apparatus according to claim 35 wherein the first color factor is Hunter b and the second color factor is Hunter L.
37. The apparatus according to claim 36 further comprising means for deriving Hunter a as one method of checking on the reliability of the test procedure, said means for establishing multiple ranges comprising means for establishing said ranges based upon previously detected values of Hunter L, a and b in subjects absent the medical condition, whereby Hunter a measured may be compared to the range of Hunter a for a particular Hunter L and b.
38. The apparatus according to claim 35 wherein the coloration is skin coloration, the medical condition is hyperbilirubinemia, the first color factor is Hunter b and the second color factor is Hunter L.
39. The apparatus according to claim 38 further comprising means for converting the value of Hunter b to a value representing serum bilirubin count.
40. A process of detecting the condition of a test subject based on coloration; the process including measuring with a color measuring instrument a color factor dependent on the content of said coloration of the test subject, assembling a range of acceptable values of the color factor, and comparing the measured color factor with the range of acceptable values to determine if the test subject color factor values lie inside or outside the range.
41. The process according to claim 40 wherein the color factor varies with relative content of opponent colors.

This Sheet Has Been Replaced

SUBSTITUTE SHEET (RULE 26)





42. The process according to claim 41 wherein the color factor is dependent on lightness of coloration of the subject.
43. The process according to claim 42 wherein the opponent colors are blue and yellow.
44. The process according to claim 42 wherein the opponent colors are green and red.
45. The process according to claim 40 wherein the color factor value is dependent on the yellowness of the test subject.
46. The process according to any of claims 40-43 wherein the color factor is Hunter b.
47. The process according to claim 45 wherein the color factor value is further dependent on the lightness of the test subject.
48. The process according to claim 45 wherein the color factor value is dependent on the redness of the test subject.
49. The process according to any of claims 40-42 and 44 wherein the color factor is Hunter a.
50. The process according to claim 48 wherein the color factor value is further dependent on the lightness of the test subject.
51. The process according to claim 42 further comprising calibrating the color measuring instrument by providing a colored tile with color and spectral characteristics specific in the quantities being mea-





sured, and adjusting the indicated measurements of the instrument to correspond to preselected values when measuring the coloration of the tile.

52. A process of detecting a condition in a subject, which condition includes a symptomatic, detectable change in coloration of the subject; the process comprising the steps of:
- (a) at a first point in time, measuring with a color measuring instrument the relative content of opponent colors in the color of the subject,
 - (b) measuring with the color measuring instrument, at least at one further point in time, the relative content of the opponent colors in the color of the subject, and
 - (c) comparing the values determined at said first and further points in time to determine whether there has been exhibited a change therein of a predetermined magnitude evidencing said medical condition.
53. The process according to claim 52 wherein the measurements include a weighting term that is a function of the lightness of the color of the subject and that modifies the value of the measured relative content of the component colors.
54. The process according to claim 16 wherein the factor is Hunter b, the range of factor-dependent values represent changes in Hunter b values, the process further includes measuring the value of the color factor in the color of the subject subsequent to the first-mentioned measurement, determining the difference between the first-mentioned and subsequent measurements and comparing the difference in mea-





sured Hunter b values to the range of values to determine whether a change in Hunter b outside said range is present, indicative of the condition.

55. The process according to claim 16 wherein the factor is Hunter b and the range of values is a range of Hunter b values.
56. The process according to claim 1, 2, 3, 4, 9, 10, 11, 12 or 13 wherein the color factor is Hunter a.
57. The process according to claim 1, 2, 3, 4, 9, 10, 11, 12 or 13 wherein the subject is human and the color factor is Hunter a.
58. The process according to claim 18, wherein the subject is human and the condition is a medical condition.
59. The process according to claim 1, wherein steps (a) and (b) comprise measuring Hunter a as a forecaster of hyperbilirubinemia. (Steps (a) and (b) being the two color factor measuring steps of claim 1.)
60. The process according to claim 1, further comprising the steps of:
 - (a) measuring a lightness factor at said first and further points in time, and
 - (b) compensating any exhibited change of said color factor for significant lightness variations.
61. The process according to claim 60 wherein step (a) comprises measuring Hunter L.

