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دستگاه اندازه گیری درصد اشباع اکسیژن خون (پالس اکسیمتر) و

روشهای نوین موجود وراه حل های کاهش خطا

پروژه درس: ***Bio Instrument***

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خلاصه

بطور کلی یکی از پارامترهای حیاتی یا اصلی ترین پارامتر حیاتی موجود زنده اکسیژن خون می باشد و اندازه گیری میزان اکسیژن خود در یک فرد بیمار می تواند کمک بسیار زیادی در جلوگیری از آسیب به سایر اندامهای بدن مثل مغز ، قلب ، کلیه و کبد و ... بکند .

لذا اندازه گیری دقیق این پارامتر در دسترس ،همه موجودات زنده کمک شایانی به علم پزشکی نوین می کند .

دستگاهی که می تواند بصورت غیر تهاجمی میزان اکسیژن اشباع خون را بدست آورد تحت عنوان پالس اکسیمتر بوده .که در آنها روش های موجود اندازه گیری تا حدود زیادی دقیق بوده و در دستگاههای موجود میزان خطا تقریبا در حدود ± 3 درصد می باشد . ولی این میزان خطا در شرایط نرمال بوده و با تغییرات محیطی و یا فیزیکی فرد بیمار می تواند تغییر کند . لذا پیدا کردن روش محاسباتی و یا اندازه گری دقیق تری می تواند در اینگونه شرایط کمک زیادی در بدست آوردن مقدار دقیق تر بکند . طبق تحقیقات بعمل آورده اینجانب کلیه دستگاه های موجود تقریبا از یک روش اندازه گیری استفاده کرده اند . همچنین روش محاسباتی اکثر آنها یکی بوده و تنها در محاسبات نویز نسبت به یکدیگر متفاوت می باشند . در دهه اخیر روش جدید محاسباتی ابداع شده است که در چند نمونه از دستگاه ها بکار رفته است .

حال اینجانب قصد داشته در خصوص تکنیکهای متداول پالس اکسی متری و همچنین روش کلی پالس اکسی متری مطالبی را عرض کرده و آنها را شرح داده و به دنبال آن روشها و تکنیکهای موجود را مقایسه نموده و در نهایت بتوان از بین آنها در خصوص بهترین روش مطالبی گفت و به آن پرداخت .

مقدمه :

پزشکان برای تشخیص بیماریها و همچنین مراقبت ویژه برای کنترل عملکرد قسمتهای مختلف بدن همواره نیازمند اندازه گیری برخی پارامترها و مشخصات فیزیولوژیک بدن انسان می باشند . پارامترها و مشخصات فیزیولوژیک در بدن انسان طیف بسیار وسیعی را شامل می شوند . غلظت هر کدام از ترکیبات موجود در بدن مانند غلظتهای موجود و مربوط به ترکیبات خون نیز در دسته مشخصات فیزیولوژیک قرار دارند . هر کدام از پارامترها و مشخه های فیزیولوژیک یک محدوده قابل قبول دارند که عدم قرار گرفتن آنها دربازه فوق بیانگر وجود بیماری یا نارسایی در یکی از مکانیسم های مرتبط با آنها می باشد . به همین علت اندازه گیری موارد فوق به خصوص در جاهایی که به عملکرد ارگانهای حیاتی بدن مانند قلب و دستگاه گردش خون مربوط می شوند از نیازهای اولیه و حیاتی پزشکان است .

یکی ازمباحث مهمی که در بررسی فیزیولوژی بدن انسان بسیار مورد توجه پزشکان قرار داشته است و در تشخیص بیماریها به آنها کمک می نماید بحث ***BloodGas*** یا گازهای موجود در خون می باشد . به این ترتیب که پزشکان با استفاده از دستگاهها و روشهای موجود ، کمیات مربوط به گازهای مورد نظر را بدست آورده و از این اندازه گیریها به نتایج مفیدی در زمینه سلامتی شخص مورد بررسی می رسند . کمیات مربوط به این گازها عموما طوری نرمالیزه و استاندارد شده اند که امکان مقایسه وضعیت بیمار را با وضعیتهای سالم به سادگی برای پزشکان فراهم می نمایند . از جمله پارامترهای مربوط به گازهای موجود در خون موارد زیر می باشند :

Po_2 : partial pressure of the oxygen
Pco_2 : partial pressure of the co_2
PH : concenteration of the hydrogen ions
So_2 : saturation of o_2

اختلال هر کدام از کمیات فوق در صورتی که به سرعت مورد درمان قرار نگیرد ممکن است منجر به صدمات جبران ناپذیری شود .

به طور کلی برای انجام هر گونه اندازه گیری در هر زمینه ای در داخل بدن انسان می توانیم دو روش زیر را مورد توجه قرار داد :

۱- روش تهاجمی ***invasive***

۲- روش غیر تهاجمی ***noninvasive***

روشهای تهاجمی عبارتند از روشهایی که در آن اندازه گیری به روش کاملاً مستقیم برروی بیمار انجام شده و غالبا با ایجاد درد و ناراحتی برای شخص بیمار همراه می باشد مانند روشهایی که شامل نمونه برداری از عضوی خاص ، گرفتن خون یا هر مایعی از بدن ، وارد کردن هر گونه الکترود به داخل بدن و غیره می باشند . روشهای تهاجمی گاهی از روشهای غیر تهاجمی دقیق تر می باشند ولی به دلیل ناراحتی که برای شخص مورد بررسی ایجاد می نمایند و همچنین عدم امکان اندازه گیری سریع و به فواصل زمانی کم دارای محدودیتهایی می باشند و همین امر منجر شده که در اکثر موارد ،روشهای غیر تهاجمی ترجیح داده می شوند .

در روشهای غیر تهاجمی به طریق کاملا غیر مستقیم و بدون هیچ گونه ناراحتی برای شخص بیمار کمیت مورد نظر ، اندازه گیری می شود .

در گذشته برای اندازه گیری ترکیبات فیزیولوژیک به عنوان مثال ترکیبات موجود در خون اولین راه حل نمونه برداری (گرفتن خون) و سپس آنالیز شیمیایی نمونه گرفته شده بود . توسط این روش ترکیبات موجود درخون مشخص می شدند اما این روش اندازه گیری دو ایراد بسیار مهم و اساسی دارد . مورد اول اینکه نمونه برداری توسط یک جسم خارجی مانند یک ***catheter*** صورت می گیرد که برای بیمار ناراحت کننده و دردآور است . ایراد دوم عدم امکان اندازه گیری مداوم و ***realtime*** یک مشخصه توسط این روش می باشد . به عنوان مثال غلظت اکسیژن اشباع موجود در خون همواره عامل مهمی برای چگونگی عملکرد سیستم تنفسی و تهویه شخص بوده و کاهش اکسیژن از مقدار قابل قبول خود به نحوی نشان دهنده نارسایی در بخشی از

سیستم اکسیژن رسانی بدن می باشد . به همین دلیل در مواقع حساس مانند عملهای جراحی برای آگاهی از چگونگی عملکرد سیستمها و دستگاههای اکسیژن رسانی بدن همواره باید مقدار اکسیژن اشباع خون را به صورت ***reallime*** تحت نظر داشت که به روش قبلی این امکان وجود ندارد .

ویژگی اصلی روشهای اپتیکی و اسپکتروفوتومتریک :

- سادگی
- غیر تهاجمی بودن
- امکان دسترسی لحظه ای (***reallime***) به اطلاعات مورد نظر می باشد .

امروزه با به کار بردن این روشها و استفاده از طول موجهای مختلف نور امکان اندازه گیری کمیتهای متغیر مختلفی در بدن انسان مانند درصد اکسیژن اشباع خون وجود دارد .

۱)تبادلات گازها :

۱-۱) فیزیولوژی انتقال اکسیژن

فرایند متابولیسم بدن در دو مرحله انجام میگیرد :

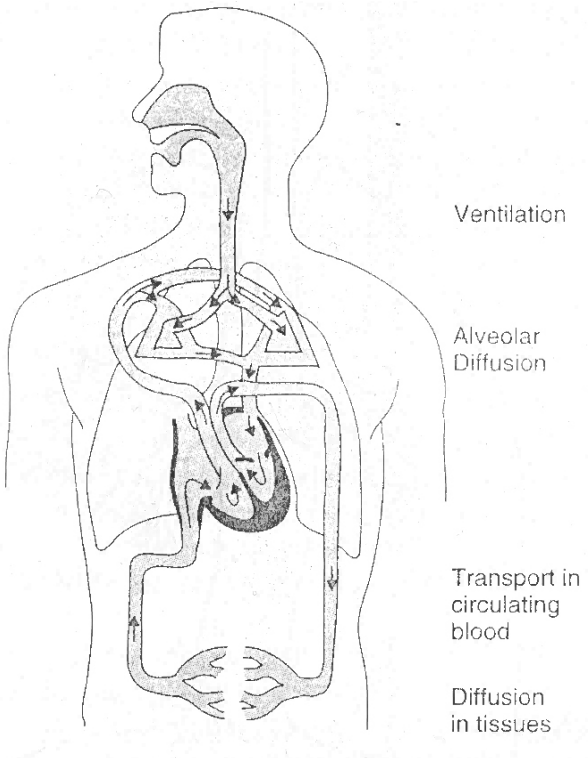
۱- ***catabolism***

۲- ***anabolism***

در مرحله کاتابولیسم مواد با یکدیگر ترکیب شده و تولید انرژی می نمایند در این فرایند جهت اکسید شدن بافت اکسیژن لازم است .

در مرحله آنابولیسم مواد تجزیه میشوند ودر نتیجه تجزیه آنها CO_2 تشکیل میشود که در فرایند تنفس با اکسیژن جایگزین می گردد.

در شکل (۱-۱) فرایند انتقال این گازها نشان داده شده است .



شکل (۱-۱)

در طی دم اکسیژن موجود در هوا به داخل ریه منتقل میگردد وبه ***alveole*** ها منتقل می گردد .

alveole ها دیواره نازکی دارند که با رگهای خونی در ارتباط است و همانند یک غشاء عمل میکند که در آنها O_2 با CO_2 جایگزین می گردد .

لازم به ذکر است که ، رگهای خونی که ، اکسیژن به آنها منتقل میگردد شریان و رگهایی که در آنها خون داکسیژنه شده را ورید گویند .

قفسهٔ سینه حفره ایی ما بین دنده ها و دیافراگم شکمی است که با انبساط آن فشار داخل قفسهٔ سینه کم شده و در نتیجه هوا از طریق مجرای تنفسی وارد ریه ها شده و همچنین در اثر انقباض قفسه سینه هوای داخل به بیرون انتقال می یابد .

۲-۱) روابط

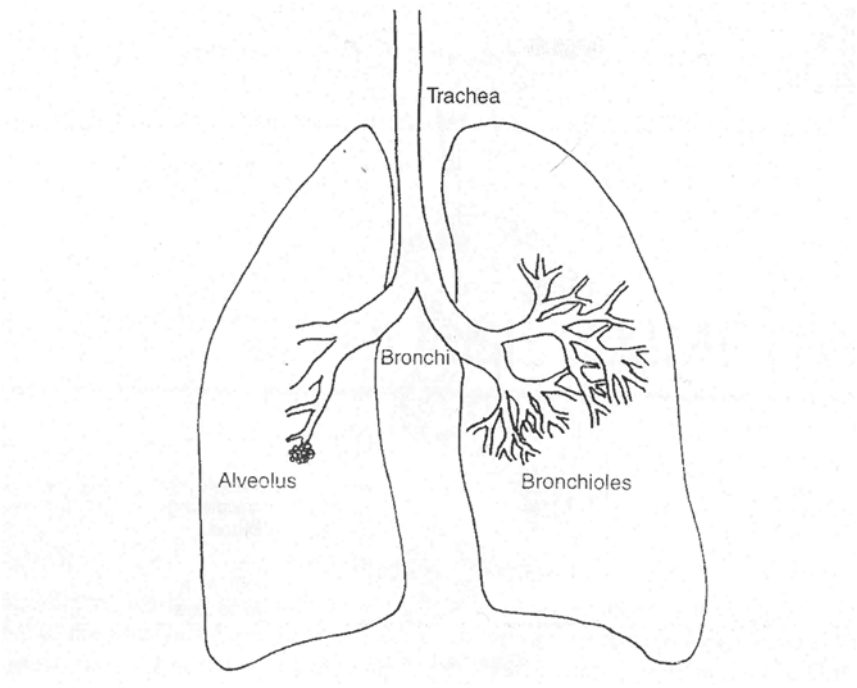
تنفس (***ventilation***) به عواملی همچون tv (***tidal volume***) و همچنین f_r (***respiration frequency***) بستگی دارد .

در طول مرحله دم هوا از طریق مجرای بینی وارد ریه ها شده ، در طول این مجرا هوا مرطوب شده و همچنین دمای آن به حدود $۳۷^{\circ}C$ میرسد .

هوا از این مجرا به داخل ***bronch*** ها وارد شده و از آنجا به ***bronchiole*** ها رفته و در نهایت به ***alveole*** ها میرود .

Bronch ها توسط اعصاب سمپاتیک تحریک میشوند.

حجم هوای انتقالی از نای به برنچها را ***anatomical dead space*** گویند زیرا در این مسیر هیچ مبادله گازی صورت نمی گیرد .



شکل (۲-۱)

محاسبات تنفسی در فاز بازدم بصورت زیر می باشد :

$V_E = V_D + V_A$ (1-1)

V_E : expiratory tidal volume

V_D : dead space tidal volume

V_A : alveolar space tidal volume

$V_E = V_E \cdot f_r$ (1-2)

V_E = the gase volume breathed in or out per minut

$V_E = V_D + V_A$ (1-3)

مقدار نرمال f_r در حدود $\mathbf{14}^{\frac{\mathbf{breaths}}{\mathbf{minute}}}$ می باشد . و tv نرمال در حدود $\mathbf{0.5}^{\frac{\mathbf{liter}}{\mathbf{minute}}}$ و برای V_E در حدود $\mathbf{7}^{\frac{\mathbf{liter}}{\mathbf{minute}}}$ میباشد .

حجم کل ***alveole*** ها تقریباً برابر ۷۰٪ حجم کل(tv) میباشد .

۳-۱) اکسیژن خون

اکسیژن و دی اکسید کربن همانند دیگر گازها بصورت محلول در خون نیستند و می توانند به راحتی توسط خون انتقال یابند .

اکسیژن از ریه ها و دی اکسیدکربن از بافت متصل به ملکولهای ***hemoglobin*** توسط ***erythrocyte*** ها می باشند .

Erythrocyte ها همان سلولهای قرمز خونی هستند .

رنگ قرمز هموگلوبین باعث شده که خون نور با طول موجهای کوتاه را شدیداً جذب نماید . لذا تا قسمت آبی طیف نوری جذب شده و نور قرمز (طول موجهای بلند) عبور می کنند .

خون داکسیژنه شده ، طول موجهای بلند را شدیداً جذب کرده و طول موجهای کوتاه را کمتر جذب می کند . لذا خون وریدی تیره تر می باشد .

بطور خلاصه اکسیژن موجود در خون انسان به دو صورت مجزا موجود می باشد :

۱. در حالت نرمال در حدود ۹۸ درصد اکسیژن خون به صورت ترکیب با هموگلوبین (Hb) در سلولهای قرمز خون می باشد .

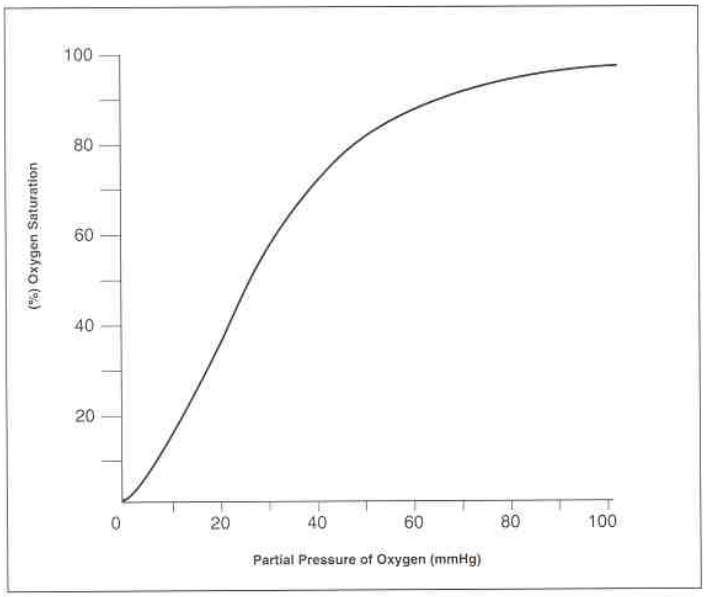
۲. ۲٪ اکسیژن باقی مانده به صورت فیزیکی محلول در پلاسماست .

با توجه به توضیحات بالا به روشنی در می یابیم که برای اندازه گیری اکسیژن موجود در خون باید مقدار هموگلوبین ترکیب شده با اکسیژن یعنی Hbo_2 را اندازه گیری نمود البته ۲٪ محلول در پلاسما قابل صرفنظر می باشد به همین منظور تابع اکسیژن اشباع را معمولا به صورت مقابل تعریف می نمایند :

$$\%S_aO_2 = \frac{[Hbo_2]}{[total:Hb]} \times 100 \qquad (1\text{-}4)$$

منظور از علامت // ، غلظت میباشد .

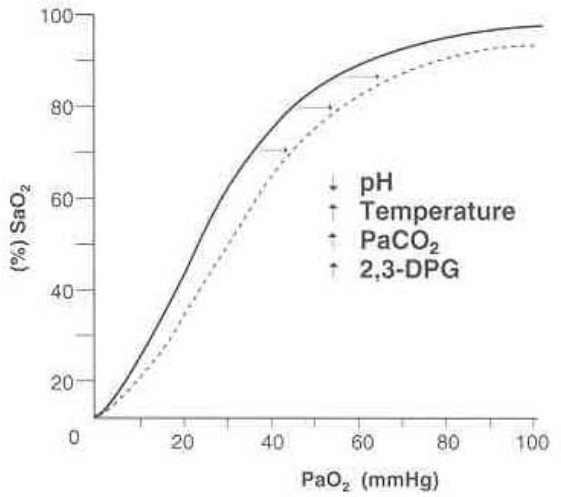
بر طبق قانون ***mass action*** میزان اشباء اکسیژن خون وابسته به میزان فشار جزئی اکسیژن است . این نسبت در منحنی ODC نشان داده شده است .



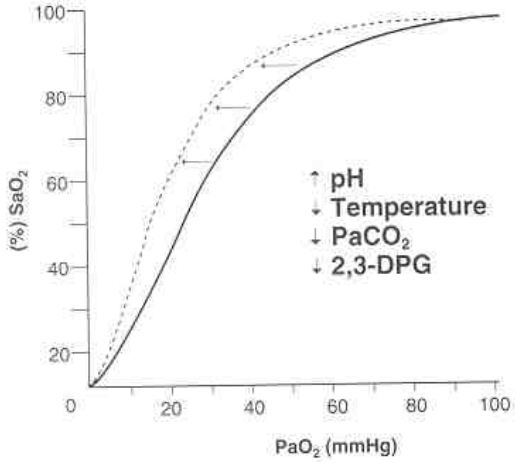
شکل (۳-۱)

همانطور که قبلا گفته شد در رابطه با اکسیژن دو کمیت مهم Po_2 و So_2 مطرح می باشد حال ممکن است این سئوال پیش آید که رابطه این دو کمیت به چه صورت می باشند و آیا یکی از آنها را می توان با استفاده از دیگری بدست آورد ؟

آنچه که در مرحله اول به ذهن می رسد این است که با توجه به اینکه به هر حال تقریباً عمده اکسیژن موجود در خون به صورت Hbo_2 (اکسی هموگلوبین) می باشد . قاعدتاً فشار جزئی آن باید با مقدارش متناسب باشد ولی چگونگی این تناسب خود جای بحث دارد . در این رابطه منحنیهایی تحت عنوان ***ODC*** یا ***Oxyhemoglobin Dissociation*** وجود دارند که بیانگر رابطه اکسیژن اشباع خون (So_2) و فشار جزئی اکسیژن (Po_2) می باشند . شکل شماره(۳-۱) این منحنی را نشان می دهد .



شکل (٤-١)



شکل (٥-١)

منحنی های فوق تغییرات ODC با تغییر $PH, Temperature, Pa\,co_2$ را نشان میدهد . آنچه که در اولین نگاه از این منحنی ها بر می آید این است که So_2 و Po_2 با همدیگر متناسبند اما به صورت غیر خطی .

با استفاده از منحنیهای ODC و دانستن یکی از مقادیر ، با توجه به اینکه اندازه گیری Po_2 به طریق شیمیایی و غیره ، ساده تر می باشد می توان مقدار دیگر را نیز تحت شرایط دمایی و PH مشخص ، بدست آورد . پس ظاهراً این منحنیها یکی از راههای بدست آوردن کمیات فوق می باشند اما در پزشکی معمولاً از این منحنیها استفاده نمی شود زیرا در وضعیتهای فیزیولوژیکی غیر نرمال که غالبا در مورد بیماران وجود دارد این نوع اندازه گیری با توجه به مقادیر

PH و دما در حالت مربوطه توأم با خطا می باشند بنابراین تقریبا در همه موارد اندازه گیری مستقیم Po_2 و So_2 ترجیح داده می شود .

۴-۱) اهمیت اکسیژن در خون

کاهش فشار جزئی اکسیژن یعنی Po_2 و همچنین اکسیژن اشباع خون (So_2) معمولا زمانی اتفاق می افتد که در محل مبادله اکسیژن ناشی از استنشاق و خون ، یعنی در آلوائلها مبادله به خوبی صورت نگیرد . علت اختلال در مبادله به دو علت می تواند باشد یعنی یا به دلیل کمبود اکسیژن در محل مورد نظر است و یا به علت کمبود خون لازم برای مبادله صحیح و نرمال .

کمبود اکسیژن در محل مبادله می تواند به یکی از دلایل زیر باشد :

- کاهش تهویه عمومی
- مصرف بیش از حد مجاز مواد مخدر
- از کار افتادگی ، فلج ، رعشه و یا رخوت ماهیچه های تنفسی
- انسداد هوایی مثلا توسط فرورفتن یک شیء خارجی مانند غذا در حلق یا آنچه در حملات سریع در بیماران آسمی اتفاق می افتد و ناشی از اسپاسم عضلات تنفسی می باشد .
- پر شدن مجراهای هوایی توسط یک مایع مثلا در ذات الریه و ادم ریوی .

کمبود خون در محل مبادله می تواند ناشی از عوامل زیر باشد :

- نارسایی قلبی مادرزادی
- انسداد جریان خون در رگهای ریوی

بیماریهایی وجود دارند که از هر دو طریق کمبود اکسیژن و همچنین کمبود خون در محل مبادله باعث کاهش اکسیژن اشباع خون می شوند مانند :

- ***emphyseme*** نفخ

- ***chrenic bronehits*** برنشیت مزمن

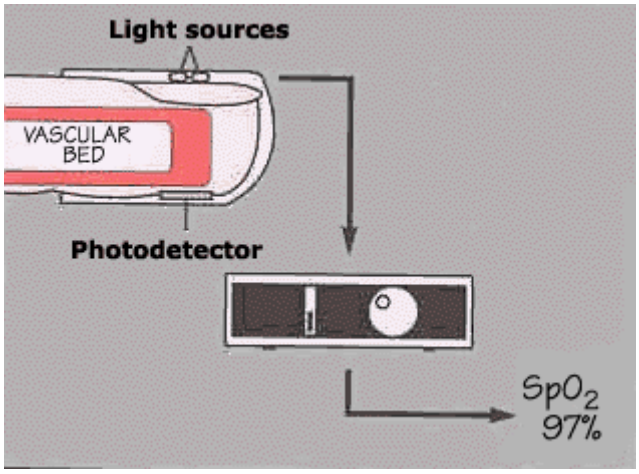
۲) پالس اکسی متر :

۲-۱) ویژگیها

همانطور که قبلا گفته شد پالس اکسی متری یکی از روشهای غیر تهاجمی برای تعیین میزان اکسیژن اشباع در خون می باشد و همین مزیت مهم سبب پیشرفت روز افزون آن در ساخت شده است.

پالس اکسی متر میزان اکسیژن اشباع خون را بوسیله آنالیز اختلاف زمانی نوری که در فازسیتول قلب از جریان خون داخل بافت عبور می کند ، تشخیص می دهد . در این دو روش پالس اکسی متری یعنی روشهای عبوری و انعکاسی برای اندازه گیری اشباع خون مقدار اکسیژن داخل خون سرخرگها مد نظر می باشد . به همین دلیل آن را به صورت S_aO_2 نشان می دهند که اندیس ***a*** بیانگر ***artrial*** یا سرخرگی می باشد . البته در روشهای دیگر مثلا روش ***Intra vasocular*** که منبع نوری توسط یک فیبراپتیکی به داخل بدن فرستاده شده و نور مستقیما به سطح رگ تابیده می شود مطالعه برروی سیاهرگها انجام می شود و به همین دلیل اکسیژن اشباع اندازه گیری شده را با S_vO_2 نمایش می دهند که V مخفف ***Venous*** می باشد .

دو روش ***transmission*** و ***reflectance*** دارای دو منبع نوری نوری با نورهای قرمز (***red***) و مادون قرمز (***infrared***) و یک آشکار ساز نوری هستند (***photodetector***) می باشند .



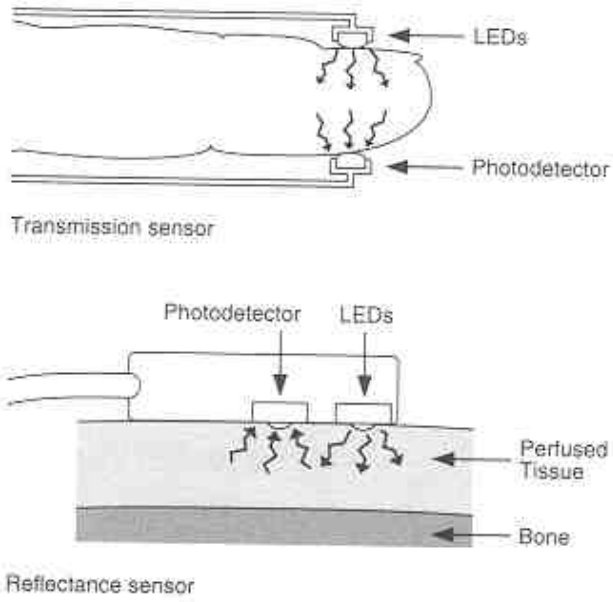
شکل (۱-۲)

۲-۲) انواع و دسته بندیها

دو نوع پالس اکسی متر وجود دارد .

۱) ***tnansmission*** عبوری

۲) ***reflectance*** انعکاسی



شکل (۲-۲)

در روش ***transmission*** منبع نوری و آشکار ساز روبروی هم قرار می گیرند و بدن بین این دو قرار دارد و طول موجها در این روش در دو ناحیه ***Red*** و ***IR*** می باشند .. روش عبوری را باید معمولا در نوک انگشتان و یا نرمی گوش بکار برد .

در روش ***reflectance*** منبع نوری و آشکار ساز مجاور یکدیگر روی سطح بدن قرار می گیرند و این مزیتی برای آن نسبت به روش ***transmission*** می باشد . زیرا می توان آن را در هر محلی از بدن قرار داد . طول موجها در این روش نیز همان دو ناحیه ***Red*** و ***IR*** می باشند .

معمولاً برای ***red*** 660^{nm} و برای ***IR*** از طول موج 940^{nm} استفاده می شود .

توجه : کاربرد طول موجهای فوق در روش ***noninvasive*** مشکلات زیر را به همراه دارد :

- تضعیف نور توسط خون و بافت
- انکسار

- پخش پرتوها
- همچنین با توجه به خصوصیات پوستی و بافت در افراد مختلف کالیبر اسیون این دستگاه مشکلاتی را به همراه خواهد داشت .

علت کاربرد پالس اکسی متر به روش عبوری در نواحی نرمی گوش و نوک انگشتان به ساختمان پوست انسان بر می گردد .

(ضخامت پوست بین 0.2^{mm} تا 2^{mm} متفاوت است .)

پوست شامل سه لایه محافظ و میانی و داخلی است . محل تقاطع و به هم رسیدن مویرگهای سیاهرگی و سرخرگی در ناحیه داخلی پوست است که بسته به بالا رفتن دما جریان خون تا حدود 36 برابر افزایش می یابد که این افزایش جریان خون در پالس اکسی متر مهم است .

در اینجا دو جزء برای نور تابیده شده در نظر می گیرند یکی را به عنوان جزء **ac** و دیگری **dc** می نامند اما منظور از این اصطلاحات با آنچه معمولا در الکترونیک ذکر می شود متفاوت است . به این ترتیب که نور **dc** طول موجی است که با شدت ثابت به سطح بافت تابیده می شود . اما نور **ac** یعنی اینکه ما نور را به صورت پالسی با یک پریود ثابت به سطح بافت بتابانیم .

لذا نوری که با شدت ثابت تابنده شود **dc** نام دارد و نوری که با حالت پالسی تابنده شود **ac** نام دارد ضریب جذب دربافت نسبت ، به نور **ac** یکسان نیست برعکس **dc** (اطلاعات از نور **ac** بدست می آید .)

اشکال نور **dc** اینست که محیط روی آن اثر می گذارد . برای تحریک رگهای خونی محل گذاشتن پالس اکسی متر را تا $41\ ^{\circ}C$ گرم می کنند .

۲-۳) محاسبات :

قانون ***Beer-Lambert*** بصورت زیر بیان می گردد :

$$\mathbf{I = I_0 e^{-\varepsilon(\lambda)CL}} \qquad (2\text{-}1)$$

که این قانون میزان نور عبوری با طول موج λ از یک ماده به ضخامت $\mathscr{L}$ و با تابش اولیه $\mathscr{I}_0$ و با غلضت $\mathscr{C}$ و همچنین ضریب جذب $\boldsymbol{\varepsilon(\lambda)}$ را بیان می کند .

از قانون فوق می توان ***optical density*** یک ماده را بصورت زیر بیان کرد :

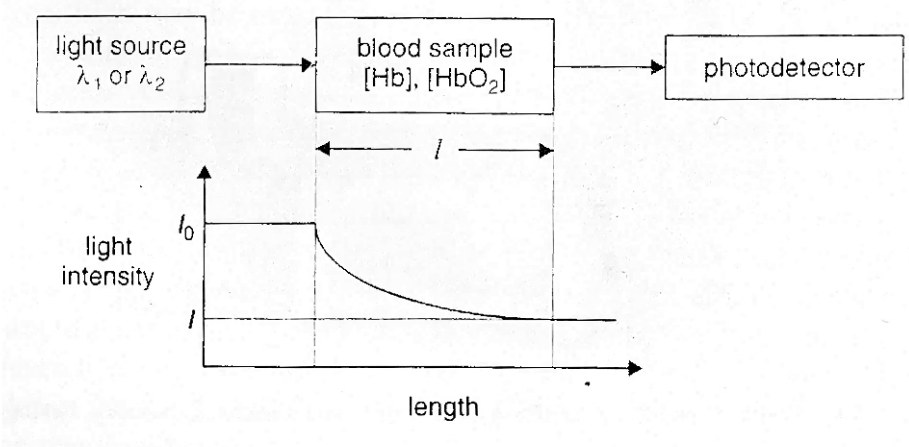
$$\mathbf{A(\lambda) = -\ln \frac{I}{I_0} = \varepsilon(\lambda)CL} \qquad (2\text{-}2)$$

و زمانی که از یک ماده بیشتر داشته باشیم داریم :

$$\mathbf{A_t(\lambda) = \sum_{i=1}^{n} \varepsilon_i(\lambda) C_i L_i} \qquad (2\text{-}3)$$

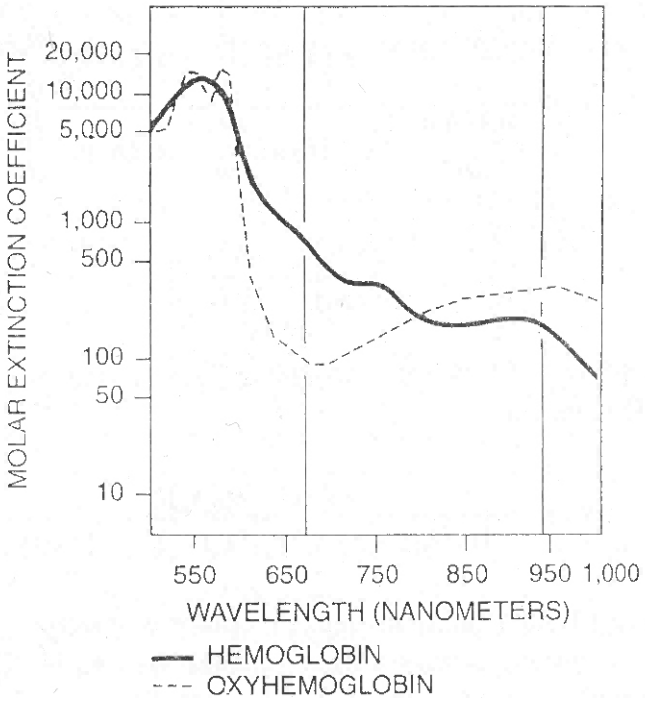
۲-۴) اکسیمتری

در اکسیمتری یک نمونه از خون را در داخل محفظه ایی به طول $\mathscr{L}$ گذاشته و در یک طرف آن منبع نور با دو طول موج λ_1 و λ_2 قرار داده و در طرف دیگر آن فتودتکتور قرار داده تا میزان نور عبوری را بسنجد .



شکل(۳-۲)

با توجه به منحنی شکل (٤-۲) می توان فهمید که ضریب جذب اکسی هموگلوبین و داکسی هموگلوبین برای طول موجهای مختلف فرق میکند .



شکل(٤-۲)

لذا میتوان غلظتهای آنها را برای این نمونه بدست آورد . و توسط رابطه

$$\%S_aO_2 = \frac{[Hbo_2]}{[total:Hb]} \times 100 \qquad (2\text{-}4)$$

میتوان درصد اشباع اکسیژن خون را بست آورد .

در ***co-oximeter*** از ٤ طول موج جهت بدست آوردن غلظتهای دی اکسی هموگلوبین ، اکسی هموگلوبین ، کربوکسی هموگلوبین و متموگلوبین از یک نمونه خون استفاده می شود .

۲-۵) معادلات

در پالس اکسیمتری تنها دو منحنی مربوط به Hb و Hbo_2 برای ما اهمیت دارند . فرض می کنیم که بخواهیم دو طول موج را با توجه به منحنی های فوق انتخاب کنیم که به درد اندازه گیری ما بخورند .

در روش غیر تهاجمی سنجش درصد اشباع خون در یک فرد می توان توسط یک منبع نور در یک طرف انگشت نیز همین محاسبات را انجام داد ولی در اینجا دیگر موادی که نور از آنها عبور می کند تنها خون شریانی نمیباشد .

این موارد میتواند شامل پوست ، رگهای شریانی ، رگهای وریدی و بافت دیگر آن نیز باشد لذا می توان رابطهٔ(۲-۳) را بصورت زیر نوشت :

$$A_t(\lambda) = \varepsilon_o(\lambda)C_oL_o + \varepsilon_d(\lambda)C_dL_d + \varepsilon_x(\lambda)C_xL_x + A_y(\lambda) \qquad (2\text{-}5)$$

که در آن ***o*** منظور اکسی هموگلوبین شریانی و ***d*** داکسی هموگلوبین شریانی و ***x*** جزبهای دیگری که غیر از خون شریانی می باشند و ***y*** شامل منابع نا معین تضعیف اپتیکی می باشد .

درابطهٔ (۲-۵) برای دو طول موج λ_1 و λ_2 داریم :

$$A_t(\lambda_1) = \varepsilon_o(\lambda_1)C_oL_o + \varepsilon_d(\lambda_1)C_dL_d + \varepsilon_x(\lambda_1)C_xL_x + A_y(\lambda_1) \qquad (2\text{-}6)$$

$$A_t(\lambda_2) = \varepsilon_o(\lambda_2)C_oL_o + \varepsilon_d(\lambda_2)C_dL_d + \varepsilon_x(\lambda_2)C_xL_x + A_y(\lambda_2) \qquad (2\text{-}7)$$

در پالس اکسی متری که هدف اندازه گیری درصد اشباع اکسیژن شریانی است تنها مقادیر مربوط به جذب o, d را در نظر می گیریم .

حال پارامتر R را بدین صورت تعریف می کنیم :

$$R = \frac{\frac{dA_1(\lambda_1)}{dt}}{\frac{dA_2(\lambda_2)}{dt}} \qquad (2\text{-}8)$$

$$R = \frac{\varepsilon_o(\lambda_1)C_o\frac{dL_o}{dt} + \varepsilon_d(\lambda_1)C_d\frac{dL_d}{dt}}{\varepsilon_o(\lambda_2)C_o\frac{dL_o}{dt} + \varepsilon_d(\lambda_2)C_d\frac{dL_d}{dt}} \qquad (2\text{-}9)$$

چون $\frac{dL_o}{dt} = \frac{dL_d}{dt}$ لذا داریم :

$$R = \frac{\varepsilon_o(\lambda_1)C_o + \varepsilon_d(\lambda_1)C_d}{\varepsilon_o(\lambda_2)C_o + \varepsilon_d(\lambda_2)C_d} \qquad (2\text{-}10)$$

که در این رابطه : $C_o = [HbO_2], C_d = [Hb]$

پس برای S_pO_2 داریم :

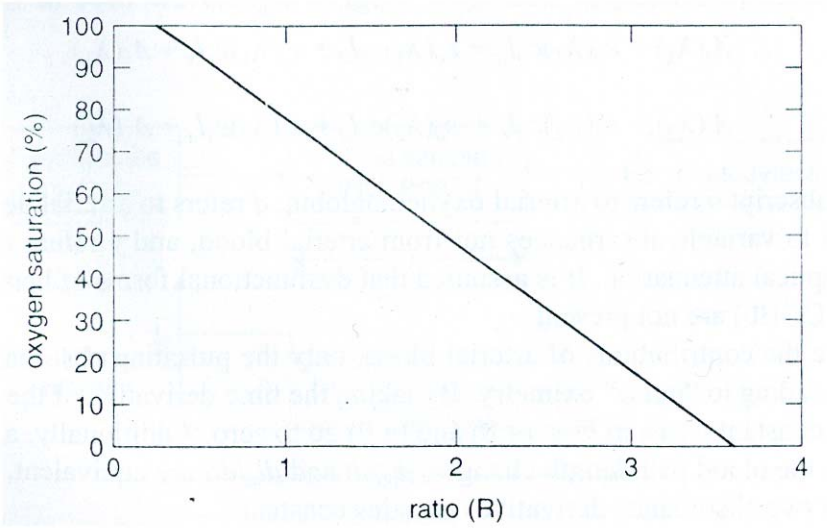
$$S_pO_2 = \frac{\varepsilon_d(\lambda_1) - \varepsilon_d(\lambda_2)R}{[\varepsilon_d(\lambda_1) - \varepsilon_o(\lambda_1)] - [\varepsilon_d(\lambda_2) - \varepsilon_o(\lambda_2)]R} \qquad (2\text{-}11)$$

در عمل جهت ساخت پالس اکسی متر برای منبع نور از فتودیود استفاده کرده که یکی بصورت فتودیود قرمز در طول موج 660^{nm} ودیگری IR باطول موج $890^{nm}\_950^{nm}$ می باشد که این فتودیودها منوکروماتیک نیستند . ولی در حدود $20^{nm}\_50^{nm}$ تغییر میکنند .

می توان رابطهٔ بین R و S_pO_2 را بصورت زیر مدل کرد :

$$S_pO_2 = \frac{a - bR}{c - dR} \qquad (2\text{-}12)$$

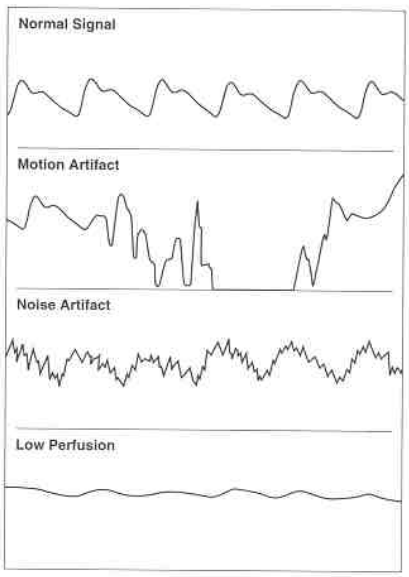
همچنیل نمودار کالیبراسیون ***R*** نسبت به مقدار درصد ***oxygen saturation*** بصورت زیر می باشد .



شکل (۵-۲)

۳) پیاده سازی

جهت پیاده سازی عملی میتوان از مترهای مختلفی استفاده نمود ، ولی اهمیت این پیاده سازی در خروجی دقیق و صحیح وبدون نویز آن می باشد . مخصوصاً در هنگام آرتیفکتهای حرکتی و همچنین زمانی که میزان درصد اکسیژن بیمار کم میشود خروجی صحیح حائز اهمیت می باشد .



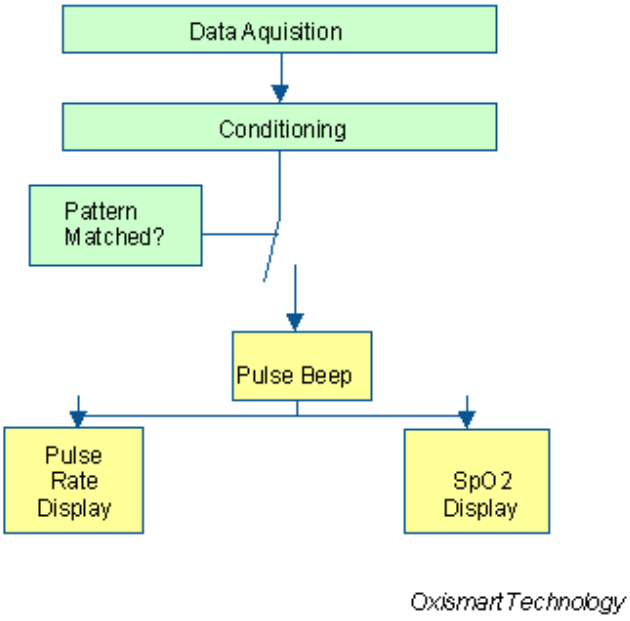
The effect of artifact on a pulsatile signal from an oximetry sensor

شکل (۱-۳)

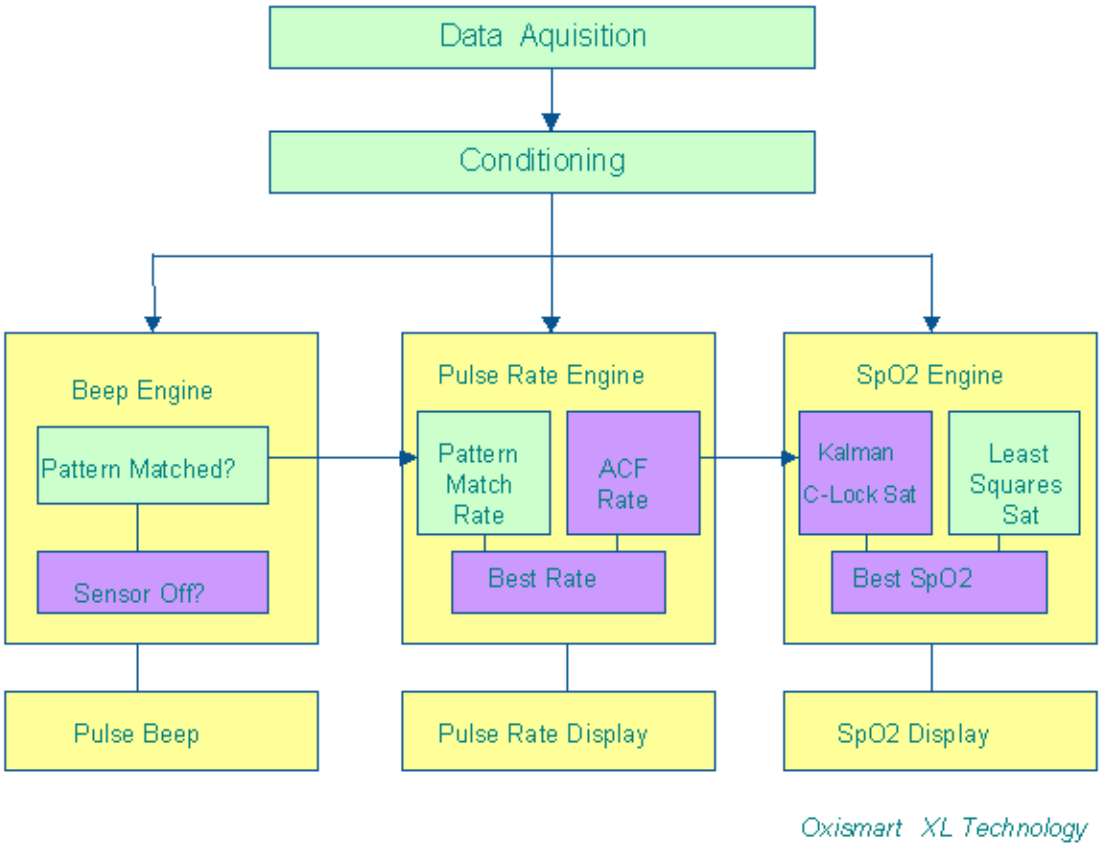
لذا حذف نویز و تحلیل درست در پیاده سازی آن مهم می باشد . تا کنون تکنیکهای زیادی جهت پیاده سازی دستگاه پالس اکسیمتری وجود داشته ولی اکثر آنها در مقابل آرتیفکتهای حرکتی و همچنین کاهش اکسیژن اشباع خون پاسخ خوبی نداشته .

۱-۳) تکنیکها

بلوک دیاگرام بعضی از تکنیکهای متداول بصورت زیر می باشد .

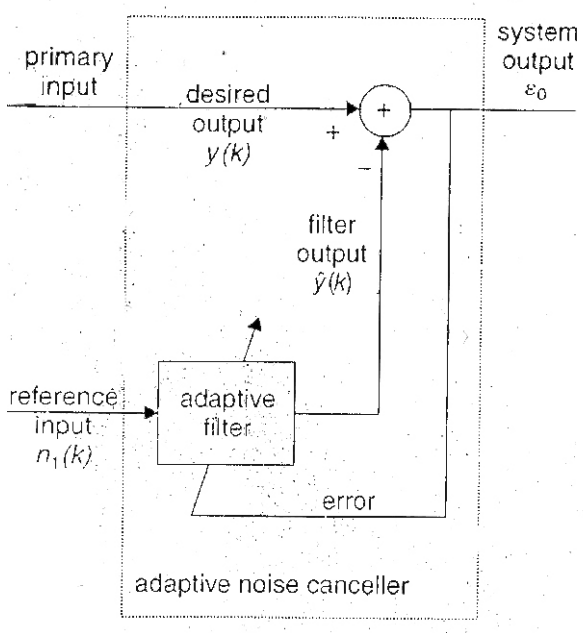

Data Aquisition
Conditioning
Pattern Matched?
Pulse Beep
Pulse Rate Display
SpO2 Display
Oxismart Technology

شکل (۲-۳)


Data Aquisition
Conditioning
Beep Engine
Pattern Matched?
Sensor Off?
Pulse Rate Engine
Pattern Match Rate
ACF Rate
Best Rate
SpO2 Engine
Kalman C-Lock Sat
Least Squares Sat
Best SpO2
Pulse Beep
Pulse Rate Display
SpO2 Display
Oxismart XL Technology

شکل (۳-۳)

تکنیک جدیدی که تازه در بعضی از دستگاهها ارائه شده است تکنیک ***masimo set (masimo signal extraction technic)*** می باشد که در آن از تکنیک ***adaptive noise cancellation (ANC)*** (شکل (٤-٣)) استفاده شده است .



شکل (٤-٣)

برای سیگنال ورودی $\mathbf{u}_{\lambda_1}(\mathbf{k})$ میتوان $\mathbf{R}$ را بصورت زیر نوشت :

$$\mathbf{R}=\frac{\boldsymbol{\varepsilon}_{\mathbf{o}}(\lambda_1,\mathbf{k})\mathbf{C}_{\mathbf{o}}(\mathbf{k})+\boldsymbol{\varepsilon}_{\mathbf{d}}(\lambda_1,\mathbf{k})\mathbf{C}_{\mathbf{d}}(\mathbf{k})}{\boldsymbol{\varepsilon}_{\mathbf{o}}(\lambda_2,\mathbf{k})\mathbf{C}_{\mathbf{o}}(\mathbf{k})+\boldsymbol{\varepsilon}_{\mathbf{d}}(\lambda_2,\mathbf{k})\mathbf{C}_{\mathbf{d}}(\mathbf{k})}=\frac{\mathbf{u}_{\lambda_1}(\mathbf{k})}{\mathbf{u}_{\lambda_2}(\mathbf{k})} \qquad (3\text{-}1)$$

چون سیگنالی که از فتودیود گرفته می شود همراه با نویز می باشد لذا :

$$\mathbf{y}_{\lambda_1}(\mathbf{k})=\mathbf{u}_{\lambda_1}(\mathbf{k})+\mathbf{n}_{\lambda_1}(\mathbf{k}) \qquad (3\text{-}2)$$

$$\mathbf{y}_{\lambda_2}(\mathbf{k})=\mathbf{u}_{\lambda_2}(\mathbf{k})+\mathbf{n}_{\lambda_2}(\mathbf{k}) \qquad (3\text{-}3)$$

که $\mathbf{n}_{\lambda}(\mathbf{k})\ \mathbf{n}_{\lambda}(\mathbf{k})$ بیانگر نویز میباشد که با سیگنال اصلی جمع شده است .

پس :

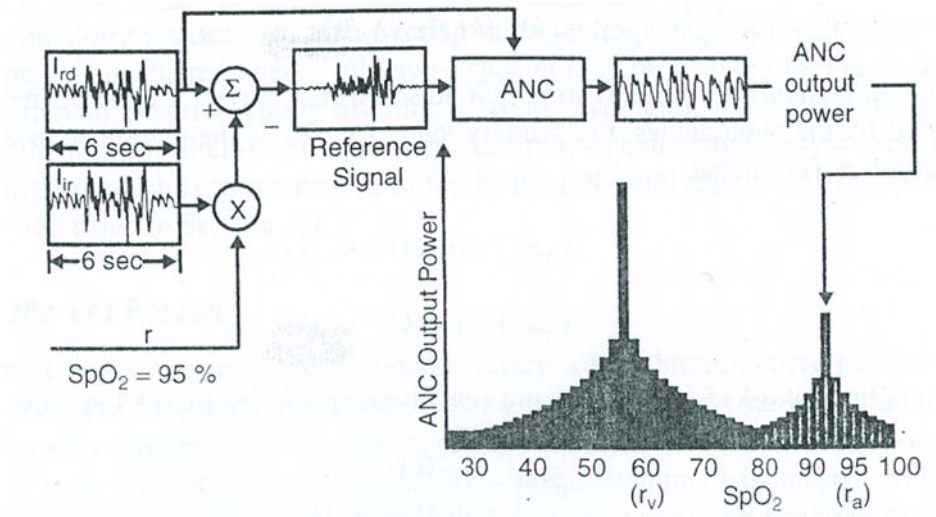
$$\mathbf{R}(\mathbf{k})=\frac{\mathbf{y}_{\lambda_1}(\mathbf{k})-\mathbf{n}_{\lambda_1}(\mathbf{k})}{\mathbf{y}_{\lambda_2}(\mathbf{k})-\mathbf{n}_{\lambda_2}(\mathbf{k})} \qquad (3\text{-}4)$$

$$\mathbf{R}(\mathbf{k})\mathbf{y}_{\lambda_2}(\mathbf{k})-\mathbf{R}(\mathbf{k})\mathbf{n}_{\lambda_2}(\mathbf{k})=\mathbf{y}_{\lambda_1}(\mathbf{k})-\mathbf{n}_{\lambda_1}(\mathbf{k}) \qquad (3\text{-}5)$$

$$\mathbf{n}_{\lambda_1}(\mathbf{k}) - \mathbf{R}(\mathbf{k})\mathbf{n}_{\lambda_2}(\mathbf{k}) = \mathbf{y}_{\lambda_1}(\mathbf{k}) - \mathbf{R}(\mathbf{k})\mathbf{y}_{\lambda_2}(\mathbf{k}) \equiv \mathbf{n}_1(\mathbf{k}) \qquad (3\text{-}6)$$

لذا منبع نویز اصلی بصورت یک ترکیب خطی از منابع نویز و $\mathbf{R}$ می باشند . لذا با دانستن منابع نویز و محاسبهٔ مقدار $\mathbf{R}$ وابسته به آنها می توان آنها را حذف کرد . این مقادیر برای S_pO_2 از ۳٤/۸ تا ۱۰۵٪ بدست آمده . پس می توان با یک سیستم ***adaptive noise cancellation*** مقدار اصلی S_pO_2 را بدست آورد .

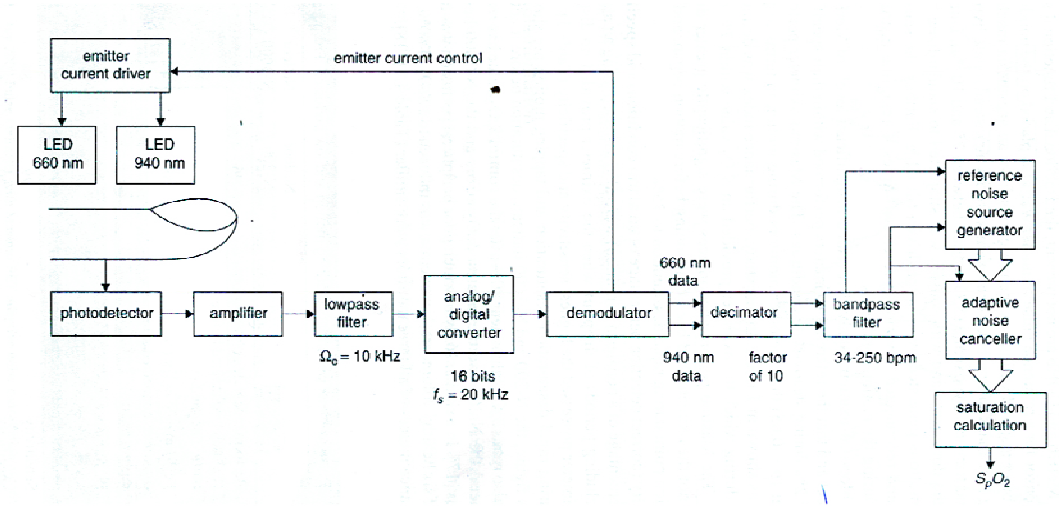
در این تکنیک خروجی $\mathbf{ANC}$ بصورت شکل زیر میباشد ، که در آن پیک اول مربوط به r_v و پیک دوم مربوط به r_a می باشد .



شکل (۵-۳)

در تکنیک ماسیمو ست ، اطلاعات توسط یک $\mathbf{LED}$ قرمز با طول موج $\mathbf{660^{nm}}$ ویک $\mathbf{LED}$, $\mathbf{IR}$ با طول موج $\mathbf{940^{nm}}$ بدست می آید . $\mathbf{LED}$ ها توسط مدار ***emitter current control*** تحریک شده که از قسمت ***demodulator*** فرمان می گیرد . فرکانس مدوله $\mathbf{625^{Hz}}$

می باشد لذا هر سیکل محاسبهٔ آن $t=1/625=1.6^{ms}$ میباشد . در یک سیکل کاری ابتدا به مدت 0.4^{ms} ،LED قرمز روشن شده و سپس به مدت 0.4^{ms} هر دو LED خاموش بوده و باز به مدت 0.4^{ms} ،IR ، LED روشن شده و سپس به مدت 0.4^{ms} دوباره هر دو LED خاموش می باشند . که در مجموع هر سیکل 1.6^{ms} طول میکشد . هنگامی که در سیکل کاری هر دو LED خاموش هستند نور زمینه بدست می آید . LED ها را به میزانی که بتوان نور را تشخیص داد درایو می شوند .



شکل(۶-۳)

یک فتودیود سیگنال حاصل از نور متشر شده LED ها را بدست آورده و سپس سیگنال تقویت شده واز یک **antialiasing** تک قطب که شامل یک فیلتر پایین گذر با فرکانس قطع 10 KHz می باشد عبور می دهند . خروجی توسط A/D با فرکانس **sampling** ، 20KHz و خروجی 16bits دیجیت می شود و پس از دمدوله کردن آن از یک تابع **decimator**

با فاکتور ۱۰ گذرانده و پس از آن وارد یک فیلتر میان گذر شده . ۱۱۷ منبع نویز اصلی ممکن ، از ۵۷۰ نمونه پکهای اطلاعاتی مربوط به IR,red بدست آورده . در نهایت به ANC میرود و خروجی توان آن پروسس می گردد تا طبق آنچه گفته شده اطلاعات مربوط به S_pO_2 استخراج گردد .

لازم به ذکر است که محاسبات هر ثانیه یک بار انجام می شوند و از ٦ محاسبه آخر همیشه میانگین گرفته شده و در خروجی نمایش داده می شود .

این تکنیک تا حدود زیادی کارآمد بوده و بر اساس تحقیقات و آزمایشاتی که صورت گرفته تا حدود زیادی پاسخ خوبی داشته که بعضی از آنها در قسمت ضمائم آمده است .

۳) ضمائم

Annotation of Pulse Oximetry Artifacts on Computerised Anaesthetic Records

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Objectives

The adoption of computerised anaesthesia record keeping systems has been limited by the concern that they record artifactual data and accurate data indiscriminately. The data resulting from artifacts does not reflect the patient's true condition and presents a problem in the later analysis of the record, in addition to the medico legal implications. This study developed an algorithm to automatically annotate artifacts and sought to evaluate the algorithm's accuracy in routine surgical procedures.

Methods

MacAnaesthetist is a semi-automatic anaesthetic record keeping system developed for the Apple Macintosh computer, which incorporated an algorithm designed to automatically detect pulse oximetry artifacts. The algorithm labeled artifactual oxygen saturation values less than 90%. This was done in real-time by analyzing physiological data captured from a Datex AS/3 Anaesthesia Monitor. An observational study was conducted to evaluate the accuracy of the artifact detection algorithm during routine surgical procedures (N=20). An anaesthetic record was made by the anaesthetist using the Datex AS/3 record keeper, while a second anaesthetic record was produced in parallel using MacAnaesthetist. An observer used an independent Nellcor N200 pulse oximeter to judge all oxygen saturation values below 90% as either true or artifact, based on the Datex AS/3 plethysmograph and the oxygen saturation readings on the independent pulse oximeter. A copy of the Datex AS/3 records were kept for later review by a group of anaesthetists (N=20), which judged whether oxygen saturation values less than 90% were either true or artifact.

Results

Collectively the 20 anaesthetic records contained 9 artifactual and 4 true desaturations. The 9 artifacts occurred during 7 procedures, with 2 desaturations present in each of 2 procedures. True oxygen desaturations occurred in 3 procedures, with 2 desaturations occurring in 1 procedure. MacAnaesthetist correctly catagorised 12/13 of the oxygen saturations < 90% resulting in an overall accuracy of 92.3%. No true desaturations were annotated as artifacts, however MacAnaesthetist failed to annotate 1 artifact out of 9. A post-operative review of the Datex AS/3 anaesthetic records (N=10) by twenty anaesthetists resulted in 127 correct responses out of total of 200, resulting in an overall accuracy of 63.5%. The number of correct responses

varied between anaesthetists from 4/10 (40.0% accuracy) to 9/10 (90.0% accuracy). For specific recorded instances of oxygen saturation <90% the accuracy of the clinicians varied from 0-100%. That is, for one desaturation episode all anaesthetists correctly judged a genuine oxygen saturation < 90% to be a true desaturation but for another of the desaturation episodes, all twenty anaesthetists incorrectly judged an artifactual oxygen saturation < 90% to be a true desaturation.

Conclusions

The real-time artifact detection algorithm developed in this study was more accurate than anaesthetists who postoperatively reviewed records produced by an existing computerised anaesthesia record keeping system. Algorithms have the potential to accurately annotate artifacts on computerised anaesthetic records, which will assist clinicians in more correctly interpreting abnormal data when reviewing computerized records. Further research however, is required to develop artifact annotation algorithms for other physiological parameters.

Performance Evaluation of Masimo SET Pulse Oximeter during Mild Hypothermic Cardiopulmonary Bypass

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Introduction: Newly developed pulse oximeters (POs) have been shown to display accurate SpO_2 during motion as well as hypoperfusion.

Purpose: To compare the performance of the Masimo SET Radical (**M**) PO (new technology) with the Nihon Kohden AY-900P (**N**), a conventional PO, during hypothermic cardiopulmonary bypass (CPB).

Methods: Patients undergoing cardiac surgery using mild hypothermic CPB were enrolled. CPB was maintained using a roller pump and non-pulsatile flow, however, a pulse pressure of about 12 mmHg was measurable on the arterial pressure tracing. PaO_2 during CPB was maintained at 250-300 mmHg. PO sensors and a skin temperature probe were applied on randomly chosen fingers on the ipsilateral hand. PO data was collected in real-time with a PC data acquisition system and handwritten notes. Poor PO performance was defined as failure to detect a pulse wave and/or of displaying SpO_2 values less than 97%. PO signal strength (SS) was calculated as modulation of the infrared (IR) photoplethysmogram ((max-min)/mean) expressed as %.

Results: Eighteen patients were studied. CPB and aortic crossclamping (AoX) durations were 203+/-78 min and 135+/-66 min, respectively. Minimum bladder temperature during CPB was 31.1+/-1.0°C. Fourteen patients had PO failures >3 min with instrument **N**. Four of those also had failures with **M** (p=0.0022, Chi-square test). The duration of PO failure during CPB also differed, 6+/-15% with **M** and 36+/-31% with **N** (p=0.0006, t-test). PO failure duration during AoX was 5+/-15% with **M**, and 46+/-43% with **N** (p=0.0005). Pulse wave was not detected during AoX for 4+/-12% with **M** and 36+/-39% with **N** (p=0.002).

Poor PO performance typically occurred immediately after the initiation of CPB or just after AoX. Skin temperature and mean arterial blood pressure (MABP) when poor performance started to occur, were almost same between **M** and **N**. The minimum MABP during which **M** displayed SpO_2 of a 100% value ranged from 25 to 56 mmHg (36+/-10 mmHg). Typical baseline SS was 1% immediately pre-bypass. CPB produced measurable pulsations of 0.1% at approximately 1.6 Hz.

Discussion: **M** displayed accurate SpO_2 values significantly longer than **N** during mild hypothermic CPB, indicating that **M** is more useful for monitoring SpO_2 during hypoperfusion. Although we used non-pulsatile flow during CPB, the roller pump generated sufficient pulsatility so that **M** was able to display SpO_2 even at extremely low MABP. In one patient with massive hemorrhage, **M** displayed SpO_2 of a 100%

value for 10 min, while the systolic blood pressure was less than 35 mmHg. Therefore, it should be noted that continuous display of accurate SpO_2 does not guarantee an adequate perfusion. Confirming plethysmography displayed on new POs is inappropriate for confirming the adequacy of the patient's circulatory function

The Performance of Six "Motion-Resistant" Pulse Oximeters during Motion, Hypoxemia, and Low Perfusion in Volunteers

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Introduction. Pulse oximeters are subject to several errors caused by patient motion. We have previously compared the performance of various pulse oximeters in volunteers during controlled motions and hypoxemia.(1,2) In the present study, we compare SpO2 accuracy and reliability in 6 recent model pulse oximeters, all of which claim to be motion resistant. For comparison with older technology, we included one earlier instrument (N-295).

Methods. Thirty healthy volunteers were each instrumented with six oximeter sensors: three on the moving test hand, and three on the stationary control hand. The Masimo SET oximeter was compared with two other units on each subject. A motor-driven motion table produced repeatable finger tapping and rubbing motions. A modified anesthesia machine with circle system and mask delivered hypoxic gas mixtures with inspired oxygen fractions as low as 10%. SpO2 and pulse rate were recorded continuously, both while subjects breathed room air and during rapid desaturations to SpO2 = 70-75%. Values obtained during motion were compared with simultaneous values from the control hand. Test and control values were compared by means of signal dropout rate, sensitivity and specificity for hypoxemia detection, and Performance Index (PI). The latter is the percentage of time during which the oximeter provides SpO2 readings that are within 7% of control values. For sensitivity and specificity, the hypoxemia alarm threshold was set at SpO2 = 90%. The room temperature was held at 15-18 deg-C during the entire study, to reduce peripheral perfusion and better simulate actual patients. Subjects' measured finger skin temperatures ranged from 20 to 26 deg-C.

Results. The results are summarized in Table 1, which shows the performance index, dropout rate, sensitivity and specificity for hypoxemia detection. The oximeters in the table are listed in descending order of performance index.

Discussion. The Masimo pulse oximeter had a PI value of 93% during motion, with a sensitivity of 99% and specificity of 97%. The next best performer was the Agilent Viridia 24C, with values of 84%, 78%, and 90% respectively. The Nellcor N-295 was included to show a comparison with older generation technology, and its PI value was much lower at 55%. The Masimo SET pulse oximeter showed the best performance

of all units during motion, in terms of both accuracy and reliability. A key difference between this and other volunteer studies is the fact that we maintained skin temperatures below normal to reduce perfusion and better represent patients in critical care settings.

REFERENCES

1. Barker S: Anesthesiology 1997; 86: 101-108.

2. Barker S: Anesthesiology 2000; 93: 3A, A549.

Table 1: Performance index, dropout rate, sensitivity and specificity for six "motion-resistant" oximeters and one earlier instrument (N-295).

Anesthesiology 2001; 95:A587

Pulse Oximeter	Perform. Index%	Dropout%	Sensitivity%	Specificity%
Masimo SET	93	0.0	99	97
Agilent Viridia 24/C	84	1.6	78	90
Agilent CMS-B	80	3.7	70	83
Nellcor N-395	73	4.0	70	73
Datex-Ohmeda 3900	68	1.0	60	52
Novametrix MARS	58	2.4	40	42
Nellcor N-295	55	7.8	39	53

A Comparison of Four Major Brand of Pulse Oximeters (PO) with Masimo SET PO during Motion and Low Perfusion under Normoxic and Hypoxic Conditions in Human Volunteers

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INTRODUCTION: Despite significant improvements in PO technology the problem of being able to accurately obtain a PO reading during patient movement in presence of low perfusion still persists. Many PO manufacturers claim better performance of their PO in those conditions. We, therefore, after approval from the

Institutional Review Board for human subjects undertook the following study to compare four major brand of POs to the Masimo SET PO during motion and low perfusion under normoxic and hypoxic conditions.

METHODS: Seven competent, healthy, adult volunteers (5-females & 2-males) between 18 and 40 years of age (mean 27 +/- 3 SD), with a physical status ASA I, after written informed consent, were enrolled in the study. Masimo Radical version v3 (Masimo I) was compared with Agilent Viridia 24C version Rev B and Novametrix MARS Model 2001 version TBD, and Masimo Radical version v3 (Masimo II) was compared with Nellcor N-395 version v1620 and HP CMS version Rev B. The left hand was used as the test hand and sensors were placed on index, middle & ring fingers. Similar fingers of the right hand had sensors for the same PO to serve as their control. Ear sensor of Ohmeda PO was used as a control for hypoxia. The room was cooled down to a temperature of 16-18 degree C to reduce peripheral perfusion. The motion (performed by a motor-driven motion table) during normoxia (breathing room air) consisted of tapping at 3 Hz, tapping at 3 Hz with disconnect and reconnect of sensors during motion, and random rubbing. The initial selection of fingers for the sensor of the PO was randomized. The sensors were than rotated in a lateral fashion allowing for sensor placement on each finger and the motion was repeated after each sensor change. The study was repeated for a second time with two other POs along with Masimo which was used in both sets of experiments.

The motion during hypoxia (induced employing a disposable re-breathing circuit with a CO2 absorber to a SpO2 of 76 +/- 0.48) consisted of random tapping with disconnect and reconnect of sensors during motion, 3 Hz tapping with disconnect and reconnect during motion, random rubbing, and 3 Hz rubbing. Once the SpO2 reached 75% as measured by ear sensor, the subjects were given 100% oxygen to breathe until his/her SpO2 on the control monitor reached 100%.

A missed event was defined as the inability of the monitor during desaturation to recover before the control monitor reached 100%. A false alarm was considered to be a reading of less than 90% during motion while breathing room air.

RESULTS: False alarms were counted out of 63 occasions during motion on room air, while missed events were counted out of 28 occasions during desaturation episodes for each PO. Sensitivity, specificity, and false alarm rates were calculated for each PO. Our results are summarized in the table. Statistical analysis was performed on the data using chi square analysis, $P < .05$ was considered statistically significant. * = $P<.05$ vs Masimo I, # = $P<.05$ vs HP Viridia 24C, @ = $P<.05$ vs Masimo II.

DISCUSSION/CONCLUSION: While no PO withstood 100% of this vigorous test schedule, Masimo SET PO performed the best and has the highest sensitivity, specificity with fewest false alarm rate. HP CMS, Nellcor N-395, HP Viridia 24C, and Novametrix MARS performed in decreasing order based on the sensitivity, specificity, and false alarm rate.

Anesthesiology 2001; 95:A586

PO	Missed Events	False Alarms	False Alarms Rate	Sensitivity	Specificity
Masimo I	6/28	5/63	7.9%	78.6%	92.1%
HP Viridia 24C	15/28*	27/63*	42.9%	46.4%	57.1%
Novametrix-MARS	23/28*£	45/63*£	71.4%	17.9%	28.6%
Masimo II	1/28	8/63	12.7%	96.4%	87.3%
N-395	13/28@	21/63@	33.3%	53.6%	66.7%
HP CMS Rev B	8/28@	15/63	23.8%	71.4%	76.2%

The Impact of Motion and Low Perfusion on the Performance of Masimo SET Pulse Oximeter (PO) and Four other POs for Measurement of Oxygen Saturation (SpO2) and Pulse Rate (PR) in Human Volunteers

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INTRODUCTION: Whenever clinically, we doubt the SpO2 value, we look for the waveform and PR displayed by PO, whether the waveform is normal or not and whether the PR correlates with the EKG HR or not. Thus PR measured by PO plays a significant role in the clinicians trust of the SpO2 value given by PO. Many manufacturers have improved their equipment with better technology thus improving the performance of POs during motion and low perfusion. The SpO2 performance of various POs has been compared during various motions (1,2). However, to our knowledge, PR performance of various POs has not been reported. We undertook this study to assess the impact of motion and low perfusion on the performance of Masimo SET technology and four other improved brands of POs on SpO2 and PR in human volunteers.

METHODS: Seven ASA I adults (5-females & 2-males) between 18 & 40 years of age were enrolled after obtaining informed consent. Masimo Radical v3 (Masimo I) was compared with HP Agilent Viridia 24C Rev B, and Novametrix MARS Model 2001 vTBD. Masimo Radical v3 (Masimo II) was compared with Nellcor N-395 v1620, and HP CMS Rev B. An Ohmeda PO ear

sensor was used as the control for hypoxemia. The room temperature was lowered to 16 to 18 degree C to lower peripheral perfusion of the volunteers. The left hand was the test hand while the right hand served as the control. The sensors were randomly placed on index, middle & ring fingers. The motion (performed by a motor-driven motion table) during normoxia (breathing room air) consisted of tapping at 3 Hz, tapping at 3 Hz with disconnect and reconnect of the sensors during motion, and random rubbing. The sensors were than rotated in a lateral fashion allowing for sensor placement of each PO on each of the three fingers and the motions were repeated after each sensor change. The study was repeated with two other POs along with Masimo which was used in both sets of experiments.

Hypoxemia was induced employing a disposable re-breathing circuit with a CO2 absorber to a SpO2 of 76 +/- 0.48 SD. The motion during hypoxemia consisted of random tapping and 3 Hz tapping with disconnect and reconnect of the sensors during motion, random rubbing, and 3 Hz rubbing. Once the SpO2 reached 75% as measured by ear sensor, the subjects were given 100% O2 to breathe until his/her SpO2 on the control monitor reached 100%.

PR & SpO2 data were recorded on-line for off-line analysis. % of the time when PR was off by 10% (Off 10) or more and SpO2 was off by 7% or more (Off 7), performance index (PI) - % of time when SpO2 was within 7% of control and PR was within 10% of control, and % of time when the POs zeroed out PR and/or SpO2 (Zero rate). Analysis of Variance was used for statistical analysis & P <.05 was considered statistically significant.

RESULTS: The table shows our results. * ANOVA analysis showed a statistically significant difference between the performance of the POs for both SpO2 and PR.

DISCUSSION/CONCLUSION: While no PO technology amongst the tested POs was able to withstand 100% of the time this vigorous testing schedule for either SpO2 or PR, Masimo SET technology performed better for both SpO2 as well as PR. Furthermore, all POs performed inferiorly for detection of PR in comparison to SpO2 detection.

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Anesthesiology 2001; 95:A553

		Pulse Rate*			Oxygen Saturation*	
Pulse Oximeter	Off10%	PI	Zerorate	Off7%	PI	Zerorate
Masimo I	20%	80%	0.5%	14%	85%	0.6%
HP Viridia 24C	53%	47%	1.6%	34%	65%	1.6%
Novametrix MARS	72%	27%	2.1%	58%	41%	2.2%
Masimo II	21%	78%	0.1%	11%	89%	0.2%
N-395	40%	50%	16.7%	33%	63%	6.0%
HP CMS Rev B	32%	67%	0.9%	21%	78%	1.6%

Is There a Difference in the Recovery Time for the Accurate Display of Oxygen Saturation (SpO2) and Pulse Rate (PR) after Motion Induced Failure of Pulse Oximeters (PO) during Low Perfusion and Normoxemia or Hypoxemia in Human Volunteers?

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INTRODUCTION: Monitoring Pulse Oximetry has become standard of care in OR and PACU. Patient movement is very common in the PACU and in the OR especially at the critical time of extubation. Unfortunately, conventional POs may not function well during motion. How long the PO takes to recover and display accurate SpO2 and PR after motion induced failure may be of paramount importance. To the best of our knowledge, recovery time of SpO2 and PR after motion have not been reported. We undertook this study to compare the recovery time for SpO2 and PR for five major brands with new PO technologies.

METHODS: Seven ASA I adult volunteers (5-females & 2-males) between 18 & 40 years of age were enrolled after obtaining informed consent. Masimo Radical v3 (Masimo I) was comapred with HP Agilent Viridia 24C Rev B, and Novametrix MARS Model v2001-10. Masimo Radical v3 (Masimo II) was compared with Nellcor N-395 v1620, and HP CMS Rev B. An Ohmeda PO with ear sensor was used as the control for titration of hypoxemia. The room temperature was lowered to 16 to 18 degree C to reduce peripheral perfusion of the volunteers. The left hand was the test hand while the right hand served as the control. The sensors were randomly placed on index, middle, & ring fingers. The motion (performed by a motor-driven motion table) during normoxia (breathing room air) consisted of tapping at 3 Hz, tapping at 3 Hz with disconnect and reconnect of the sensors during motion, and random rubbing. The sensors were then rotated in a lateral fashion allowing for sensor placement of each PO on each of the three fingers and the motions were repeated after each sensor change. The study was repeated with two other POs along with Masimo which was used in both sets of experiments.

Hypoxemia was induced employing a disposable re-breathing circuit with a CO2 absorber to a SpO2 of around 75%. The motion during hypoxemia consisted of random tapping and 3 Hz tapping with disconnect and reconnect of the sensors during both motions, random rubbing and 3 Hz rubbing. Once the SpO2 reached 75% as measured by ear sensor, the subjects were given 100% O2 to breathe until the SpO2 on the ear PO monitor reached 100%. SpO2 & PR data were recorded by a computer for off-line analysis. Recovery time (RT), (defined as the time required for the POs to recover for SpO2 and PR to the control value after the end of motion) of SpO2 and PR were calculated for all POs. Furthermore, failure rates (FR) (defined as the % of time the POs displayed values which were off by 7% of the control value for SpO2 and off by 10% of the control value for PR) were also calculated. Analysis of Variance (ANOVA) was used for statistical analysis & $P<.05$ was considered statistically significant.

RESULTS: There were a total of 91 motion tests (63 during normoxemia and 28 during hypoxemia) when POs could fail. The table shows our results. * ANOVA showed a statistically significant difference between the performance of the POs for both SpO2 and PR. # ANOVA showed a statistically significant difference in the RT of PR within the subjects as well.

DISCUSSION/CONCLUSION: Amongst the POs studied it appears that Masimo Radical may serve better for monitoring as it has the shortest RT and lowest FR for both SpO2 as well as PR.

Anesthesiology 2001; 95:A552

	SpO2*			PR*£		

PO	Mean RT in Seconds(range)	No. of times Fail/Total	FR	Mean RT in Seconds (range)	No. of times Fail/Total	FR
Masimo I	21.3 (10-50)	12/91	13%	14.4 (3-35)	24/91	26%
Novametrix MARS	22.2 (5-55)	67/91	74%	23.1 (4-63)	73/91	80%
HP Viridia 24C	31.1 (10-85)	42/91	46%	45.5 (10-192)	65/91	71%
Masimo II	17.8 (10-40)	10/91	11%	13.6 (1-39)	27/91	30%
HP CMS Rev B	40.5 (11-97)	21/91	23%	37.8 (5-103)	35/91	38%
Nellcor N-395	19.9 (10-141	36/91	40%	38.2 (7-155)	50/91	55

Masimo signal extraction pulse oximetry.

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OBJECTIVE: To describe a new pulse oximetry technology and measurement paradigm developed by Masimo Corporation.

INTRODUCTION: Patient motion, poor tissue perfusion, excessive ambient light, and electrosurgical unit interference reduce conventional pulse oximeter (CPO) measurement integrity. Patient motion frequently generates erroneous pulse oximetry values for saturation and pulse rate. Motion-induced measurement error is due in part to widespread implementation of a theoretical pulse oximetry model which assumes that arterial blood is the only light-absorbing pulsatile component in the optical path.

METHODS: Masimo Signal Extraction Technology (SET) pulse oximetry begins with conventional red and infrared photoplethysmographic signals, and then employs a constellation of advanced techniques including radiofrequency and light-shielded optical sensors, digital signal processing, and adaptive filtration, to measure SpO2 accurately during challenging clinical conditions. In contrast to CPO which calculates O2 saturation from the ratio of transmitted pulsatile red and infrared light, Masimo SET

pulse oximetry uses a new conceptual model of light absorption for pulse oximetry and employs the discrete saturation transform (DST) to isolate individual "saturation components" in the optical pathway. Typically, when the tissue under analysis is stationary, only the single saturation component produced by pulsatile arterial blood is present. In contrast, during patient motion, movement of non-arterial components (for example, venous blood) can be identified as additional saturation components (with a lower O2 saturation). When conditions of the Masimo model are met, the saturation component corresponding to the highest O2 saturation is reported by the instrument as SpO2.

CONCLUSION: The technological strategies implemented in Masimo SET pulse oximetry effectively permit continuous monitoring of SpO2 during challenging clinical conditions of motion and poor tissue perfusion

Real-Time Pulse Oximetry Artifact Annotation on Computerized Anaesthetic Records

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Objectives. Adoption of computerised anaesthesia record keeping systems has been limited by the concern that they record artifactual data and accurate data indiscriminately. Data resulting from artifacts does not reflect the patient's true condition and presents a problem in later analysis of the record, with associated medico-legal implications. This study developed an algorithm to automatically annotate pulse oximetry artifacts and sought to evaluate the algorithm's accuracy in routine surgical procedures. **Methods.** MacAnaesthetist is a semi-automatic anaesthetic record keeping system developed for the Apple Macintosh computer, which incorporated an algorithm designed to automatically detect pulse oximetry artifacts. The algorithm labeled artifactual oxygen saturation values < 90%. This was done in real-time by analyzing physiological data captured from a Datex AS/3 Anaesthesia Monitor. An observational study was conducted to evaluate the accuracy of the algorithm during routine surgical

procedures (*n* = 20). An anaesthetic record was made by an anaesthetist using the Datex AS/3 record keeper, while a second anaesthetic record was produced in parallel using MacAnaesthetist. A copy of the Datex AS/3 record was kept for later review by a group of anaesthetists (*n* = 20), who judged oxygen saturation values < 90% to be either genuine or artifact. **Results.** MacAnaesthetist correctly labeled 12 out of 13 oxygen saturations < 90% (92.3% accuracy). A post-operative review of the Datex AS/3 anaesthetic records (*n* = 8) by twenty anaesthetists resulted in 127 correct responses out of total of 200 (63.5% accuracy). The remaining Datex AS/3 records (*n* = 12) were not reviewed, as they did not contain any oxygen saturations < 90%. **Conclusions.** The real-time artifact detection algorithm developed in this study was more accurate than anaesthetists who post-operatively reviewed records produced by an existing computerised anaesthesia record keeping system. Algorithms have the potential to more accurately identify and annotate artifacts on computerised anaesthetic records, assisting clinicians to more correctly interpret abnormal data.
Keywords
Anesthesia, automated record keeping, artifact detection, pulse oximetry, computerized, monitoring

Pulse oximetry in severe carbon monoxide poisoning

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STUDY OBJECTIVES: To evaluate the accuracy and quantitate the error of pulse oximetry measurements of arterial oxygenation in patients with severe carbon monoxide (CO) poisoning. DESIGN: Retrospective review of patient clinical records. SETTING: Regional referral center for hyperbaric oxygen therapy. PATIENTS: Thirty patients referred for treatment of acute severe CO poisoning who demonstrated carboxyhemoglobin (COHb) levels >25%, with simultaneous determinations of arterial hemoglobin oxygen saturation by pulse oximetry (SpO2) and arterial blood gas (ABG) techniques. MEASUREMENTS AND RESULTS: COHb levels and measurements of arterial oxygenation from pulse oximetry, ABG analysis, and laboratory CO oximetry were compared. SpO2 did not correlate with COHb levels. SpO2 consistently overestimated the fractional arterial oxygen saturation. The difference between arterial hemoglobin oxygen saturation (SaO2) calculated from ABG analysis and SpO2 increased with increasing COHb level. CONCLUSIONS: Presently available pulse oximeters overestimate arterial oxygenation in patients with severe CO poisoning. An elevated COHb level falsely elevates the SaO2 measurements from pulse oximetry, usually by an amount less than the COHb level, confirming a prior observation in an animal model. Accurate assessment of arterial oxygen content in patients with CO poisoning can currently be performed only by analysis of arterial blood with a laboratory CO-oximetry.

Pulse Oximetry Monitoring: Understanding and Adapting to a New Technology Market

The pulse oximetry market has dramatically changed. Historically speaking, pulse oximetry has been a fairly unstable technology plagued by false alarms and unreliable readings during motion and low perfusion. In contrast, practically every vendor in the market is now claiming to be able to accurately monitor patients under these conditions. Most assert that false alarms will significantly decline with their new technology and that these changes will positively affect the quality of care given to the patients.

Pulse oximetry technology has definitely changed. The problem is that not all vendor claims are accurate, and end-users are being forced to sort through a myriad of marketing claims to arrive at the truth. Additionally, caregivers must ultimately decide whether the new changes are significant enough to warrant migrating to a new platform or to a new way of conducting patient monitoring within the pulse oximetry arena.

To this end, the standard for judging the performance of this medical technology must start with the patient and provider benefit aspects. Ultimately, all patient-related technologies should demonstrate at least a comparable benefit to other existing technologies. Likewise, any vendor claiming to have exceeded existing industry standards should be met with a thorough analysis to insure the realities of the technology are separated from the marketing ploys used for and/or against these claims.

The following list outlines the critical aspects that should be considered when making these vendor comparisons regarding pulse oximetry technologies.

Critical Evaluation Aspects

- SpO2 Sensitivity (detection of true desaturation)
- SpO2 Specificity (as it relates to absence of false alarms)
- False Alarm Rates (generically)
- Drop-out Rates
- Missed Monitoring Events
- Impact of Motion on Monitoring
- Impact of Low Perfusion on Monitoring
- Clinical Performance
- Realistic Comparisons of Data
- Independent Aspect of Information, Clinical Acceptability and Research

- Comparisons of Sensor Usage to Acceptable Clinical Performance
- Relative Vendor-to-Vendor Equipment Comparisons
- Cost Effectiveness of Technology
- Quality of Technology Compared to Existing Market Offerings
- Impact and/or Potential Changes to Current Industry Practices
- Similar Technology Claims from Competitive Vendors

New pulse oximetry technology usage may also bring about clinical practice and patient treatment changes. Certainly, reliable readings during motion and low perfusion should be reflective of lower overall treatment costs assuming that providers begin to rely more on the improved accuracy of the technology and as a result order fewer tests/procedures.

Outlined below are some of the test/procedure areas that are expected to decline as a result of transitioning to a leading-edge pulse oximetry technology platform.

- Ultrasound Tests
- Ventilator Usage
- Chest X-Rays
- Arterial Blood Gas Tests
- Oxygen Usage
- Provider Intervention
- Septic Work-Ups
- Sensor Usage
- Transillumination
- 2D Echo
- Discharge Delays
- Other Lab/Specialty Tests

Test/Procedure Treatment Cost Reductions

To further illustrate, consider the supply-related costs associated with these potential cost reductions. Sensor usage is a critical cost driver to pulse oximetry monitoring. Sensor usage directly correlates to the degree of reliability of the pulse oximetry technology being used by the providers. For instance, many clinicians will use three or four sensors per patient to try to receive a reliable reading from their pulse oximetry equipment. It is very common for staff to place a sensor on one finger of each hand. Likewise, many add an extra sensor to either an ear and/or a toe in order to protect against a reading dropout. This extra “insurance” is very costly to health care organizations.

Sensor waste is even more problematic during motion or low perfusion. This means wasted dollars for unnecessary sensors, which is directly related to poor technology performance.

Additionally, given the current nursing shortage, many hospitals and healthcare organizations may want to assess the impact that reliable pulse oximetry would have on lessening the need for nurse intervention, especially as it relates to the amount of wasted effort expended responding to false alarms. The following table outlines some of the factors affecting nurse response times and costs.

The technology changes within the pulse oximetry marketplace clearly affect many important decision areas for healthcare managers and clinicians. Better technology can translate into improved patient care, less overall operating costs, a safer environment and lower patient treatment risks. The market has changed and each organization must effectively evaluate these changes and decide to what extent they will embrace these improvements.

Finally, pulse oximetry technology review comparisons between vendors should be orchestrated to objectively challenge existing pulse oximetry performance values. Data collection, reference signal methodologies, sensor bias, positional differences and true arterial saturations must be accounted for in order to make sure organizations are truly testing the existing standards against the new measures of performance that are now achievable within the pulse oximetry monitoring arena.

Pulse Oximetry in Neonates

This valuable tool has optimized care for newborns with chronic lung disease.

Krishna Mullahoo, RRT

In the management of critically ill neonates, measurement of arterial oxygenation is frequently required to prevent hypoxia or hyperoxia.[1] Hypoxia may lead to pulmonary vasoconstriction and pulmonary hypertension. In addition, the resulting alterations in systemic blood flow may lead to neurologic and other organ damage.[2] Hyperoxia is associated with oxygen free radical production, which may cause cellular and tissue damage.[3] In neonatology, the most common example of this process is seen in preterm infants with immature retinal vascularization. Hyperoxia has been associated with damage to the retina, resulting in the retinopathy of prematurity.[4]

Oxygen supplementation is critical to the survival of many infants with respiratory disease. In the neonatal intensive care unit (NICU), when oxygen therapy is used alone or in addition to other supportive therapies (such as mechanical ventilation, surfactant replacement therapy, or inhaled nitric oxide), there is a risk of rapid change in the patient's oxygen saturation, requiring an immediate response from the clinician. An effective method for monitoring arterial oxygenation levels continuously in these patients is a high priority. Direct blood gas sampling from indwelling umbilical or peripheral arterial lines to measure Po2 and oxygen saturation is considered to be the gold standard for accuracy. This method, however, only provides intermittent oxygen monitoring, is invasive, and (in the neonatal population) can lead to significant blood loss and erroneous results if an improper sampling technique is used.[5]

The ideal monitor would offer hypoxia, hypoxemia, and hyperoxia detection, minimal false alarms, and information storage. It would also be noninvasive, continuous, self-calibrating, and easy to use.

The first widely accepted noninvasive oxygen monitoring system used in infants was the transcutaneous oxygen (tcPo2) monitor. Introduced in the 1970s, the tcPo2 monitor uses electrodes that measure Po2 through the skin. This method has some disadvantages, however, including frequent calibrations, a long stabilization period, slow response time, inaccuracy in older infants with bronchopulmonary dysplasia, and the risk of skin burns from the heated electrode. Hypotension, hypovolemia, hypothermia, and acid-base abnormalities also affect the accuracy of the tcPo2 electrode.[6] Despite these limitations, the importance of tcPo2 monitoring in detecting hyperoxia must not be overlooked.[7]

PRINCIPLES OF PULSE OXIMETRY

Pulse oximetry (Spo2) combines spectrophotometry, plethysmography, and microprocessor technology to determine arterial oxygen saturation. Oxygenated hemoglobin and deoxygenated hemoglobin have different light-absorption characteristics. Oxygenated hemoglobin absorbs less light in the red band (600 to 750 nm) and more in the infrared band (850 to 1,000 nm) than deoxygenated hemoglobin.[8] Pulse oximeter probes use a light source consisting of two light-emitting diodes (LEDs), one emitting red light (at 660 nm), the other, infrared light (at 940 nm). This light is transmitted across a tissue bed (finger or toe). A photodetector placed opposite the LEDs (Figure 1, page 50) measures the intensity of the transmitted light across the vascular bed. During transillumination of the tissue bed, there are periodic changes in both the length of the light path and the tissue absorbance. This is because of the volume input of pulsatile arterial blood. This pulsatile surge represents the inflow of oxygenated hemoglobin into the tissue bed.[8] A plethysmographic waveform is generated (Figure 2). The peaks and troughs of this waveform are detected by measuring the transmitted light many times per second. By dividing the absorbency values at the peaks by those at the troughs, a pulse-

added absorbency is obtained. This value is independent of the absorbency characteristics of the nonpulsatile parts of tissue (tissue, bone, and venous and capillary blood). The red-to-infrared ratio of these pulse-added values is translated into a digital signal that is displayed as the saturation percentage, along with the pulse rate.

APPLICATION IN THE NEONATE

Studies[9,10] have established the efficacy of pulse oximetry in accurately monitoring oxygen saturation in term and preterm infants with respiratory disease. Furthermore, studies[11,12] have shown that there is a good correlation between pulse oximetry measurements and laboratory co-oximeter values of 75 percent to 95 percent. This range of oxygenation is encountered in most clinical situations.

The most frequent use for the pulse oximeter is the detection of hypoxemia.[13] The relationship between Po2 and oxygen saturation is depicted by the oxygen- hemoglobin dissociation curve (Figure 3). Along the steep portion of the curve, relatively small changes in Po2 lead to large changes in oxygen saturation. Pulse oximetry provides instantaneous information that is sensitive to any change in the infant's oxygen status in that important range in which there is a risk of hypoxia. As a result, clinical procedures such as weaning from supplemental oxygen, adjusting positive end-expiratory pressure during mechanical ventilation, endotracheal intubation, and endotracheal suction can be carried out using the pulse oximeter to detect early episodes of desaturation that are not yet apparent to the clinician. Continuous pulse oximetry can also detect an acute decompensation in clinical status. For example, a sudden drop in Spo2 may indicate the development of a pneumothorax, pneumopericardium, or blocked endotracheal tube.

Infants being treated with exogenous surfactant, inhaled nitric oxide, and high- frequency ventilation may experience dramatic improvements in oxygenation. Pulse oximetry allows the clinician to titrate the fraction of inspired oxygen (Fio2) rapidly to a predetermined Spo2 value in order to prevent prolonged hyperoxia.

Infants with persistent pulmonary hypertension of the newborn (PPHN) have increased pulmonary vascular resistance that prevents normal pulmonary blood flow. This causes a right-to-left shunting of blood across the patent foramen ovale and patent ductus arteriosus.[14] The diagnosis of PPHN is usually confirmed by echocardiography, along with analysis of blood gas samples from preductal and postductal sites. A simpler way to detect this right-to-left shunting is to use two pulse oximeters and measure preductal and postductal Spo2. In one study[15] it was found that arterial saturation in the right arm (preductal) of at least 3%above the lower limb (postductal) is evidence of right-to-left ductal shunting. During this critical phase of the infant's disease, the rapid response time of the pulse oximeter at detecting a right-to-left ductal shunt may lead to earlier treatment of PPHN.

Clinical situations outside the NICU in which pulse oximetry is used in infants include surgery, cardiac catheterization, neonatal transport, outpatient management of chronic lung disease, and sleep studies for the detection of neonatal apnea.

Pulse oximetry depends on adequate peripheral perfusion. In low-cardiac-output states or shock, the oximeter may not detect a pulse waveform. Most pulse oximeters require a pulse pressure of more than 20 mm Hg and a systolic blood pressure greater than 30 mm Hg to operate reliably.[7]

Pulse oximeters use calibration curves derived from healthy volunteers. Low saturations (from less than 70 percent to 80 percent) cannot be obtained from these calibrations; therefore, they are extrapolated from measurements at higher saturations. This approach tends to overestimate actual oxygen saturation values that are less than 70 percent.[7] The accuracy of pulse oximetry is questionable at these low saturations.[16]

Because the pulse oximeter operates on two wavelengths, it can detect only oxygenated and deoxygenated hemoglobin. It does not take into account other types of hemoglobin, such as carboxyhemoglobin (HbCO), methemoglobin (MetHb), and fetal hemoglobin (HbF). It has been shown there is a slight inaccuracy in Spo2 values in the presence of high HbF levels. This degree of error is acceptable for clinical practice.[10] MetHb is produced during inhaled nitric oxide therapy; high levels of MetHb can cause Spo2 readings to stay around 855 independent of actual oxygen saturation. Increasing levels of HbCO cause slight overestimation of the actual oxygen saturation as measured by pulse oximetry.[7]

Because of the shape of the oxygen-hemoglobin dissociation curve, pulse oximetry is not ideal in preventing hyperoxia. This is of great importance in the care of premature infants who are at risk for development of the retinopathy of prematurity. As oxygen saturation increases to more than 90 percent, the curve flattens (Figure 3, page 50). Along this flat part of the curve, Po2 can increase dramatically with only a small change in oxygen saturation. The measurement of Pao2 is therefore important in these infants. A current practice in NICUs, aimed at preventing hyperoxia in the premature infant, is to set the high alarm limit on the pulse oximeter at 90 percent to 92 percent (the point at which the O2Hb curve starts to flatten). The infant's Fio2 can then be titrated to keep the Spo2 at around 90 percent, with periodic verification of Pao2.

The extreme sensitivity of these monitors, along with the location of the probes, sometimes allows motion artifact to produce false Spo2 readings and false alarms. This may be a particular problem in an active neonate, rendering the pulse oximeter inaccurate. A solution to this problem is to increase the sampling interval of the monitor. To decrease this type of artifact, synchronization of the pulse waveform with the QRS complex has been developed for newer models.[13]

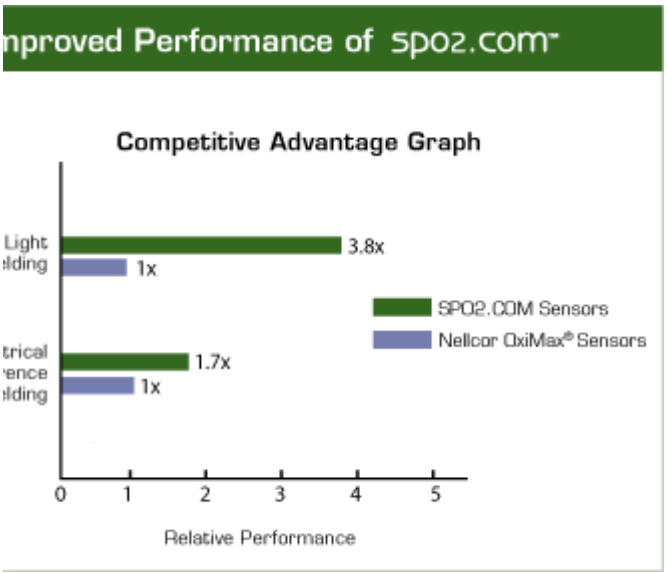
CONCLUSION

Pulse oximetry is a simple and reliable technique for the continuous, noninvasive monitoring of oxygenation in newborn infants and babies with chronic lung disease. This valuable tool has optimized care for these infants. Although there is still a need to know Po2 in some infants, and there are certain limitations that need to be understood clearly for the proper application of this technique, pulse oximetry adds an important degree of control to oxygen management.

SPO2.COM™ vs. Nellcor® Oximax® SpO2 sensors*

Appearances are deceiving. The new SPO2.COM family of adhesive SpO2 pulse oximetry sensors have the form to which clinicians have grown accustomed. However, we have leveraged Masimo's engineering and design expertise to design a sensor that functions better on the inside -where it counts most!

Designed and built by Masimo engineers, innovators of low perfusion and motion tolerant pulse oximetry, the SPO2.COM family of adhesive sensors outperforms the Nellcor OxiMax sensors.



Superior ambient light shielding
By moving our detector into a patented recessed detector configuration, the detector is protected from the path of ambient light sources. Without this protective shielding, light can easily enter the detector from the sides and compromise the integrity of the measurement. SpO2.com sensors enable the signal from the Red/Infrared emitter to shine directly onto the photo detector/sensor. This protection provides nearly four (4) times improvement in immunity to errors or dropouts caused by bright lights interfering with the pulse oximetry signal. By reducing undesirable interference from light sources, we are able to provide a more accurate output signal than Nellcor's Oximax sensor line.

Superior electrical noise rejection
SPO2.COM sensors build upon the experience gained in the design of Masimo SET sensors - the best performing motion tolerant, low perfusion SpO2 sensors available. Our shielding design fully encapsulates the sensor against external sources of electrical noise (electrosurgical units, motors). This improved shielding enables the SPO2.COM sensor to deliver a "cleaner" signal to the Oximeter, a signal that contains almost two (2) times less noise - noise which could cause erroneous readings, particularly at lower perfusions.

Safe and easy to use
All SPO2.COM sensors are tested to, and comply with, all recognized and accepted safety and regulatory requirements. SPO2.COM sensors are manufactured with the same quality and attention to detail as the industry-leading Masimo LNOP sensor line.

*Data available upon request

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SPO2.COM Sensors Clinical Evaluation Study

SPO2.COM Sensors Clinical Evaluation Study
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Tim Motes, RRT, Clinical Research Specialist

Introduction
The innovation of Masimo SET read through motion pulse oximetry has raised the standard of performance for oxygenation monitoring through a combination of sophisticated algorithms and low-noise, electrically shielded pulse oximetry sensors. Although higher end, state-of-the-art technologies are now available to clinicians for oxygenation monitoring, sensor interconnect patents have allowed Nellcor to maintain price points for conventional sensors connecting to their older generation technology. These patents expired in November 2003, opening up the market for equivalent, generic sensors, which are now available for these older oximeters at a considerable savings to the hospital.

SPO2.COM sensors are designed to replace Nellcor sensors for older generation Nellcor compatible oximeters, which previously accepted Oxisensor II and prior generation Nellcor sensors. SPO2.COM sensors have received FDA 510(k) clearance, and have passed rigorous in-house quality and safety testing, which has shown an increased ability to shield against ambient light and electrical interference when compared to Nellcor OxiMax sensors.*

A Clinical Evaluation was designed to evaluate the clinical utility and acceptance of the new SPO2.COM sensors compared to the Nellcor sensors they are designed to replace.

Methods
SPO2.COM sensors were given to clinical staff at five different teaching institutions, which had previously used Nellcor sensors. Each sensor was attached to a survey form, which the clinician was asked to complete after using the new SPO2.COM sensor in the clinical

environment. The survey included 6 questions with responses rated on a scale of 1 to 5. A reply of 1 meant the Nellcor sensor was clinically superior, 3 meant there was no clinical difference, and a 5 meant that the SPO2.COM sensor was clinically superior. Adult, neonatal and pediatric sensors were evaluated.

Results*

65 clinicians from 5 hospitals participated in the evaluation (10 RNs and 55 RRTs), with an average clinical experience using pulse oximetry of 8 years (range 1 year to 15 years). The following table summaries the results of the survey.

Question of concern	SPO2.COM Sensor Clinically Equal to or Superior to Nellcor
Ease of application of sensor	99%
Ease of removal and reapplication of sensor	100%
Durability of sensor	95%
Useful life of sensor	97%
Ease of acquiring initial oximetry signal	99%
Confidence in (reliability of) oximetry values	95%

Additionally, 69% rated the SPO2.COM sensor superior in ease of acquiring initial oximetry signal. 57% rated their confidence in the reliability of the oximetry signal with SPO2.COM sensors as superior versus the Nellcor sensors and 48% of the clinicians who evaluated the SPO2.COM sensors rated their useful life as superior to Nellcor.

Conclusion

The results obtained from this evaluation of clinical staff, experienced with the use of pulse oximetry technology, demonstrate that the SPO2.COM Nellcor compatible sensors provide clinically acceptable performance. When considering reliability of the measurement and ease of acquiring signals, the performance of the SPO2.COM sensor was judged to be at least equivalent to, and in many cases superior to, the performance of the Nellcor sensors. The improved signal acquisition and reliability of the SPO2.COM generic sensor alternative, as demonstrated in this evaluation, offers hospitals a valid replacement for the traditional Nellcor sensors, and may result in fewer wasted sensors while saving the institution considerable money.