Hanley: It's http://www.ahrq.gov/prep/projxtreme. Or call them at (800)358-9295.

Rubinson: This is a question from Dennis Archer from Harborview Medical Center in Seattle. Will disaster preparation be incorporated into a specialty section in the AARC [American Association for Respiratory Care]?

Branson: I don't know. There's a movement for it, but we don't know if it is actually going to happen. There aren't that many specialty sections, and a lot of it depends on membership. We'll see.

Rubinson: I can see someone from the audience suggesting that if you all write e-mails to the AARC, it probably would happen faster.

Dennis also has a question for Lee. Did Toronto stop their aggressive PPE [personal protection equipment] and environmental controls too soon and trigger SARS 2 [severe acute respiratory syndrome]? He says that a news article suggested that precautions were lifted for political rather than scientific reasons.

Daugherty: In their final report the SARS Commission concluded that there was no evidence to suggest that political pressure resulted in a premature declaration of the end of the SARS outbreak. They concluded that the decision to lift precautions at the end of SARS 1 was made "in good faith on the best medical advice available."[1] Perhaps the most important lesson is that consistent PPE use on an ongoing basis, regardless of heightened concern, is incredibly important. It's very easy for us to breathe a sigh of relief when we perceive a lower infectious risk and then become less vigilant about using precautions. SARS taught us that it behooves us to be very consistent on an ongoing basis.

1. Campbell A. Spring of fear: volume one: the SARS Commission executive summary. 2006. http://www.sarscommission.ca/report/v1-pdf/volume1.pdf. Accessed October 30, 2007.

Rubinson: Michael McGee from Saint Francis Medical Center in Peoria, Illinois, asks, do you see a role for respiratory therapists [RTs] in hazardous materials and/or hospital decontamination teams outside of the emergency department, to manage patients before they enter the hospital?

Talmor: Originally, our decontamination team was composed of nurses, RTs, and physicians. We soon realized that this was unnecessary. To decontaminate somebody—strip their clothes off and wash them in water—you don't need any medical credentials. The only people who will need to be medically trained on that team are the triage team, who need to be highly trained and experienced. They will need to rapidly assess patients' respiratory status and differentiate between walking and nonwalking victims. There will also be an intubation team, which will need to include an RT. So it will be one or 2 positions that will require a protected RT working outside the facility. We will probably need several teams, because functioning in the protective suits is physically exhausting. But each team would require only one or 2 RTs.

Rubinson: The next questions are from Frank Rando of the U.S. Department of Homeland Security and U.S. Department of Energy from Tucson, Arizona. Eileen, the forward deployment of SNS assets such as the Chempack system is a wise move. Are there any plans for strategic placement, meaning forward deployment, of any medical equipment in addition to the Chempack?

Malatino: The Push Packages and some of our Managed Inventory are already strategically placed throughout the United States. We guarantee that Push Packages will arrive within 12 hours. So that's already in place.

Branson: Jan Bard from Virginia Mason Hospital in Seattle asks, are there any online ways for RTs to get continuing education units for emergency preparedness? I don't think there is anything specific. There are always classes that you can take from your state and systems in your state to get basic disaster preparedness. But the AARC does have at least 3 Webcasts.[1-3] On all 3 of those I think they would qualify and they are free on the AARC Web site.

1. American Association for Respiratory Care. The Strategic National Stockpile: what respiratory therapists need to know. Featuring Richard D Branson MSc RRT FAARC and Eileen Malatino MSc RN. November 1, 2006. http://www.aarc.org/education/webcast/archives/national_stockpile/index.asp. Accessed November 15, 2007.
2. American Association for Respiratory Care. Mechanical ventilation in mass casualty care. Featuring Richard D Branson MSc RRT FAARC. April 5, 2006. http://www.aarc.org/education/webcast/archives/mass_casualty_care/index.asp. Accessed November 15, 2007.
3. American Association for Respiratory Care. SARS: lessons from the front lines. Featuring members of the critical care and respiratory therapy staff at Mount Sinai Hospital, University of Toronto. June 17, 2003. http://www.aarc.org/education/webcast/archives/sars/index.asp. Accessed November 15, 2007.

Malatino: I recommend the National Response Plan, the National Incident Management System, and the FEMA courses that talk about incident command systems, to learn about the processes that go on when stuff is requested, and how it's managed, and the hierarchy of processes during a disaster. I think it's important to know that.

Rubinson: Charles Reick from Greater Baltimore Medical Center asks, in a major event how can you optimize getting your staff in to work when they may have fears about safety, or that they may never be able to leave the facility once they get there, if they have family care or other care issues,

such as childcare, caring for a partner, or elder care?

O'Laughlin: Most hospitals have an annual safety fair, and those offer a perfect opportunity to reinforce family emergency planning. Nobody is going to feel comfortable coming to work if they haven't taken care of their own family emergency planning and made sure their kids, elders, dog, cat, or whatever are taken care of. Family preparedness planning has to be done ahead of time, and it's relatively easy to do. It just takes some time to sit down as a family and figure out how you'll do things. And once you have addressed that, then there's still an education component, because if it is an infectious disease event, PPE and basic infection-control education will need to be reinforced. Do the basics over and over again, and that will take care of a lot of things, though not everything.

Talmor: The people I've talked to about the SARS epidemic told me there was minimal absenteeism. In Hong Kong the only people who were absent were the equivalent of traveling nurses, who weren't rooted in the community. In Toronto essentially anybody who wasn't told to stay at home for quarantine reasons was at work. So I think that health care workers tend to "run towards the fire" so to speak. I think absenteeism may less of a problem than some people are worried it will be.

On the other hand, you do need to set up family support mechanisms and be creative about them. In Israel during the Gulf War we went through a lot of very similar issues. The high school students in the community and the medical students served as family support workers. A lot of the medical students were working in kindergartens and daycare centers for the hospital staffs. They were set up in teams to go visit the health care workers' homes. These aren't jobs that you need people from the hospital to do; these are perfect jobs for volunteers from the community or educational institutions around your hospital. This is fairly easy to plan for, and I think that it would prevent a lot of problems in a time of need.

Rubinson: I went up and visited North York General Hospital in Toronto as SARS 2 was ending. The people that really kept their staff coming were their human resources folks. They took it upon themselves to make a number of things possible. Some people were on work quarantine and they couldn't even fill their gas tanks because they were only allowed to go to work and go home. They had a gas filling station come on site. People weren't allowed to buy groceries, so they bought groceries for people. Kids were getting kicked out of daycare, because of fear of the disease, so they provided daycare. It's really important that human resources provides crucial services to allow staff to focus on patient care.

On the other hand, it's also the employees' responsibility to be as prepared as possible, and we need to give them good guidance. I would like to see that no one gets promoted without providing evidence that they have an adequate personal family plan. We need to add incentive or it's never going to be an institutional priority. We need to make it the culture of the institution to be able to keep people coming.

Malatino: I'm also a Navy reserve nurse, and we are required to have a family plan in place for dependents such as kids, spouse, or elderly parents living with you. They also encourage people to think about their pets and other things. And it's not simply bringing in a plan and showing it to them; I had to sign a piece of paper that says I have a plan, so I had no excuses if I got recalled. We need to warn employees that this may happen, that they have to come to work, and these are the consequences if they don't.

Rubinson: We have a question from Dave Pierson from Harborview in Seattle. He says that in many ICUs under normal conditions there's numerous different modes and different ventilators in use and that the choice of ventilator and mode are discretionary. For instance, some people always use pressure control and other people always use APRV [airway pressure-release ventilation]. People always use high-frequency for refractory hypoxemia or ventilatory failure in ARDS [acute respiratory distress syndrome].

Rich, considering those practice patterns, what are the crucial device features you are going to consider for a surge ventilator that's acceptable for patients and supported by evidence but doesn't necessarily need to have all of the "bells and whistles," or does it?

Branson: We have to look at what the literature dictates; what's the standard of care? I think the right ventilator weighs 10 pounds, offers volume-control, PEEP up to 20 cm H_2O, controls F_{IO_2} [fraction of inspired oxygen], triggers reliably, works for adult and pediatric patients, and has low gas consumption and good battery life, versus if I had to spend another $8,000 to have the options of APRV, active exhalation valve, pressure control, and/or PRVC [pressure-regulated volume-control ventilation].

We should stockpile ventilators that meet the demands of the disease we anticipate. It's not like your full-feature ICU ventilators go away. You would use the less expensive stockpile ventilators for stable patients, and put the new avian flu patients or whatever on the full-feature ventilators. Obviously we can't afford a lot of $30,000 ventilators. Stockpile ventilators should only provide what is minimally required to meet standard of care. Perhaps this is an aspect of triage. Maybe a patient who can't be supported with low-tidal-volume ventilation, PEEP,

and a certain F_{IO_2} should only receive palliative care and the ventilator should be used for a patient who has a better chance.

I look at ventilators all the time and I still haven't heard a reason why every ventilator has to give a tidal volume of at least 2.2 liters. That seems ludicrous now that we know the importance of low-tidal-volume (6 mL/kg) ventilation. But it continues, because if I make a ventilator that provides 2.2 liters and somebody else comes out with one that only provides 1.2 liters, I would tell all of his customers that the reason he can't provide 2.2 liters is because his system is inferior, ignoring the fact that the ventilator that provides only 1.2 liters makes more sense because it has a smaller blower, which provides greater efficiency. Manufacturers engage in this "spec-manship" that does not help us. We need to be smarter consumers and get past that. Everybody should have the same absolute high threshold.

Rubinson: If you had a blank check and you could use $30,000 ventilators for surge ventilators, would you have hesitancy about getting more complex vents because of issues about staff knowledge, in-service needs, and whether the devices come with compressors and can operate on low-flow oxygen? If money were not an issue—say I give you 6 billion dollars to do surge mechanical ventilation—would you suggest any other strategy than you're proposing now?

Branson: If money were no object and you could start from scratch, you would build a ventilator that would operate on alternating current when it's available, but it could also operate just on pneumatic power.

My colleague Jay Johannigman suggested that we need a device where the first screen that comes up asks who you are: an EMT [emergency medical technician], a nurse, an RT, a surgeon, an intensivist, et cetera, and what you select determines what knobs you see. [Laughter and applause] If you're an EMT you can control rate, tidal volume, PEEP, and F_{IO_2}, and that's it. The device could also ask how tall is the patient? And when you tell it how tall the patient is, it sets ventilator parameters for you based on ideal body weight from height, per the ARDS Network [low-tidal-volume ventilation] algorithm. Such a device could act as multiple devices. For an EMT it's a simple replacement for a bag-valve-mask resuscitator; in the hands of an intensivist it's a full-featured critical-care ventilator.

I would also build an oxygen concentrator into it. I don't mean to disparage any one group's expertise in mechanical ventilation, but it would be a big advantage to have the device perform relative to the caregiver's skill and experience, as has been done with the AED [automatic external defibrillator].

Talmor: I agree with Rich that the type of ventilator is an aspect of triage. If you can't survive with what a transport ventilator can deliver, then you are probably so ill that you would be triaged to expectant [palliative] care. If I had an unlimited budget I would try to fill another large hole in our preparedness, which is monitoring. We've talked a lot about ventilation, but there is no monitoring capability in the Strategic National Stockpile. Most states, as far as I know, have not stockpiled any monitoring capability. That is more important than purchasing a slightly better mechanical ventilator.

Branson: Yes, an ideal stockpile ventilator would have a built-in pulse oximeter. Pulse oximeters are now so small and require very little power, if you don't need all the fancy stuff and you just want to see the heart rate and blood oxygen saturation; that would be a simple addition to a ventilator. And I would suggest the same if I were a manufacturer making mass casualty ventilators. I would also include noninvasive blood pressure measurement. Perhaps it would also be possible to get blood pressure from a pulse oximetry probe? This is wishful thinking, but adding those functions should not be that expensive or difficult.

Rubinson: And I think cost is going to be the key; it's the trade-off of cost. We as a group need to come up with what are the appropriate trade-offs. I also think we need to take it on ourselves to study what are the minimum features that would allow a device to work for many, where we have optimized the interplay of cost and features. Whether it's with animal models or utilizing other surrogates to find out what is really essential, we need more data.

When you look at the ARDS Network data, generally about 13% of the 30 – 40% who died did so due to hypoxemia or ventilatory failure.

Pierson:* I think you're referring to 2 studies from Harborview (rather than from the ARDS Network per se) that examined the causes of death in patients with ARDS.[1,2] Consistently over a 25-year period, of all patients who developed ARDS and did not survive, only about 15% died of refractory respiratory failure and our inability to support them with the machine. So if overall ARDS mortality is about 35%, and 15% of those people die of actual respiratory failure, as you say, Lewis, only around 5% of the time are we unable to support them in terms of ventilation and gas exchange. The great majority of ARDS patients die of multiple organ failure and things other than respiratory failure.

1. Montgomery AB, Stager MA, Carrico CJ, Hudson LD. Causes of mortality in patients with the adult respiratory distress syndrome. Am Rev Respir Dis 1985;132(3):485-489.

* David J Pierson MD FAARC, Division of Pulmonary and Critical Care Medicine, Harborview Medical Center, University of Washington, Seattle, Washington.

2. Stapleton RD, Wang BM, Hudson LD, Rubenfeld GD, Caldwell ES, Steinberg KP. Causes and timing of death in patients with ARDS. Chest 2005;128(2):525-532.

Rubinson: I think that goes to Danny's comment on how the ventilator is a triage mechanism.

Branson: Regarding the whole market—and this is just the way things are driven, I guess, for the military and the government—you make a ventilator, and all of sudden states are buying thousands of ventilators, so you run back to the office and you take your ventilator and you spray paint it bright orange and put a hazmat [hazardous materials] sticker on it and take out an ad that says it's ideal for mass casualty ventilation.

What we really need is to sit down and design a ventilator for mass casualty ventilation, rather than trying to find a mass casualty niche for an existing ventilator, with marketing and add-ons. So far the market isn't big enough to attract big companies to pursue this, and only small companies have been doing it.

Rubinson: Sandra Barnes from Olive Harvey College School of Respiratory Care in Chicago asks, has anyone approached the governor of their state to ask for a Good Samaritan law to cover mass disaster training for Project XTREME trainees or other volunteers?

Hanley: I don't know. One of our recommendations was that we thought that laws should be passed to protect extenders who are to some degree practicing outside their scope of practice.

O'Laughlin: In Minnesota we've adopted that as part of the Emergency Health Powers Act. Some other states have also looked at that, but I don't know how good the language is; it differs from state to state.

Rubinson: But your Emergency Powers Act would cover people working outside their scope of practice?

O'Laughlin: Persons who are acting consistent with a regional emergency plan, even if operating out of their usual area of care (such as at an alternate care site), have some Good Samaritan protections if acting in good faith, as long as they adhere to what would be considered the accepted level of care for the situation.

Hanley: As I recall, for issues of personal liability, those are governed by statues at the state level, not the federal level. Though it's important to encourage the passage of statutes that would protect extenders, it's not a federal issue, but a state issue.

Rubinson: At least that is how the legal folks have explained it to us. There's no legal expertise on this panel, although some of us have had consultations from some very bright legal minds on these issues. So it seems to be a state issue. However, the "investigational new drug" designation and paperwork is under federal control, under FDA, I think. Scope of practice is controlled at the state level.

If we have regional uniformity of practice, that would presumably help in the case of a criminal or civil liability case. And if there is federal guidance, it may not be a mandate or it may not be legally binding, but it can be a 2-pronged approach from grassroots going up and federal going down, to states being able to support the folks who are doing their best to care for patients during a difficult situation.

Malatino: We do exercises with the states, maybe every month or a couple of times a month, and a lot of questions have come up about the use of items from the Stockpile, such as who can dispense the medicines? The Stockpile does not make recommendations. That's CDC's job. SNS is part of CDC, but we're more logistics than anything else, even though we have medical people working for SNS.

If you get a chance, do participate in an exercise in your state, particularly if it involves Stockpile assets. Our trainers go out to the states, and they practice taking Push Package materials off, distributing them, going to points of distribution, and getting whatever those products happen to be, usually pills or antibiotics, and getting those to people, and they do these drills. So there are some opportunities there for people to learn and to be heard, because they're dealing with state emergency people at that time, and these issues can be brought up.

Rubinson: It's best to get guidance from legal authorities in your own jurisdiction, because it varies state by state. There are various interpretations, because there's a lot of uncertainty. I encourage everyone working on disaster preparedness to make sure you have good legal consultation. Don't rely on legal advice from medical people.

The last question is from Eric Gjerde from Airon in Melbourne, Florida, who asks, taking an all-hazards perspective, should we rely only on ventilators that operate on electrical power or should we have a mixture of pneumatic and electrical ventilators?

Ritz: I am hesitant to recommend a pneumatically powered ventilator, given the possible difficulty of supplying oxygen in a disaster scenario. As well, many hospitals have reasonably robust electrical backup systems that will probably supply adequate electricity. Having lived through a couple of these disasters myself, our institution ran on reserve generators for 4 or 5 days and could have gone longer than that. Although, as Rich said, it would be nice to have a ventilator that could use either electrical or pneumatic power.

Branson: I think Eric asked the question partly because his company makes pneumatic ventilators, which is OK, but

the issue is, does the ventilator meet all the other criteria, such as can it deliver a tidal volume small enough for pediatric patients and how high is its gas consumption? Does it meet the important disaster-ventilator criteria? If so, then perhaps a pneumatic ventilator is worth considering, but, like Ray, I would not recommend stockpiling them. If your hospital wants some of them for patient transport, that's great, but the big problems are situational.

If we have 3 RTs who usually work in the pulmonary function testing lab each watching 6 or 8 ventilators and tasked with alerting the physician to problems—if all they have is pneumatic ventilators and they're only capable of telling me when they're disconnected, and there's no high-pressure alarm or other alarms, then it's a safety concern.

I stress that I am commenting only about stockpile ventilators for use in the hospital. We have not discussed use in the field, or in moving patients to the hospital, or between hospitals; those are where pneumatic ventilators could play an important role.

Rubinson: I would also advocate, if you are ultimately moving patients towards hospital evacuation, then you're probably going to be outside of the ICU, but not able to move all of your patients immediately to another location with copious high-pressure medical gas. You're not going to have 50 air medical units landing all at once. It's going to take a while. Most of our air medical units can only move in onesies or twosies for people who are critically ill. So because of that, the expectation is that you are going to be out of the unit and you're probably going to be working on compressed gas for a while.

And the question is, will your oxygen-conserving device be more appropriate? When you're prospectively planning on stockpiling, what equipment do you really want to buy? Do you want to buy equipment that just gets you by, or do you want to buy equipment that is most likely to meet the needs that you have? Different places have different needs. I would encourage you to deliberately think about the need and then determine the product, rather than just getting a product and hoping that it meets your need.

Branson: OK, we're done. I want to thank you all. You didn't sign a form of consent, but you have been part of an experiment; we've never done a Journal conference in front of an audience before. Thanks to Ray Masferrer and the AARC for sponsoring the conference. Thanks to Lewis Rubinson, who over the last 5 years has taught me a lot and become a good friend. His expertise was essential for putting this conference together. Special thanks to Ray Ritz, because I gave him the hardest job, which was to figure out something that nobody knows anything about: oxygen. He took it on without complaining. I would have complained a lot. And thanks to everyone else who came. You've all done a great job.

Ritz: I complained behind your back a lot. [Laughter]

Branson: I'm going to have Dave Pierson give us a final comment.

Pierson: I think what we have heard and discussed and learned in the last day and a half is something unprecedented, certainly for this organization, and for people in this specific field. I was tremendously impressed with all the presentations. The primary purpose of our Journal conferences—this one, like all 39 previous ones—was to generate the corresponding 2 special issues of RESPIRATORY CARE that come in your mailbox a few months later. The articles, which will be written by the individual speakers, in some cases with collaboration from other coworkers at home and elsewhere, will cover everything that has been discussed, and in some cases a lot more. They will certainly be resources that we will all find informative and helpful in a practical sense.

Finally, let me add my thanks as editor, on behalf of the Journal and the AARC, to all the faculty members—and especially to Rich Branson and Lewis Rubinson—for the tremendous amount of effort they put into the conference and the great success it has been.

別添５

厚生労働科学研究費補助金（厚生労働科学特別研究事業）
分担研究報告書
「非常時対応人工呼吸器の標準化に関する研究(H21-特別-指定-011)」
（分担研究テーマ：仕様検討と評価実験）

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研究要旨
本研究で検討された非常時対応人工呼吸器について、安全性、有効性、使いやすさについて、臨床現場での意見、モデル肺を用いた病態シミュレーション等から検討した。仕様等についていくつか改良すべき点があるものの、機能や使いやすさ等は概ね良好の評価であった。

A．研究目的

新型インフルエンザや広域災害等などの非常時に人工呼吸器管理が必要な患者が爆発的に急増した場合、多くの医療従事者が自施設のみではなくあらゆる場所や治療で関わる可能性がある。そのため、どこでも、だれでも使用できるような標準化された人工呼吸器が配備されていることは非常に重要な要素のひとつになる。この研究では、従来からあるクリティカルケアで使用するような高機能の人工呼吸器ではなく、人工呼吸管理を行う上で最低限必要な機能の検討および標準化を検討し、かつそれを基に試作した人工呼吸器の安全性や有効性、および使いやすさ等について評価することを目的とする。

B．研究方法

１．基本概念からの仕様の検討

１）基本概念をもとにした検討項目

緊急時での使用と言うこともあり、短時間に可能な限り多数の人工呼吸器が用意でき、かつ呼吸管理の経験の長短や知識レベルに大きく関係しないように、使いやすく分かりやすい最低限必要と思われる換気機能を装備すること基本概念とした。そのため下記の内容について検討を加えた。

①気道確保を前提として、起動後直ちにガス送気が開始できること。
②自発呼吸を優先とするガス許容機能び機構をもつこと。
③安定したガス供給と規定圧（または規定量）を維持できること。
④直感的に分かりやすく、誤操作を防ぐ操作部であること。
⑤機能や設定項目は広く普及し、認識に共通性があること（多機能化を目指さない）。
⑥ARDS のような重度の肺損傷への適応を考慮すること。
⑦電源投入後早期(15-20 秒)に換気が開始されること。

２）仕様の項目

前述の基本概念をもとに、試作する人工呼吸器の仕様（機能）に検討する。

①換気モードの種類
②各種換気条件の設定範囲
③モニタ項目
④アラーム項目
⑤付帯機能
⑥操作方法

などについて検討し、その結果をもとに試作

の人工呼吸器を製造することになった。

2．試作人工呼吸器の評価実験

試作した人工呼吸器の評価として、外観および操作的な問題点（視認性などを含む）についての検討と、モデル肺を用いた病態シミュレーションで機能などの評価を行う。

1）外観および操作的な問題点

使用（移動を含む）の際に間違いの無いような表示や操作方法になっているかどうかを中心に下記の項目について問題点を抽出した。また、試作した人工呼吸器を医療現場（医療機器管理部門：北里大学病院MEセンター）に搬入し、医療スタッフからの意見も収集した。

①基本的換気機能
- 十分な換気モードを備えているか。
- 十分な設定項目を備えているか。
- 必要十分なガス供給流量があるか。
- トリガーの感度および応答速度とも満足できるか。
- 十分なプレッシャーサポート動作か。
- 必要十分な安全機構を備えているか。

②付帯機能（深呼吸、初期設定など）
- 必要十分な付帯機能を備えているか。
- 加温加湿器の外部オプション使用に支障がないか。

③モニタ機能
- 必要十分なモニタ項目を備えているか。
- 視認性がよく、隣接する項目と読み間違えることはないか。

④アラーム機能
- 必要十分なアラーム項目を備えているか。
- 視覚、聴覚アラームとも確実に報知できるか。

⑤操作関連
- 分かりやすい操作面をもち、迷うことがないか。
- 装置移動がスムーズに行えるか。

⑥動作状態
- 不快な動作音や機械的な振動を周囲に与えないか。
- 電源電圧許容範囲内での動作に異常はないか。
- 消費電流はどの程度か。

2）病態シミュレーションでの機能評価

コンプライアンスおよび気道抵抗を任意に変更可能なテスト肺を用いて、各種設定条件でガス供給動作を行わせた時、換気量や換気圧を測定してガス供給能力を評価する。設定の詳細については結果の中に記載するため、ここでは省略する。

①評価実験場所

北里大学医療衛生学部臨床工学実習室

②使用器具

(1)電源電圧関連の動作確認
- 消費電流測定：Sanwa DIGITAL CLAMP METER PLC-400A
- 電源電圧変動での影響

電圧変動：ボルトスライダ（山菱 6N-33）
電圧測定：Sanwa(DIGITAL MULTIMETER CD-780C)

(2)医療ガス供給圧変動での動作確認
- 圧力調整器（簡易的な減圧器：市販品）

(3)動作音および警報音の測定
- 音圧測定：リオン精密騒音計

(4)圧・量の測定
- Calibration Analyzer RT-200(Timeter Inc. S-No.R12BS)
- 記録器(NEC)

(5)モデル肺
- 単独試験の時：
SMS Lung Simulator(S-No.AC091203)
- 自発呼吸シミュレーション時：
TTL(Michigan Instruments Inc. S-No.0929)

(6)人工呼吸器
- 自発呼吸シミュレーション時：
Servo i(MAQUET S-No.2200050)

(7)呼吸回路
- フレックスチューブ（成人用）
INTER SURGICAL

C．研究結果および個々の項目への考察

試作した人工呼吸器の性能評価は以下の通りである。なお、人工呼吸器の製造にあたってはJISまたは規格についてはIEC規格に準拠されているが、下記の項目について検討した。

1．駆動源の異常に対する動作

［換気条件］

PCV　設定圧:20 cmH_2O, 換気回数:10/min, PEEP:0 cmH_2O

①電源に関する項目

(1)消費電流

・ 人工呼吸器のみ　0.74 A

・人工呼吸器＋コンプレッサ　1.85 A

(2)電源電圧下降による動作

JIS または IEC 規格で規定する定格商用電源値の±10%では問題なく動作する。まお、61V 以下に低下した場合に異音や表示の異常があるものの換気については規定範囲内で条件通りに作動し、53V で内蔵バッテリでの駆動に移行することがわかった。

②医療ガスの異常に対する動作

酸素の供給圧が 0.1MPa 以下になった時に片側駆動（フェールセーフ）になり換気が保たれることが分かった。また圧縮空気では 0.17MPa 以下で内蔵のコンプレッサに移行した。

2．動作中の音および警報音

実験室の環境騒音レベルは 44 dB(A)であった。この環境下で試作した人工呼吸器を作動させた時の音は下記の通りであった。なお測定部位は、人工呼吸器の表示面から 1m で、高さは床から 150cm（耳の高さ程度）の位置で測定した。吸気時の若干気になることもあるが、実際の医療現場では環境騒音が高いために問題のない範囲であると考える。

	音圧レベル:dB(A)	備考
環境騒音	44	
駆動音	53	吸気時
駆動音	47	アキュムレータ
警報音	70	最大音量
警報音	48	最小音量

3．各部評価

1）基本的換気機能

①.必要十分な換気モードを備えているか。

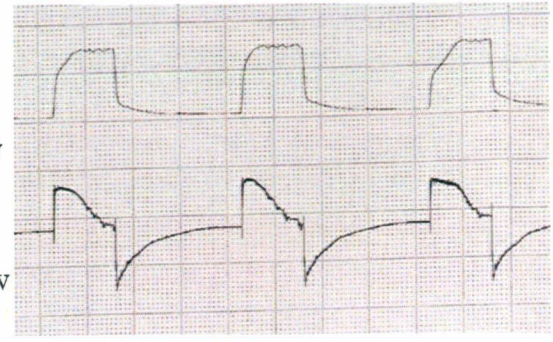
通常の使用では十分であるが、CPAP使用時、換気量が減少し$PaCO_2$が増加することがある。可能であればBIPAPまたはAPRV（P_{low}は大気開放でよい）の機能を追加してはどうか。

②必要十分な設定項目を備えているか。

PCV では難しいかもしれないが、一回換気量（数呼吸の平均）の警報設定項目が必要ではないか。

③必要十分なガス供給流量があるか。

a．PCVまたはPSVでは初期流量が最も速いが、本器で設定圧（10cmH_2O以上）を増加させると立ち上がりから設定値まで時間がかかる傾向が見られた（図1）。



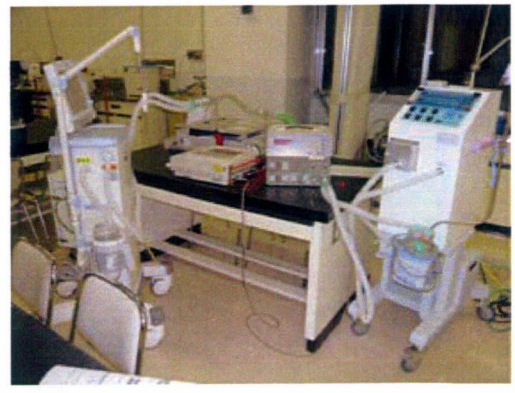
［設定］

mode:PCV　P:20cmH_2O,　f:15/min,
C:50ml/cmH_2O,　R:5cmH_2O/L/s　T_I:1.3s

図1　回路内圧波形と吸気流量波形

④トリガ感度及び応答速度ともに満足できるか。

TTL を用いた呼吸シミュレーション（図2）でも概ね良好であった。



人工呼吸器
(Servo i)

人工呼吸器
(HLW-011)

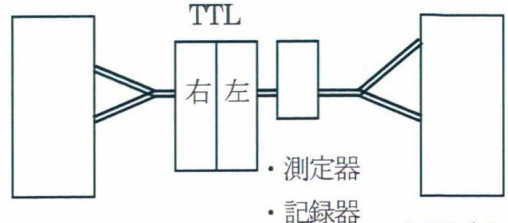
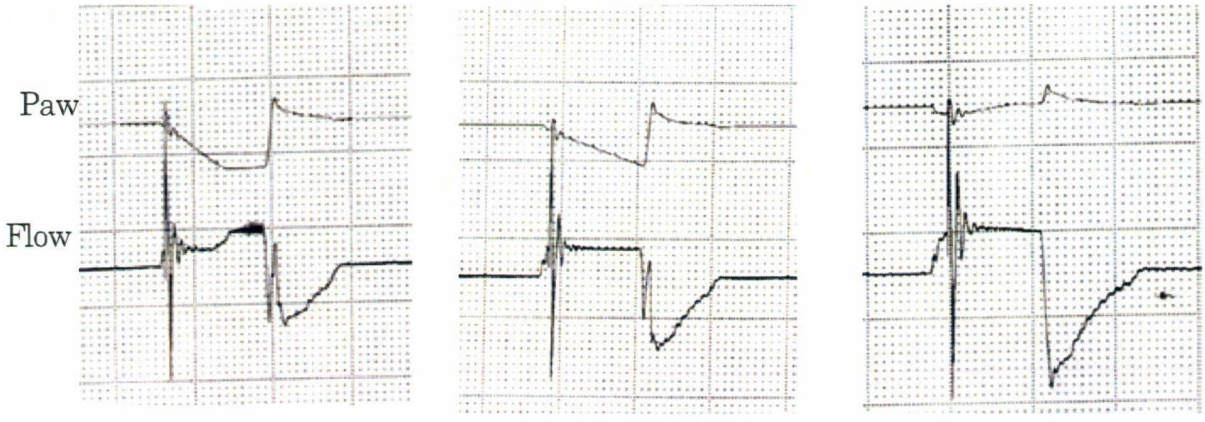


図2　自発シミュレーション風景と概要

・CPAP(10 cmH_2O)の際にトリガ 1(L)よりも10(L)の方が、圧変動が少なかった。



［設定］　CPAP:10 cmH_2O,　V_T: 350 ml,　T_I:1.3sec

図3　トリガ流量の違いによる回路内圧波形と流量波形

⑤.必要十分なプレッシャーサポート動作であるか。

PSV では 10cmH2O のみであるが良好である。それ以上の圧レベルについては実験を行っていないが、PCV と同様の圧波形、流量波形になると考える。

⑥必要十分な安全機構を備えているか。

安全弁（リリーフ弁）の機能や停電時の自発呼吸が負荷無くできるかどうかは確認していない。

2）付帯機能（深呼吸、初期設定など）

①必要十分な付帯機能を備えているか。

・電源投入時に過去の設定になるのは良い（同一患者で使用する場合に）。

・条件設定変更時に警報設定の変更を促す表示が必要ではないか。

②加温加湿器等の外部オプション使用時に支障がないか。

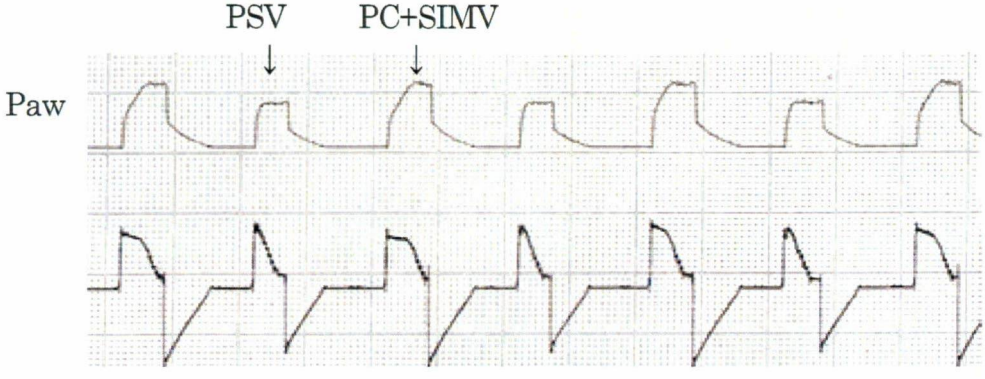
最大ガス流量から考えて一般に使用されている加温加湿器および人工鼻の性能に支障を来すことはない。

3）モニタ機能

①必要十分なモニタ項目を備えるか。

追加すべきモニタ項目：呼吸回数が常時表示されると良い。今後検討すべきモニタ項目として気道内圧表示は設定範囲の 60cmH_2O程度で良い。また分時換気量表示は 20L/min以下で良い。トリガ時の点滅は呼吸回数の表示があれば、その横に表示してはどうか。

②視認性が良く、隣接する項目と読み違えることがないか



flow

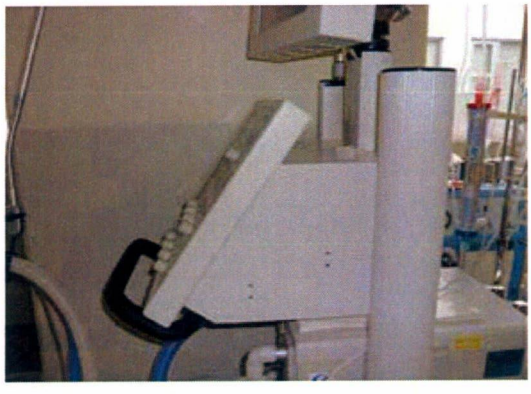
［設定］PC- SIMV:8/min, PSV: 10 cmH_2O, (Servo i V_T: 350ml RR: 15/min)

図４　PC- SIMV+ PSV の回路内圧と流量波形

・パネルの角度

遠くからパネル面がみにくいため、パネル面の傾きをもう少しつけてはどうか。

ａ．試作器



ｂ．現在市販されている機種

図５　パネル面の傾斜角度の比較

③表示について

モニタ(Paw,換気量)項目の LED は大きくし、青色の方が視認しが向上すると思われる。また、モニタ項目別に色別することや、吸気口と呼気口の表示は大きく表示することも必要と考える。

４）アラーム機能

①必要十分なアラーム項目を備えているか。

ナースコールを含め最低限のアラームは装着しているが、以下のことを検討してはどうか。

・アラームの自動消去（２分後）は不要で、リセット後消灯する方が良い。（起こった異常の確認は重要では）

・「休止」は「消音」に変更してはどうか。

・「消音」時は点灯するとよい。

・アラームの「リセット」が必要ではないか。

・呼気弁ブロックの取り付けエラー（温度センサ部の動きを利用してはどうか）

・一回換気量の警報設定は必要ではないか。

・電源 OFF 時には、それを知らせるアラーム発生→消音の操作が必要ではないか。

・クイック警報設定の是非については賛否あった（教育的にはクイックは不要で、設定を促すことが必要ではないか）。

②視覚・聴覚アラームともに確実に報知できる。

・アラーム表示部を大きくしてはどうか。小さすぎる。

・最低警報音量は医療現場の環境騒音を考慮して 60dB(A)以上が必要と考える。(参考 ICU は 60dB 程度) 本器は　MIN 48dB(A), MAX 70dB(A)：パネルから 1m の位置

・設定後の「ENTER」音は他機種では異常設定時に鳴るパターン（周波数も）であるため間違った操作をしていると感じてしまう。

・停電時に上部表示ランプも点滅させてはどうか（遠くからも見える）。

５）操作関連

①.分かりやすい操作面をもち、迷うことはない。

ダイアルでの操作は非常に良く、現場向きである。設定項目が限られていることから、操作に迷うことは少ないと考えるが、下記のことについて検討してはどうか。

・換気条件変更時に警報設定の変更を促すような方法を（警報設定の点滅など）

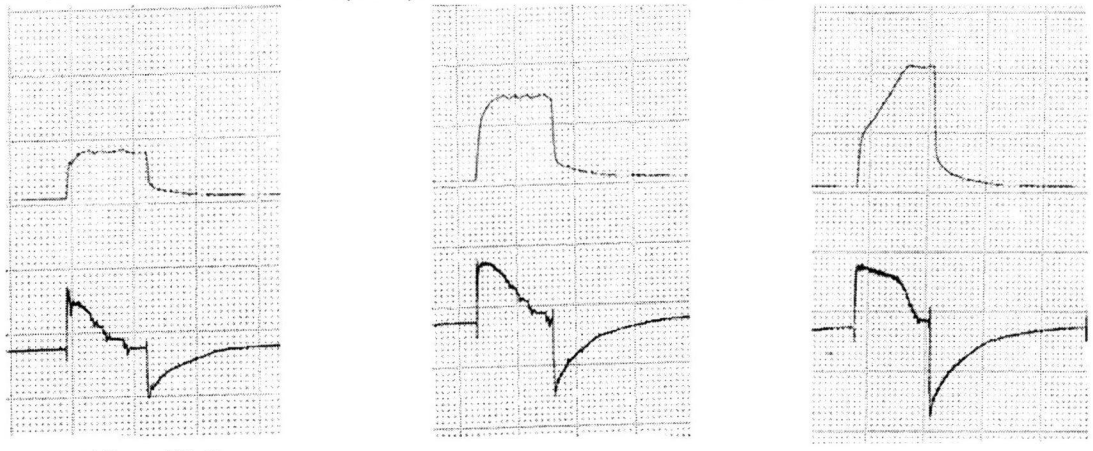
・圧設定表示部(PCV, PSV,に「above PEEP」

の表示は必要と考える。
②装置移動がスムーズに行えるか。
・キャスタの大きさは問題ないが、本体前から押す場合に足がぶつかる（前のキャスタ間をもう少し拡げてはどうか。
6）動作状態
①不快な動作音や機械的振動を周囲に与えないか。
・呼気弁駆動音が大きい。吸気時：53dB(A)
環境騒音：44dB(A)
・アキュムレータ駆動時（充填時？）：47dB(A)
コンプライアンスおよび気道抵抗を任意に変更可能なテスト肺を用いて、各種設定条件でガス供給動作が行われたときに、換気量や換気圧を測定してガス供給を評価した結果、検討すべき点もあるが、十分使用に耐えられ概ね良好であった。以下に各換気モードにおける気道内圧および吸気流量波形を示す。

7）その他、気付いたこと
・呼気弁ブロックが取り外せない時を想定して、ドライバーが使える様、マイナス（－）の溝も追加してはどうか。

4．性能評価

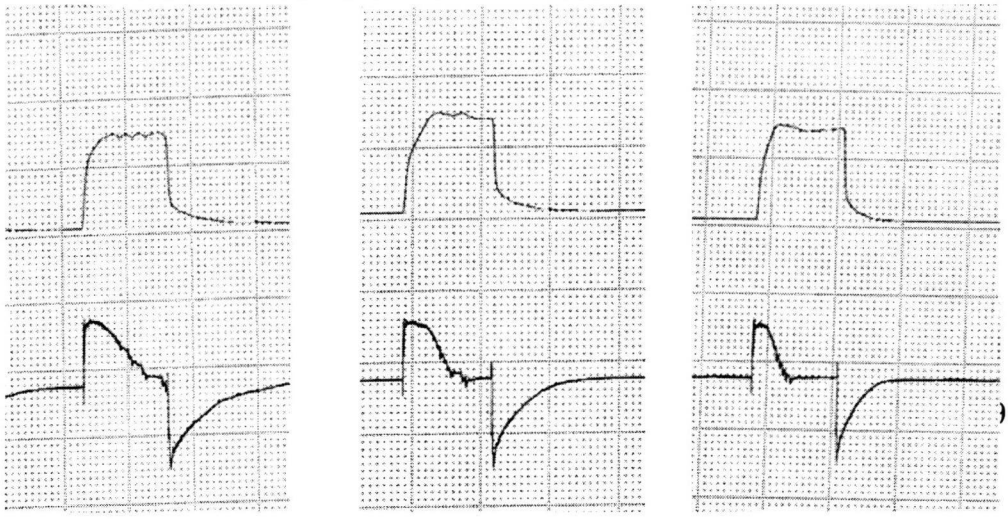
1） PCV
圧設定が高くなれば設定圧に達するまで時間がかかる（遅れがある）
［人工呼吸器の設定条件］
PCV, RR:15/min, T_I:1.3 sec, PEEP(-)
①一般的な状態（テスト肺の条件：C:50, R:5,RR:15/min）での波形の変化



PCV圧 → 10 cmH_2O
20 cmH_2O 30 cmH_2O

図6 一般的な状態での波形の変化

②コンプライアンスの変化による波形の変化 (PCV 20 cmH_2Oの時, R:5)



ｺﾝﾌﾟﾗｲｱﾝｽ → 50 ml/cmH_2O 20 ml/cmH_2O 10 ml/cmH_2O

図７　コンプライアンスの変化による波形の変化

③抵抗の変化による波形の変化　(PCV :20 cmH_2O　C:5０)

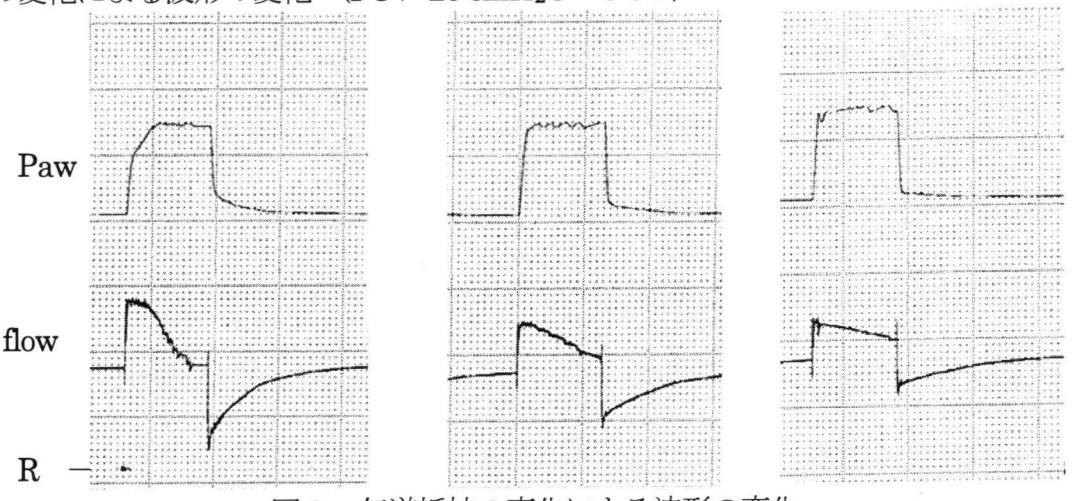


図８　気道抵抗の変化による波形の変化

２）CPAP 時（換気量の違いによる波形の変化）　→　圧変動が生じる。

①一回換気量の違いによる回路内圧の変化（Trigger:10L, PEEP:10cmH_2O）

換気量が多い方が CPAP のレベルが低下しない。なぜかについては今後検討しなければならない。

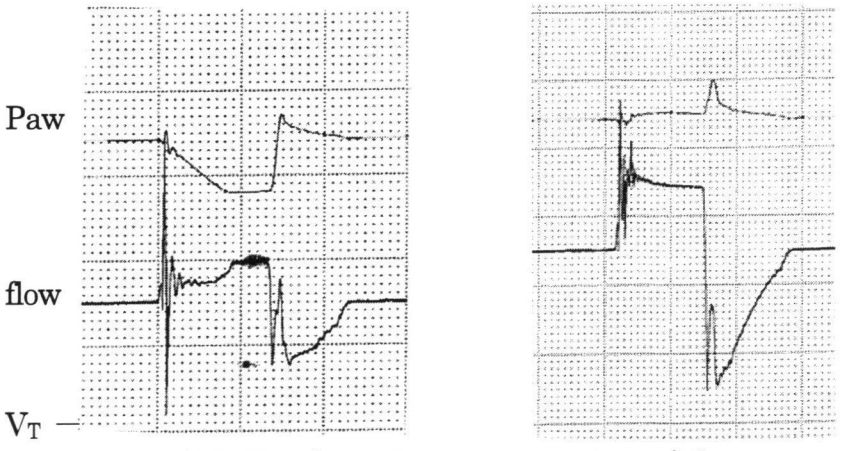


図９　換気量の違いによる CPAP レベルの変化

②圧の一時的な低下（ほぼ周期的なもの：↓の部分）

一時的なガス供給不足により一回換気量が 1000ml から 700mL に減少(30%)している。

一呼吸のみであるため臨床上は問題ないと考えるが、ガス供給方式について今後検討が必要である。

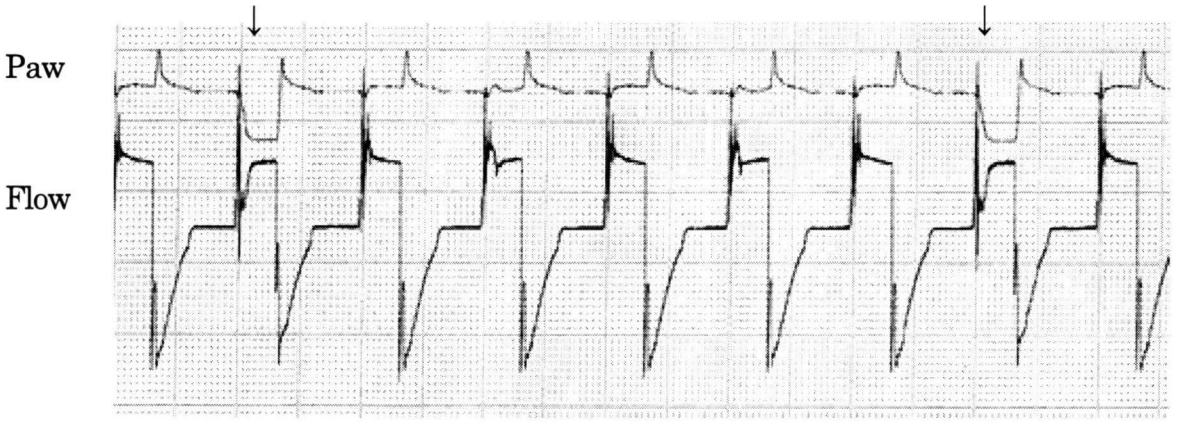
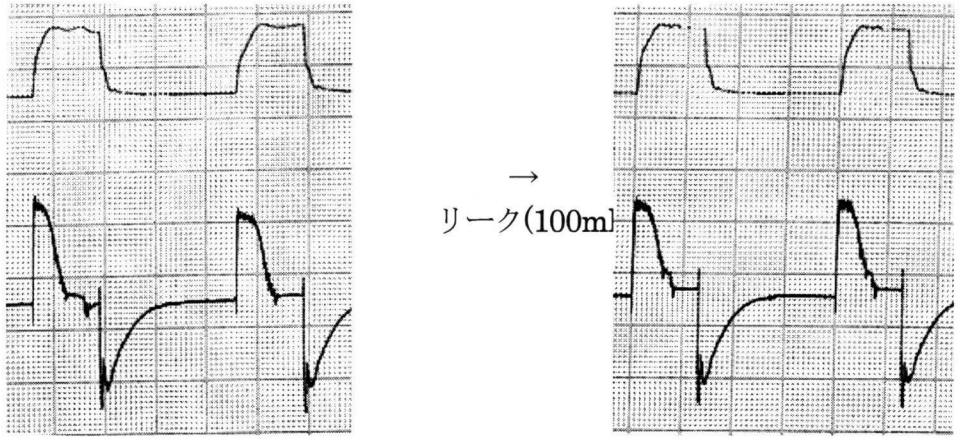


図８　CPAP 施行中のレベルの変化

3）PCV+PEEP 時のリークの補正　→　追従できる。

PCV:20 cmH_2O, PEEP:5 cmH_2O



リーク無し　　変化がない

図９　リーク時の波形

D．考察（全体）

今回試作した人工呼吸器は、新型インフルエンザ等の大流行により人工呼吸管理を必要とする患者が爆発的に急増した場合、多くの医療従事者が自施設のみではなくあらゆる場所や治療で関わる可能性がある。そのため、どこでも、だれでも使用できるように呼吸管理で必要最小限の機能を持った人工呼吸器を検討・開発することを目的とした。

この研究で試作した人工呼吸器の各部のコメントについては前項のコメントの通りであり、全体な総合評価として下記のようにまとめることができる。

1．機能とその評価

より重症化した患者への対応は他の多機能人工呼吸器への変更で良く、当該機器の緊急時対応という使用目的から考えると十分な機能を備えている。形状（全面の呼吸回路装着ポート、背面の電源接続部）やパネル表示・警報等については表示の追加や改良を検討する必要がある。

また、各部の評価については、概ね良好の評価であり、前項に記載したように若干検討すべき項目もあるが、人工呼吸管理を行う上で問題にならないものである。各部の評価として、

1）起動後直ちにガス送気を開始できる。

2）自発呼吸優先のガス供給機能・機構がある。

3）呼吸ガス供給と設定圧維持の動作が安定し

ている。
4）操作が分かりやすく、誤操作防止機能がある。
5）最低必要な機能をすべて備えている。
6）重症肺疾患に対して必要十分なガス供給できる。
など、機能的には問題がないと考える。
以上から、臨床で十分使用できる仕様の人工呼吸器が開発できたものと考える。

2．保守点検のしやすさ

試作器は消耗品も少なく簡単な構造であるため、保守点検を担当する者には非常に理解しやすいものである。そのため我が国で各社が共通で保守ができるものと考える。また、医療機関では臨床工学技士でもメンテナンス講習会等を行うことで十分対応できるものと考える。そのため緊急事態に備えて備蓄した際にも、各製造メーカで保守点検を分担することによって、大きな負担が無く定期点検やオーバーホールが実施できるものと考える。

E．結論

臨床で最小限必要な機能を備えた人工呼吸器の仕様を検討し試作器を作成した。試作した人工呼吸器を病態シミュレーションができる人工肺を用いての機能評価などを行った結果、臨床使用が十分可能な仕様を持った人工呼吸器であることが分かった。

F．健康危険情報

なし

G．研究発表

なし

H．知的財産権の出願・登録状況

なし

別添6

厚生労働科学研究費補助金（厚生労働科学特別研究事業）
分担研究報告書

『非常時対応人工呼吸器の標準化に関する研究』
非常時対応人工呼吸器 HLW-011 の機能性の評価

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［研究要旨］
新型インフルエンザ(A/H1N1)が蔓延し重症急性呼吸不全患者が増加し、人工呼吸器が不足状態にならないように、非常時に対応できる人工呼吸器の開発を行った。

A．研究目的］
人工呼吸器（HLW-011）の機能的評価をおこなった。

B．研究方法
人工呼吸器HLW-011 の機能性の評価は、SMS社製モデル肺を用いて酸素濃度、呼吸回数、吸気圧とPEEPの機能テストをimtメディカル社製フローアナライザ（PF-300）を使用し測定を行った。換気モードを圧規定換気、吸気圧 20cmH_2O、換気回数 12 回、吸気時間 1 秒、PEEP 0cmH_2Oに設定し、酸素濃度は 21、30、40、50、60、70、80、90、100％の濃度をランダムに設定し測定を行った。
次に呼吸回数の検定は、換気モードを圧規定換気、酸素濃度は 21％、吸気圧 20cmH_2O、吸気時間 1 秒、PEEP 0cmH_2Oに設定し、換気回数を 6、10、15、20、30、40 回/分の検定を行った。
吸気圧と PEEP の検定は、酸素濃度 21％、呼吸回数 12 回/分、吸気時間 1 秒の条件下で
PEEP値が 0、5、10、15、20cmH_2O のとき、圧規定換気の吸気圧を 5、10、15、20cmH_2O、と変化させ検定を行った。

C．研究結果
① 酸素濃度
21％設定時の測定濃度は 21.0±0.1、30％では 35.6±1.2、40％では 40.1±1.2、50％では 48.9±0.6、60％では 58.6±0.7、70％では 69.0±1.0、80％では 78.7±0.5、90％では 88.8±0.4、100％では 99.9±0.1 と良好な値を示した（表 1)。

② 呼吸回数
6 から 40 回/分の設定では、誤差なく追従性が良く設定回数を換気させていた（表 2)。

③ PEEPの検定では 0cmH_2Oの設定で 0.5±0.1 cmH_2O、5 cmH_2O設定では 5.7±0.1 cmH_2O、10 cmH_2Oの設定で 10.6±0.2 cmH_2O、15 cmH_2Oの設定で 15.4

$_2O$、
20 cmH_2Oの設定で20.5±0.4 cmH_2Oであった（表3）。

④ 圧規定換気における吸気圧とPEEPの検定では、PEEP 0cmH_2Oのとき吸気圧 5cmH_2Oの設定で最大吸気圧が 9.1±0.4cmH_2O、一回換気量は175±9 mlであった。 吸気圧 10cmH_2Oでは、最大吸気圧 12.2±0.1cmH_2O、一回換気量は、301±10ml 、吸気圧 15cmH_2Oでは最大吸気圧 16.6±0.9cmH_2O、一回換気量は、390±9ml 、吸気圧 20cmH_2Oでは、最大吸気圧 22.0±0.2cmH_2O、一回換気量は、466±20ml 、吸気圧 30cmH_2Oでは最大吸気圧 31.8±0.2cmH_2O一回換気量は、599±13mlであった（表4-①②）。

PEEP 5cmH_2O設定で、吸気圧が5cmH_2Oの場合では、最大吸気圧 14.1±0.3cmH_2O 、一回換気量は 140±7ml 、吸気圧 10cmH_2Oでは最大吸気圧17.3±0.2cmH_2O、一回換気量は241±6ml 、吸気圧 15cmH_2Oで最大吸気圧 22.2±0.2cmH_2O、一回換気量は、324±2ml、吸気圧 20cmH_2Oでは、最大吸気圧 6.6±1.1cmH_2O、一回換気量は、398±5ml 、吸気圧 30cmH_2Oでは最大吸気圧 37.0±0.2cmH_2O、一回換気量は526±3mlであった（表5-①②）。

PEEP 10cmH_2O設定で、吸気圧が5cmH_2Oの場合では、最大吸気圧 18.9±0.2cmH_2O、一回換気量は 101±2ml 、吸気圧 10cmH_2Oでは最大吸気圧 21.3±1cmH_2O、一回換気量は 185±3 ml 、吸気圧 15cmH_2Oで最大吸気圧27.1±0.3cmH_2O、一回換気量は261±6ml 、吸気圧 20cmH_2Oでは最大吸気圧 32.2±0.2cmH_2O、一回換気量は329±5ml、吸気圧 30cmH_2Oでは最大吸気圧 40.8±2.5cmH_2O、一回換気量は451±8mlであった（表6-①②）。

PEEP 15cmH_2O設定で吸気圧が5cmH_2Oの場合では、最大吸気圧 23.4±0.2cmH_2O、一回換気量は96±7ml 、吸気圧 10cmH_2Oでは 28.5±2.5cmH_2O、一回換気量は171±2ml 、吸気圧 15cmH_2Oで最大吸気圧 32.1±0.3cmH_2O、一回換気量は232±1ml 、吸気圧 20cmH_2Oでは最大吸気圧 37.1±0.2cmH_2O、一回換気量は295±3ml、吸気圧 30cmH_2Oでは 47.0±0.3cmH_2O、一回換気量は 406±1ml、であった（表7-①②）。

PEEP 20cmH_2O設定で、吸気圧が5cmH_2Oの場合では最大吸気圧 28.2±0.2cmH_2O、一回換気量は101±10ml 、吸気圧 10cmH_2Oでは最大吸気圧 32.1±0.3cmH_2O、一回換気量は 149±2ml 、吸気圧 15cmH_2Oでは最大吸気圧37.1±0.3cmH_2O、一回換気量は216±10ml 、吸気圧 20cmH_2Oでは最大吸気圧 42.0±0.2cmH_2O、一回換気量は263±1ml 吸気圧 30cmH_2Oでは最大吸気圧 51.8±0.2cmH_2O、一回換気量は365±1mlであった（表8-①②）。

D．考察

酸素濃度の検定では、酸素濃度30%設定のとき、35.6±1.2 と 19%ほど高値を示したが、他の設定酸素濃度では信頼の高い値を示した（表1）。

呼吸回数の検定では表 2 に示すように満

足のいく信頼の高い値を示した。

PEEPの検定では0から20 cmH_2Oの設定においても、ほぼ安定した値を示した。

圧規定換気おける吸気圧とPEEPの検定では、換気量的には影響を及ぼさないが、低い吸気圧の設定5から10 cmH_2O（表1-①、1-②、2-①、2-②、3-①、3-②、4-①、4-②、5-①、5-②、の丸印）のときに最大吸気圧が設定吸気圧より高い値を示した。低い吸気圧設定のときの流量波形と圧波形を見ると吸気立ち上がり時に高いノイズ（アーチファクト）が出現している。この高いノイズが測定値に誤差を招いていると考えられる。しかし設定圧が高い吸気圧15から30 cmH_2Oにおいては吸気時の高いノイズが消失して安定した流量が得られた。

E．結論

非常時対応人工呼吸器HLW-011 の吸気圧が 15cmH_2O以上の設定では安定した換気が得られるが、低い吸気圧の設定ではノイズが出現し、設定値よりも高い気道内圧を示した。

今回このノイズに関しては今回解明できなかったが、今後の研究課題になると思われる。

F．健康危険情報

なし

G．研究発表

なし

H．知的財産権の出願・登録状況

なし

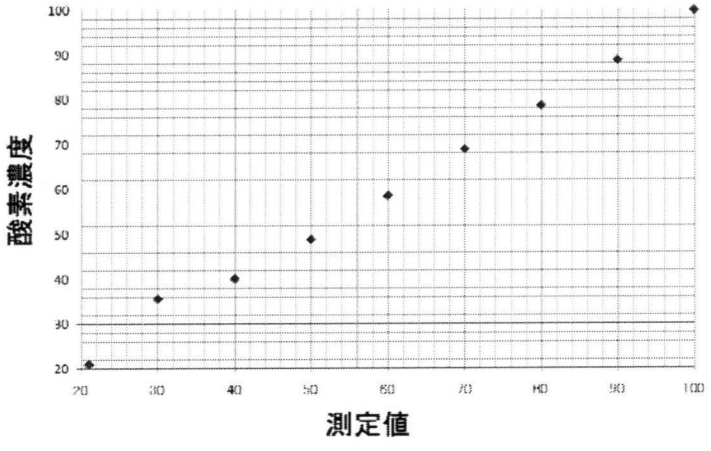


表1. 酸素濃度の検定

設定	6 回	10 回	15 回	20 回	30 回	40 回
Avg	6	10	15.1	20.1	30.1	40.1

表 2. 呼吸回数の検定

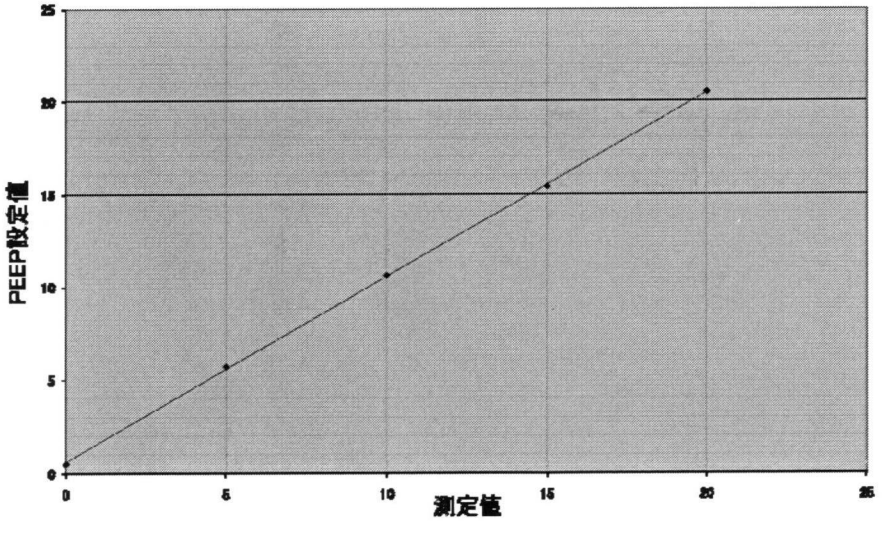


表 3. PEEP の検定

① 吸気圧：5cmH_2O　② 吸気圧：10cmH_2O　③ 吸気圧：15cmH_2O

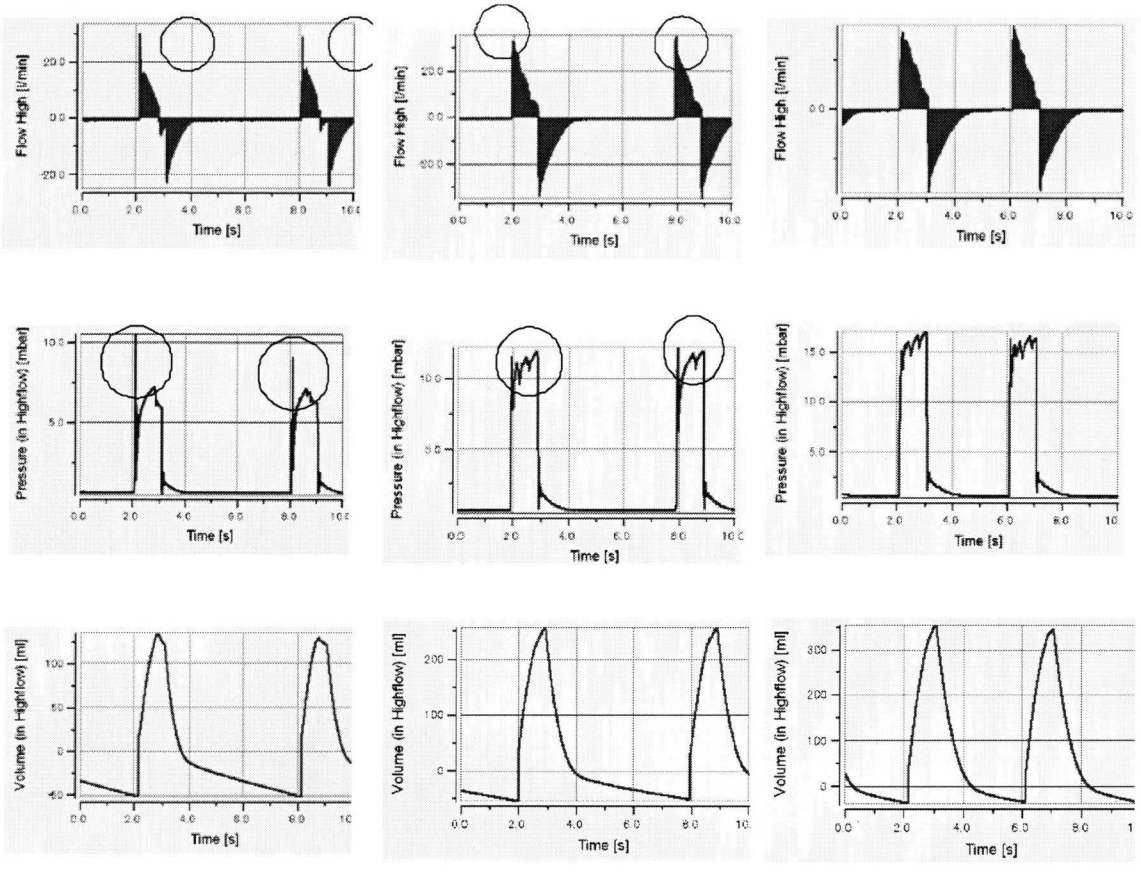
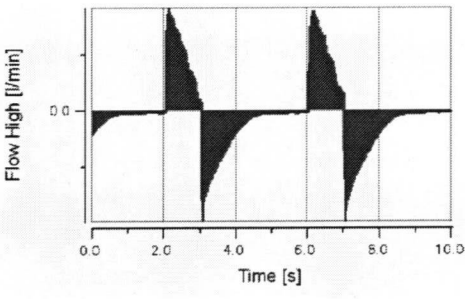
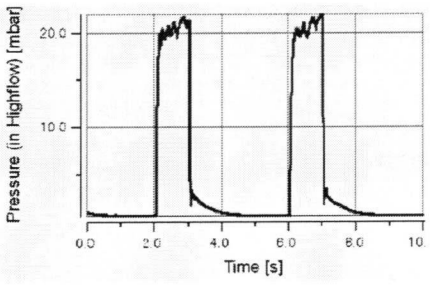
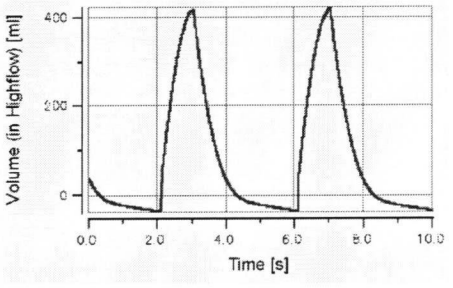


表 4-①　PEEP 0cmH_2Oと各吸気圧の測定

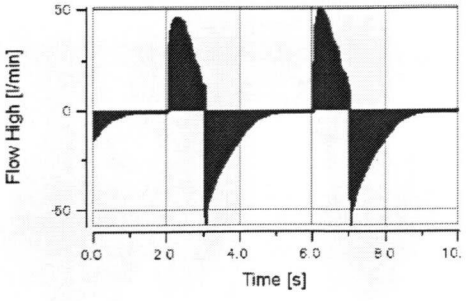
④　吸気圧：20cmH_2O

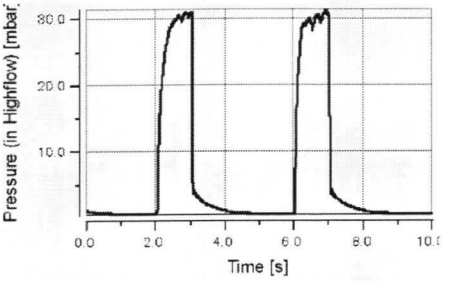






⑤　吸気圧：30cmH_2O





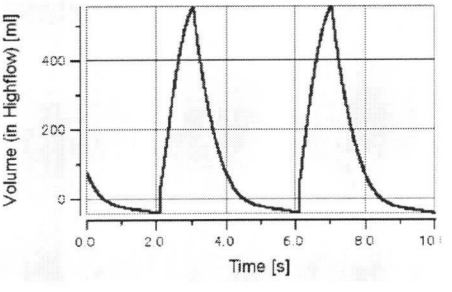


表 4-②　PEEP 0cmH_2Oと各吸気圧の測定